DETAILED DESCRIPTION OF THE INVENTION

[020] The present invention provides improved sodium nonatitanate compositions, a method using the composition for recovery of $^{82}Sr$ from irradiated targets, and a method using the composition for generating $^{82}Rb$. The sodium nonatitanate materials of the invention are far more selective at separating strontium from solutions derived from the dissolution of irradiated target materials than current ion exchange resins used in the production of $^{82}Sr$. The present invention reduces the number of processing steps required, and thus leads to a decrease in target processing times and a reduction in the cost of the $^{82}Sr$ product. Waste generation and disposal are also decreased.

[021] According to the present invention, synthetic conditions are adjusted to produce a material with improved properties more applicable to $^{82}Sr$ processing. The sodium nonatitanate of the present invention has been found to have a very low affinity for rubidium in addition to an exceptionally high affinity for strontium, making it ideal for use as a replacement for the hydrous tin dioxide used in current $^{82}Rb$ generators. Sodium nonatitanate materials of this type will both improve the retention of $^{82}Sr$ and lead to a safer, more effective $^{82}Rb$ generator system for clinical applications.

[022] Sodium nonatitanate, $Na_4Ti_9O_{20}xH_2O$, is an inorganic ion exchange material that has been used for the removal of $^{90}Sr$ from neutral and alkaline nuclear wastes. The sodium nonatitanate of the present invention has a number of advantages over conventional organic ion exchange resins (*e.g.*, Chelex 100) that include: very high selectivity for trace levels of strontium in the presence of molar concentrations of other ions at alkaline pH; very low affinity for rubidium; excellent radiation, chemical and thermal stability so that there is no release of contaminants (*e.g.*, Ti) into the $^{82}Rb$ product; rapid reaction kinetics; high cation exchange capacity; absorbed ions are readily stripped by treatment with dilute mineral acid allowing the sodium nonatitanate to be recycled, if desired; scale up of similar synthesis has already been demonstrated; and the sodium nonatitanate powder can be manufactured into pellets appropriate for column operations. Other chemically related sodium titanate materials suitable for use in the same manner as the aforementioned sodium nonatitanate ($Na_4Ti_9O_{20}xH_2O$) include other titanate materials exhibiting high Sr affinity and low Rb affinity, including Sr-Treat (available from Selion Oy) and monosodium titanate (available from Boulder Scientific) It is also anticipated that analogous zirconates may exhibit similar properties.

[023] The invention also provides important improvements in the processing of irradiated targets to recover $^{82}$Sr. Sodium nonatitanate has a much greater affinity for $^{82}$Sr than currently used ion exchange resins, and a low affinity for other radioactive isotopes. Consequently, the use of sodium nonatitanate greatly simplifies the extraction process by reducing the number of separation steps that are required to produce chemically pure $^{82}$Sr. Thus, targets can be processed more rapidly and the recovery of $^{82}$Sr improved. Improved isotope selectivity may also facilitate the isolation of other useful isotopes from the targets, leading to greater payback from target processing operations.

[024] Furthermore, less than 1 g of sodium nonatitanate material is needed in a $^{82}$Rb generator and 1 kg of this material is expected to be sufficient to process a large number of targets, even if the sodium nonatitanate material is not recycled and is disposed of after one use. Consequently, the additional cost incurred by the use of sodium nonatitanate will be negligible in comparison with the cost savings achieved in the $^{82}$Sr production.

[025] It has been determined that replacing hydrous tin dioxide with sodium nonatitanate reduces the amount of $^{82}$Sr released during the operation of the $^{82}$Rb generator, thereby reducing the exposure of the patient to $^{82}$Sr. Sodium nonatitanate is also more chemically stable and less likely to leach non-radioactive contaminants into solution during operation of the generator. The sodium nonatitanate is also more amenable to recycling since the $^{82}$Sr can readily be stripped with mineral acid without producing additional impurities. Recycling of $^{82}$Sr generators is already being used as a source of additional $^{82}$Sr, and improvements to the recycling procedure (obtained by using a superior ion exchange material) will facilitate the recovery of $^{82}$Sr from this source.

[026] Although the sodium nonatitanate may be used as a direct replacement for hydrous tin dioxide in the $^{82}$Rb generator, it is also possible to use sodium nonatitanate in the form of a disposable add-on filter that could be used to trap any $^{82}$Sr that is leached from the generator during the production of $^{82}$Rb.

[027] The first step in preparing a $^{82}$Rb generator is to load the parent $^{82}$Sr onto the sodium nonatitanate material and place the ion exchange material into a suitable column. It is essential that sufficient time be allowed for the $^{82}$Sr to be absorbed by the sodium nonatitanate material in order to maximize the loading of the parent radioisotope per gram of ion exchange material.

[028] For an $^{82}$Rb generator, the sodium nonatitanate may be loaded into the column and then loaded with $^{82}$Sr although this method results in depositing a disproportionate amount of the $^{82}$Sr at the top of the column with the remainder of the column remaining as a guard bed to collect any $^{82}$Sr that migrates down the column. Alternatively, the sodium nonatitanate may be loaded with $^{82}$Sr before being placed in an ion exchange column to avoid preferentially loading the $^{82}$Sr on the top of the ion exchange. A high concentration of radioactivity on a very small volume of sodium nonatitante may result in undesirable radiolytic problems. Although sodium nonatitanate has been shown to be highly resistant to radiation damage, it is always considered prudent to avoid any unnecessary radiation exposure.

[029] In the medical field, use of the $^{82}$Rb generator preferably provides a saline solution that can be intravenously injected into a patient as an imaging agent at a pH of between about 4.5 and about 7. To achieve the desired pH range of the eluted $^{82}$Rb solution, a neutralization step may be performed on the sodium nonatitanate to lower the pH of the sodium nonatitanate. An $^{82}$Rb generator having sodium nonatitanate that has not been neutralized to a lower pH produces an $^{82}$Rb eluate solution having a higher pH than is desired for an injectable pharmaceutical in the medical field. For example, using a normal saline eluant having an initial pH of about 7.6 to elute $^{82}$Rb from an $^{82}$Rb generator having sodium nonatitanate that has not been neutralized to a lower pH can produce an eluate with a pH as high as 9.5. Even though over time the pH of the eluate slowly declines as more eluant is run through the generator, it is preferable and more efficient that the $^{82}$Rb eluate produced from the generator is immediately suitable for medical use. In one experiment, it was determined that a 2.92 g alkaline nonatitanate column required about 44 L of pH 6.2 saline eluant throughput to lower the pH level of the eluate to within the desired pH range. However, the use of such a high volume of eluant before the $^{82}$Rb solution is produced at a desired pH level is unacceptable.

[030] The neutralization step added to the nonatitanate synthesis effectively lowers the pH of the ion exchanger and provides an $^{82}$Rb solution having the desired pH range from the first use of the generator. The neutralization step includes adding an acid to the final stage of the nonatitanate synthesis. This neutralization step has no significant effect on the high separation factor that the nonatitanate possesses for strontium and rubidium as required for use in an $^{82}$Rb generator. However, using the sodium nonatitanate that has been neutralized to a lower pH results in an $^{82}$Rb product having an acceptable pH difference of less than one pH unit between the eluant and the eluate.

[031] The neutralization step includes resuspending the sodium nonatitanate product in a liquid and then adding an acid to lower the pH to between about 7 and about 9, preferably between about 7.2 and about 8.5. The pH is more preferably lowered to between about 7.5 and about 8.3 and most preferably to between about 7.8 and about 8.2. Sodium nonatitanate is partially neutralized by contacting the sodium nonatitanate product with the acidic liquid. The product may be centrifuged, the supernatant poured off, and, if desired, the process repeated to neutralize the sodium nonatitanate product again to obtain the target pH. The liquid may be any suitable liquid such as normal saline, dilute sodium chloride, water or preferably, deionized water. Any strong acid may be added to lower the pH such as, for example, nitric acid, sulfuric acid, or preferably hydrochloric acid.

[032] It is important to maintain the pH of the sodium nonatitanate above a minimum pH during the neutralization step because lowering the pH below neutral also lowers the separation efficiency of Sr/Rb. There is a correlation shown in between pH and the uptake of both $^{85}Sr$ and $^{82}Rb$. At high pH, the uptake of $^{85}Sr$ is high while the uptake of $^{82}Rb$ is low. At pH between about 6 and about 7, the uptake of $^{85}Sr$ starts to decrease while the uptake of $^{82}Rb$ remains the same or slightly increases. At pH values lower than about 4, the affinity for $^{85}Sr$ decreases dramatically.

[033] As the pH of the equilibrium saline solution passing through the column increases, the nonatitanate affinity for the strontium increases while the affinity for the rubidium decreases. Therefore, lowering the pH of the produced nonatitanate by performing a neutralizing step at the end of the method of producing the nonatitanate results in generator having a shorter life. To optimize the life time and separation efficiency, either the neutralization step may be omitted or a less complete neutralization step may be performed to achieve a lesser degree of neutralization.

[034] Optionally, an adjustment may be made to the pH of the eluate product obtained from the nonatitanate column that was produced without a neutralization step or was only slightly neutralized during the neutralization step. If the eluate product from the generator has a pH above the desired range, the pH of the eluate product may be decreased to the desired pH range by adding an acid. Acceptable acids include any acid suitable for neutralizing the eluant without rendering the neutralized eluant unsuitable for injection into a patient during a medical procedure as known by those having ordinary skill in the art. Suitable acids would include, for

example, hydrochloric acid (HCl) and acetic acid ($CH_3COOH$). HCl is preferred because the salt produced by the neutralizing reaction is NaCl, which is already present in the solution.

[035] The acid may be added automatically to adjust the pH or the acid may be added manually. A pH meter preferably measures the pH of the eluate product. Alternatively, other means, such as pH indicating strips, may be used to measure the pH of the eluate. Preferably a pH meter monitors the pH of the eluate as the acid is added to obtain the eluate target pH of between about 4.5 and about 7. The acid may be added using a gravity system to drip or pour the acid into the eluate. Alternatively, a pressure system, such as a syringe, a pump or a gas pressurized system may be used to add the acid to the eluate. When the acid is added automatically, a controller monitors the output signal from a pH meter and adjusts a valve or a pump rate to add the amount of acid necessary to obtain the eluate target pH. If adjusted manually, acid may be added to the eluate by an operator, preferably in pre-packaged amounts, until a pH meter or indicator strip indicates that the target pH has been achieved. Preferably, the acid is added automatically to the eluate as the eluate flows from the column.

[036] The size of the sodium nonatitanate particles used in the generator is an important factor. The use of large particles of sodium nonatitanate in a column provides low flow resistance of the eluant through the column but large particles cannot be packed into a column or elutable container as densely as smaller particles may be packed. Furthermore, large particles create long diffusion paths over which the $^{82}Rb$ generated by the decay of $^{82}Sr$ atoms located deep in the particle must travel while diffusing from the centers of the large particles. In contrast, fine particles of sodium nonatitanate permit more material to be packed into a column of a given volume and provide shorter diffusion paths out of the particles, but the fine particles produce greater flow resistance to the eluant during the elution of the $^{82}Rb$ from the generator.

[037] Therefore, the $^{82}Rb$ generator preferably includes smaller particles of sodium nonatitanate because the shorter diffusion path allows the particles to equilibrate with the eluant more quickly and because the smaller particles pack more densely into a column of a given size. Both of these factors together promote the elution of $^{82}Rb$ using a small volume of saline solution as the eluant and obtaining a high concentration of $^{82}Rb$ in the eluate. Preferably, the particles of sodium nonatitanate are made as small as possible without causing excessive back pressure from the flow of the eluant through the column. Preferably, the size of the particles used in the $^{82}Rb$ generator range between about 50 μm and about 200 μm. More preferably, the particle size of

the sodium nonatitanate is between about 75 and about 150 μm and most preferably between about 75 and about 100 μm.

[038] Low porosity is a preferred characteristic of the sodium nonatitanate particles for use in the $^{82}$Rb generator of the present invention. If the particles are highly porous, much of the parent $^{82}$Sr deposits within the pores, which creates a longer diffusion path for the $^{82}$Rb to diffuse from the pores into the saline eluant. The $^{82}$Rb generated from the $^{82}$Sr deposited deep within a pore continues to decay while diffusing from the pore into the eluant stream, which results in a loss of the generated $^{82}$Rb and thereby, a lower $^{82}$Rb yield.

[039] The column aspect ratio is a factor that contributes to the optimum operation of the $^{82}$Rb generator of the present invention. The aspect ratio of a column is the column length over the column diameter. Increasing column length at constant diameter provides for greater retention of $^{82}$Sr and thereby minimizes the amount of leached $^{82}$Sr in the final eluate product. However, as the column length increases, total pressure drop through the column increases, causing higher back pressure at the inlet to the column. The column aspect ratio affects the properties of the $^{82}$Rb generator even at constant column volume and sodium nonatitanate mass.

[040] A long, narrow column having a high aspect ratio offers greater resistance to the flow of the eluant and generates a higher backpressure at the inlet to the column. Because the velocity of a given volume of eluant is higher in a column having a high aspect ratio, the flow through the column having a high aspect ratio is more turbulent, which increases mixing within the eluant stream. Comparatively, a short, wide column having a low aspect ratio operates with a lower velocity of a given volume of eluant through the column and operates at lower pressure drop with less mixing. However, channeling through the bed can occur at low velocities resulting in the eluant bypassing some of the ion exchange material and providing a lower yield. While a wide range of column aspect ratios are acceptable, preferably, without limitation, the aspect ratio may be between about 4 and 50, more preferably between about 6 and about 20.

[041] Preferably, the column or other elutable container is not loaded with uniform material over its entire length. The portion of the column closest to the generator outlet preferably holds sodium nonatitanate containing no $^{82}$Sr, serving as a guard bed to intercept any $^{82}$Sr or $^{85}$Sr released from the generator. By intercepting and capturing any released $^{82}$Sr and $^{85}$Sr, the product eluant is safe for use as an $^{82}$Rb tracer. The guard bed may be formed with sodium nonatitanate that was produced without the neutralization step so that the affinity to capture strontium is at its highest level and the affinity to capture rubidium is at its lowest level.

Optionally, the guard bed may be placed in a second separate container, receiving the eluate from the outlet of the generator, to filter any strontium from the eluant eluted from the $^{82}$Rb generator. Alternatively, a guard bed may be installed in the generator as described above coupled with a separate filter containing sodium nonatitanate as an added precaution.

[042] Optionally, the sodium nonatitanate may be supported on the surface of a non-porous support. Placing the sodium nonatitanate in a thin layer on a non-porous support provides the advantage of placing all of the sodium nonatitanate in close contact with the eluant, thereby minimizing the length of the diffusion path of the $^{82}$Rb from the nonatitanate to the eluant. Suitable non-porous support materials include inorganic materials that are not damaged in a high radiation field, such as fiberglass, fine glass beads, ceramics, and other similar materials known to those skilled in the art. It is critical that any material chosen for this function does not release anything into the eluate that could contaminate the product.

[043] The examples that follow disclose the methods and materials for the $^{82}$Rb generator. Examples 12-18 further disclose the nonatitanate neutralized to a lower pH for providing an eluate having a pH within the desired range.

EXAMPLES

[044] These Examples investigated the suitability of sodium nonatitanate for the use in separating $^{82}$Sr from irradiated targets and in the construction of an $^{82}$Sr/$^{82}$Rb generator. Initial batch experiments compared the rubidium and strontium selectivities of a number of different sodium nonatitanate samples with commercially available ion exchange materials (*e.g.*, AW 500, Chelex 100) and some experimental materials that had also exhibited high strontium selectivities (*e.g.*, sodium titanosilicate). Column experiments were then performed using target simulants and generator simulants on materials that exhibited favorable selectivity characteristics. Some work was also performed to investigate the likely interference from other isotopes present in irradiated targets on the production of $^{82}$Sr.

Example **1** - Preparation of Sodium Nonatitanate

[045] Sodium nonatitanate (NaTi) was synthesized hydrothermally as follows. 77.5 g of titanium isopropoxide was added to 84.35 g of a 50 wt% solution of NaOH with vigorous stirring and 60 mL of deionized water was added. The resultant gel was heated at approximately 108 °C

for 3 hours, transferred to a hydrothermal pressure vessel with an additional 90 mL of deionized water, and heated at either 170 °C or 200 °C for times ranging from 21 hours to 1 week. After the allotted time, the materials were filtered, washed with ethanol to remove residual base and dried at 60 °C. The mass of sodium nonatitanate produced was approximately 31 g. Each sample was characterized using x-ray powder diffraction (XRD). The reaction is outlined in Equation 1.

$$9\ Ti(OC_3H_7)_4 + 4\ NaOH(aq) \rightarrow Na_4Ti_9O_{20}xH_2O + 9\ C_3H_7OH \qquad (1)$$

[046] The crystallinity of the material was shown to be dependent upon the reaction time and temperature, with the most crystalline materials being produced after 1 week of hydrothermal treatment (200 °C for 7 days). Samples that received no hydrothermal treatment, or only a few days, were virtually amorphous with only a few very broad reflections visible on the XRD pattern.

[047] The theoretical cation exchange capacity (CEC) of sodium nonatitanate is quite high and has a value of 4.74 meq/g, which compares favorably with organic ion exchange resins.

[048] Alternative titanium salts that could be used to manufacture sodium nonatitanate include titanium tetrachloride, $TiCl_4$, and titanium sulfate, $TiOSO_4.xH_2SO_4.yH_2O$. However, hydrolysis of these salts leads to the generation of hydrochloric acid and sulfuric acid, respectively, and thus additional base is required to neutralize the acids during the hydrothermal process. The final product also needed to be exhaustively washed to remove residual sodium chloride or sodium sulfate. Consequently, titanium isopropoxide (which hydrolyzes to form propanol) or titanium dioxide $TiO_2$ is the preferred starting material because the final product is free from additional sodium salts.

Example **2** - Determination of Strontium Selectivity

[049] Sodium nonatitanate and a variety of other ion exchange materials were obtained and evaluated for use in the separation of $^{82}Sr$ from targets and in a $^{82}Rb$ generator. These materials are described below in Table **1**.

Table 1 - Characteristics of Ion Exchange Materials Evaluated in this Study

| Material | Source | Sample Preparation |
|---|---|---|
| Na-Clinoptilolite | GSA Resources, AZ | Ground to powder. |
| AW500 | Aldrich (1.6 mm Pellets) | Ground to powder |
| Hydrous $SnO_2$ | Synthesized in house | NaOH + $SnCl_4$. Washed with acetic acid/sodium acetate buffer |
| K+ Pharmacosiderite ($K_3H(TiO)_4(SiO_4)_3.4H_2O$) | Synthesized according to literature method | None. Used as synthesized |
| Sodium Titanosilicate ($Na_2Ti_2O_3SiO_4.2H_2O$) | Synthesized according to literature method | None. Used as synthesized |
| AG 50W-X8 (Na+) (25 - 50 Mesh) | BioRad. Strong acid ion exchange resin. | Converted to Na+ form (for alkaline solutions only) |
| Chelex 100 (Na+) (50 - 100 Mesh) | BioRad. Chelating resin with iminodiacetic acid functionality | None. Used as received |
| Sodium Nonatitanate | Honeywell, IL | None. Used as received |
| Hydrous $SiO_2$ | Synthesized in house | Acetic acid hydrolysis of tetraethyl orthosilicate. Washed with $H_2O$ |
| Hydrous $TiO_2$ | Synthesized in house | Hydrolysis of titanium isopropoxide. Washed with $H_2O$ |
| Hydrous $ZrO_2$ | Synthesized in house | $ZrOCl_2$ + NaOH. Washed with deionized water |

[050] The strontium selectivity of the ion exchange materials of Table 1 was evaluated in sodium chloride and rubidium chloride solutions using radiotracer techniques. Samples were evaluated using a simple batch technique to allow the rapid screening of a large number of materials over a range of ionic strengths. Blanks were run for each matrix to check for any loss of strontium during filtration or absorption of strontium onto the scintillation vials. In all solutions evaluated, strontium absorption was negligible.

[051] 0.05 g of each of the ion exchange materials was contacted with 10 mL of a solution, spiked with $^{89}Sr$, in a capped scintillation vial. (The total strontium content was approximately 1.6 ppm, thus preventing any loss of strontium in solution due to precipitation of sparingly soluble $Sr(OH)_2$ at alkaline pH values.) The mixtures were shaken for 6 hours, filtered through a 0.2 μm syringe filter and the residual activity determined using liquid scintillation counting (LSC). Distribution Coefficients ($K_d$ values) were then determined according to Equation 2:

$$K_d = (A_i - A_f) / A_f * V/m \qquad (2)$$

where: $A_i$ = initial activity in solution (counts per minute (cpm)/mL)

$A_f$ = final activity in solution (cpm/mL)

V = volume of solution (mL)

m = mass of exchanger (g)

[052] The final pH of the solution was also noted. The period of 6 hours was chosen to allow equilibrium to be reached for each of the ion exchange materials. However, previous work on the titanosilicates and titanates had shown the reaction rates to be rapid with the majority of the uptake occurring in only a few minutes. The concentration of the chloride solutions was varied from 1M to 0.001M to evaluate the effect of increasing $Rb^+$ and $Na^+$ concentrations on the uptake of $Sr^{2+}$. All experiments were performed in duplicate, and if significant variations between duplicate samples occurred, the experiments were repeated until good agreements on the $K_d$ values were obtained. The results are shown in Tables 2 and 3 and represented the average $K_d$ obtained, quoted to 3 significant figures.

Table **2** - Strontium Selectivity Data from Unbuffered Sodium Chloride Solutions

| **Ion Exchange Material** | **$K_d$ mL/g** | | | |
|---|---|---|---|---|
| | **1M NaCl** | **0.1M NaCl** | **0.01M NaCl** | **0.001M NaCl** |
| Na-Clinoptilolite | 8 | 124 | 3,260 | 36,900 |
| AW500 | 1,860 | 88,300 | 1,270,000 | 1,210,000 |
| Hydrous $SnO_2$ | 767 | 43,000 | 124,000 | 51,800 |
| K+ Pharmacosiderite | 18,300 | 251,000 | 594,000 | 281,000 |
| Sodium Titanosilicate | 556,000 | 273,000 | 119,000 | 42,900 |
| AG 50W (Na+) | 32 | 3,380 | 365,000 | 2,510,000 |
| Chelex 100 (Na+) | 610 | 26,400 | 726,000 | 1,300,000 |
| NaTi (Honeywell) | 80,600 | 1,030,000 | 258,000 | 166,000 |
| NaTi (No hydrothermal) | 1,530,000 | 2,570,000 | 739,000 | 372,000 |
| NaTi (170°C, 21hr) | 1,030,000 | 1,240,000 | 272,000 | 172,000 |
| NaTi (170°C, 3d) | 959,000 | 633,000 | 218,000 | 93,100 |
| NaTi (170°C, 7d) | 167,000 | 834,000 | 264,000 | 90,400 |
| NaTi (200°C, 21hr) | 439,000 | 1,390,000 | 197,000 | 120,000 |
| NaTi (200°C, 3 d) | 261,000 | 898,000 | 251,000 | 158,000 |
| NaTi (200°C, 7d) | 195,000 | 955,000 | 265,000 | 214,000 |
| $ZrO_2$ | 3,360 | 52,200 | 213,000 | 232,000 |

Table 3 - Strontium Selectivity Data from Unbuffered Rubidium Chloride Solutions

| Material | $K_d$ mL/g 1M RbCl | 0.1M RbCl | 0.01M RbCl | 0.001M RbCl |
|---|---|---|---|---|
| Na-Clinoptilolite | 19 | 3 | 88 | 11,000 |
| AW500 | 9,750 | 107,000 | 1,020,000 | 1,280,000 |
| Hydrous $SnO_2$ | 766 | 66,100 | 104,000 | 51,800 |
| K+ Pharmacosiderite | 1,950 | 40,800 | 419,000 | 427,000 |
| Sodium Titanosilicate | 12,600 | 94,700 | 164,000 | 179,000 |
| AG-50W (Na+) | 44 | 3,870 | 237,000 | 800,000 |
| Chelex 100 (Na+) | 1,580 | 38,400 | 555,000 | 977,000 |
| NaTi (Honeywell) | 13,900 | 108,000 | 279,000 | 324,000 |
| NaTi (No hydrothermal) | 14,220 | 116,000 | 345,000 | 429,000 |
| NaTi (170°C, 21hr) | 10,500 | 71,700 | 193,000 | 205,000 |
| NaTi (170°C, 3d) | 15,100 | 39,500 | 68,000 | 95,200 |
| NaTi (170°C, 7d) | 23,000 | 55,800 | 31,200 | 110,000 |
| NaTi (200°C, 21hr) | 11,000 | 66,400 | 110,000 | 103,000 |
| NaTi (200°C, 3 d) | 10,600 | 56,800 | 146,000 | 158,000 |
| NaTi (200°C, 7d) | 10,500 | 57,400 | 146,000 | 158,000 |
| $ZrO_2$ | 3,000 | 42,400 | 184,000 | 221,000 |

[053] Comparing the selectivity data from sodium and rubidium solutions, it is evident that rubidium ions cause a reduction in affinity for the strontium ion for all of the exchangers indicating that the affinity of these materials for rubidium is significantly higher than the affinity for sodium ions. The pH of the final solutions was generally alkaline for the nonatitanates (NaTi) and titanosilicates, with pH values as high as 12 being measured. This was due to hydrolysis of the exchangers resulting in the absorption of protons and the release of sodium ions, thus increasing the pH of the aqueous phase. This effect can be overcome, if desired, by buffering the solution.

[054] The most distinct trend was observed in 1M NaCl solutions for the sodium nonatitanate samples. The highest $K_d$ was observed for the non-hydrothermal material and the $K_d$ values decreased with increasing reaction time for both the 200 °C and 170 °C materials. Clearly, strontium uptake is facilitated by having a low-crystallinity material. This suggests that as the crystallinity increases and the size of the nonatitanate crystallites also increases, it becomes thermodynamically less favorable for exchange of the sodium ions by strontium. It is also interesting to note that the majority of the sodium nonatitanates exhibit a higher selectivity for strontium in 1M NaCl than in 0.001M NaCl. This indicates that the higher ionic strength facilitates the $Na^+/Sr^{2+}$ exchange reaction and more than compensates for the increased competition for the ion exchange sites from the additional $Na^+$ ions.

[055] This data shows that sodium nonatitanate is an ideal material for the recovery of $^{82}Sr$ from irradiated rubidium and rubidium chloride targets and in the manufacture of a $^{82}Rb$ generator.

Example 3 - Rubidium Selectivity from NaCl Solutions

[056] For an ion exchange material to be suitable for use in a $^{82}Rb$ generator, it must have a very high selectivity for strontium to prevent any loss of $^{82}Sr$ from the ion exchange column and release to the patient undergoing a PET scan. This property was clearly demonstrated in Example 2. It must also have a very low selectivity towards rubidium, thus allowing $^{82}Rb$ to be released into solution as saline is passed through the $^{82}Rb$ generator. Consequently, the rubidium selectivity of the ion exchange materials was evaluated in sodium chloride media following the procedure described in Example 2. The same procedure was followed using $^{86}Rb$ to spike the solutions to give an activity of approximately 200,000 cpm/mL. Total rubidium in solution was < 0.05 ppm. The distribution coefficients of the materials are shown below in Table 4.

Table 4 - Rubidium Selectivity Data from Unbuffered Sodium Chloride Solutions

| Ion Exchange Material | 1M NaCl | 0.1M NaCl | 0.01M NaCl | 0.001M NaCl |
|---|---|---|---|---|
| AW500 | 116 | 620 | 4920 | 21900 |
| Hydrous $SnO_2$ | 1 | 6 | 36 | 290 |
| K+ Pharmacosiderite | 148 | 475 | 2030 | 4020 |
| Sodium Titanosilicate | 8,010 | 194,000 | 114000 | 75800 |
| AG 50W (Na+) | 7 | 75 | 688 | 6680 |
| Chelex 100 (Na+) | 3 | 8 | 43 | 256 |
| NaTi (Honeywell) | 9 | 102 | 488 | 817 |
| NaTi (No hydrothermal) | 4 | 59 | 280 | 446 |
| NaTi (170°C, 21hr) | 9 | 56 | 209 | 297 |
| NaTi (170$_o$C, 3d) | 7 | 46 | 198 | 311 |
| NaTi (170°C, 7d) | 3 | 15 | 47 | 71 |
| NaTi (200°C, 21hr) | 8 | 79 | 334 | 502 |
| NaTi (200°C, 3d) | 8 | 52 | 207 | 307 |
| NaTi (200°C, 7d) | 4 | 25 | 111 | 178 |
| $ZrO_2$ | 1 | 12 | 60 | 154 |

Table **4A** - Strontium-Rubidium Separation Factor

| Ion Exchange Material | 1M NaCl | 0.1M NaCl | 0.01M NaCl | 0.001M NaCl |
|---|---|---|---|---|
| AW500 | 16.0 | 142 | 258 | 55.3 |
| Hydrous SnO2 | 767 | 7,167 | 3,444 | 179 |
| K+ Pharmacosiderite | 124 | 528 | 293 | 69.9 |
| Sodium Titanosilicate | 69.4 | 1.41 | 1.04 | 0.57 |
| AG 50W (Na+) | 4.57 | 45.1 | 531 | 376 |
| Chelex 100 (Na+) | 203 | 3,300 | 16,884 | 5,078 |
| NaTi (Honeywell) | 8,956 | 10,098 | 529 | 203 |
| NaTi (No hydrothermal) | 382,500 | 43,559 | 2,639 | 834 |
| NaTi (170 C, 21hr) | 114,444 | 22,143 | 1,301 | 579 |
| NaTi (170 C, 3d) | 137,000 | 1,370 | 1,101 | 299 |
| NaTi (170 C, 7d) | 55,667 | 55,600 | 5,617 | 1,273 |
| NaTi (200 C, 21hr) | 54,875 | 17,595 | 590 | 239 |
| NaTi (200 C, 3d) | 32,625 | 17,269 | 1,213 | 515 |
| NaTi (200 C, 7d) | 48,750 | 38,200 | 2,387 | 1,202 |
| ZrO2 | 3,360 | 4,350 | 3,550 | 1,506 |

Table **4B** - Percent Rubidium Retention Generated on 0.1 g of Exchanger in NaCl Solution

| Ion Exchange Material | 1M NaCl | 0.1M NaCl | 0.01M NaCl | 0.001M NaCl |
|---|---|---|---|---|
| AW500 | 18.8 | 55.4 | 90.8 | 97.8 |
| Hydrous SnO2 | 0.2 | 1.2 | 6.7 | 36.7 |
| K+ Pharmacosiderite | 22.8 | 48.7 | 80.2 | 88.9 |
| Sodium Titanosilicate | 94.1 | 99.7 | 99.6 | 99.3 |
| AG 50W (Na+) | 1.4 | 13.0 | 57.9 | 93.0 |
| Chelex 100 (Na+) | 0.6 | 1.6 | 7.9 | 33.9 |
| NaTi (Honeywell) | 1.8 | 16.9 | 49.4 | 62.0 |
| NaTi (No hydrothermal) | 0.8 | 10.6 | 35.9 | 47.1 |
| NaTi (170 C, 21hr) | 1.8 | 10.1 | 29.5 | 37.3 |
| NaTi (170 C, 3d) | 1.4 | 8.4 | 28.4 | 38.3 |
| NaTi (170 C, 7d) | 0.6 | 2.9 | 8.6 | 12.4 |
| NaTi (200 C, 21hr) | 1.6 | 13.6 | 40.0 | 50.1 |
| NaTi (200 C, 3d) | 1.6 | 9.4 | 29.3 | 38.0 |
| NaTi (200 C, 7d) | 0.8 | 4.8 | 18.2 | 26.3 |
| ZrO2 | 0.2 | 2.3 | 10.7 | 23.5 |

[057] From the data in Table **4**, it is clear that the all of the sodium nonatitanate materials have a very low affinity for rubidium, particularly in the presence of relatively high amounts of sodium ions. In general, the rubidium selectivity decreased with increasing reaction time for both series of nonatitanates (170 °C and 200 °C) with the lowest affinity being demonstrated by the sample that was heated hydrothermally at 170 °C for 1 week. Uptake was negligible in 1M NaCl and the very low reduction in activity that was noted could be accounted for by absorption of rubidium during filtration and by pipetting errors during the counting procedure. Consequently, samples with $K_d$ values that were below 10 mL/g can be considered to

have no affinity at all for $^{86}Rb$. Some rubidium uptake was evident in very dilute sodium solutions, but the $K_d$ values were low for all of the titanate samples. This suggests that the uptake of rubidium was more likely due to the materials having an exceptionally low affinity for sodium rather than any real affinity for rubidium. All of the sodium nonatitanate materials performed better than the commercially available sample obtained from Honeywell, Inc. The materials are clearly ideal for use in a $^{82}Rb$ generator.

[058] Hydrous tin dioxide exhibited some of the lowest rubidium affinities and was comparable with Chelex 100, the best of the nonatitanates and the hydrous zirconium dioxide. However, hydrous tin dioxide exhibited much lower strontium $K_d$ values than the nonatitanates. Therefore, nonatitanate materials are preferred because they have higher strontium/rubidium separation factors. Hydrous tin dioxide also has a limited pH stability range and significant dissolution and release of absorbed strontium is likely to occur should any significant pH perturbations occur outside the range of pH 4 to pH 9. Radiation stability of hydrous tin dioxide is also limited, with particle breakdown causing current $^{82}Rb$ generators to be replaced before decay has reduced the $^{82}Rb$ below useable levels.

[059] The rubidium selectivity data also indicates that AW500, potassium Pharmacosiderite and the sodium titanosilicate have a strong affinity for rubidium in a range of saline solutions. Consequently, these materials will be unsuitable for use in a 82Rb generator and have only limited applications in the processing of irradiated target materials.

Example 4 - Strontium and Rubidium Selectivity in 0.1M Sodium Acetate/Acetic Acid Buffer

[060] In order to prevent hydrolysis reactions from raising the pH as described above, some strontium and rubidium selectivity experiments were performed in a 0.1M sodium acetate / acetic acid buffer solution. In these tests, the final pH remained between 5.2 and 6.3, which is a more clinically acceptable pH for an $^{82}Rb$ infusion. Rubidium $K_d$ values remained low, as expected, following the trend observed in Table 5. Strontium $K_d$ values were considerably lower, with a maximum $K_d$ value of 80,000 mL/g being obtained for the sodium nonatitanate sample that was heated hydrothermally at 170 °C for 21 hours. This is considerably lower than the $K_d$ value of over 1,200,000 mL/g that was obtained in unbuffered 0.1M NaCl (pH ~ 12). The $K_d$ values obtained for the other ion exchange materials were also considerably lower. However, the Sr/Rb separation factors remained high and the sodium nonatitanates still outperformed hydrous

tin dioxide and the organic ion exchange resins. The affinity of sodium nonatitanate for strontium is greatest at higher pH values.

Example **5** - Molybdenum Targets

[061] The basic steps of a proposed process to obtain $^{82}Sr$ from irradiated molybdenum targets are as follows:

1. Dissolve the irradiated molybdenum target in 30% hydrogen peroxide, ensuring excess hydrogen peroxide is destroyed.

2. Add sodium hydroxide to bring the pH to approximately 12.

3. Filter the solution to remove any precipitate. It is predicted that the majority of $^{88}Zr$ and $^{59}Fe$ will be found in the precipitate, and experiments have confirmed that 99% or more of the $^{88}Y$ precipitated out of solution on the addition of NaOH.

4. Pass the solution through a column of sodium nonatitanate and wash the column with two bed volumes of 0.1M NaCl, adjusted to pH 12 with NaOH. $^{82}Sr$ and $^{85}Sr$ will be absorbed. $^{82}Rb$ and other Rb isotopes will remain in the aqueous phase. Molybdate anions will also pass through the column.

5. The column can then be stripped using dilute mineral acid to recover the $^{82}Sr$ and the sodium nonatitanate reused or discarded.

[062] There is a range of other isotopes present in addition to $^{82}Sr$, including $^{75}Se$, $^{73}As$, $^{74}As$, $^{7}Be$, $^{68}Ge$, $^{48}V$, $^{60}Co$ (and other Co isotopes), $^{54}Mn$, $^{51}Cr$ and $^{95m}Tc$. In the alkaline target solution, Se, As, V, Ge, Cr, Mn and Tc are expected to be present as anions and thus will not be absorbed onto the sodium nonatitanate. Significant amounts of Co would be expected to precipitate when the target solution is neutralized, and thus little is expected to be available under alkaline conditions to absorb onto the sodium nonatitanate. The most likely isotope to be absorbed is beryllium, because it is a Group II metal with a similar aqueous chemistry to strontium. However, the affinity of sodium nonatitanate for Group II metals decreases in the order Sr > Ca > Mg. No data is available for beryllium, but if the trend continues, the affinity would be expected to be low. Thus, any absorbed $^{7}Be$ would be readily removed by an alkaline sodium chloride (or similar) wash.

[063] The current process for recovering $^{82}Sr$ from irradiated rubidium metal and rubidium chloride targets requires minimal modification to facilitate the use of sodium nonatitanate. Both targets are processed following standard processing procedures to generate

rubidium chloride solutions in an ammonia/ammonium chloride buffer solution. These solutions are then passed through a sodium nonatitanate column and washed with additional buffer to remove any weakly held rubidium cations. Strontium and possibly some other cationic species present will be absorbed onto the nonatitanate column, whereas rubidium cations, ammonium cations and anions will rapidly pass through the column. If additional cations are absorbed onto the sodium nonatitanate, they can be selectively removed by washing with an appropriate eluant (*e.g.*, citrate, nitrilotriacetate.) The strontium selectivity of sodium nonatitanate has been shown to be unaffected by a number of common complexants and as a consequence, it should be a relatively simple manner to elute any undesirable cations from the column, leaving pure $^{82/85}Sr$.

[064] FIG. **1** clearly shows the exceptionally high affinity of the sodium nonatitanate materials in comparison with the currently utilized organic resin Chelex 100. All of the sodium nonatitanates performed equally well in the buffered rubidium target solutions indicating that the synthetic conditions are not too important when the material is being used in solutions containing high concentrations of rubidium ions. Thus, by replacing the Chelex 100 with sodium nonatitanate, a more efficient $^{82}Sr$ isolation can be achieved.

[065] It has also been shown that it is possible to tailor the selectivity of the sodium nonatitanate to achieve the optimum Sr/Rb separation by manipulating the reaction conditions. The differing selectivities were most obvious in sodium solutions, with the less crystalline materials exhibiting the highest strontium distribution coefficients. However, the series of nonatitanates showed little difference in behavior when the predominant cation in solution was $Rb^+$. The materials synthesized clearly demonstrated superior characteristics to the commercially available sample in almost all matrices evaluated. The majority of the sodium nonatitanate samples also exhibited greater strontium selectivities than hydrous tin dioxide in a range of sodium chloride solutions, from 1M to 0.001M. Rubidium selectivities were low, making the sodium nonatitanate ideal as a replacement for hydrous tin dioxide in a $^{82}Rb$ generator.

[066] Commercially, one method of $^{82}Sr$ production is *via* the proton spallation reaction with natural molybdenum metal targets. A simulated molybdate target solution was prepared as follows: 12.5 g of molybdenum powder was carefully dissolved in 30% $H_2O_2$ solution and made up to a total volume of 500 mL to produce a clear yellow solution of molybdic acid, $H_2MoO_4$. Solid sodium hydroxide granules totaling 10.9 g were then carefully added to neutralize the solution and bring the pH to approximately 12.3. The colorless solution was then filtered to remove any precipitate. This alkaline molybdate solution was spiked with either $^{86}Rb$ or $^{89}Sr$ and

$K_d$ values determined as described previously. Separation factors for the strontium/rubidium selectivity were also calculated by dividing the strontium $K_d$ by the rubidium $K_d$, thus allowing the relative affinities of the ion exchange materials to be directly compared. The results are illustrated below in Table 5.

Table 5 - Strontium and Rubidium Absorption from Simulated Molybdate Target Solutions

| Material | Sr Kd, mL/g | Rb Kd, mL/g | Separation Factor |
|---|---|---|---|
| AW500 | 7,070 | 194 | 36.4 |
| K+ Pharmacosiderite | 187,000 | 142 | 1320 |
| Sodium Titanosilicate | 547,000 | 6500 | 84.2 |
| Chelex 100 (Na+) | 3,120 | 5 | 624 |
| AG 50W-X8 (Na+) | 69 | 18 | 3.83 |
| NaTi (Honeywell) | 337,000 | 27 | 12,500 |
| NaTi (No hydrothermal) | 1,690,000 | 12 | 141,000 |
| NaTi (170°C, 21hr) | 1,000,000 | 12 | 83,300 |
| NaTi (170°C, 3d) | 829,000 | 14 | 59,200 |
| NaTi (170°C, 7d) | 324,000 | 3 | 108,000 |
| NaTi (200°C, 21hr) | 954,000 | 12 | 79,500 |
| NaTi (200°C, 3 d) | 687,000 | 11 | 62,500 |
| NaTi (200°C, 7d) | 772,000 | 9 | 85,800 |
| $ZrO_2$ | 168,000 | 8 | 21,000 |

[067] From this data, it is clear that the sodium nonatitanate materials are far superior to Chelex 100 and AG 50W-X8 ion exchange resins for the recovery of $^{82}Sr$ from irradiated molybdenum targets. High $K_d$ values in excess of 500,000 mL/g indicate that almost 100% strontium removal was achieved by some of the nonatitanate samples, with the residual strontium in solution approaching background levels. In the alkaline conditions used in this test, the Chelex 100 resin had the lowest affinity for strontium of all of the materials evaluated. The selectivity of the sodium nonatitanate for rubidium was lowest for the sodium nonatitanate material that was prepared by heating for 1 week at 170 °C to obtain a relatively crystalline product. However, strontium selectivity also decreased with increasing reaction time.

[068] The best overall strontium/rubidium separation factor was obtained for the material that had not undergone any hydrothermal treatment. All of the materials performed better than the commercially available nonatitanate materials. Thus, it is possible to alter the selectivity of the material by controlling the reaction conditions to produce an improved sodium nonatitanate material for use in $^{82}Sr$ separations. Rubidium selectivities were very low for all of

the nonatitanates, indicating minimal rubidium absorption would occur in a column process and that any rubidium absorbed would be readily removed by a dilute saline wash.

[069] The sodium titanosilicate, potassium Pharmacosiderite and AW500 exhibit selectivities for rubidium that are too high to allow their use in the selective removal of $^{82}Sr$ from irradiated molybdenum targets. This high selectivity would result in some rubidium being retained on the column that would not be readily removed by a simple saline wash, thus leading to contamination of the $^{82}Sr$ product with both radioactive and stable rubidium isotopes. Hydrous tin oxide was not evaluated because, due to the amphoteric nature of tin, significant dissolution would be expected at a pH in excess of 12.

Example **6** - Acid Molybdate Target Solutions

[070] Sodium nonatitanate has a relatively low affinity for strontium at pH values less than 6, and was not expected to exhibit any affinity for strontium from the acidic molybdate target solutions prior to the addition of sodium hydroxide. $K_d$ values were determined to confirm this and to compare it with the $K_d$ values for both Chelex 100 and AG 50W-X8 under identical conditions. The data obtained is shown below in Table **6**.

Table **6** - Affinity of Selected Ion Exchange Materials for Strontium in Acidic Molybdate Target Solutions

| **Ion Exchange Material** | **Sr $K_d$ mL/g** | **Final pH of Solution** |
|---|---|---|
| Chelex 100 | 25 | 1.43 |
| AG 50W-X8 | 18,300 | 1.42 |
| Sodium Nonatitanate (Honeywell) | 1,260 | 1.53 |

[071] These data clearly indicate that for the processing of acid molybdate solutions, the strong acid ion exchange resin AG 50W-X8 is the preferred medium. However, the Sr $K_d$ value of 18,300 mL/g in the acidic media is nearly two orders of magnitude lower than the $K_d$ value of 1,690,000 mL/g that was obtained for the best of the sodium nonatitanate materials in alkaline molybdate solutions. Consequently, it is evident that $^{82}Sr$ can be recovered more effectively from alkaline solution using sodium nonatitanate than is currently achieved using AG 50W-X8 from acidic media.

Example 7 - Rubidium and Rubidium Chloride Target Solutions

[072] The processing of either rubidium chloride or rubidium metal targets follows a similar procedure once the target has been successfully dissolved. In essence, $^{82}Sr$ needs to be selectively extracted from a solution of RbCl in a 0.1 M $NH_3$ / 0.1M $NH_4Cl$ buffer adjusted to a pH of between 9 and 10. Batch experiments were performed in simulated buffer solutions to determine the strontium selectivity in the presence of high concentrations of rubidium ions. Only the ion exchange materials that exhibited high strontium selectivities in the initial scoping studies with NaCl solutions were evaluated. $K_d$ values were obtained as described previously. Two rubidium chloride solutions were selected which represent typical rubidium concentrations obtained during the processing of rubidium metal (1.95 M $Rb^+$) and rubidium chloride targets (0.68 M $Rb^+$). In both cases, Chelex 100 is used in the preliminary step to remove the $^{82}Sr$ from the buffered rubidium solutions. The $K_d$ values for the ion exchange materials are shown in FIG. 1.

[073] In the buffered rubidium solutions, there is little difference between the different nonatitanates evaluated. This is in stark contrast to the sodium molybdate solutions where a large variation in the performance of the titanates was observed. The nonatitanates were clearly the most effective materials at removing strontium from the buffered solutions with strontium $K_d$ values of around 15,000 mL/g in 0.68 M $Rb^+$ solutions and approximately 5,000 mL/g in 1.96 M $Rb^+$ solutions. By contrast, Chelex 100 ion exchange resin gave $K_d$ values of less than 1,000 mL/g in both solutions. Hydrous titanium oxide and hydrous tin oxide also exhibited appreciable $K_d$ values, but they performed less efficiently than the nonatitanates in both solutions. Consequently, this data demonstrates that using sodium nonatitanate in place of Chelex 100 ion exchange resin will greatly increase the amount of strontium extracted from the target solutions.

[074] The ion exchange materials were also evaluated for their rubidium selectivity from 0.1 M $NH_3$ / 0.1M $NH_4Cl$ buffer solution. The buffer was prepared, spiked with $^{86}Rb$ and the pH adjusted to approximately 9.25 with concentrated ammonia. $^{86}Rb$ $K_d$ values were then determined following the method described earlier. All of the sodium nonatitanates had a $K_d$ $< 20$ mL/g. The very low rubidium selectivity in the pure buffer is almost certainly due to competition from $NH_4^+$ ions for the available ion exchange sites. Consequently, absorption of rubidium during the processing of rubidium and rubidium chloride targets will be minimal, and any rubidium absorbed will be readily removed by washing with additional 0.1 M $NH_3$ / 0.1M

$NH_4Cl$ buffer solution. Thus, a clean separation of $^{82}Sr$ from these targets can be obtained using sodium nonatitanate.

[075] The performance could also be improved by removing the buffer and increasing the pH to improve the amounts of strontium absorbed. (Buffers were initially utilized to maximize the performance of the organic ion exchange resins currently used and are not essential to the $^{82}Sr$ recovery process.)

Example **8** - Kinetic Experiments

[076] In order for the sodium nonatitanate materials to find applications in the processing of irradiated target solutions, they must exhibit fast ion exchange kinetics allowing solutions to be passed through an ion exchange column at an acceptable rate. The kinetics of strontium absorption from alkaline molybdate target solutions was evaluated using a simple batch procedure. Ion exchange material, in the amount of 0.05 g, was shaken with 10 mL of molybdate solution spiked with $^{89}Sr$ to give a total activity of approximately 155,000 cpm/mL. After an allotted time, the material was filtered through a 0.2 m syringe filter and the activity in the aqueous phase determined by LSC. The results are shown below in FIG. **2**.

[077] From the data in FIG. **2**, it is clear that the reaction kinetics for the sodium nonatitanate powder is extremely rapid, with over 99 % of the $^{89}Sr$ removed in only 1 minute. By contrast, the reaction kinetics of the organic ion exchange resins was much slower and the total amount of $^{89}Sr$ removed after 1 hour was much less.

[078] The exceedingly rapid kinetics can partly be explained by the fact that the nonatitanate was in the form of a fine powder, whereas the two resins were in the form of beads (see Table 1). As a consequence, a relatively slow reaction rate would be expected for the beads because the uptake of $^{82}Sr$ will be dependent upon the rate of diffusion of the $^{82}Sr$ to the internal exchange sites. The rate of uptake of a sample of sodium nonatitanate pellets (using hydrous titanium dioxide as a binder) was significantly slower than the powdered form, but the kinetics and amount of $^{82}Sr$ absorbed was still significantly better than for either of the two organic resins. As the pelletization process is improved, it is expected that the kinetics and selectivity of the pelletized sodium nonatitanate will improve substantially. Other sodium nonatitanate powders of varying crystallinities also showed rapid kinetics. Other potentially suitable binders for forming suitable pellets include titanium isopropoxide or tetraethyl orthosilicate (TEOS) as a binder precursor.

Example **9** - $^{82}Sr$ Removal from Irradiated Targets Using Pelletized Sodium Nonatitanate

[079] A sample of sodium nonatitanate was mixed with titanium isopropoxide as a binder and the resulting paste dried at 105 °C for 12 hours. The material was gently broken up using a mortar and pestle and then sieved to produce particles in the range 40 to 60 mesh. The binder content was approximately 20%. These particles were then used to assess the extraction of $^{89}Sr$ from simulated target solutions.

[080] 1 mL of pelletized sodium nonatitanate was slurried into a column and the target simulant that had been spiked with $^{89}Sr$ to give an activity of approximately 200,000 cpm/mL was passed through the column at a flow rate of 15 mL per hour. The amount of activity removed from solution was then determined. The results are given below in Table 7.

Table **7** - Removal of $^{89}Sr$ from Irradiated Target Solutions

| Target | Solution Composition | Volume (mL) | $^{89}Sr$ Removed (%) |
|---|---|---|---|
| Rubidium Metal | 1.95M RbCl in 0.1M $NH_3/NH_4Cl$ Buffer, pH10 | 20 | 97.3 |
| Rubidium Chloride | 0.68M RbCl in 0.1M $NH_3/NH_4Cl$ Buffer, pH 10 | 28 | 98.8 |
| Molybdenum Metal | 0.26M $Na_2MoO_4$, pH 12 | 20 | 99.9 |

[081] This data clearly shows the effectiveness of sodium nonatitanate for removing strontium isotopes from $^{82}Sr$ target materials. Rubidium absorption under these conditions is minimal.

Example **10** - Elution of Strontium

[082] Strontium was quantitatively eluted from the sodium nonatitanate column of Example **9** using 6M nitric acid. Hydrochloric acid was found to be much less effective and also resulted in breakdown of the sodium nonatitanate particles and blocked the ion exchange column.

Example **11** – Formation of Acid Washed Sodium Nonatitanate Pellets

[083] As described in Example **1**, sodium nonatitanate (NaTi) was synthesized hydrothermally as follows. 77.5 g of titanium isopropoxide was added to 84.35 g of a 50 wt. % solution of NaOH with vigorous stirring and 60 mL of deionized water was added. The resultant gel was heated at approximately 108 °C for 3 hours, transferred to a hydrothermal pressure vessel

with an additional 90 mL of deionized water, and heated at either 170 °C or 200 °C for times ranging from 21 hours to 1 week.

[084] After the hydrothermal treatment disclosed in Example **1**, the vessel was cooled down and the sodium nonatitanate was transferred into a centrifuge tube and separated from solution by centrifugation (3,300 rpm for 14 minutes). The recovered nonatitanate was washed by resuspending it in 500 mL of deionized water (DIW) by mixing it thoroughly and then again separated by centrifugation. These washing steps were repeated twice.

[085] The pH of deionized water was adjusted to 3 by the addition of HCl. The washed nonatitanate was added to the low pH DIW and mixed thoroughly. The nonatitanate was recovered through centrifugation and dried in a 60 °C oven for two nights. The hard acid washed nonatitanate was then ground, sized and sieved to 50x100 mesh and 100x200 mesh using nylon screens. Fines were washed off and the pellets were dried at 60 °C.

Example **12** – Formation of Neutralized Nonatitanate Pellets

[086] Sodium nonatitanate was prepared by treating it hydrothermally for 21 hours at 200 °C. The white product was washed by suspending it in DIW with stirring. 3 M nitric acid was added dropwise to maintain a pH of 8.0 for one hour. After a final DIW wash, the material was dried overnight at 60 °C. The dried material was sized into particles using a series of nylon sieves, and collecting the 100x200 mesh particles for column use. The sized material was rinsed of fines.

[087] Pellet size is a factor that affects the performance of the 82Sr/82Rb generator column because higher Sr uptake is obtained with finer particles due to the faster sorption with the material having the smaller particle size and resulting greater surface area. FIG. **4** is a graph showing the $^{85}Sr$ $K_d$ values in normal saline for NaTi samples of various pellet size, without a binder.

Example **13** – Packing Column with Sodium Nonatitanate and Loading with Parent $^{82}Sr$

[088] To prepare the generator column, the sodium nonatitanate particles were suspended in saline and slurried into the column. First, 1.125 g of exchanger was introduced into the column and sandwiched between two filters (GB003, Schleicher & Schuell blotting paper). This bed provided a guard bed to trap any strontium that was released from the bed above. Next, about 0.375 g of exchanger was equilibrated with inactive strontium ($SrCl_2$) in saline, to simulate

a full loading of $^{82}Sr$. This material was placed on top of the guard bed and topped with a third filter.

Example **14** – Balancing pH by the Addition of Acid

[089] Nonatitanate is prepared as described in Example **12** except that the pH is adjusted to 11 instead of 8.0. The material is equilibrated with $^{82}Sr$ and loaded into a column having a guard bed as described in Example **13**. The column is eluted with normal (0.9 %) saline with 50 mL/min flow. The resulting solution contains a high yield of $^{82}Rb$ in 49mL of solution at pH 10. This solution is dosed with 1 mL of 0.05 M HCl, neutralizing the basicity of the saline to yield 50 mL of solution at pH 7, suitable for use as a medical pharmaceutical as previously described.

Example **15** – Supported Sodium Nonatitanate

[090] Fine glass helices of the type commonly used to pack a high efficiency distillation column are dipped in a dilute (5 wt. %) solution of sodium metasilicate. The helices are allowed to drain so only a thin film of solution remains on their surfaces. The helices are then gently rolled in finely powdered (<400 mesh, < 38 μm) sodium nonatitanate to coat the surfaces with the powder. The coated helices are dried and the metasilicate solution is rendered insoluble by heating to 175 °C in air for 16 hours. The helices are now ready for use in a generator.

Example **16** – Pelletization of the Ion Exchanger

[091] After hydrothermal treatment and washing the material was then resuspended in DIW that has had the pH adjusted to 3 with HCl, mixed thoroughly after which the solid and liquid phases were separated as before. The wet exchanger was dried in a 60 °C oven for two nights, the hard product ground, sized and sieved to 50x100 mesh and 100x200 mesh using nylon screens. Fines were washed off and the pellets dried at 60 °C. These pellets were ready for further testing.

Example **17** – Elution at Lower pH

[092] The column packed with NaTi (neutralized to pH 8.0 as described in Example **12**) was eluted using the syringe pump system as shown in FIG. **5**. USP saline (purchased in 1 L bottles from Fisher Scientific), was methodically drawn into a 60 mL syringe and pushed through

the column in 50 mL increments at a flow rate of 50 mL/min. The eluates were collected in 50 mL falcon tubes. A 5 mL sample of each eluate was analyzed for $^{85}Sr$ activity by gamma spectroscopy (Wallac 1480 Wizard 3) and the pHs recorded. Over 20 L of USP saline were pumped through the column during the experiment with no $^{85}Sr$ breakthrough observed.

[093] The results are shown in FIGS. **6A-6B**, which show that all of the saline was eluted at pH values acceptable for injection into a human. The neutralized material retains its strong strontium binding ability and no breakthrough of $^{82,85}Sr$ was observed in over 20 L of eluted USP saline (after the initial washout in 200 mL).

[094] Table **8** provides reproducibility and quality control data of final batches of sodium nonatitanate described by the synthesis procedure, sizing of pellets and $^{85}Sr$ and $^{86}Rb$ $K_d$ values.

| | | | Sizing of pellets | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| ID | Treatment | Synthesis Yield (Dry weight, g) | 50-100 mesh (% of total) | 100-200 mesh (% of total) | >100 mesh (% of total) | >200 mesh (% of total) | Loss to sizing (% of total) | $^{85}Sr$ Kd in saline/ equilibration pH | $^{86}Rb$ Kd in saline/ equilibration pH |
| TA-A-78 | 'Acid wash' | 28.3 | 65.6 | 23.0 | x | 9.5 | 1.98 | 1,970,632.5 / 9.89 | 56.6 / 9.89 |
| TA-A-80 | 'Acid wash' | 19.3 | 47.2 | 27.5 | x | 21.6 | 3.77 | **10,603,837.65 / 9.44** | **84.65 / 9.39** |
| TA-A-83 | 'Acid wash' | 21.4 | 48.9 | 21.0 | x | 25.7 | 4.48 | 5,866,141.8 / 9.43 | x |
| TA-A-84 1-12 | Neutralized (pH 8) | 12.3 | x | 46.9 | x | 53.1 | 0.00 | 520,951.3 / 6.82 | 188.6 / 6.87 |
| TA-A-84 3-19 | Neutralized (pH 8) | 13.0 | 38.4 | x | 59.7 | x | 1.85 | 1,518,239.55 / 6.72 | 232.75 / 6.79 |
| TA-A-87 3-30 | Neutralized (pH 8) | 13.2 | 60.8 | x | 34.0 | x | 5.16 | 1,120,327.3 / 6.72 | 232.65 / 6.70 |
| TA-A-87 4-1 | Neutralized (pH 8) | 12.1 | 52.9 | x | 42.2 | x | 4.88 | 1,007,944.3 / 6.78 | 245.3 / 6.78 |
| TA-A-88 | 'Acid wash' | 25.0 | 49.4 | x | 43.0 | x | 7.64 | 4,656,739.8 / 9.67 | 71.5 / 9.62 |

designates materials used for Kd determination
**equilibration time of several days for Kd determination**

[095] While the foregoing is directed to the preferred embodiment of the present invention, other and further embodiments of the invention may be devised without departing from the basic scope thereof, and the scope thereof is determined by the claims that follow.

## CLAIMS

What is claimed is:

1. A rubidium-82 generator, comprising:

a strontium-82 support medium comprising partially neutralized sodium nonatitanate characterized by a strontium/rubidium separation factor greater than 12,500.

2. The rubidium-82 generator of claim 1, wherein the separation factor is determined in an aqueous sodium chloride solution.

3. The rubidium-82 generator of claim 2, wherein the aqueous sodium chloride solution has a sodium chloride concentration from 0.001 molar to 1 molar.

4. The rubidium-82 generator of claim 2, wherein the aqueous sodium chloride solution is buffered to control acidity.

5. The rubidium-82 generator of claim 2, wherein the aqueous sodium chloride solution is unbuffered.

6. The rubidium-82 generator of claim 1, wherein the sodium nonatitanate is characterized by a strontium selectivity greater than about 85,000 mL/g in a 0.1 molar or 1 molar aqueous sodium chloride solution.

7. The rubidium-82 generator of claim 1, wherein the sodium nonatitanate is characterized by a rubidium selectivity less than 100 mL/g in a 0.1 molar aqueous sodium chloride solution.

8. The rubidium-82 generator of claim 1, wherein the sodium nonatitanate is characterized by a strontium/rubidium separation factor greater than 10,000 in a 1 molar aqueous sodium chloride solution.

9. The rubidium-82 generator of claim 1, wherein the sodium nonatitanate is characterized by a rubidium retention of less than 1.8 % in a 1 molar aqueous sodium chloride solution.

10. The rubidium-82 generator of claim 1, wherein the sodium nonatitanate is characterized by a rubidium retention of less than about 13.6 % in a 0.1 molar aqueous sodium chloride solution.

11. The rubidium-82 generator of claim 1, wherein the sodium nonatitanate is characterized by a rubidium retention of less than about 40 % in a 0.01 molar aqueous sodium chloride solution.

12. The rubidium-82 generator of claim 1, wherein the sodium nonatitanate is characterized by a rubidium retention of less than about 50 % in a 0.001 molar aqueous sodium chloride solution.

13. The rubidium-82 generator of claim 1, wherein the sodium nonatitanate is characterized by a strontium selectivity greater than 250,000 mL/g at an alkaline pH.

14. The rubidium-82 generator of claim 1, wherein the sodium nonatitanate is characterized by a rubidium selectivity less than 100 mL/g at an alkaline pH.

15. The rubidium-82 generator of claim 1, wherein the sodium nonatitanate is characterized by a strontium/rubidium separation factor greater than 100,000.

16. The rubidium-82 generator of claim 1, further comprising strontium-82 absorbed on the sodium nonatitanate.

17. The rubidium-82 generator of claim 1, further comprising a sodium nonatitanate filter medium disposed to receive effluent from the strontium-82 support medium to trap strontium-82 leached from the generator.

18. The rubidium-82 generator of claim 1, further comprising a column, wherein the sodium nonatitanate is disposed in the column.

19. The rubidium-82 generator of claim 1, wherein the sodium nonatitanate is characterized by a strontium/rubidium separation factor greater than 59,200.

20. The rubidium-82 generator of claim 1, wherein the sodium nonatitanate is characterized by a strontium/rubidium separation factor greater than or equal to 79,500.

21. The rubidium-82 generator of claim 1, wherein the partially neutralized sodium nonatitanate is characterized by raising a pH of a normal saline eluant from about 7 to less than about 8 when eluted from the generator, wherein the generator has eluted less than about 1 L of eluate.

22. The rubidium-82 generator of claim 1, wherein the partially neutralized sodium nonatitanate is characterized by raising a pH of a normal saline eluant from about 6.5 to less than about 7.5 when eluted from the generator, wherein the generator has eluted less than about 1 L of eluate.

23. The rubidium-82 generator of claim 1, further comprising:

means for neutralizing an eluate eluted from the partially neutralized sodium nonatitanate.

24. The rubidium-82 generator of claim 1, wherein the sodium nonatitanate is supported on a surface of a substrate.

25. The rubidium-82 generator of claim 13, wherein the substrate is non-porous.

26. The rubidium-82 generator of claim 14, wherein the substrate is selected from glass, fiberglass, ceramics, fine glass beads or combinations thereof.

27. A rubidium-82 generator, comprising:

a strontium-82 support medium comprising sodium nonatitanate characterized by a strontium/rubidium separation factor greater than 12,500 at an alkaline pH; and

means for neutralizing an eluate eluted from the generator.

28. The rubidium-82 generator of claim 27, wherein the eluate is neutralized to a pH of between about 4.5 and about 7.

29. The rubidium-82 generator of claim 27, wherein the eluate is neutralized to a pH suitable for injection into a patient during a medical procedure.

30. The rubidium-82 generator of claim 27, wherein the means for neutralizing an eluate comprise automatic means.

31. The rubidium-82 generator of claim 27, wherein the separation factor is determined in an aqueous sodium chloride solution.

32. The rubidium-82 generator of claim 31, wherein the aqueous sodium chloride solution has a sodium chloride concentration from 0.001 molar to 1 molar.

33. The rubidium-82 generator of claim 31, wherein the aqueous sodium chloride solution is buffered to control acidity.

34. The rubidium-82 generator of claim 31, wherein the aqueous sodium chloride solution is unbuffered.

35. The rubidium-82 generator of claim 27, wherein the sodium nonatitanate is characterized by a strontium selectivity greater than about 85,000 mL/g in a 0.1 molar or 1 molar aqueous sodium chloride solution.

36. The rubidium-82 generator of claim 27, wherein the sodium nonatitanate is characterized by a rubidium selectivity less than 100 mL/g in a 0.1 molar aqueous sodium chloride solution.

37. rubidium-82 generator of claim 27, wherein the sodium nonatitanate is characterized by a strontium/rubidium separation factor greater than 10,000 in a 1 molar aqueous sodium chloride solution.

38. The rubidium-82 generator of claim27, wherein the sodium nonatitanate is characterized by a rubidium retention of less than 1.8 % in a 1 molar aqueous sodium chloride solution.

39. The rubidium-82 generator of claim 27, wherein the sodium nonatitanate is characte4rized by a rubidium retention of less than about 13.6 % in a 0.1 molar aqueous sodium chloride solution.

40. The rubidium-82 generator of claim 27, wherein the sodium nonatitanate is characterized by a rubidium retention of less than about 40 % in a 0.01 molar aqueous sodium chloride solution.

41. The rubidium-82 generator of claim 27, wherein the sodium nonatitanate is characterized by a rubidium retention of less than about 50 % in a 0.001 molar aqueous sodium chloride solution.

42. The rubidium-82 generator of claim 27, wherein the sodium nonatitanate is supported on a surface of a substrate.

43. The rubidium-82 generator of claim 42, wherein the substrate is non-porous.

44. The rubidium-82 generator of claim 43, wherein the substrate is selected from glass, fiberglass, ceramics, fine glass beads or combinations thereof.

45. A process for preparing a rubidium-82 generator, comprising:

preparing sodium nonatitanate from titanium isopropoxide and aqueous sodium hydroxide;

heating the sodium nonatitanate at a temperature between 100°C and 250°C for a period between 12 hours and 2 weeks;

lowering the pH of the sodium nonatitanate; and

absorbing strontium-82 on the neutralized sodium nonatitanate from an aqueous solution comprising strontium-82 and a soluble sodium salt.

46. The method of claim 45, wherein the soluble sodium salt concentration is between about 0.1 and about 1 molar.

47. The process of claim 45, wherein the soluble sodium salt is sodium chloride.

48. The process of claim 45, wherein the molar ratio of aqueous sodium hydroxide to titanium isopropoxide is in excess of 0.44.

49. The process of claim 45, wherein the molar ratio of aqueous sodium hydroxide to titanium isopropoxide is between 2 and 6.

50. The process of claim 45, wherein the aqueous sodium hydroxide is about 50 wt% sodium hydroxide.

51. The process of claim 45, further comprising:

filtering the sodium nonatitanate from the solution.

52. The process of claim 51, further comprising:

washing the sodium nonatitanate with ethanol.

53. The process of claim 52, further comprising:

drying the sodium nonatitanate.

54. The process of claim 45, wherein the molar ratio of aqueous sodium hydroxide to titanium isopropoxide is between about 1 and 10.

55. The process of claim 45, wherein the sodium nonatitanate is heated in a pressure vessel.

56. The process of claim 45, wherein the sodium nonatitanate is prepared in the absence of titanium chlorides and sulfates.

57. The process of claim 45, wherein the step of neutralizing the sodium nonatitanate further comprises:

suspending the sodium nonatitanate in a liquid; and

adding an acid to the liquid to lower the pH.

58. The process of claim 57, wherein the step of adding an acid lowers the pH to between about 7 and about 9.

59. The process of claim 57, wherein the step of adding and acid lowers the pH to between about 7 and about 8.3.

60. The process of claim 57, wherein the liquid comprises water.

61. The process of claim 57, wherein the acid is a strong mineral acid.

62. The process of claim 45, further comprising:

loading the sodium nonatitanate into a column.

63. The process of claim 45, further comprising:

supporting the sodium nonatitanate on a non-porous substrate.

64. The process of claim 45, wherein the solution containing strontium-82 is an acidic aqueous solution.

65. A method of chemically isolating strontium-82 from a proton-irradiated molybdenum target, comprising:

(a) dissolving the molybdenum target containing the strontium-82;

(b) adjusting the pH of the dissolved molybdenum target solution to an alkaline pH;

(c) removing precipitates from the solution; and then

(d) absorbing the strontium-82 from the solution onto a support comprising sodium nonatitanate.

66. The method of claim 65, wherein the molybdenum target is dissolved in hydrogen peroxide.

67. The method of claim 65, wherein the pH is adjusted with sodium hydroxide.

68. The method of claim 65, wherein the pH is adjusted to about 12.

69. The method of claim 65, further comprising:

stripping the strontium-82 from the sodium nonatitanate.

70. The method of claim 65, wherein the strontium-82 is stripped from the sodium nonatitanate with mineral acid.

71. The method of claim 65, further comprising:

washing the sodium nonatitanate with a buffer solution

72. The method of claim 65, wherein the sodium nonatitanate is characterized by a strontium/rubidium separation factor greater than 12,500.

73. The method of claim 65, wherein the sodium nonatitanate is characterized by a strontium/rubidium separation factor greater than or equal to 59,200.

74. The method of claim 65, wherein the sodium nonatitanate is characterized by a strontium/rubidium separation factor greater than or equal to 100,000.

75. A process for preparing a solution containing rubidium-82, comprising:
providing a solution containing strontium-82;
absorbing strontium-82 onto a sodium nonatitanate support medium; and
eluting rubidium-82 from the sodium nonatitanate support medium with an eluant:
receiving a rubidium-82 eluate formed from the eluting step; and
adjusting a pH of the eluate.

76. The process of claim 75, wherein the eluant is selected from the group consisting of water and saline solutions.

77. The process of claim 75, wherein the eluant is an aqueous solution having a sodium chloride concentration between 0.001 molar and 1 molar.

78. The process of claim 75, wherein the eluant is an aqueous solution having a sodium chloride concentration between 0.2 molar and 1 molar.

79. The process of claim 75, wherein the eluant is a pharmaceutical-grade saline and buffer solution.

80. The process of claim 75, wherein the sodium nonatitanate is characterized by a strontium/rubidium separation factor greater than 12,500.

81. The process of claim 75, wherein the sodium nonatitanate is characterized by a strontium/rubidium separation factor greater than or equal to 59,200.

82. The process of claim 75, wherein the sodium nonatitanate is characterized by a strontium/rubidium separation factor greater than or equal to 100,000.

83. The process of claim 75, further comprising:
disposing the sodium nonatitanate support medium into a column.

84. The process of claim 75, wherein the eluate is alkaline.

85. The process of claim 75, further comprising:
buffering the solvent.

86. The process of claim 75, wherein the pH of the eluate is adjusted to between about 4.5 and about 7.

87. The process of claim 75, wherein the pH of the eluate is adjusted to a pH suitable for injecting into a patient during a medical procedure.

88. The process of claim 75, wherein the step of adjusting a pH of the eluate comprises;
adding an acid to the eluate.

89. The process of claim 88, wherein the acid is HCl.

90. The process of claim 75, further comprising:
partially neutralizing the sodium nonatitanate before the step of absorbing strontium-82 onto a sodium nonatitanate support medium.

91. A method of chemically isolating strontium-82 from a proton-irradiated rubidium or rubidium chloride target, comprising:

(a) dissolving the target containing the strontium-82;

(b) adjusting the pH of the dissolved target solution to an alkaline pH;

(c) removing precipitates from the solution; and then

(d) absorbing the strontium-82 from the solution onto a support comprising sodium nonatitanate without absorbing rubidium.

92. The method of claim 91, wherein the dissolved target solution includes a buffer.

93. The method of claim 92, wherein the buffer is an ammonia/ammonium chloride buffer.

94. The method of claim 92, wherein the pH is between 9 and 10.

95. The method of claim 91, wherein the pH is greater than 10.

96. The method of claim 91, further comprising:

stripping the strontium-82 from the sodium nonatitanate.

97. The method of claim 96, wherein the strontium-82 is stripped from the sodium nonatitanate with mineral acid.

98. The method of claim 91, further comprising:

washing the sodium nonatitanate with a buffer solution.

99. The method of claim 91, wherein the sodium nonatitanate is characterized by a strontium/rubidium separation factor greater than 12,500.

100. The method of claim 91, wherein the sodium nonatitanate is characterized by a strontium/rubidium separation factor greater than or equal to 59,200.

101. The method of claim 91, wherein the sodium nonatitanate is characterized by a strontium/rubidium separation factor greater than or equal to 100,000.

102. A process for preparing a rubidium-82 generator, comprising:

preparing sodium nonatitanate from titanium tetrachloride or titanium sulfate and aqueous sodium hydroxide;

heating the sodium nonatitanate at a temperature between 100°C and 250°C for a period between 12 hours and 2 weeks;

lowering the pH of the sodium nonatitanate; and

absorbing strontium-82 on the neutralized sodium nonatitanate from an aqueous solution comprising strontium-82 and a soluble sodium salt.

103. The process of claim 102, wherein the soluble sodium salt concentration is between about 0.1 and about 1 molar.

104. The process of claim 102, wherein the soluble sodium salt is sodium chloride.

105. The process of claim 102, wherein the aqueous sodium hydroxide is about 50 wt% sodium hydroxide.

106. The process of claim 102, wherein the molar ratio of aqueous sodium hydroxide to titanium tetrachloride or titanium sulfate is between about 1 and 12.

107. The process of claim 102, further comprising:

filtering to collect the sodium nonatitanate; and

washing the sodium nonatitanate to remove sodium chloride or sodium sulfate.

108. The process of claim 102, wherein the step of neutralizing the sodium nonatitanate further comprises:

suspending the sodium nonatitanate in a liquid; and

adding an acid to the liquid to lower the pH.

109. The process of claim 108, wherein the step of adding an acid lowers the pH to between about 7 and about 9.

110. The process of claim 108, wherein the step of adding and acid lowers the pH to between about 7.2 and about 8.

111. The process of claim 108, wherein the liquid comprises water.

112. The process of claim 108, wherein the acid is a strong mineral acid.

113. The process of claim 102, further comprising:

loading the sodium nonatitanate into a column.

114. The process of claim 102, further comprising:

supporting the sodium nonatitanate on a substrate.

115. The process of claim 102, wherein the solution containing strontium-82 is an acidic aqueous solution.

116. A process, comprising:

eluting a solution of rubidium-82 from a strontium-82 support medium comprising sodium nonatitanate with an aqueous eluant; and

adjusting a pH of the solution.

117. The process of claim 116, wherein the aqueous eluant is selected from the group consisting of water and saline solutions.

118. The process of claim 116, wherein the aqueous eluant has a sodium chloride concentration between 0.001 molar and 1 molar.

119. The process of claim 116, wherein the aqueous eluant has a sodium chloride concentration between 0.2 molar and 1 molar.

120. The process of claim 116, wherein the aqueous eluant is a saline and buffer solution suitable for human injection.

121. The process of claim 116, wherein the sodium nonatitanate is a reaction product of titanium isopropoxide and aqueous sodium hydroxide.

122. The process of claim 116, further comprising passing the rubidium-82 solution through a sodium nonatitanate filter to selectively remove any strontium-82 or strontium-85 from the solution.

123. The process of claim 116, further comprising disposing of the sodium nonatitanate filter.

124. The process of claim 116, further comprising using the rubidium-82 solution as a medical diagnostic agent or medical imaging agent.

125. The process of claim 124, further comprising injecting the rubidium-82 solution intravenously.

126. The process of claim 116, further comprising stripping strontium-82 from the sodium nonatitanate.

127. The process of claim 126, further comprising recovering the stripped strontium-82.

128. The process of claim 127, further comprising recycling the sodium nonatitanate.

129. The process of claim 116, wherein the sodium nonatitanate has not undergone hydrothermal treatment.

130. The process of claim 116 wherein the step of adjusting the pH further comprises:
adding an acid to the solution.

131. The process of claim 116, wherein the pH is adjusted to between about 4 and about 7.5.

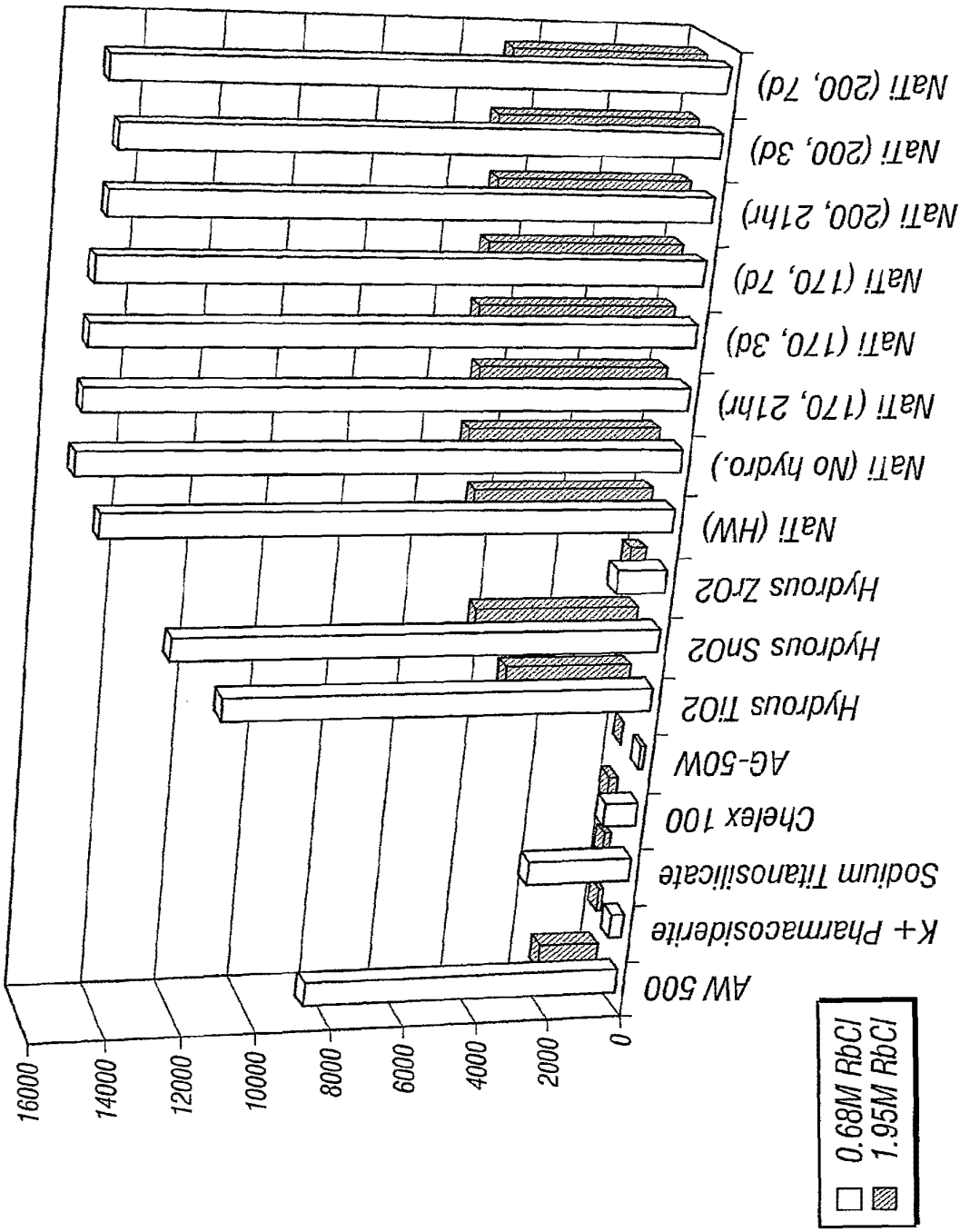
0.68M RbCl
1.95M RbCl
AW 500
K+ Pharmacosiderite
Sodium Titanosilicate
Chelex 100
AG-50W
Hydrous TiO2
Hydrous SnO2
Hydrous ZrO2
NaTi (HW)
NaTi (No hydro.)
NaTi (170, 21hr)
NaTi (170, 3d)
NaTi (170, 7d)
NaTi (200, 21hr)
NaTi (200, 3d)
NaTi (200, 7d)
0
2000
4000
6000
8000
10000
12000
14000
16000

FIG. 1

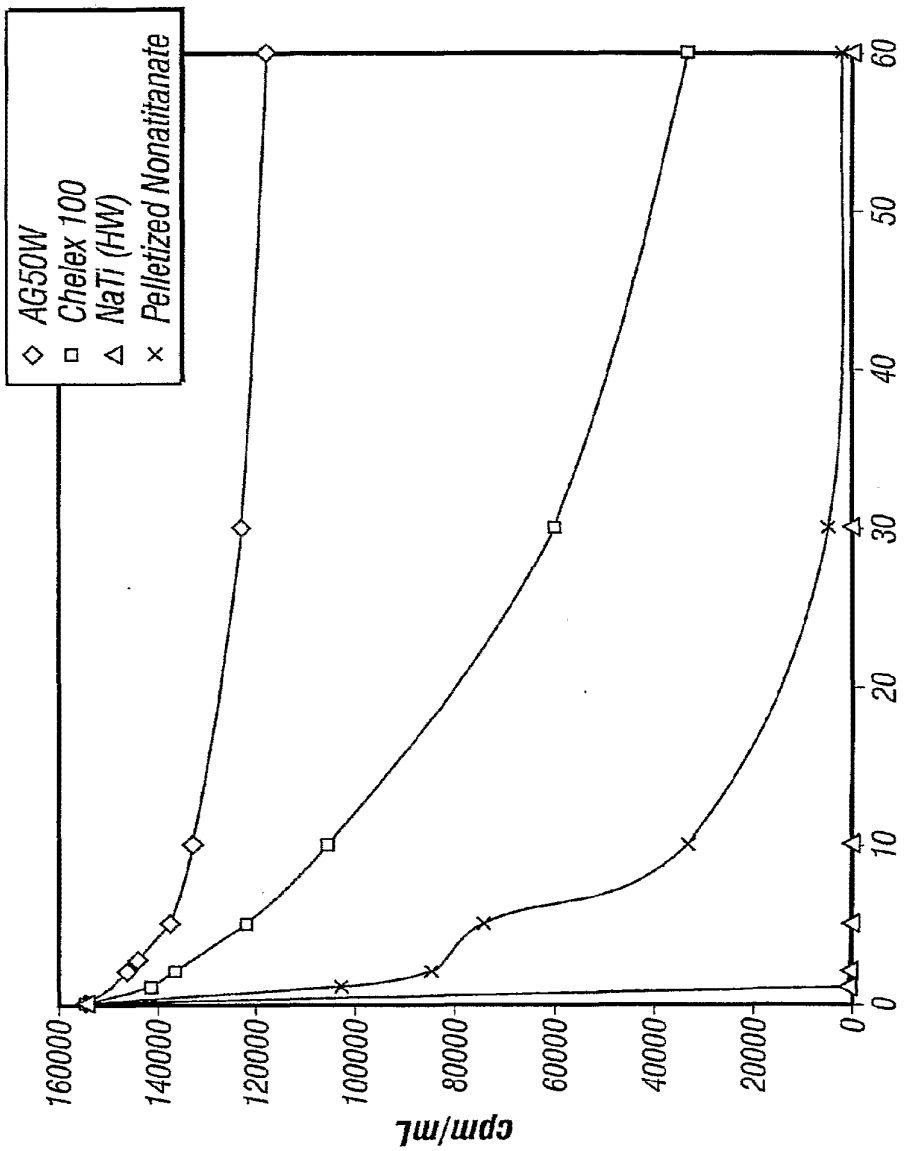
AG50W
Chelex 100
NaTi (HW)
Pelletized Nonatitanate
cpm/mL
160000
140000
120000
100000
80000
60000
40000
20000
0
0
10
20
30
40
50
60
Time (minutes)

FIG. 2

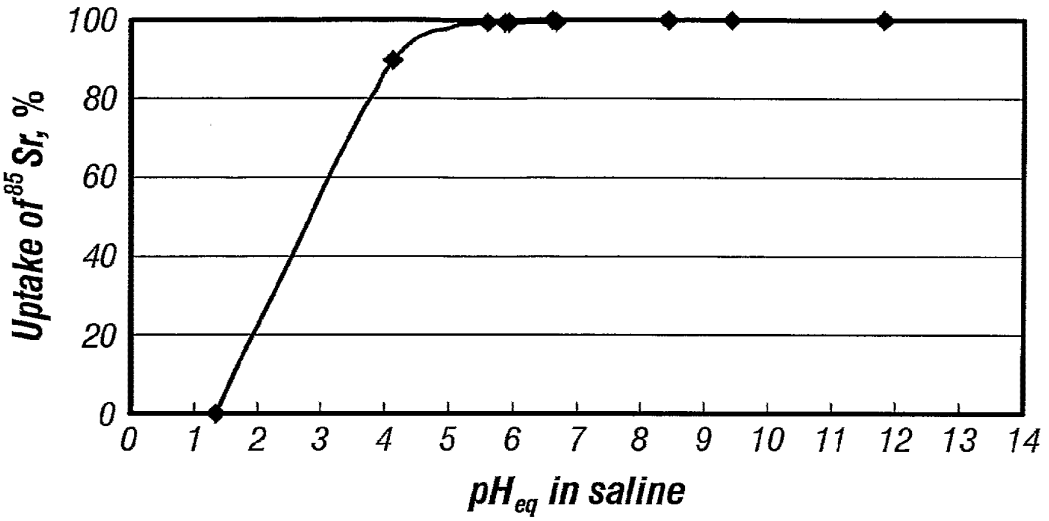
100
80
60
40
20
0
Uptake of $^{85}Sr$, %
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14
$pH_{eq}$ in saline

FIG. 3

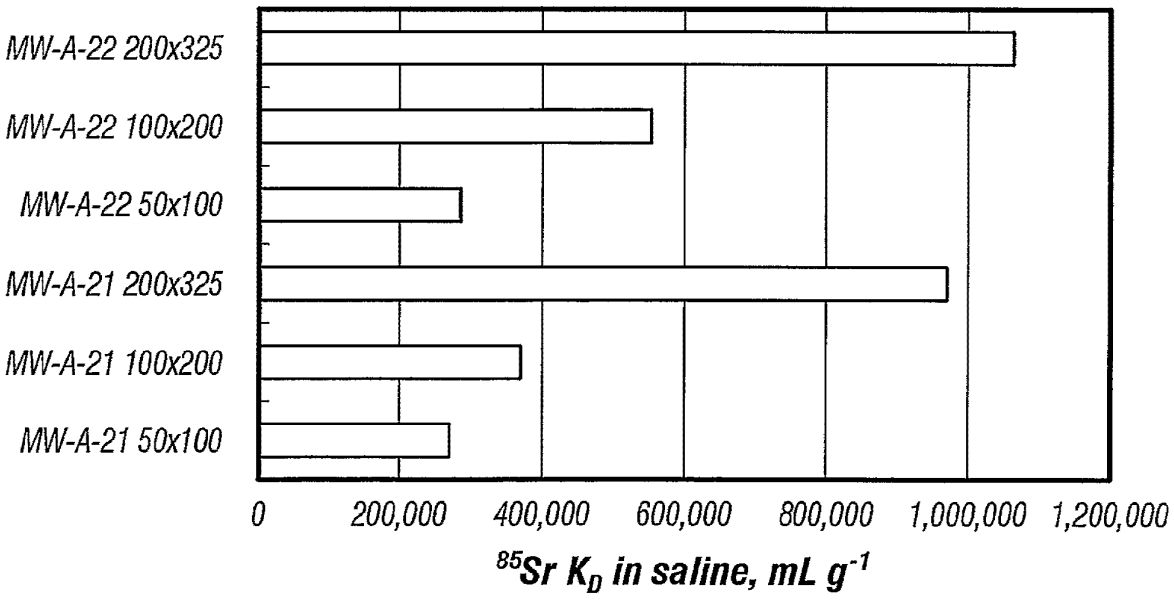
MW-A-22 200x325
MW-A-22 100x200
MW-A-22 50x100
MW-A-21 200x325
MW-A-21 100x200
MW-A-21 50x100
0 200,000 400,000 600,000 800,000 1,000,000 1,200,000
$^{85}Sr$ $K_D$ in saline, mL $g^{-1}$

FIG. 4

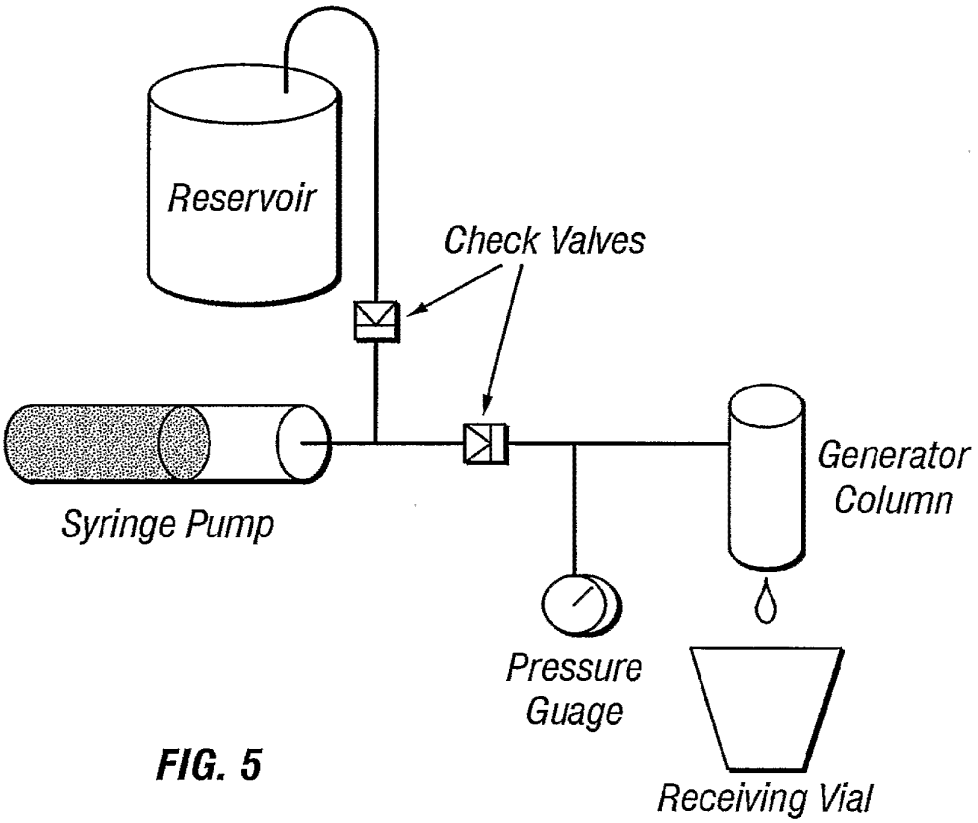
Reservoir
Check Valves
Syringe Pump
Generator Column
Pressure Guage
Receiving Vial

FIG. 5

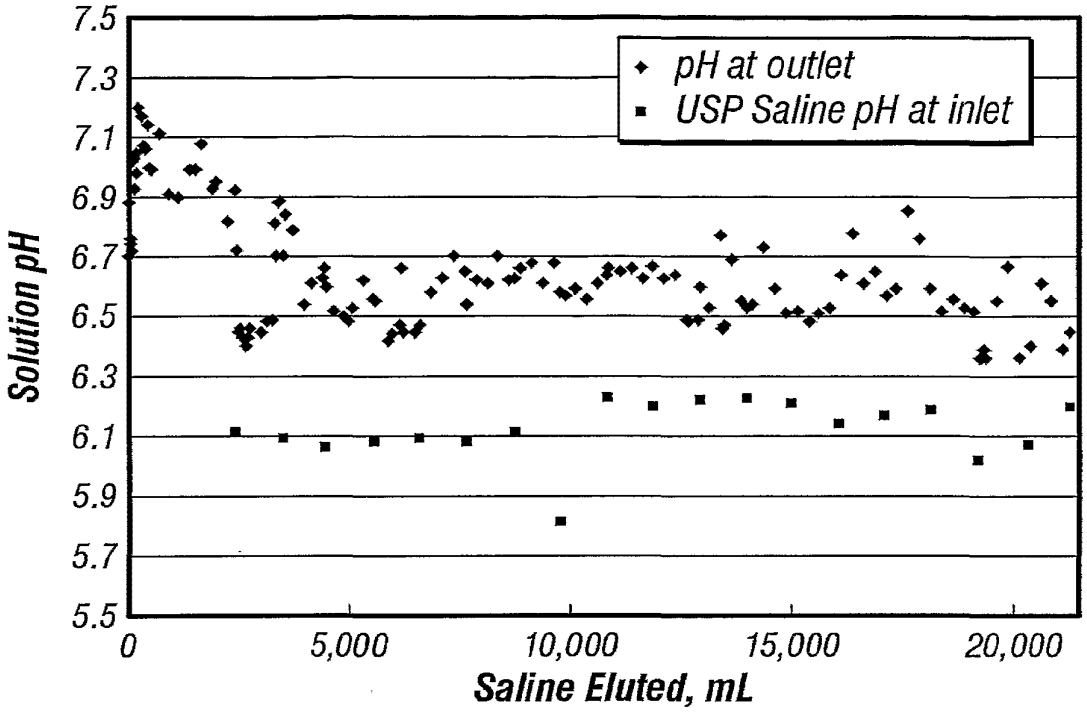
pH at outlet
USP Saline pH at inlet
Solution pH
7.5
7.3
7.1
6.9
6.7
6.5
6.3
6.1
5.9
5.7
5.5
0
5,000
10,000
15,000
20,000
Saline Eluted, mL

FIG. 6A

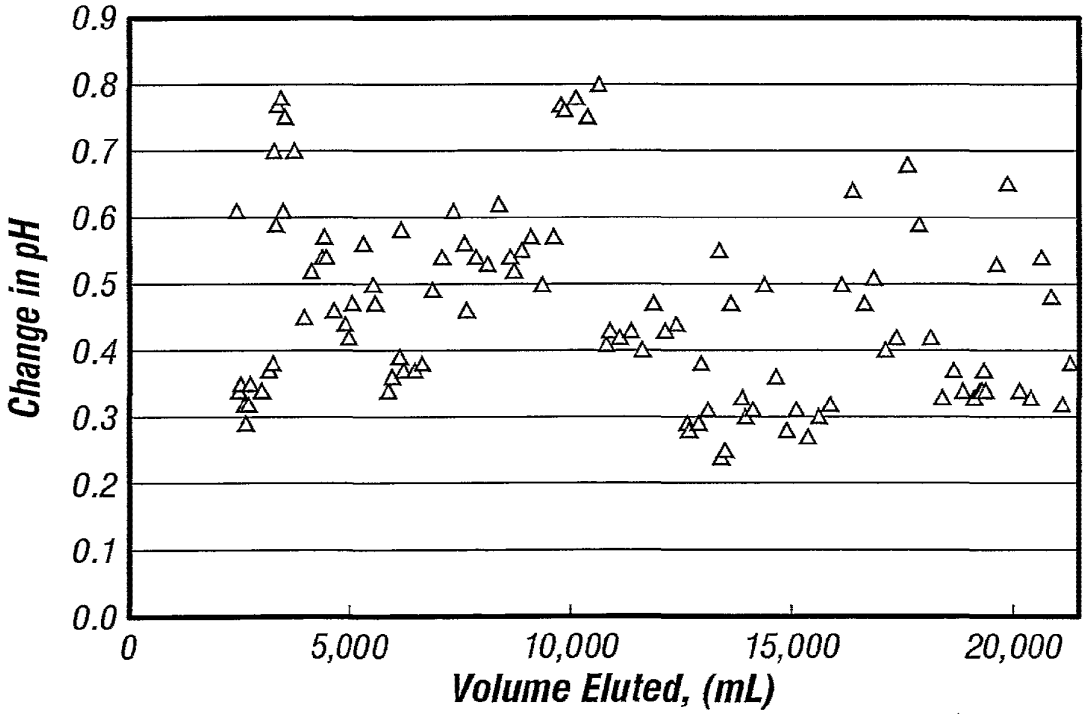
Change in pH
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0.0
0
5,000
10,000
15,000
20,000
Volume Eluted, (mL)

FIG. 6B

# AUTOMATED STRONTIUM-RUBIDIUM INFUSION SYSTEM

The invention relates to medical engineering, and particularly to means for automation of a process for producing a diagnostic solution from a radionuclide strontium-rubidium generator and remote carrying out a checked infusion with automatic checking main process characteristics, such as an introduced activity value, presence of air bubbles as well as a solution weight and activity in a waste container.

One of the most perspective directions in the nuclear diagnostics is the positron emission tomography (PET). Such short and ultra-short living isotopes as C-11, O-15, N-13, and F-18 are used in the PET centers. This obliges to have cyclotrons at the place of diagnostic for making such isotopes. It is possible to widen the functionality of the PET diagnostics in use of generator systems having a parent radionuclide lifetime significantly longer that a lifetime of radionuclides made in cyclotrons of the PET centers. Generator systems $^{82}Sr$ ($t_{1/2}$ = 25.6 days) → $^{82}Rb$ ($t_{1/2}$ = 75 seconds) and $^{68}Ge$ ($t_{1/2}$ = 271 days) → $^{68}Ga$ ($t_{1/2}$ = 78.3 minutes) are the most promising systems among the PET isotope generators.

Therefore, it is possible to say with respect to generator isotopes that any clinics having PET scanners within a region, a country or a group of countries are to be provided with said isotopes.

Generator systems can find the widest use in so called mobile PET scanners mounted in auto-trailers and called for servicing clinics that have no both own cyclotrons and own PET scanners. Absence of "affixment" of such a mobile PET scanner to an isotope base substantially widens a radius of the territory serviced thereby.

A strontium-rubidium infusion system for producing a diagnostic solution from a radionuclide strontium-rubidium generator and carrying out a checked infusion is known (US 4,562,829, 1986), said system comprising: an eluent tank connected by respective pipes of a transporting system via a first three-way valve to a syringe pump; a strontium-rubidium generator with a first filter and a first pressure sensor at an input; a second three-way valve whose first opening is coupled via a second filter to means for infusing an eluent into a patient and whose second opening is coupled to an eluate surplus storing and collecting means; radioactivity measurement means; and a check and control system. The prior art system is not optimal in a degree of radioactive radiation protection and in a service life of a generator column.

The disclosed invention is directed to elimination of the listed disadvantages. The technical result to be accomplished by using the inventive system consists in enhancement of

effectiveness in carrying out of a diagnostic procedure due to automation of the infusion procedure, reducing undesirable irradiation doses for a patient and maintenance personnel, increasing exploitation lifetimes of a generator column.

The essence of the disclosed invention consists in that an automated strontium-rubidium infusion system comprises: an eluent tank, a strontium-rubidium generator with a filter and a pressure sensor at an input; means for infusing an eluent into a patient, said tank, generator and means being connected by a transporting system to pipes and two three-way valves; radioactivity measuring means; and a check and control unit. At the same time, the eluent tank is connected via first and second openings of the first three-way valve to a syringe pump, a first opening of the second three-way valve is coupled by pipes via a second filter to the means for infusing the eluent into the patient and is coupled by a second opening thereof to a waste receptacle. The system further comprises: third and fourth three-way valves; first and second air bubble detectors coupled to the check and control unit being in communication with a computer, said third three-way valve being connected by first and second openings via pipes to a third opening of the first three-way valve and to an input of the strontium-rubidium generator, respectively, an output of the generator being coupled to a first opening of the fourth three-way valve, wherein the third opening of the third valve and a second opening of the fourth valve are in communication by a pipe, the first air bubble detector is mounted on a pipe between the eluent tank and the first opening of the first valve while the second detector is mounted on a pipe between the third openings of the fourth and second valves.

Further, the radioactivity measurement means include first and second activity sensors. At the same time, the first activity sensor is placed on a pipe between the third openings of the fourth and second valves and is embodied as a beta detector.

A radiation protection of the eluate surplus collecting and storing means may be implemented as a protection box including waste weight check means in the form of a force sensor, while the second activity sensor in the form of a gamma detector may be mounted within an opening of the protective box in order to determine a radioactivity level.

A column of the strontium-rubidium generator has a radiation protection including external main and transportation protective containers, said main protection container being mounted stationary on a shelf of a bogie.

The system is mounted in a closed movable housing. Further, the housing is provided with a shifting tabletop.

The essence of the invention is explained by drawings as follows:

Fig. 1 is a diagram of an infusion system;

Fig. 2 is a general side view of a generator plant;

Fig. 3 is a general top view of the generator plant.

Conditional notation used in drawings is listed below:

1 – Eluent tank

2, 3, 4, 5 – three-way valves

6, 7 – activity sensors

8, 9 – pressure sensors

10 – Syringe pump

11 – strontium-rubidium generator

12 – Check and control unit

13 – Weight sensor

14 – Remote computer

15, 16 – filters

17, 18 – air bubble detectors

19 – Means (needle) for infusing an eluent into a patient

20 – Eluent and eluate waste receptacle

21 – Movable housing

22 – Stand

23 – Protective container of strontium-rubidium generator

24 – Protective container for beta detector

25 – Power supply source

26 – Protective box of waste reservoir

27 – Shifting tabletop

An automated strontium-rubidium infusion system includes means for generating rubidium-82 in a solution which can be infused into a patient, exactly, a rubidium-strontium generator 11 (Fig. 1) of a traditional type in a transporting container. This container is placed in a protective external main container 23 and fulfils a main radiation protection function together with the latter. The assembled system may be mounted in a movable housing 21 (Fig. 2) covered by decorative panels (not shown). There is a stand 22 mounted on a tabletop and having an eluent tank fastened thereon. There are a syringe pump 10 and a computer 14 further mounted here. Components mounted on an upper shelf of the movable housing 21 are as follows:

- the main protective container 23 into which a standard transporting container with the strontium-rubidium generator 11 is placed;

- a protective box 24 with a beta activity detector placed therein and measuring the activity of a solution passed through the strontium-rubidium generator 11;

- a power supply source 25.

A protective box 26 is placed at a lower shelf, said box having an eluent and eluate waste receptacle arranged therein.

A top lid of the container 23 is turned back in Fig. 3, which makes it possible to see a cavity into which the transporting container with the strontium-rubidium generator 11 is placed. In order to make easier the access to the main protective container 23 during recharging a generator system (there are removal of the transporting container with the used column of the strontium-rubidium generator 11 and installation of a transporting container with a fresh column), a tabletop part is made as a shifting tabletop 27 which provides convenience in operation.

Further, the system includes means for infusion, exactly (Fig. 1): a remote-controlled syringe pump 10 whose rod is actuated, for example, by a step motor; means for automated filling the syringe pump with an eluent (a 0.9% NaCl solution); a system for transporting an eluent and an eluate to a patient or an eluent and eluate waste receptacle, said transporting system being provided with multi-way (three-way) valves 2 to 5 (Fig. 1) that ramify the transporting system in accordance with a job making program; antibacterial protection means, exactly, antibacterial filters 15 and 16 at an input and at an output of the transporting system; eluate activity measurement means 6 and 7 for monitoring and dozing in infusion into a patient; pressure measurement means 8 and 9 for measurement a pressure in the transporting system, said means being designed for measuring occlusion as well; an eluent and eluate waste receptacle 20 also capable of measuring a solution activity value and a solution weight in a waste reservoir 13; means 12 for automated check throughout the eluation process and components thereof, implemented by on-board or remote computers 14.

The tank 1 with an eluent (for example, brine) is connected by a plastic fitting to a pipe (for example, an infusion tube that has an outer diameter of 2.5 mm with an inner diameter of 1.5 mm). Lengths of such tubes (pipes) are used further to build the transporting system as a whole for infusion. Other end of the pipe is attached via an air bubble detector 17 that generates a signal to a check and control unit 12 in case of passing an air bubble, and said unit generates a control signal to valves 2, 3, 4, and 5 as a result of which the eluent solution comprising the air bubble is removed into the eluent and eluate waste receptacle 20 and does not passes through the column of the strontium-rubidium generator 11.

The valve 2 switches the infusion system into one of two possible operating modes for: (1) filling the syringe when the syringe pump 10 operates for suction the brine from the eluent tank 1 (via the first and second openings of the valve); or (2) infusing, that is, supplying the brine from the filled syringe of the syringe pump 10 into the infusion system (via the first and third openings of the valve).

Further, the three-way valve 2 is connected by a length of a connecting tube to the first opening of the third three-way valve 4 whose second opening is connected via the first filter 15 to an input of the column of the strontium-rubidium generator 11. The first pressure sensor 8 checks a pressure at the input of the column of the strontium-rubidium generator 11.

The third opening of the valve 4 via a length of a connecting tube is connected to the second opening of the fourth three-way valve 5. This valve (the first opening) also has connections to an output tube of the column of the strontium-rubidium generator 11 and an extension of the infusion system in the third opening.

When the syringe pump operates in the operating "infusion" mode, the pair of three-way valves 4, 5, while operating in synchronism, allows either pumping the brine from the syringe 10 via the column of the strontium-rubidium generator 11 further to the infusion system already in the form of an eluate, that is, a Rb-82-enriched solution, or pumping the brine into the infusion system while by-passing the strontium-rubidium generator 11. Thus operating mode is used when a necessary Rb-82 activity amount has been made and should be delivered to a patient 19 while the infusion system should be filled with the inactive brine at the end of infusion into the patient. When the brine pumping mode is used, practically the entire transporting system, exceptive for a connecting pipe from the strontium-rubidium generator output to the fourth three-way valve, will be filled with the non-radioactive brine and will not be a source of additional undesirable radioactivity for the patient and the maintenance personnel; additionally, a brine volume necessary to after-press the made eluate into the patient will not pass through and deplete the column of the strontium-rubidium generator, because it is known that a potency of the generator depends not only upon a time of using thereof but also upon a volume of the brine passed through the generator.

There are a first radioactivity detector 6 (a beta detector) and a second air bubble detector 18 mounted on a pipe from the third opening of the fourth three-way valve 5 to the third opening of the second three-wave valve 3, said air bubble detector being similar to the first air bubble detector 17.. When an air bubble is detected, the detector 18 generates a signal to the check and control unit that generates a control signal to the second three-way valve 3. As a result, an eluate comprising the air bubble is removed into the eluent and eluate waste

receptacle 20. If an air bubble is not detected, the eluate is directed via the first of said three-way valve 3 and the second filter 16 into the patient, that is, onto a needle 19.

The radioactivity detector 6 operates in real time and measures the Rb-82 activity at a location of the detector 18.

The check for filling said waste receptacle with a liquid is carried out by a force sensor (not shown). To measure a radioactivity present in the eluent and eluate waste receptacle, the second radioactivity sensor 7 (a gamma detector) is used. The radiation protection of the eluate surplus collecting and storing means is implemented as a protection box including a force sensor, while the second activity sensor is mounted within an opening of the protective box.

During infusion into the patient, the second three-way valve 3 is switched for passing the eluent to a pipe connected to the needle 19 via a Millipore filter 16. There is a second pressure sensor 9 mounted in this section which allows measurement of an occlusion pressure when an Rb-82-containing solution in administered into the patient.

The process of operating the strontium-rubidium infusion system takes place under control of a control computer program that registers a status of each of devices included in the infusion system at moments of starting and finishing a step, and also registers actions of said devices under condition of their normal functioning and in case if an emergency situation occurs.

To exclude overfilling the eluent and eluate waste receptacle 20 with a radioactive liquid, a level of said liquid is remotely checked using the force sensor; in doing so, there is monitoring of a total container and liquid weight (volume) and a limit value thereof. Additionally, by fixing a weight of the empty waste collection receptacle, a system for scheduled interrogating the check and control unit receives information that the receptacle is mounted in a container. A maximum waste volume in the receptacle is 250 ml.

The check and control unit 12 is coupled to a remote computer whose display displays a graphical mnemonic diagram of the generator device, said diagram providing observation of parameters to be checked in an automatic mode and parameters for operating control of individual members (the electromagnetic three-way valves 2 to 5 and the pump 10) in a manual mode. The diagram makes it possible to observe a current state of all members (the valves 2 to 5, the air bubble detectors 17, 18) of the disclosed infusion system, and operation of the syringe pump 10. The system also allows reception of information about parameters of a pressure in a line from the pressure sensors 8, 9, and reception of information about an

eluate activity at an output of the generator column 11 and a total activity, a weight of the eluate and eluent waste receptacle 20, an activity in said receptacle from the detectors 6, 7.

The check and control unit 12 of the system is connected to control members of the generator plant, that is, the electromagnetic three-way valves 2, 3, 4, 5 and the pump 10, and also includes members for gathering and processing signals from the sensors 6, 7 (the radioactivity sensors), 8, 9 (the pressure sensors), and 17, 18 (the bubble detectors). The control unit 12 is in communication with a panel personal computer (PPC) or any other remote computer (14) through an Ethernet channel. The control unit receives commands from the PPC or remote computer to execute individual steps of the generator plant operating program and informs said computers about a current state of members controlled thereby and a state of system sensors.

The disclosed system improves the safety of use due to the fact that automation of the infusion process has allowed significant reduction in the radioactive irradiation because the system includes additional members that provide ramification of pipes. As a result, it is possible to after-press the made eluate into the patient by the eluent while by-passing the strontium-rubidium generator. At the same time, the pipe is pumped through by the non-radioactive eluent and there is no additional depletion of the strontium-rubidium generator, which makes the life thereof longer. Further, the risk of presence of air bubbles in the eluent delivered into the patient is excluded because of introducing air bubbles into the system of detectors, while detection of said air bubbles immediately results in direction of the eluent and eluate wastes to the eluent and eluate waste receptacle via branches of the pipe without depletion of the strontium-rubidium generator.

## CLAIMS

1. An automated strontium-rubidium infusion system comprising:

an eluent tank;

a strontium-rubidium generator with a filter and a pressure sensor at an input;

means for infusing an eluent into a patient, said tank, generator and means being connected by a transporting system to pipes and two three-way valves;

radioactivity measuring means; and

a check and control unit,

wherein the eluent tank is connected via first and second openings of the first three-way valve to a syringe pump, a first opening of the second three-way valve is coupled by pipes via a second filter to the means for infusing the eluent into the patient and is coupled by a second opening thereof to a waste receptacle,

said system being characterized in that it further comprises:

third and fourth three-way valves;

first and second air bubble detectors coupled to the check and control unit being in communication with a computer,

said third three-way valve being connected by first and second openings via pipes to a third opening of the first three-way valve and to an input of the strontium-rubidium generator, respectively, an output of the generator being coupled to a first opening of the fourth three-way valve,

wherein the third opening of the third valve and a second opening of the fourth valve are in communication by a pipe, the first air bubble detector is mounted on a pipe between the eluent tank and the first opening of the first valve while the second detector is mounted on a pipe between the third openings of the fourth and second valves.

2. The system according to claim 2, characterized in that the radioactivity measurement means include first and second activity sensors.

3. The system according to claim 3, characterized in that the first activity sensor is placed on a pipe between the third openings of the fourth and second valves and is embodied as a beta detector.

4. The system according to claim 2, characterized in that the waste receptacle is implemented as a protection box including waste weight check means in the form of a force

sensor, while the second activity sensor in the form of a gamma detector is mounted within an opening of the protective box.

5. The system according to claim 1, characterized in that the strontium-rubidium generator has a radiation protection including external main and transportation protective containers, said main protection container being mounted stationary on a shelf of a bogie.

6. The system according to claim 1, characterized in that it is mounted in a closed movable housing.

7. The system according to claim 6, characterized in that the housing is provided with a shifting tabletop.

(12) МЕЖДУНАРОДНАЯ ЗАЯВКА, ОПУБЛИКОВАННАЯ В СООТВЕТСТВИИ С ДОГОВОРОМ О ПАТЕНТНОЙ КООПЕРАЦИИ (PCT)

(19) Всемирная Организация Интеллектуальной Собственности
Международное бюро

(43) Дата международной публикации
20 ноября 2008 (20.11.2008)

PCT

(10) Номер международной публикации
WO 2008/140351 A1

(51) Международная патентная классификация:
*A61M 5/168* (2006.01) *A61B 6/00* (2006.01)
*A61M 36/06* (2006.01)

(21) Номер международной заявки: PCT/RU2008/000211

(22) Дата международной подачи:
4 апреля 2008 (04.04.2008)

(25) Язык подачи: Русский

(26) Язык публикации: Русский

(30) Данные о приоритете:
2007113009 9 апреля 2007 (09.04.2007) RU

(71) Заявитель *(для всех указанных государств, кроме US)*: **ОБЩЕСТВО С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ "ПОЗИТОМ-ПРО" (OBSHCHESTVO S OGRANICHENNOY OTVETSTVENNOSTIU "NAUCHNO-PROIZVODSTVENNAYA FIRMA "POZITOM-PRO")** [RU/RU]; ул. Большая Черемушкинская, д. 25, кв. 180, Москва, 117218, Moscow (RU).

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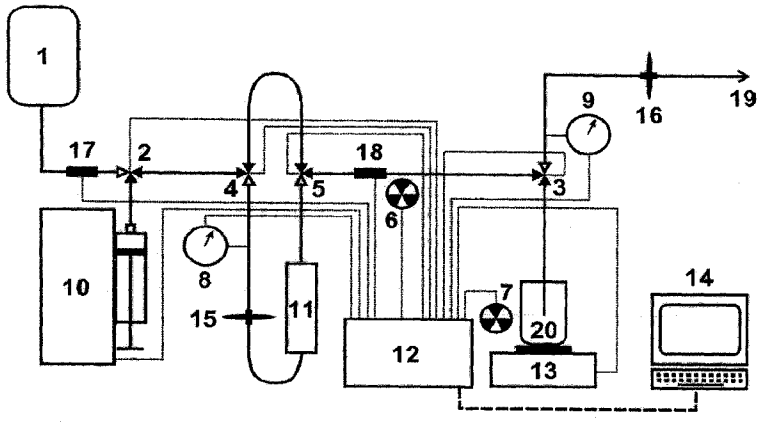
*[продолжение на следующей странице]*

(54) **Title:** AUTOMATED STRONTIUM-RUBIDIUM INFUSION SYSTEM

(54) **Название изобретения:** АВТОМАТИЗИРОВАННАЯ СТРОНЦИЙ - РУБИДИЕВАЯ ИНФУЗИОННАЯ СИСТЕМА




Фиг. 1

(57) **Abstract:** The invention relates to medical engineering. The inventive automated strontium-rubidium infusion system comprises a container with eluent, a strontium-rubidium generator with a filter and a pressure sensor and an eluate infusion unit, which are connected by means of a transporting system provided with pipes and two three-way valves, radioactivity measuring means and a control and operating unit. An eluent container is connected to a syringe pump via the first valve, the second three-way valve is connected to the eluate infusion unit and a waste receptacle via the second filter. First and second air bubbles detectors are connected to the control and operating unit. The second three-way valve is connected to the first three-way valve and to the input of the strontium-rubidium generator. The generator output is connected to the fourth valve which is connected to the third valve. The first air bubbles detector is placed between the eluent container and the first valve and the second air bubbles detector is placed between the fourth and second valves.

*[продолжение на следующей странице]*

WO 2008/140351 A1

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**(81) Указанные государства** *(если не указано иначе, для каждого вида национальной охраны)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

**(84) Указанные государства** *(если не указано иначе, для каждого вида региональной охраны)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), евразийский (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), европейский патент (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Декларация в соответствии с правилом 4.17:**
— *об авторстве изобретения (правило 4.17 (iv))*

**Опубликована:**
— *с отчётом о международном поиске*

**(57) Реферат:** Изобретение относится к медицинской технике. Автоматизированная стронций - рубидиевая инфузионная система содержит емкость с элюентом, стронций-рубидиевый генератор с фильтром и датчиком давления, средство для инфузии элюата, соединенные системой транспортировки с трубопроводами и двумя трехходовыми клапанами, средства для измерения радиоактивности и блок контроля и управления. Емкость с элюентом через первый клапан соединена со шприцевым насосом, второй трехходовой клапан соединен через второй фильтр со средством для инфузии элюата и со сборником отходов. Первый и второй детекторы воздушных пузырьков подключены к блоку контроля и управления. Второй трехходовой клапан связан с первым трехходовым клапаном и входом стронций-рубидиевого генератора. Выход генератора подключен к четвертому клапану, соединенному с третьим клапаном. Первый детектор воздушных пузырьков установлен между емкостью с элюентом и первым клапаном, а второй детектор - между четвертым и вторым клапанами.

# Автоматизированная стронций – рубидиевая инфузионная система

Изобретение относится к медицинской технике, в частности к средствам автоматизации процесса производства диагностического раствора от радионуклидного стронций-рубидиевого генератора и дистанционного проведения контролируемой инфузии, с автоматическим контролем основных характеристик процесса, таких как величина вводимой активности, величина окклюзии, наличие воздушных пузырей, а также вес и активность раствора в контейнере с отходами.

Одним из наиболее перспективных направлений в ядерной диагностике является позитронно-эмиссионная томография (ПЭТ). Для работы в ПЭТ-центрах используют такие коротко и ультра-короткоживущие изотопы как – C-11, O-15, N-13, F-18. Это обязывает иметь на месте проведения диагностики циклотроны для наработки таких изотопов. Возможности ПЭТ-диагностики могут быть существенно расширены при использовании генераторных систем, время жизни материнского радионуклида которых значительно превышает время жизни нарабатываемых на циклотронах ПЭТ-центров радионуклидов. Наиболее перспективными среди изотопных генераторов для ПЭТ стоят генераторные системы $^{82}Sr$ ($t_{1/2}$=25,6 дней) → $^{82}Rb$ ($t_{1/2}$=75 сек) и $^{68}Ge$ ($t_{1/2}$=271 дней) → $^{68}Ga$ ($t_{1/2}$=68,3 мин).

Поэтому в применении к генераторным изотопам можно говорить о снабжении ими любых клиник, обладающих ПЭТ-сканнерами, в рамках региона, государства или группы государств.

Наибольшее применение генераторные системы могут найти в смонтированных в автотрейлерах так называемых мобильных ПЭТ, вызываемых для обслуживания клиник, не имеющих не только собственных циклотро́нов, но и собственных ПЭТ-сканнеров. При отсутствии «привязки» такого мобильного ПЭТ-сканнера к изотопной базе существенно расширяется радиус обслуживаемой им территории.

Известна стронций-рубидиевая инфузионая система производства диагностического раствора от радионуклидного стронций-рубидиевого генератора и проведения контролируемой инфузии (US 4562829, 1986), включающая емкость с элюентом, соединенную соответствующими трубопроводами системы транспортировки через первый трехходовой клапан с шприцевым насосом, стронций-рубидиевый генератор с первыми фильтром и датчиком давления на входе, второй трехходовой клапан, первое отверстие которого подключено через второй фильтр к средству для инфузии элюата пациенту, а второе – к средству для сбора и хранения излишков элюата, средства для измерения радиоактивности и система контроля и управления. Известная система не является оптимальной по степени защиты от радиоактивного излучения и по сроку службы генераторной колонки.

Предлагаемое изобретение направлено на устранение перечисленных недостатков. Достигаемый при ее использовании технический результат заключается в повышении эффективности проведения диагностической процедуры за счет автоматизации процедуры инфузии, снижении доз нежелательного радиоактивного облучения пациента и обслуживающего персонала, увеличении сроков эксплуатации генераторной колонки.

Сущность предлагаемого изобретения заключается в том, что автоматизированная стронций – рубидиевая инфузионная система, содержит емкость с элюентом, стронций-рубидиевый генератор с фильтром и датчиком давления на входе, средство для инфузии элюата пациенту, соединенные системой транспортировки с трубопроводами и двумя трехходовыми клапанами, средства для измерения радиоактивности и блок контроля и управления. Причем емкость с элюентом через первое и второе отверстия первого трехходового клапана соединена с шприцевым насосом, первое отверстие второго трехходового клапана подключено трубопроводами через второй фильтр к средству для инфузии элюата пациенту, а второе отверстие – к сборнику отходов. В систему

дополнительно введены третий и четвертый трехходовые клапаны, первый и второй детекторы воздушных пузырьков, подключенные к блоку контроля и управления, связанного с компьютером, при этом третий трехходовой клапан связан первым и вторым отверстиями через трубопроводы с третьим отверстием первого трехходового клапана и входом стронций – рубидиевого генератора, соответственно. Выход генератора подключен к первому отверстию четвертого трехходового клапана, причем третье отверстие третьего клапана и второе отверстие четвертого клапана связаны трубопроводом, первый детектор воздушных пузырьков установлен на трубопроводе между емкостью с элюентом и первым отверстием первого клапана, а второй детектор установлен на трубопроводе между третьими отверстиями четвертого и второго клапанов.

Кроме того, средства для измерения радиоактивности включают первый и второй датчики активности. При этом первый датчик активности размещен на трубопроводе между третьими отверстиями четвертого и второго клапанов и выполнен в виде бета-детектора.

Радиационная защита средства для сбора и хранения излишков элюата может быть выполнена в виде защитного бокса, включающего средство контроля веса отходов в виде датчика усилия, а в отверстии защитного бокса установлен второй датчик активности для определения уровня радиоактивности отходов в виде гамма-детектор.

Колонка стронций – рубидиевого генератора имеет радиационную защиту, включающую, предпочтительно, внешний основной и транспортный защитные контейнеры, при этом основной защитный контейнер стационарно установлен на полке тележки.

Система устанавливается в закрытом перемещаемом корпусе. Кроме того, корпус снабжен сдвигающейся столешницей.

Сущность изобретения поясняется следующими чертежами:

Фиг. 1 – схема инфузионной системы;

фиг. 2 – представлен общий вид генераторной установки сбоку;

фиг. 3 – общий вид генераторной установки сверху.

Ниже перечислены условные обозначения, используемые на черетже:

1 – емкость с элюентом

2, 3, 4, 5 – трехходовые клапаны

6, 7 – датчики активности

8, 9 – датчики давления

10 – шприцевой насос

11 – стронций-рубидиевый генератор

12 – блок контроля и управления

13 – датчик веса

14 – удаленный компьютер

15, 16 – фильтры

17, 18 – детекторы воздушных пузырьков

19 – средство для инфузии элюата пациенту (игла)

20 – сборник отходов элюента и элюата

21 – перемещаемый корпус

22 – штатив

23 – защитный контейнер стронций – рубидиевого генератора

24 – защитный контейнер для бета – детектора

25 – источник питания

26 – защитный бокс емкости для отходов

27 – сдвигающаяся столешница.

Автоматизированная стронций – рубидиевая инфузионная система включает в себя средства для генерации рубидия-82 в растворе, который может быть введен пациенту, а именно стронций-рубидиевый генератор 11 (фиг.1), обычного типа в транспортном контейнере. Этот контейнер помещается в защитный внешний основной контейнер 23 и совместно с последним осуществляет функцию основной радиационной защиты. Система в сборе может устанавливаться в перемещаемом корпусе 21 (фиг.

2), закрытым декоративными панелями (не показано). На столешнице установлен штатив 22 с укрепленном на нем емкостью с элюентом 1. Кроме того, здесь установлен шприцевой насос 10 и компьютер 14. На верхней полке перемещаемого корпуса 21 установлены:

- основной защитный контейнер 23, внутрь которого помещен стандартный транспортный контейнер со стронций-рубидиевым генератором 11;
- защитный бокс 24 с размещенным внутри него детектором бета-активности, измеряющим активность раствора, прошедшего через стронций-рубидиевый генератор;
- источник питания 25.

На нижней полке размещен защитный бокс 26, внутри которого располагается сборник отходов элюента и элюата.

На фиг. 3 верхняя крышка контейнера 23 откинута, что позволяет увидеть полость, внутрь которой помещается транспортный контейнер со стронций-рубидиевым генератором 11. Для того, чтобы облегчить доступ к основному защитному контейнеру 23 во время перезарядки генераторной системы (извлекается транспортный контейнер с отработавшей колонкой стронций-рубидиевого генератора 11 и устанавливается транспортный контейнер со свежей генераторной колонкой) – часть столешницы выполнена в виде сдвигающейся столешницы 27, обеспечивающей удобство при работе.

Кроме того, система включает в себя средства для проведения инфузии, а именно (фиг. 1): шприцевой дистанционно управляемый инфузионный насос 10, шток которого приводится в действие, например, шаговым двигателем; средства для автоматизированного заполнения шприцевого насоса элюентом 1 (0.9 % раствором NaCl); систему транспортировки элюента и элюата до пациента или сборника отходов элюента и элюата, снабженную многоходовыми (трехходовыми) клапанами 2 – 5 (фиг.1), осуществляющими ветвление системы транспортировки в

соответствии с программой проведения работ; антибактериальные средства защиты, а именно антибактериальные фильтры 15 и 16 на входе и выходе системы транспортировки; средства измерения активности элюата для текущего контроля и дозирования при инфузии в пациента 6 и 7; средства измерения давления 8 и 9 в транспортной системе, в том числе и для измерения окклюзии; сборник отходов элюента и элюата 20, в том числе с измерением величины активности и веса раствора в емкости для отходов 13 и осуществления защиты от радиоактивности; средства автоматизированного контроля всего процесса элюации и его составных частей 12, осуществляемого с помощью бортового или удаленного компьютеров 14.

В описываемой системе емкость с элюентом 1 (соляным раствором) соединена пластиковым фитингом с трубопроводом (например, трубочкой для инфузий, которая имеет внешний диаметр 2.5 мм при внутреннем диаметре 1.5 мм). Отрезки таких трубочек (трубопроводы) далее используются для построения всей транспортной системы для инфузии. Другой конец трубопровода подсоединен через детектор воздушных пузырьков 17, который, в случае прохождения воздушного пузырька, вырабатывает сигнал на блок контроля и управления 12, который вырабатывает управляющий сигнал на клапаны 2, 3, 4 и 5, в результате чего, раствор элюента, содержащий воздушный пузырек, удаляется в сборник отходов элюента и элюата 20, не проходя колонку стронций-рубидиевого генератора 11.

Клапан 2 осуществляет перевод инфузионной системы в один из двух возможных режимов работы: (1) заполнение шприца при работе шприцевого насоса 10 на всасывание соляного раствора из емкости с элюентом 1 (через первое и второе отверстия клапана) или (2) инфузию, т.е. подачу соляного раствора из заполненного шприца шприцевого насоса 10 в инфузионную систему (через первое и третье отверстия клапана).

Трехходовой клапан 2 далее соединен отрезком соединительной трубки с первым отверстием третьего трехходового клапана 4, второе отверстие которого соединено через первый фильтр 15 с входом колонки стронций-рубидиевого генератора 11. Контроль давления на входе в колонку стронций-рубидиевого генератора 11 осуществляется первым датчиком давления 8.

Третьим отверстием клапан 4, через отрезок соединительной трубки, подсоединен ко второму отверстию четвертого трехходового клапана 5. Этот клапан также имеет соединения с выходной трубкой колонки стронций-рубидиевого генератора 11 (первое отверстие) и продолжением инфузионной системы на третьем отверстии.

В режиме работы шприцевого насоса «инфузия» пара трехходовых клапанов 4, 5, работая синхронно, позволяет либо прокачивать соляной раствор из шприца 10 через колонку стронций-рубидиевого генератора дальше в инфузионную систему уже в виде элюата, т.е. раствора, обогащенного Rb-82, либо прокачивать соляной раствор в инфузионную систему, минуя стронций-рубидиевый генератор 11. Этот режим работы используется тогда, когда необходимое количество активности Rb-82 наработано и оно должно быть доставлено пациенту 19, а инфузионная система должна быть заполнена неактивным соляным раствором на конец инфузии в пациента. При использовании режима прокачки соляного раствора практически вся инфузионная система, за исключением соединительного трубопровода от выхода из стронций-рубидиевого генератора до четвертого трехходового клапана, будет заполнена нерадиоактивным соляным раствором и не будет являться источником дополнительной нежелательной радиоактивности на пациента и обслуживающий персонал; кроме того, объем соляного раствора, необходимый для додавливания наработанного элюата в пациента не будет проходить через колонку стронций-рубидиевого генератора и истощать ее, т.к. известно, что потенция генератора зависит не только от времени его

эксплуатации, но также и от объема пропущенного через него соляного раствора.

На трубопроводе от третьего отверстия четвертого трехходового клапана 5 до третьего отверстия второго трехходового клапана 3 установлены первый детектор радиоактивности 6 (бета-детектор) и второй детектор воздушных пузырьков 18, аналогичный первому детектору пузырьков 17. При обнаружении воздушного пузырька, детектор 18 вырабатывает сигнал на блок контроля и управления, который вырабатывает управляющий сигнал на клапан второго трехходового клапана 3. В результате, элюат содержащий воздушный пузырек, удаляется в сборник отходов элюента и элюата 20. Если воздушный пузырек не обнаружен, элюат направляется через первое отверстие трехходового клапана 3 и второй фильтр 16 в пациента, т.е. на иглу 19

Детектор радиоактивности 6 работает в режиме реального времени и измеряет активность Rb-82 в месте расположения детектора 18.

Контроль за наполнением сборника для отходов жидкостью осуществляется с помощью датчика усилий (не показан). Для измерения радиоактивности, содержащейся в сборнике для отходов элюента и элюата используется второй датчик радиоактивности 7 (гамма-детектор). Радиационная защита средства для сбора и хранения излишков элюата выполнена в виде защитного бокса, в состав которого включен датчик усилия, а в отверстии защитного бокса установлен второй датчик активности.

При осуществлении инфузии в пациента второй трехходовой клапан 3 переключен на пропускание элюата на трубопровод соединенный с иглой 19 через миллипоровский фильтр 16. На этом отрезке установлен второй датчик давления 9, позволяющий измерять давление окклюзии при введении раствора, содержащего Rb-82, в пациента.

Процесс работы стронций-рубидиевой инфузионной системы происходит под управлением управляющей компьютерной программы, в которой прописывается состояние каждого из устройств, входящих в инфузионную систему, на момент начала и окончания выполнения шага, также прописываются действия этих устройств и условия их функционирования в нормальных условиях и в случае возникновения аварийной ситуации.

Для исключения переполнения в сборнике отходов элюента и элюата 20 радиоактивной жидкости, осуществляется дистанционный контроль за предельным значением ее уровня с помощью датчика усилия, при этом контролируется общий вес тары и жидкости, осуществляется текущий контроль за значением веса (объема) жидкости и за предельным его значением. Кроме того, фиксируя вес пустой тары для сбора отходов, система регламентного опроса блока контроля и управления установки получает информацию о том, что тара установлена в контейнере. Максимальный объём отходов в таре составляет 250 мл.

Блок контроля и управления подключен к удаленному компьютеру, на дисплее которого отображается графическая мнемосхема генераторного устройства, обеспечивающая наблюдение контролируемых параметров в автоматическом режиме и оперативного управления отдельными элементами (электромагнитными трехходовыми клапанами 2 - 5, насосом 10) в ручном режиме. Схема позволяет наблюдать за текущим состоянием всех элементов описываемой системы инфузии (клапанов 2-5, детекторов воздушных пузырьков 17, 18) и за работой шприцевого насоса 10. Также она позволяет получать информацию о параметрах давления в магистралях от датчиков давления 8, 9, активности элюата на выходе из генераторной колонки 11 и суммарной активности, веса емкости сборника отходов элюента и элюата 20, активности в емкости с отходами от детекторов 6,7.

Блок контроля и управления 12 системы связан с управляющими элементами генераторной установки – электромагнитными трехходовыми

клапанами 2, 3, 4, 5 и насосом 10, а также включает элементы для сбора и обработки сигналов с датчиков 6, 7 (датчики радиоактивности), 8, 9 (датчики давления), 17, 18 (детекторы воздушных пузырьков). Блок управления 12 связан с панельным персональным компьютером (PPC) или любым другим удаленным компьютером (14) по каналу Ethernet. Он получает команды от PPC или удаленного компьютера на выполнение отдельных шагов программы работы генераторной установки и информирует их о текущем состоянии управляемых им элементов и состоянии датчиков системы.

Описываемая система повышает безопасность эксплуатации, так как автоматизация процесса инфузии позволила значительно сократить радиоактивное облучение за счет введения в систему дополнительных клапанов, обеспечивающих ветвление трубопроводов. В результате, появилась возможность додавливания наработанного элюата в пациента элюентом, минуя стронций – рубидиевый генератор. При этом трубопровод прокачивается нерадиоактивным элюентом и не происходит дополнительного истощения стронций – рубидиевого генератора, что увеличивает срок его эксплуатации. Кроме того, исключается риск содержания воздушных пузырьков в элюанте, доставляемого пациенту, за счет введения в систему детекторов воздушных пузырьков, при обнаружении которых, элюент сразу направляется к сборнику отходов элюента и элюата через ответвления трубопровода, не истощая стронций – рубидиевый генератор.

## Формула изобретения

1. Автоматизированная стронций – рубидиевая инфузионная система, содержащая емкость с элюентом, стронций-рубидиевый генератор с фильтром и датчиком давления на входе, средство для инфузии элюата пациенту, соединенные системой транспортировки с трубопроводами и двумя трехходовыми клапанами, средства для измерения радиоактивности и блок контроля и управления, причем емкость с элюентом через первое и второе отверстия первого трехходового клапана соединена с шприцевым насосом, первое отверстие второго трехходового клапана подключено трубопроводами через второй фильтр к средству для инфузии элюата пациенту, а второе отверстие – к сборнику отходов, отличающаяся тем, что дополнительно введены третий и четвертый трехходовые клапаны, первый и второй детекторы воздушных пузырьков, подключенные к блоку контроля и управления, связанного с компьютером, при этом третий трехходовой клапан связан первым и вторым отверстиями через трубопроводы с третьим отверстием первого трехходового клапана и входом стронций – рубидиевого генератора, соответственно, выход генератора подключен к первому отверстию четвертого трехходового клапана, причем третье отверстие третьего клапана и второе отверстие четвертого клапана связаны трубопроводом, первый детектор воздушных пузырьков установлен на трубопроводе между емкостью с элюентом и первым отверстием первого клапана, а второй детектор установлен на трубопроводе между третьими отверстиями четвертого и второго клапанов.

2. Система по п.1, отличающаяся тем, что средства для измерения радиоактивности включают первый и второй датчики активности.

3. Система по п.2, отличающаяся тем, что первый датчик активности размещен на трубопроводе между третьими отверстиями четвертого и второго клапанов и выполнен в виде бета-детектора.

4. Система по п.1, отличающаяся тем, что радиационная защита сборника отходов выполнена в виде защитного бокса, включающего

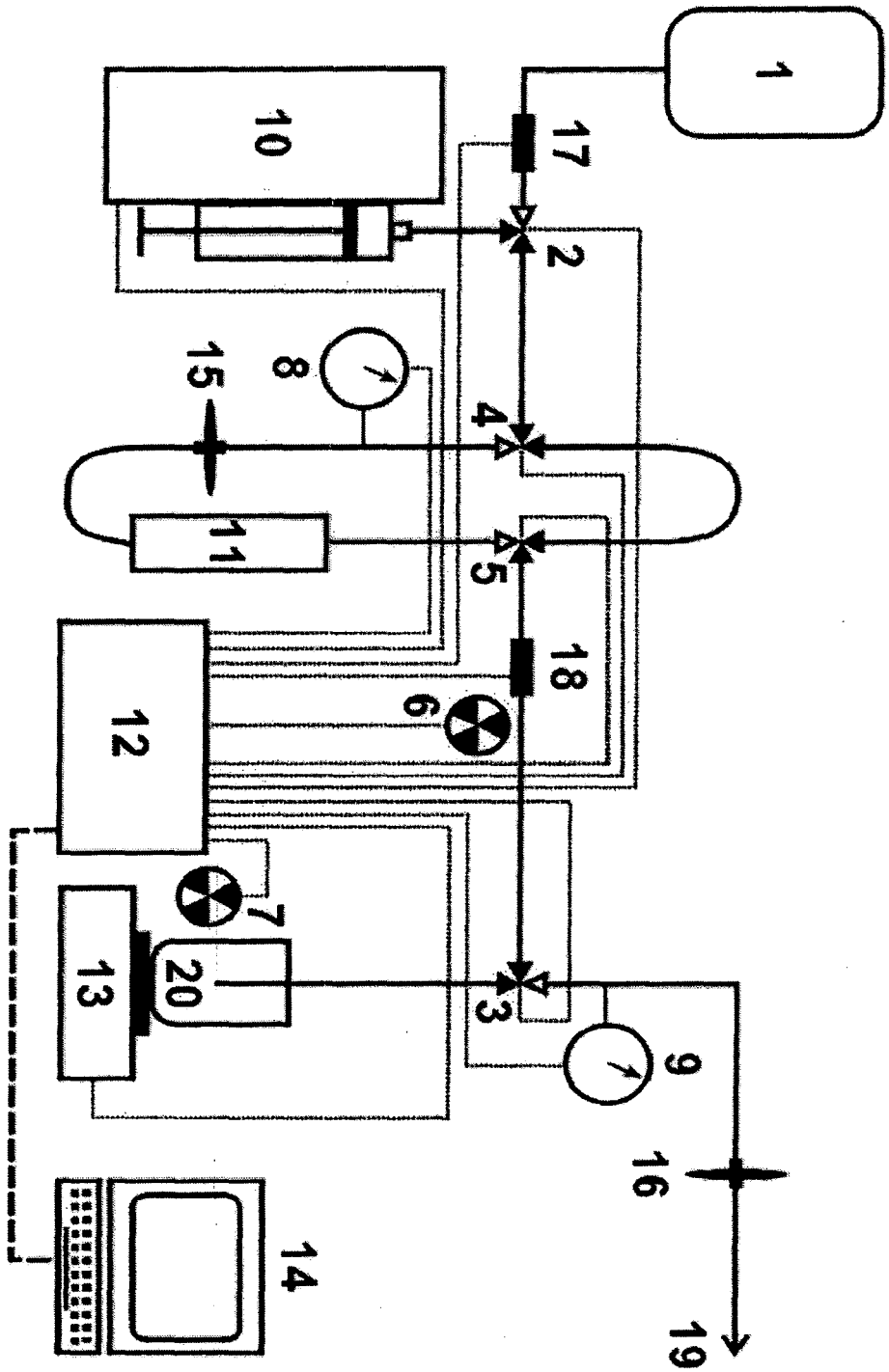
средство контроля веса отходов, выполненного в виде датчика усилия, а в отверстии

защитного бокса установлен второй датчик активности для определения радиоактивности отходов, в виде гамма-детектора.

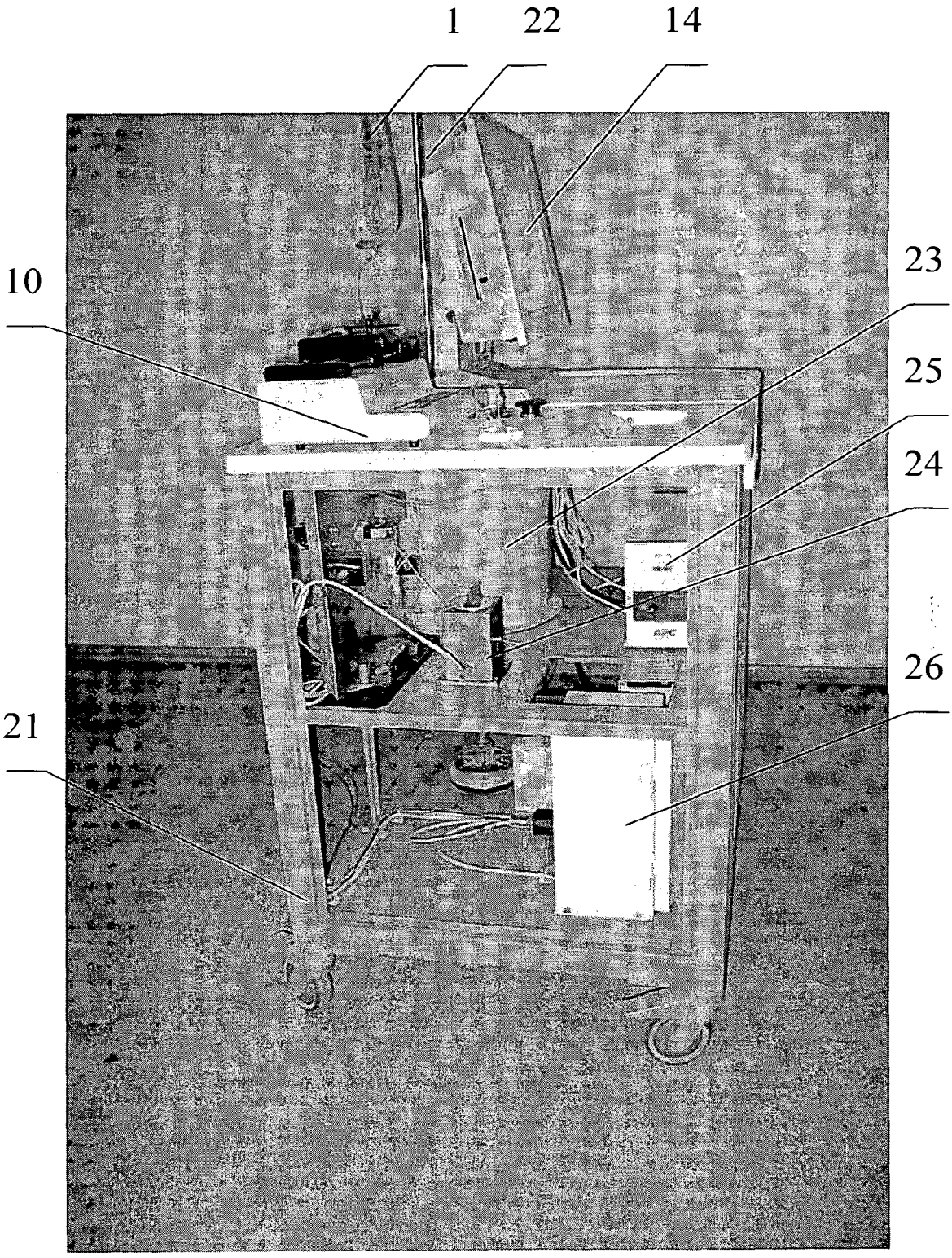
5. Система по п.1, отличающаяся тем, что стронций – рубидиевый генератор имеет радиационную защиту, включающую внешний основной и транспортный защитные контейнеры, при этом основной защитный контейнер стационарно установлен на полке тележки.

6. Система по п.1, отличающаяся тем, что она установлена в закрытом перемещаемом корпусе.

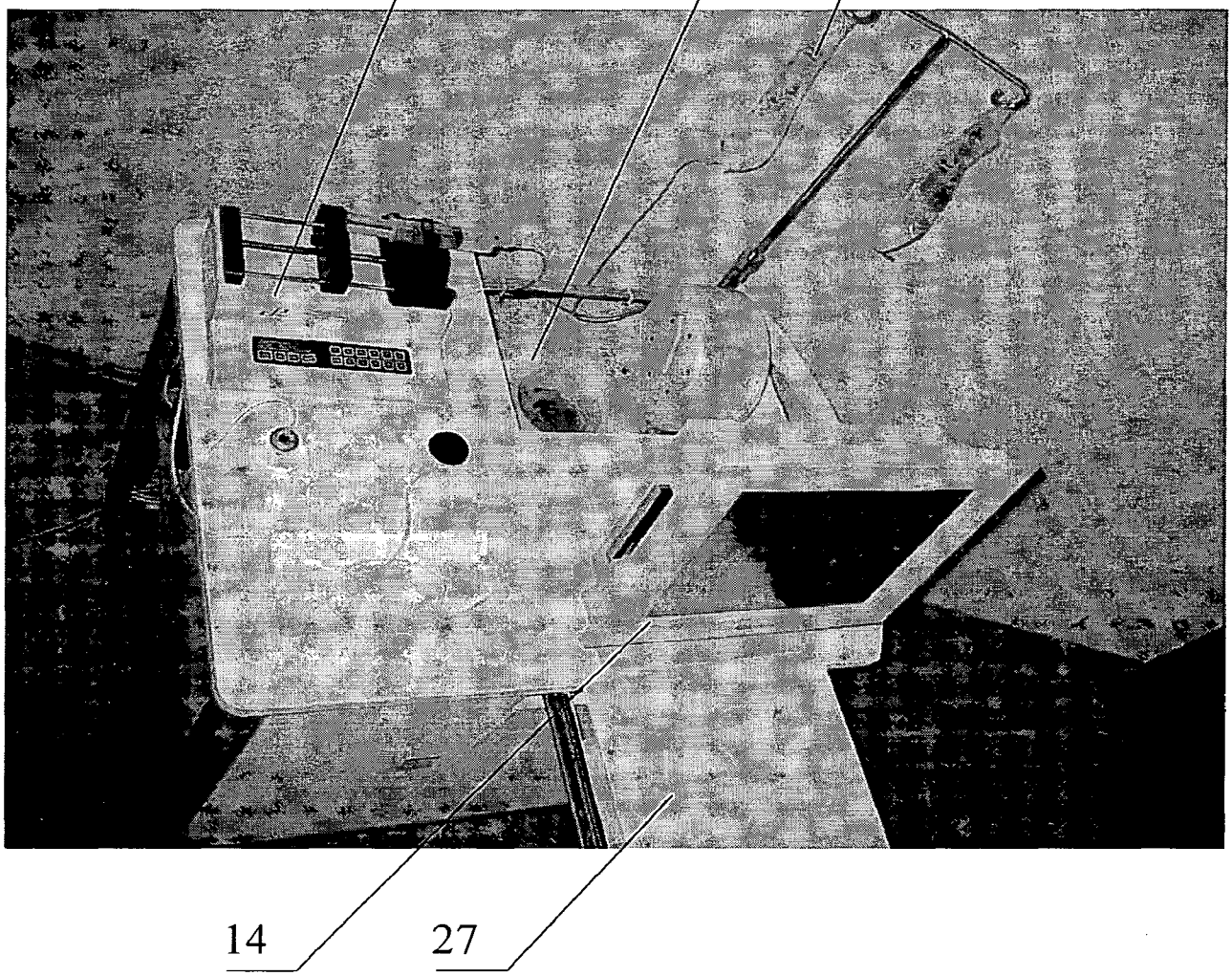
7. Система по п.6, отличающаяся тем, что корпус снабжен сдвигающейся столешницей.




Фиг. 1




Фиг. 2




Фиг. 3

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/RU2008/000211

A. CLASSIFICATION OF SUBJECT MATTER

*A61M 5/168 (2006.01)*
*A61M 36/06 (2006.01)*
*A61B 6/00 (2006.01)*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M 36/00-36/06, 5/00-5/155, AGIB 6/00-6/10, A61M 5/168

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
http://www. uspto. gov; http://depatisnet.dpma.de; http://ep.espacenel.com; http://www.fips.ru; http://www.eapatis.com

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 4562829 A (E.R. SQUIBB & SONS, INC.), 07.01.1986, the abstract, figure 1 | 1-7 |
| A | EP 0310148 A (E.R. SQUIBB & SONS, INC), 05.04.1988, the claims, figure | 1-7 |
| A | RU 2219959 C2 (FEDERALNOE GOSUDARSTVENNOE UNITARNOE PREDPRIYATIE NAUCHNO-ISSLEDOVATELSKY INSTITUT ELEKTROMEKHANIKI) 27.12.2003, the claims, figure 1 | 1-7 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

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# ОТЧЕТ О МЕЖДУНАРОДНОМ ПОИСКЕ

Международная заявка № PCT/RU 2008/000211

А. КЛАССИФИКАЦИЯ ПРЕДМЕТА ИЗОБРЕТЕНИЯ: ***A61M 5/168*** *(2006.01)*
***A61M 36/06*** *(2006.01)*
Согласно Международной патентной классификации МПК ***A61B 6/00*** *(2006.01)*

В. ОБЛАСТИ ПОИСКА:

Проверенный минимум документации (система классификации с индексами классификации):

Другая проверенная документация в той мере, в какой она включена в поисковые подборки:

A61M 36/00-36/06, 5/00-5/155, A61B 6/00-6/10, A61M 5/168

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|---|---|---|
| A | US 4562829 A (E.R. SQUIBB & SONS, INC.) 07.01.1986, реферат, фиг. 1 | 1-7 |
| A | EP 0310148 A (E.R. SQUIBB & SONS, INC) 05.04.1989, формула, фиг. | 1-7 |
| A | RU 2219959 C2 (ФЕДЕРАЛЬНОЕ ГОСУДАРСТВЕННОЕ УНИТАРНОЕ ПРЕДПРИЯТИЕ НАУЧНО-ИССЛЕДОВАТЕЛЬСКИЙ ИНСТИТУТ ЭЛЕКТРОМЕХАНИКИ) 27.12.2003, формула, фиг. 1 | 1-7 |

☐ последующие документы указаны в продолжении графы С. ☐ данные о патентах-аналогах указаны в приложении

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Дата действительного завершения международного поиска: 24 июля 2008 (24.07.2008)

Дата отправки настоящего отчета о международном поиске: 04 сентября 2008 (04.09.2008)

Наименование и адрес ISA/RU
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Форма PCT/ISA/210 (второй лист)(июль 2008)

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
25 February 2010 (25.02.2010)

PCT

(10) International Publication Number
WO 2010/020596 A1

(51) International Patent Classification:
*G21G 4/08* (2006.01)

(21) International Application Number:
PCT/EP2009/060584

(22) International Filing Date:
14 August 2009 (14.08.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
08075710.7 18 August 2008 (18.08.2008) EP

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published**:

— *with international search report (Art. 21(3))*

WO 2010/020596 A1

(54) Title: STRONTIUM-82/RUBIDIUM-82 GENERATOR, METHOD FOR PRODUCING A RUBIDIUM-82 COMPRISING DIAGNOSTIC AGENT, SAID DIAGNOSTIC AGENT AND ITS USE IN MEDICINE

(57) Abstract: The invention relates to a strontium-82/rubidium- 82 generator, comprising a column filled with a cationic exchanger loaded with strontium-82, and having an inlet and an outlet, and a liquid medium, wherein parts of the column, inlet and outlet coming into contact with the liquid medium are iron-free, preferably metal-free, to a method for producing rubidium-82, and to the obtained diagnostic agent.

# STRONTIUM-82/RUBIDIUM-82 GENERATOR, METHOD FOR PRODUCING A RUBIDIUM-82 COMPRISING DIAGNOSTIC AGENT, SAID DIAGNOSTIC AGENT AND ITS USE IN MEDICINE

The present invention relates to a strontium-82/rubidium-82 generator, to a method for producing a rubidium-82 comprising diagnostic agent using such strontium-82/rubidium-82 generator, to the diagnostic agent obtainable therewith, and to the use of this diagnostic agent in medicine.

In nuclear medicine conventional diagnostic techniques are applied for coronary artery disease imaging and for the determination of the severity of the disease. Diagnostic agents used for the determination of myocardial perfusion comprise thallium-201 or technetium-99m. However, these diagnostic agents are limited in use by the occurrence of attenuation artefacts and do not permit an accurate estimation of extension and severity of coronary artery disease.

These drawbacks make rubidium a better choice as a potassium-analog. Rubidium-82 is suitable for positron emission tomography, because Rubidium-82 is a positron emitter rendering higher quality images than conventional gamma camera imaging. Moreover Rubidium-82 is a radionuclide with an ultra-short half-life ($t_{1/2}$=75s). This ultra-short half life allows high doses at short imaging times but urges production of rubidium-82 near the patient.

Presently, a strontium-82/rubidium-82 generator comprises a generator column assembly comprising adaptors with nuts and ferrules, a column and two micro filters. The generator column is about 2.6cm in length, 6mm internal diameter and has a 0.5mm wall thickness. All

components are made of stainless steel type 316. The cationic exchanger may be α-hydrous tin oxide loaded with about 50mCi strontium-82. The liquid medium in the strontium-82 loaded cationic exchanger is physiological 0.9% sodium chloride. Sterile and pyrogen free 0.9% sodium chloride is also used as elution medium.

This known strontium-82/rubidium-82 generator may be used for several days to several weeks. However, the known generator is not sufficiently stable for use during an extended period of time. Such stability is determined by a so-called breakthrough of strontium-82 during elution. An early breakthrough of strontium-82 blocks the possibility of reloading the cationic exchanger with strontium-82 for a continued production of the rubidium-82 diagnostic agent. Furthermore, using a generator for an extended period of time requires a method of sterilization of it.

Further research revealed that by using a physiological buffer having a pH of 6-8.5 as an elution medium for rubidium-82, the stability of the strontium-82/rubidium-82 generator can be substantially improved. A substitution of the physiological 0.9% sodium chloride elution medium by a physiological buffer having a pH of 6-8.5 as such is not recommendable in relation to the daily use of the generator. In particular, after use of a sterilization medium in the form of hypochlorite solution it turned out that a gelatinatious material is formed jeopardizing the functionality of the strontium-82/rubidium-82 generator, in particular because the column filters become clogged and ultimately blocked.

The present invention is based on the insight that a strontium-82/rubidium-82 generator having parts coming into contact with the liquid medium, which part has been made of iron-free and preferably of metal-free

material, that such clogging gelatinatious material is not formed and the generator has the desired improved stability and may be reloaded with strontium-82 several times without any significant breakthrough of strontium-82. At the same time, optimal performance and sterility are maintained. The continued use of the strontium-82/rubidium-82 generator and the option of reloading without significant strontium-82 breakthrough results in an extended operation time period before the generator is to be recycled and the cationic exchanger renewed and subsequently loaded again with strontium-82. This results in an extensive reduction in costs.

For instance, a generator according to the invention may be used over an extended period of time such as 2-6 months at substantially constant stability.

Accordingly, the present invention provides a strontium-82/rubidium-82 generator, comprising a column filled with a cationic exchanger loaded with strontium-82, and having an inlet and an outlet, and a liquid medium, wherein parts of the column, inlet and outlet coming into contact with the liquid medium are iron-free, preferably metal-free.

This strontium-82/rubidium-82 generator according to the invention is suitable for elution with a physiological buffer having a pH of 6-8.5 and for sterilization using a hypochlorite solution, without the occurrence of deteriorating clogging and ultimately blocking of the generator due to the formation of gelatinatious material. Without being bound to any theory, it might be that the gelatinatious material formed comprises a water insoluble iron salt. Iron likely originates from the metallic parts of the generator and the counter ions such as phosphate, originate from the elution medium being a physiological buffer, for instance

a phosphate buffer saline solution having a pH of 7.2-7.4.

It is possible that the strontium-82/rubidium-82 generator during storage, transport or out of use for other reasons, may comprise a liquid medium other than the elution medium according to the invention. But, for elution and for maintaining the extended stability, it is required according to the invention that the elution medium for rubidium-82 is a physiological buffer having a pH of 6-8.5. The lower limit for the pH is selected such as to allow to an acceptable extent such as per volume, the elution of rubidium-82 from the cationic exchanger. Accordingly, the lower is the pH, the better is the rubidium-82 elution. However, due to the very short half time of rubidium-82, it is required that the elution medium is almost directly to be administered by for instance intravenous injection into the patient. Preferred is therefore a physiological buffer having a pH in the range of 7-8 and more preferably in the range of 7.2-7.4. A physiological buffer involves that the osmolarity of the buffer is selected such that the injection into a patient will not result in any adverse effects, taking into account a volume to be injected of about 2-30ml at a rate of about 10-80ml/minute.

Suitable physiological buffers comprise citrate/sodium hydroxide buffer, citrate/phosphate buffer, borate/hydrogen chloride buffer, boric acid/sodium hydroxide buffer, Tris buffer, veronal/HCl buffer and piperazine/sodium hydroxide buffer. Preferred physiological buffers are carbonate buffers, phosphate buffers and Tris buffers.

In order to avoid any leaching of metal from the generator, the part of column, inlet and outlet inclusive ferrules, tubings and the like are to be made of iron-

free and preferably metal-free material or coated with metal-free material.

Metal-free means in particular iron-free. Accordingly, it is possible that the column, inlet and outlet or any generator elements may be made of an iron-free metal, such as titanium. However, in the alternative it is preferred that the relevant parts of the column inlet and outlet coming into contact with the liquid medium are made of less expensive metal-free material. A suitable metal-free material is a plastic such as PEEK or Teflon. PEEK material is preferred because PEEK material is already used for columns, inlet and outlet within the HPLC chromatography technique. Such plastic material is of lower costs than iron-free metal material suitable for use in the generator.

In order to guarantee that the rubidium-82 produced as a diagnostic agent with the strontium-82/rubidium-82 generator is suitable for human use intravenously it is mandatory that the generator is frequently, and when needed, sterilized using a sterilization medium. Such sterilization medium is preferably hypochlorite solution of suitable concentration. Hypochlorite has the advantages of a broad anti-bacterial and anti-viral spectrum, relatively easy removal by washing from the generator, and a low detection level. Prior to use this sterilization medium has to be exchanged for either a storage and transportation medium, or directly with the physiologically buffer intended as the elution medium.

A full operation generator assembly for generating and producing the rubidium-82 diagnostic agent in the direct presence of a patient is feasible when the generator comprises

i) a source for the physiological elution buffer;

ii) a source for the sterilisation buffer;

iii) a pump for connecting and transporting the sources to the inlet of the column;

iv) a dose calibrator connected to the outlet of the column; and

v) a patient administration line connected to the dose calibrator.

Such generator is a full service generator for elution, sterilization, and application to the patient and for measuring the radioactive dose generated and a continuous survey of a possible breakthrough of strontium-82. With such full service generator it is preferred that the generator is arranged on a mobile vehicle, such as it is easily transportable between the storage, the radiopharmacy laboratory and the diagnostic room.

It is noted that any cationic exchanger may be used as long as rubidium-82 is selectively eluted. A suitable material is tin oxide, such as α-hydrous tin oxide ($Sn_2O.xH_2O$; x=1-2) or α stannic acid.

Another aspect of the present invention relates to the production of rubidium-82. This method comprises the use of the afore mentioned strontium-82/rubidium-82 generator according to the invention and to elute the generator with the elution buffer being a physiological buffer having in general a pH of 6-8.5, preferably a pH of 7-8 and more preferably of 7.2-7.4. Accordingly, this rubidium-82 diagnostic agent is essentially characterized by the presence of this well defined elution buffer.

As discussed here and above, the methods of the present invention allow the sterilization of the strontium-82/rubidium-82 generator using a sterilization buffer, preferably in the form of a hypochlorite solution. Accordingly, the sterilization of the generator

is guaranteed as well as the sterile and pyrogen free character of the rubidium-82 produced therewith.

A last aspect of the present invention relates in particular to the diagnostic agent being in the form of a solution with the elution buffer being the afore mentioned physiological buffer having a pH of 6-8.5. Such diagnostic agent is suitable for use in medicine such as for myocardial perfusion imaging.

Mentioned and other features and advantages of the generator, its production process and its use as a diagnostic agent will be further illustrated in the description of the drawings and the example which follow and which are given for illustrative purposes without the intention to limit the present invention to any extent.

Figure 1 is a schematic illustration of the rubidium-82 generator in the form of a full surface generator suitable for direct application to a patient;

Figure 2 shows the activity of strontium-82 (Bq) in the eluate per 37MBq rubidium-82, the maximum allowable ratio of Sr-82/Rb-82 is about 750 (ppm); and

Figure 3 shows the activity of strontium-85 (Bq) in the eluate of the generator per 37MBq rubidium-82. The maximum ratio Sr-85/rubidium-82 is about 7500 ppm.

Figure 4 shows the contamination of Sr-82 in the generator's eluate.

Figure 5 shows the contamination of Sr-82 in the eluates expressed as Bq Sr-82 per MBq Rb-82.

Figure 6 shows the contamination of Sr-85 in the eluates expressed as Bq Sr-85 per MBq Rb-82.

Figure 1 shows a strontium-82/rubidium-82 generator 1 according to the invention. The generator 1 comprises a column 2 made of PEEK. The column has the following dimensions (length 5.0 cm, internal diameter 0.75 cm, wall thickness 3.25 mm). The column 2 is loaded

with 4 grams α stannic acid (particle size 75-150µm) in 0.1N ammonium chloride buffer. The column 2 is washed with 0.1N ammonium chloride (pH 10). Subsequently, the column is washed with 2M sodium chloride and with 0.05% hypochlorite solution. The inlet 3 and the outlet 4 are provided with a valve 5 and 6. The inlet 3 is connected to a multi-valve 7 and the outlet 4 to a multi- valve 8. A bypass 9 extends between the multi-valves 7 and 8 which allows transporting liquid medium through the generator 1 while bypassing the column 2.

Strontium-82 (>25mCi Sr-82/mg Sr, Sr-85/Sr-82<5, Rb-83/Sr-82<0.15; Rb-84/Sr-82< 0.15; Sr-83/Sr-82<0.0015; other nuclides/SR-82<0.01) was neutralized with 0.5ml 0.5M Tris buffer (pH 7.5). After the addition of 3.5ml physiological buffered saline, the mixture was applied via a milipore filter (22µm) on the column 2. Subsequently, the column 2 is washed with phosphate buffered saline pH 7.4 (8.2g sodium chloride, 3.1g $Na_2HPO_4.12H_2O$ and 0.3g $NaH_2PO_4.2H_2O$ from the container 15.

The 0.05% hypochlorite solution was applied from a container 11 via a multi-valve 12, an air bubble trap 13, the peristaltic pump 14, the filter 10 and then via the valve 7 and 5 to the column 2. It is noted that the tubings are made of PEEK tubings. The column filters (not shown) are 10 µm titanium filters or metal filter holders coated with PEEK or Teflon coating. The sterile filters are Millex Millipore 0.22 µm membrane filters, diameter 25 mm.

Prior to use for patients, the generator 1 is flushed with physiological buffered saline originating from the container 15 until the eluate does not color a 10% potassium iodide solution. Subsequently, the phosphate elution buffer (pH 7.4) is applied from the source 16 through the column 2. The eluate comprising

rubidium-82 is passed through a dose calibrator 17 calibrated for rubidium-82 measurement.

Figure 2 shows the activity of strontium-82 in the eluate of the column 2 dependent on the elution volume. Clearly, the maximum allowable ratio of SR-82/RB-82 (about 750ppm) was never surpassed except for one occasion which occurred after the third reload of the column 2 with strontium-82. During testing a large amount of air was introduced on the column 2. In an attempt to remove this air the increased leakage of strontium-82 occurred. After normalization the ratio SR-82/RB-82 remained far below the maximum allowable value over several reloads of the same column 2.

The dose calibrator 17 is connected via a multi valve 18 with either a waste container 19 or to a valve 20 for subsequent administration to the patient. However, the tubing 21 could be disconnected at the connection 22 and directly used for administration to the patient.

Filters 23, 24 and 25 guarantee sterile manipulation of the generator 1.

The measuring mode of the dose calibrator 17 is the integral mode. Accordingly, after the desired dose of strontium-82 is eluted from the column 2 the valves towards the column 2 are closed and elution medium is transported via the bypass tube 9 for flushing the system.

After a waiting time of about 5 minutes a subsequent elution and generation of a new strontium-82 diagnostic agent dose is possible.

After use the system is sterilized by flushing from the container 11 the 0.05% hypochlorite solution. The generator 1 may be stored in the hypochlorite solution or in physiological buffered saline or in the elution buffer.

The diagnostic agent comprising rubidium-82 in the physiological buffer having a pH of 6-8.5 showed during myocardial perfusion imaging with positron emission tomography with better imaging quality at lower radiation exposure to patient. The function of the heart could be determined under rest and stress with an in between waiting time of about 6 minutes for applying the adenosine or dobutamine infusion as a stress generating agent.

Figure 3 shows the activity of strontium-85 (Bq) in the eluate of the generator per 37MBq rubidium-82. The maximum ratio SR-85/rubidium-82 is about 7500 ppm. The activity of strontium-85 is well below the maximum of the ratio of Sr-82/Rb-82.

The increased stability of the strontium binding to the carrier material (hydrous stannic oxide) is obtained by increasing the pH to a value of 7.4 by means of a phosphate buffered saline, used as elution fluid. This increased stability allows an extended period of use of the generator of at least 3 supplementary months as compared to commercially available generators which have to be replaced each month. The generator can be refilled every 4 weeks reducing the costs for strontium-82 significantly.

**EXAMPLE**

In order to illustrate the contamination of generator eluates with Sr-82 and Sr-85 the following experiment was performed.

On day 1 a typical generator column was loaded with 2.3 GBq Sr-82. The generator was eluted repeatedly with phosphate buffered saline (PBS) at pH=7.4. On day 26 and at an elution volume of 3.2 liter the generator was reloaded with 2.2 GBq Sr-82. Again, the generator was

eluted repeatedly with PBS. On day 66 and at a total elution volume of 6.3 liter the generator was reloaded for a second time with 1.2 GBq Sr-82. Again, the generator was eluted repeatedly with PBS (pH=7.4). The total elution volume was 7.9 liter.

Figure 4 represents the contamination of Sr-82 in the generator's eluate. The curve spikes represent the moments of reloading. Figure 5 shows the contamination of Sr-82 in the eluates (lower curve) expressed as Bq Sr-82 per 37 MBq Rb-82 and the maximal contamination of Sr-82(higher curve) acceptable in the currently commercially available Rb-82 generators (Bracco). The level of contamination of Sr-82 is well below the acceptable contamination in the known generators. Figure 6 shows the contamination of Sr-85 in the eluates (lower curve) expressed as Bq Sr-85 per 37 MBq Rb-82 and the maximal contamination of Sr-85 (higher curve) acceptable in currently commercially available Rb-82 generators (Bracco). The level of contamination of Sr-82 is well below the acceptable contamination in the known generators. After three loadings and an elution volume of approximately 8 liters the contaminations of Sr-82 and Sr-85 are still far below the limit. Reloading a Sr-85/Rb-82 generator is of advantage because it reduces costs for Sr-82 by 30% and makes the transport of the generator back to the factory unnecessary.

**CLAIMS**

1. Strontium-82/rubidium-82 generator, comprising a column filled with a cationic exchanger loaded with strontium-82, and having an inlet and an outlet, and a liquid medium, wherein parts of the column, inlet and outlet coming into contact with the liquid medium are iron-free, preferably metal-free.

2. Generator according to claim 1, wherein the liquid medium is an elution medium for rubidium-82, and is a physiological buffer having a pH of 6 to 8.5, preferably a pH of 7 to 8, more preferably a pH of 7.2 to 7.4.

3. Generator according to claim 1 or 2, wherein the physiological buffer is a carbonate buffer, phosphate buffer or Tris buffer.

4. Generator according to any one of claims 1 to 3, wherein the parts of the column, the inlet and the outlet are coated with a iron-free material and/or are made from a iron-free material, preferably metal free material.

5. Generator according to claim 4, wherein the metal-free material is a plastic, such as PEEK or Teflon.

6. Generator according to any one of claims 1 to 5, wherein the liquid medium is a sterilization medium, preferably a hypochlorite solution.

7. Generator according to any one of claims 1 to 6, comprising:

i) a source for the physiological elution buffer;

ii) a source for the sterilisation buffer;

iii) a pump for connecting and transporting the sources to the inlet of the column;

iv) a dose calibrator connected to the outlet of the column; and

v) a patient administration line connected to the dose calibrator.

8. Generator according to claim 7, arranged on a mobile vehicle.

9. Generator according to any one of claims 1 to 8, wherein the cationic exchanger is reloaded at least one time with strontium-82.

10. Method for producing a rubidium-82 comprising a diagnostic agent, comprising the steps of eluting a strontium-82/rubidium-82 generator according to any one of claims 1 to 9 with the elution buffer defined in any one of claims 2 to 9.

11. Method according to claim 10, comprising the step of sterilizing the strontium-82/rubidium-82 generator using a sterilization buffer, preferably a hypochlorite solution.

12. Method according to claim 10 or 11, comprising the step of storing/transporting the strontium-82/rubidium-82 generator.

13. Diagnostic agent obtainable with the method according to any one of claims 10 to 12.

14. Diagnostic agent according to claim 13, for use in medicine, such as for myocardial perfusion imaging.

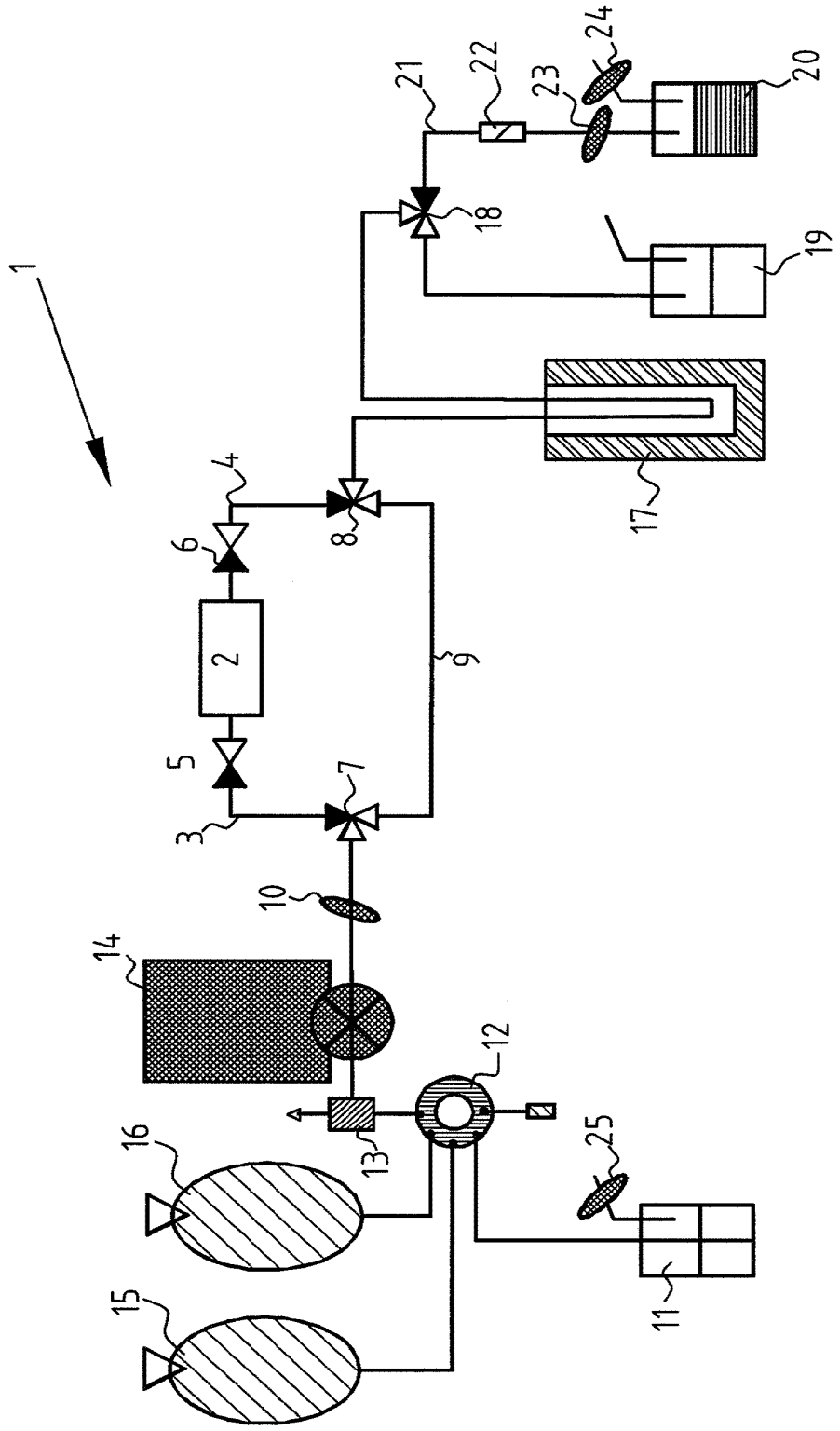



FIG. 1

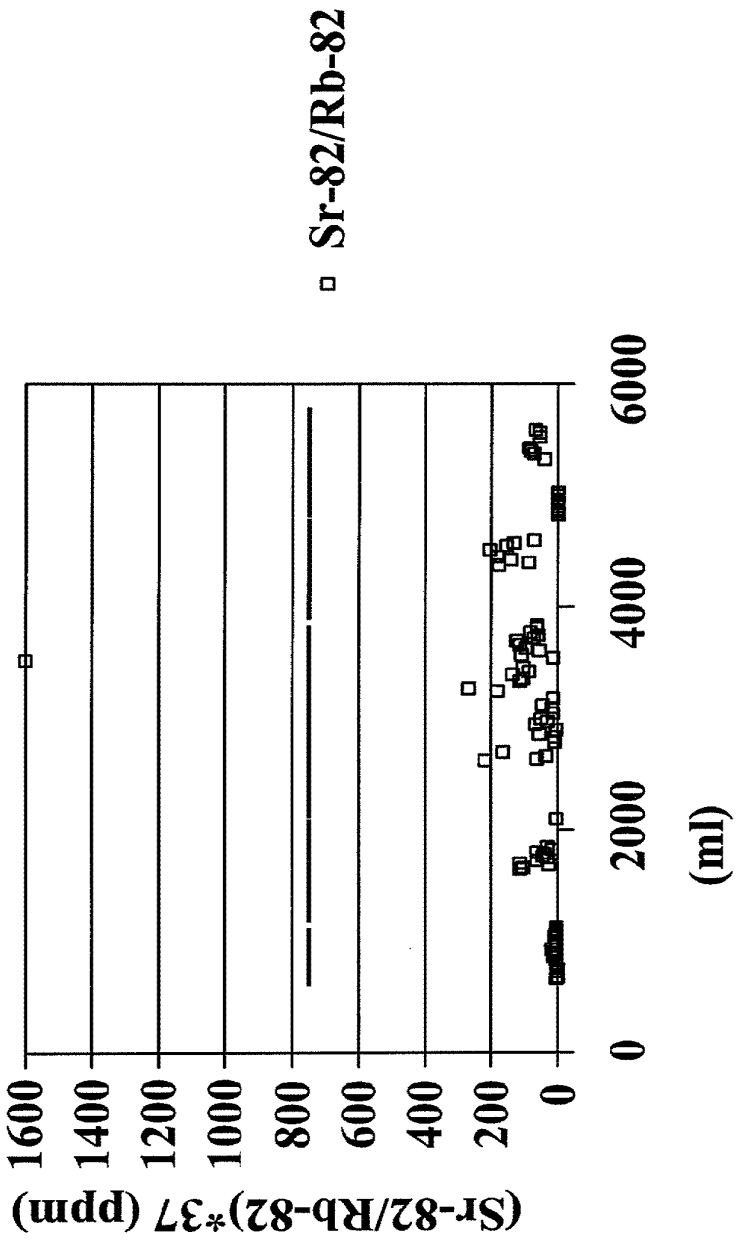

Sr-82/Rb-82
(Sr-82/Rb-82)*37 (ppm)
1600
1400
1200
1000
800
600
400
200
0
0
2000
4000
6000
(ml)

FIG. 2

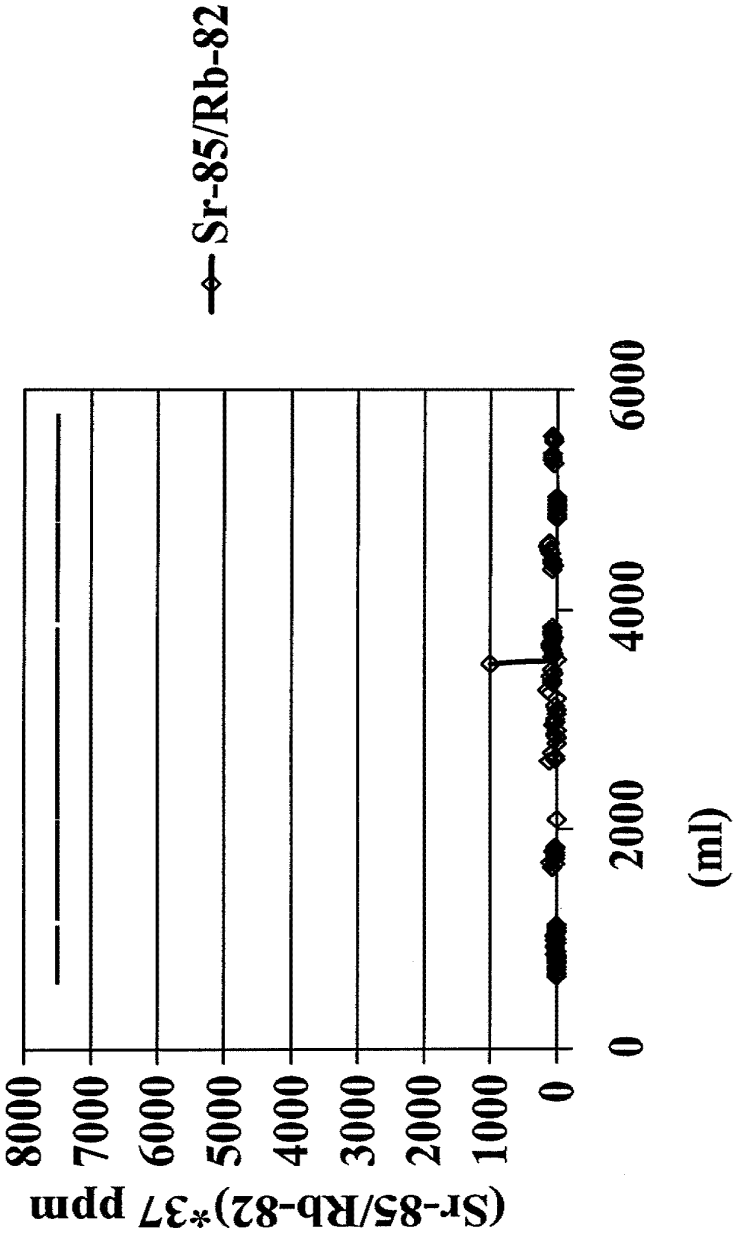
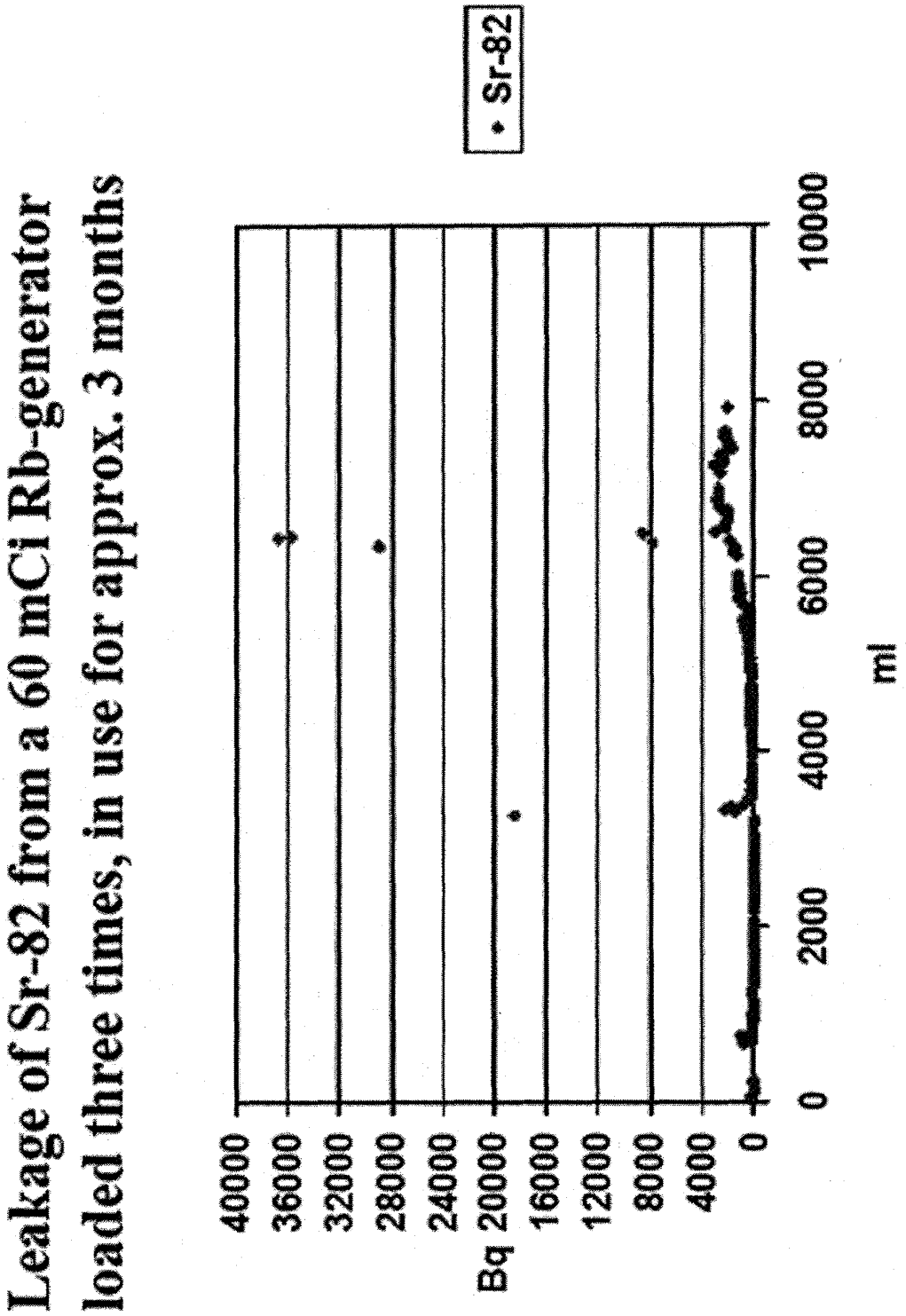
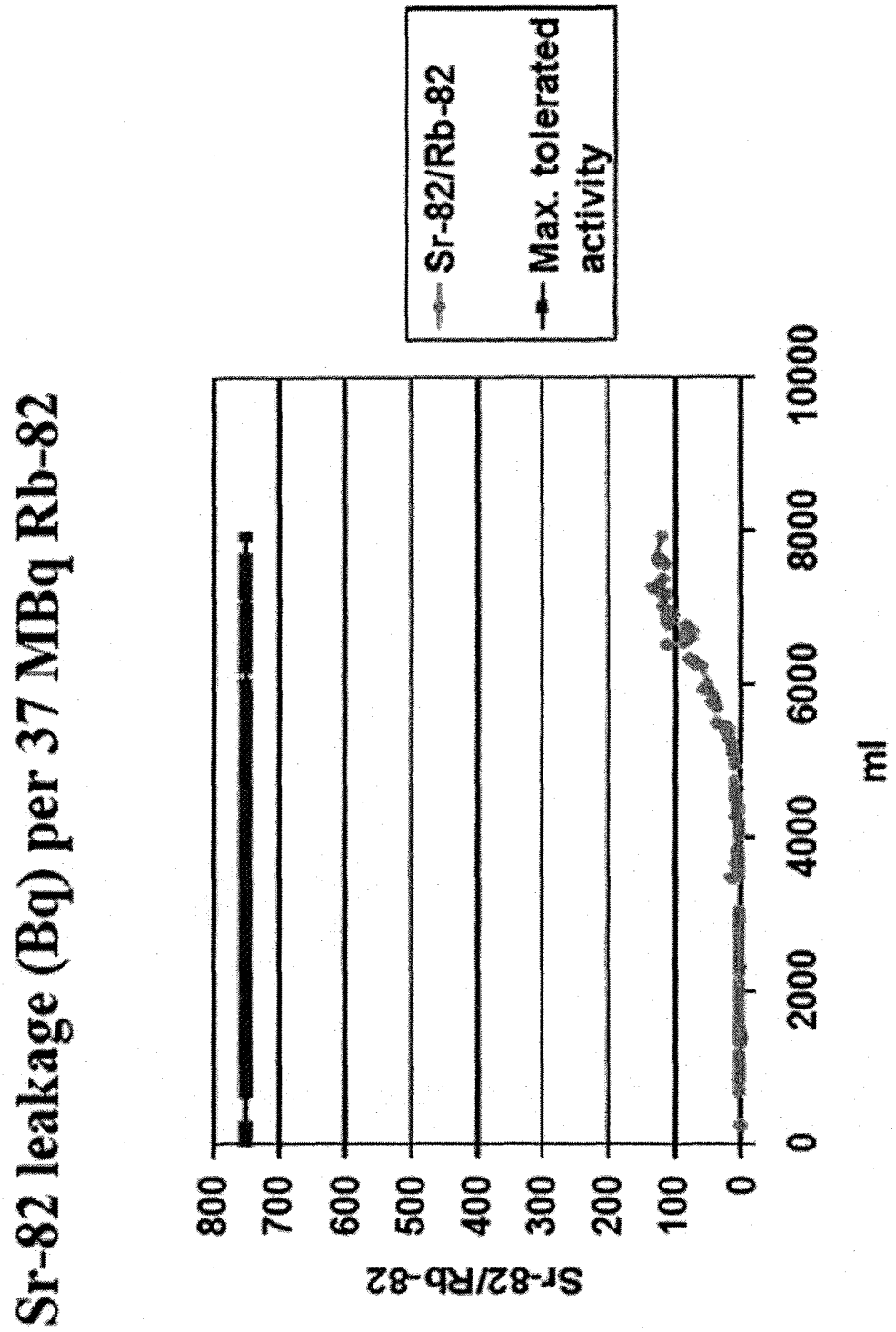
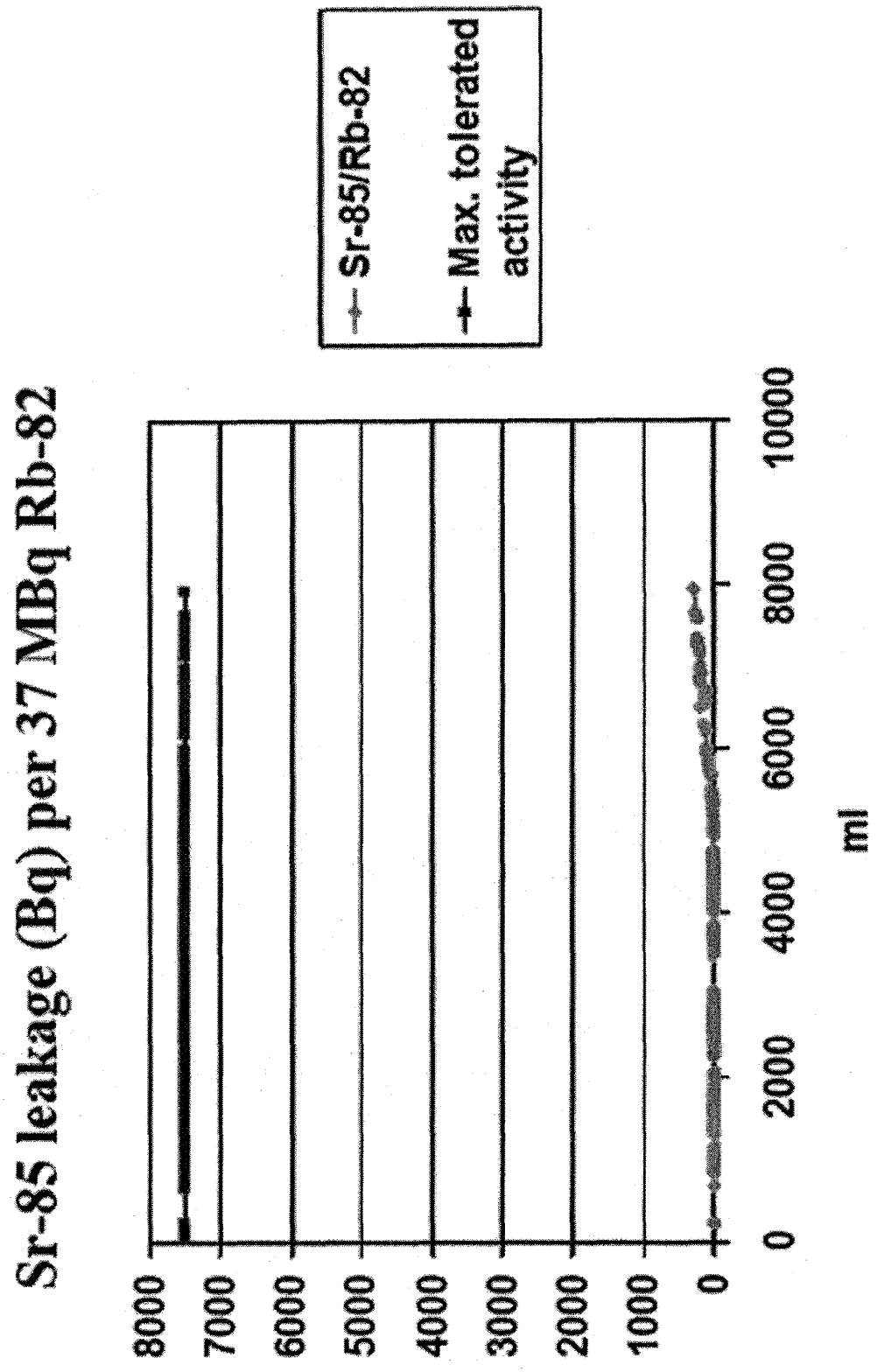

Sr-85/Rb-82
(Sr-85/Rb-82)*37 ppm
8000
7000
6000
5000
4000
3000
2000
1000
0
0
2000
4000
6000
(ml)

FIG. 3


Leakage of Sr-82 from a 60 mCi Rb-generator loaded three times, in use for approx. 3 months
Sr-82
Bq
ml
0
4000
8000
12000
16000
20000
24000
28000
32000
36000
40000
0
2000
4000
6000
8000
10000


Sr-82 leakage (Bq) per 37 MBq Rb-82
Sr-82/Rb-82
Max. tolerated activity
Sr-82/Rb-82
800
700
600
500
400
300
200
100
0
0
2000
4000
6000
8000
10000
ml


Sr-85 leakage (Bq) per 37 MBq Rb-82
Sr-85/Rb-82
Max. tolerated activity
8000
7000
6000
5000
4000
3000
2000
1000
0
0
2000
4000
6000
8000
10000
ml

# INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2009/060584

A. CLASSIFICATION OF SUBJECT MATTER
INV. G21G4/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
G21G A61K B01D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | WO 2006/135374 A (LYNNTECH INC [US]; MOLLER TERESIA [US]; ADAMS TODD [US]; CISAR ALAN [U]) 21 December 2006 (2006-12-21) paragraphs [0008], [0009], [0029] - [0040], [0042], [0092] - [0095]; figure 5 | 1-4,6, 9-14 |
| X | WO 2004/105049 A (UNIV ALBERTA SIMON FRASER UNIV [CA]; ZYUZIN ALEXANDER [CA]) 2 December 2004 (2004-12-02) page 2, lines 1-18 | 1,4,9, 10,12-14 |
| A | US 2007/140958 A1 (DEKEMP ROBERT A [CA]) 21 June 2007 (2007-06-21) paragraph [0019] | 1-14 |

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

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| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 26 November 2009 | 07/12/2009 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31–70) 340–2040,<br>Fax: (+31–70) 340–3016 | Lohberger, Severin |

Form PCT/ISA/210 (second sheet) (April 2005)

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2009/060584

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| WO 2006135374 A | 21-12-2006 | NONE | |
| WO 2004105049 A | 02-12-2004 | US 2006022127 A1 | 02-02-2006 |
| US 2007140958 A1 | 21-06-2007 | AU 2006326814 A1 | 28-06-2007 |
| | | CA 2562340 A1 | 21-06-2007 |
| | | WO 2007071022 A1 | 28-06-2007 |
| | | EP 1973624 A1 | 01-10-2008 |
| | | JP 2009520953 T | 28-05-2009 |

# Electronic Acknowledgement Receipt

| | |
|---|---|
| **EFS ID:** | 8149862 |
| **Application Number:** | 12137364 |
| **International Application Number:** | |
| **Confirmation Number:** | 7377 |
| **Title of Invention:** | INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE |
| **First Named Inventor/Applicant Name:** | Stephen E. Hidem |
| **Customer Number:** | 22859 |
| **Filer:** | Elisabeth Lacy Belden |
| **Filer Authorized By:** | |
| **Attorney Docket Number:** | 56782.1.7 |
| **Receipt Date:** | 04-AUG-2010 |
| **Filing Date:** | 11-JUN-2008 |
| **Time Stamp:** | 10:43:11 |
| **Application Type:** | Utility under 35 USC 111(a) |

## Payment information:

| | |
|---|---|
| Submitted with Payment | no |

## File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
|---|---|---|---|---|---|
| 1 | Information Disclosure Statement (IDS) Filed (SB/08) | 6thSIDS_56782-1-7.pdf | 857873<br>9d0315f2360762e457aa5a8dfdb6330241d79182 | no | 5 |

| | |
|---|---|
| **Warnings:** | |
| **Information:** | |

| | | | | | |
|---|---|---|---|---|---|
| 2 | Foreign Reference | WO2004059661A1.pdf | 1378510<br>90312f92d7372cc3550f43aebce82c4c3bd9cd9d | no | 27 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 3 | Foreign Reference | WO2006026603A2.pdf | 2131441<br>5c57ca5831eba5bdeb48e1135fbd24aeca2aabe1 | no | 58 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 4 | Foreign Reference | WO2006135374A2.pdf | 2328171<br>b564acc91f94f50b33ee35c287905b5ebdeffa25 | no | 49 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 5 | Foreign Reference | WO2008140351.pdf | 7418231<br>d0ce814cc2983495bdb5706c807d21fd88031eaa | no | 28 |
| **Warnings:** | | | | | |
| **Information:** | | | | | |
| 6 | Foreign Reference | WO2010020596A1.pdf | 855471<br>cce61168205cab3246c9da57caa8a9e4ef9f0749 | no | 22 |
| **Warnings:** | | | | | |
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PTO/SB/08a (01-10)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE



# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**( Not for submission under 37 CFR 1.99)**

| | |
|---|---|
| Application Number | 12137364 |
| Filing Date | 2008-06-11 |
| First Named Inventor | Stephen E. Hidem |
| Art Unit | 3763 |
| Examiner Name | Jenna Zhang |
| Attorney Docket Number | 56782.1.7 |

**U.S.PATENTS**

| Examiner Initial* | Cite No | Patent Number | Kind Code[1] | Issue Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|---|
| | 1 | 5590648 | | 1997-01-07 | Mitchell et al. | |

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**U.S.PATENT APPLICATION PUBLICATIONS**

| Examiner Initial* | Cite No | Publication Number | Kind Code[1] | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
|---|---|---|---|---|---|---|
| | 1 | 20070213848 | | 2007-09-13 | DeKemp et al. | |
| | 2 | 20080093564 | | 2008-04-24 | Tartaglia et al. | |
| | 3 | 20080242915 | | 2008-10-02 | Jackson et al. | |

If you wish to add additional U.S. Published Application citation information please click the Add button.

**FOREIGN PATENT DOCUMENTS**

| Examiner Initial* | Cite No | Foreign Document Number[3] | Country Code[2] ¡ | Kind Code[4] | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear | T[5] |
|---|---|---|---|---|---|---|---|---|
| | 1 | 9615337 | WO | | 1996-05-23 | Nilsson | | ☐ |

| INFORMATION DISCLOSURE STATEMENT BY APPLICANT ( Not for submission under 37 CFR 1.99) | | |
|---|---|---|
| | Application Number | 12137364 |
| | Filing Date | 2008-06-11 |
| | First Named Inventor | Stephen E. Hidem |
| | Art Unit | 3763 |
| | Examiner Name | Jenna Zhang |
| | Attorney Docket Number | 56782.1.7 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 2 | 02096335 | WO | | 2002-12-05 | Hill ROM Services | | ☐ |
| | 3 | 2006074473 | WO | | 2006-07-13 | Atlas Systems | | ☐ |
| | 4 | 2008028165 | WO | | 2008-03-06 | Catholic Health | | ☐ |

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**NON-PATENT LITERATURE DOCUMENTS**

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published. | T[5] |
|---|---|---|---|
| | 1 | NEIL J. EPSTEIN, et al., "A Rb82 infusion system for quantitative perfusion imaging with 3D PET" Applied Radiation and Isotopes, vol. 60, 9 February 2004, pages 921-927, XP002557544 DOI:10, 1016/j. apradiso.2004.02.002 | ☐ |
| | 2 | R. KLEIN, et al., "Precision controlled elution of a Sr82/Rb82 generator for cardiac perfusion imaging with positron emission tomography" Physics in Medicine and Biology, vol. 52, 11 January 2007, pages 659-673, XP002557545 DOI:10, 1088/0031-9155/52/3/009 | ☐ |
| | 3 | International Search Report and Written Opinion, dated 02-25-2010 for PCT Application No. PCT/US2009/047027, 22 pages | ☐ |
| | 4 | International Search Report and Written Opinion, dated 02-17-2010 for PCT Application No. PCT/US2009/047030, 17 pages | ☐ |
| | 5 | International Search Report and Written Opinion, dated 03-01-2010 for PCT Application No. PCT/US2009/047031, 20 pages | ☐ |
| | 6 | International Search Report and Written Opinion, dated 02-25-2010 for PCT Application No. PCT/US2009/047034, 15 pages | ☐ |

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|---|---|---|
| | Application Number | 12137364 |
| | Filing Date | 2008-06-11 |
| | First Named Inventor | Stephen E. Hidem |
| | Art Unit | 3763 |
| | Examiner Name | Jenna Zhang |
| | Attorney Docket Number | 56782.1.7 |

| **EXAMINER SIGNATURE** | | | |
|---|---|---|---|
| Examiner Signature | | Date Considered | |

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**( Not for submission under 37 CFR 1.99)**

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|---|---|
| Application Number | 12137364 |
| Filing Date | 2008-06-11 |
| First Named Inventor | Stephen E. Hidem |
| Art Unit | 3763 |
| Examiner Name | Jenna Zhang |
| Attorney Docket Number | 56782.1.7 |

## CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

**OR**

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☐ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ None

## SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

| | | | |
|---|---|---|---|
| Signature | /Elisabeth L. Belden/ | Date (YYYY-MM-DD) | 2010-03-12 |
| Name/Print | Elisabeth L. BELDEN | Registration Number | 50,751 |

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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(51) International Patent Classification 6 : E04B 9/06, A61G 12/00, A61B 19/02 — A1

(11) International Publication Number: WO 96/15337

(43) International Publication Date: 23 May 1996 (23.05.96)

(21) International Application Number: PCT/SE95/01346

(22) International Filing Date: 14 November 1995 (14.11.95)

(30) Priority Data:

| | | |
|---|---|---|
| 9403972-4 | 15 November 1994 (15.11.94) | SE |
| 9404354-4 | 14 December 1994 (14.12.94) | SE |
| 9501522-8 | 24 April 1995 (24.04.95) | SE |

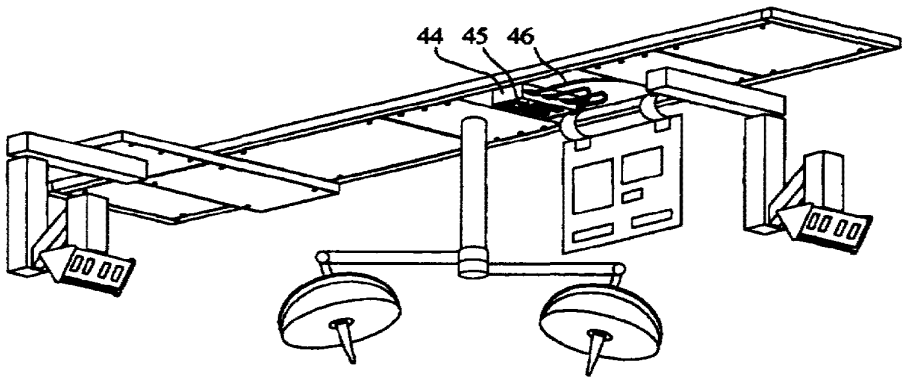
(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, LS, MW, SD, SZ, UG).

Published
*With international search report.*

(71)(72) Applicant and Inventor: NILSSON, Agne [SE/CY]; Aloni House, Phinikaria Village, Limasol (CY).

(74) Agent: ASKETORP, Göran, P.; Asketorp Patent & Juridik AB, P.O. Box 1, S-239 21 Skanör (SE).

(54) Title: MOUNTING DEVICE FOR HOSPITAL EQUIPMENT, MEDICAL SUPPORT SERVICE UNIT THEREFOR AND SERVICE MOBIL




(57) Abstract

Supportive structure to be attached to a ceiling of a hospital room for supporting hospital equipment. The supporting structure comprises beams attached to the ceiling and forming a rectangular space. Inside the space, there are non-interchangeable gas connectors attached to a gas supply of the hospital and a gas-tight electric box comprising terminals connected to the electric supply of the hospital. The equipment is mounted on support plates, which in turn are supported by support profiles attached to beams. The equipment is connected to the non-interchangeable gas connectors inside the space. Gas-tight hoses are provided between the electric box and the equipment for enclosing the electric wires between the terminals of the electric box and the equipment. In this way separate gas-tight passages are provided for the electric wires, avoiding hazard risks. The support plates support medical support service units for intensive care rooms forming a support structure for equipment necessary close to the bed in an intensive care room, such as a monitor (90), suction units (97), blood pressure monitors. The service unit is a rectangular frame (85, 86, 87, 88) supported by a pivotable arm (82, 83, 80) and a bearing (84), in order to extend essentially vertically from the arm and downwards to adjacent the floor. The rectangular space is sufficiently open for allowing sight through the frame for supervision of the patient. The space outside the vertical beams is free for service staff to work. The service unit can also be supported by a stand including wheels.

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TITLE: Mounting device for hospital equipment, medical support service unit therefor and service mobil

AREA OF INVENTION

The present invention relates to a mounting device for mounting hospital equipment in the ceiling of a operation room and medical support service unit mounted in said mounting device as well as a service mobil to be used in hospital rooms.

PRIOR ART

A mounting device for mounting equipment in the ceiling of a hospital room is previously known from e.g. EP-A2-0 215 212. Said mounting device comprises electric wires and/or fluid ducts. Moreover, it includes a support device for medical equipment.

EP-A2-0 257 299 discloses a support arm suspended in the ceiling and for supporting equipment close to a bed at a hospital.

Another support arm system and mounting equipment for a hospital is disclosed in CH-A5-568 459 (correspondig to US -A-3,931,452).

US-A-5,108,064 discloses a applicance support for use in particular in intensive care stations and comprising a support arm for receiving support members for the appliances and supply connections for operating the same.

EP-A1-0 219 274 discloses a support frame for medical appartuses to be used close to the bed at a hospital and supported by wheels.

An intravenous infusion device mobile is disclosed in EP-B1-477 551. The mobile carries a number of infusion devices necessary for the patient. DE-C1-41 04 814 discloses an intravenous infusion device in more details.

The mounting devices for support close to the ceiling of a hospital room and as disclosed in the prior art have the drawbacks that they do not solve the problem of separating the supply means for gas and electricity, which results in a potential risk.

Moreover, in a hospital room, the equipment to be used at the bed side need to be supported in a convenient and practical way. The prior art support devices have drawbacks as to the practicallity and availability of the electric connectors as well as gas connectors.

Within intensive care there is required many service functions such as: several types of drip and infusion systems for nutrition, liquid balance and drug supply; monitoring systems for various vital systems; respiratory support systems and also complete take-over of respiration.

All the above service must be present since the actual need cannot be pre-planned. It is also required that the personnel can conveniently reach the patient for exchanging drip cannulas, making free the respiratory tracts and even be able to do heart massage.

The necessary equipment has to be supported, either by a ceiling attached support

system or by a mobile provided with wheels.

DISCLOSURE OF THE INVENTION

According to the present invention, there is provided a supportive structure intended to be attached to the ceiling of the hospital room for supporting hospital equipment and comprising support beams and profiles enclosing internal gas connections and electric connections. The connections for electricity are separated in a gas tight enclosure preventing any contact with gases, which may leak from the gas supplies. Thus, a completely safe installation is obtained.

According to the present invention, there is also provided a new medical support service unit for intensive care which is more convenient and less cumbersome than previous systems, and is moveable in relation to the bed and still is sufficiently rigid to support also heavy equipment. Thus, there is provided a medical support service unit for intensive care rooms comprising connectors for gas supply and suction, electric power supply and other electric connectors as required and forming a support structure for equipment necessary close to the bed in an intensive care room, such as a monitor, suction units, gas supply units, blood pressure monitors. According to the invention, the unit comprises a rectangular frame of beams, encircling a rectangular space, said frame being supported by a pivotable arm and a bearing mounted in the ceiling of the room, in order to extend essentially vertical from the arm and downwards to adjacent the floor of said room. The rectangular space encloses equipment which are well protected inside the frame, and said rectangular space is sufficiently open for allowing sight through the frame for supervision of the patient and contact with other staff and the area around the vertical beams being free for service. The vertical beams comprises electric connections and outlets mounted in or at the vertical beams. A gas panel is mounted across the vertical beams.

A further object of the present invention is to provide a mobile where all equipment needed for the intravenous supply services can be included, such as intravenous pumps of the peristaltic or syringe type, nipples, catheters, needles, valves and other small parts, monitors which analyses and monitors the operation of the equipment and the vital functions of the patient. In this way all equipment required for this function can be gathered to one unit. A complete medical support system is obtained for intensive or critical care, which means that the nurses and doctors are given ample place to do their contributions to the care of the patient. The ergonomic and working environmental situation is enhanced, which means that the staff feel more safe and will not be stressed.

Further details appear from the attached patent claims.

SHORT DESCRIPTION OF THE DRAWINGS

Further objects, features and advantages of the present invention will appear from the following detailed description of preferred embodiments shown on the attached drawings.

Fig. 1 is a perspective view of a supportive structure according to the invention.

Fig. 2 is an enlarged cross-sectional view of a part of the supportive structure

according to the invention.

Fig. 3 is an enlarged cross-sectional view of another part of the supportive structure according to the invention.

Fig. 4 is a perspective view similar to Fig. 1 and shows the gas conduits.

Fig. 5 is a perspective view of the lower side of the supportive structure and shows the electric box.

Fig. 6 is a perspective view in an enlarged scale of the electric box according to the invention.

Fig. 7 is a perspective view of an equipment mounted beside the supportive structure in a side bracket.

Fig. 8 is an exploded view of the side bracket mounting according to Fig. 7.

Fig. 9 is a perspective view of a service unit according to prior art.

Fig. 10 is a perspective view similar to Fig. 1 of a preferred embodiment of a service unit according to the invention.

Fig. 11 is a perspective view of the service unit according to Fig. 10 from the other side.

Fig. 12 is a side view of the unit seen from the bedside without any equipment.

Fig. 13 is an end view of the unit according to Fig. 12.

Fig. 14 is a side view of the unit according to Fig. 12 seen from the nurse side.

Figs. 15 and 16 are elevation views of the side of the vertical beams.

Fig. 17 is a cross-sectional view of a vertical beam with a bracket mounted thereon.

Fig. 18 is a perspective view of a ventilation mobile, seen from the nurse side.

Fig. 19 is a perspective view of the ventilation mobile according to Fig. 18, seen from the patient side.

Fig. 20 is a perspective view of a critical care mobile according to the invention, seen from the patient side.

Fig. 21 is a perspective view of the critical care mobile according to Fig. 20, seen from the opposite side compared to Fig. 3.

Fig. 22 is a perspective view of a pump module intended to be attached to the mobile according to Figs. 20 and 21.

Fig. 23 is a perspective view of a standard mobile according to the invention, seen from the nurse side.

Fig. 24 is a perspective view of the standard mobile according to Fig. 23, seen from the opposite side compared to Fig. 23.

Fig. 25 is a perspective view of the standard mobile according to Figs. 23 and 24, seen from the patient side and used for another purpose.

Fig. 26 is a perspective view of the standard mobile according to Fig. 25, seen from the opposite side compared to Fig. 25.

## DETAILED DESCRIPTION OF THE INVENTION

Fig. 1 is a perspective veiw of the supportive structure comprising steel girders making up the installation.

The supportive structure comprises a rectangular framework of rigid square steel girders. In the drawings there are shown two longitudinal girders 1, 2, each for example 3600 mm long, interconnected by two transversal girders 3, 4, each for example 600 mm long. Several vertical L-beams 5 - 12 are welded to the square girders at suitable locations as shown on the drawings. Further horizontal L-beams 13 - 17 interconnect the vertical L-beams to form a supportive structure as shown on the drawing.

Each vertical L-beam is intended to be connected to mounting members 18, one of which is shown on the drawing above L-beam 6. It is to be understood that such mounting members are positioned above each of the vertical L-beams.

The mounting member comprises a vertical, hollow, square beam 19 attached to a support plate 20. The support plate 20 is attached to the ceiling of the operating room by several screws 21, schematically shown on the drawing.

The square beem 19 of the mounting member 18 has an inner dimension suitable for entering the vertical L-beam inside it. As an example, the square beem can have an external size of 50 x 50 mm, and a wall thickness of about 2 mm, and thus the inside dimension is about 46 x 46 mm. The L-beam can have a corresponding dimension so that it fits inside the square beam, such as a width of 45 mm.

When mounting the supporting structure in an operating room, the mounting members are attached to the ceiling in appropriate locations. The vertical L-beams 5 - 12 are introduced into the square beams until the supportive structure is horizontal, and then the L-beams 5 - 12 are welded to the square beams. In this way it is possible to obtain a horizontal supportive structure also when the ceiling is not completely horizontal or is uneven.

As mentioned above, the supportive structure comprises four girders, such as square girders of steel and having a dimension of 50 x 50 mm. The girders have to be strong enough for supporting heavy equipment and can be made with a wall thickness of 2,4 mm.

In order to adapt this supportive structure to support different operating equipment, such as operation lamps, connector centrals for gas supply and electric supplies etc., there is provided according to the invention a support profile made from extruded aluminum having a shape shown in Fig. 2 to the left, and being generally L-shaped. The support profile is intended to be placed along the longitudinal girders. If the support profile is as long as the girder, such as 3600 mm, then the support profile has recesses for passing the vertical L-beams 5 - 12.

The support profile 22 is shown in more details in Fig. 2 and comprises a first horizontal leg 23 intended to be placed on the horizontal upper surface 24 of the girder, and a vertical leg 25 intended to the placed along the vertical side surface 26 of the girder facing the inside of the rectangular space formed by the supportive structure. The horisontal leg 23 has a hook flange 27 passing a short distance along the opposite vertical side surface of the girder

facing outwards. Thus, the support profile is hanged upon the girder by placing the hook flange 27 over the girder and the profile will hang as shown in Fig. 2. The support profile has several other flanges, the operation of which will be described below.

Somewhere along the upper horizontal surface of the support profile, there is a flange 28 inclined about 45° upwards as shown to the left in Fig. 2. This flange is for supporting a ceiling or lid plate 39 extending from one girder to the other and covering the whole supporting structure at the top. Preferably, the ceiling plate 39 is extending inclined upwards about 50 mm and then extends in a horizontal direction. The ceiling plate 39 is attached to the flange 28 by rivets or screws.

The support profile is further provided with a depending flange 29 close to the intersection between the horizontal and vertical legs 23, 25 forming a pocket 30 facing downwards and extending along the entire length of the support profile. Furthermore, the vertical leg 25, at the bottom is provided with a horizontal flange or support surface 31 extending inside the rectangular area of the supportive structure. The object of the pocket 30 and the surface or flange 31 is to support an L-beam, as shown in broken lines in Fig. 2. The pocket 30 is provided with an enlargement 32 enabling the introduction of a L-beam 33 as shown in Fig. 2 by broken lines.

As shown at the right side of Fig. 3, each girder is provided with a cover profile 34 extending along the entire length of the girder. The cover profile is locked in place by a lock profile 35, which can be placed on intermediate positions or can be a longitudinal profile. The lock profile 35 is screwed to the hook flange 27 of the support profile 22, thus completing the grip around the girder. In this way, a very reliable support profile construction is attached to the girders.

As shown to the left in Fig. 2, a longitudinal L-beam 33 can be inserted with its vertical leg into said pocket 30 and resting upon the support surface 31. The L-beam 33 has three holes along its horizontal leg, into which holes are inserted screws for supporting any equipment to be attached to the supportive structure. Such equipment is mounted on a strong support plate 36 having a standardized size, such as 600 x 300 mm. The girders are mounted so that the distance between a depending inverted T-flange 37 of one girder to the corresponding T-flange 37' of the other girder is 600 mm. The above-mentioned L-beam 33 has a length of 300 mm. Thus, the support plate 36 for the equipment can be inserted between the T-flanges and attached to the L-beams arranged as described above. By drawing the screws, the L-beam 33 and the support plate 36 will squeeze the support surface 31 therebetween forming a tight attachment between the support plate 36, the L-beam 33 and the support profile 22. Preferably, the L-beam has a cushion 38 outside the holes as shown in Fig. 2, to the right.

By loosening the screws, the support plate will be moveable along the length of the support profiles and thus along the girders, in order to place the equipment where needed. When the right position has been obtained, the screws are tightened. The equipment can be

remounted by loosening the screws and removing them completely, whereupon the support plate is free from the L-beams. Mounting and dismounting of the equipment can take place without making or leaving screw holes in the supportive structure.

When the equipment has been mounted as mentioned above, the spaces between the support plates of respective equipment is downwardly covered by lid plates 40, which preferably are of standard size, or can be cut to the desired size. It is preferred to use a modular size, so that the support plates are placed within modules of a width of 300 mm.

The lid plates 40 are shown in more details in Fig. 3 and are provided with hooks 41, hooking around one of the edges of the inverted T-flange 37. The other side interact with the corresponding edge by a locking arrangement such as an excentric lock (not shown). When the lock is disengaged, the lid plate 40 can be swung down hanging in the hooks 41 when access to the interior of the supportive structure is required a shown in broken lines in Fig. 3.

As shown in Fig. 4, gas conduits 42 are entering the supportive structure from above. Such gas conduits come from the hospital central supply of gas into each room at convenient locations and are connected to non-interchangeable connectors inside the supportive structure. From such connectors, the gas is further supplied to the equipment needing gas supply.

Moreover, electric wires 43 enter the supportive structure from above, as also shown in Fig. 4. These wires enter an electric box 44 (see Fig. 5), provided with suitable terminals. The box is completely gas tight and the holes, through which the wires enter the box are sealed. Thus, there is provided separate and sealed compartments for the electric supply as is required for avoiding risks in connection with gases, such as oxygen gas.

The electric box has a removeable and sealed cover, which is removed in Fig. 5 exposing the terminals 45 inside the box 44. The electric box is also provided with further holes, which originally are sealed or unbroken. When an equipment needs electric supply, a hose 46 is provided from the electric box to the equipment as shown more clearly in Fig. 6. The hose 46 is gas tightly attached to the electric box by a coupling 47 connected to the box 44 with screws and having a sealing thereto. The other end of the hose is connected to the equipment in a similar way. The electric wires are placed inside said hose and connected to the terminals 45 in the electric box and to the contactors (not shown) of the equipment. Thus, the electric wires are places inside said hose and are sealed from any space that might include gas. Thus, there is obtained a completely safe mounting of electric wires in combination with gas conduits.

As further shown in Figs. 5 and 6, the lid plate 40 is shown swung down and hanging in the hooks 41. The inside surface of said lid plate 40 can be provided with circuit diagrams and instruction notes 48 as shown. Morover, the lid plate is provided with several holes 49. These holes operate as vent holes for venting any gas leaking from the gas non-interchangable couplings to the surroundings. Further such holes 49 are provided in the bottom closures of the supportive structure where necessary.

As shown in Fig. 3, the cover profile 34 is provided with a horizontal flange 47

extending outwards from the space occupied by the supportive structure. This flange 47 is intended to support an extra ceiling 48 of the room, such as a slab, which is often used for obtaining a more clean ceiling surface in the operation room.

It is obvious that the lock profile 35 can be constructed as an integral portion of the cover profile 34 if this is more convenient.

Sometimes it is desired to place the equipment displaced in the side direction in relation to the supportive structure. Such a bracket mounting is shown in more details in Figs. 7 and 8. The side bracket is made up of four U-beams forming a rectangular frame 50. The frame is provided with a transversal beam 51. Said beam 51 and one transversal side 52 of said frame are connected to the L-beams 33 as shown in Fig. 2 so that the entire frame 50 is moveable along the supportive structure shown at 53. The frame 50 is locked in position by several screws 54 engaging said L-beams 33 as described above. The frame 50 is provided with screw bolts 55 adapted for engagement with a support plate 56 of the equipment as shown in Fig. 16. The final mounting is shown in Fig. 7.

Fig. 9 is a perspective view of a service unit according to the prior art, the POWER COLUMN from Hill-Rom. It comprises a rectangular column 61 extending from the ceiling 62 to the floor 63 and fixed thereto. The column is about 2400 mm x 600 mm x 200 mm. The column is mounted about 45° in relation to the adjacent wall. A bed is placed so that the head portion thereof is close to the column. Usually, the bed extends perpendicular to the wall.

The column is provided with several electric outlets 64 and connectors along the vertical short sides 65. Along the long side 66 facing the bed, there is mounted equipment of different types, such as suction devices 69, gas outlets 68. Moreover, a monitor 70 is mounted at a support 71. On the backside there is mounted a shelf 72, where the nurse can write on the patient card, and several boxes 73 for different purposes such as including small details used at the place and a waste basket.

There are several drawbacks with such a service column. It is fixed at the floor which makes it necessary to move the bed, if access to the bed should be required from all four sides in an emergency situation. It happens sometimes that the weight of the patient is monitored by weighting units between the bed and the floor, and a movement of the bed disturbs such a set-up and requires re-calibration of the weighting units.

Since the column is fixed to the floor, it is difficult to clean around the column.

The equipment, and specifically the monitor extends rather long out from the column, which takes up a lot of place. When the nurse makes her patient records, she is positioned behind the column and cannot see the patient, if an emergency situation should arise.

If new equipment is to be mounted, such as a further suction outlet, it is necessary to make new holes in the column construction which is difficult and disturbs other intensive care patients and functions.

A service unit for an intensive care room obviating all the above-mentioned drawbacks with the fixedly mounted column, is shown in Figs. 10 and 11.

The service unit according to the invention hangs in a support arm supported from the ceiling of the room. Such support arms are frequently used in hospitals, especially in operating rooms.

A support plate 80 is attached to the ceiling fixture by several bolts 81. To the support plate 80 is attached a support arm 82 extending horizontally below the ceiling and being pivotable by bearings 83. At the end of the arm, there are further bearings 84 attached to the middle of a horizontally extending beam 85. At the end of beam 85, two vertical beams 86, 87 are attached interconnected at the lower end by a bottom beam 88. Thus, beams 85, 86, 87 and 88 form a rectangular frame as shown in Figs. 10 and 11. The rectangular frame is supported at its vertical symmetry axis by said bearing 84. The bottom beam 88 is placed a short distance above the floor, such as 30 cm above the floor for the necessary convenient cleaning of the floor.

The support plate is attached in the room so, that the rectangular frame can be positioned close to the wall in a first position when not used and swung out close to the head end of an adjacent bed when used. The rectangular frame is pivotable around its vertical symmetry axis as shown by arrow 89.

The equipment which must be present close to the bed, is mounted in the free space between the vertical beams 86 and 87, as shown by monitor 90 mounted on a shelf 91. The equipment is inserted between the vertical beams and facing the bed side.

On the backside shown in Fig. 10, there is inserted between the vertical beams other types of equipment necessary for the nurse, such as a writing table 92 or commode for the nurse where she can have the patient record and further things for writing purposes. The commode may comprise small boxes containing needles, connector and other accessories for drip, drainage etc.

Alternatively, the commode can be replaced by a PC-station connected to a centralised patient monitoring and recording system, including a video display and keyboard.

At the bottom there is a file box 93. Above the table 92 there is a further shelf 94 for placing stationery, scalpels and other small things handy when arranging for drips etc. A lamp 95 provides a good working light.

It is clear from Figs. 10 and 11 that a nurse doing her patient records can still observe the patient, through the free space in the interior of the rectangular frame. Only the vertical beams occlude the sight.

At the side usually facing the bed and shown in Fig. 11 there is provided all equipment needed for the patient, such as the monitor 90 mentioned above, a gas panel 96 having gas inlets and a connector for suction connected to a suction collector bottle 97. Several horizontal support rails 98 extend between the vertical beams for supporting further equipment, such as an oxygen therapy unit, timers in case of heart arrest, etc. A lamp 99 provides convenient lighting to the support service system equipment arranged on the unit. The lamp has an oval light up area only to light up the equipment.

A support stand 100 for infusion bags can be attached to the vertical beams as explained in more details below.

The service unit according to Figs. 10 and 11 is shown without equipment and in side and end views in Figs. 12, 13 and 14. The same details as in Figs. 10 and 11 have the same reference numerals.

In Fig. 13 there is shown a different type of lamp 101 included below the shelf 94.

As appears clearly from Fig. 12, the gas panel 96 is provided with several modules 102, 103, 104, 105 and 106. Modules 103 and 105 are blank modules without anything mounted. Module 104 comprises three medical gas pressure indicators showing bright red warning colour when pressure is too low from the central supply, such as oxygen, nitrous oxide and compressed air. To the left, 102 and to the right 106 are two modules having suction units. Other modules can be mounted at positions 103 and 105 without any mechanical work.

The gas panel is connected to the hospital's central gas supply via flexible hoses inside beam 86, beam 85, through bearing 84, arm 82, bearing 83 and support plate 80.

At the sides of the vertical beams 86 and 87 there are several connectors for electric power supply and for signal lines. Thus, the left beam 86, seen according to Fig. 12 is provided with the connectors shown in Fig. 15. Such connectors are power supply outlet 107 and small signal connector 108 intended for the monitor 90. Thus, the wires to the monitor are short. At the bottom there are shown five outlets 109 for power supply (220 V). In between there are two blank modules 110, 111, but these modules can be provided with electric outlets and connectors if required. Other module configurations can easily be arranged.

The corresponding right beam 87 is provided with other connectors as required and shown in Fig. 16. The electric power supply wires and signal wires are enclosed inside the vertical beams 86 and 87 and pass to the hospital's central supply and network the same way as the gas lines.

Thus, it is clear that the rectangular frame can include all functions and equipment necessary for the service function intended. It is easy to adapt the rectangular frame to whatever need should there be.

Since the interior of the rectangular frame is available, compared to the column shown in Fig. 9, the large equipment such as the monitor etc. can be housed between the vertical beams 86, 87 so that they do not occupy large area and do not extend far away from the frame. Such equipment will be positioned below the support bearing 84, and thus, the rectangular frame will be steadily supported by the bearing 84. The equipment will not tend to twist the frame. Thus, a stable service unit is obtained in spite of the fact that it is moveable, which makes it easy to clean the floor. Such equipment is inserted inside the space limited by the vertical beams interleaved from one side or the other. The area outside the vertical beams is free for the support service and comprises the outlets necessary for the service, such as gas outlets and electric outlets.

It is noted that the bearings 83, 84 are of a type allowing very limited movement but

rotation around the vertical axis of the bearing. Thus, the rectangular frame is rather rigid and do not move easily, unless movement is wanted. Since all equipment is rather central in the frame, it will be still further stable.

The stability can be further improved by adding a lock in the bearing so that they are locked in position as soon as the frame has been moved into place. Such lock can be a friction clutch or key locking. The lock can be operated by hand, via a wire that can be pulled by hand, or be electrically and/or magnetically operated. Such lock can be included in one or both of the bearings 83, 84.

Moreover, the space between the vertical beams is free so that the patient can be observed even if the personnel is behind the service unit.

In Fig. 17 there is shown a cross-section through a corner of the vertical beams 86, 87. The beam is provided with vertical grooves 115, 116 in which a bracket 112 can engage. To the bracket 112 can be attached further equipment such as a holder 100 for infusion bags etc. The bracket 112 is locked to the beam by a latch 118 and a screw connection 117 as shown. Other types of equipment can also be attached in this manner.

In Fig. 11 there is shown a treatment lamp 113 attached to the end of the pivotable arm 82. This lamp will be relatively fixed even when the rectangular frame is pivoted around the axis of bearing 84. Thus, said lamp 113 can conveniently be used for illuminating the patient being treated with a constant light. moreover, in Fig. 10 there is shown a telephone 114 in a convenient place. It is easy to install telephone lines in the rectangular frame or the beams.

Critical care of today manage to handle more and more severely ill patients, due to the high capacity of the technique of today in combination with specially educated doctors and nurses. However, this make it necessary to use a great number of different equipment around the patient. In addition to equipment analysing and monitoring the patient, he also requires supply of a lot of nutrients, blood plasma, different anaesthesia etc. Such supply must be controlled which means that old-fashion drop controlled infusion cannot be used any longer and are replaced with electronically controlled infusion pumps and syringes. Up to sixteen such pumps can be used at the same time for a single patient. One common way of using such automatic pumps today is to attach such a pump to the infusion stand with a coupling. The pump is provided with electric power via a wire and is connected to supervisory equipment via a signal cable. It is realised that such a system will be a mess of wires and hoses if used for sixteen pumps. The environment in such critical care rooms can be stressing for the nurses leading to errors and mistakes. It is necessary to further structure and integrate the different functions at such a critical care room.

Fig. 17 shows a ventilation mobile including equipment necessary for respiratory support and for keeping the respiratory ways free, such as oxygen supply units and suction units, as well as further equipment necessary for the critical care, such as supplies for anaesthesia gases. The ventilation mobile is supported by several swivel wheels.

The ventilation mobile 121 comprises a bottom frame 122 supported by several wheels

123 to form a transportable unit. Two vertical pillars 124, 125 extend from the bottom frame to define a vertical rectangular space. Each vertical pillar comprises several outlets for electric power supply 127 and medical gas outlets 126. All power outlets are supplied with 220 V mains power by a power wire 128 connected to a power outlet 129 at the wall of the room and the signal outlets are connected to a corresponding wall mounted signal connector 130, if used (no wire shown in Fig. 17). Moreover, the mobile is provided with a suction unit panel 131 connected to the hospital's central supply of gas via lines or hoses 132, 133, 134. As shown, power wire 128 and hoses 132, 133, 134 are supported by a pivotable arm 135 having hooks 136 supporting said wire and hoses. In this way the pivotable arm 135 can be made smaller and cheaper, compared to if the arm should enclose the hoses.

The vertical pillars 124, 125 and the bottom frame 122 form a vertical rectangular space inside which equipment can be mounted without extending into the space needed for the treatment of the patient. Thus, a large monitor is shown at the top on a shelf, which can be inclined. Moreover, the pillars encloses a writing table facing away from the bed, where the nurse can make the necessary recording and still observe the patient through the open space between the pillars.

As shown in broken lines in Fig. 19, the mobile can be provided with the equipment desired for a specific patient, such as a ventilator supported by said mobile bottom frame 122.

As further shown in Figs. 20 and 21, the same mobile can instead be constructed as an intravenous mobile or critical care mobile 140. In this case it is not necessary to have gas supplies from the hospital's central supply, but the mobile is only connected to 220 V by a power wire (not shown). The mobile can also be connected to the hospital's central computer system, in order to take advantage of the computerised patient recording system used at many hospitals today. Such wires are connected to wall mounted outlet sockets.

As appears from Figs. 20 and 21, the critical car mobile has the same bottom frame 122, wheels 123 and vertical pillars 124, 125. The side of the mobile facing the bed is provided with several mounting rails, for example four rails 141 as shown in Fig. 21. On said rails 141 are mounted several infusion pumps represented by rectangular boxes 142 if Fig. 20. Said infusion pumps can be of the peristaltic type providing infusion solutions from infusion bags hanging on hooks 143 of a stand 144. There are two such stands 144, one at each pillar, each stand being provided with five hooks. The infusion pumps can also be of the syringe type providing a beneficial agent to the patient, such as antibiotics, insulin etc.

The CC (critical care) mobile 140 is furthermore provided with a shelf 145 bridging the two pillars 124, 125 at the upper end thereof. The shelf 145 can support a monitor (not shown) or whatever is needed in the specific circumstance, such as fluid balance monitors and other analysis and monitoring equipment. Two of the rails support infusion pumps 142. The two bottom rails 141 support one shelf 146, which can be used for syringe pumps and a second shelf 147 which can be used for accessories, such as needles, catheters, etc. If more infusion or syringe pumps are needed, such pumps can replace on or both of said shelves 146,

147.

At the side opposite the patient, the CC mobile 140 is provided with a writing table 148 and a few drawers 149 for enclosing accessories at a convenient position for the nurse.

The pillars 124, 125 of the CC mobile 140 are provided with outlet sockets for providing electric power and signal wires to the pumps etc. of the mobile.

Fig. 22 shows the infusion pump sets in more details regarding the attachment to the rails 141. The infusion pumps are mounted in modules, for example a module 150 of two infusion pumps or a module 151 of three infusion pumps as shown in Fig. 22. Each module 150, 151 is interconnected so that only one power wire and one signal wire are needed for each module. The module comprises a holder 152, which in principle is a spring loaded hook, grasping around the support rail 141 when brought into engagement therewith.

Each module is provided with handles 153 for easy mounting and dismounting. The modules are stored in the hospital equipment store and when needed taken out and hooked on the support rail. As many pumps as required are mounted and used. By such a module system, it is possible to adapt each mobile to the requirements of each patient. Each module is provided with some co-operating means for engagement with the respective infusion pump. In this way, pumps of different manufacturers can be mounted together if that is desired.

Figs. 23 and 24 shows a standard mobile according to the invention. The standard mobile 160 is provided with a bottom frame 162 of a more simple structure having four wheels 163 and a single vertical pillar 164. The single pillar is provided with four support rails 161, two infusion bag stands 165, a couple of shelves 166, 167, 168, and a writing table 169. Moreover, an electric panel 170 is provided instead of providing the pillar with electric outlets. This standard mobile 160 can in principle have the same equipment as the CC module 140 described above, but it is smaller and designed for more normal IC cases.

As shown in Figs. 25 and 26, the standard mobile 160 can alternatively be provided as a surgical mobile having one or two individual operation suction units 171, 171' connected to a gas panel 172. Moreover, there is provided a top shelf 173 for any equipment, such as a monitor or a fiber optical light source etc., and a table 174 with a drawer for other equipment, e.g. electrosurgical units. As shown in Fig. 26, there is provided an electric panel 175 with automatic circuit breakers. The gas panel 172 and electric panel 175 are connected to the hospital's central supply via flexible cables 176 and hoses 177 supported by a stand 178 as shown in Fig. 26. The pillar 179 is provided with compressed air outlets 180 for connection to any surgical tools. The upper shelf 173 is pivotable for convenient access from all sides.

Such a standard mobile can be used for many purposes within a hospital.

Although several embodiments have been described above with reference to the appended drawings, it is obvious to a skilled person that different modifications can be made to the embodiments shown on the drawings and different combinations can be made without departing from the inventive idea of the invention. Such modifications obvious to a skilled person reading this specification is intended to be within the scope of the invention.

PATENT CLAIMS

1. Supportive structure intended to be attached at a ceiling of a hospital room for supporting hospital equipment, comprising supporting beams (1, 2, 3, 4) and suppport profiles (22) for supporting the equipment and for forming a space enclosing gas connections and electric connections for said equipment, c h a r a c t e r i z e d in that gas ducts (42) are adapted to enter said space and connected to outlets for connection to said equipment, and that electrical wires (43) are adapted to enter inside an electric box (44), comprising contacts (45) and being gas tight, and in that hoses (46) are adapted between said equipment and said electric box and including gastight connections (47) for comprising said electrical wires (43) between the contacts in said electric box and said equipment.

2. Structure according to claim 1, c h a r a c t e r i z e d by a framework of beams (1, 2, 3, 4), being attached, by several vertical beams (5 - 12), to mounting members (18) attached to the ceiling, so that said framework is adapted essentially horizontally close to the ceiling, whereby said support profiles (22) each comprises a horisontal leg (23) intended to cooperate with an upper surface of the corresponding beam and a vertical leg (25) intended to cooperate with the inner surface of the corresponding beam; and in that said support profile (22) each comprises a connection means (33, 30, 31) for connection to said equipment and for supporting it.

3. Structure according to claim 2, c h a r a c t e r i z e d in that said connection means comprises a longitudinal L-beam (33), the vertical leg of which being adapted to be inserted in a pocket (30) adapted in the support profile (22) and the horizontal leg of which being adapted to cooperate with a flange surface (31) so that said L-beam is supported by said support profile (22) and in that said L-beam is provided with a connection means for connection to said equipment.

4. Structure according to claim 3, c h a r a c t e r i z e d in that said equipment is mounted at a support plate (36) extending over said rectangular framwork and in that the support plate is provided with several holes corresponding to holes in said L-beam so that said support plate can be attached to said L-beam and at the tightening of the screws, jamming said flange surface between said support plate and said L-beam.

5. Structure according to claim 2, 3 or 4, c h a r a c t e r i z e d in that said support profile (22) further comprises a hook flange (27) adapted to hook around said beam at the opposite side of said vertical leg.

6. Structure according to claim 5, c h a r a c t e r i z e d in that said support profile (22) comprises a lock profile (35) adapted to be attached to said hook flange (27) and a cover profile (34) adapted below said beam so that said beam is completely surrounded by said support profile, at least along a portion of the length thereof.

7. Structure according any one of the previous claims, c h a r a c t e r i z e d in that said space is covered by plates (36, 40) at least one of which being provided with ventilation holes (49).

8. Structure according any one of the previous claims, c h a r a c t e r i z e d in that said gas connections are non-interchangeable gas connections.

9. Medical support service unit for intensive care rooms comprising connectors, such as for gas supply and suction, electric power supply and other electric connectors as required and forming a support structure for equipment necessary close to the bed in an intensive care room, such as a monitor (90), suction units (97), blood pressure monitors, c h a r a c t e r i z e d by

a rectangular frame, preferably of four beams (85, 86, 87, 88), encircling an essentially rectangular space, said frame being supported by a pivotable arm (82, 83, 80) and a bearing (84), in order to extend essentially vertical from the arm and downwards to adjacent the floor of said room;

said rectangular space enclosing equipment (90, 92) interleaved from one side or the other which are well protected by the frame, and said rectangular space being sufficiently open for allowing sight through the frame for supervision of the patient and the area around the vertical beams being free for service.

10. Service unit according to claim 9, c h a r a c t e r i z e d in that said rectangular frame comprises two vertical beams (86, 87) interconnected at the top and bottom by horizontal beams (85, 88), the upper horizontal beam being connected to said bearing (84) at the pivotable arm (82, 83) at or adjacent the middle of the horizontal beam (85).

11. Service unit according to claim 9 or 10, c h a r a c t e r i z e d in that said rectangular frame comprises electric connections (108) and outlets (107, 109) mounted in or at the vertical beams (86, 87).

12. Service unit according to claim 9, 10 or 11, c h a r a c t e r i z e d in that a gas panel (96) is mounted across the vertical beams.

13. Service unit according to anyone of claims 9 - 12, c h a r a c t e r i z e d in that said vertical beams (86, 87) comprises grooves extending along the beams for attachment of brackets (112) for supporting holders (100) or other equipment.

14. Service unit according to anyone of claims 9 - 13, c h a r a c t e r i z e d by a locking device in one or both of the bearings (83, 84) for further improving the stability of the rectangular frame.

15. Service mobile for carrying medical equipment, comprising a bottom frame (122) supported by wheels (123), **characterised** by at least one vertical pillar (124, 125) including electric outlets of power type and signal type, said pillar supporting equipment required for monitoring vital functions and for the medical service, such as infusion pumps of the peristaltic or syringe type, oxygen therapy units, surgical suction units, gas supplies etc.

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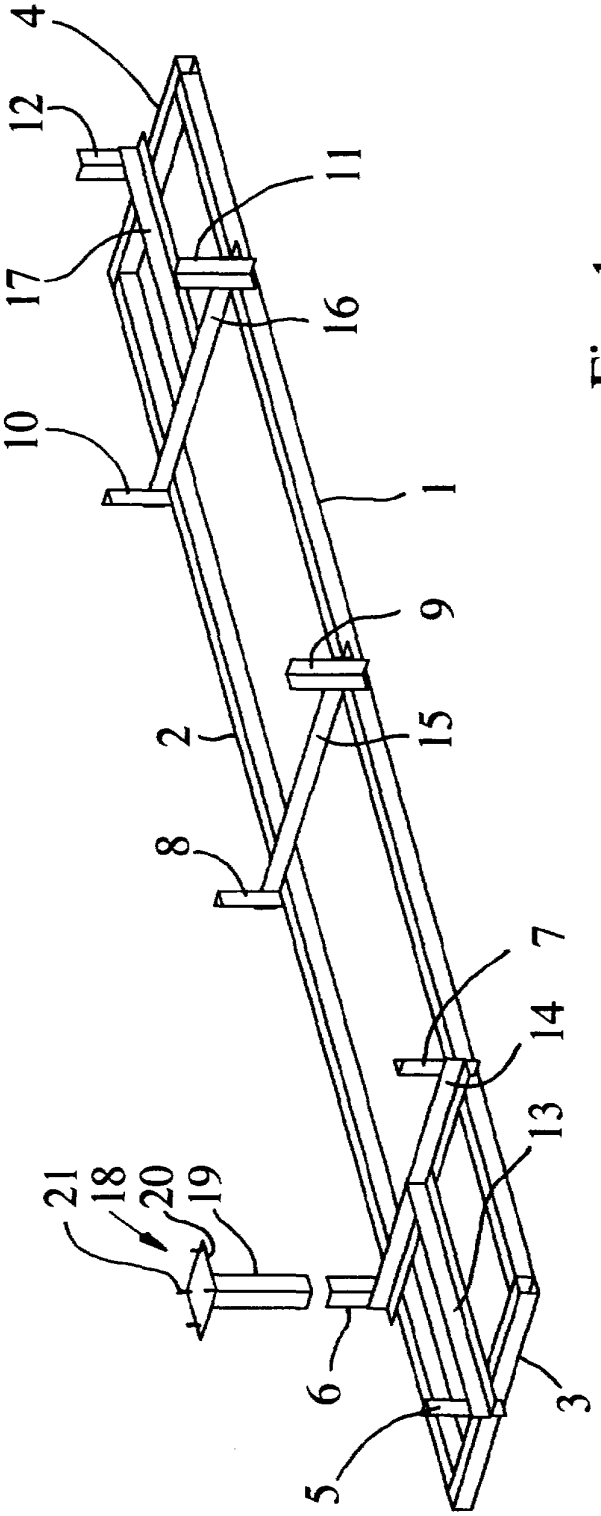



Fig. 1

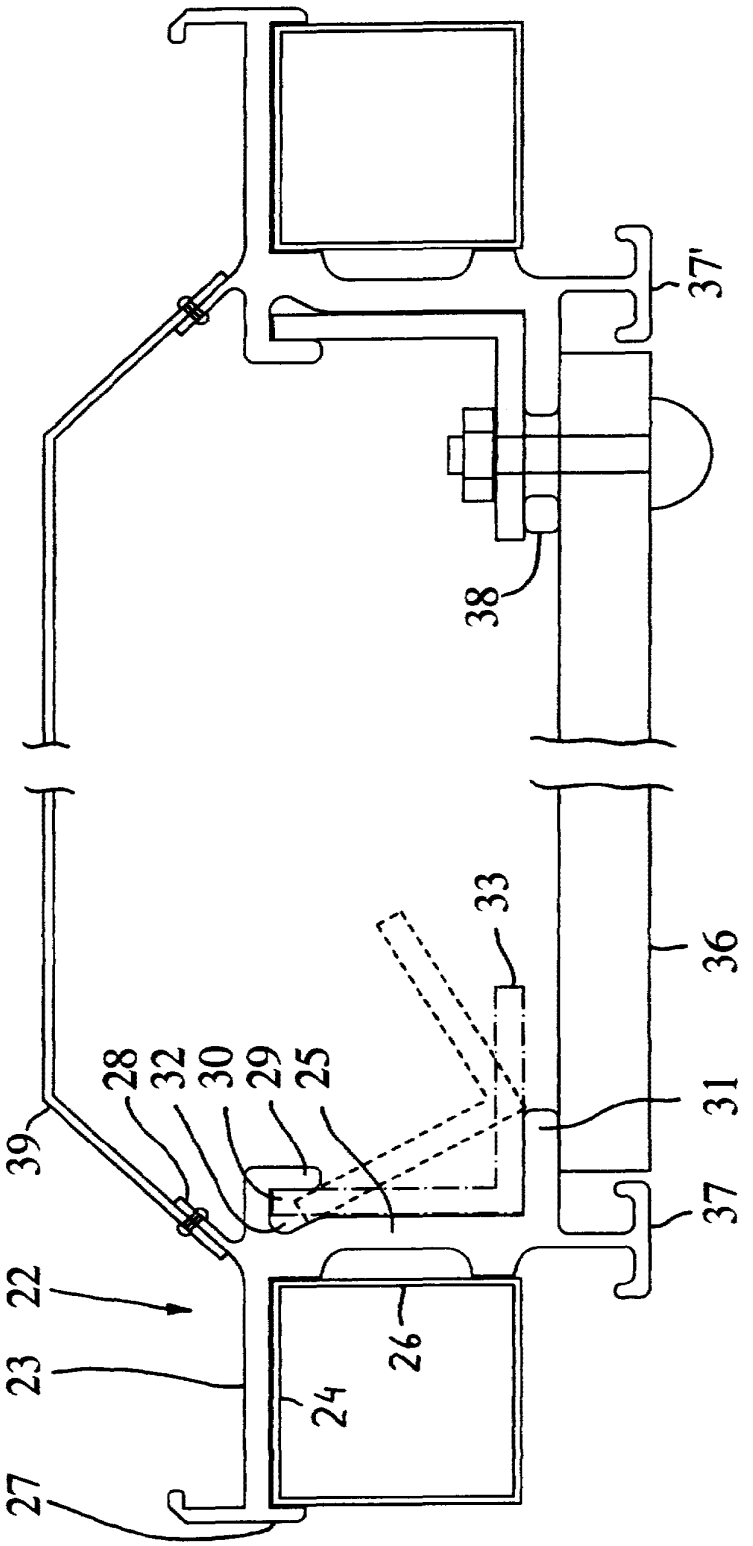



Fig. 2

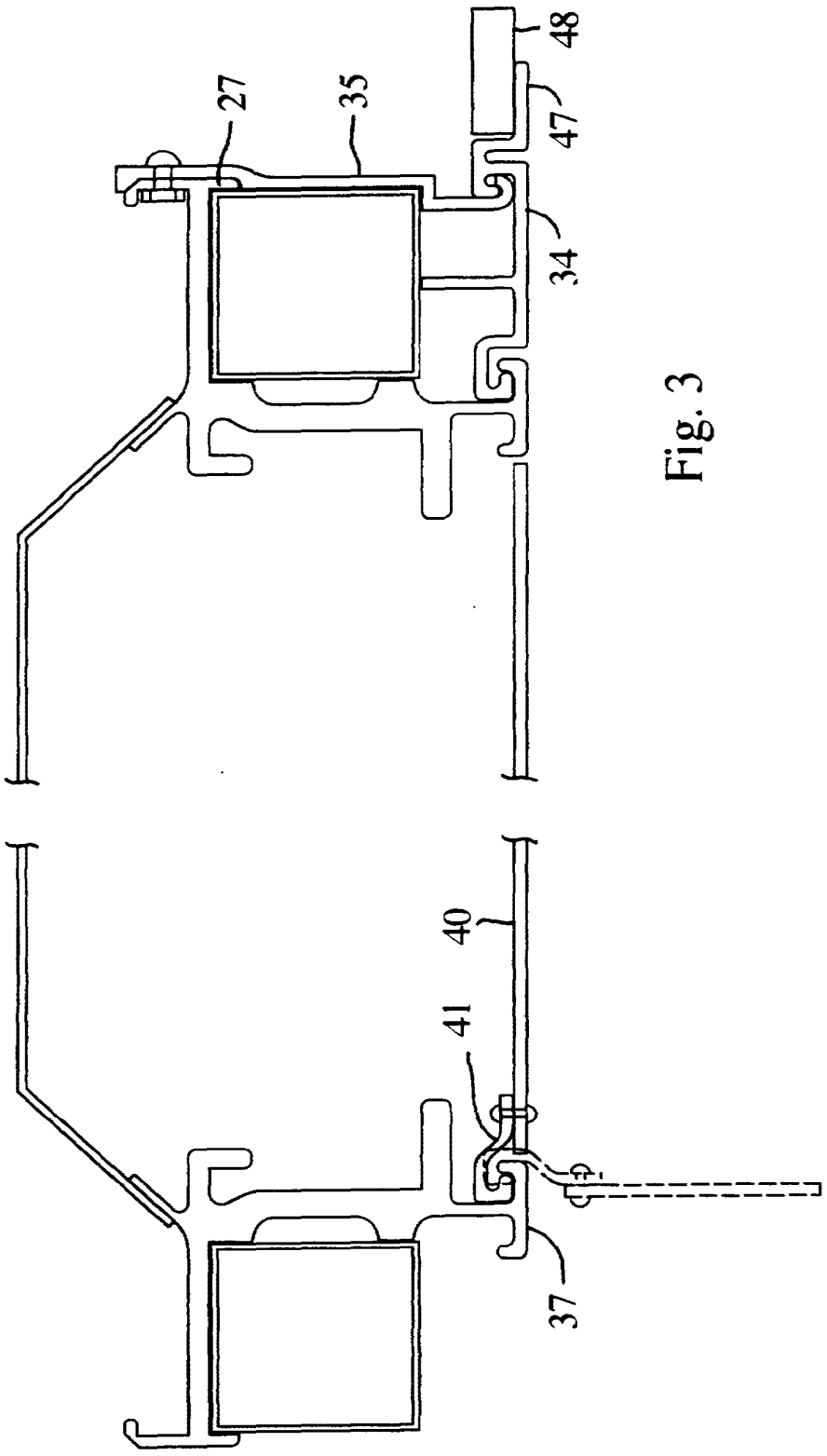



Fig. 3

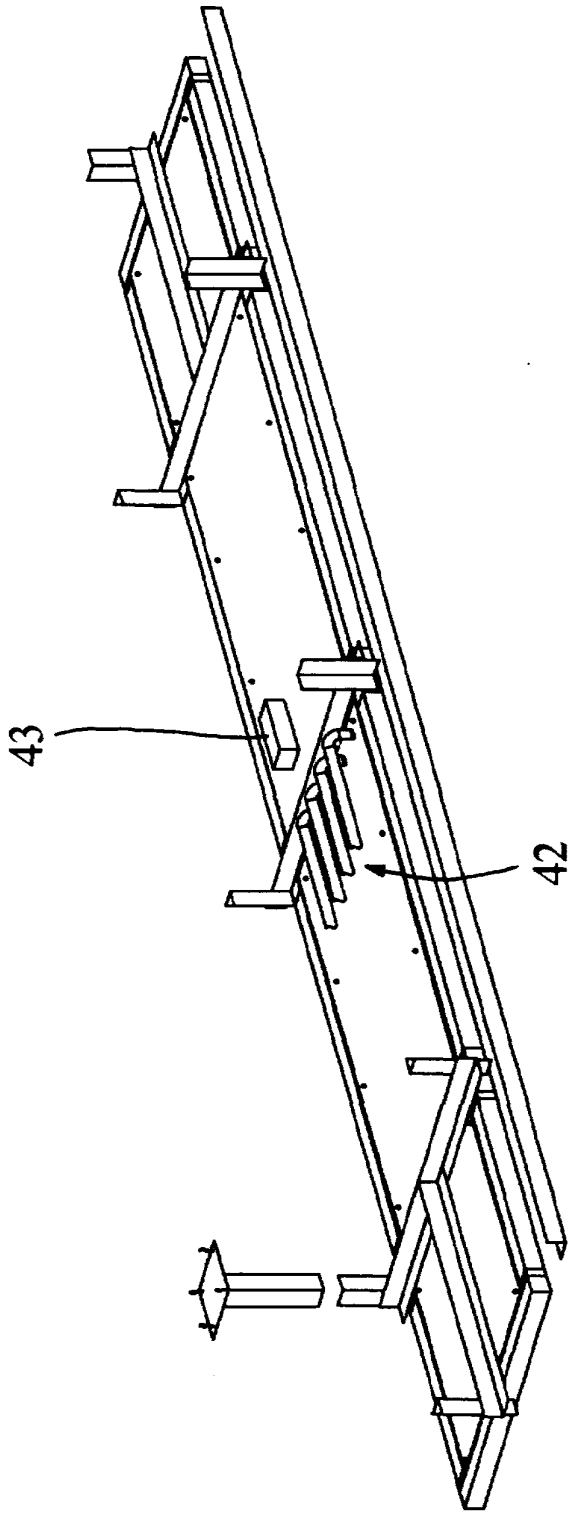
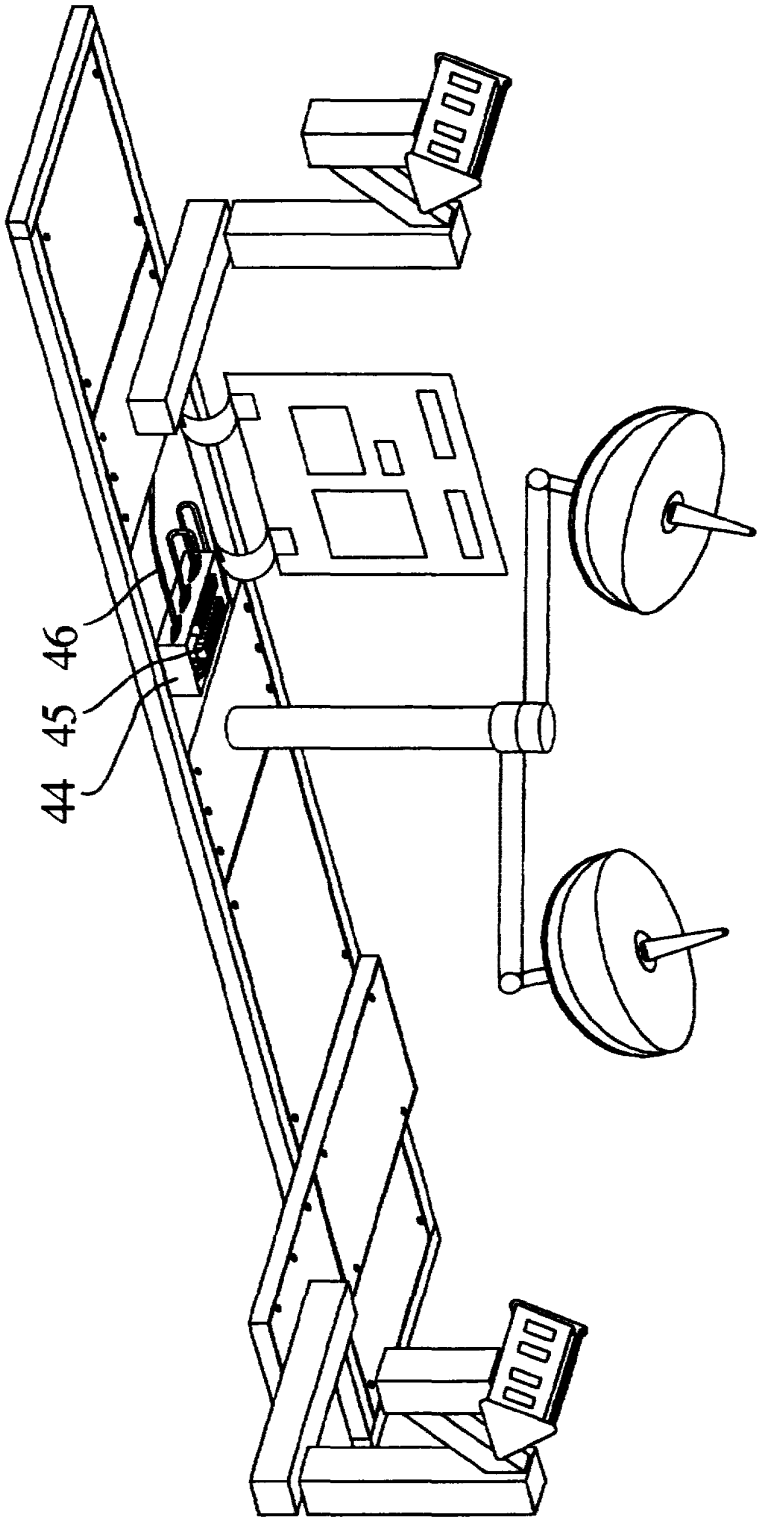



Fig. 4

Fig. 5



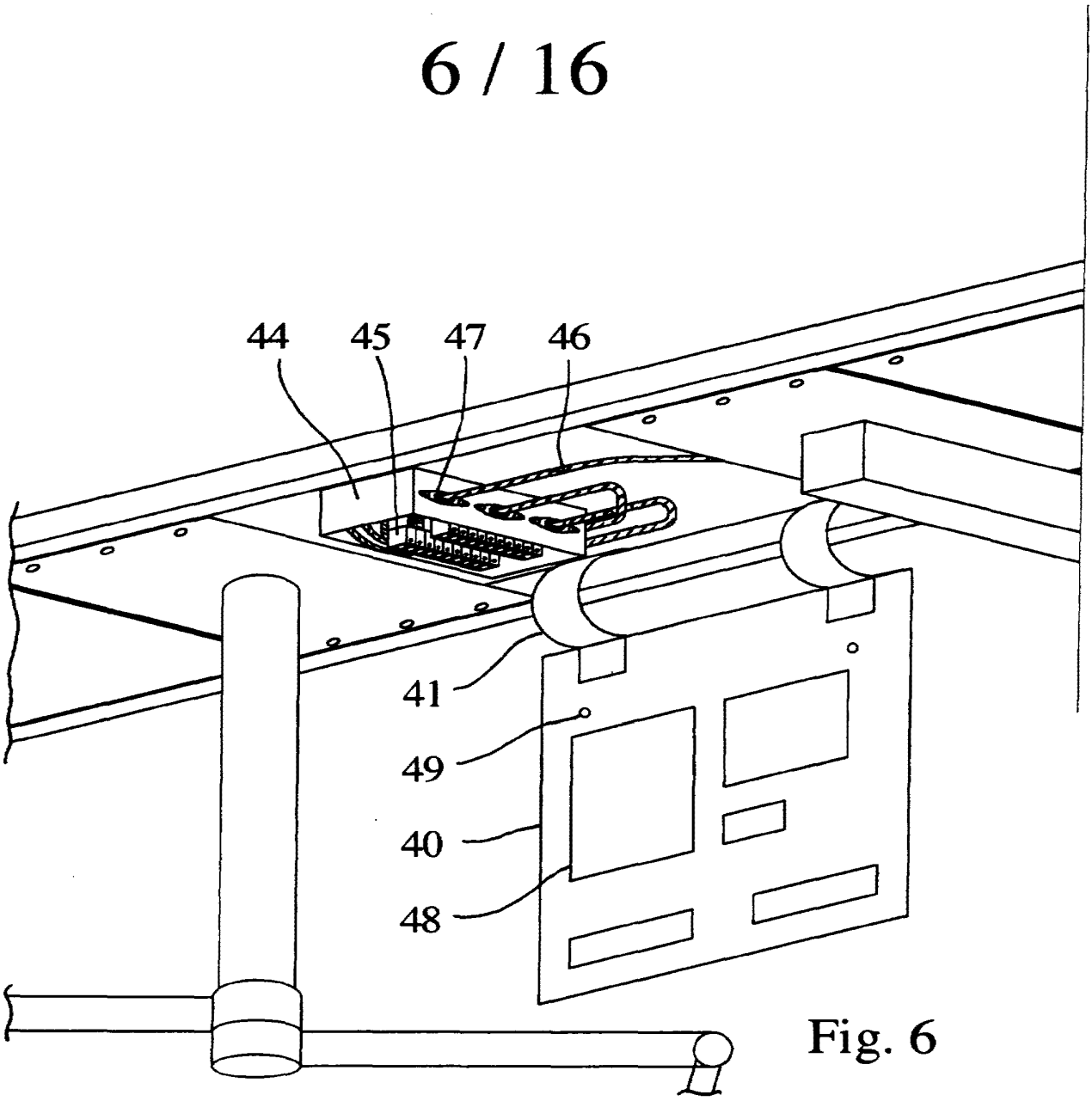



Fig. 6

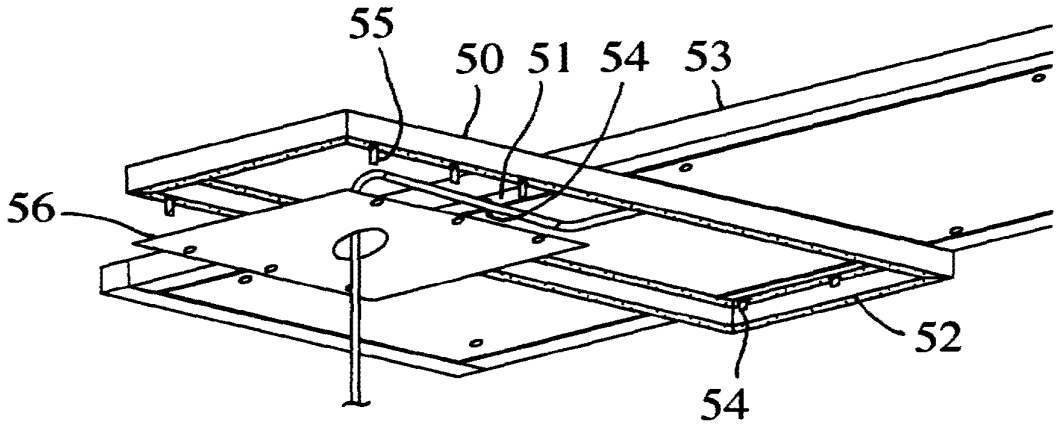



Fig. 8

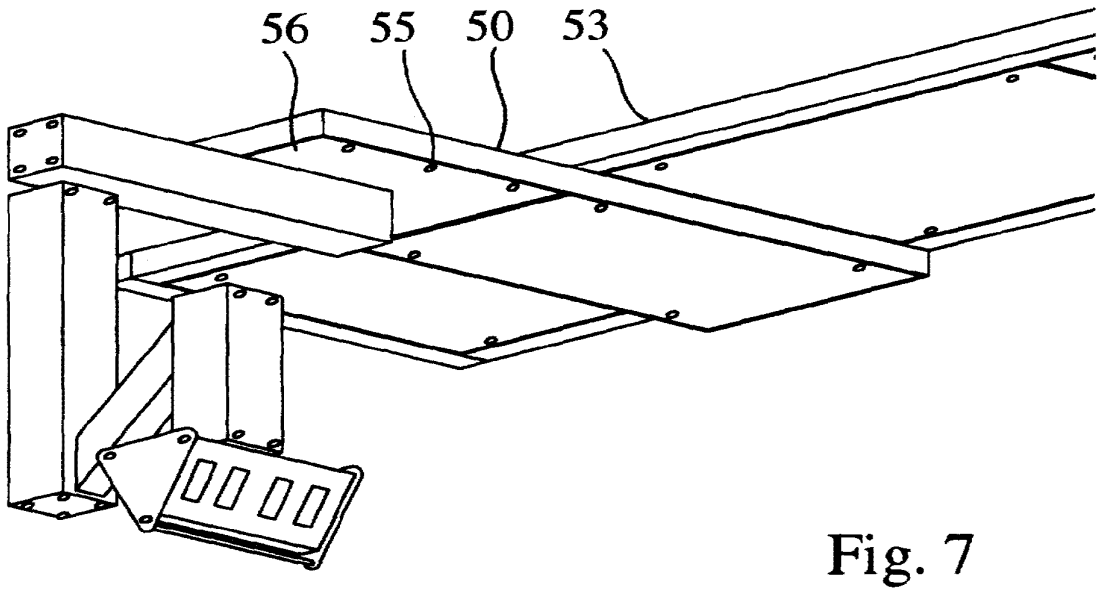



Fig. 7

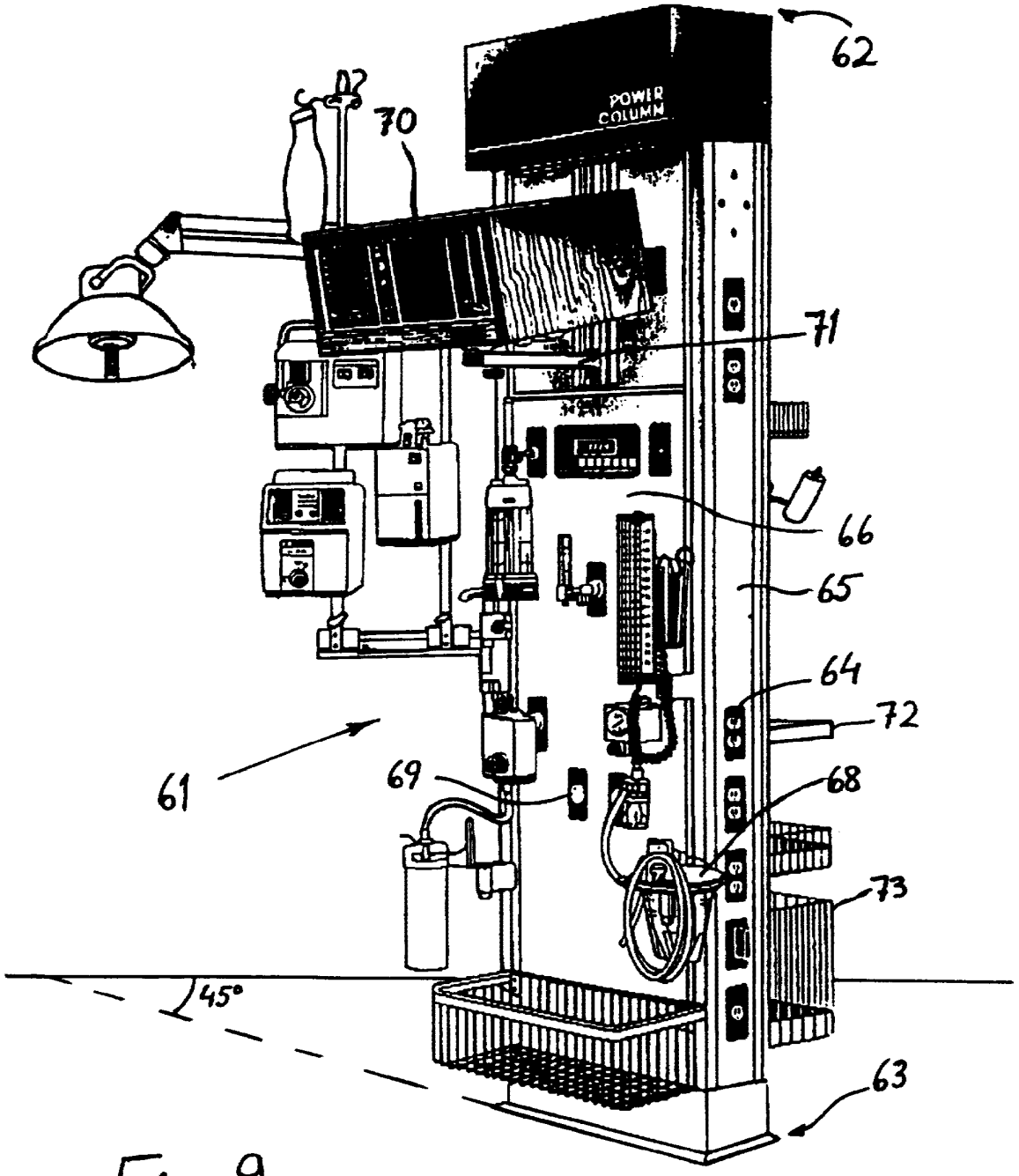



Fig. 9

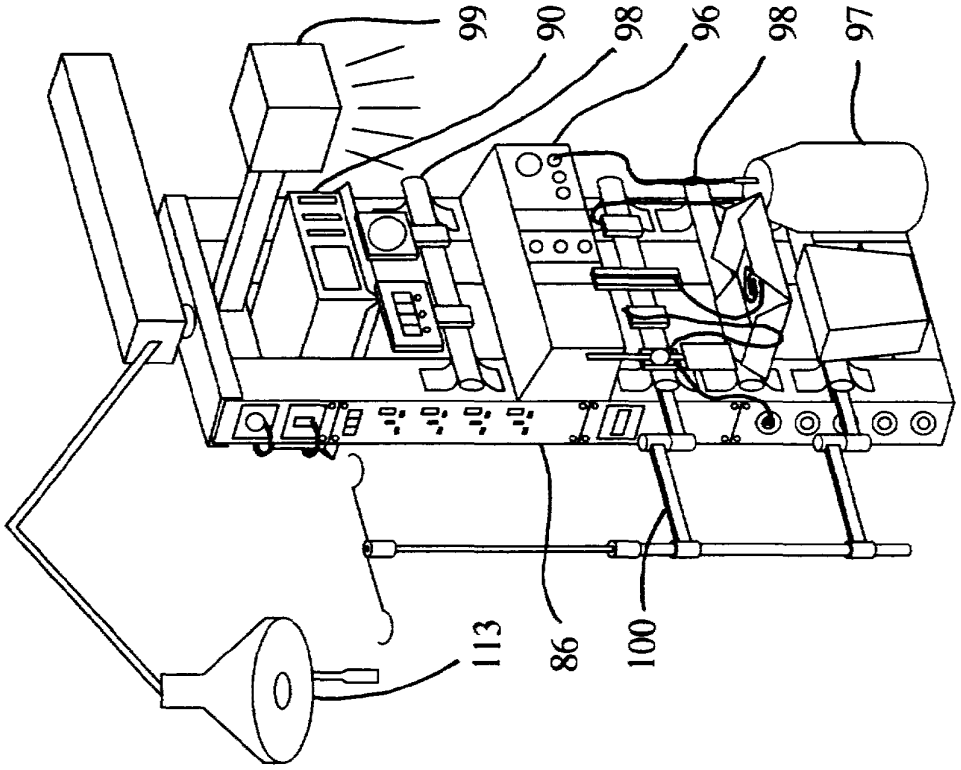

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Fig. 11

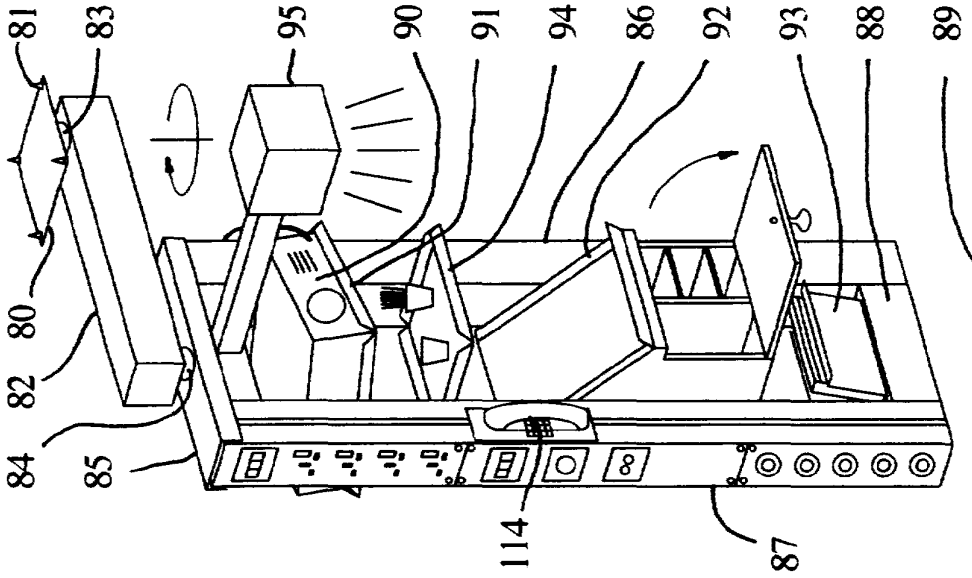
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Fig. 10

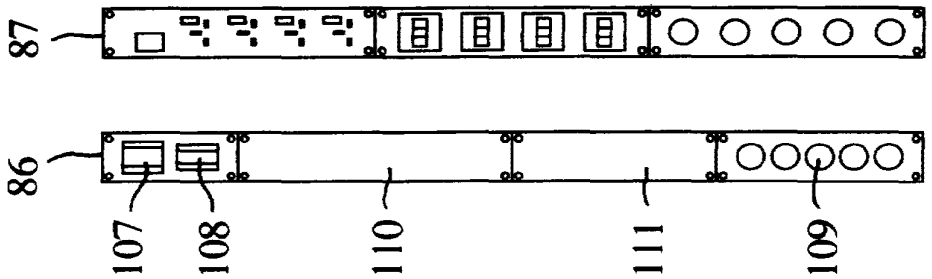


Fig. 15 Fig. 16

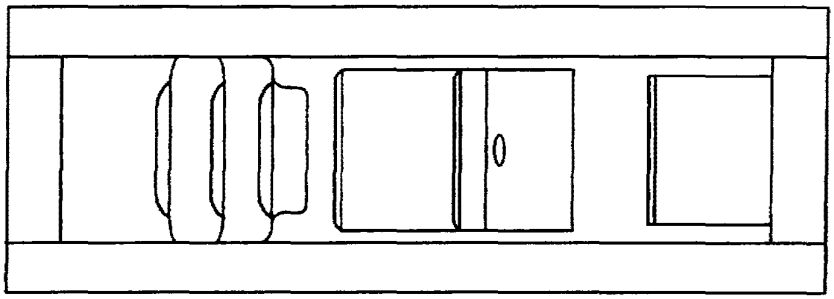

Fig. 14

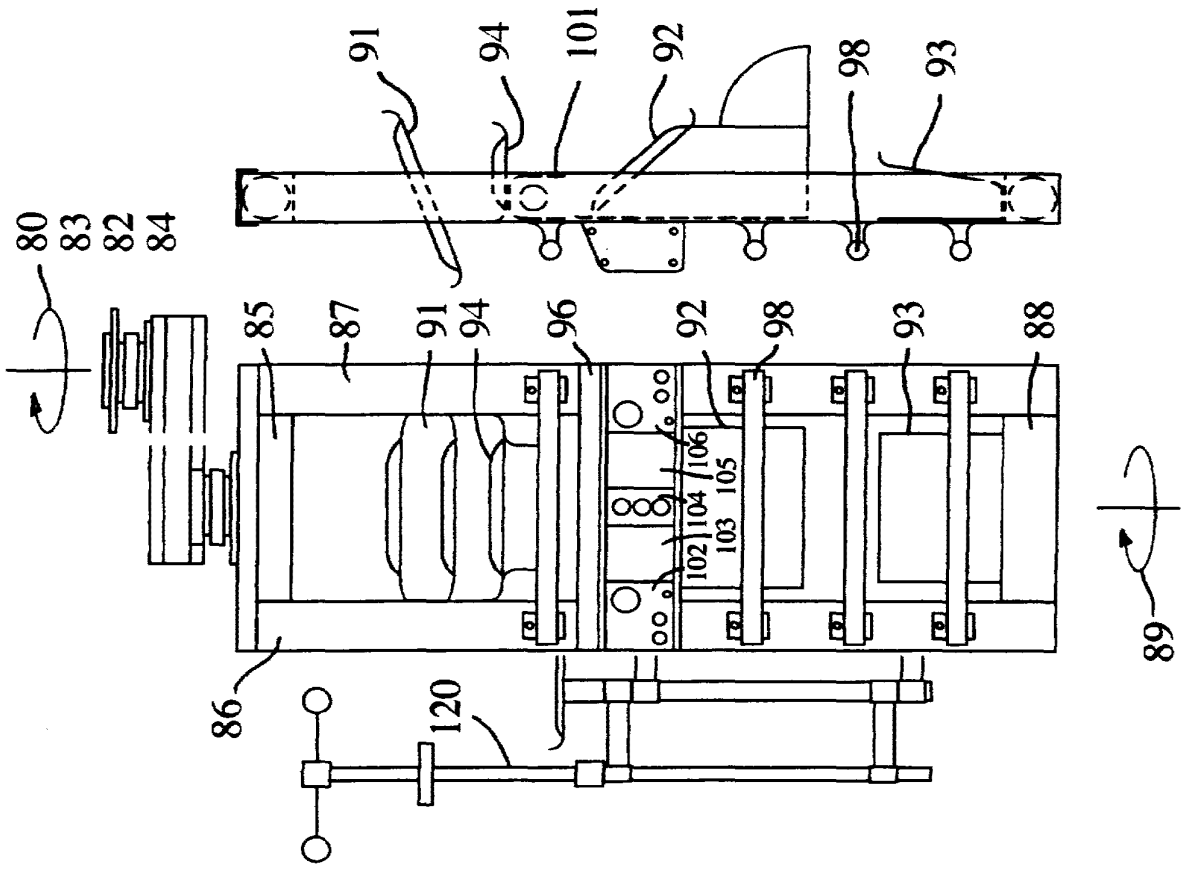


Fig. 13

Fig. 12

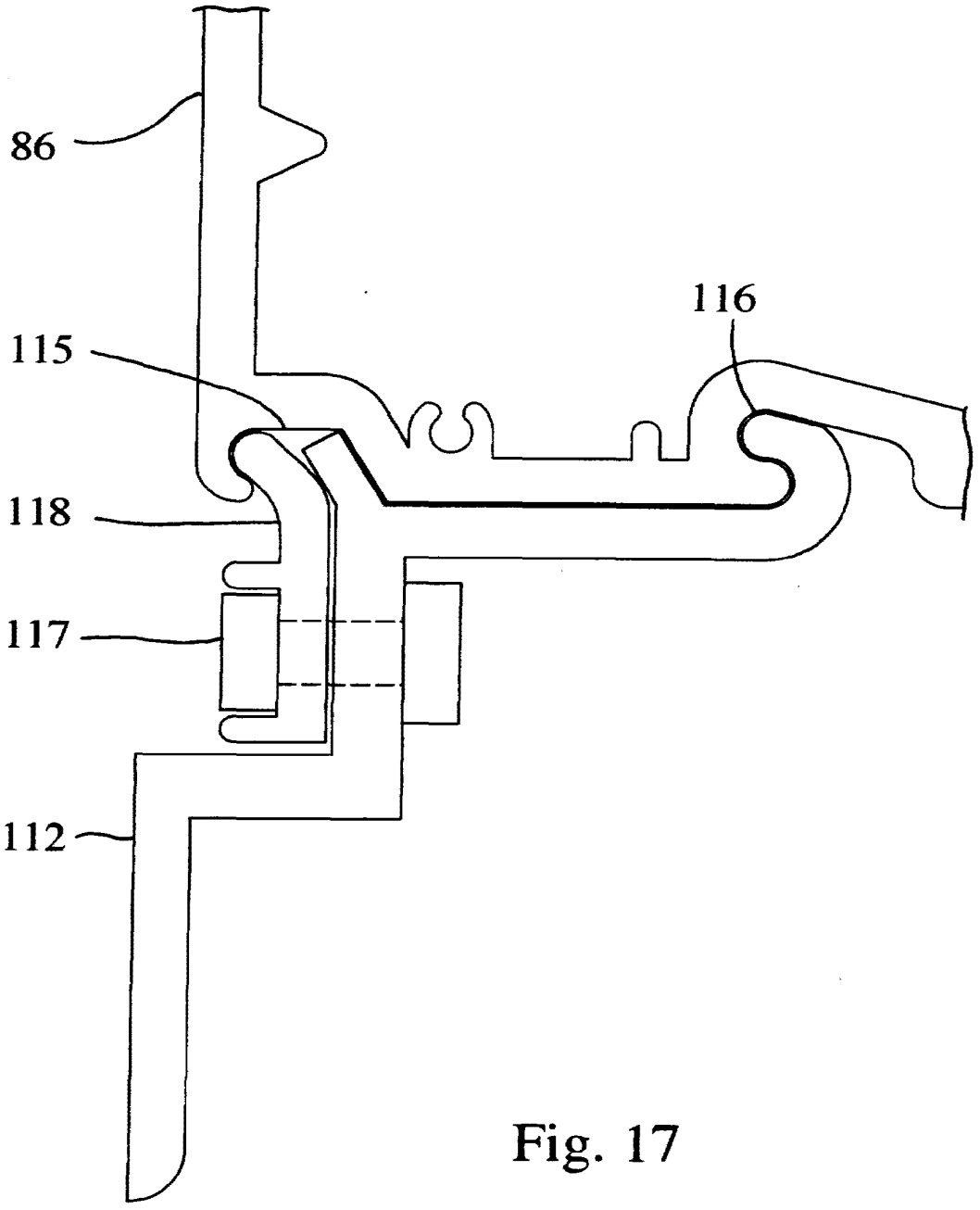


Fig. 17

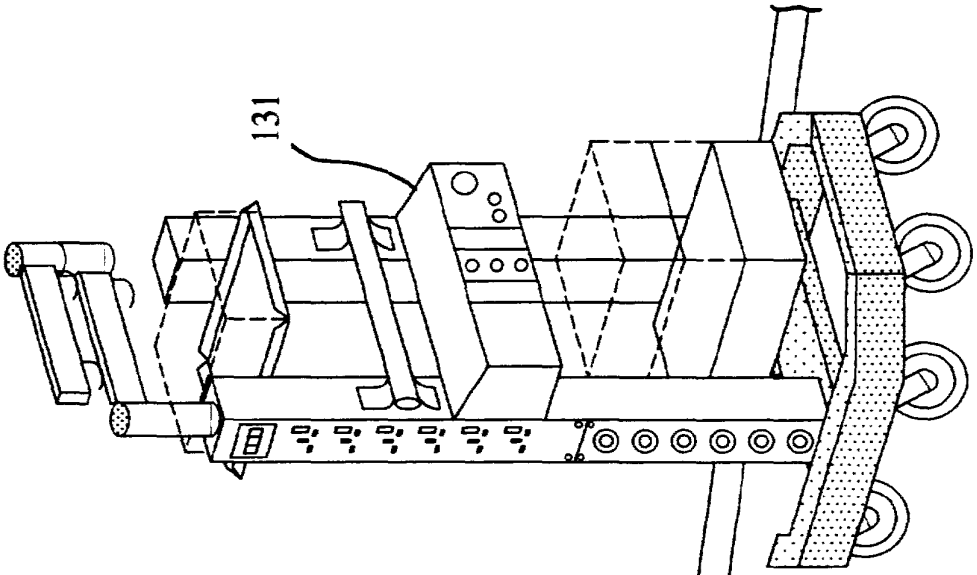


Fig. 19

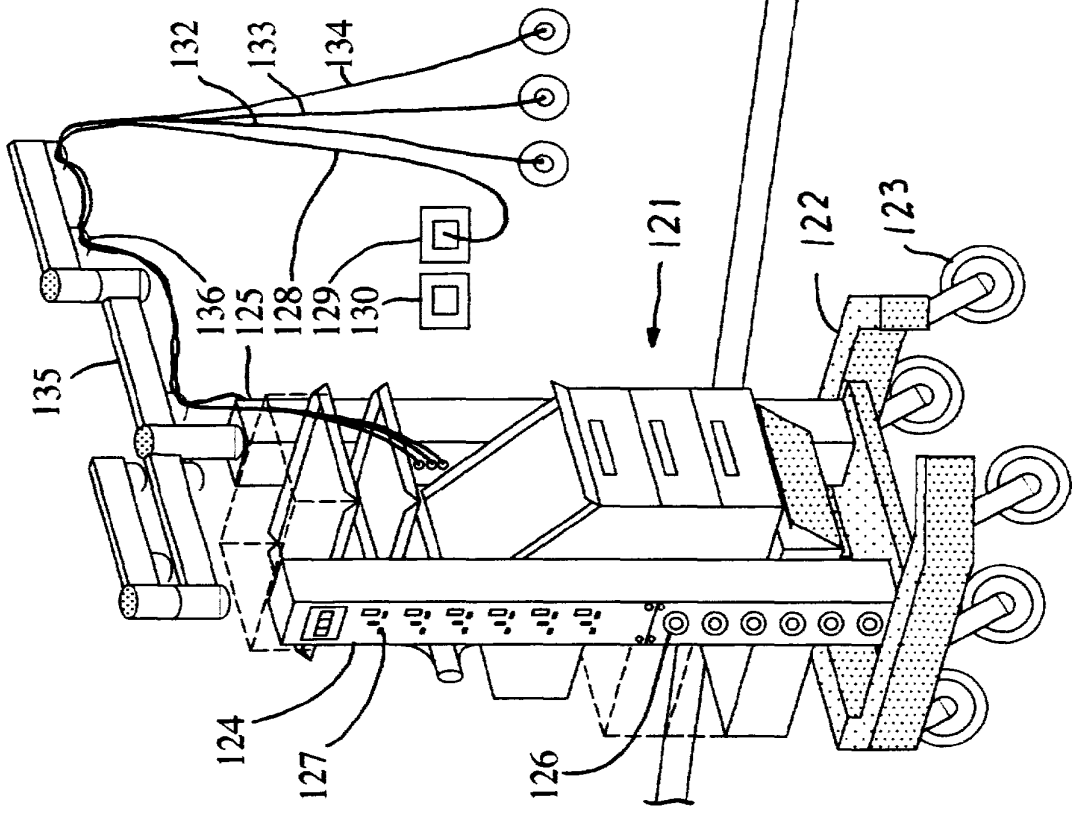


Fig. 18

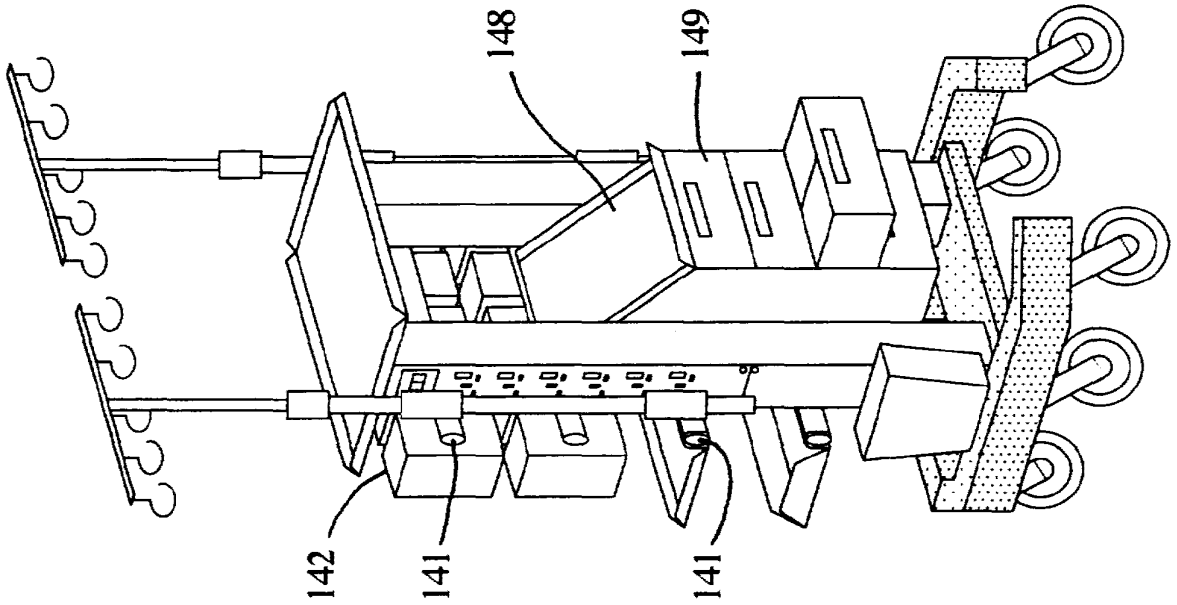
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Fig. 21

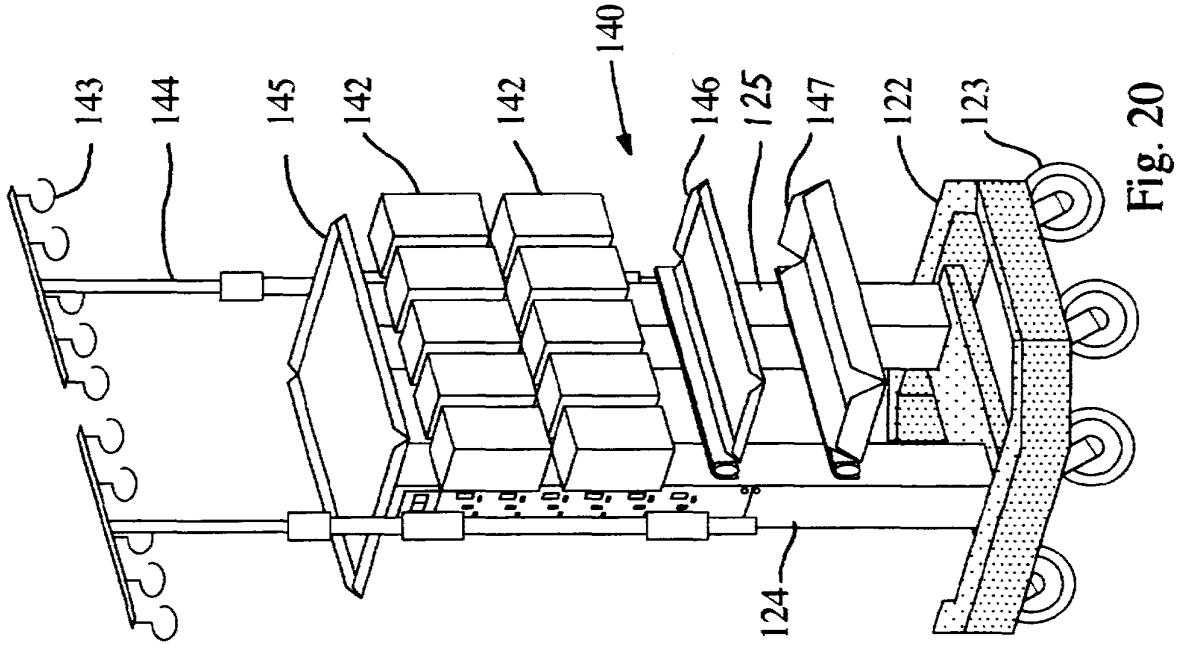
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Fig. 20

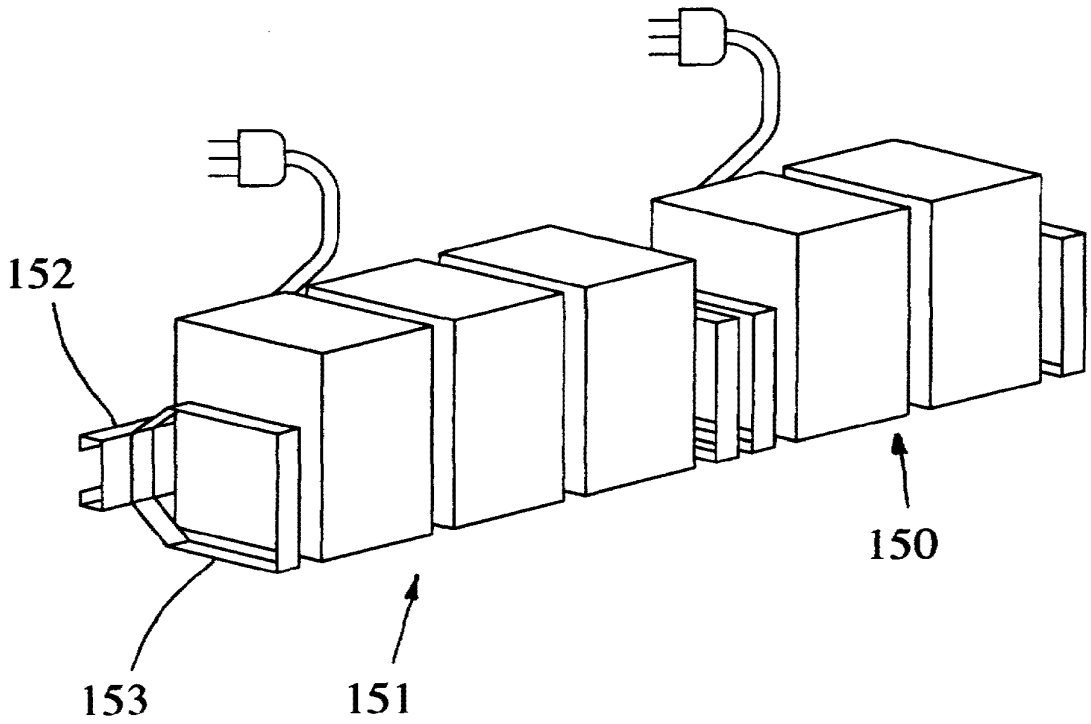


Fig. 22

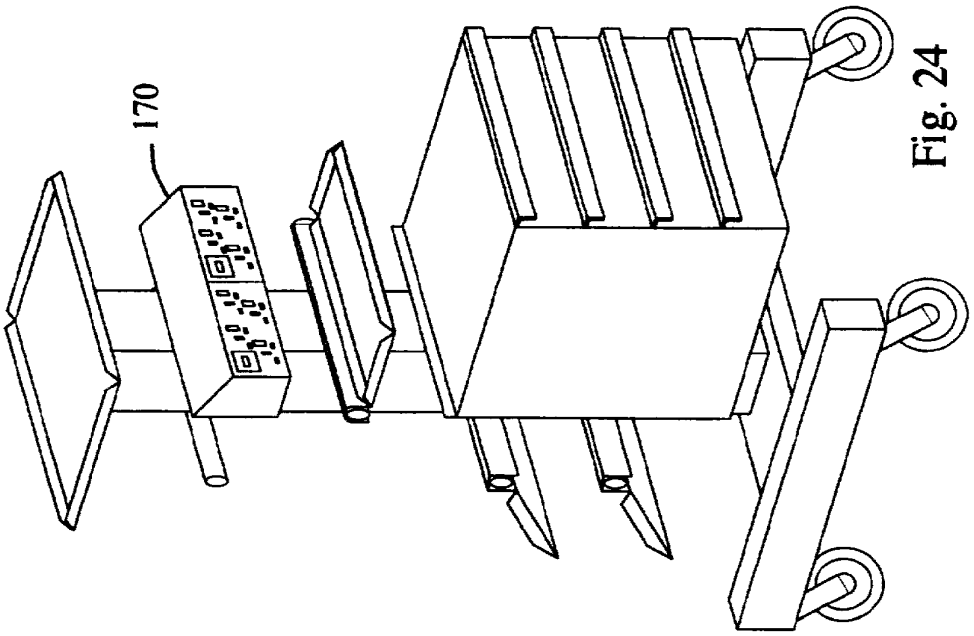


Fig. 24

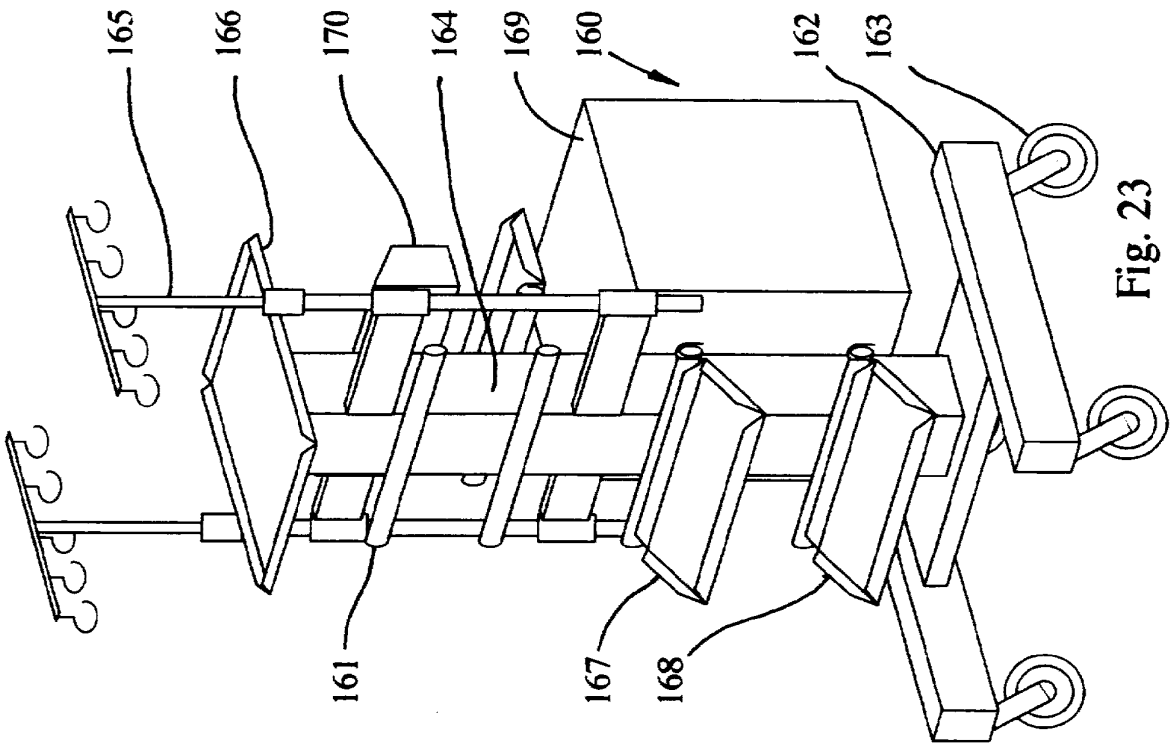


Fig. 23

# 16 / 16

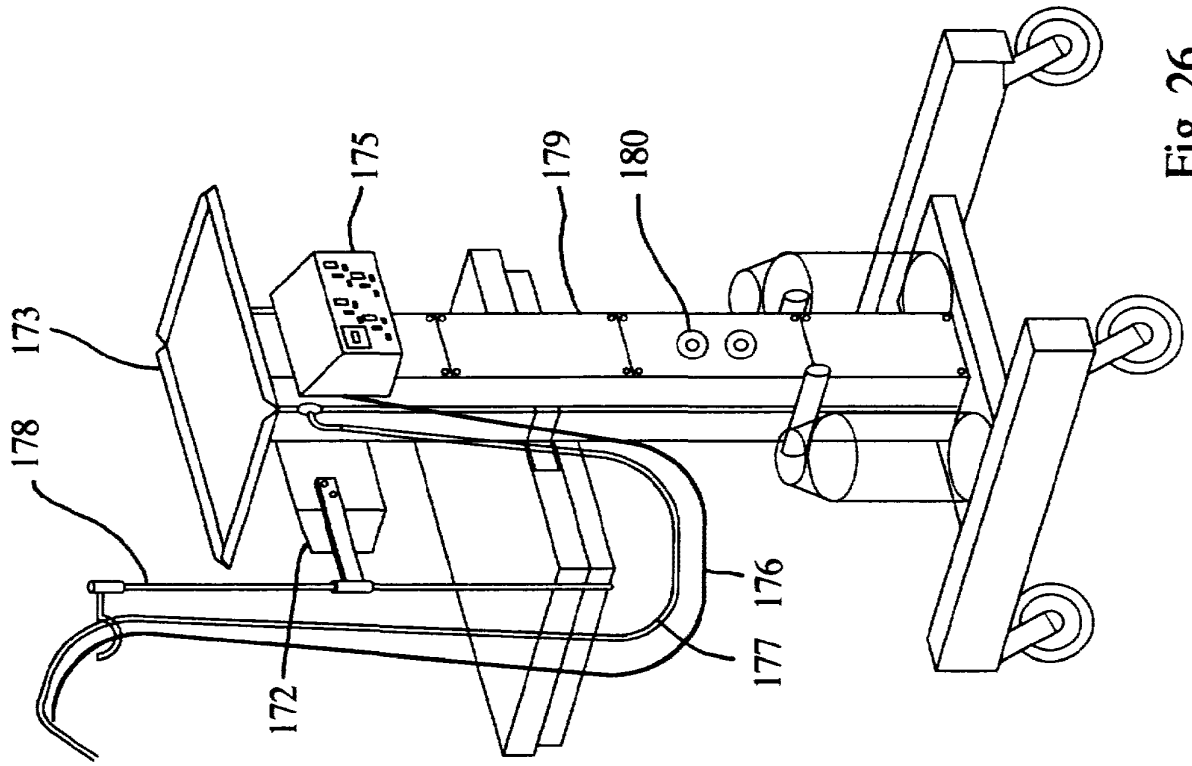


Fig. 26

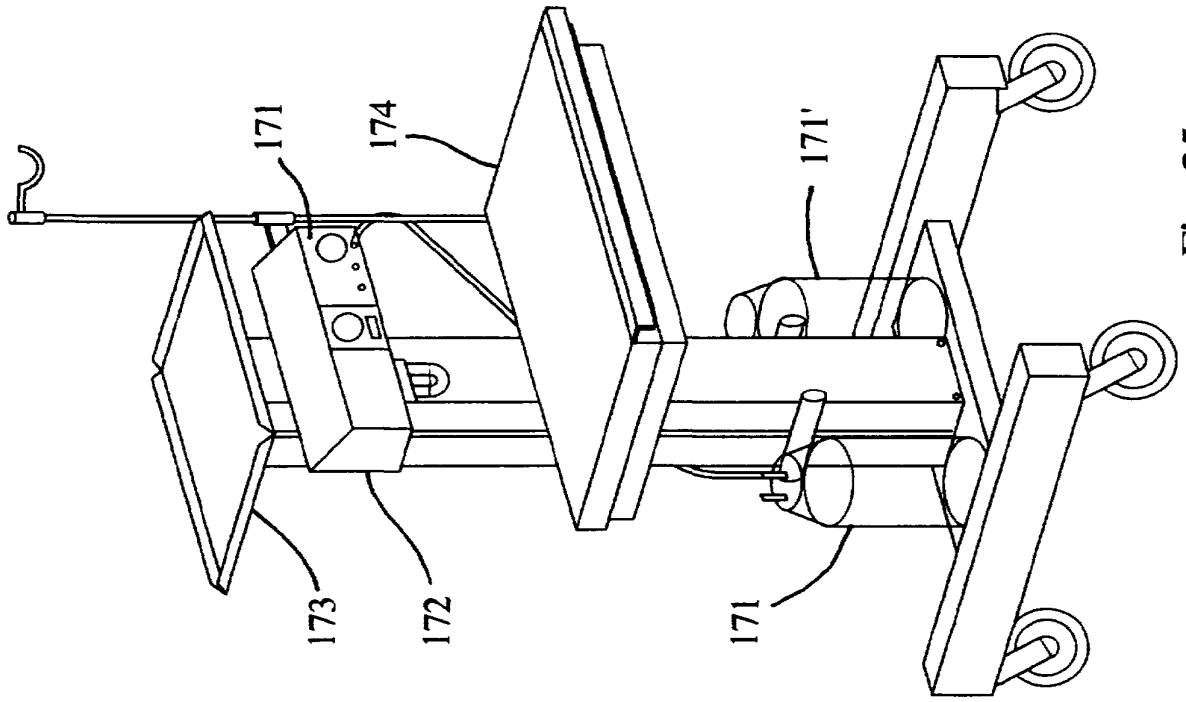


Fig. 25

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/01346

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: E04B 9/06, A61G 12/00, A61B 19/02
According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, A61G, E04B, E04F, E04H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | EP 0215212 A2 (TRILUX-LENZE GMBH & CO. KG), 25 March 1987 (25.03.87), column 4, line 37 - column 6, line 8, figures 1-4 | 1,2,7,8 |
| X | CH 568459 A5 (A.L.H., NILSSON), 31 October 1975 (31.10.75), column 3, line 42 - column 4, line 45, figures 1-5 | 1,7,8 |
| A | | 15 |
| A | EP 0257299 A2 (KREUZER, F.), 2 March 1988 (02.03.88), column 2, line 13 - line 43, figures 1, 2 | 1,7,8 |

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 12 February 1996 | 15 -02- 1996 |
| Name and mailing address of the ISA/<br>Swedish Patent Office<br>Box 5055, S-102 42 STOCKHOLM<br>Facsimile No. +46 8 666 02 86 | Authorized officer<br>Ingemar Hedlund<br>Telephone No. +46 8 782 25 00 |

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/01346

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 4993683 A (F. KREUZER), 19 February 1991 (19.02.91), column 2, line 21 - line 58, figures 1-3 | 9 |
| A | | 15 |
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| | -- | |
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| | -- | |
| A | US 5108064 A (F. KREUZER), 28 April 1992 (28.04.92), figure 1, claim 1 | 9 |
| | -- | |
| X | EP 0477551 A1 (B. BRAUN MELSUNGEN AG), 1 April 1992 (01.04.92), column 4, line 12 - line 46, figures 1,2 | 15 |
| | -- | |
| X | FR 2702140 A1 (TECHNOBLOC SOCIETE A RESPONSABILITE LIMITEE), 9 Sept 1994 (09.09.94), figures 1,2, abstract | 15 |
| | -- | |
| | -------- | |

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/01346

**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

Supportive structure intended to be attached at a ceiling of a hospital room according to claims 1-8.

Medical support service unit for intensive care rooms according to claims 9-14.

Service mobile for carrying medical equipment according to claim 15.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (1)) (July 1992)

**INTERNATIONAL SEARCH REPORT**
Information on patent family members

05/01/96

International application No.
PCT/SE 95/01346

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| EP-A2- 0215212 | 25/03/87 | DE-A- 3533229 | 26/03/87 |
| CH-A5- 568459 | 31/10/75 | AT-B- 342254 | 28/03/78 |
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| | | DE-U- 8716928 | 27/04/89 |
| | | EP-A,A,A 0321822 | 28/06/89 |
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| EP-A1- 0603093 | 22/06/94 | NONE | |
| EP-A2- 0219274 | 22/04/87 | AU-B,B- 572032 | 28/04/88 |
| | | AU-A- 6272386 | 30/04/87 |
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| | | DE-U- 8916163 | 09/06/94 |
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| EP-A1- 0477551 | 01/04/92 | AT-T- 117535 | 15/02/95 |
| | | DE-C- 4030368 | 14/11/91 |
| | | DE-D- 59104385 | 00/00/00 |
| FR-A1- 2702140 | 09/09/94 | NONE | |

Form PCT/ISA/210 (patent family annex) (July 1992)

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
5 December 2002 (05.12.2002)

PCT

(10) International Publication Number
WO 02/096335 A2

(51) International Patent Classification[7]: A61G

(21) International Application Number: PCT/US02/16404

(22) International Filing Date: 23 May 2002 (23.05.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/293,949 25 May 2001 (25.05.2001) US

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(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent

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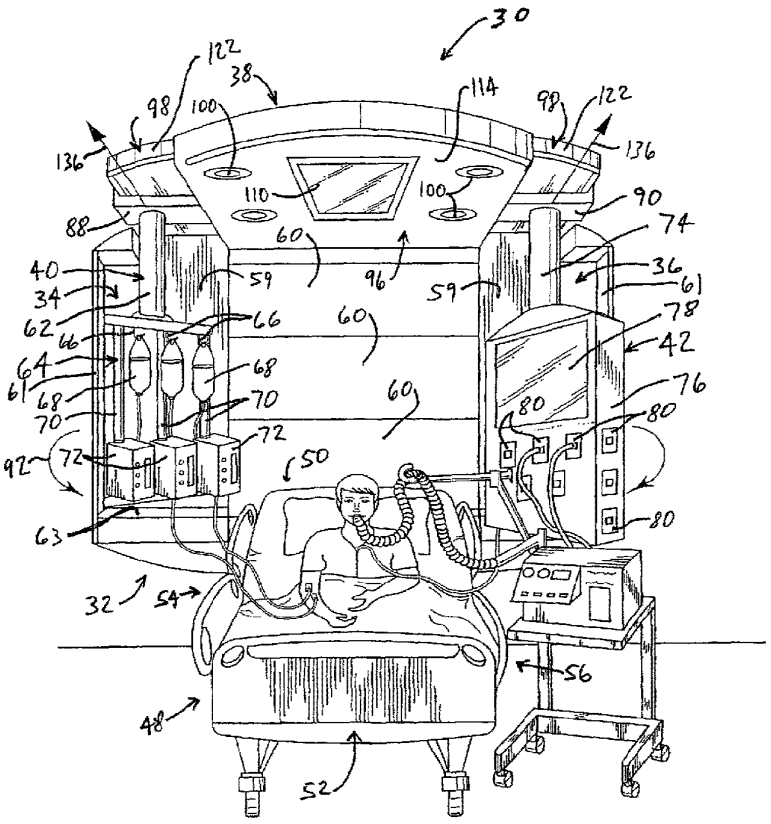
(54) Title: ARCHITECTURAL SYSTEM ADAPTABLE TO PATIENT ACUITY LEVEL




(57) Abstract: An architectural system (30, 230, 330) adaptable to patient acuity level has headwall unit (32, 232) with a cavity (34, 36, 234, 236), a ceiling unit (38, 238, 338), and a column (40,42) coupled to the ceiling unit (38, 238, 338). The column (40, 42) is movable between a first position in which at least a majority of the column (40, 42) is situated in the cavity (34, 36, 234, 236) and a second position in which the column (40, 42) is situated outside the cavity (34, 36, 234, 236). Various types of patient-care equipment are also disclosed. The patient-care equipment is included in, or is coupleable to, one or more of the ceiling unit (38, 238, 338), the headwall unit (32, 232), or the column (40, 42).

WO 02/096335 A2

(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— *without international search report and to be republished upon receipt of that report*

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# ARCHITECTURAL SYSTEM ADAPTABLE TO PATIENT ACUITY LEVEL

## CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application Serial No. 60/293,949, filed on May 25, 2001, the disclosure of which is hereby incorporated by reference herein.

## BACKGROUND AND SUMMARY

The present disclosure relates to architectural systems, such as headwalls, columns, and ceiling-suspended arm assemblies used in hospitals, and particularly to an architectural system adaptable to patient acuity level. More particularly, the present disclosure relates to an architectural system that is configured to deliver services, such as medical gases, to a patient and/or that is configured to support patient-care devices for delivering intensive care services to a patient.

Architectural systems, such as headwalls, columns, and ceiling-suspended arm assemblies, through which medical gases are accessible via medical service outlets are known. Headwalls, columns, and arm assemblies having rails, tracks, or brackets for attachment of patient-care devices and having electrical outlets for delivering power to the patient-care devices are also known. Patients in critical condition are oftentimes located in an intensive care unit of a hospital, whereas patients in stable condition are oftentimes located in a standard patient room. Architectural systems in intensive care units are generally configured to hold more patient-care devices and provide more types of medical services than architectural systems found in a standard patient room.

The numbers of patients in critical condition and the numbers of patients in stable condition fluctuate in a hospital over time. Thus, at any given time there may be either a shortage or excess of spaces for patients in an intensive care unit. In addition, at any given time there may be either a shortage or surplus of standard hospital rooms. Thus, there is a need for an architectural system that is adaptable to patients having high, medium, and low acuity levels so that hospitals have the flexibility to meet the needs of the patient population at any give time.

According to this disclosure, an architectural system adaptable to an acuity level of a patient supported by a hospital bed in a patient room having a wall

and a ceiling is provided. The architectural system comprises a wall unit coupled to the wall and having a cavity, a ceiling unit coupled to the ceiling, and a column coupled to the ceiling unit for movement between a first position in which at least a majority of the column is situated in the cavity and a second position in which the column is situated outside the cavity.

Various patient-care devices and equipment are attachable to the column. Such patient care devices include, for example, IV racks, infusion pumps, ventilation equipment, heart rate monitoring equipment, and patient data acquisition equipment. In an illustrative embodiment, a number of medical service outlets, such as gas outlets and electrical outlets, are coupled to the column. Also in the illustrative embodiment, a number of doors are coupled to the wall unit for opening and closing the cavity. Thus, when the column is in the cavity, the doors may be moved to closed positions shielding the column and the equipment carried by the column from view and blocking access to the medical service outlets on the column. Opening the doors, but leaving the column in the cavity of the headwall unit, permits access to some of the medical service outlets and to some portions of the equipment carried by the column. When the column is moved out of the cavity, all of the medical service outlets and all pertinent portions of the equipment carried by the column are accessible.

Also according to this disclosure, a ceiling unit having one or more pieces of equipment coupled thereto is provided. Such equipment includes, for example, a reading light, an examination light, a display screen, air curtain generation equipment, a privacy curtain, a temperature sensor, an air quality sensor, an air purifier, aroma therapy equipment, a motion sensor, and a proximity sensor. In one illustrative embodiment, an arm assembly is coupled to the ceiling unit and supports an overbed table. The arm assembly permits the overbed table to be moved from one side of a hospital bed to an opposite side of the hospital bed.

A mobile cart is also disclosed herein. In an illustrative embodiment, the mobile cart comprises an upstanding pedestal, a plurality of legs coupled to a bottom of the upstanding pedestal, and a plurality of wheels. Each wheel is coupled to a respective leg of the plurality of legs. The legs, along with the wheels coupled thereto, are each movable between a first position extending outwardly from beneath the upstanding pedestal and a second position tucked beneath the upstanding pedestal.

The mobile cart is attachable to a ceiling-mounted column or an arm assembly. The mobile cart is also attachable to a hospital bed to be transported with the bed. When the mobile cart is attached to either the column, the arm assembly, or the bed, the wheels of the mobile cart are spaced apart for the floor. A headwall unit having a cavity configured to receive the mobile cart is also disclosed. The mobile cart carries one or more pieces of patient-care equipment such as, for example, an IV pole, an infusion pump, a ventilator control unit, a gas tank, a gas control unit, a vital signs monitor, an on-board computer, a receiver, a transmitter, and a battery.

Further according to this disclosure, a set of hospital equipment comprises a headwall, a blanket, a unit housed in the headwall, and a hose coupled to the blanket and coupled to the unit, a thermoregulation medium being moved between the blanket and the unit through the hose. The thermoregulation medium includes, for example, heated air, cooled air, a heated liquid, or a cooled liquid. In some embodiments, in which the thermoregulation medium is heated or cooled air, the blanket has a plurality of perforations through which the heated or cooled air is expelled.

Additional features will become apparent to those skilled in the art upon consideration of the following detailed description of illustrative embodiments exemplifying the best mode of carrying out the various inventions disclosed herein as presently perceived.

## BRIEF DESCRIPTION OF THE DRAWINGS

The detailed description particularly refers to the accompanying figures, in which:

Fig. 1 is a perspective view of an architectural system adaptable to patient acuity level according to this disclosure showing a headwall unit behind a hospital bed on which a patient is resting, a ceiling unit extending from the headwall unit, the ceiling unit overlying the hospital bed, an IV rack situated in a first cavity of the headwall unit, and a housing having a display screen and a number of medical service outlets situated in a second cavity of the headwall unit;

Fig. 2 is a perspective view, similar to Fig. 1, showing a first column moved out of first cavity so that the IV rack carried by the first column is situated alongside a first side of the hospital bed and a second column moved out of the

second cavity so that the housing included as part of the second column is situated alongside a second side of the hospital bed;

Fig. 3 is a top plan view of a portion of the architectural system of Fig. 1 showing the first and second columns received in the first and second cavities, respectively, of the headwall unit and showing a head end of the hospital bed situated in close proximity to the headwall unit;

Fig. 4 is a top view, similar to Fig. 3, showing the first and second columns moved out of the first and second cavities, respectively, of the headwall unit and showing the hospital bed moved away from the headwall unit by a sufficient amount to permit a caregiver to stand between the head end of the hospital bed and the headwall unit;

Fig. 5 is a transverse sectional view of a portion of the architectural system of Fig. 1 showing rollers of the second column engaging a track of the ceiling unit and showing medical service lines (in phantom) extending from each of the medical service outlets, through the second column, and through the ceiling unit;

Fig. 6 is a longitudinal sectional view of a portion of the architectural system of Fig. 1 showing the second column being movable between a first position (in solid) in close proximity to the headwall unit and a second position (in phantom) spaced from the headwall unit and showing the medical lines being routed into a central region of the ceiling unit to accommodate the movement of the second column between the first and second positions;

Fig. 7 is a top plan view of a portion of the architectural system of Fig. 1 showing the first and second columns in a number of positions and showing the routing of the medical lines from the central region of the ceiling unit to the first and second columns;

Fig. 8 is a perspective view of the architectural system of Fig. 1 showing the first column carrying an IV rack having a bottom plate arranged for coupling to a pair of upright posts that are mounted to a distal end of a support arm extending from a bed frame of the hospital bed;

Fig. 9 is a side elevation view of the architectural system of Fig. 8 showing the first column (in solid) supporting the IV rack above the upright posts and showing the first column (in phantom) supporting the IV rack in the first cavity of the headwall unit;

Fig. 10 is a side elevation view, similar to Fig. 9, showing the IV rack decoupled from the first column and coupled to the hospital bed to be transported with the hospital bed;

Fig. 11 is a perspective view of a first alternative embodiment of an architectural system according to this disclosure showing the ceiling unit having lateral extensions for supporting auxiliary equipment laterally outward of the first and second columns, a first set of door panels covering the first column, and a second set of door panels being opened by varying amounts to partially uncover various portions of the second column;

Fig. 12 is a perspective view of a portion of the architectural system of Fig. 11 showing a privacy curtain moved out of an auxiliary cavity of the headwall unit and hanging from one of the lateral extensions of the ceiling unit;

Fig. 13 is a perspective view, similar to Fig. 12, showing an alternative embodiment of a privacy curtain extending downwardly from one of the lateral extensions of the ceiling unit;

Fig. 14 is a perspective view, similar to Figs. 12 and 13, but of another portion of the architectural system of Fig. 11 showing an auxiliary IV pole moved out of an auxiliary compartment of the headwall unit and hanging from one of the lateral extensions of the ceiling unit;

Fig. 15 is a perspective view of a second alternative embodiment of an architectural system according to this disclosure showing a plurality of openings formed in a perimetral region of the ceiling unit and showing air curtain generation equipment (in phantom) operating to move air out of the plurality of openings to form vertical air curtains along the foot end and opposite sides of the hospital bed;

Fig. 16 is a bottom plan view of the ceiling unit of Fig. 15 showing, in phantom, a fan and a set of channels through which air moves to reach the plurality of openings;

Fig. 17 is a perspective view of an environmentally-controlled hospital room showing a patient supported by a hospital bed in the room, a disposable thermoregulation blanket covering a portion of the patient, the disposable thermoregulation blanket being coupled via a hose to a thermoregulation unit housed in a headwall of the hospital room, and an environmental control canopy coupled to a ceiling of the hospital room above the hospital bed;

Fig. 18 is a perspective view of a mobile cart according to this disclosure showing the mobile cart having a somewhat rectangular upstanding pedestal, the pedestal having a fairly small depth dimension between a front face and a rear face of the pedestal, the mobile cart having four horizontally extending support legs coupled to the bottom of the pedestal, a set of casters coupled to distal ends of the support legs, and each support leg being pivotable relative to the pedestal about a respective vertical axis between a first position (in solid) extending outwardly from beneath the pedestal and a second position (in phantom) tucked beneath the pedestal;

Fig. 19 is a side plan view of a first hospital room showing the mobile cart of Fig. 18 being mounted to a head end of a hospital bed, a second mobile cart, like the mobile cart of Fig. 18, being suspended from a ceiling of the room by an arm assembly, the support legs of the two mobile carts all being in their respective second positions, and the casters of the two mobile carts all being spaced apart from a floor of the room;

Fig. 20 is side plan view of a second hospital room showing the mobile cart (in phantom) being situated in a cavity (in phantom) formed in a headwall of the hospital room;

Fig. 21 is a perspective view of a hospital bed supported on a floor of a hospital room and an overbed table assembly that is suspended from a ceiling of a hospital room showing the overbed table assembly including a hub unit coupled to the ceiling above the hospital bed, an arm assembly coupled to the hub unit and extending downwardly therefrom, an entertainment-and-control panel coupled to a vertical arm of the arm assembly, an overbed table coupled to the vertical arm beneath the entertainment-and-control panel, and a telephone coupled to the overbed table;

Fig. 22 is a perspective view of a portion of the overbed table assembly of Fig. 40 showing the overbed table assembly including a service-delivery housing coupled to an underside of the overbed table and a plurality of medical service outlets on an end face of the service-delivery housing; and

Fig. 23 is a top plan view of the hospital bed and the overbed table assembly of Fig. 22 showing the arm assembly moving between a first position (in solid) having the overbed table extending over a lap of the patient from a first side of the hospital bed and a second position (in phantom) having the overbed table extending over the lap of the patient from a second side of the bed and showing that

the service-delivery housing moves around a foot end of the bed as the arm assembly moves between the first and second positions.

DETAILED DESCRIPTION OF THE DRAWINGS

An first embodiment of an architectural system 30 according to this disclosure comprises a headwall unit 32 having a first cavity 34 and a second cavity 36, a ceiling unit 38, a first column 40, and a second column 42 as shown in Figs. 1 and 2. Columns 40, 42 hang downwardly from ceiling unit 36 and are each independently movable between respective storage positions situated within a respective cavity 34, 36 and a plurality of use positions situated outside of cavities 34, 36. Headwall unit 32 is configured for attachment to a wall 44 of a hospital room and ceiling unit 38 is configured for attachment to a ceiling 46 of the hospital room.

A hospital bed 48 is situated in the hospital room such that a head end 50 of the bed 48 is near headwall unit 32 and a foot end of the bed is spaced from head wall unit 32 as shown in Figs. 1-4. Columns 40, 42 are spaced apart by a sufficient distance to permit hospital bed 48 to occupy the space defined between columns 40, 42 when columns 40, 42 are situated outside of cavities 34, 36 as shown, for example, in Figs. 2 and 4. Thus, column 40 is positioned alongside a first side 54 of hospital bed 48 when outside of cavity 34 and column 42 is positioned alongside a second side 56 of hospital bed 48 when outside of cavity 36.

Columns 40, 42 each carry patient-care equipment, some of which is configured to provide medical services to high acuity patients, such as critical patients requiring intensive care. Patient-care equipment needed for medium acuity patients, such as patients requiring medical gas to aid respiration and intravenous (IV) fluids are also carried on one or both of columns 40, 42. For medium acuity patients, columns 40, 42 are usually placed in cavities 34, 36 in the respective storage positions and the needed medical services are provided to the patient from columns 40, 42 as shown in Figs. 1 and 3. Optionally, columns 40, 42 may be moved out of cavities 34, 36 for medium acuity patients. For high acuity patients, columns 40, 42 are usually moved out of cavities 34, 36 to positions alongside bed 48 so that multiple medical services are accessible to the patient and to other pieces of medical equipment as shown, for example, in Figs. 2 and 4. For low acuity patients that do not require

medical services from columns 40, 42, columns 40, 42 are usually placed in the storage positions so as to be out of the way.

Headwall unit 32 has a plurality of doors 58 that are movable between closed positions covering associated portions of columns 40, 42 and opened positions allowing access to the associated portions of columns 40, 42. For low acuity patients, doors 58 are typically closed to conceal columns 40, 42 from view. In the illustrative embodiment, each of doors 58 slides horizontally behind an associated central panel 60 of headwall unit 32. In some alternative embodiments, doors 58 slide horizontally in front of the associated central panels 60. In other alternative embodiments, doors 58 either raise or lower or pivot when moving between opened and closed positions. In the illustrative embodiment in which doors 58 slide horizontally behind panels 60, each of panels 60 is large enough to accommodate both of the associated doors 58 therebehind. It is within the scope of this disclosure for headwall unit 32 to have tracks or other surfaces (not shown) on which doors 58 slide. It is also within the scope of this disclosure for rollers (not shown) to be coupled to doors 58 and for the rollers to roll on tracks or surfaces as doors 58 move between the opened and closed positions.

In the illustrative embodiment, three doors 58 are associated with cavity 34 to cover top, middle, and lower portions of cavity 34 and three doors 58 are associated with cavity 36 to cover top, middle, and lower portions of cavity 36. In alternative embodiments, more or less than three doors are provided for covering respective cavities 34, 36. Optionally, locking mechanisms (not shown) are mounted to each door 58 for locking the respective door in the closed position to prevent a patient or any other unauthorized person from opening doors 58 to gain access to the equipment mounted on columns 40, 42.

Headwall unit 32 has a frame (not shown) to which central panels 60 couple. Headwall unit 32 has other panels or walls, such as a vertical back wall 59 and a pair of outer side walls 61 that extend from back wall in perpendicular relation therewith. In addition, headwall unit 32 has horizontal walls 63 that underlie cavities 34, 36 and inner side walls 65 that are spaced from, but parallel with, walls 61 as shown in Fig. 8. Cavities 34, 36 are defined, in part, by walls 59, 61, 63, 65. One or more of walls 59, 61, 63, 65 are coupled to the frame of headwall unit 32. In the illustrative embodiment, headwall unit 32 includes a lower portion 67 that is situated

between a floor 69 of the hospital room and the portion of headwall unit 32 having central panels 60 associated therewith as shown in Fig. 8. A set of auxiliary medical service outlets 71 are coupled to lower portion 67. In addition, the portions of headwall unit 32 in which cavities 34, 36 are defined overhang underlying portions of floor 69 that are laterally outward of lower portion 67.

As previously mentioned, columns 40, 42 carry patient-care equipment. Column 40 is configured to have patient-care equipment attached thereto and detached therefrom, whereas column 42 has patient-care equipment integrated therewith as shown in Figs. 1 and 2. In the illustrative example, column 40 has a vertical arm 62 and an IV rack 64 coupled to vertical arm 62 by suitable couplers such as, for example, clamps, brackets, latches, grippers, or hooks. IV rack 64 has one or more hooks 66 to which IV bags 68 couple and one or more poles 70 to which infusion pumps 72 couple. It is within the scope of this disclosure for any type of medical equipment capable of coupling to an IV pole to be coupled to IV rack. As shown in Figs. 9 and 10, one or more medical service outlets 73 are mounted to arm 62 of column 40. Services accessible via outlets 73 include electrical services, such as electrical power and data transfer, and pneumatic services, such as medical gases or suction. Illustratively, electrical power is provided to infusion pump 72 from one of outlets 73 as shown in Fig. 9.

In the illustrative example, column 42 has a vertical arm 74 and a housing 76 coupled to arm 74. A display screen 78 is coupled to an upper portion of housing 76 and a plurality of medical service outlets 80 are coupled to a lower portion of housing 76. Services available via outlets 80 include similar electrical and/or pneumatic services as are available from outlets 73. Service-delivery lines 82 are routed from each of outlets 80 through housing 76 and arm 74 of column 42 and through ceiling unit 38 as shown in Figs. 5-7. In addition, service-delivery lines 84 are routed from each of outlets 73 through arm 62 of column 40 and through ceiling unit 38 as shown in Fig. 7. In addition, lines 82, 84 are routed into ceiling 46 through an opening 86 that is formed in ceiling above a central region of ceiling unit 38.

Column 40 has a carriage 88 to which arm 62 is coupled and column 42 has a carriage 90 to which arm 74 is coupled as shown in Fig. 2. In some embodiments, arm 62 and IV rack 64 (or any other patient-care equipment coupled to arm 62) are pivotable about a vertical axis relative to carriage 88 in a first direction as

indicated by arrow 92, shown in Fig. 2, and in an opposite, second direction as indicated by arrow 94, shown in Fig. 4. In other embodiments, arm 62 is fixed relative to carriage 88 but the coupler to which IV rack 64 (or other patient-care equipment) couples is pivotable relative to arm 64 in directions 92, 94. Similarly, in some embodiments, arm 74 and housing 76 are pivotable about a vertical axis relative to carriage 90 in first and second directions and, in other embodiments, arm 74 is fixed relative to carriage 90 and housing 76 is pivotable relative to arm 74 about a vertical axis in first and second directions. Various angular orientations of columns 40, 42 about their respective vertical axes are shown in Fig. 7. In illustrative embodiments, the vertical axes about which IV rack 64 and housing 76 pivot extend through associated vertical arms 62, 74.

Ceiling unit 38 of system 30 has a central portion or canopy 96 and a pair of side portions or tracks 98 as shown, for example, in Figs. 1 and 2. Canopy 96 generally overlies bed 48, whereas tracks 98 are situated laterally outward of canopy 96. Canopy 96 has a set of lights 100 integrated therein. Lights 100 include reading lights and/or examination lights. In some embodiments, reading lights comprise standard incandescent or fluorescent bulbs, whereas examination lights comprise, for example, halogen bulbs and color-correction filters. All types of reading lights and examination lights are contemplated by this disclosure as being included in ceiling unit 38. Illustrative canopy 96 also has a display screen 110 integrated therein. In other embodiments, display screen 110 is omitted. Various images, such as family photos and nature scenes may be displayed on screen 110.

Ceiling unit 38 has a first or proximal end coupled to or overlying portions of headwall unit 32 and an opposite, distal end that is spaced apart from headwall unit 32. Thus, ceiling unit 38 extends from headwall unit 32 along ceiling 46 of the hospital room. Canopy 96 comprises a housing or frame 112 and a cosmetic cover or panel 114 that couples to frame 112 as shown in Figs. 5 and 6. Frame 112 includes portions (not shown) that couple to ceiling 46 and/or to headwall unit 32 with suitable couplers such as, for example, bolts, rivets, welds, clamps, tabs, and the like. The various pieces of equipment carried by ceiling unit 38, including lights 100 and screen 110, are mounted to frame 112 and extend through appropriately sized openings formed in panel 114. In addition, portions of lines 82, 84 loosely drape over frame 112 and cover 114 as shown in Figs. 5 and 6. Lines 82, 84 are routed through

suitably sized slots or spaces 116 that are provided between frame 112 and ceiling 46, or alternatively, between other portions of ceiling unit 38 through which lines 82, 84 are routed.

As columns 40, 42 move between the storage and various use positions, lines 82, 84 move relative to ceiling unit 38 in a somewhat random manner. However, frame 112 and cover 114 are situated beneath portions of lines 82, 84 to shield these portions of lines 82, 84 from view. Other portions of lines 82, 84 are shielded from view by columns 40, 42, respectively. In the illustrative embodiment, panel 114 has lateral side portions 118 that underlie portions of carriages 88, 90 as shown in Fig. 5 with respect to carriage 90. Side portions 118 further shield lines 82, 84 from view. Lines 82, 84 have sufficient slack in the interior region of canopy 96 to permit columns 40, 42 to move from the respective storage positions to the respective farthest use positions adjacent the distal end of associated tracks 98. It is within the scope of this disclosure for one or more line management mechanisms, such as strain reliefs, hoses, conduits, cables, cable ties, articulating segmented channels, and the like, to be coupled to lines 82, 84 either to guide or control the movement of lines 82, 84 or to restrain the movement of lines 82, 84 in a desired manner as columns 40, 42 move between the storage positions in cavities 34, 36, respectively, and the various positions outside of cavities 34, 36.

Each illustrative track 98 comprises a track member 120 and a cosmetic cover or panel 122 coupled to the respective member 120 as shown in Fig. 5. Suitable couplers, such as illustrative bolts 123, couple track member 120 to ceiling 46 or, in alternative embodiments, to portions of frame 112 that overlie tracks 98. The proximal ends of track members 120 overlie respective cavities 34, 36 to permit carriages 88, 90 to move along track members 120 into cavities 34, 36, respectively. Columns 40, 42 each comprise a plurality of rollers 124 some of which engage a first roller-engaging surface 126 of the associated member 120 and others of which engage a second roller-engaging surface 128 of the associated member 120 as also shown in Fig. 5. Surfaces 126, 128 are each elongated and extend generally perpendicularly relative to wall 44 of the hospital room. Thus, surfaces 126 are parallel with surfaces 128. In addition, surfaces 126, 128 lie in a common horizontal plane. In some alternative embodiments, track members 120 are curved and in other alternative embodiments, track members 120 are not parallel to each other.

Carriages 88, 90 are each somewhat U-shaped having central portions 130 that underlie track members 120 and having a pair of side portions 132 that extend upwardly from respective central portions 130 such that track members 120 are situated between respective side portions 132. Rollers 124 each have shafts 134 that are coupled to side portions 132 and that extend horizontally therefrom in a cantilevered manner toward associated track members 120. As columns 40, 42 move along tracks 98, such as, for example, in directions 136 away from respective cavities 34, 36 as shown in Figs. 2, 4, and 6-8, rollers 124 roll along corresponding surfaces 126, 128. Of course, rollers 124 also roll along surfaces 126, 128 when columns 40, 42 move along tracks 98 in directions opposite to directions 136.

According to this disclosure, housing 76 carries electrical circuitry to control the operation of display screen 78. In some embodiments, housing also carries electrical circuitry to control the operation of display screen 110 and lights 100. In other embodiments, some or all of the circuitry that controls the operation of screens 78, 110 and lights 100 are housed in portions of head wall unit 32. Such circuitry includes for example, one or more of a microprocessor or microcontroller, input/output circuitry, signal conditioning circuitry, signal conversion (analog-to-digital and/or digital-to-analog) circuitry, power conditioning circuitry, memory circuitry, and the like. In addition, a user interface is provided on column 42 to permit a user to enter commands and retrieve data for display on screen 78. In the illustrative embodiment, screen 78 is a touch screen and the user input on column 42 comprises user input buttons 138 displayed on screen 78 as shown, for example, in Fig. 8.

In some embodiments, the electrical circuitry that controls the operation of display screen 78 is coupled to the hospital's computer network or ethernet. In such embodiments, any of the information available on the network is viewable on display screen 78. For example, a caregiver is able to retrieve a patient's medical records (e.g., laboratory test results, medical diagnosis, patient charts, x-rays, and so on) from the network for viewing on screen 78. In addition, patient point-of-care data, such as vital signs data (e.g., heart rate, blood pressure, neurological activity, respiration rate, patient temperature, pulse oximetry) and data associated with the operation of patient-care equipment (e.g., data from one or more ventilators, infusion pumps, electrocardiographs, electroencephalographs), may be displayed on

screen 78. Thus, the circuitry associated with screen 78 is programmed and/or configured to receive and process various types of data signals indicative of the information to be displayed on screen 78. It is within the scope of this disclosure for all types of data associated with the care of a patient to be displayed on screen 78. In addition, it is within the scope of this disclosure for screen 78 to display multiple types of data simultaneously, such as in a split screen format. Furthermore, in those embodiments in which the hospital computer network is coupled to the Internet, then information accessible via the Internet is also able to be displayed on screen 78.

An alternative IV rack 164 that is attachable to and detachable from vertical arm 62 is shown in Figs. 8-10. IV rack 164 is similar to IV rack 64 and therefore, where appropriate, like reference numerals are used to denote components of IV rack 164 that are substantially similar to like components of IV rack 64. As was the case with IV rack 64, IV rack 164 couples to arm 62 with suitable couplers such as, for example, clamps, brackets, latches, grippers, hooks, or the like. The main difference between IV rack 164 and IV rack 64 is that IV rack 164 has a horizontal plate 140 coupled to the lower ends of poles 70. Plate 140 has one or more openings or sockets 142 as shown in Fig. 8.

An arm assembly 144 for carrying IV rack 164 includes an arm 146 coupled to bed 48 for pivoting movement about a vertical axis, a horizontal plate 148 coupled to arm 144, and a pair of posts 150 extending vertically upwardly from plate 146. Arm 146 is movable to a first position extending laterally outwardly from bed 48 to support plate 148 and posts 150 at a location which permits coupling of IV rack 164 to arm assembly 144 as shown in Figs. 8 and 9. Vertical arm 62 and carriage 88 are movable along track 98 to position IV rack over plate 148 and posts 150. In addition, IV rack 164, or the combination of arm 62 and IV rack 164, is rotatable about the vertical axis extending through arm 62 to orient IV rack 164 such that sockets 142 are aligned with posts 150. After IV rack 164 is properly oriented over arm assembly 144, as shown in Figs. 8 and 9, IV rack 164 is lowered in the direction of arrow 152, shown in Fig. 8, so that posts 150 are received in sockets 142 and so that plate 140 rests upon plate 148, thereby to couple IV rack 164 to arm assembly 144.

In some embodiments, the coupler that couples IV rack 164 to arm 62 is movable vertically relative to arm 62 to permit raising and lowering of IV rack 164

and, in other embodiments, arm 62 comprises telescoping segments that permit raising and lowering of IV rack 164. Alternatively, IV rack 164 is decoupled from arm 62 and is lowered manually onto arm assembly 144. It is also within the scope of this disclosure for an upper frame 154 of bed 48 to be lifted relative to a base 156 of bed 48 so that posts 150 enter into openings 142 and so that plate 148 moves into engagement with plate 140. In some embodiments, additional mechanisms (not shown), such as latches on plate 142 or plate 150, pins that extend through posts 150, caps that snap or thread onto posts, clamps that grip plates 140, 148, and the like, are provided to lock IV rack 164 to arm assembly 144. After IV rack 164 is coupled to arm assembly 144 and decoupled from arm 62, arm 146 is pivotable relative to bed 48 to a second position having IV rack 164 supported alongside bed 48 as shown in Fig. 10. Thus, bed 48 and IV rack 164 coupled to bed 48 are transportable through the hospital without needing to disconnect IV lines from the patient carried by bed 48.

Referring now to Figs. 11-14, an alternative architectural system 230 has a headwall unit 232 and a ceiling unit 238 that are substantially similar to headwall unit 32 and ceiling unit 38, respectively, of system 30. Therefore, where applicable, like reference numerals are used to denote components of system 230 that are substantially similar to like components of system 30. One of the differences between system 230 and system 30 is that headwall unit 232 of system 230 has a pair of auxiliary cavities 234, 236 (see Figs. 12 and 14) that are laterally outboard of cavities 34, 36, respectively. A pair of doors 235, 237 are each independently movable between a closed position, shown in Fig. 11, in which the respective cavity 234, 236 and any items or equipment stored therein are inaccessible and an opened position in which the respective cavity 234, 236 and any items or equipment stored therein are accessible. In the illustrative embodiment, doors 235, 237 pivot about respective vertical axes when moving between the opened and closed positions. Suitable locking mechanisms are provided in some embodiments for locking doors 235, 237 in the closed positions. As was the case with system 30, doors 58 of system 230 are movable to open and close cavities 34, 36.

Headwall unit 232 has additional medical service outlets 216 mounted on a pair of lower vertical panels 218 which are situated beneath the lowermost pair of doors 58 as shown in Figs. 11, 14, and 14. Headwall unit 232 also has a pair of lower doors 220 that are movable between respective first positions in which doors

220 cover the associated outlets 216 and respective opened positions in which outlets 216 are uncovered for use. It is within the scope of this disclosure for system 30 to also have outlets 216, panels 218, and doors 220. In some embodiments, auxiliary outlets 71 and outlets 216 are included in the headwall unit and, in other embodiments, only one or the other set of outlets 71, 216 are included in the headwall unit.

Another of the differences between system 230 and system 30 is that ceiling unit 238 of system 230 has tracks 198 which are wider than tracks 98 of system 30. Thus, tracks 198 extend laterally outward from canopy 96 of ceiling unit 238 by a greater amount than tracks 98 extend laterally outward from canopy 96 of ceiling unit 38. Each of tracks 198 has a cosmetic cover or panel 210. Each panel 210 has a first elongated slot 212 and a second elongated slot 214. In the illustrative embodiment, slots 212 are parallel with slots 214. Each slot 212 receives a respective side portion 132 of the associated carriage 88, 90 of the respective column 40, 42. Thus, provision of slots 212 in covers 210 allows columns 40, 42 of system 230 to move without interference from panels 210 between the respective storage positions within cavities 34, 36 and the various positions outside of cavities 34, 36.

In some embodiments, slots 214 are situated beneath respective track members (not shown) that are configured to support auxiliary equipment which is moved out of auxiliary cavities 234, 236 and, in other embodiments, auxiliary equipment is situated above slots 214. In the example shown in Fig. 12, a privacy curtain 240 is movable from a storage position in which curtain 240 is situated within cavity 236 to a use position in which a majority of curtain 240 is drawn out of cavity 236. In the use position, curtain 240 hangs downwardly from substantially the entire length of the track member situated above the respective slot 214. Illustrative curtain 240 has a flexible curtain panel 242, a plurality of sliders 244, and a plurality of strands 246. Each strand 246 extends between panel 242 and a respective slider 244. Sliders 244 are movable along the track member situated above slot 214. Thus, when curtain 240 is in the storage position, all of sliders 244 are grouped together within cavity 236 and when curtain 240 is in the use position, sliders 244 are spaced apart along the length of slot 214.

In the example shown in Fig. 13, a privacy curtain 250 is extendable downwardly out of the associated slot 214 to a use position and is retractable

upwardly through slot 214 to a storage position. Curtain 250 has a flexible curtain panel 252 and a bottom member 254 coupled to a bottom portion of panel 252. Member 254 adds weight to curtain 250 to prevent excessive movement of curtain 250 away from a vertical hanging configuration as shown in Fig. 13. A rotatable shaft (not shown) on which panel 252 winds when retracting and unwinds when extending is situated above slot 214. In some embodiments, a motor (not shown) is coupled to shaft and is operated to rotate the shaft in the appropriate directions to wind and unwind panel 252. In such embodiments, a user input, such as one or more switches, buttons, levers, or the like, is accessible on headwall unit 232 to control the motor. In alternative embodiments, curtain 250 is extended and retracted manually, similar to the manner in which conventional window shades are pulled down to cover a window and are manipulated so that a spring causes an associated shaft to wind up the window shade.

In the example shown in Fig. 14, an auxiliary IV pole 160 hangs downwardly from a carriage 162 that is slideable along a track member (not shown) which is situated above the respective slot 214. Pole 160 and carriage 162 are movable between a storage position in cavity 234 and a number of use positions outside of cavity 234. One or more hooks 166 are coupled to pole 160 for holding IV bags 68. In the illustrative embodiment, a dedicated infusion pump 172 is mounted to a bottom end of pole 160. In alternative embodiments, infusion pumps 72 are attachable to and detachable from other portions of pole 160. It is within the scope of this disclosure for any type of patient-care equipment that is capable of coupling to an IV pole to be coupled to pole 160.

Although curtain 240 is shown in Fig. 12 has being associated with cavity 236 and although pole 160 is shown in Fig. 14 as being associated with cavity 234, it is within the scope of this disclosure for curtains, IV poles, and any other type of track-mounted auxiliary equipment, such as exam lights, water hoses, suction hoses, traction devices, and the like, to be associated with either of cavities 234, 236. In addition, it is within the scope of this disclosure for the various walls of headwall unit 232 that bound cavities 234, 236, such as back wall 259, side wall 261, and bottom wall 263 (see Fig. 14), to be appropriately sized and configured so that cavities 234, 236 are large enough to receive the track mounted equipment to be stored therein. In addition, in those embodiments having auxiliary equipment, such as

curtain 250 that extends and retracts out of slots 214, then cavities 234, 236 may have storage shelves therein.

Referring now to Figs. 15 and 16, an alternative architectural system 330 includes a headwall unit 232, that is substantially similar to headwall unit 232 of system 230, and a ceiling unit 338 from which a set of air curtains 270 are directed downwardly around three sides of hospital bed 48. In the illustrative embodiment, the set of air curtains are adjacent foot end 52 and sides 54, 56 of bed 48. A suitable amount of space is provided between air curtains 270 and bed 48 to permit a caregiver to stand therebetween. Air curtains 270 provide a modicum of environmental isolation for the patient on bed 48. Thus, air borne contaminants outside the patient space bounded by air curtains 270 are prevented from entering the patient space. In some embodiments, air curtains 270 are heated and/or humidified to control the temperature and humidity of the patient space. In such embodiments, heating equipment (not shown) and/or humidifying equipment (not shown) is housed in either ceiling unit 338 or headwall unit 232 or both.

An air curtain generator 272, such as a fan, blower, pump, or the like, is housed in canopy 96 of ceiling unit 338 as shown in Figs. 15 and 16. An air-intake opening 274 is formed in cover 114 of canopy 96 and an air filter 276 covers opening 274 to filter contaminants from the ambient environment. Air curtain generator 272 is situated in a central chamber 278 of canopy 96 and an air-inlet duct 280 extends from opening 274 to chamber 278. A network of air-outlet ducts 282 extend from chamber 278 throughout ceiling unit 338, including along the outer regions of lateral side portions 198 and including along the front distal regions of canopy 96 and portions 198. Duct 280 overlies some of ducts 282 as shown in Fig. 16. In the illustrative embodiment of system 330, a plurality of air-exit openings or slots 284 are formed along the side and front peripheral regions of the underside of ceiling unit 338. Operation of air curtain generator 272 moves air from the ambient environment through each of filter 276, duct 280, chamber 278, ducts 282, and openings 284 to form air curtains 270.

A controller (not shown) housed in ceiling unit 338 or headwall unit 232 or both operates to control air curtain generator 272, the heating equipment (if any), and the humidification equipment (if any). A user interface is provided on one or both of columns 40, 42 or on headwall unit 232. A user inputs operational

parameters, such as, for example, fan speed (high, medium, low), air temperature, and air humidity, to the controller via the user interface. In addition, system 330 has various sensors, such as, for example, a fan speed sensor, a temperature sensor, and a humidity sensor that provides feedback to the controller so that appropriate commands from the controller can be provided to air curtain generator 272, the heating system, and the humidification system to adjust the operation of these devices, if appropriate.

According to one aspect of the present disclosure, a patient rests on a hospital bed 534 in an environmentally-controlled hospital room 532 as shown in Fig. 17. Covering the patient is a disposable heating/cooling blanket 536. Blanket 536 is coupled via a pair of heating/cooling hoses 540 to a heating/cooling unit 538 housed in a headwall 542 of room 532. When the patient is to be cooled, unit 538 operates to provide a cooling medium, such as cool air or cool liquid, through one of hoses 540 to blanket 536 and the other of hoses 540 provides the cooling medium back to unit 538 after circulation of the cooling medium through blanket 536. When the patient is to be heated, unit 538 operates to provide a heating medium, such as heated air or heated liquid, through one of hoses 540 to blanket 536 and the other of hoses 540 provides the cooling medium back to unit 538 after circulation of the heating medium through blanket 536. In those embodiments having heated air or cooled air circulated through blanket 536, perforations are formed in the surface of blanket 536 facing the patient so that a portion of the heated or cooled air being circulated through blanket 536 is able to escape from blanket 536 through the perforations and convectively heat or cool, as the case may be, the patient.

Bed 534 includes a pendant controller 544 that a patient uses to control heating/cooling unit 538 in a desired manner when pendant controller 544 is not locked out. In some embodiments, pendant controller 544 also is used to control other bed functions, such as articulation, raising, and lowering of the bed deck, and to control room entertainment and communication functions, such as television, radio, and nurse call. Bed 534 includes a footboard 546 having a control panel 548 that is used by a caregiver to control operation of unit 538, to control operation of various bed functions, and to control various entertainment and communication functions. Control panel 548 is also used by the caregiver to lock out one or more functions of

pendant controller 544. For example, the caregiver can lock out the ability of pendant controller 544 to operate unit 538.

An ceiling unit or overhead canopy 550 is coupled to a ceiling 552 of hospital room 532 above bed 534 as shown in Fig. 17. Canopy 550 includes various systems that control the environment of room 532. For example, canopy 532 includes an overhead temperature sensor (not shown), an overhead air quality sensor (not shown), an overhead air purifier (not shown), aroma therapy equipment (not shown), motion or proximity sensors 554 for detecting the presence of other people in the hospital room, examination lights 556, reading lights (not shown), and a video screen 558 for displaying one or more preselected images. Such images may include a scene from nature or other restful scenes. Such images may also include images that transition at the appropriate times during a 24-hour period from day images, such as clouds and sun, to night images, such as moon and stars. Images of the patients family may also be displayed on screen 558.

In some embodiments of room 532, the room lights are controlled to dim slowly as the daytime turns to evening. In addition, a recording of evening sounds, such as owls, night birds, crickets, and wind in the trees is played by audio equipment housed in overhead canopy 550. Eventually, the room lights are turned completely off and the night sounds fade away. In other embodiments of room 532, a video screen similar to or larger than video screen 558 is mounted to a room wall, preferably a wall that confronts the foot end of bed 534. In such alternative hospital rooms, television images, internet images, educational information, patient schedule, imagery to promote relaxation, and video conferencing images are selectively displayed on the video screen.

Bed 534, unit 538, and ceiling unit 550 each have their own controllers for monitoring and controlling the various functions associated with these devices. Each of such controllers include, for example, one or more microprocessors, microcontrollers, memory circuitry, input/output circuitry, signal conditioning circuitry, signal conversion circuitry, power conditioning circuitry, and the like. It is within the scope of this disclosure for each of the controllers of bed 534, unit 538, and canopy 550 to be coupled to the hospital computer network to exchange data with the network. In some embodiments, parameters for controlling bed 534, unit 538, and canopy 550 are entered by computers that are located remotely from room 532. Thus,

for example, if a patient places a nurse call requesting the heating/cooling function of unit 538 and blanket 536 be adjusted or discontinued, the nurse receiving the call is able to adjust the amount of heating/cooling provided to the patient via blanket 536.

Referring now to Figs. 18-20, a mobile cart 560 includes a somewhat rectangular upstanding pedestal 562, four horizontally extending support legs 564 coupled to the bottom of pedestal 562, and a set of wheels or casters 566 coupled to distal ends of corresponding support legs 564. Pedestal 562 has a fairly small depth dimension between a front face 568 thereof, shown best in Fig. 18, and a rear face 570 thereof, shown in Figs. 19 and 20. Each support leg 564 is pivotable relative to pedestal 562 about a respective vertical axis between a first position extending outwardly from beneath pedestal 562 as shown in Fig. 18 and a second position tucked beneath pedestal 562 as shown in Figs. 18-20.

When legs 564 are in the second positions, legs 564 and casters 566 are positioned to lie completely under and within the foot print of pedestal 562. In addition, when legs 564 are in the second positions, legs 564 extend in substantially parallel relation with front and rear faces 568, 570 of pedestal 562. When legs 564 are in the first positions, a majority of legs 564 are positioned to lie outside the foot print of pedestal 562 and legs 564 extend in substantially perpendicular relation to front and rear faces 568, 570 of pedestal 562. Suitable locking or retention mechanisms are provided either on legs 564 or pedestal 562 to lock or retain legs 564 in the respective first and second positions. The stability of cart 560 on a floor is greater when legs 564 are in the first positions than when legs 564 are in their second positions.

Mobile cart 560 is couplable to and transportable with a wheeled hospital bed or stretcher 572 from an operating room 574, shown in Fig. 19, to an intensive care unit room (not shown), and then to a regular hospital room 578, shown in Fig. 20. Of course, rooms 574, 578 are shown merely as examples of hospital rooms and therefore, cart 560 may be transported with stretcher 572 to any location in a hospital that stretcher 572 is capable of going. Cart 560 may also be transported by itself throughout a hospital when legs 564 are in their first positions having casters 566 rolling along the floor of the hospital.

An asset tracking system (not shown) included in a hospital includes a plurality of transmitters, receivers, and/or transmitter/receiver units 576 (collectively

referred to as "transmitter/receiver units 576") located throughout the hospital. One such transmitter/receiver unit 576 is shown in Fig. 36. Transmitter/receiver units 576 cooperate with remote equipment, such as computers, included in the asset tracking system to track the whereabouts of mobile carts 560 throughout the hospital. Thus, each cart 560 to be tracked includes a transmitter/receiver unit (not shown) that, when prompted by a signal from transmitter/receiver units 576, emits a signal that is sensed by one or more transmitter/receiver units 576 in the vicinity thereof.

Cart 560 is couplable to hospital bed 572 as previously mentioned. Cart 560 is also couplable to arm assemblies 598 included, for example, in operating room 574 and in intensive care unit rooms (not shown). Arm assemblies 598 extend from the ceilings of the respective rooms, such as room 574 as shown in Figs. 19. When cart 560 is coupled to arm assemblies 578, cart 560 is suspended from the ceiling of the respective room so that casters 566 of cart 560 are spaced apart from the floor of the respective rooms. Casters 566 are also spaced apart from the floor of the respective rooms when cart 560 is coupled to bed 572. It is within the scope of this disclosure for cart 560 to be coupled to or included in columns 40, 42 of any of architectural systems 30, 230, 330, as well as any alternatives of these, described above with regard to Figs. 1-16.

Cart 560 includes suitable couplers (not shown) that interface with couplers (not shown) included in bed 572, with couplers (not shown) included in arm assemblies 578, and with couplers (not shown) included in columns 40, 42. Suitable couplers may include, for example, hooks, clips, posts, latches, sockets, rails, channels, slots, bands, straps, fingers, flanges, lugs, bails, wires, magnets, plates, and the like, as well as combinations of these. Cart 560 includes a handle 580 appended to the top of pedestal 562 as shown in Figs. 18 and 19. A caregiver grips handle 580 to maneuver cart 560 along a floor of the hospital and to carry cart 560, such as during attachment to or detachment from bed 572, arm assemblies 578, or columns 40, 42.

A headwall 582 of room 578 is formed to include a cavity 584 that is configured to receive cart 560 as shown in Fig. 20. In addition, cart 560 is received in cavities 34, 36 (or cavities 23, 236) when cart 560 is coupled to or included in columns 40, 42 and columns 40, 42 are moved to the storage positions. When cart 560 is situated in cavity 584, legs 564 are in the respective second positions and

casters 566 rest upon a ledge surface 586 that underlies cavity 584. Pedestal 562 of cart 560 is configured to carry one or more IV poles 588 as shown in Figs. 18-20. Cavity 584 has sufficient height to accommodate cart 560 and any IV poles 588 coupled thereto as shown in Fig. 20. Hooks 587 are provided at the top of IV poles 588 for attachment of IV bags 68.

Pedestal 562 includes recesses or compartments 589 that are adapted to carry various patient-monitoring and patient-care modules or equipment 590, shown best in Fig. 18. Such patient-care equipment includes, for example, infusion pumps, ventilator control units, gas control units, vital signs monitors, and the like. Some modules 590 are coupled to the patient, via sensor lines, to monitor various physiological conditions and vital signs of the patient. In some embodiments, cart 560 includes an on-board computer system that interfaces with modules 590 and with a receiver/transmitter unit on cart 560. In such embodiments, patient-data from modules 590 is either transmitted to the hospital network via the receiver/transmitter unit or the patient-data is stored in the computer system until a hard-wire or optical connection is made to the network. When the computer system is communicatively coupled to the network, a caregiver located in the hospital remote from cart 560 is able to access the network with a remote computer terminal, for example, to obtain the status of the patient being monitored by modules 590 carried by cart 560. Cart 560 includes a battery (not shown) to provide power to any electrical components, such as modules 590 and the computer system, carried by cart 560.

Pedestal 562 is formed to include service delivery ports 592. Tanks (not shown) containing oxygen or other types of medical gases are situated in an interior region of pedestal 562. In some embodiments, such tanks are included in a ventilator system carried by cart 560. In such embodiments, hoses 594, one of which is shown in Fig. 20, are coupled to respective ports 592 and extend from ports 592 either to the patient or to associated medical equipment. Cart 560 is configured to carry other types of medical devices, including drug infusion devices, that are associated with providing intensive care to a patient. Such devices are sometimes referred to as LSTAT (Life Support for Trauma and Transport) devices. Because cart 560 carries most, if not all, of the medical equipment necessary to provide intensive care to the patient and because cart 560 is transported with the patient throughout the hospital, the need to disconnect and reconnect IV lines, ventilator hoses, sensor lines,

and the like from the patient before and after transport is avoided, as is the need to manage multiple wheeled stands or carts during transport of the patient throughout a hospital.

Referring now to Figs. 21-23, a ceiling-mounted overbed table assembly 656 includes a ceiling unit or hub unit 658 coupled to ceiling 46 of a hospital room, an arm assembly 660 coupled to hub unit 658, an overbed table 662 coupled to arm assembly 660, and a patient-care housing 664 coupled to and extending downwardly from an undersurface of table 662. In alternative embodiments, housing 664 is coupled to arm assembly 660 and is situated, at least in part, beneath table 662. Hub unit 658 includes an annular upper portion 666 having a frustoconical shape, an annular lower portion 668 shaped like a disc, and an annular slot 670 defined between portions 666, 668 as shown in Fig. 40. Hub unit 658 further includes a plurality of exam and reading lights 672 coupled to lower portion 668 and arranged to direct light downwardly therefrom. In alternative embodiments, hub 568 has shapes other than annular, such as elliptical, polygonal (i.e., square, rectangular, triangular, and so on), and the like.

Arm assembly 660 includes a first arm 674 extending horizontally from slot 670 and a second arm 676 extending vertically downwardly from a distal end 678 of first arm 674 as shown in Fig. 21. Hub unit 658 includes a shaft assembly (not shown) that interconnects portions 666, 668 of hub unit 658. A proximal end (not shown) of first arm 674 is coupled to the shaft assembly for pivoting movement about a vertical axis 680. Table 662 and housing 664 are coupled to a lower end of arm 676 for pivoting movement about a vertical axis 682, shown in Figs. 21 and 22. Alternatively, table 662 and housing 664 are fixed with respect to arm 676 and arm 676 is coupled to arm 674 for rotation about axis 682.

Second arm 676, table 662, and housing 664 are movable between a first position situated on a first side of a hospital bed 684 and a second position situated on a second side of hospital bed 684 as shown in Fig. 23. During movement between the first and second positions, arm 676, table 662, and housing 664 move along an arcuate path, indicated by a curved double-headed arrow 688 shown in Fig. 23, around a foot end 686 of bed 684. First arm 674 has sufficient length to allow housing 664 to clear foot end of bed 684 during movement between the first and second positions. Assembly 656 includes suitable locking mechanisms to lock arm

assembly 660 and table 662 in the first and second positions. When in either the first position or the second position, table 662 extends horizontally from arm 676 in a cantilevered manner and is positioned, in part, over the lap of a patient supported by bed 684. In some embodiments, assembly 656 includes drive mechanisms that operate to adjust the vertical position of table 662 and housing 664 relative to arm 676.

Assembly 656 includes a telephone 690 having a handset that resides in a recess formed in the upper surface of table 662. Assembly 656 also includes an entertainment-and-control panel 692 that is coupled to arm 676 of arm assembly 660 via a post 694 that extends horizontally away from arm 676 above table 662 as shown in Figs. 40 and 41. Illustrative panel 692 is a touch screen that permits the patient to control, for example, room lighting, room temperature, television functions, nurse call functions, and the like. Panel 692 is also operable to display various images such as, for example, television images, internet images, educational information, patient schedule, patient billing information, and video conferencing images. Controls panels having any combination of the above-mentioned control functions and entertainment functions are within the scope of this disclosure. Telephone 690 is used in a conventional manner for placement of phone calls.

A plurality of medical service outlets 696 and a plurality of patient-monitor modules 698 are coupled to an end face 700 of housing 664 as shown in Fig. 22. Modules 698 are arranged in side-by-side relation along an upper portion of end face 700 and medical service outlets 696 are arranged in side-by-side relation beneath modules 698. Each of modules 698 receive patient-data signals via patient-data lines (not shown) that are coupled to modules 698 and to the patient to monitor various physiological conditions of the patient. Patient conditions to be monitored may include temperature, heart rate, blood oxygenation, respiration, brain activity, and the like. Services provided by outlets 696 may include, for example, medical gases, vacuum, and power. Outlets 696 receive the associated services via lines (not shown) that are routed to outlets 696 from the ceiling of the hospital room, through hub unit 658, though interior regions of arms 674, 676, through an opening in table 662, and into an interior region of housing 664. Outlets 696 and modules 698 are positioned on housing 664 so as to be generally inaccessible to a patient lying on bed 684 when assembly 656 is in either the first position or the second position.

It is contemplated by this disclosure that table 662 and/or housing 664, along with outlets 696 and modules 698 associated with housing 664 may be suspended from a ceiling of a hospital room by other types of arm assemblies or columns. For example, it is within the scope of this disclosure for table 662 and/or housing 664 to be coupled to or included in columns 40, 42 of any of architectural systems 30, 230, 330 described above. In such embodiments, table 662 or a part thereof flips up, such as by pivoting about a horizontal axis, thereby placing table 662 is in a substantially vertical orientation for storage in the associated cavity 34, 36, 234, 236 of the associated headwall unit 32, 232. When the column 40, 42 associated with table 662 is moved out of the associated cavity 34, 36, 234, 236, table 662 is flipped down to a substantially horizontal orientation for use.

Although various apparatus and systems have been described in detail with reference to certain preferred embodiments, variations and modifications of each of these apparatus and systems exist within the scope and spirit of the invention as described and defined in the following claims.

CLAIMS

1. An architectural system adaptable to an acuity level of a patient supported by a hospital bed in a patient room having a wall and a ceiling, the architectural system comprising

a wall unit coupled to the wall and having a cavity,

a ceiling unit coupled to the ceiling, and

a column coupled to the ceiling unit for movement between a first position in which at least a majority of the column is situated in the cavity and a second position in which the column is situated outside the cavity.

2. The architectural system of claim 1, wherein the column includes a vertical member and a patient care device coupled to the vertical member.

3. The architectural system of claim 2, wherein the patient care device comprises an IV rack that is situated in the cavity when the column is in the first position.

4. The architectural system of claim 2, wherein the patient care device comprises a housing having a plurality of medical service outlets and the housing is situated in the cavity when the column is in the first position.

5. The architectural system of claim 4, wherein at least one of the medical service outlets is a medical gas outlet.

6. The architectural system of claim 4, wherein at least one of the medical service outlets is an electrical outlet.

7. The architectural system of claim 4, wherein the wall unit has a door that is movable between a closed position blocking access to the plurality of medical service outlets when the column is in the first position and an opened position allowing access to the medical service outlets when the column is in the first position.

8. The architectural system of claim 2, wherein the patient care device comprises a display screen that is situated in the cavity when the column is in the first position.

9. The architectural system of claim 8, wherein the wall unit has a door that is movable between a closed position covering the display screen to shield the display screen from view when the column is in the first position and an opened

position uncovering the display screen to permit the display screen to be viewed when the column is in the first position.

10. The architectural system of claim 2, wherein the patient care device is pivotable about an axis relative to the vertical member when the column is in the second position.

11. The architectural system of claim 10, wherein the axis is vertical and extends through the vertical member.

12. The architectural system of claim 1, wherein the ceiling unit comprises a track member and the column comprises a carriage that moves along the track member as the column moves between the first and second positions.

13. The architectural system of claim 12, wherein a portion of the track member overlies the cavity.

14. The architectural system of claim 12, wherein the track member comprises elongated first and second roller-engaging surfaces, the first roller-engaging surface is parallel to the second roller-engaging surface, the carriage comprises a housing and a plurality of roller coupled to the housing, at least one of the plurality of rollers engages the first roller-engaging surface, and a least another of the plurality of roller engages the second roller-engaging surface.

15. The architectural system of claim 1, wherein the ceiling unit comprises a housing and a light coupled to the housing.

16. The architectural system of claim 1, wherein the ceiling unit comprises a housing and a display screen coupled to the housing.

17. The architectural system of claim 1, wherein the ceiling unit comprises a housing having a plurality of openings and the ceiling unit comprises an air curtain generator that operates to expel air downwardly from the plurality of openings to create at least one air curtain.

18. The architectural system of claim 17, wherein the housing has an air-intake opening, the ceiling unit comprises an air-permeable filter covering the air-intake opening, and operation of the air curtain generator draws air from the patient room through the filter.

19. The architectural system of claim 1, wherein the column comprises a medical service outlet and further comprising a medical service delivery

line that is routed from the medical service outlet, through the column, and through the ceiling unit.

20. The architectural system of claim 1, further comprising a privacy curtain hanging downwardly from the ceiling unit, the wall unit having a compartment, and the privacy curtain being movable between a storage position in which a majority of the privacy curtain is situated in the compartment and a use position in which a majority of the privacy curtain is situated outside the compartment.

21. The architectural system of claim 1, further comprising a privacy curtain coupled to the ceiling unit and movable between a use position hanging downwardly from the ceiling unit and a storage position retracted into the ceiling unit.

22. An architectural system adaptable to an acuity level of a patient supported by a hospital bed in a patient room having a wall and a ceiling, the architectural system comprising

a wall unit coupled to the wall, the wall unit having a first cavity and a second cavity,

a first track member coupled to the ceiling,

a second track member coupled to the ceiling,

a first column coupled to the first track member for movement between a first position in which at least a majority of the first column is situated in the first cavity and a second position in which the first column is situated outside the cavity alongside a first side of the hospital bed, and

a second column coupled to the second track member for movement between a first position in which at least a majority of the second column is situated in the second cavity and a second position in which the second column is situated outside the cavity alongside a second side of the hospital bed.

23. The architectural system of claim 22, wherein the wall unit has a first door that is movable between a closed position blocking access to at least a portion of the first column when the first column is in the first position and an opened position permitting access to the portion of the first column.

24. The architectural system of claim 22, wherein the first track member is elongated, the second track member is elongated, and the first track member is parallel with the second track member.

25. The architectural system of claim 22, wherein the first track member comprises elongated first and second roller-engaging surfaces, the first roller-engaging surface is parallel to the second roller-engaging surface, the column comprises a carriage having a housing and a plurality of rollers coupled to the housing, at least one of the plurality of rollers engages the first roller-engaging surface, and a least another of the plurality of roller engages the second roller-engaging surface.

26. The architectural system of claim 22, further comprising a canopy situated at least in part between the first and second track members and a light coupled to the canopy.

27. The architectural system of claim 22, further comprising a canopy situated at least in part between the first and second track members and a display screen coupled to the canopy.

28. The architectural system of claim 22, further comprising a canopy situated at least in part between the first and second track members and air curtain generation equipment coupled to the canopy.

29. An apparatus for use in a hospital room having a ceiling, the apparatus comprising

a canopy adapted to be coupled to the ceiling of the hospital room, and environmental control equipment coupled to the canopy.

30. The apparatus of claim 29, wherein the environmental control equipment comprises a temperature sensor.

31. The apparatus of claim 29, wherein the environmental control equipment comprises an air quality sensor.

32. The apparatus of claim 29, wherein the environmental control equipment comprises an air purifier.

33. The apparatus of claim 29, wherein the environmental control equipment comprises aroma therapy equipment.

34. The apparatus of claim 29, further comprising a motion sensor coupled to the canopy.

35. The apparatus of claim 29, further comprising a proximity sensor coupled to the canopy.

36. The apparatus of claim 29, wherein the environmental control equipment comprises at least one examination light.

37. The apparatus of claim 29, wherein the environmental control equipment comprises at least one reading light.

38. The apparatus of claim 29, further comprising a video screen coupled to the canopy.

39. A mobile cart for use in a hospital to provide care to a patient, the mobile cart comprising

an upstanding pedestal,

a plurality of legs coupled to a bottom of the upstanding pedestal,

a plurality of wheels, each wheel being coupled to a respective leg of the plurality of legs, the legs along with the wheels coupled thereto each being movable between a first position extending outwardly from beneath the upstanding pedestal and second position tucked beneath the upstanding pedestal, and

a plurality of patient-care modules coupled to the upstanding pedestal.

40. The mobile cart of claim 39, further comprising at least one IV pole coupled to the upstanding pedestal.

41. The mobile cart of claim 39, wherein the upstanding pedestal has a top wall and further comprising a handle coupled to the top wall, the handle being grippable to maneuver the mobile cart.

42. The mobile cart of claim 39, wherein each wheel of the plurality of wheels is able to swivel about a respective vertical axis.

43. The mobile cart of claim 39, wherein each leg of the plurality of legs is able to swivel about a respective vertical axis.

44. The mobile cart of claim 39, wherein the upstanding pedestal has a compartment adapted to carry at least one of the plurality of patient-care modules.

45. The mobile cart of claim 39, wherein at least one of the plurality of patient-care modules is an infusion pump.

46. The mobile cart of claim 39, wherein at least one of the plurality of patient-care modules is a ventilator control unit.

47. The mobile cart of claim 39, wherein at least one of the plurality of patient-care modules is a gas control units.

48. The mobile cart of claim 39, wherein at least one of the plurality of patient-care modules is a vital signs monitor.

49. The mobile cart of claim 39, wherein at least one of the plurality of patient-care modules is configured to monitor a physiological condition of the patient.

50. The mobile cart of claim 39, further comprising an on-board computer system that interfaces with at least one of the plurality of patient-care modules.

51. The mobile cart of claim 50, further comprising a receiver and a transmitter and the on-board computer system interfaces with the receiver and the transmitter.

52. The mobile cart of claim 50, wherein the on-board computer system is configured to transmit wirelessly patient data from at least one of the plurality of patient-care modules.

53. The mobile cart of claim 50, wherein the on-board computer system is configured to store patient data from at least one of the plurality of patient-care modules until a hard-wire connection is made between the on-board computer system and an external computer network.

54. The mobile cart of claim 50, wherein the on-board computer system is configured to store patient data from at least one of the plurality of patient-care modules until an optical connection is made between the on-board computer system and an external computer network.

55. The mobile cart of claim 50, further comprising a battery configured to provide power to the on-board computer system and to at least one of the plurality of patient-care modules.

56. The mobile cart of claim 39, wherein at least one of the plurality of patient-care modules comprises a medical gas tank housed in the upstanding pedestal and further comprising a service delivery port that is coupled to the upstanding pedestal and through which medical gas from the medical gas tank is accessible.

57. A set of equipment for use in a hospital room having a floor, the set of equipment comprising

a hospital bed supported by the floor,

an arm assembly hanging in the hospital room, and

a mobile cart that is selectively couplable to the hospital bed and to the arm assembly and that is selectively decouplable from the hospital bed and from the arm assembly, the mobile cart having wheels that are spaced apart from the floor when the mobile cart is coupled to the hospital bed and when the mobile cart is coupled to the arm assembly, the wheels engaging the floor when the mobile cart is decoupled from the hospital bed and decoupled from the arm assembly.

58. The set of equipment of claim 57, wherein the mobile cart comprises a pedestal and at least one IV pole coupled to the pedestal.

59. The set of equipment of claim 57, wherein the mobile cart comprises a pedestal having a top wall, the mobile cart has a handle coupled to the top wall, and the handle is grippable to maneuver the mobile cart.

60. The set of equipment of claim 57, wherein the mobile cart comprises a pedestal and a patient-care module coupled to the pedestal.

61. The set of equipment of claim 60, wherein the pedestal has a compartment adapted to carry the patient-care module.

62. The set of equipment of claim 60, wherein the patient-care module is an infusion pump.

63. The set of equipment of claim 60, wherein the patient-care module is a ventilator control unit.

64. The set of equipment of claim 60, wherein the patient-care module is a gas control unit.

65. The set of equipment of claim 60, wherein the patient-care module is a vital signs monitor.

66. The set of equipment of claim 60, wherein the patient-care module is configured to monitor a physiological condition of the patient.

67. The set of equipment of claim 60, wherein the mobile cart has an on-board computer system that interfaces with the patient-care module.

68. The set of equipment of claim 60, wherein the mobile cart has a receiver, the mobile cart has a transmitter, and the on-board computer system interfaces with the receiver and the transmitter.

69. The set of equipment of claim 60, wherein the on-board computer system is configured to transmit wirelessly patient data from the patient-care module.

70. The set of equipment of claim 60, wherein the on-board computer system is configured to store patient data from the patient-care module until a hard-wire connection is made between the on-board computer system and an external computer network.

71. The set of equipment of claim 60, wherein the on-board computer system is configured to store patient data from at least one of the plurality of patient-care modules until an optical connection is made to an external computer network.

72. The set of equipment of claim 60, wherein the mobile cart has a battery configured to provide power to the on-board computer system and to the patient-care module.

73. The set of equipment of claim 60, wherein the patient-care module comprises a medical gas tank housed in the pedestal, the mobile cart has a service delivery port coupled to the pedestal, and medical gas from the medical gas tank is accessible via the service delivery port.

74. The set of equipment of claim 57, wherein the arm assembly has a plurality of articulated arm segments.

75. The set of equipment of claim 57, wherein the arm assembly comprises a vertical column.

76. The set of equipment of claim 75, further comprising a track member along which the vertical column is movable.

77. A set of hospital equipment comprising

a mobile cart carrying patient-care equipment and having a plurality of wheels, and

a headwall formed to include a cavity that receives the mobile cart, the headwall having a ledge surface, the plurality of wheels of the mobile cart engaging the ledge surface when the mobile cart is received in the cavity.

78. The set of hospital equipment of claim 77, wherein a portion of the headwall overlies the cavity.

79. The set of hospital equipment of claim 77, wherein the mobile cart has a pedestal and an IV pole coupled to the pedestal and wherein the cavity is sized to receive the pedestal and the IV pole.

80. The set of hospital equipment of claim 77, wherein the mobile cart has a pedestal and a plurality of legs coupled to the pedestal and wherein each wheel of the plurality of wheels is coupled to a respective leg of the plurality of legs.

81. The set of hospital equipment of claim 80, wherein the plurality of legs, along with the wheels coupled thereto, are each movable between a first position extending outwardly from beneath the pedestal and second position tucked beneath the pedestal.

82. The set of hospital equipment of claim 77, wherein the headwall has a panel and at least one medical service outlet that is coupled to the panel and through which a medical service is accessible.

83. An apparatus comprising

an arm assembly adapted to be suspended from a ceiling of a hospital room, and

an overbed table coupled to the arm assembly to be supported by the arm assembly above a floor of the hospital room.

84. The apparatus of claim 83, wherein the overbed table has a table surface that is substantially horizontal, the arm assembly is configured to permit repositioning of the overbed table in the hospital room, and the table surface remains at a substantially constant elevation above the floor as the overbed table is repositioned.

85. The apparatus of claim 83, further comprising a control panel coupled to the arm assembly and the control panel having a user input.

86. The apparatus of claim 85, wherein the user input is engageable to control a light in the hospital room.

87. The apparatus of claim 85, wherein the user input is engageable to control a temperature of the hospital room.

88. The apparatus of claim 85, wherein the user input is engageable to control at least one function of a television situated in the hospital room.

89. The apparatus of claim 85, wherein the user input is engageable to place a nurse call signal.

90. The apparatus of claim 85, wherein the control panel has a screen on which video images are displayed.

91. The apparatus of claim 85, wherein the control panel has a screen on which images accessed via the internet are displayed.

92. The apparatus of claim 85, wherein the control panel has a screen on which a patient schedule is displayed.

93. The apparatus of claim 85, wherein the control panel has a screen on which education information is displayed.

94. The apparatus of claim 85, wherein the control panel has a screen on which patient billing information is displayed.

95. The apparatus of claim 85, wherein the control panel has a screen on which video conferencing images are displayed.

96. The apparatus of claim 85, wherein the control panel is situated above the overbed table.

97. The apparatus of claim 85, wherein the control panel comprises a touch screen and the user input comprises an area on the touch screen.

98. The apparatus of claim 83, further comprising a telephone, the overbed table having a recess, and the telephone having a handset that resides in the recess.

99. The apparatus of claim 83, further comprising a housing coupled to the overbed table, a medical service outlet coupled to the table, and a service-delivery line routed from the medical service outlet, through the housing, and through the arm assembly.

100. The apparatus of claim 99, wherein the housing extends downwardly from the overbed table and terminates at a bottom end that is spaced apart from the floor.

101. The apparatus of claim 83, further comprising a housing coupled to the overbed table and a patient-monitor module coupled to the housing, the patient-monitor module being configured to receive a patient-data signal indicative of a physiological condition of a patient.

102. An apparatus comprising

a hub unit adapted to mount to a ceiling of a hospital room,

an arm assembly coupled to the hub unit,

an overbed table coupled to the arm assembly, and

a housing coupled to one of the arm assembly and the overbed table, the housing carrying one of a medical service outlet and a patient-monitor module.

103. The apparatus of claim 102, wherein the hub unit comprises an upper portion, a lower portion, and an annular slot defined between the upper and lower portions and wherein the arm assembly comprises a first arm segment that is rotatable relative to the first and second portions within the slot.

104. The apparatus of claim 103, wherein the first arm segment extends from the slot and terminates at a distal end and the arm assembly comprises a second arm segment extending downwardly from the distal end of the first arm segment.

105. The apparatus of claim 104, wherein the overbed table is coupled to a lower end portion of the second arm segment.

106. The apparatus of claim 104, wherein the second arm, the overbed table, and the housing rotate as a unit relative to the first arm segment.

107. The apparatus of claim 104, wherein the overbed table and the housing rotate as a unit relative to the second arm segment.

108. The apparatus of claim 103, wherein the hub unit further includes a plurality lights coupled to the lower portion and arranged to direct light downwardly from the lower portion.

109. A set of hospital equipment comprising

a headwall,

a blanket,

a unit housed in the headwall, and

a hose coupled to the blanket and coupled to the unit, a thermoregulation medium being moved between the blanket and the unit through the hose.

110. The set of hospital equipment of claim 107, wherein the thermoregulation medium comprises a cooled liquid.

111. The set of hospital equipment of claim 109, wherein the thermoregulation medium comprises cooled air.

112. The set of hospital equipment of claim 109, wherein the thermoregulation medium comprises a heated liquid.

113. The set of hospital equipment of claim 109, wherein the thermoregulation medium comprises heated air.

114. The set of hospital equipment of claim 109, wherein the blanket has internal passages through which the thermoregulation medium travels.

115. The set of hospital equipment of claim 114, wherein the blanket has a plurality of perforations through which a portion of the thermoregulation medium escapes from the internal passages of the blanket.

116. The set of hospital equipment of claim 109, wherein the thermoregulation medium is a heated medium when the patient is to be heated and the thermoregulation medium is a cooled medium when the patient is to be cooled.

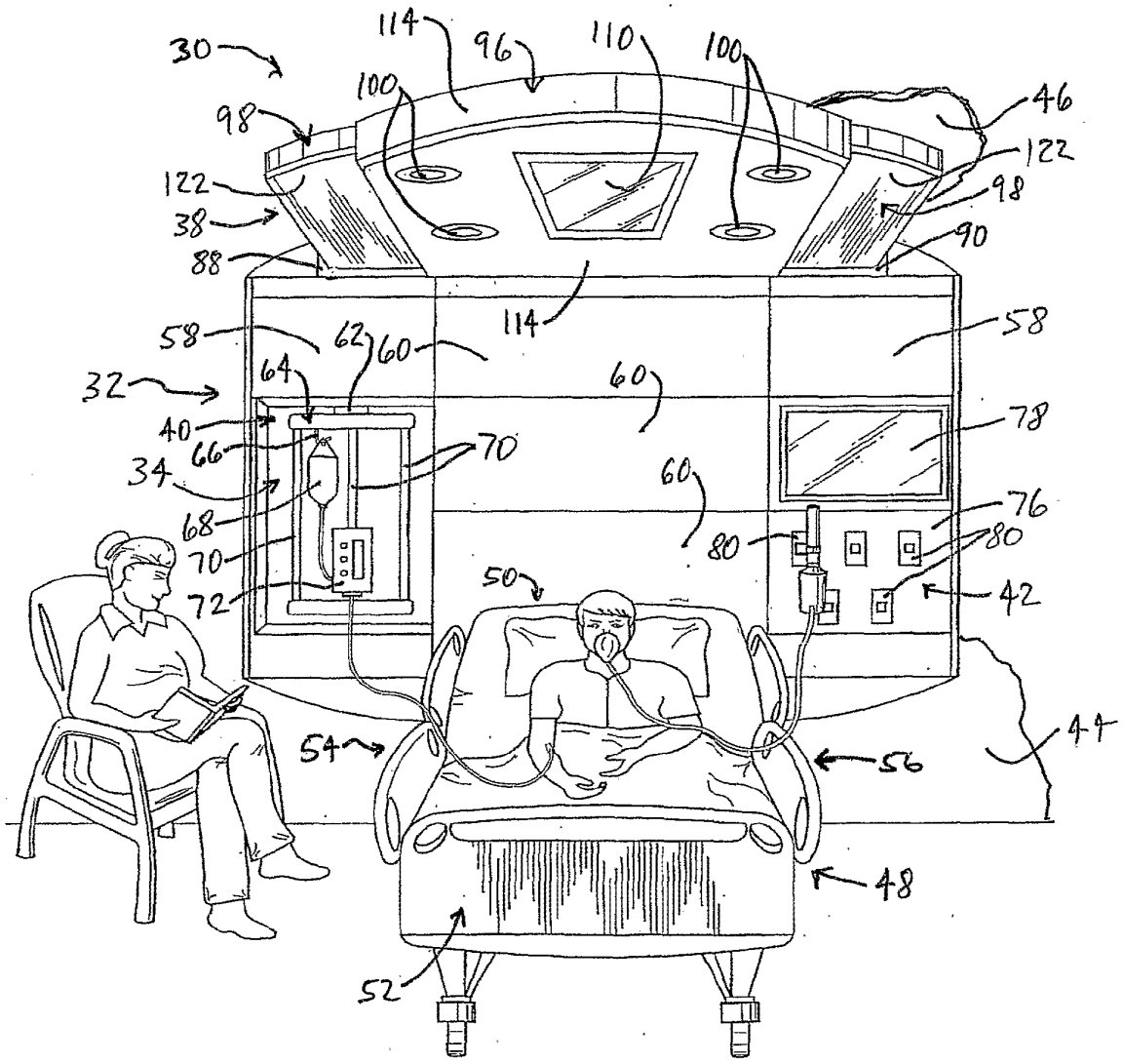
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Fig. 1

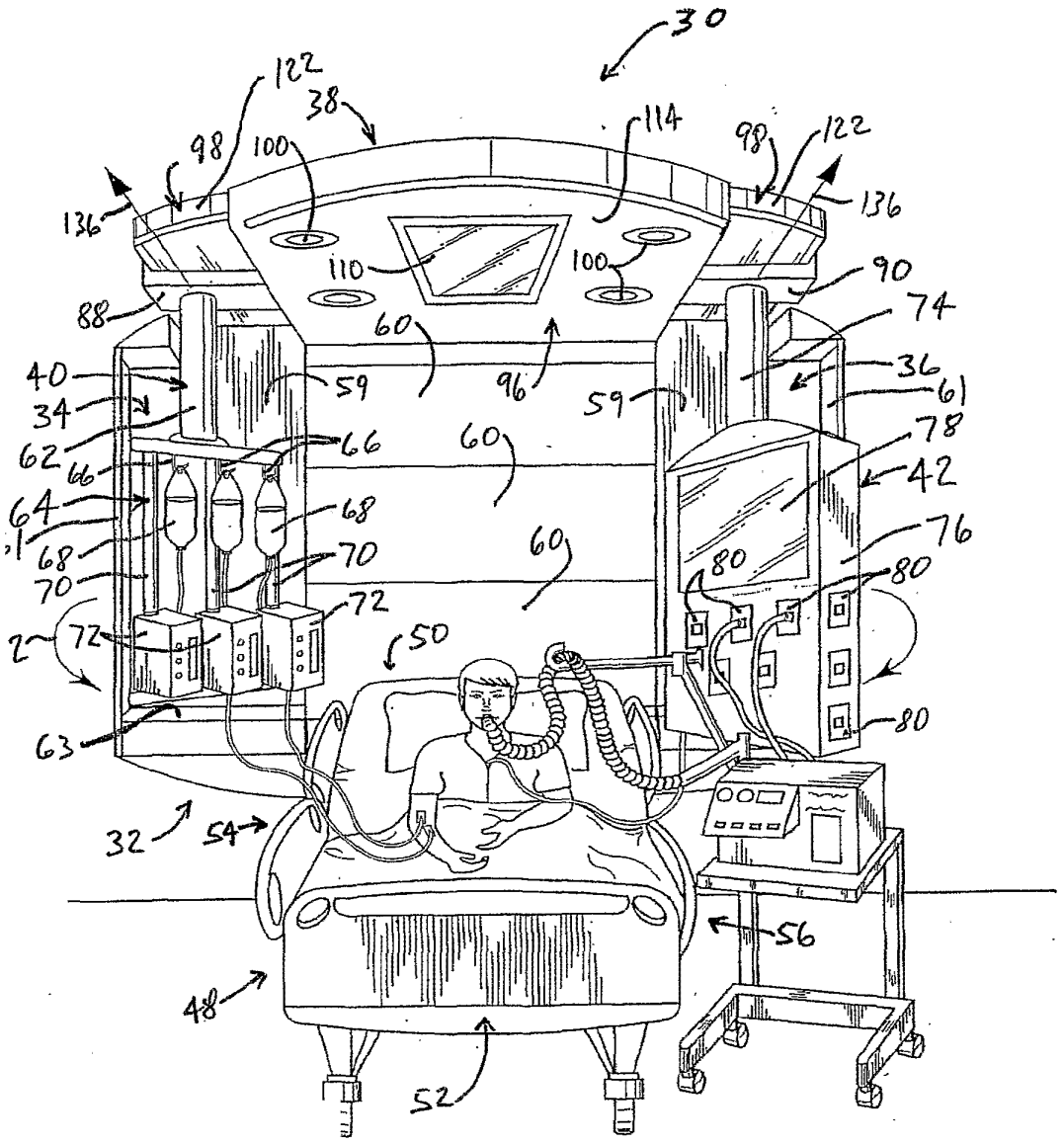
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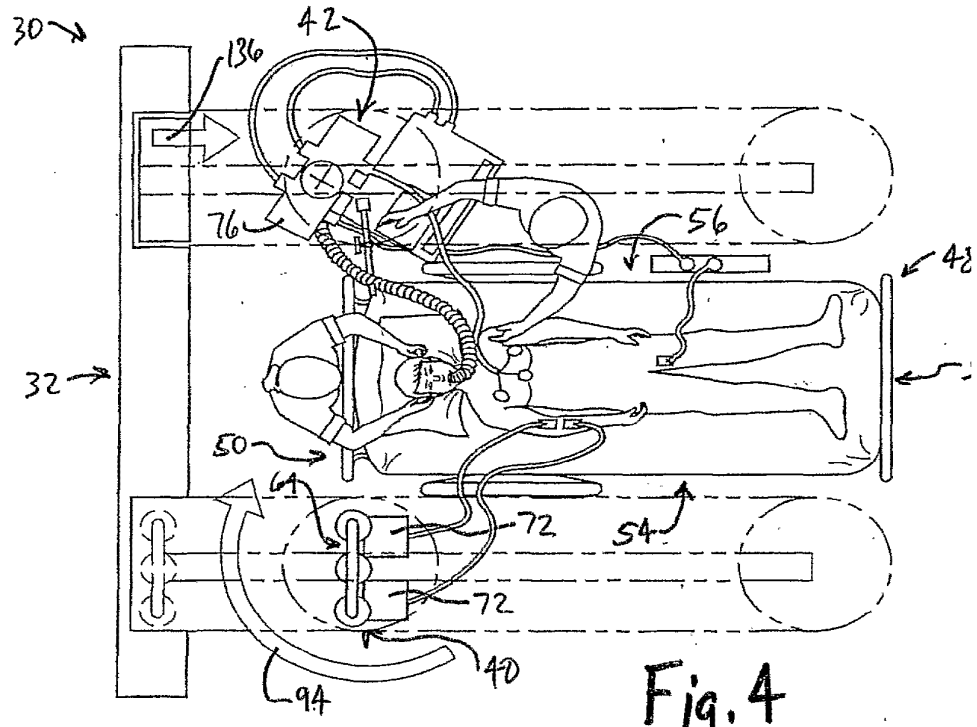
Fig. 2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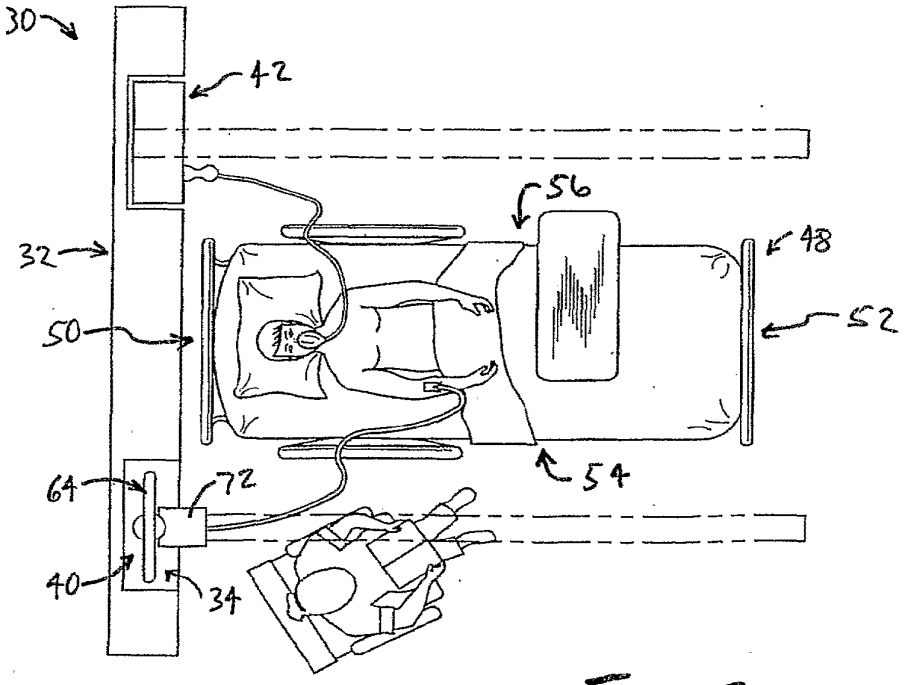
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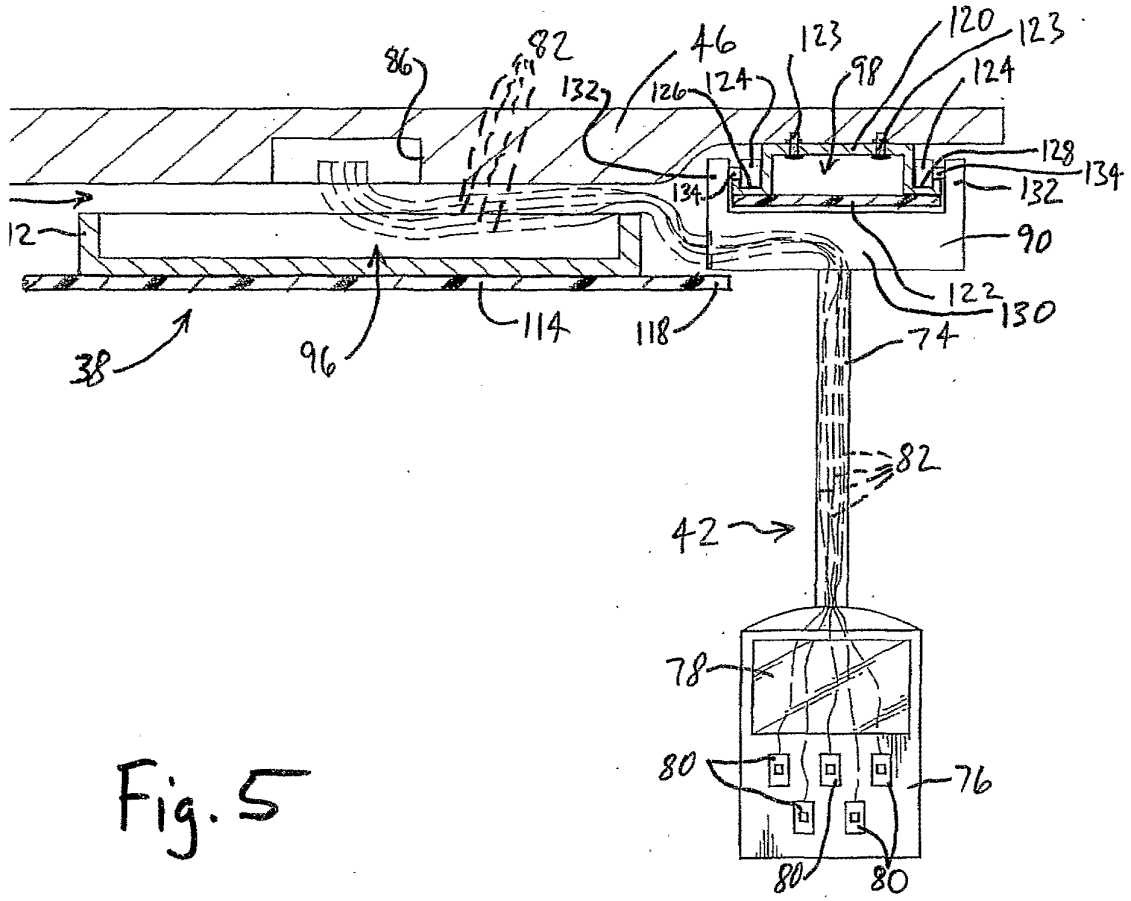
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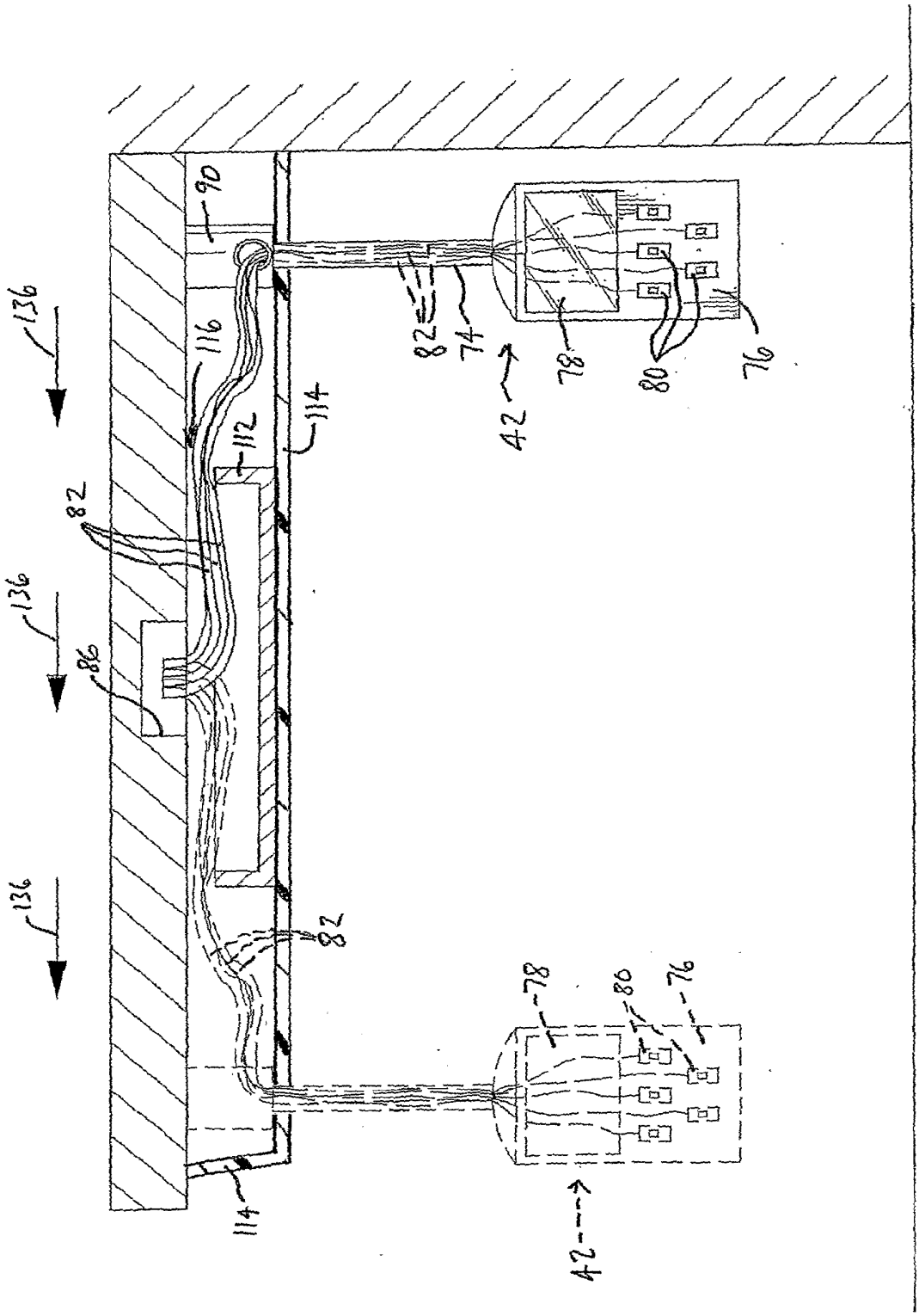
Fig. 5

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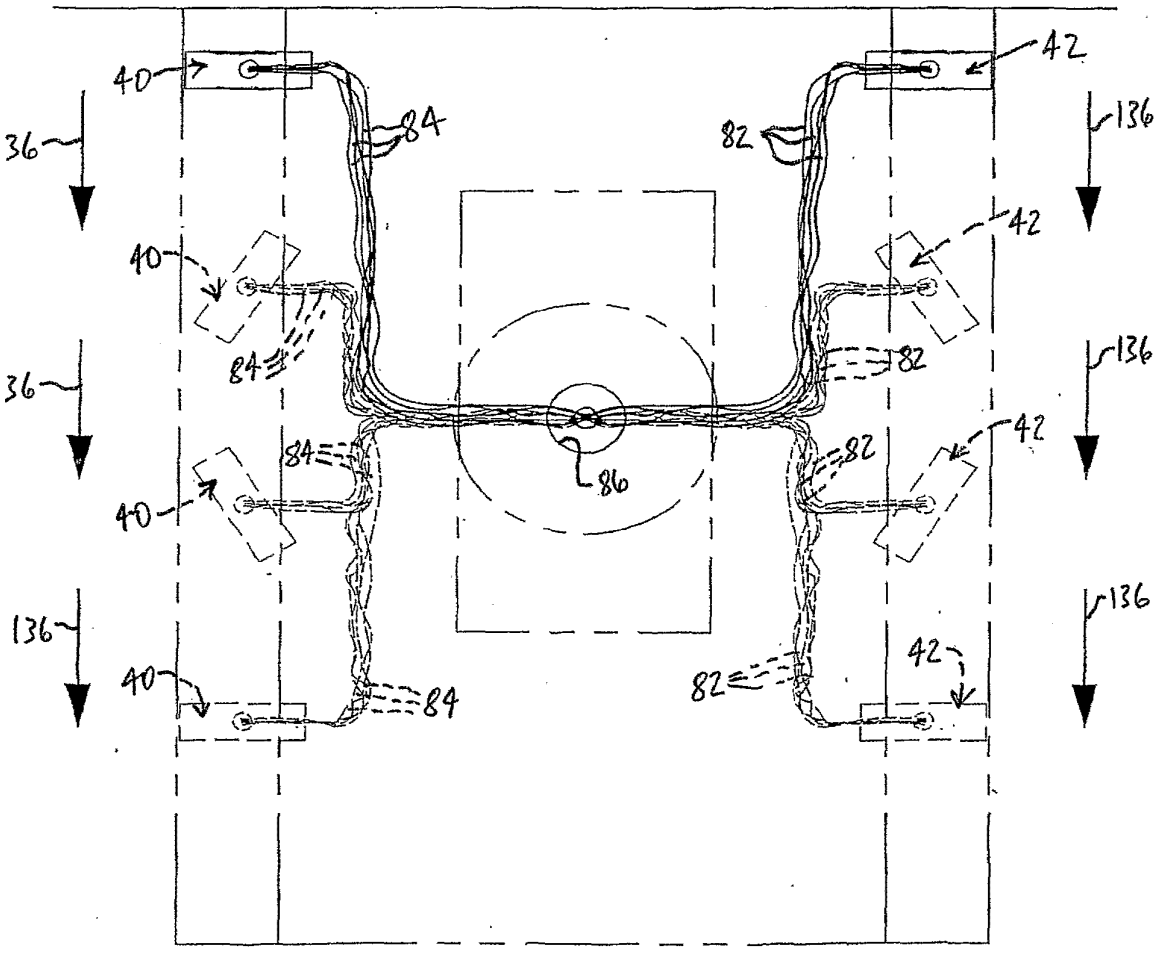


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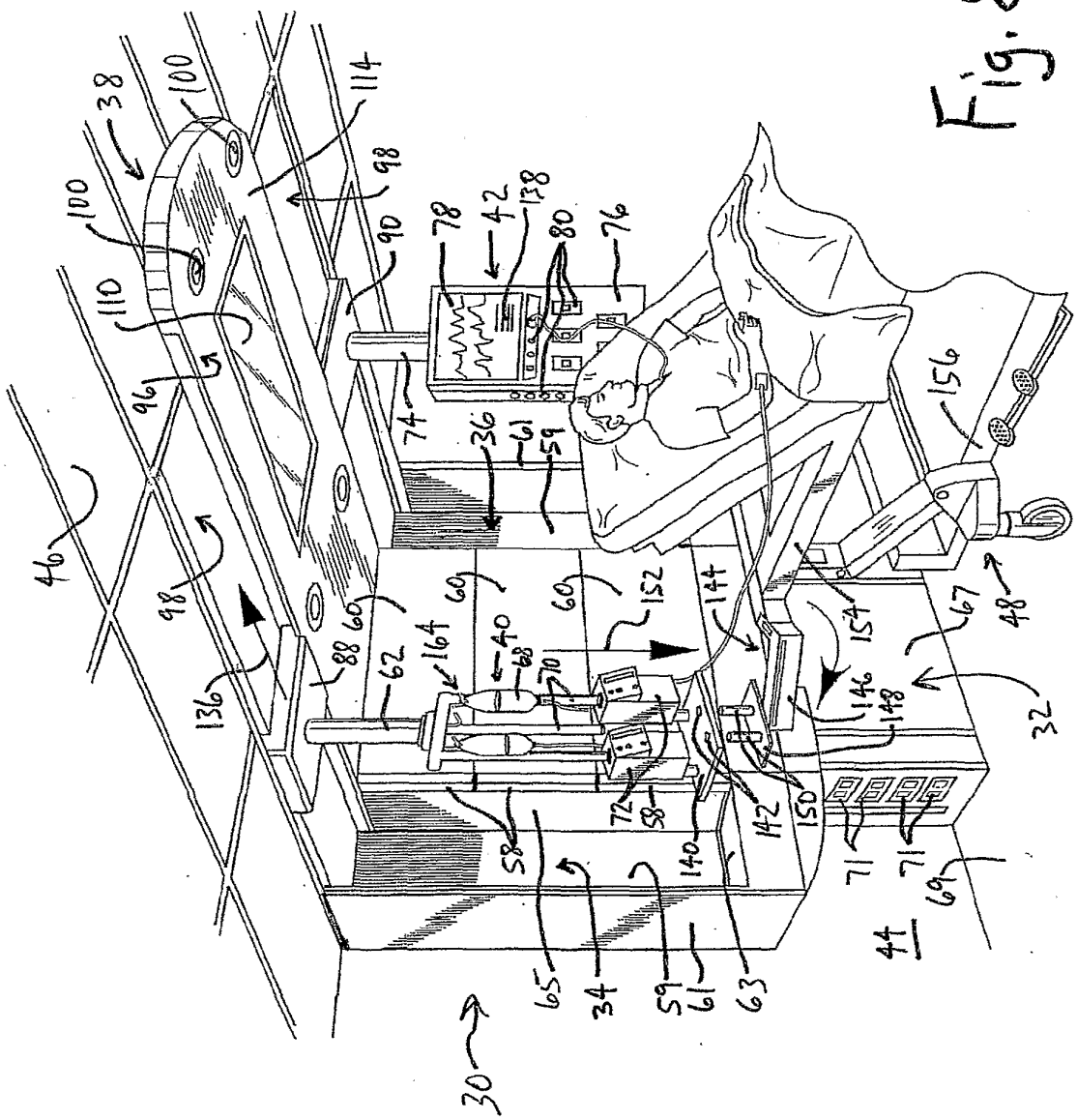
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Fig. 8

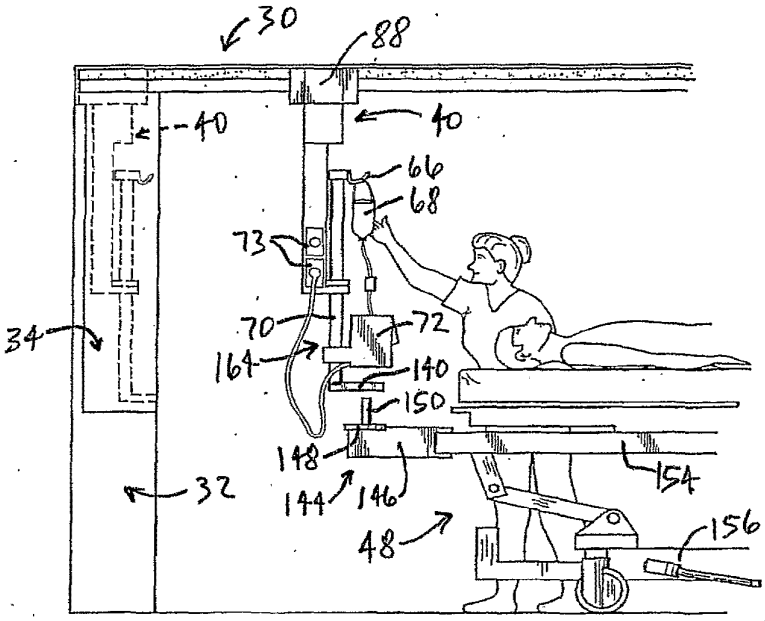
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Fig. 9

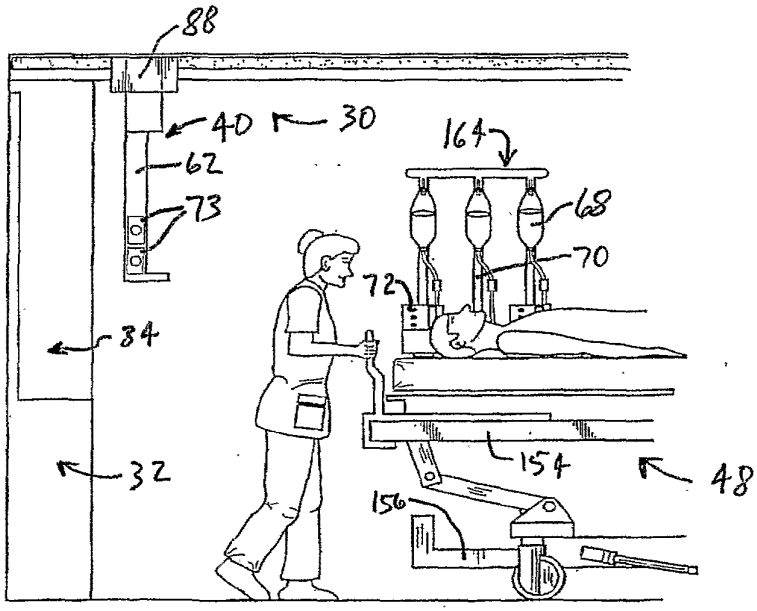
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Fig. 10

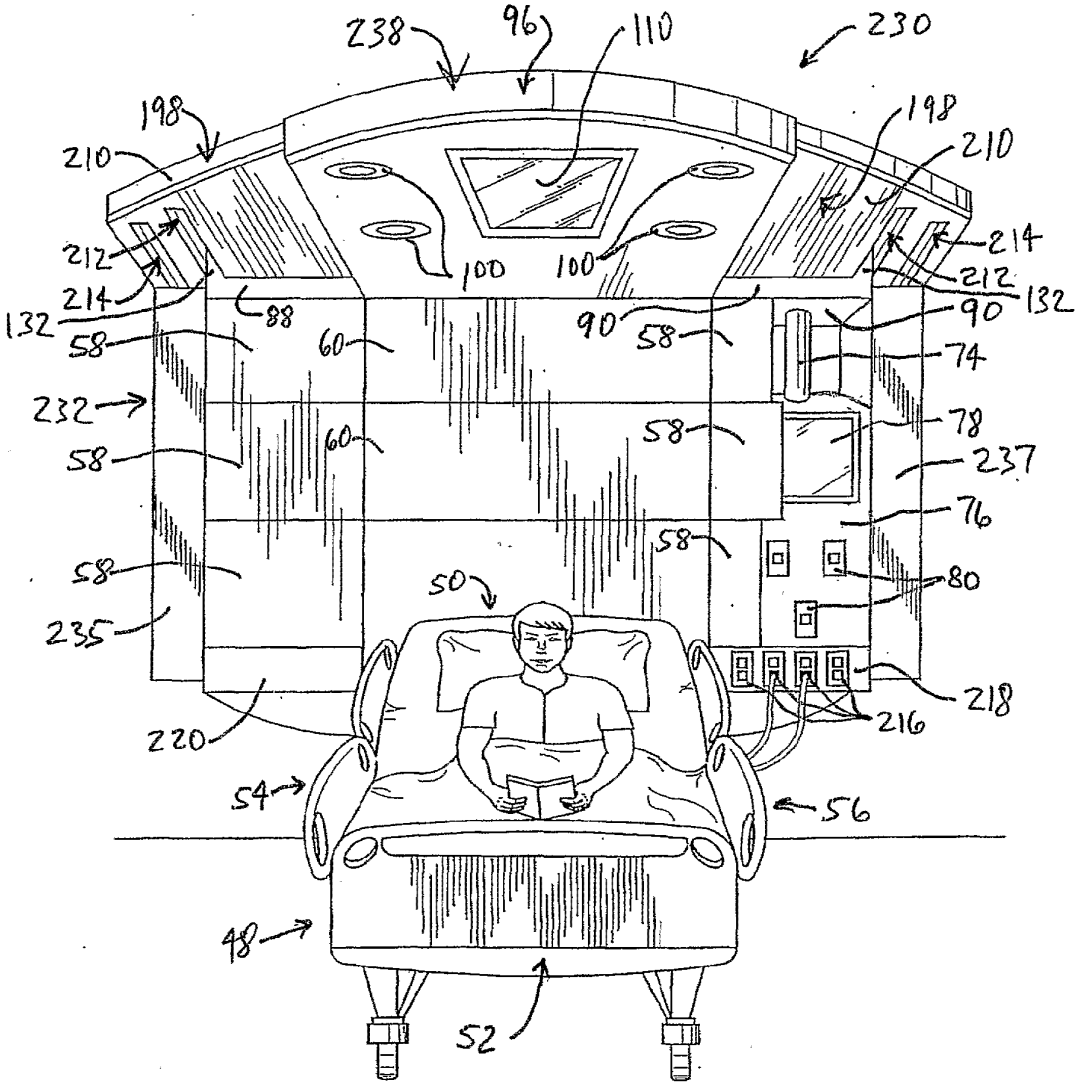
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Fig. 11

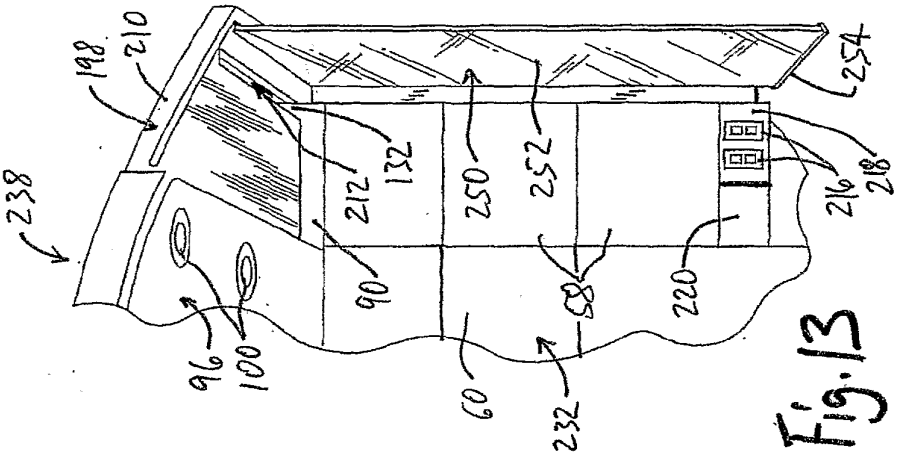



Fig. 13

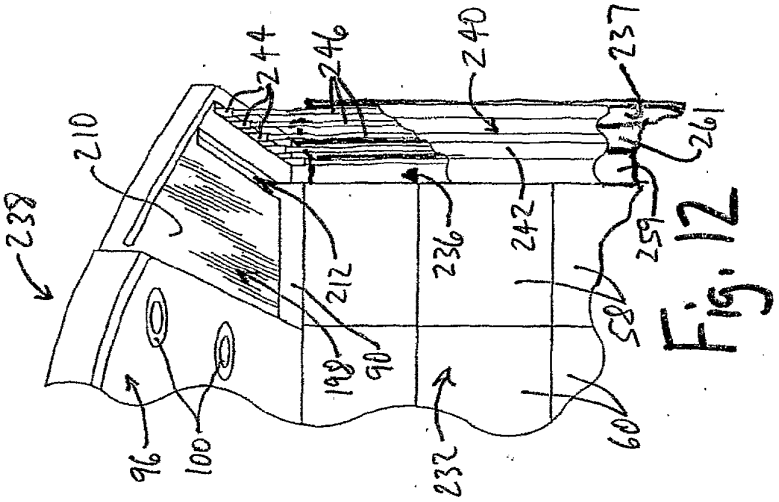
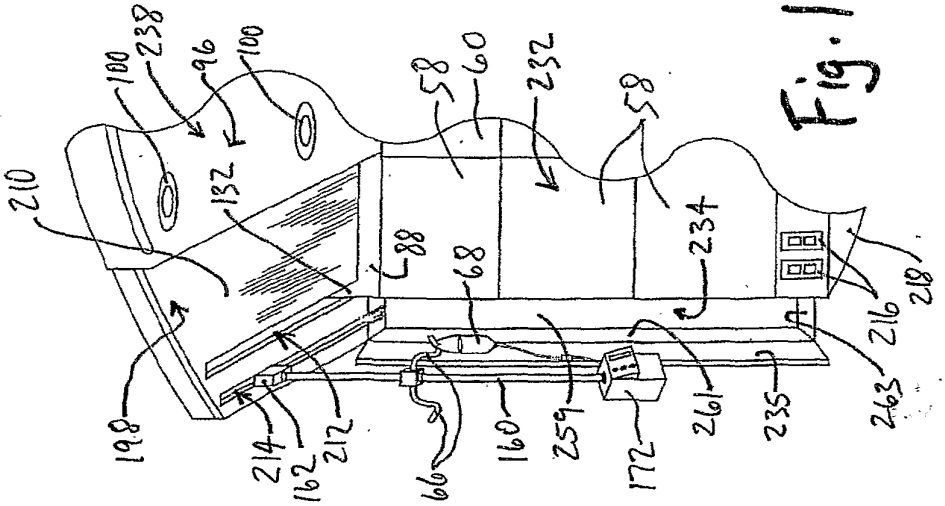



Fig. 12

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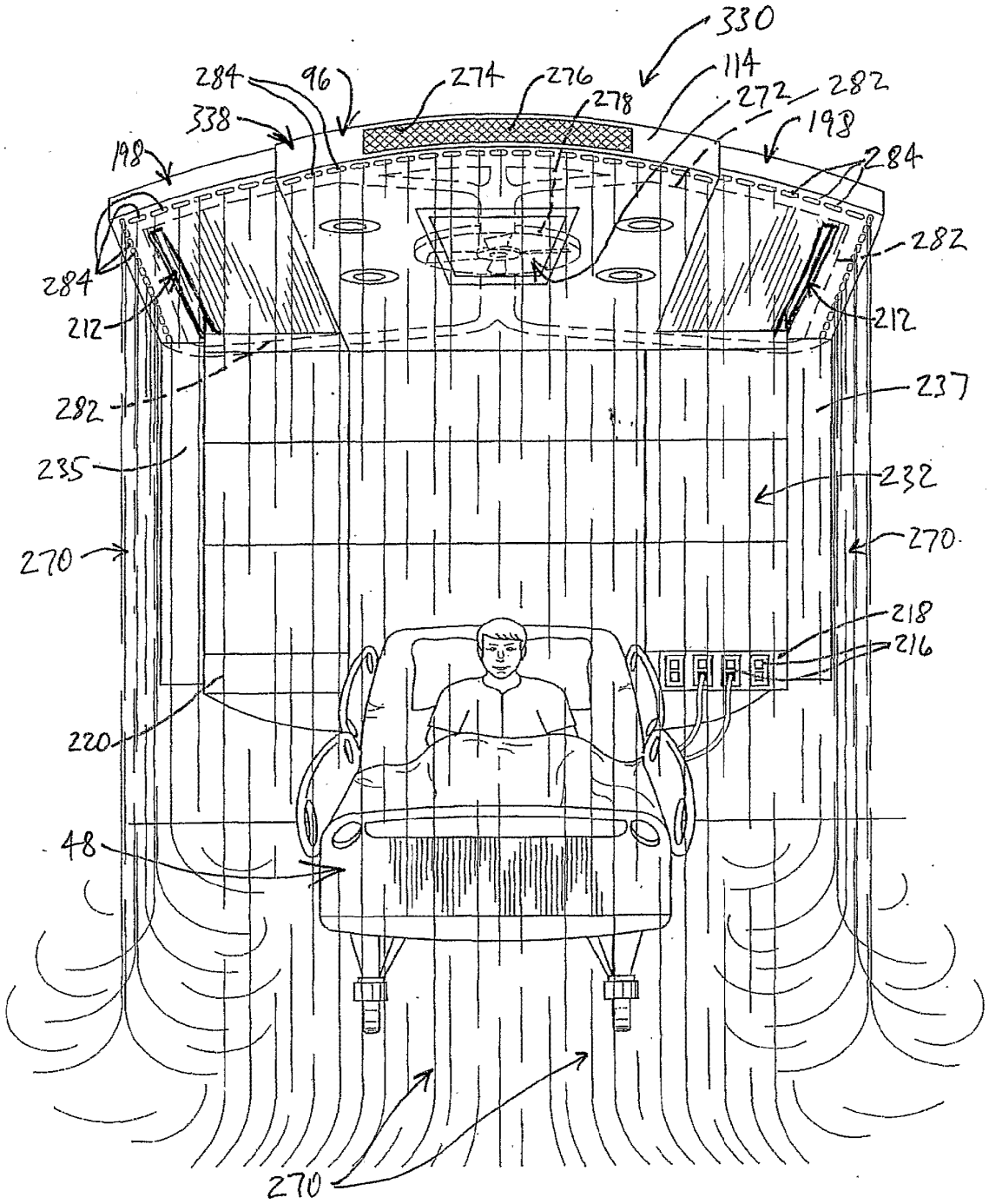
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Fig. 15

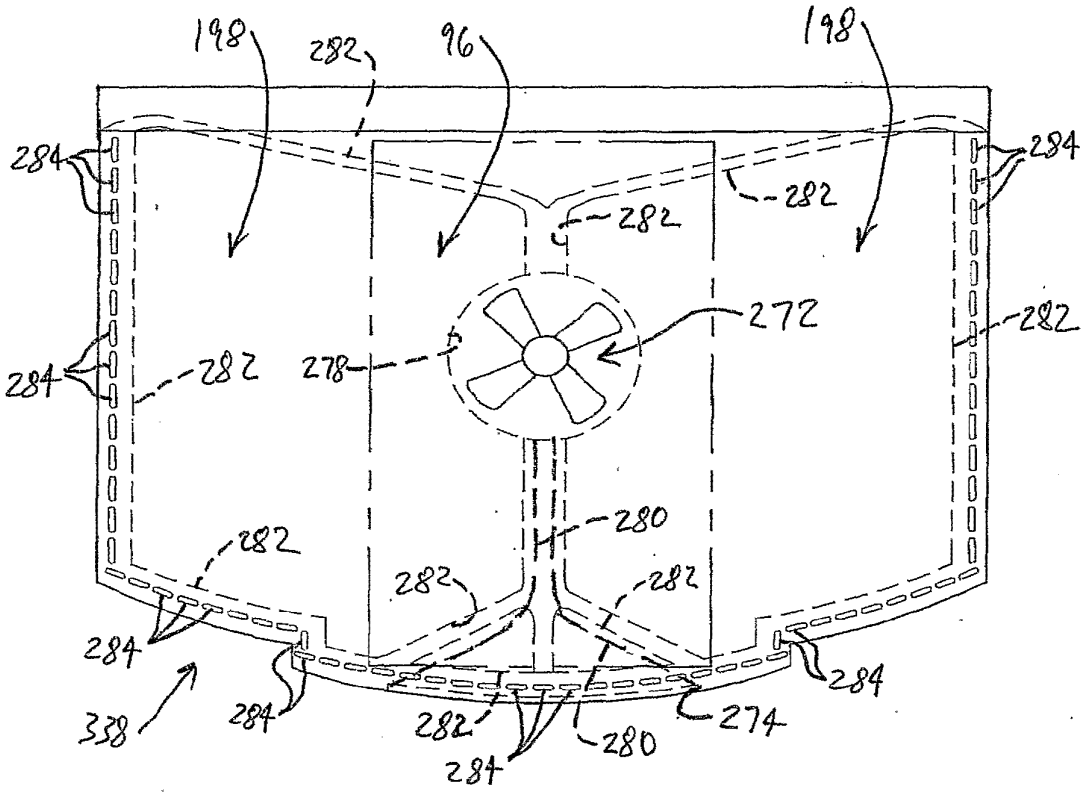
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Fig. 16

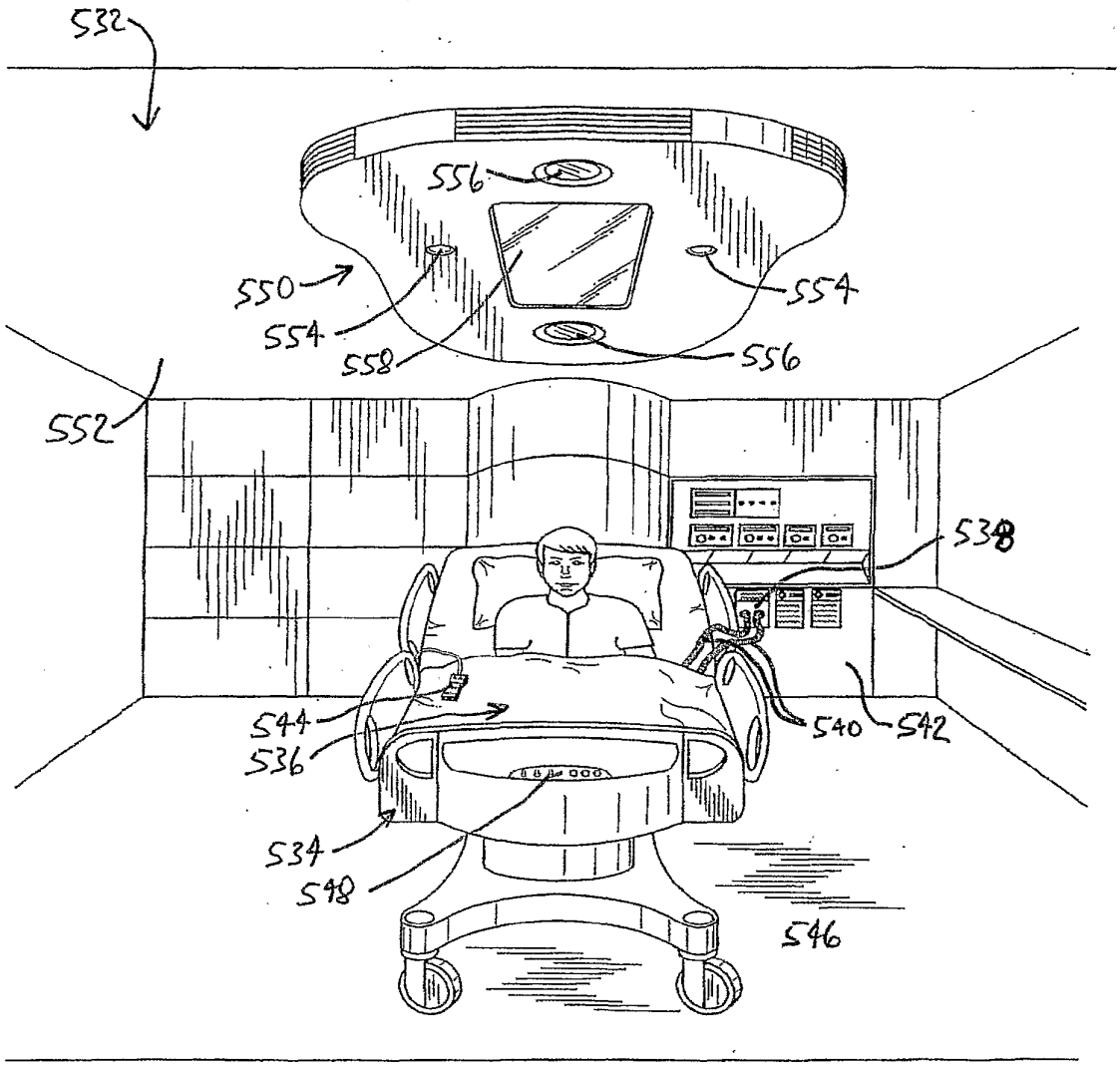


Fig. 17

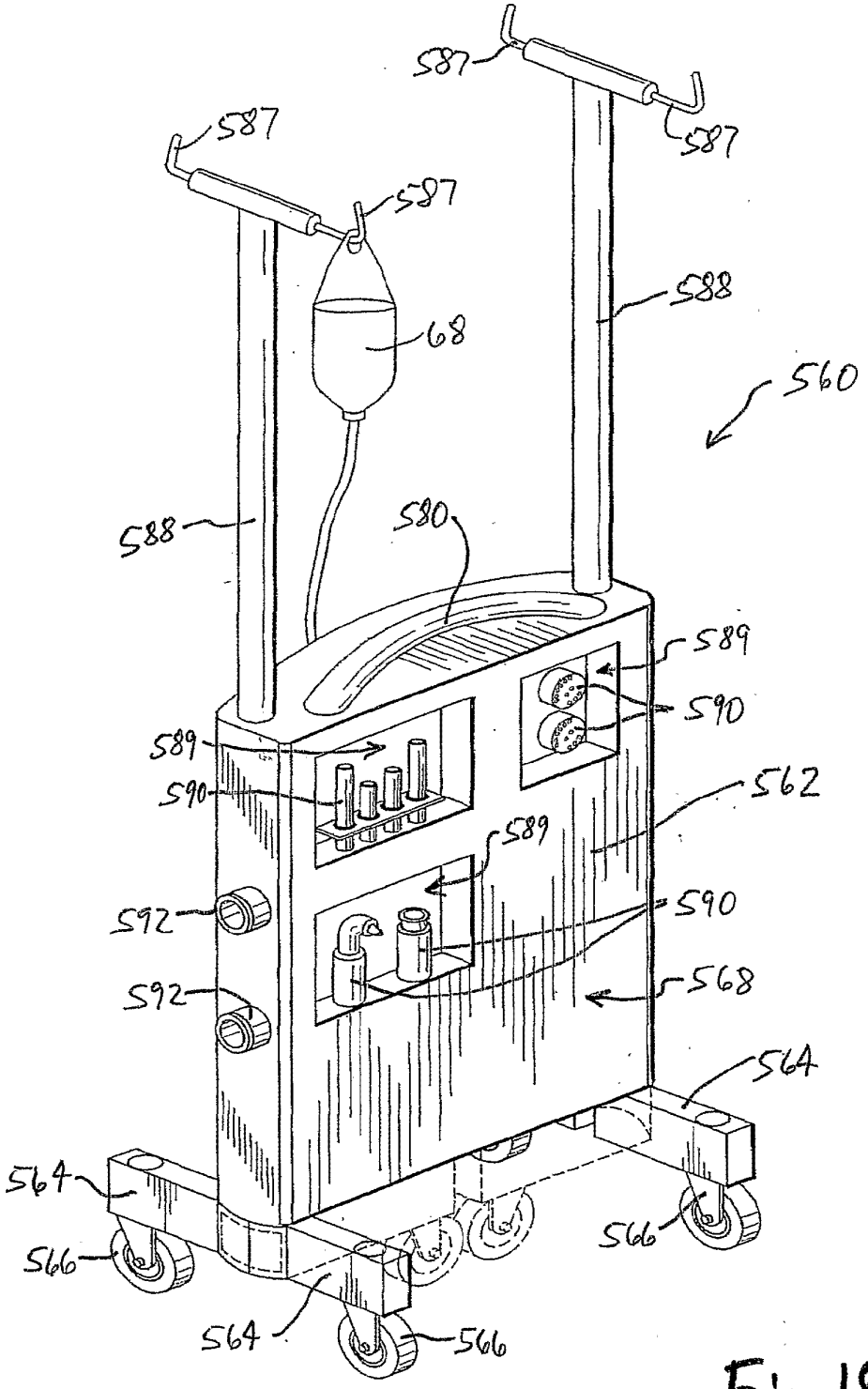
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Fig. 18

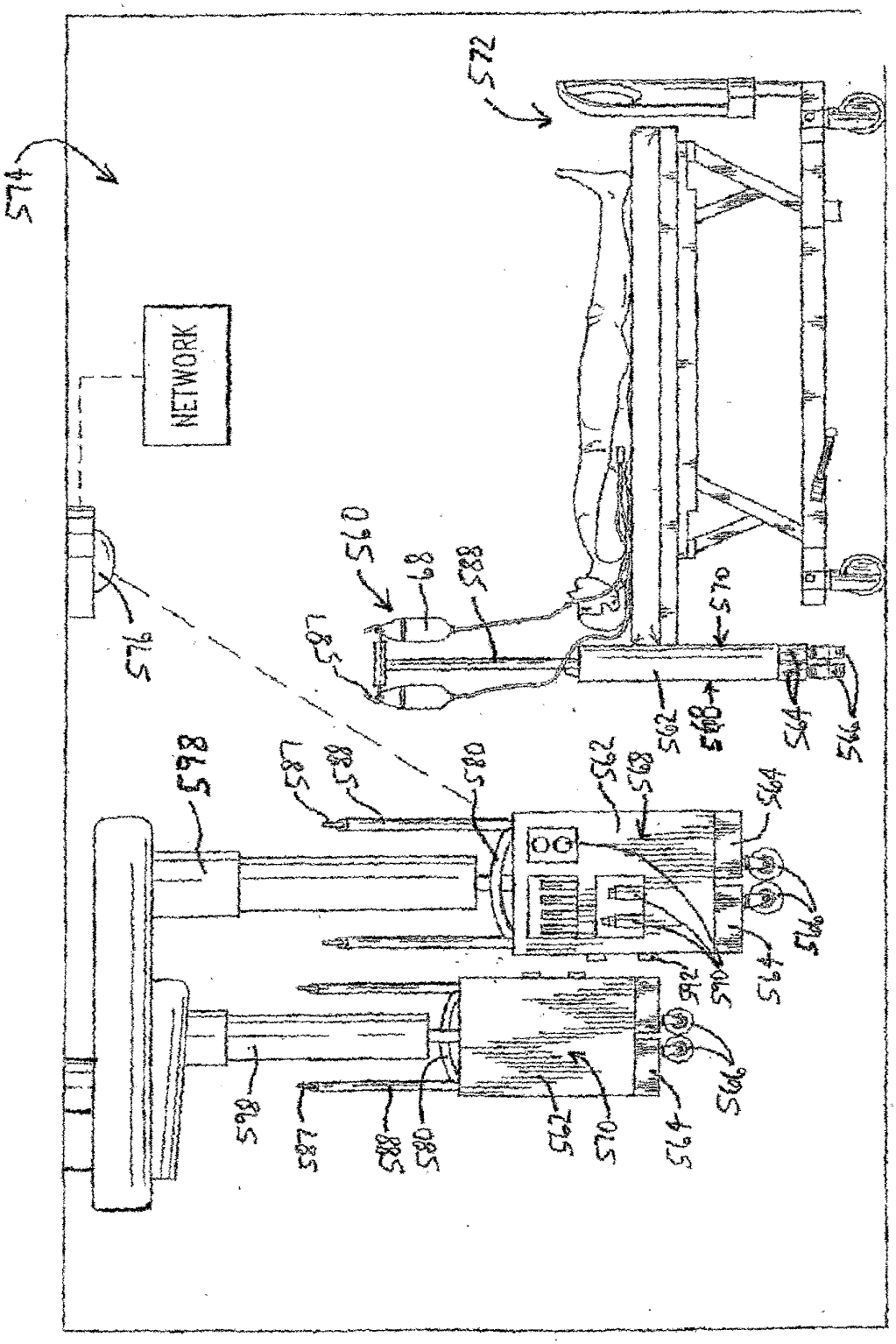
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Fig. 19

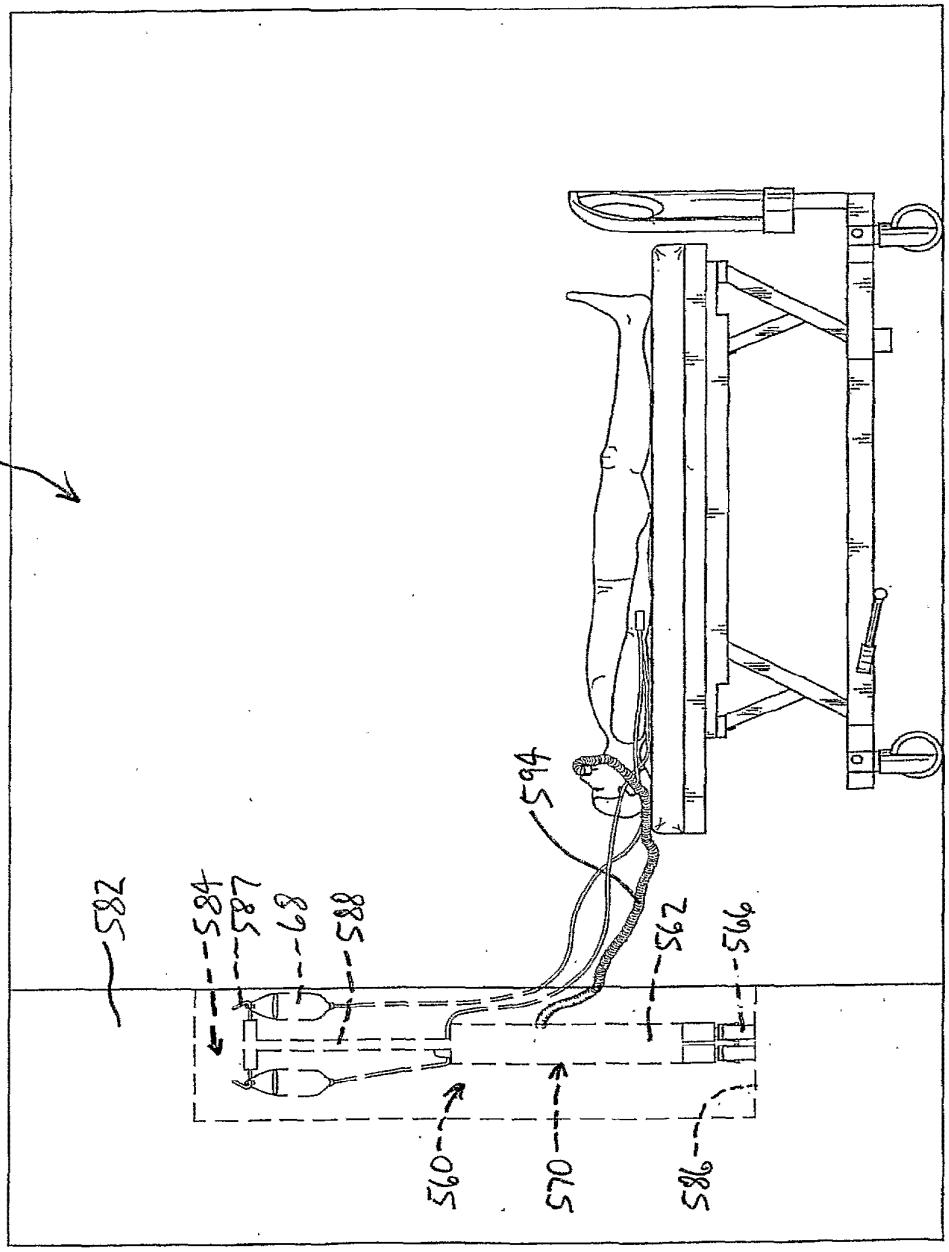
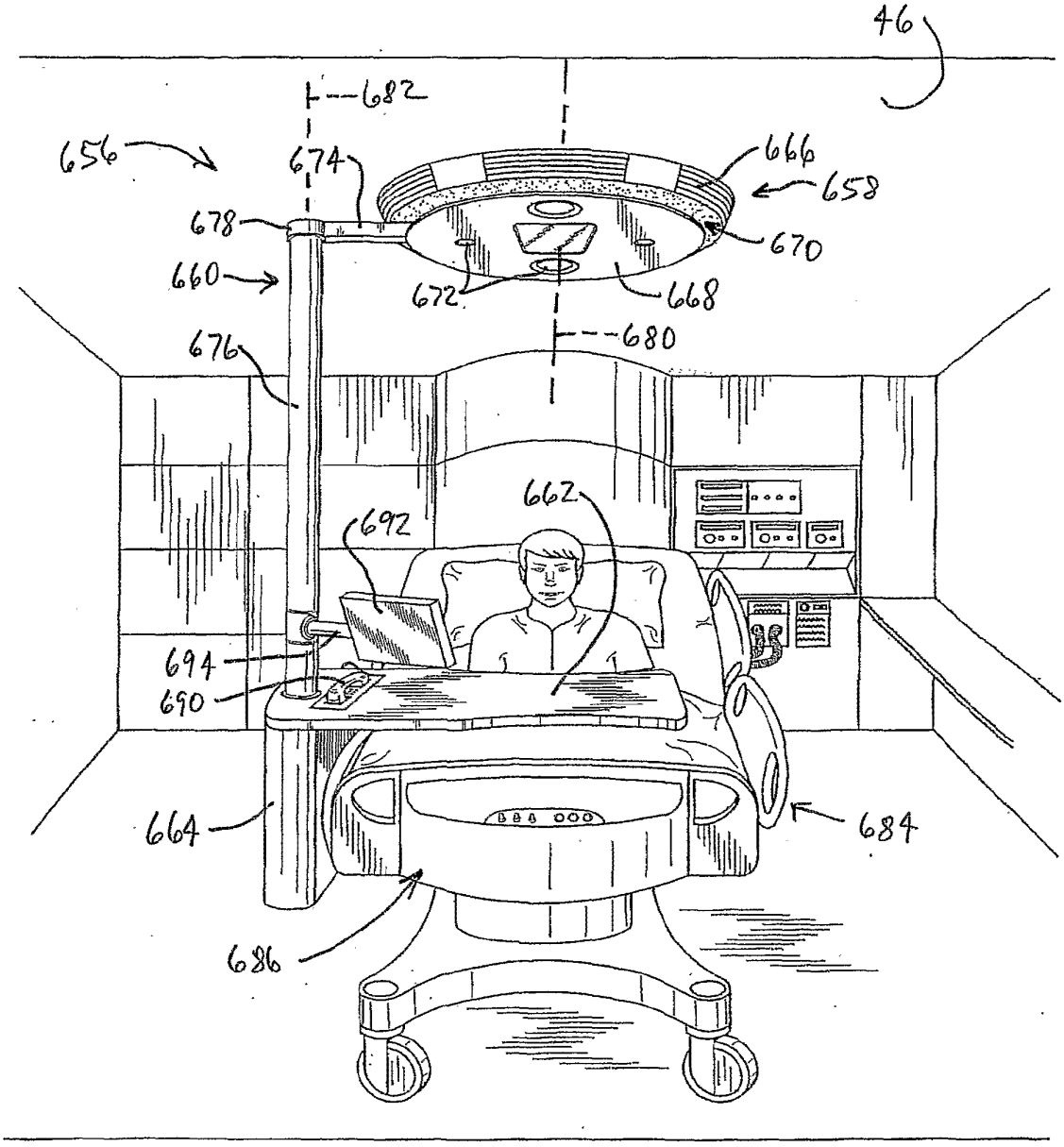



Fig. 20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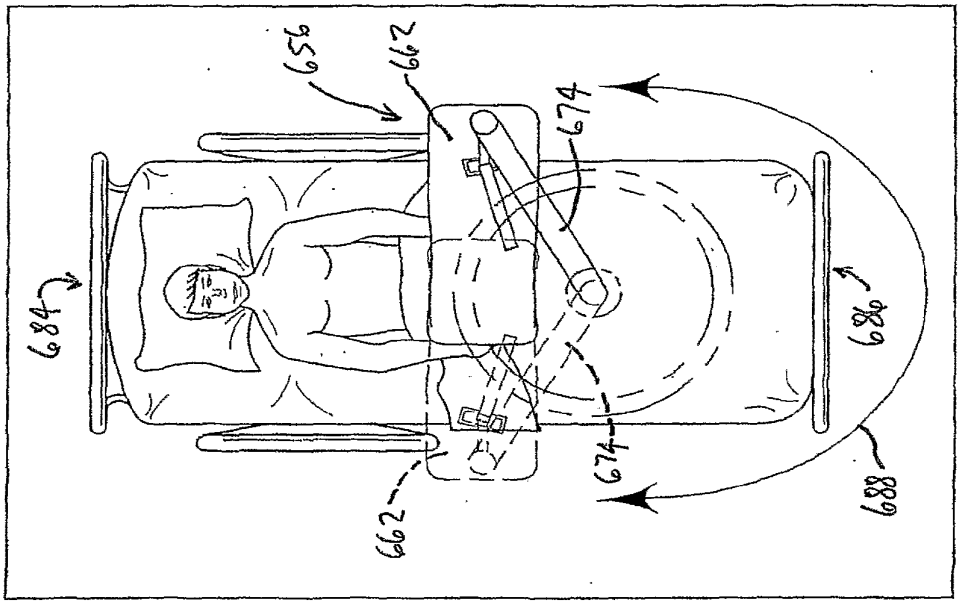
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Fig. 23

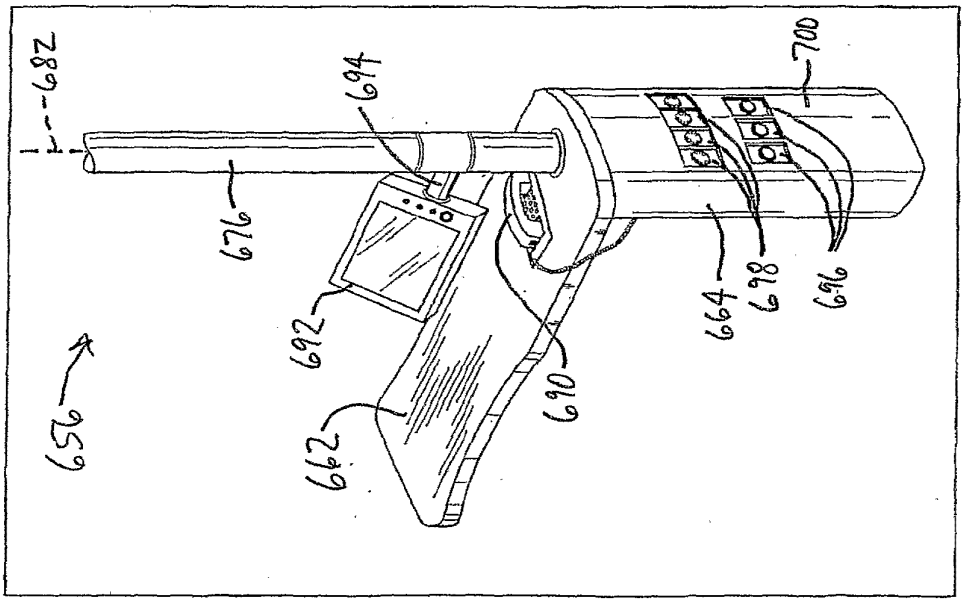
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Fig. 22

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 July 2006 (13.07.2006)

PCT

(10) International Publication Number
WO 2006/074473 A2

(51) International Patent Classification:
*B62M 1/00* (2006.01) *A61H 3/00* (2006.01)

(21) International Application Number:
PCT/US2006/000893

(22) International Filing Date: 10 January 2006 (10.01.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/642,836 10 January 2005 (10.01.2005) US

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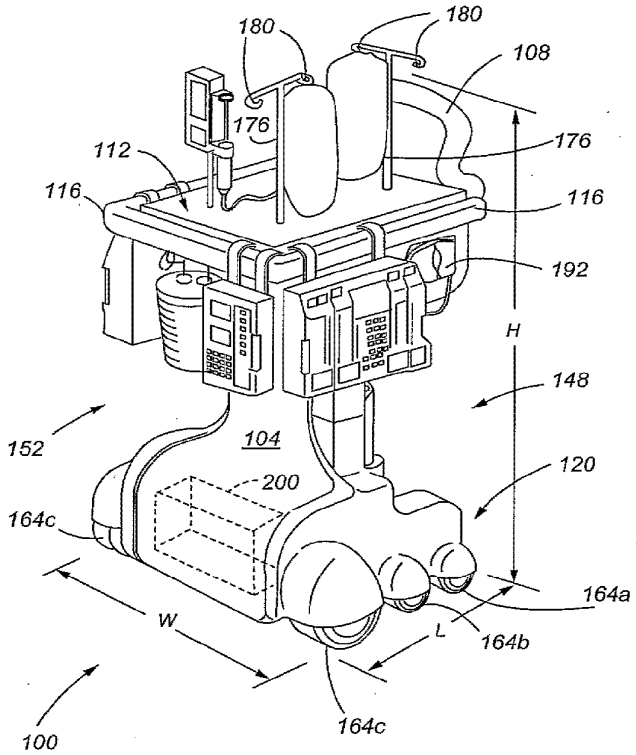
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),

*[Continued on next page]*

(54) Title: MODULAR PATIENT SUPPORT SYSTEM




(57) Abstract: A patient support platform provides a solution for healthcare facilities and nursing staff to address patient and staff safety, patient mobility, patient comfort, the availability of patient information, monitoring drugs and therapy provided, and controlling health care expenses. The patient support platform preferably includes a transmission system that allows the patient and/or medical staff member to choose a stop, walk or roll mode. The transmission system preferably includes a drag wheel for applying a braking force in response to a voltage generated by a braking motor. The platform supports a plurality of devices that may be attached or associated with a patient throughout their stay at a healthcare facility. The support platform also preferably includes a mechanism for releasably attaching the support platform to another structure, such as a bed. Embodiments of the present invention include multiple non-medical uses of the platform.

WO 2006/074473 A2

European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— *without international search report and to be republished upon receipt of that report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# MODULAR PATIENT SUPPORT SYSTEM

## FIELD OF THE INVENTION

The present invention is directed to an apparatus used in the field of medicine, and more particularly, to a moveable and modular patient support system with a relatively small form factor.

## BACKGROUND OF THE INVENTION

Current practice for patients in a healthcare facility involves having multiple unrelated treatment, maintenance and/or monitoring devices that are attached to the patient. These include intravenous fluids and drugs, drainage catheters, suction catheters, leg compression stockings and vital sign monitoring devices. Such devices often create a hazard for the patient both directly and indirectly. The myriad of devices may become entangled and inadvertently removed if not adequately accounted for by the patient or caregiver. This may require an invasive intervention, including surgery, in order to replace the removed device.

The number of devices generally associated with the patient require the patient to have the physical and mental ability to manage organizing or carrying the devices to ambulate even as far as the bathroom. Since patients are debilitated by the nature of their illness and medications, two staff persons are frequently required to help the patient move even short distances. One staff member must assist the patient, providing physical support, while the other manages the attached devices. The patients thus do not get out of bed and ambulate as often since the staff of the typical health facility is not able to provide this kind of support readily to all of the patients at all times.

The resulting immobility increases the patient's risk for deep venous thrombosis, pulmonary embolus and pneumonia. Additionally, mobility improves gut motility and decreases the time a patient must wait before obtaining enteral nutrition and ultimately discharge from the healthcare facility. Patients that require prolonged hospital stays or admission to skilled-nursing facilities for non-medical indications related to mobility and personnel support may be able to be discharged home sooner with a device that provides the

same type of care. The cost to the healthcare system may be reduced by decreasing the stays in expensive healthcare facilities and decreasing complications that are costly both in patient morbidity and monetary value.

The patient-care staff is also at risk for injury, as they must provide physical support to the debilitated patient. Back injuries are frequent in healthcare staff as a result of the physical nature of assistance provided. Allowing the patient to rely on an ambulatory assist device will help the patient-care staff as well by keeping them out of harm's way.

Current poles that provide an intravenous ("IV") fluid and/or liquid medication delivery source are often times taken with patients when the patient moves around, such as when a patient walks in a hospital hallway. The patient typically places at least one hand on the IV pole to move the IV pole while walking. However, typical IV poles are approximately 6 to 7 feet tall, and are often unstable for providing weight support to a patient, particularly when one or more substantially full IV bags are positioned near the top of the pole. As a result, a patient is at risk of further injury by falling if the IV pole tips and/or falls over. In addition, in order to prevent tipping, conventional IV poles have widely spread wheels, which require a large amount of floor space. IV poles are completely unable to manage uneven terrain as is found outside the confines of the patient care facility, and as may be found at home or in the field for disasters or military operations.

In addition to being relatively unstable, current IV poles do not provide for the additional needs of a patient that is moving about. For example, IV poles do not include an oxygen source for assisting the patient with breathing. Current IV poles also do not include various pumps or suction devices that may be necessary for continuous operation to provide proper medical treatment to the patient. In addition, vitals monitoring equipment and communication devices are typically not present on a standard IV pole. Furthermore, even if an IV pole is adapted to include a monitoring device or pump, the IV pole tends to become even more unstable because the resulting added weight of the device typically is positioned

relatively high along the pole.

In connection with patients that require assistance walking, various "walker" devices are available. A typical walker includes handrails interconnected to a stable base. However, because use of a walker usually requires both hands of the patient, a patient is typically unable to take an IV pole with them when using a walker.

A further difficulty exists when a patient needs to be moved from one room to another while in their bed. If the patient requires oxygen, an oxygen bottle must be provided, and is typically placed on the bed while moving the bed. This can create difficulties depending upon the size of the bed and the patient. Additionally, portable suction and vitals monitoring are not readily available for every patient. Accordingly, it would be advantageous to provide an apparatus that includes oxygen and other physiological support adjacent to the bed, wherein the apparatus can be attached to the bed while moving the bed. Such an apparatus would therefore also be advantageous to overcome the difficulty of maintaining monitoring equipment and/or IV fluids adjacent to the patient while moving the patient's bed. The efficiency of the staff will benefit since only a single staff member will be required to move a patient since a second staff member is not required to push the IV pole and attachments. This also prevents the need for the staff member to move the patient to a wheelchair for transfer as is currently often done in order for a single staff member to manage the transfer. Eliminating this move prevents an opportunity for a patient fall resulting in injury with only a single staff member assisting.

Patient care devices and services such as suction and oxygen are not built in to the facilities of several countries and regions. This is also true in field situations of military conflict or civilian disaster. Patients may be far from a medical facility or in the hallway of a medical facility not equipped with patient support equipment/services.

Yet a further difficulty exists in maintaining electrical power to electronic devices such as monitoring equipment, suction pumps and/or injection pumps while the patient is

walking with an IV pole or walker, or while the patient is being moved in their bed or while the patient is not located next to an electrical outlet. This may occur in: 1) the operating room while needing to adjust the bed height or keep the pumps charged during a long procedure, 2) during a disaster when patients may be stationed in hallways or temporary areas, 3) during military conflict or civilian situations that require creation of field hospitals with limited generator availability, and 4) in countries or regions that do not have consistent access to power. Accordingly, an apparatus that maintains electrical power to these devices would be advantageous, as would an apparatus that provides power in case of an electrical outage or blackout.

## SUMMARY OF THE INVENTION

The present invention solves the above-mentioned deficiencies by providing a mobile cart or platform that is structurally stable, and can thereby provide weight-bearing assistance to a patient without being predisposed to tipping over. In addition, the platform preferably includes one or more additional features, such as an oxygen source, power supply, injection pump, suction pump, body fluid collection devices, vital monitoring equipment, integrated IV pole and communication equipment.

In accordance with embodiments of the present invention, a modular patient support system is provided, wherein the support system typically resembles a platform, and includes a handrail interconnected to a base having three or more wheels. The support system or platform additionally may include a battery or uninterruptible power supply for serving as an emergency power supply, and/or for powering associated equipment, including the bed, while the patient is walking or being moved in a bed with the support system positioned adjacent the bed. The support platform also may include modular receptacles for receiving a variety of devices, including suction pumps, injection pumps, collection devices, monitoring equipment, and communication devices. An electrical wiring network may be provided such that the

modular devices interconnected to the support platform receive electrical power directly at the modular receptacles, thereby minimizing the presence of numerous power cords. Such additional equipment is powered by the uninterruptible power supply when the support platform is disengaged from a stationary power supply, such as an electrical wall outlet.

In accordance with other embodiments of the present invention, the support platform may include an on-board communication system to send monitoring information or other data to a nurses' PDA, central station or alarm system. The communication system may include wireless communication to transmit a patient's vitals, equipment status, fluid volumes, therapy status and location for providing information while a patient is using the support platform as a walking aid. An interface may be provided for the healthcare providers to be able to access and interact with the facility's electronic medical record system.

In accordance with other embodiments of the present invention, the support platform may include a checkpoint validation system to ensure the correct therapy is administered to the correct patient. This may involve identification of the patient, platform and therapy (such as intravenous fluids, medications or equipment) with devices such as barcodes, radiofrequency identifiers or other similar technology to match and track all therapy provided.

In accordance with other embodiments of the present invention, the support system also may also include an on-board oxygen supply and associated tubing. Additionally, the support platform may include an IV fluids/medication support assembly, such as an IV pole with an attachment hook.

The support platform may be configured in a variety of ways, to include a cabinet or other enclosure for holding items such as a urine collection bag, body fluid collection bag and suction canister. The configuration of the support platform also may include specially sized compartments for bottles or cups, and may include other built-in features such as a tray, radio, television, phone, computer or other communication device, wherein some of these devices may also be interconnected to the support platform's power supply.

In a separate aspect of the invention, an attachment device is provided for detachably attaching the support platform to another structure, such as the patient's bed. The attachment device may include an attachment adapter capable of being interconnected to a variety of bed frame structures, regardless of whether the framing includes square or round rails or posts. The attachment device not only secures the support platform to the bed so that it is not moved when accidentally bumped, but it also enables the support platform to be moved with the bed without the need for a separate attendant to move the support platform. In at least one embodiment, a plurality of bed hooks are used to enable the platform to grasp another object, such as a bed, when the bed is raised to impinge upon the underside of the bed hooks.

In a separate aspect of the invention, the support platform includes an umbilical cord having a common plug for interconnecting a plurality of systems to a single outlet, such as a wall outlet. The umbilical cord may support a variety of systems, including electrical power, oxygen, suction, and/or a communication connection.

In accordance with embodiments of the present invention, a locking brake may optionally be provided to limit movement of the platform if the brake is engaged. The brake may have mechanisms that engage it actively and/or passively. This may include a 'kill-switch' device that detects separation of the patient from the platform in situations that may result in patient injury if such event occurs.

In accordance with embodiments of the present invention, a transmission system may be provided to allow a user or other person to place the platform in one of a plurality of possible translation modes. In at least one embodiment, the transmission system includes stop, walk and roll modes. The stop mode engages a brake to contact the underlying surface, thereby substantially preventing the platform from rolling. In addition, in at least one embodiment, both a drag wheel and a brake are in contact with the floor when the platform is set in the stop mode. The walk mode includes raising the brake, if present, and engaging a drag wheel to contact the floor. Although not prevented from moving, the walk mode helps

prevent undesirable fast movement of the platform. In one embodiment, the drag wheel may comprise a wheel that is preset to turn at a very slow rate. Alternatively, in at least one embodiment the drag wheel may be interconnected to a braking motor, operated as a generator powered by the drag wheel, that applies a resistive force or an increased resistive force to the drag wheel when velocities increase above an undesirable level. For example, if a patient is standing adjacent the support platform and starts to slip while holding the handle of the platform, the braking motor will apply a resistive force to the drag wheel, thereby preventing the support platform from moving away from the patient and/or moving away from the patient at a high rate of speed. A variety of motor braking circuit configurations and braking functions are available for controlling the resistive force applied to the drag wheel using the braking motor. For example, a motor braking circuit may provide different resistive loads to the braking motor based on the velocity of the braking motor. In addition, the motor braking circuit does not require any source of power other than the power generated as a result of the rotation of the braking motor by the drag wheel. In the roll mode the transmission disengages both the brake and the drag wheel, such that the platform may be easily rolled. This setting is anticipated for use, for example, when an attendant is moving the platform.

Thus, in accordance with at least one embodiment of the present invention, a personal support platform for traversing an underlying surface is provided, the platform comprising a frame and a plurality of wheels interconnected to the frame. In addition, the platform comprises a transmission system interconnected to the frame, the transmission system providing a number of user selectable modes, the user selectable modes comprising at least a stop mode, a walk mode and a roll mode. Finally, in at least one embodiment, the platform further comprises a means for selectively choosing one of the stop, walk and roll modes by a user from a standing position adjacent the frame.

In a separate aspect of the invention, a transmission system of the platform comprises

a drag wheel that is selectively moveable from a first raised position in the roll mode to a second lowered position in the walk mode, and wherein the drag wheel is for contacting the underlying surface when in the second lowered position. In addition, in accordance with at least one embodiment, the transmission system comprises a cam interconnected to the frame and the drag wheel, wherein the cam is rotatably movable to raise and lower the drag wheel from the first raised position in the roll mode to the second lowered position in the walk mode. The transmission system may also further comprise an automatic brake interconnected to the drag wheel, wherein the automatic brake comprises a braking motor driven by the drag wheel and circuitry, wherein the circuitry provides a resistive load to the braking motor to apply a braking force on the drag wheel. In addition, in at least one embodiment, the resistive load comprises a number of load ranges, wherein a first load range provides a first resistive load within a first velocity range for the braking motor, and wherein a second load range provides a second resistive load within a second velocity range for the braking motor. Also, the second velocity range may be automatically selected once a threshold velocity of the braking motor is reached.

In a separate aspect of the invention, a transmission system of the platform may comprise a brake interconnected to the frame, wherein the brake is selectively moveable from a first raised position in the walk and roll modes to a second lowered position in the stop mode, and wherein the brake is for contacting the underlying surface when in the second position. In at least one embodiment, the brake comprises a stopper frictionally engaging the underlying surface. In yet a separate aspect of the invention, the platform may comprise a cam having a first channel interconnected to the brake. In at least one embodiment of the invention, the cam comprises a second channel interconnected to a drag wheel. In accordance with at least one embodiment of the invention, the first channel comprises a first ramp for raising and lowering a first post interconnecting the drag wheel to the cam, and wherein the second channel comprises a second ramp for raising and lowering a second post

interconnecting the stopper to the cam.

In a separate aspect of the invention, a means for selectively choosing the mode of the transmission system comprises a first handle at a rear portion of the frame, wherein the handle is selectively adjusting a setting of the transmission system. In at least one embodiment, the transmission system may further comprise a second handle at a front portion of the frame, wherein the second handle can also be used for selectively adjusting a setting of the transmission system.

In a separate aspect of the invention, the platform comprises at least one grasping mechanism for interconnecting the frame to another structure. In at least one embodiment of the invention, the grasping mechanism comprises a rotatable gripper arm that engages the other structure. In addition, in at least one embodiment, the rotatable gripper arm rotates about a first axis in a direction away from the frame, and rotates about a second axis to grasp the other structure, wherein the second axis is transverse to the first axis.

It is a further aspect of the present invention to utilize a variety of devices to provide functionality to a personal support platform. Accordingly, in at least one embodiment of the present invention, a personal support platform for traversing an underlying surface is provided, comprising a frame and means for rotating interconnected to said frame and contacting the underlying surface. The platform further comprises means for frictionally engaging the underlying surface and interconnected to said frame; and means for variably controlling a resistance provided by said means for frictionally engaging. In at least one embodiment of the invention, the means for rotating comprises a plurality of wheels. In addition, it in at least one embodiment of the invention the means for frictionally engaging comprises a drag wheel. In accordance with at least one embodiment of the invention, the means for frictionally engaging is interconnected to a means for adjusting a position of said means for frictionally engaging, wherein said means for adjusting may alter a position of said means for frictionally engaging from a first position in contact with the underlying surface to

second position wherein said means for frictionally engaging does not contact the underlying surface. In at least one embodiment of the invention, the means for adjusting comprises a selectably positionable cam for raising and lowering said means for frictionally engaging. In addition, in at least one embodiment of the invention the means for variably controlling a resistance comprises a passive braking motor. In a separate aspect of the invention, the passive braking motor comprises a motor braking circuit interconnected to the passive braking motor. In at least one embodiment, the braking circuit includes a first circuit stage, including a switching mechanism, wherein an activation voltage for the first circuit stage is defined. The circuit also includes, a load resistor, wherein when the passive braking motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or greater than the activation voltage and above a current is allowed to pass through the load resistor.

As noted above, embodiments of the present invention may comprise a braking system. Thus, in accordance with at least one embodiment of the invention, a passive variable braking system is provided, comprising:

a motor;

a motor braking circuit interconnected to the motor, including:

a first circuit stage, including:

a switching mechanism, wherein an activation voltage for the first circuit stage is defined; and

a load resistor, wherein when the motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or greater than the activation voltage and above a current is allowed to pass through the load resistor.

In a separate aspect of the invention, the motor braking circuit of the passive variable braking system further comprises:

a second circuit stage in parallel with the first circuit stage, the second circuit stage including:

a switching mechanism, wherein an activation voltage for the second stage is defined;

a load resistor, wherein when the motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or greater than the activation voltage and above a current is allowed to pass through the load resistor, wherein the activation voltage for the second stage is greater than the activation voltage for the first stage, and wherein when the activation voltage for the second stage is met or exceeded a current continues to be allowed to pass through the load resistor of the first circuit stage.

In yet a separate aspect of the invention, the passive variable braking system further comprises:

a switch, wherein the first and second circuit stages comprise a number of load resistors, wherein the switch is operable to select one of each of the load resistors included in the first and second circuit stages to provide a selected resistance at the motor.

In a separate aspect of the invention, the motor braking circuit of the passive variable braking system further comprises:

a second circuit stage in parallel with the first circuit stage, the second circuit stage, including:

a switching mechanism, wherein an activation voltage for the second stage is defined; and

a load resistor, wherein when the motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or greater than the activation voltage and above a current is allowed to pass through the load

resistor, and wherein the activation voltage for the second stage has a polarity that is opposite the activation voltage for the first stage.

In a separate aspect of the invention, the switching mechanism of the passive variable braking system comprises a zener diode.

In a separate aspect of the invention, the switching mechanism of the passive variable braking system comprises a pair of voltage dividing resistors and a transistor, wherein a voltage divided by the pair of resistors is provided to a gate of the transistor.

In yet a separate aspect of the invention, the switching mechanism of the passive variable braking system comprises a resistor interconnected to a Silicon Controlled Rectifier.

In yet a separate aspect of the invention, the passive variable braking system further comprises a drag wheel interconnected to the motor, wherein the motor is driven by the drive wheel. In yet a separate aspect of the invention, the drive wheel is interconnected to the motor by a gearbox.

In still yet a separate aspect of the invention, the switching mechanisms of the passive variable braking system of the first and second circuit stages each comprise a zener diode, and wherein the first and second stages each additionally include a blocking diode.

It is a separate aspect of the present invention to provide a method of using a support platform that comprises one or more features of the device described herein. Accordingly, a method of using a personal support platform is provided, the method comprising selecting a transmission mode for a transmission system operably associated with the personal support platform, wherein the transmission system provides a number of user selectable transmission modes, and wherein the user selectable transmission modes comprise at least a stop mode, a walk mode and a roll mode. In accordance with at least one embodiment of the present invention, the personal support platform for use includes a frame, a plurality of wheels interconnected to the frame, and a transmission control device operably interconnected to the transmission system, the transmission control device adapted for allowing a user to selectively

choose one of the stop, walk and roll modes. In the method of use, the selecting step comprises manipulating the transmission control device to one of the stop, walk and roll modes. In addition, in at least one embodiment, the manipulating step comprises moving a control bar operably interconnected to the frame and a cam, wherein the control bar controls positions of a drag wheel and a brake that are operably interconnected with the cam. In a separate aspect of the invention, in at least one embodiment the method of use also comprises inducing a braking force on the drag wheel by at least temporarily increasing a velocity of the frame, wherein the resistive force is imposed by an automatic brake interconnected to the drag wheel, wherein the automatic brake comprises a braking motor driven by the drag wheel and circuitry, and wherein the circuitry provides a resistive load to the braking motor to apply a braking force on the drag wheel. In addition, in at least one embodiment, the method also comprises releasably connecting the platform to another structure using at least one grasping mechanism interconnected to the frame, and may further comprise impinging at least a portion of the other structure against the rotatable gripper arm.

In accordance with embodiments of the present invention, a method of using a personal support platform is provided comprising: providing a drag wheel interconnected to the platform, the drag wheel for contacting a surface under the platform; positioning the drag wheel to contact the surface under the platform; and applying a braking to the platform through the drag wheel by applying at least a first braking resistance to the drag wheel for at least a first velocity range of the drag wheel. In at least one aspect of the invention, the method may further comprise providing at least a second braking resistance to the drag wheel for at least a second velocity range of the drag wheel. In another aspect of the invention, the second velocity range is automatically selected once a threshold velocity of a braking motor is reached. In accordance with at least one embodiment of the invention, the positioning step of the drag wheel further comprises manipulating a transmission control device to lower the drag wheel in contact with the surface under the platform. The method may further comprise

engaging a stopper to contact the surface underlying the platform. In addition, the method may comprise releasably connecting the platform to another structure using at least one grasping mechanism interconnected to the platform. In accordance with at least one embodiment of the invention, the step of releasably connecting the platform to another structure may also comprise impinging at least a portion of the other structure against a portion of the grasping mechanism.

Various embodiments of the present invention are set forth in the attached figures and in the detailed description of the invention as provided herein and as embodied by the claims. It should be understood, however, that this Summary of the Invention may not contain all of the aspects and embodiments of the present invention, is not meant to be limiting or restrictive in any manner, and that the invention as disclosed herein is and will be understood by those of ordinary skill in the art to encompass obvious improvements and modifications thereto.

Additional advantages of the present invention will become readily apparent from the following discussion, particularly when taken together with the accompanying drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an apparatus in accordance with embodiments of the present invention;

Fig. 2 is a perspective view of another apparatus in accordance with embodiments of the present invention;

Fig. 3 is a front elevation view of yet another apparatus in accordance with embodiments of the present invention;

Fig. 4 is a front perspective view of the platform shown in Fig. 3;

Fig. 5 is a rear perspective view of the platform shown in Fig. 3;

Fig. 6 is a rear perspective view of the platform shown in Fig. 3, wherein the platform

is shown without a surface layer;

Fig. 7 is a bottom view of the wheels of the platform shown in Fig. 3;

Figs. 8 and 9 are bottom views of alternate wheel orientations and platform base shapes;

Fig. 10 is a partial enlarged rear perspective view of an upper portion of the platform shown in Fig. 3;

Figs. 11A and 11B are side elevation views of an embodiment of a bed hook;

Figs. 12-14 are side elevation views of the bed hook of Figs. 11A and 11B in various operable positions with a bed;

Fig. 15 is a transparent rear perspective view of the platform shown in Fig. 3, wherein the platform structure is superimposed over an embodiment of a transmission system;

Fig. 16 is a partial enlarged rear perspective view of the platform shown in Fig. 15, wherein the handle of the transmission control mechanism is shown in its alternate positions;

Fig. 17 is a perspective view of alternate positions of the transmission control mechanism shown in Fig. 15;

Fig. 18 is an enlarged perspective view of a portion of the device shown in Fig. 17;

Fig. 19 is a perspective view of a portion of the transmission system shown in Fig. 15;

Fig. 20 is an enlarged side elevation view of the device shown in Fig. 19;

Fig. 21 is perspective view of an alternate embodiment of the device shown in Fig. 19;

Figs. 22-25 are various embodiments of motor braking circuits associated with the automatic braking system feature;

Fig. 26 is a braking force to velocity diagram associated with the automatic braking system feature; and

Fig. 27 is a schematic depiction of components that may be included in embodiments

of the present invention.

## DETAILED DESCRIPTION OF THE INVENTION

In accordance with embodiments of the present invention, a platform is provided that has application for use in a variety of fields, one of which is in the field of health care. Various embodiments of the platform may include an ergonomic structure suited for a patient to use the platform as a walking aid. In addition, embodiments of the invention may also comprise structure for accommodating on-board health monitoring and/or treatment equipment. These and other features are described in detail below.

Referring now to Fig. 1, an apparatus constructed in accordance with an embodiment of the present invention is generally identified by reference numeral 100. Support platform 100 includes a chassis, support frame or body 104 having a platform handle 108 located at or near a top 112 of the platform 100. The platform 100 also includes a perimeter rail 116 at its top 112, wherein the perimeter rail 116 is adapted for receiving a variety of health monitoring, treatment, or maintenance devices, such as equipment currently available for these purposes. The platform 100 further includes a base 120 described in further detail below.

Referring now to Fig. 2, an embodiment in accordance with the present invention is depicted wherein support platform 100' internalizes at least one of a number of ancillary devices that may be associated with the platform, and more preferably, the platform 100' internalizes a plurality of such ancillary devices. Accordingly, the support platform 100' preferably includes one or more modular receptacles 124 for items such as suction pumps, IV pumps, infusion pumps, and/or monitoring equipment. In addition, the support platform 100' may further included a receptacle or port for a personal computer 128. The receptacles replace the current pump technology and incorporate the devices into the platform to reduce its profile, overall weight and simplify the total set of devices attached to the patient.

Referring now to Figs. 3-5, an embodiment in accordance with the present invention

is depicted as support platform 100″. Support platform 100″ features a substantially open top 112 with a pair of elevated rails 132. In accordance with embodiments of the present invention, the perimeter of the top 112 includes a skirt 136 with one or more openings 138 for receiving hooks or other connecting hardware to attach a variety of health monitoring, maintenance and/or treatment devices.

Thus, embodiments of the present invention may comprise a substantially open configuration, as shown in Fig. 1 as support platform 100, or a modular and substantially internalized configuration, as shown in Fig. 2 as support platform 100′, or an alternate configuration having interior cabinet space with a substantially open top 112, as shown in Figs. 3-5 as support platform 100″, or other configurations, all of which are encompassed by the present invention and this description. Although support platforms 100, 100′, 100″ may have a variety of different features, they may also share similar structure and have various combinations of features. The following text and associated referenced drawings describe features that may be used individually or in combination for various embodiments of the present invention.

Referring to Figs. 1-3, support platform 100, 100′, 100″ include a body 104 having a height H. Height H is preferably a sufficient height for allowing a patient to stand and grasp platform handle 108 at the top 112 of the support platform 100, 100′, 100″ to aid the patient in support and/or balance while walking or standing. Height H is preferably adjustable, thereby allowing the support platform 100, 100′, 100″ to be modified to accommodate the height of the patient. Since patients vary from small children to large adults, the height H of the support platform 100, 100′, 100″ pertains to a functional aspect of the invention. Accordingly, the body 104 may include an adjustable or telescoping means for selectively varying the height H of body 104. The telescoping means may include one or more adjustable columns, and/or otherwise include interchangeable columns 140, such as those shown in Fig. 6, wherein Fig. 6 depicts a skeletonized view support platform 100″. In

accordance with embodiments of the present invention, the columns 140 allow for adjustment of the height of the platform. Further, and in accordance with other embodiments of the present invention, one or more spacers 144 may also be incorporated into the body 104 of the support platform 100, 100′, 100″, wherein each spacer 144 serves to add additional height. In at least one embodiment, the spacer 144 comprises a supplemental height member having a thickness of between about 1-6 inches, and more preferably between about 2 to 4 inches. For the various embodiments of the present invention, the height H of the support platform 100, 100′, 100″ is between about 24 and 48 inches tall, and more preferably, between about 30 and 40 inches tall. However, other heights for short, tall and physically challenged individuals, and/or for platforms having other uses other than in the health care field are all within the scope of the present invention.

As noted above, the frame 104 of support platform 100, 100′, 100″ preferably includes a base 120, wherein the base has a stable configuration for supporting both the items on the support platform 100, 100′, 100″, as well as being able to support the added weight of a patient leaning on the platform handle 108. Accordingly, the base 120 is relatively large, but not too large so as to be clumsy to manipulate. For the embodiments shown in Figs. 1-5, the base 120 is substantially rectangular in shape, with a width W and a length L. For a rectangular base 120, the width W is preferably between about 16 to 28 inches wide, and more preferably between about 18 to 24 inches wide. The length L is preferably between about 16 to 28 inches long, and more preferably between about 18 to 24 inches long. However, it is to be understood that the base 120 may be a variety of shapes and configurations. For example, the base 120 may have a footprint that is substantially circular or hexagonal in shape.

As best seen in Fig. 6, the base 120 has a rear portion 148 and a front portion 152. Rear portion 148 preferably includes spaced apart base beams 156. The base beams 156 are preferably spaced apart to provide a preferential unobstructed area or opening 160 for the

patient to place their feet while holding the platform handle 108 and walking. Accordingly, the base beams 156 are preferably spaced apart a distance D, where distance D preferably varies between about 10 inches and 24 inches, and more preferably between about 14 inches and 20 inches. Providing a properly sized spaced apart distanced D provides for increased safety for the patient so that the patient does not trip when walking with the support platform 100, 100′, 100″.

In accordance with other embodiments of the invention, the base 120 may not be directional, or alternatively, the direction may be determined by the user to maximize the benefit of the wheel design to their health and expected use. For example, the wheel configuration may benefit weaker patients to overcome small obstacles when the base is oriented in a first direction. Conversely, healthier patients that expect to travel farther and faster may find that they have better control of the invention by changing the direction of the platform by 180°.

The base 120 preferably includes a plurality of casters or wheels 164. More preferably, the base 120 includes at least three wheels set in a triangular orientation, and more preferably yet, at least four, five or six wheels spaced apart in various configurations along the bottom of the footprint of base 120. As seen in Fig. 6, and in accordance with embodiments of the present invention, at least some of the wheels 164 preferably include a swivel connector 172 between the wheel 164 and the base 120 of support platform 100, 100′, 100″. For example, the middle pair of wheels 164b and the rear pair of wheels 164a (interconnected by the base beams 156) may include swivel connectors 172, while the orientation of the front wheels 164c may be fixed. Alternatively, all wheels 164 may have a swivel connector 172 between the wheel 164 and the base 120.

Referring now to Fig. 7, the underside of base 120 of a first preferred embodiment is illustrated. Base 120 is shown having a substantially C-shaped overall footprint when viewed from a side of the support platform 100, 100′, 100″. In accordance with at least one

embodiment of the present invention, the base 120 comprises six wheels 164 that provide a means for rotating that is interconnected to the frame and contacting the underlying surface, such as a floor surface. A first pair of wheels 164a is preferably positioned under beams 156 at the rear portion 148 of the base 120, such that one wheel 164a is under a left base beam 156 and another 164a is under the right base beam 156. In addition, a second pair of wheels 164b is preferably positioned at an intermediate position along the length of the support platform 100, 100′, 100″, such as along a mid-axis MA-MA of base 120. Again, one wheel 164b is preferably located under the left side of the platform, and another wheel 164b is located under the right side of the support platform 100, 100′, 100″. Finally, a third set of wheels 164c is preferably located toward a front portion 152 of the support platform 100, 100′, 100″. In at least one embodiment of the invention, the front wheels 164c are set closer to a center longitudinal axis C-C of the platform as compared to the first and second pairs of wheels 164a, 164b at the rear and intermediate positions along the support platform 100, 100′, 100″. In accordance with at least one embodiment of the invention, the third set of wheels 164c preferably comprise a larger diameter than at least one of the first pair of wheels 164a and the second pair or wheels 164b. In addition, for the wheel configuration shown in Fig. 7, the first wheels 164a on the right and left sides are substantially equidistant from the center longitudinal axis C-C as the second wheels 164b on both the right and left sides of the support platform 100, 100′, 100″.

Referring now to Figs. 8 and 9, and in accordance with embodiments of the present invention, alternative arrangements of the wheels 164 are within the scope of the present invention. Fig. 8 depicts a configuration wherein the wheels 164a, 164b, and 164c are all equidistant from the center longitudinal axis C-C of the support platform 100, 100′, 100″. With regard to Fig. 9, a modified shape of the base is shown as base 120'. Base 120' is shown with five wheels 164, wherein the base 120' has a substantially circular footprint but with an arcuate shaped opening 160 bounded by an arcuate shaped front base portion 168 for the

patient's feet as they walk with the support platform 100, 100′, 100″. Other configurations of the base are considered within the scope of the present invention.

In accordance with various embodiments of the present invention, the wheel positions includes alternate configurations designed to best address the issues of overcoming a raised obstacle such as a carpet/tile transition or door threshold, spanning a gap such as an elevator threshold, maintaining extreme maneuverability in areas with limited space, and maintaining directional tracking to aid with control as a patient ambulates. Accordingly, the alternative wheel configurations of the present invention provide for advantageous maneuverability and stability, and thus increased safety for the patient using the support platform 100, 100′, 100″.

The wheels 164 are preferably sized to provide added stability to the support platform 100, 100′, 100″. Accordingly, wheels 164 are preferably between about 2 to 10 inches in diameter, and more preferably between about 3 to 9 inches in diameter, and more preferably yet, a combination of wheels with the smaller wheels 164a, 164b measuring about 3 to 5 inches in diameter and the larger wheels 164c measuring about 7 to 8 inches in diameter.

Referring again to Figs. 1-3, the platform handle 108 is an integral part of the support platform 100, 100′, 100″. In at least one embodiment of the invention, the handle 108 comprises a particular ergonomic design that allows the user to push and use the platform while their hands are kept in a comfortable position. The design also minimizes the ability of the user to tip the platform when applying a force to the platform handle 108.

In accordance with another aspect of the invention, the support platform 100, 100′, 100″ includes a platform top 112 for holding a number of optional components (also referred to as "ancillary devices") as discussed hereafter. The platform top 112 is preferably operatively interconnected to a means for holding an IV bag. The means for holding an IV bag preferably includes at least a section of a pole 176, and/or a hook 180, and/or a rail 132, and/or the skirt 136 with a carabiner clip, and/or other hook attachment located either above or below the platform top 112. Additionally, existing IV, enteral and syringe pumps used by

health-care facilities will be accommodated on either a pole 176 or rail system 132 located on top of the platform top 112. The support platform 100, 100′, 100″ will be able to accommodate from zero to six pumps, and more preferably zero to four pumps. For the embodiments depicted in Figs. 1-5, various maintenance and treatment devices are hung or otherwise interconnected to the support platform 100, 100′, 100″, on the rails 132, resting on the top 112, or hanging from the skirt 136.

In accordance with embodiments of the present invention, an attachment device comprising a custom carabiner may be provided and used to releasably attach IV bags or other medical equipment, such as an infusion pump, to the platform's support structure. For example, such attachment devices may be used both on the rail 132 or the skirt 136 the support platform 100, 100′, 100″. In accordance with at least one embodiment of the present invention, the carabiners provide adequate gate clearance to accommodate both the rail 132 or skirt 136, and provide easy interconnectivity and removability of the previously listed devices or IV bags from the support platform 100, 100′, 100″. In another aspect of the invention, the carabiners preferably comprise of different colors in order to categorize IV fluids for rapid easy identification by healthcare providers. For example, IV fluids without added medication may hang from blue carabiners, IV fluids with antibiotic additives may hang from green carabiners, and IV fluids containing vasopressor additives my hang from red carabiners.

The platform top 112 or other portions of the frame 104 can include one or more other devices or apparatus, including such items as fluid reservoirs, metering pumps, cup/bottle holders, trays, a sitting stool, monitoring devices, computers, and communication devices, as well as a television, camera, phone or radio. Power receptacles 184 may also be provided either associated with the platform top 112 or frame 104 that will allow for multiple electronic devices to be plugged into either side of the platform. The consumer may or may not decide the number of receptacles. In addition, a retractable power cord 188 may also be provided on the support platform 100, 100′, 100″.

In a separate aspect of the invention, the support platform 100, 100′, 100″ preferably includes communication equipment to receive vital sign information from the patient by wired or wireless means. The information may then be transmitted wirelessly to the appropriate medical staff or alarm systems while the patient is using the support platform 100, 100′, 100″. The support platform 100, 100′, 100″ preferably is interconnected to a stationary outlet while at the patient's bed, and then when disconnected to allow movement, the on-board communication system preferably provides wireless signals.

The vital sign collection equipment is considered an integral part of the invention as these interact explicitly with the support platform 100, 100′, 100″. The devices gather information regarding a patient's heart rate, non-invasive blood pressure, arterial blood pressure, central venous pressure, urine output, abdominal compartment pressure, respiratory rate, oxygen saturation and any other information that may be relevant to a patient's care. Other data from devices such as the bed and ventilator to include patient weight, bed alarms and ventilator parameters may be received and transmitted through the support platform as well.

In a separate aspect of the invention, the support platform 100, 100′, 100″ preferably includes an on-board oxygen supply 192. In use, for those patients needing an oxygen supply, the tubing is preferably directly interconnected to the patient. The oxygen supply may be an existing oxygen bottle system or preferably includes tubing connections to allow the support platform 100, 100′, 100″ to be interconnected to a stationary oxygen source, such as a wall outlet that carries and delivers oxygen to a patient's hospital room. Accordingly, the support platform 100, 100′, 100″ can be positioned at the side of the patient's bed, and when the patient leaves his or her bed, the tubing from the support platform 100, 100′, 100″ is disconnected from the stationary oxygen source, without substantial interruption in the flow of oxygen to the patient. Accordingly, the support platform 100, 100′, 100″ preferably includes a bypass connection for utilizing a stationary oxygen source when the support

platform 100, 100′, 100″ has tubing interconnected to the stationary oxygen source.

In yet a separate aspect of the invention, the support platforms 100, 100′, 100″ preferably includes a chargeable battery and/or chargeable uninterruptible power supply, (where a chargeable battery and/or chargeable uninterruptible power supply is herein referred to collectively or singularly simply as "UPS") 200. The UPS 200 is preferably located near the base 120 to provide a relatively low center of gravity for the support platform 100, 100′, 100″. The UPS 200 allows the support platform 100, 100′, 100″ to be unplugged from a stationary power source, such as a wall outlet, with the platform's UPS 200 maintaining power to all of the on-board systems, such as the injection pumps, suction pumps, and vital sign monitoring equipment. In addition, the UPS 200 provides a back-up power supply to the electronic devices interconnected to it. Therefore, in the event of a power outage, the UPS 200 provides emergency power to the electrical devices interconnected to the platform's UPS 200. This is particularly advantageous for site locations that do not have an emergency back-up generator connected to the building's power supply. Preferably, the UPS 200 charges when it is plugged into a wall outlet while the devices remain operational.

For platforms utilizing electrical devices, the support platform 100, 100′, 100″ is preferably pre-wired and includes an electrical system. Therefore, the support platform's built-in modularity and electrical system limits the number of cords to power the modular electrical devices, such as pumps or monitoring devices. Accordingly, in one preferred embodiment, injection pumps, suction pumps, monitoring devices, and/or communication equipment can be quickly snapped into place into the frame 104 of support platform 100, 100′, 100″, such as in the platform top 112 of the support platform, with the power supply to the subject device provided by the hook-up port 184 or receiving connector on the support platform 100, 100′, 100″.

In a separate aspect of the invention, the support platform 100, 100′, 100″ preferably includes an umbilical cord (not shown) having common plug for interconnecting a plurality of

systems to a single outlet, such as a wall outlet. The umbilical cord may include a variety of systems, including electrical power, oxygen, suction, and/or a communication connection. When the patient uses the support platform 100, 100′, 100″ as a walking aid, or when the patient is moved in their bed with the support platform 100, 100′, 100″ interconnected to the bed or the support platform 100, 100′, 100″ is otherwise made mobile, the common plug is removed from the wall outlet, thereby not only freeing the support platform from being tethered to the wall, but also engaging the on-board UPS 200 to power any interconnected devices, as well as engaging the on-board oxygen supply and suction pump to the patient, if in use. Therefore, the umbilical cord and associated common plug allows for a quick and easy disengagement from a stationary hook-up. In addition, in order to engage the support platform 100, 100′, 100″ to the systems available from a stationary source, such as a wall outlet, the common plug attached to the umbilical cord is simply engaged with the wall outlet, thus bypassing and/or recharging the support platform's on-board systems.

In yet a separate aspect of the invention, the support platform 100, 100′, 100″ preferably includes tube and wiring bundling channels or clips to organize the various tubes or wires that lead from the platform to the patient. The tube and wiring bundles are preferably situated to minimize the potential for the tubes or wires to interfere with objects as the support platform 100, 100′, 100″ is pushed by the patient or the patient is transferred by other personnel.

In yet a separate aspect of the invention, a hip or other body attachment (not shown) or aid can be provided to assist a patient in moving the support platform when the patient has a physical impediment to grasping the platform handle 108, such as may be the case if the patient has a broken arm, leg, pelvis, shoulder, scapula or ribs. Other physical impairments such as arm and leg amputations can be addressed with other attachments either to the platform or patient. A hip attachment would be one such attachment that would interconnect the support platform 100, 100′, 100″ to the patient, such as by a cushioned bar positioned at or

near the patient's hip.

In a separate aspect of the invention, the support platform may include an interior space and/or compartments for holding reservoirs or bags. For example, as shown in Figs. 2-5, the support platform 100', 100" may include a cabinet area 204 or other enclosure, the cabinet area 204 preferably including one or more drawers 208, doors 212 and/or access panels 216. Hooks or modular receptacles can be provided within the cabinet space. The interior space or cabinet area 204 can be configured to receive one or more urine or drainage bags. More preferably, in accordance with embodiments of the invention, the collection chambers can accommodate canister assemblies (not shown) designed to provide a mechanism of measuring the volume of the canisters automatically. This system may include a float, conduction or transmission mechanism. This information could then be converted to electronic data that could be transmitted along with other patient vital statistics as described elsewhere in this document.

Referring now to Figs. 10-14, and in accordance with another aspect of the invention, the support platform 100, 100', 100" comprises a mechanism for being releasably attached to another object, such as a bed, hand rail, vehicle, etc. In accordance with at least one embodiment of the invention, support platform 100, 100', 100" includes at least one bed hook 1000, and more preferably, a plurality of bed hooks 1000. The bed hooks 1000 provide a means for temporarily docking the support platform 100, 100', 100" to a bed when the platform is not being used as walker by a patient. The bed hooks 1000 allow the support platform 100, 100', 100" to remain stationary and attached to the patient's bed if it is inadvertently bumped by a hospital staff member, patient, or visitor. In addition, the bed hooks 1000 can be used to secure the support platform to the patient's bed if the patient is moved while remaining within the bed and the support platform is required to move with the bed. For this type of use, an additional staff member is not needed to roll the support platform 100, 100', 100" adjacent to the moving bed. The bed hooks 1000 allow the support

platform 100, 100′, 100″ to be lifted by another object, such as the patient's bed, such that the wheels 164 the platform are suspended, thereby making transportation easier because only the wheels on the bed need be controlled.

Referring now to Figs. 5 and 10, an upper portion 220 of a support platform 100, 100′, 100″ is shown that includes a pair of bed hooks 1000, wherein a first bed hook 1000 is located adjacent to or at a right side of the support platform 100, 100′, 100″ and a second bed hook 1000 is located adjacent to or at a left side of the support platform 100, 100′, 100″. For the embodiment of the support platform 100″ shown in Figs. 3-5, the bed hooks 1000 are located at the rear portion 148 of the support platform 100″. However, it is to be understood that the bed hooks 1000 may be used on any version of the support platform, including support platform 100, 100′, 100″, and furthermore, the bed hooks 1000 may be located not only at the rear 148 of the support platform, but also at the front 152 or along a side of the support platform.

Each bed hook 1000 preferably includes an arm member 1004 that is rotatable in at least one direction, or outward from the support platform, such as per arrow $A_1$. In addition, at least a portion of the arm member 1004 is also rotatable in a second direction when engaging a bed or other object to which it is being attached, such as per arrow $A_2$. More particularly, and as described in additional detail below, the arm member 1004 is first rotated to extend away from the platform, as per arrow $A_1$, and then the arm member 1004 may be rotated again as per arrow $A_2$ to engage the bed or other object. As shown in Fig. 10, arm member 1004 is preferably located in a retracted or first position 1008, wherein the arm member 1004 is closed or positioned substantially adjacent the upper portion 220 of the support platform 100, 100′, 100″. More particularly, when closed, a side surface 1012 of the arm member 1004 is situated adjacent a rear side 1016 of the support platform 100, 100′, 100″. The arm member 1004 is then rotated on a hinge 1020 to an open or second position

1024 for engagement with an object, such as a bed. Thus, the bed hooks 1000 preferably feature a plurality of positions so that they remain unobtrusive when not in use. In addition, the bed hooks 1000 preferably include a material suitable for gripping, such as a plastic or rubber pad (not shown).

Referring now to Figs. 11A and 11B, the arm member 1004 is shown in an extended or open position 1024. In accordance with embodiments of the present invention, the arm member 1004 includes a lateral branch 1100 and a rotatable gripper portion 1104. The gripper portion 1104 is rotatably interconnected to the lateral branch 1100 by a pin 1108. In accordance with embodiments of the present invention, the gripper portion 1104 includes a pinching finger 1112 that has an inside surface 1116 for contacting the bed or object to which the support platform 100, 100′, 100″ is to be attached. In addition, the gripper portion 1104 further includes an upper finger 1120 with an underside 1124 for also contacting the bed or object to which the support platform is to be attached. As shown in Fig. 11A, the gripper portion 1104 is in an unhooked position 1128. Upon rotation of the gripper portion 1104 about pin 1108, the pinching finger 1112 moves toward the support platform to clamp or engage the bed.

Referring now to Figs. 12-14, a support platform 100, 100′, 100″ with bed hooks 1000 is shown in use. As shown in Fig. 12, the bed hooks 1000 are depicted in the open position 1024 prior to engaging a portion of the bed B, such as a head board, foot board or rail. The portion of the bed B to engage the support platform 100, 100′, 100″ is then raised. As seen in Fig. 13, an upper surface BS of the bed B contacts the underside 1124 of the upper finger 1120 of the gripper portion 1104. Referring now to Fig. 14, as the bed B is raised further, the gripper portion 1104 rotates about pin 1108 relative to the lateral branch 1100. In so doing, the pinching finger 1112 rotates toward the rear side 1016 of the support platform 100, 100′, 100″, thereby pinching the bed B between the inside surface 1112 of the pinching finger and the rear surface 1016 of the support platform 100, 100′, 100″. With continued

raising the bed B, the bed B will lift the support platform 100, 100′, 100″ from the floor. The bed B can then be moved with the support platform 100, 100′, 100″ releasably attached to the bed B. The bed hooks 1000 thus provide a means for moving the platform and the bed as a unit, without the need for a separate attendant or nurse to guide the support platform as another person moves the bed.

In accordance with embodiments of the present invention, an alternative attachment device (not shown) may be used to releasably attach the support platform 100, 100′, 100″ to a bed or other object. For example, the platform handle 108 may be modified for engaging a portion the bed or another object. Such alternative attachment device may include an adjustable setting that allows the alternative attachment device to be configured for use with a variety of bed frames or wheelchair configurations or other vehicles, such as automobiles or motorized platforms.

Referring now to Fig. 15, and in accordance with at least one embodiment of the invention, the support platform 100, 100′, 100″ may include a selectable transmission system 1500. Fig. 15 illustrates a number of components of the transmission system 1500 in solid lines, with other aspects of the support platform 100, 100′, 100″ superimposed over the transmission system. It is to be understood that the transmission system 1500 is also applicable to support platform 100, 100′, 100″, as well as other platforms that embody the present invention.

In general, the transmission system 1500 comprises a selectable control bar 1504 that is connected to a control shaft 1508 that controls a transmission applicator mechanism 1512. In accordance with embodiments of the present invention, transmission system 1500 preferably has a plurality of settings or modes that can be selected using the control bar 1504. For the embodiments illustrated in Figs. 15-21, three different settings are provided; however, it is to be understood that a transmission system with an alternate number settings is possible, such as two settings.

Referring now to Figs. 16 and 17 that each show a portion of the transmission system 1500, the control bar 1504 is preferably interconnected to a handle 1600, wherein the handle 1600 is movable along slot 1604, thereby allowing a user or healthcare staff member to select the setting for the transmission system 1500. More particularly, as shown in Fig. 16, a first setting corresponds to a stop mode, a second setting corresponds to a walk mode, and a third setting corresponds to a roll mode. In accordance with the embodiment and view shown in Fig. 16, the stop mode is the left-most position 1608a shown for the handle 1600, the walk mode is an intermediate position 1608b shown for handle 1600, and the roll mode is the right-most position 1608c shown for handle 1600. In general, the stop mode corresponds to having the support platform 100, 100′, 100″ stationary, the walk mode corresponds to placing the support platform 100, 100′, 100″ in a controlled state for a patient to ambulate using the support platform 100, 100′, 100″ as a walking aid, and the roll mode corresponds to a free-rolling state wherein the support platform 100, 100′, 100″ can be quickly and easily rolled, such as by a healthcare staff member moving the support platform 100, 100′, 100″ to a patient's room from a storage area.

In accordance with embodiments of the present invention, and as best seen in Figs. 17 and 18, although not required, a second handle 1600 may be positioned at the front of the support platform 100, 100′, 100″ to allow control of the transmission system 1500 from the front of the support platform 100, 100′, 100″. This configuration offers several advantages, including that a healthcare staff member can set the transmission system 1500 when a patient is at the rear of the support platform 100, 100′, 100″ and substantially blocking the handle 1600 at the rear of the support platform 100, 100′, 100″. Whether at the front or back of the support platform 100, 100′, 100″, the handle 1600 is generally moved transversely to a vertical axis V-V of the support platform 100, 100′, 100″ within the slot 1604. The handle 1600 is preferably interconnected to the control bar 1504 using an interconnection mechanism

1800 comprising connecting hardware 1804 that allows an end 1700 of the control bar 1504 to rotate relative to the handle 1600, such that a longitudinal axis H-H of the handle 1600 remains substantially parallel to a front to rear axis A-A of the support platform 100, 100', 100" as the handle 1600 is moved along slot 1604. The control bar 1504 rotates at pivot point 1704 about a rotational axis that corresponds to the longitudinal axis S-S of the control shaft 1508. Although only one control shaft 1508 is shown, the control bar 1504 may be interconnected to a plurality of shafts that lead to one or more transmission applicator mechanisms.

Referring now to Figs. 19 and 20, and in accordance with at least one embodiment of the present invention, a transmission applicator mechanism 1512 is shown that includes functionality corresponding to the three transmission settings of stop mode 1608a, walk mode 1608b and roll mode 1608c. The transmission applicator mechanism 1512 generally includes a cam 1900 that is connected to the control shaft 1508. In at least one embodiment, the cam 1900 provides at least a means for adjusting the position of the drag wheel. When the handle 1600 is moved along slot 1604, the control bar 1504 rotates the control shaft 1508, and the cam 1900 also rotates. As the cam 1900 rotates, the transmission applicator mechanism 1512 either (1) applies both a brake assembly 1904 and a drag wheel assembly 1908 to the floor (or other surface under the platform) when the transmission system 1500 is set to the stop mode 1608a, (2) maintains the brake assembly 1904 in a raised position while the drag wheel assembly 1908 contacts the floor when the transmission system 1500 is in the walk mode 1608b, or (3) maintains both the brake assembly 1904 and the drag wheel assembly 1908 in raised positions while the transmission system 1500 is in the roll mode 1608c.

The brake assembly 1904 may comprise a variety of configurations, and in one embodiment comprises a post 2000 that is connected to a stopper 2004 at the distal end 2008 of the post 2000. The stopper 2004 may comprise a variety of materials and configurations, but generally includes characteristics that will generate a relatively large frictional force with

the underlying floor. For example, the stopper 2004 may comprise a rubber or plastic structure that tends to generate a large amount friction with the floor. Although the example stopper 2004 shown in Fig. 20 is cylindrical in shape with a circular distal end 2012 for contacting the floor, the stopper 2004 may be elongated in a direction transverse to the post 2000 such that a relatively wide contact area is formed with the floor. The post 2000 extends from the stopper 2004 to the cam 1900, and includes an upper flange 2016 at its proximal end 2020 at the cam 1900, and a lower flange 2024 that resides adjacent and below a base panel 2028. As will be discussed in more detail below, the brake assembly 1904 also preferably includes a biasing member 2032 that resides between the lower flange 2024 and the stopper 2004. As shown in Fig. 20, and in accordance with at least one embodiment, the biasing member 2032 comprises a compression spring, but may also comprise other structure, such as an air cylinder.

The drag wheel assembly 1908 provides a means for frictionally engaging the underlying surface, and in at least one embodiment comprises a wheel 2036 interconnected to the base panel 2028 by a movable linkage arm 2040, wherein the linkage arm 2040 can be lowered and raised to either apply the wheel 2036 to the floor, or to raise the wheel 2036 from contacting the floor. As discussed in more detail below, the drag wheel assembly 1908 preferably incorporates a rotation resistance mechanism that is interconnected to the wheel 2036 such that the wheel 2036 acts as a governor to control the speed of the support platform 100, 100′, 100″. The linkage arm 2040 is preferably interconnected to the cam 1900 by a post 2044 that extends from a pivot point 2048 at the linkage arm 2040 to the cam 1900. The post 2044 includes an upper flange 2016 at its proximal end 2020 at the cam 1900, and a lower flange 2024 that resides adjacent and below the base panel 2028. The assembly for the drag wheel assembly 1908 also preferably includes a biasing member 2032 that resides between the lower flange 2024 and the pivot point 2048 at the linkage arm 2040.

Referring still to Figs. 19 and 20, and in accordance with at least one embodiment of

the present invention, the cam 1900 includes a first curved or arc-shaped channel 1912 to control the brake assembly 1904, and a second curved or arc-shaped channel 1916 to control the drag wheel assembly 1908. When handle 1600 is moved to the stop mode 1608a, the control bar 1504 rotates the control shaft 1508 such that the post 2000 of the brake assembly 1904 and the post 2044 of the drag wheel assembly 1908 are located at first positions 1920 and 1924 of the channels 1912 and 1916, respectively. At these first positions 1920 and 1924, both the brake assembly 1904 and the drag wheel assembly 1908 are engaged such that the stopper 2004 and wheel 2036 are in contact with the floor. When at the first position 1920, the post 2000 is in a lowered position because the cam thickness at the first position 1920 is such that the upper flange 2016 of post 2000 is lower relative to the base panel 2028. When in the first position 1920, the biasing member 2032 of post 2000 forces the stopper 2004 downward and in contact with the floor. Similarly, when post 2044 is in the first position 1924, the upper flange 2016 of post 2044 is also lower relative to the base panel 2028 and the biasing member 2032 of post 2044 forces the linkage arm 2040 downward and places the wheel 2036 in contact with the floor.

Upon sliding handle 1600 to the walk mode 1608b position, the control bar 1504 rotates and turns the control shaft 1508, thereby turning the cam 1900. As the cam 1900 is turned, posts 2000 and 2044 remain laterally stationary and traverse the cam 1900 along channels 1912 and 1916, respectively. The posts 2000 and 2044 are then located at the second positions 1928 and 1932 along the first and second channels 1912 and 1916, respectively. In addition, as the proximal end 2020 of post 2000 for the brake assembly 1904 moves along first curved channel 1912 from the first position 1920 toward the second position 1928, the post 2000 rises because the upper flange 2016 of post 2000 encounters cam transition ramp 1936. The rise in cam transition ramp 1936 pulls the stopper 2004 off the floor and compresses the biasing member 2032 between the stopper 2004 and the lower flange 2024. In addition, as the cam 1900 is turned, the post 2044 remains in its lowered

position because the elevation of the upper flange 2016 of the post 2044 at the second position 1932 is substantially equal in elevation to the elevation of the upper flange 2016 when the post 2044 is in the first position 1924.

Upon sliding handle 1600 from the walk mode 1608b position to the roll mode 1608c position, the control bar 1504 again rotates and turns the control shaft 1508, thereby once again turning the cam 1900. Once again, the posts 2000 and 2044 remain laterally stationary and traverse the cam 1900 further along channels 1912 and 1916, respectively. The posts 2000 and 2044 are then located at the third positions 1940 and 1944 along the first and second channels 1912 and 1916, respectively. In addition, as the proximal end 2020 of post 2044 for the drag wheel assembly 1908 moves along second curved channel 1916 from the second position 1932 toward the third position 1944, the post 2044 rises because the upper flange 2016 of post 2044 encounters a second cam transition ramp 1936. The rise in cam transition ramp 1936 pulls the linkage arm 2040 upward and the wheel 2036 off the floor and also compresses the biasing member 2032 between the pivot point 2048 of the linkage arm 2040 and the lower flange 2024 of post 2044. In addition, as the cam 1900 is turned from the walk mode 1608b to the roll mode 1608c, the post 2000 remains in its upper position because the elevation of the upper flange 2016 of the post 2000 between the second position 1928 and third position 1940 is substantially equal in elevation.

The biasing members 2032 for both posts 2000 and 2044 place the brake assembly 1904 and the friction wheel assembly 1908 in a preferred state of engagement because the biasing members 2032 tend to force the down the stopper 2004 and the wheel 2036. That is, work has to be done against the biasing member 2032 for post 2000 to move the handle 1600 from the stop mode 1608a to the walk mode 1608b, and work also has to be done against the biasing member 2032 for post 2044 to move the handle 1600 from the walk mode 1608b to the roll mode 1608c. Thus, if a person is operating the support platform 100, 100′, 100″ in walk mode 1608b, it is relatively easy to place the handle 1600 in stop mode 1608a and apply

the stopper 2004 to the floor because the biasing member 2032 of post 2000 tends to want to force the post 2000 and stopper 2004 downward. This is a safety feature of the transmission system 1500.

Referring now to Fig. 21, an alternate embodiment of a transmission applicator mechanism 1512′ is shown. For clarity, the base panel 2028 has been omitted from Fig. 21. Similar to that described above for the assembly 1512 shown in Figs. 19 and 20, the cam 1900′ shown in Fig. 21 includes a first channel 1912 for controlling post 2000 of the brake assembly 1904. The transmission applicator mechanism 1512′ further includes a drag wheel assembly 1908′ that utilizes two posts 2004a′ and 2004b′ to control the vertical position of the wheel 2036 through two channels 1916a′ and 1916b′ in cam 1900′. Although a linkage arm 2040 is not used with transmission applicator mechanism 1512′, the operation of the transmission applicator mechanism 1512′ is similar to that described above for transmission applicator mechanism 1512. Thus, upon rotation of the cam 1900′ in stop mode, the stopper 2004 and wheel 2036 are lowered to contact the floor, and in walk mode the stopper 2004 is raised, while in roll mode both the stopper 2004 and the wheel 2036 are raised from contacting the floor. Thus, the transmission system 1500 may take on a variety of configurations, including alternate transmission applicator mechanisms, and such alternate embodiments and modifications are encompassed by the present invention.

Referring now to Figs. 20 and 21, and as mentioned above, the drag wheel assembly 1908 preferably includes a rotation resistance mechanism 2052 that is interconnected to the drive wheel 2036, thereby enabling the wheel 2036 to restrict the speed of the support platform 100, 100′, 100″. In accordance with embodiments of the present invention, the rotation resistance mechanism 2052 may take the form of a friction pad (not shown) that engages at least a portion of the wheel 2036 and/or structure operably interconnected to the wheel 2036. More preferably, however, the rotation resistance mechanism 2052 comprises a braking motor 2056 interconnected to the wheel 2036, such as by way of the wheel's axle. In

accordance with embodiments of the present invention, the braking motor 2056 is interconnected to the wheel 2036 through a gearbox. The braking motor 2056 applies a force to the wheel 2036 to slow the wheel 2036 under the principle that little or no wheel speed requires the application of no braking, but high wheel speed requires the application of braking work on the wheel 2036 by the braking motor 2056. More particularly, as wheel speed increases, the output of the braking motor 2056 increases. The increased output results in an increased load on the braking motor 2056, increasing the braking force applied to the wheel 2036. The braking motor 2056 may comprise a permanent magnet DC motor. Furthermore, as can be appreciated by one of skill in the art after consideration of the present invention, the braking motor 2056 is not connected to a source of electrical power, but is instead driven as a generator (i.e., a source of electrical power) by the wheel 2036.

Referring now to Fig. 22, a schematic of a motor braking circuit 2200 for applying a braking force to the wheel 2036 in response to a voltage generated by the braking motor 2056 in accordance embodiments of the present invention is illustrated. The circuit shown in Fig. 22 is a multi-stage Zener diode auto-transmission system or braking circuit 2200 for automatically applying a braking force to the wheel 2036. In general, use of a number of different Zener diodes allows different stages of resistance to be applied progressively, as the voltage produced by the motor increases. As can be appreciated by one of skill in the art, the voltage produced by the braking motor 2056 will tend to increase as the rotational velocity of the wheel 2036 driving the braking motor 2056 increases. Furthermore, by switching in additional resistive loads as the voltage produced by the braking motor 2056 increases, and therefore drawing more current, the braking effect of the braking motor 2056 can be increased in steps.

In accordance with embodiments of the present invention, each stage 2204 of the circuit 2200 comprises at least one zener diode 2208 and at least one load resistor 2212. The zener diode ZD1 2208 of the first stage 2204a is selected to have a turn on or a breakdown

voltage (*i.e.* a zener voltage) that is relatively low. When the zener voltage is exceeded, the zener diode ZD1 2208 conducts, allowing current to pass through the load resistor R1 2212. Accordingly, the zener diode ZD1 2208 acts as a switching mechanism. The current draw from the introduction of this load will load the braking motor 2056 such that the resistance to rotation of the wheel 2036 (not shown in Fig. 22) will increase essentially linearly with increased speed. The second stage 2204b is in parallel with the first stage 2204a and has a zener diode ZD2 2208 that is selected to have a zener voltage that is higher than the first zener diode ZD1 2208. If the voltage produced by the braking motor 2056 meets or exceeds the zener voltage of the second zener diode ZD2 2208, the second zener diode ZD2 2208 conducts, allowing current to pass through the load resistor R2 2212 associated with the second stage 2204b of the circuit 2200. Accordingly, this zener diode ZD2 2258 also acts as a switching mechanism. Since the first zener voltage is lower than the second zener voltage, the first zener diode ZD1 2208 will continue to conduct while the second zener diode ZD2 2208 is conducting. Accordingly, two current paths through two of the stages 2204 will be active, increasing the rate at which the load increases with increased braking motor 2056 speed as compared to when only the first zener diode ZD1 2208 is conducting. As shown in Fig. 22, additional parallel circuit branches or stages 2204 comprising additional zener diode 2208 and load resistor 2212 pairs can be included, to provide any number of steps in the resistance produced at the wheel 2036 as the rotational speed of the wheel 2036 increases. For example, in Fig. 22 three stages 2204 (stages 2204a, 2204b and 2204c) are included. However, fewer or additional stages 2204 may be included depending on the desired number of steps in the rate of resistance provided by the circuit 2200.

As can be appreciated by one of skill in the art, the zener voltage is generally higher than the voltage at which a zener diode will conduct a forward current. Therefore, if the braking motor 2056 is operated in the opposite direction, such that if a negative voltage is produced at the first terminal of the braking motor 2056, a circuit with branches or stages

configured like the first three branches 2204a-c of Fig. 22 will allow the load introduced by the associated resistors to be applied at a much lower voltage than when the motor is operated in the other direction. This may be desirable, for example where it is desirable to have the platform move only in a forward direction while in the walk mode. In order to allow for resistance to be applied in a similar fashion in either a forward or reverse direction, blocking diodes 2216 can be introduced in the circuit branches. By introducing blocking diodes 2216, current is only conducted by a stage 2204 when a voltage is applied to that stage's 2204 zener diode 2208 as a reverse voltage, because the blocking diode 2216 will prevent a forward voltage from being applied to this zener diode 2208. Additional circuit branches 2204 can then be provided for progressively introducing a load when the braking motor 2056 is operated in the reverse direction. These additional circuit branches 2204 (see branches 2204d, 2204e and 2204f in Fig. 22) are oriented such that the associated zener diode 2208 and blocking diode 2216 are opposite the orientation of those included in the circuit branches for providing progressively increasing braking force in the forward (opposite) direction (branches 2204a, 2204b and 2204c in Fig. 22). Although only three stages or branches 2204 for applying a braking force in a reverse direction are shown, it should be appreciated that fewer or additional of such stages may be provided.

Referring now to Fig. 23, an alternate embodiment for motor braking circuitry is shown. The motor braking circuit 2300 shown in Fig. 23 is a multi-stage metal-oxide semiconductor field-effect transistor (MOSFET) auto-transmission system for automatically applying a braking force to the drive wheel 2036. In general, in the first stage 2302a, when the voltage divided down by resistors R2 2304 and R7 2304 is greater than Vth of transistor Q1 2308, transistor Q1 2308 will turn on and apply the load resistor R8 2312 to the braking motor 2056. Accordingly, the voltage dividing resistors 2304 and the transistor 2308 comprise a switching mechanism. Subsequent stages in parallel with the first stage set to different points will add more load in a similar fashion once the set voltage for such stages is

met or exceeded. For example, a second stage 2302b is illustrated in Fig. 23, which may be configured to turn on at a higher voltage than the first stage 2303a. The transistors Q3 and Q4 2308 in the third 2302c and fourth 2302d stages are set in the opposite direction and will work in the reverse direction. Accordingly, the third and fourth stages 2303 and may be included in order to apply stages of resistance when the braking motor 2056 is turned in a direction opposite the direction the braking motor 2056 is turned to activate the first and second stages 2302a-b. Also, the body diodes of the transistors 2308 may be blocked or protected by a blocking diode 2316. Although four stages 2302 are shown in Fig. 23 (two for activation in a forward direction and two for activation in a reverse direction), it should be appreciated that any number of stages 2302 can be provided.

Referring now to Fig. 24, an additional alternate embodiment for motor braking circuitry is shown. The motor braking circuit 2400 shown in Fig. 24 is a multi-stage Silicon Controlled Rectifier (SCR) braking system for automatically applying a braking force to the wheel 2036 (not shown in Fig. 24). In general, in the first stage 2404a, when the voltage across resistor R15 2408 gets high enough to send a trigger current through SCR D1 2412 allowing current to pass through load resistor R16 2416, SCR D1 2412 latches on and applies the load resistor R16 2415 to the motor 2056 until the motor voltage drops to the point where there is almost no more current through R16. The SCR 2412 and the resistor 2408 therefore comprise a switching mechanism. The second stage 2404b, in parallel with the first stage 2404a, has a resistor R17 2408 selected such that a trigger current is not sent through the associated SCR D5 2412 until after the first stage 2404a has turned on. Accordingly, the resistance to movement of the braking motor 2056 can be stepped up once the output of the braking motor 2056 exceeds a predetermined amount. Third 2404c and fourth 2404d stages, each having an SCR 2412 having an orientation that is opposite the orientation of the SCRs 2412 of the first 2404a and second 2404b stages can be provided to apply stages of braking force in a reverse direction. The third 2404c and fourth 2404d stages also include trigger

resistors R19 and R20 that are connected to an opposite node of the braking motor 2056 as compared to the trigger resistors R15 2408 and R17 2408 of the first 2404a and second 2404b stages. Although only two stages are shown for providing braking resistance in each direction, it can be appreciated that any number of stages maybe provided. Unlike embodiments described in connection with Figs. 22 and 23, the embodiment illustrated by Fig. 24 does not switch out the load resistor of a stage at the trigger voltage for that stage, but instead retains the current path through the load resistor until a much lower voltage is reached (*e.g.* almost zero).

Referring now to Fig. 25, an alternate embodiment for motor braking circuitry is shown. The motor braking circuit 2500 shown in Fig. 25 is a hybrid circuit for automatically applying a braking force to the drive wheel 2036. In general, both an auto-transmission and an auto-braking feature are applied when different set resistances are achieved as a result of the voltage generated by the braking motor 2056. More particularly, the first stage 2502a is a stage incorporating a first switching mechanism for introducing a load resistor at a first voltage, while the second stage 2502b, which is in parallel with the first stage 2502a, incorporates a second switching mechanism for introducing a second load resistor at a second voltage. In the particular example of Fig. 25, the first stage 2502a uses a field effect transistor 2510 that allows current to pass through a first load resistor R23 2504 when the voltage divided down by set resistors R21 and R22 2508 is at a selected value. The second stage 2502b incorporates a silicone controlled rectifier 2512 that is switched on by a trigger current through resistor R24 2516 when the voltage across that resistor reaches a predetermined value, allowing current to pass through the load resistor R25 2520. The particular arrangement illustrated in Fig. 25 may be useful in selected applications, for example where it is desirable to have a mobile platform brought back to a standstill (or near standstill) after it has reached a velocity that exceeds a pre-determined bound. Specifically, the first stage load resistor R23 2504 can be switched in at a relatively low voltage, while the second load

resistor R25 2520 can be switched in at a higher voltage, and the second load resistor will remain switched in until the voltage is almost zero. As can be appreciated by one of skill in the art, additional stages, hybrid or otherwise, can be combined with the illustrated stages 2502a-b, for applying a load resistance in the same or in opposite direction from the illustrated stages 2502.

Fig. 26 is a graph depicting how the braking force produced by a braking motor 2056 can be progressively increased with increased braking motor 2055 velocity by using an auto transmission or braking system circuit in accordance with embodiments of the present invention. With specific reference to plot 2600, in a first speed range 2604, the force may remain essentially constant, for example due to the friction of the various platform wheels and of the unloaded braking motor 2056. The first speed range 2604 corresponds to a platform velocity (and therefore a drive wheel 2036 and braking motor 2056 velocity) at which the output produced by the rotation of the braking motor 2056 produces a voltage that is not high enough to cause a stage of a motor braking circuit to establish a current path across a load resistor. Once the maximum speed in the first speed range is exceeded, a second speed range 2608 may be entered in which the braking motor 2056 is operated to apply a braking force, by applying a load through a braking circuit. More particularly, the minimum speed of the second speed range 2608 occurs at a rotationally velocity of the braking motor 2056 at which the braking motor 2056 produces a voltage sufficient to trigger application of a load stage or branch of the motor braking circuit. The force applied by the braking motor 2056, and therefore the force required to continue moving the platform initially experiences a step increase, and then increases at an essentially linear rate due to the introduction of the resistive load. In a third speed range 2612, the braking motor 2056 is producing a voltage that is high enough to trigger application of a second load branch, as well as the first load branch. Upon application of the second load branch, the resistance takes a step increase, and then increases with the voltage output by the braking motor at a rate that is greater than the rate of increase

when only the first load was active. Where the first and second load branch or branches each add equal resistive loads, the slope of the increase in the force required to continue rotating the braking motor 2056 increases with velocity at approximately twice the previous rate. If a third stage is included in the circuit, a fourth speed range 2616 can be defined. When the fourth range 2616 is entered, another step increase in the force occurs when the third stage load resistor is added, and the resistance then increases at a linear rate that is greater than the rate of increase in the previous range.

When the velocity of the braking motor 2056 is decreasing, the force applied to the drive wheel 2036 by the braking motor 2056 will follow the same curve as when the velocity was increasing if a zener diode or a pair of dividing resistors and a transistor are used as the switching mechanisms. However, where a resistor and an SCR are used as a switching mechanism, the load resistor associated with such a switching mechanism will continue to be applied until the velocity of the braking motor 2056 (and hence its output) is almost zero. For instance, in a three stage braking circuit in which every stage comprises a resistor and an SCR switching mechanism, once the third speed range 2616 is entered, as the velocity of the motor decreases path 2618 will be followed.

In accordance with other embodiments of the present invention, the values of load resistors included in stages of a braking circuit can be selected from a number of different values to provide a selected resistance at the drive wheel 2036. For example, a ganged switch may be used to select from two or more load resistors that are applied at one or more of the speed ranges. In accordance with still other embodiments of the present invention, a switch for selecting a load resistor can be separately provided for selecting the load resistor or resistors that are applied in forward and reverse directions with respect to the platform. User selectable resistance can also be achieved through use of a potentiometer in place of one or more of the provided load resistors, provided the potentiometer has a suitable load rating. An example of the effect of selecting different, higher resistance load resistors applied at different

stages of the braking motor circuit is shown in Fig. 26 as plot 2620. As alternative to being user selectable, the load resistors may be selected or (in the case of a potentiometer) tuned by operation of a switch that is not normally user accessible. In addition, it should be appreciated that a braking motor circuit in accordance with embodiments of the present invention may be tuned such that a load resistor is immediately or almost immediately provided with current by the braking motor 2056, which would eliminate or shorten the first range 2604 during which there is no or almost no increase in the resistive force produced by the braking motor 2056 with increased velocity of the platform. Such tuning may be user adjustable. It can be appreciated by one of skill in the art that the motor braking circuitry provides a means for variably controlling a resistance to the braking motor 2056.

In accordance with embodiments of the present invention, the weight of platform may be adjustable to provide a larger normal force for allowing more braking and/or stopping force to be effectively applied when the brake assembly 1904 and/or drag wheel assembly 1908 are engaged. For example, additional ballast (sand filled articles, weights, etc.) may be located on the support platform 100, 100′, 100″ to increase the weight of the support platform 100, 100′, 100″.

It is noted that the transmission system 1500 and/or the rotation resistance mechanism 2052 have application to a variety of platforms and/or mobile devices. For example, a walker may be adapted to incorporate one or more of the transmission system 1500 and the rotation resistance mechanism 2052. As other possible examples of alternative uses, a wheel chair, a baby stroller, a beverage platform for airlines, and/or a serving platform for cruise ships may incorporate these systems, and such applications and others are within the scope of the present invention.

Referring now to Fig. 27, a block diagram or schematic depiction of some of the possible components of the support platform 100, 100′, 100″ are illustrated. Additional components other than those shown in Fig. 27 are also within the scope of the present

invention, including other components described herein, as well as additional items such as a built-in folding seat or a shade canopy/umbrella.

In use, the support platform 100, 100′, 100″ is initially positioned near the patient's bed. The support platform 100, 100′, 100″ can be then be modified to meet the patient's needs, such as by adding an IV bag, suction pump, injection pump, and/or oxygen supply, and by adding one or more devices to monitor the vital signs of the patient. By plugging the UPS 200 into an electrical outlet, such as a wall outlet, power can be supplied directly to the support platform, and therefore, power is supplied to items interconnected to the electrical system of the platform. In addition, if available and prescribed, oxygen can be directly supplied to the patient by connecting a stationary oxygen supply to the platform. The platform may also be secured to the patient's bed by utilizing bed hooks 1000 mounted on the support platform 100, 100′, 100″ to clamp the platform to the framing of the patient's bed.

When the patient is required to be moved from the room while in bed, the support platform can be disengaged from the provided stationary connections by unplugging or otherwise disengaging the connections to the platform, and then subsequently moving the support platform 100, 100′, 100″ while moving the patient's bed. If the support platform is interconnected to the bed, such as by bed hooks 1000, a separate attendant or nurse may not be needed to move the support platform 100, 100′, 100″ while moving the bed.

As the patient becomes mobile, the support platform can be used as a walking aid by disengaging the support platform systems from the stationary supply sources, such as electrical power or oxygen. By grasping the handle with one or two hands and pushing the platform, the patient can move away from the bed while IV fluids, pumps, and monitoring equipment on the support platform maintain treatment to the patient.

As can be appreciated by one of skill in the art after consideration of the present disclosure, embodiments of the present invention may provide physiological support to a patient that might not otherwise be conveniently available. For example, in connection with

hospitals or clinics in underdeveloped areas, a support platform 100, 100′, 100″ in accordance with the present invention may provide an integrated package for supplying a patient with oxygen, fluids, suction, waste receptacles, monitoring devices, and electrical power. Furthermore, a support platform 100, 100′, 100″ in accordance with embodiments of the present invention provides an integrated structure from which such physiological support can be supplied. As can also be appreciated from the description provided herein, the particular features or modules included as part of a support platform 100, 100′, 100″ in accordance with embodiments of the present invention can be selected according to the particular needs of a patient and can be changed as the needs of the patient change.

In summary, the present invention provides a stable apparatus for assisting a patient walking. Nurses will be able to make better use of their time in the direct care of patients. Patients may have decreased hospital stays, complication rates and less time in skilled-nursing facilities. Fewer therapeutic errors will result and nurses will be at decreased risk for back injuries. The apparatus may include an IV fluids assembly, while also optionally providing modular receptacles for receiving a pump, and further providing an optional uninterruptible power supply for powering one or more electronic devices, such as a pump or one or more pieces of monitoring equipment. The support platform preferably includes adjustable components, including an adjustable handle. The support platform also preferably includes an expandable configuration, such that while the platform may initially be used for simply holding an IV bag, it can be quickly modified to incorporate other prescribed treatments, such as an oxygen supply or injection pump. As the patient progresses through treatment, the support platform transitions from a bedside equipment station and emergency power supply, to a walking aid and wireless communications apparatus.

In accordance with the embodiments of the invention, the platform comprises a ruggedized version that enables the platform to be used in conditions outside of the confines of a healthcare facility. This may include conditions such as military field operations, on-site

disasters and underdeveloped regions. The basic premise of the platform is described above, with one or more of the following modifications:

1) larger wheels between the diameters of 6 to 12 inches to traverse rough terrain;

2) a raised base in order to provide greater ground clearance;

3) a broadened base width in order to provide greater stability on unlevel terrain; and

4) the materials may be altered in order to have greater impact tolerance and protection in extreme environments such as high dust, extreme temperatures, air drops, high humidity and inclement weather.

In accordance with still other embodiments of the invention, the platform can be adapted for use in the operating suite environment. Devices such as a headlamp, cautery device, sequential compression device, suction, laparoscopy equipment and gasses may be incorporated onto the platform. This places all of these devices on a single platform both in their current form and in future forms that are designed to fit in as modules that would reduce the overall size and weight of the device. A UPS would again be provided to power the devices and allow the batteries to be removed from each of the individual devices. This would be of benefit both in current OR's and in conditions such as military field conditions or less-developed regions where a self-contained platform would simplify the equipment and reduce the overall bulk. Each platform would be able to be individually configured to meet the specific needs to the user. The user would be able to easily swap modules at the site of use to change the configuration as well.

In accordance with yet another embodiment of the invention, a platform is provided for use in veterinary medicine. One variation comprises a platform for use in small-animal veterinary medicine that is designed for indoor use with modules specific for the care of smaller animals. A second variation comprises a platform for use with larger animals that is more akin to the ruggedized version described above to address the specific concerns of large-animal veterinary medicine.

In accordance with still other embodiments of the present invention, non-medical applications of the device are within the scope of this invention. Brief descriptions of some of the variations are provided. This is not limiting in nature and other variations which utilize the common core of the platform with modifications of the functions and modules provided are intended to be included in the scope of this invention. Several features may be considered common in the platform design or may be found in several variations. The cosmetic appearance of the platform is flexible and appealing including the ability for the user to select color. The small form factor of the invention is maintained and it is to be portable and remain unobtrusive in the environment of use. The device may be modified in order to be moved up and down stairs by a single user without damage to the platform or stairs. A motorized wheel or wheels may be added to aid in the motion of the invention for certain applications. The invention may be modified to include a stepping stool or mini-ladder that provides a stable system for the user with the brake enabled. Additionally, the invention may be modified to help stabilize a ladder by applying the brake and attaching directly to a taller ladder than provided on the platform. A universal power supply may be provided to power internal and external electrical devices.

A non-medical embodiment of this invention may be for use in a beauty salon. The invention may include a sink with drain, water supply and storage compartments in order to provide a beautician or stylist with all of the elements required to cut, style and wash a client's hair.

A non-medical embodiment of this invention may be for use in pet and animal grooming. The invention may include a sink, drain, grooming surface, hooks and compartments for grooming supplies, food and toys. The device may be expected to be used at professional grooming salons, in showmanship venues and at home.

A non-medical embodiment of this invention may be for use in a garage for auto mechanics. The invention may contain an air compressor, hangar for a light source, tool

compartments, hangar for a sleeper platform and compatibility with diagnostic hardware and software. This may include wireless transmission of data to a central diagnostic unit. This would allow a single mechanic or multiple mechanics with similar devices to work autonomously in a garage with their vital equipment readily available at their side.

A non-medical embodiment of this invention may be for use at home or in a handyman shop as a tool caddy. The invention may contain an air compressor, light source, tool compartments, compartments for accessories such as screws and nails, and an attachment to help stabilize a footstool or ladder.

A non-medical embodiment of this invention may be for use in indoor or outdoor landscaping. The wheel base will be modified to indoor or outdoor as similarly described previously for the medical aspect of this invention. The invention may also include a pressurized liquid tank or tanks for water, pesticides or fertilizers. Additional features may include a debris bin and storage bins for tools.

A non-medical embodiment of this invention may be for use in building maintenance. The invention may include a power supply, air compressor, compressed fluid storage, diagnostic equipment, wireless transmission capability, computer integration, tool compartments, attachments for spools of wire or tubing, a work stool and the ability to stabilize a ladder by enabling the brake and attaching to a ladder. It may also have a built in stepping stool or mini-ladder.

A non-medical embodiment of this invention may be for use by the elderly or handicapped in order to become more independent in or outside of the home. The stability of the structure will provide the user an aide in ambulation. Additionally, the invention will provide support, unlike current ambulatory aide devices, such as oxygen, compartments to hold drainage bags, cellular/wireless support to provide emergency aide, compartments to hold supplies, personals and groceries or other personal goods, a resting stool and an umbrella. Aide devices as in the medical version of the platform will be used for persons with

disabilities such as amputations, paralysis or other chronic conditions to allow them to use the platform effectively. A connector or system, such as the one previously developed to connect the invention to a hospital bed, may be developed to connect to a trailer hitch for easy transport with a vehicle. A portion or portions of the invention may easily detach for transfer of the module to a vehicle or residence without requiring transfer of the entire platform. The hope with this embodiment is to mobilize and reintroduce persons into society that were previously confined or restricted secondary to their disabilities.

While various embodiments of the present invention have been described in detail, it is apparent that modifications and adaptations of those embodiments will occur to those skilled in the art. However, it is to be expressly understood that such modifications and adaptations are within the spirit and scope of the present invention.

What is claimed is:

1. A personal support platform for traversing an underlying surface, comprising:

a frame;

a plurality of wheels interconnected to said frame;

a transmission system interconnected to said frame, said transmission system providing a number of user selectable modes, said user selectable modes comprising at least a stop mode, a walk mode and a roll mode; and

means for selectively choosing one of said stop, walk and roll modes by a user from a standing position adjacent said frame.

2. The platform as claimed in Claim 1, wherein said transmission system comprises a drag wheel that is selectively moveable from a first raised position in said roll mode to a second lowered position in said walk mode, and wherein said drag wheel is for contacting the underlying surface when in said second lowered position.

3. The platform as claimed in Claim 2, wherein said transmission system comprises a cam interconnected to said frame and the drag wheel, wherein said cam is rotatably movable to raise and lower said drag wheel from said first raised position in said roll mode to said second lowered position in said walk mode.

4. The platform as claimed in Claim 3, further comprising an automatic brake interconnected to said drag wheel, said automatic brake comprising a braking motor driven by said drag wheel and circuitry, wherein said circuitry provides a resistive load to the braking motor to apply a braking force on the drag wheel.

5. The platform as claimed in Claim 4, wherein said resistive load comprises a number of load ranges, wherein a first load range provides a first resistive load within a first velocity range for said braking motor, and wherein a second load range provides a second resistive load within a second velocity range for said braking motor.

6. The platform as claimed in Claim 5, wherein said second velocity range is automatically selected once a threshold velocity of said braking motor is reached.

7. The platform as claimed in Claim 1, wherein said transmission system comprises a brake interconnected to said frame, wherein said brake is selectively moveable from a first raised position in said walk and roll modes to a second lowered position in said stop mode, wherein said brake is for contacting the underlying surface when in said second position.

8. The platform as claimed in Claim 7, wherein said brake comprises a stopper frictionally engaging the underlying surface.

9. The platform as claimed in Claim 7, further comprising a cam having a first channel interconnected to said brake.

10. The platform as claimed in Claim 9, wherein said cam comprises a second channel interconnected to a drag wheel.

11. The platform as claimed in Claim 10, wherein first channel comprises a first ramp for raising and lowering a first post interconnecting said drag wheel to said cam,

and wherein said second channel comprises a second ramp for raising and lowering a second post interconnecting said stopper to said cam.

12. The platform as claimed in Claim 1, wherein said means for selectively choosing comprises a first handle at a rear portion of said frame, said handle selectively adjusting a setting of said transmission system.

13. The platform as claimed in Claim 12, further comprising a second handle at a front portion of said frame, said second handle selectively adjusting a setting of said transmission system.

14. The platform as claimed in Claim 1, wherein the user can select stop mode to engage a friction mechanism with the underlying surface.

15. The platform as claimed in Claim 1, further comprising at least one grasping mechanism for interconnecting said frame to another structure.

16. The platform as claimed in Claim 15, wherein said grasping mechanism comprises a rotatable gripper arm that engages the other structure.

17. The platform as claimed in Claim 16, wherein said rotatable gripper arm rotates about a first axis in a direction away from said frame, and rotates about a second axis to grasp the other structure, wherein said second axis is transverse to said first axis.

18. A personal support platform for traversing an underlying surface, comprising:

a frame;

means for rotating interconnected to said frame and contacting the underlying surface;

means for frictionally engaging the underlying surface and interconnected to said frame; and

means for variably controlling a resistance provided by said means for frictionally engaging.

19. The platform as claimed in Claim 18, wherein said means for rotating comprises a plurality of wheels.

20. The platform as claimed in Claim 18, wherein said means for frictionally engaging comprises a drag wheel.

21. The platform as claimed in Claim 18, wherein said means for frictionally engaging is interconnected to a means for adjusting a position of said means for frictionally engaging, wherein said means for adjusting may alter a position of said means for frictionally engaging from a first position in contact with the underlying surface to second position wherein said means for frictionally engaging does not contact the underlying surface.

22. The platform as claimed in Claim 21, wherein said means for adjusting comprises a selectably positionable cam for raising and lowering said means for frictionally engaging.

23. The platform as claimed in Claim 18, wherein said means for variably controlling a resistance comprises a passive braking motor.

24. The platform as claimed in Claim 23, wherein said passive braking motor comprises:

a motor braking circuit interconnected to the passive braking motor, including:

a first circuit stage, including:

a switching mechanism, wherein an activation voltage for the first circuit stage is defined;

a load resistor, wherein when the passive braking motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or greater than the activation voltage and above a current is allowed to pass through the load resistor.

25. A method of using a personal support platform, the method comprising:

providing a drag wheel interconnected to the platform, the drag wheel for contacting a surface under the platform;

positioning the drag wheel to contact the surface under the platform; and

applying a braking to the platform through the drag wheel by applying at least a first braking resistance to the drag wheel for at least a first velocity range of the drag wheel.

26. The method as claimed in Claim 25, further comprising providing at least a second braking resistance to the drag wheel for at least a second velocity range of the drag wheel.

27. The method as claimed in Claim 26, wherein said second velocity range is automatically selected once a threshold velocity of a braking motor is reached.

28. The method as claimed in Claim 25, wherein said positioning step further comprises manipulating a transmission control device to lower the drag wheel in contact with the surface under the platform.

29. The method as claimed in Claim 25, further comprising engaging a stopper to contact the surface underlying the platform.

30. The method as claimed in Claim 25, further comprising releasably connecting the platform to another structure using at least one grasping mechanism interconnected to the platform.

31. The method as claimed in Claim 30, further comprising impinging at least a portion of the other structure against a portion of said grasping mechanism.

32. A passive variable braking system, comprising:

a motor;

a motor braking circuit interconnected to the motor, including:

a first circuit stage, including:

a switching mechanism, wherein an activation voltage for the first circuit stage is defined;

a load resistor, wherein when the motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or

greater than the activation voltage and above a current is allowed to pass through the load resistor.

33. The system of Claim 32, wherein the motor braking circuit further comprises:

a second circuit stage in parallel with the first circuit stage, the second circuit stage including:

a switching mechanism, wherein an activation voltage for the second stage is defined;

a load resistor,

wherein when the motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or greater than the activation voltage and above a current is allowed to pass through the load resistor,

wherein the activation voltage for the second stage is greater than the activation voltage for the first stage, and

wherein when the activation voltage for the second stage is met or exceeded a current continues to be allowed to pass through the load resistor of the first circuit stage.

34. The system of Claim 33, further comprising:

a switch,

wherein the first and second circuit stages comprise a number of load resistors,

wherein the switch is operable to select one of each of the load resistors included in the first and second circuit stages to provide a selected resistance at the motor.

35. The system of Claim 32, where the motor braking circuit further comprises:

a second circuit stage in parallel with the first circuit stage, the second circuit stage, including:

a switching mechanism, wherein an activation voltage for the second stage is defined;

a load resistor,

wherein when the motor produces an amount of power sufficient to produce a voltage at the switching mechanism that is equal to or greater than the activation voltage and above a current is allowed to pass through the load resistor, and

wherein the activation voltage for the second stage has a polarity that is opposite the activation voltage for the first stage.

36. The system of Claim 32, wherein the switching mechanism comprises a zener diode.

37. The system of Claim 32, wherein the switching mechanism comprises a pair of voltage dividing resistors and a transistor, wherein a voltage divided by the pair of resistors is provided to a gate of the transistor.

38. The system of Claim 32, wherein the switching mechanism comprises a resistor interconnected to a Silicon Controlled Rectifier.

39. The system of Claim 32, further comprising:

a drag wheel interconnected to the motor, wherein the motor is driven by the drive wheel.

40. The system of Claim 39, wherein the drive wheel is interconnected to the motor by a gearbox.

41. The system of Claim 33, wherein the switching mechanisms of the first and second circuit stages each comprise a zener diode, and wherein the first and second stages each additionally include a blocking diode.

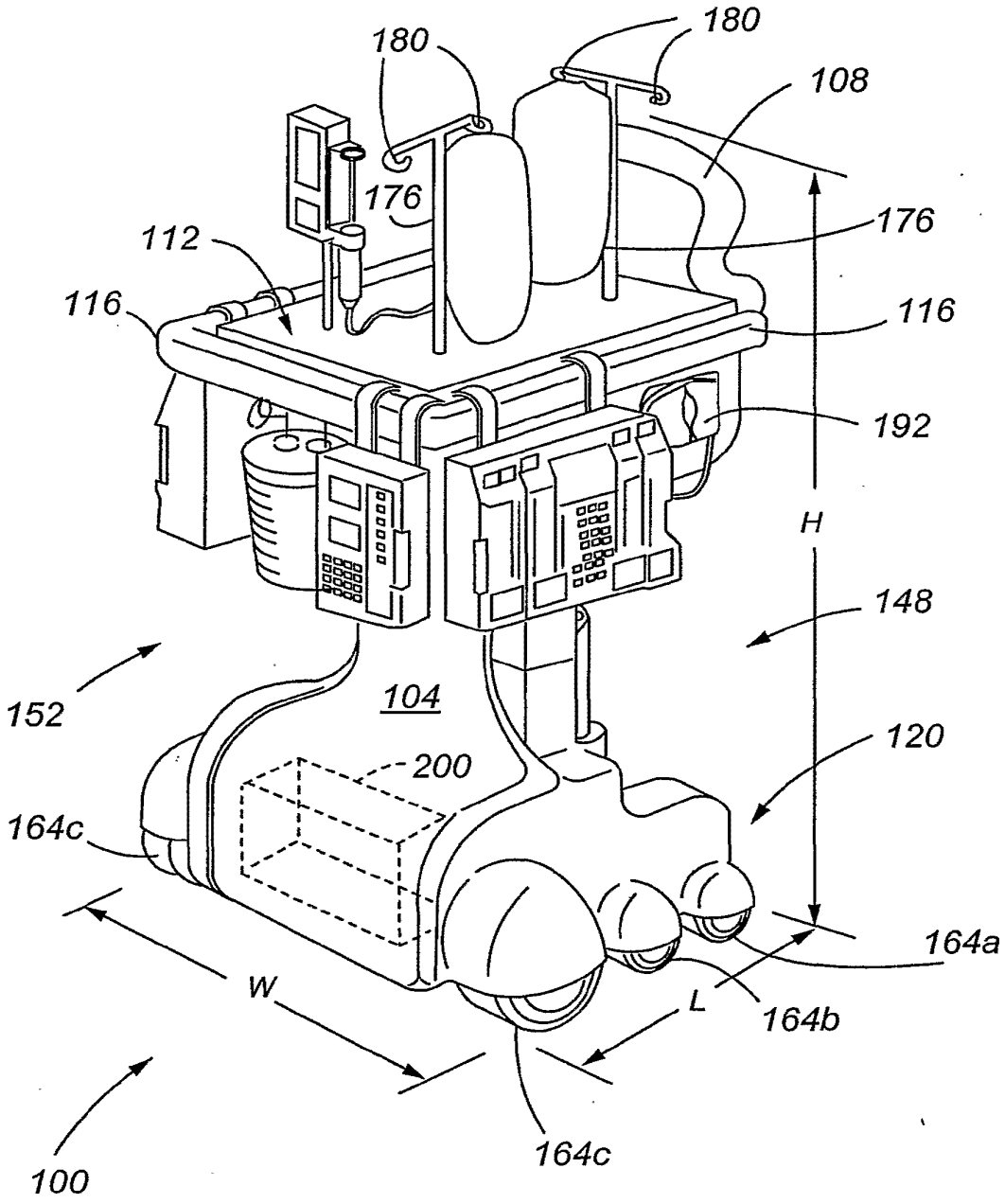

180
180
108
176
176
112
116
116
192
H
148
152
104
120
200
164c
164a
W
L
164b
164c
100

Fig. 1

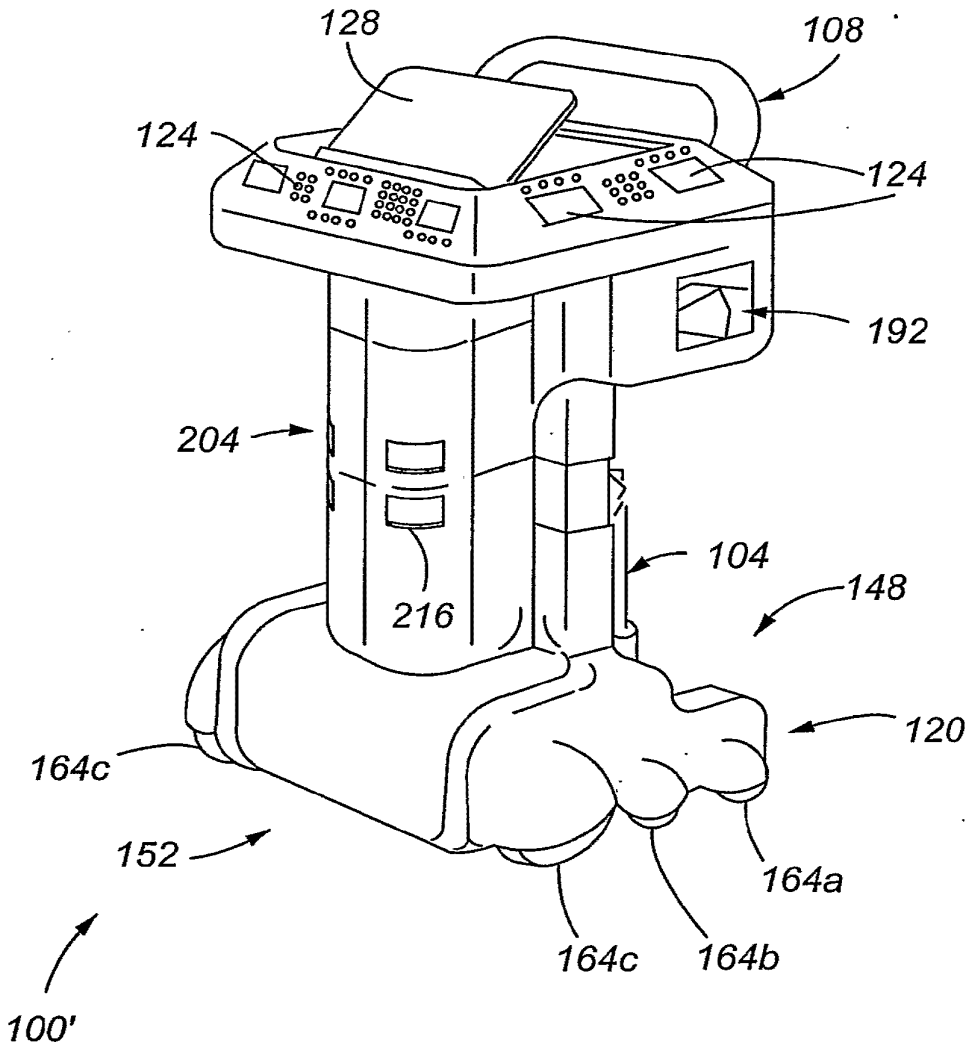

128
108
124
124
192
204
104
148
216
120
164c
152
164a
164c
164b
100'

Fig. 2

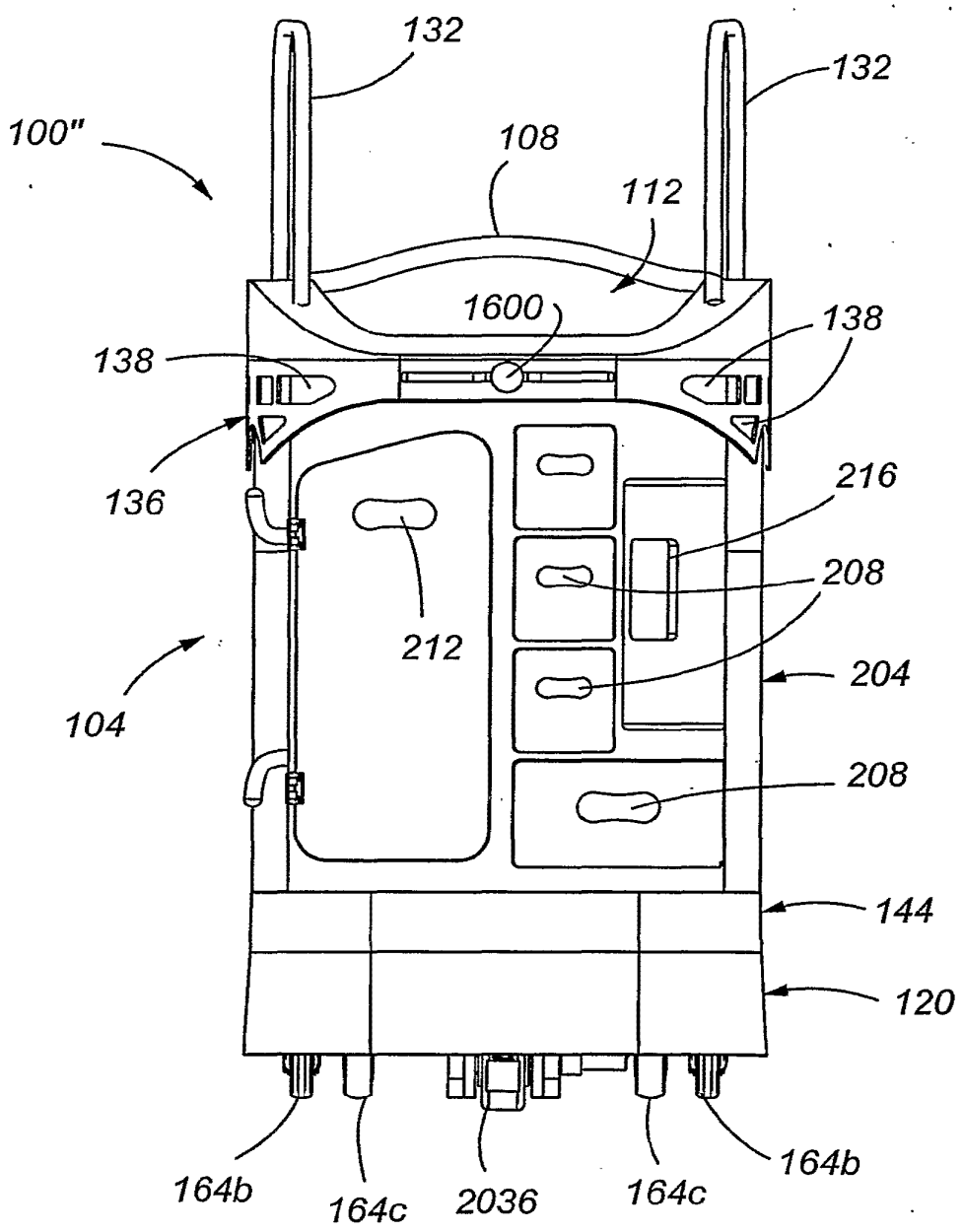

132
132
100"
108
112
1600
138
138
136
216
208
212
104
204
208
144
120
164b
164c
2036
164c
164b

Fig. 3

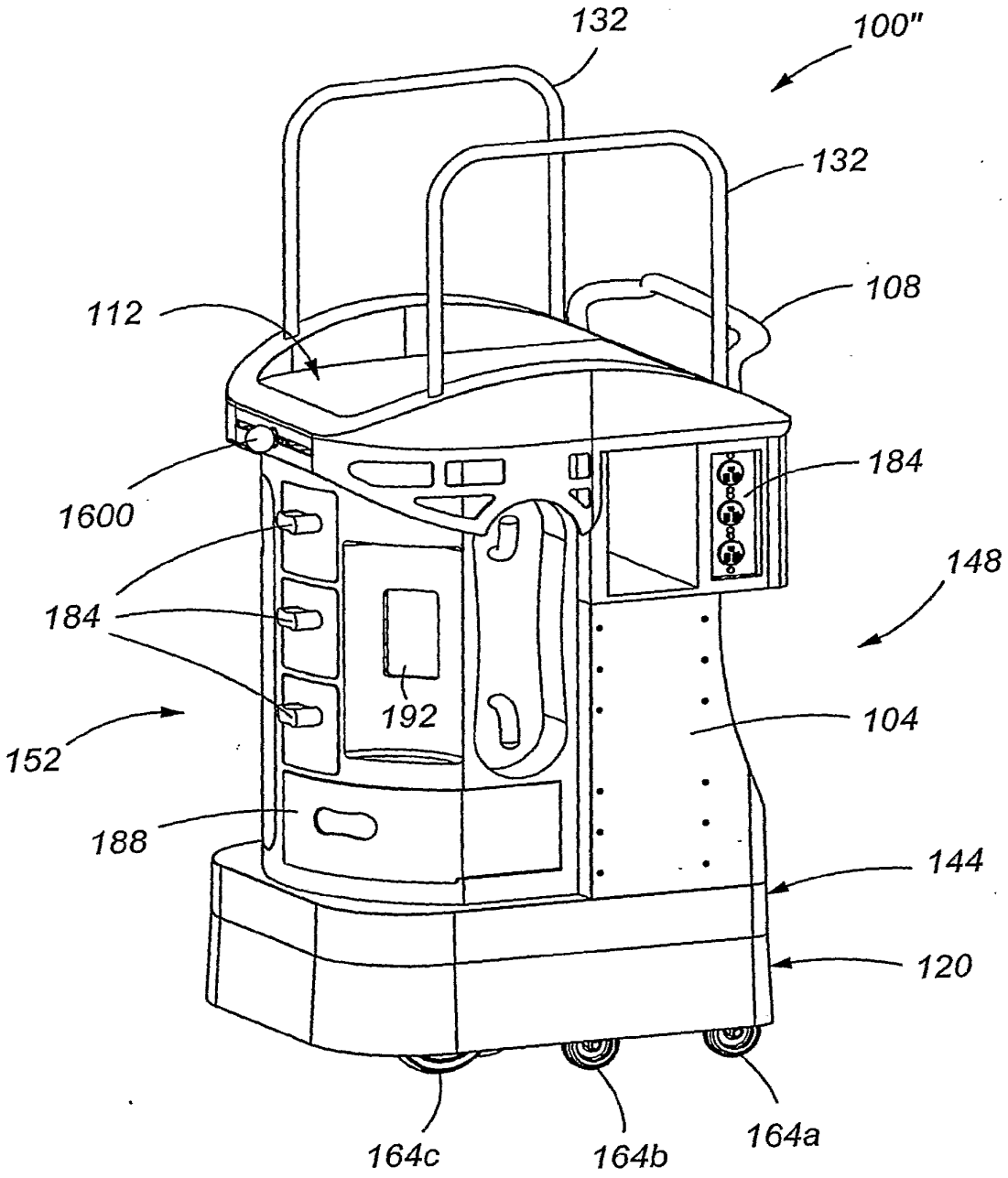

132
100"
132
112
108
1600
184
184
148
192
104
152
188
144
120
164c
164b
164a

Fig. 4

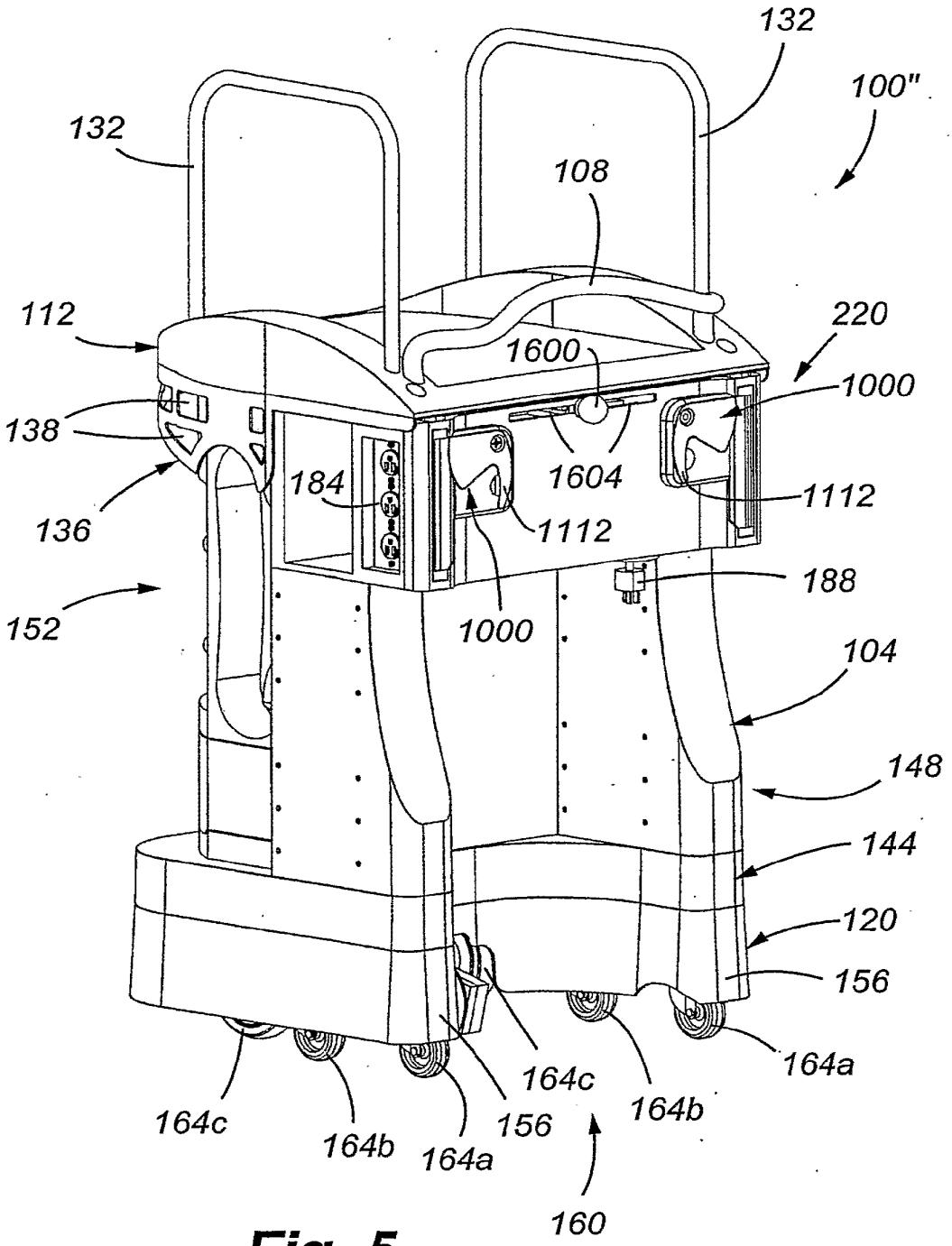

132
100"
132
108
112
220
1600
1000
138
184
1604
1112
136
1112
188
152
1000
104
148
144
120
156
164a
164c
164b
164c
156
164a
164b
160

Fig. 5

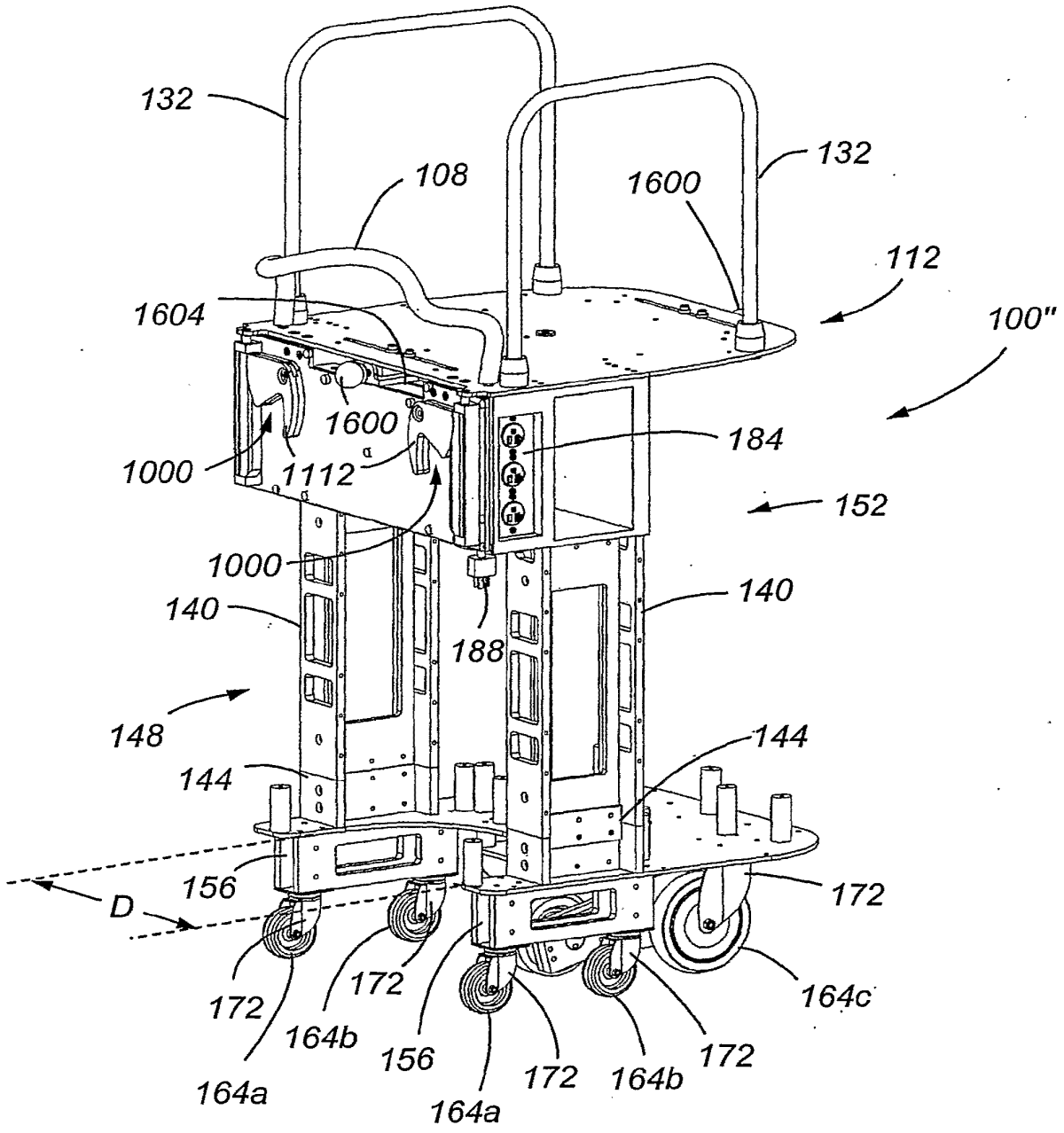

132
108
1600
132
112
1604
100"
1600
184
1000
1112
152
1000
140
140
188
148
144
144
156
D
172
172
172
164b
156
172
164b
172
164c
164a
164a

Fig. 6

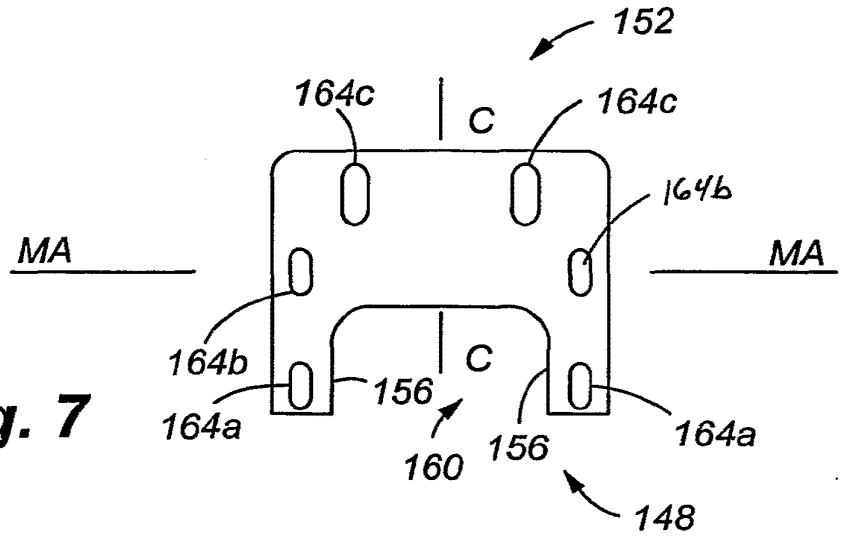



Fig. 7

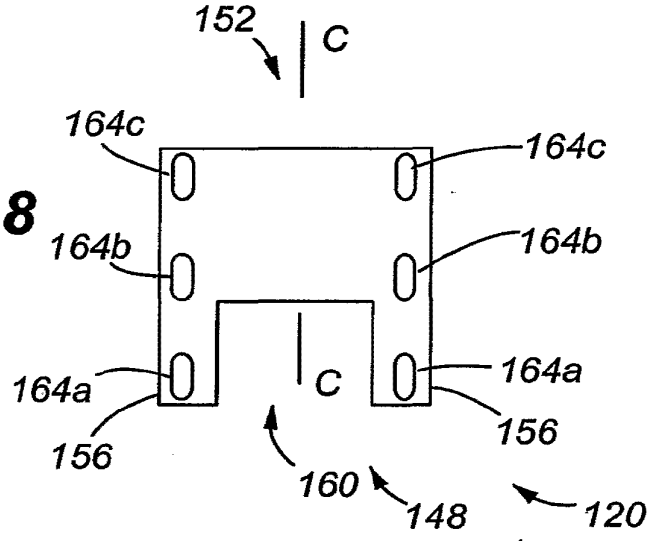



Fig. 8

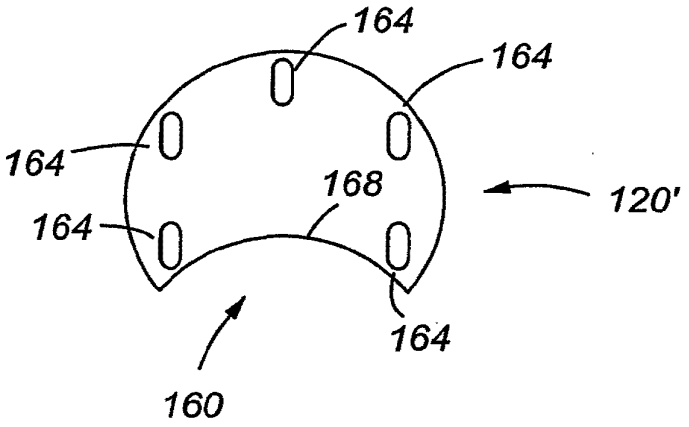



Fig. 9

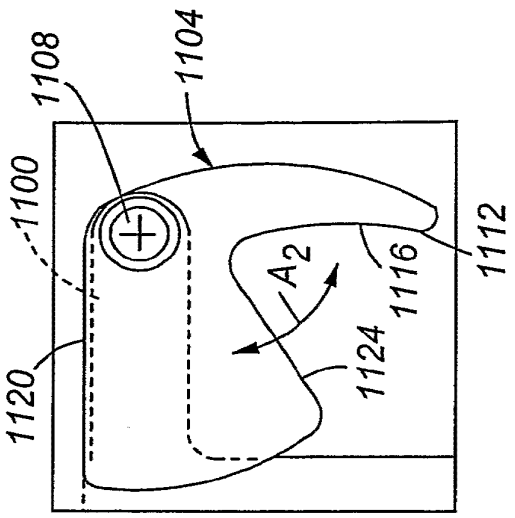



Fig. 11A

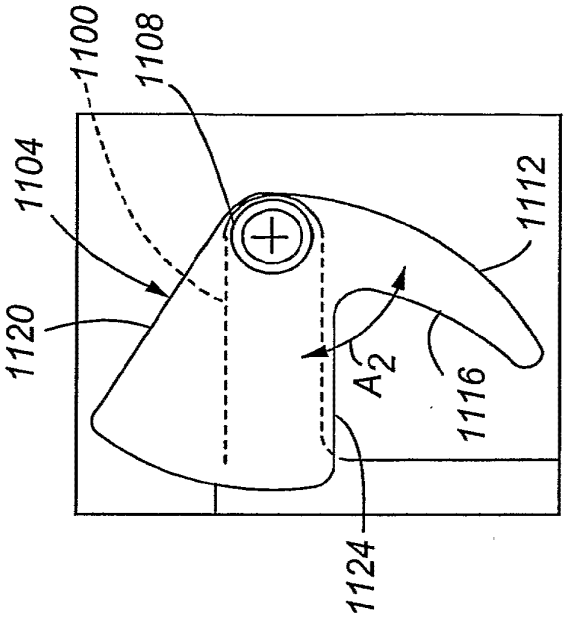



Fig. 11B

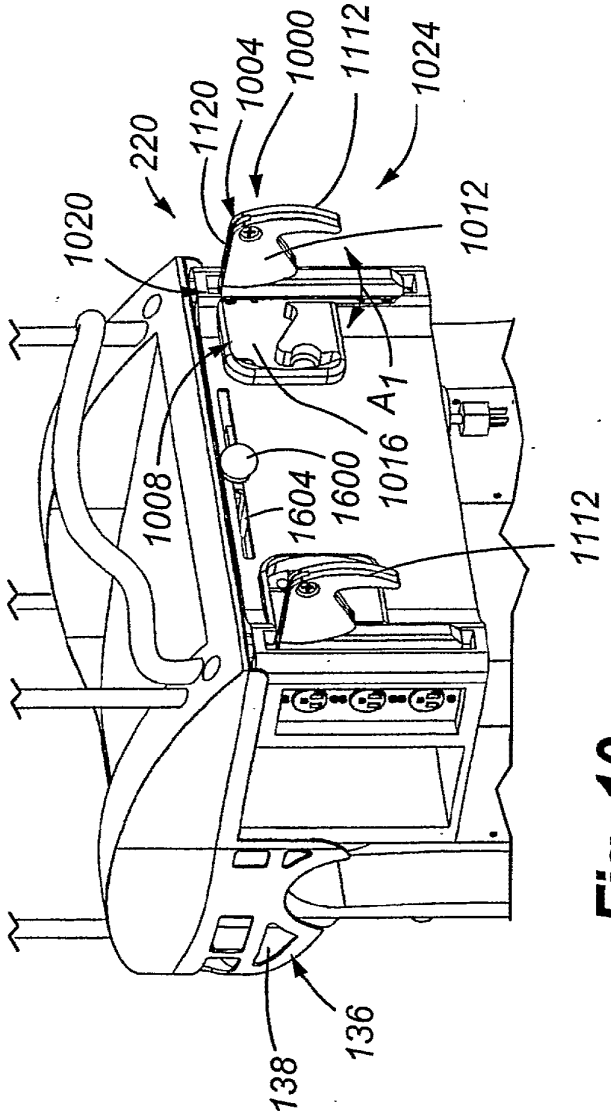



Fig. 10

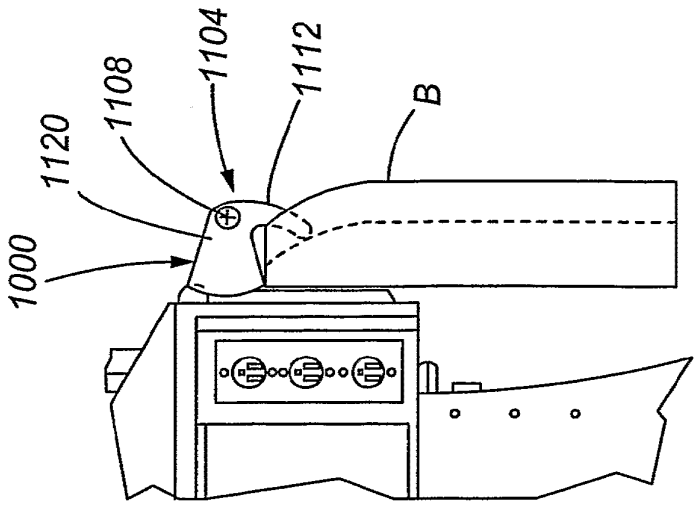



Fig. 14

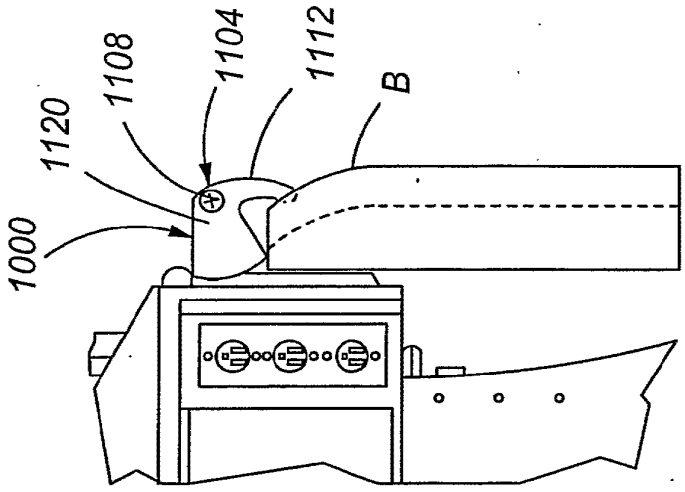



Fig. 13

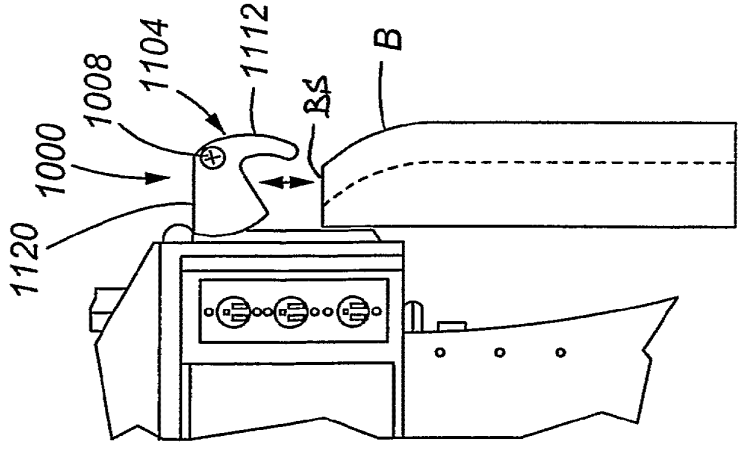
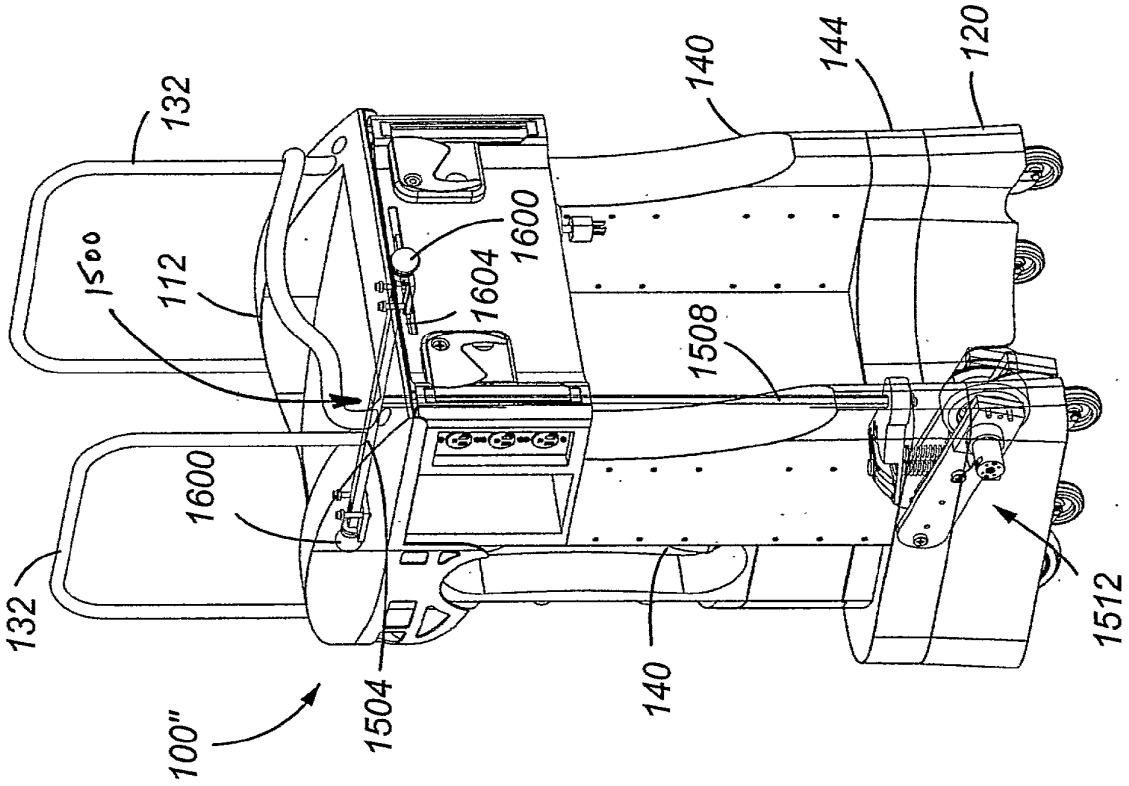



Fig. 12

Fig. 15


132
1500
112
1600
1604
1600
140
144
120
1508
132
100"
1504
140
1512

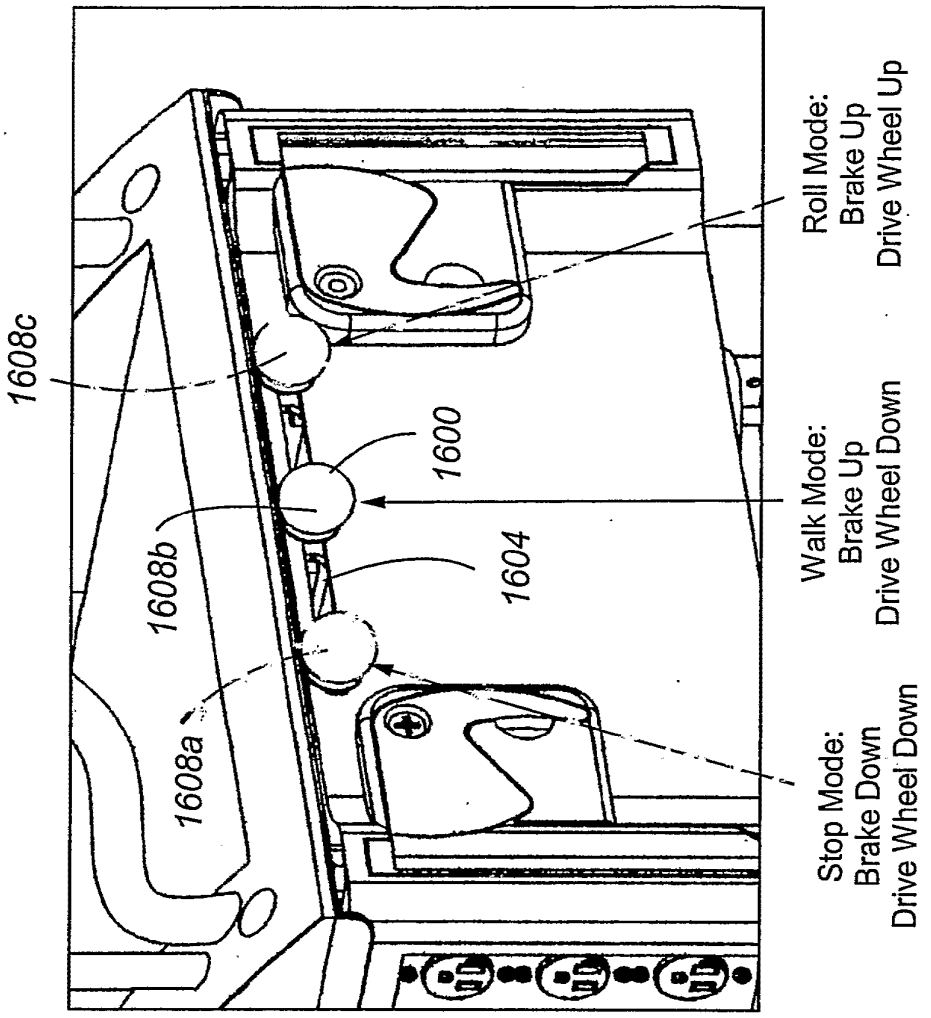

1608c
1600
1608b
1604
1608a
Roll Mode:
Brake Up
Drive Wheel Up
Walk Mode:
Brake Up
Drive Wheel Down
Stop Mode:
Brake Down
Drive Wheel Down

Fig. 16

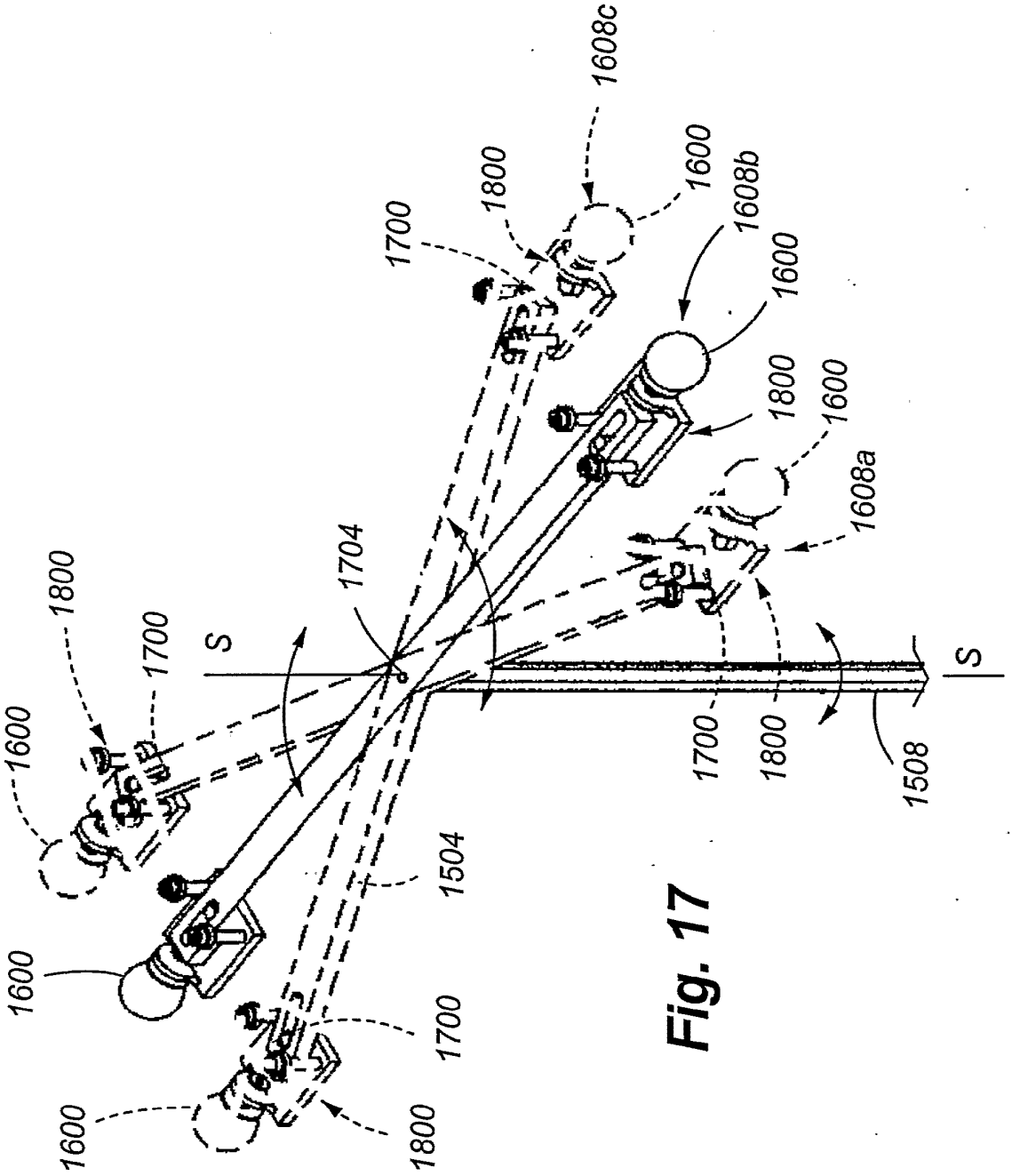

1608c
1600
1800
1700
1608b
1600
1800
1600
1608a
1704
S
S
1800
1700
1600
1700
1800
1508
1504
1600
1700
1600
1800

Fig. 17

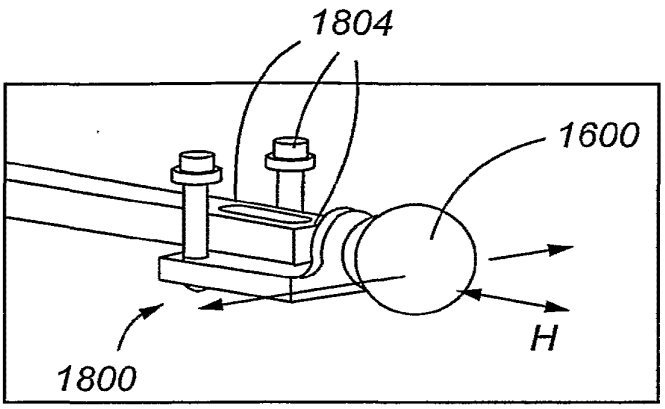

1804
1600
H
1800

Fig. 18

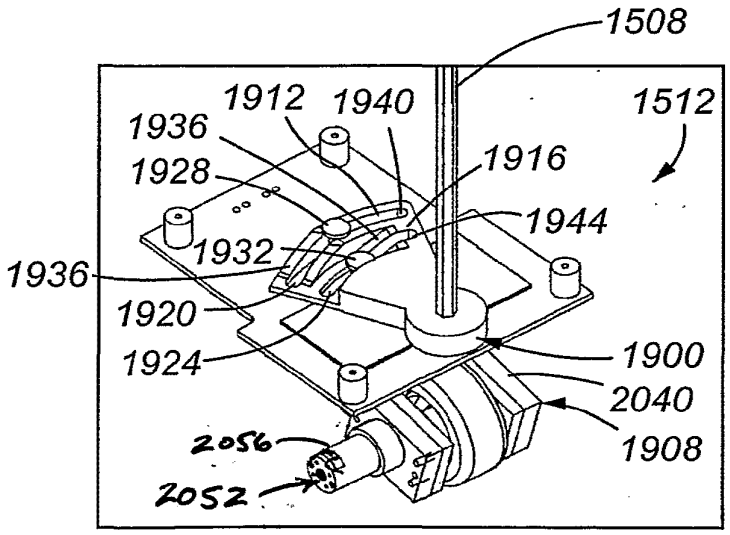

1508
1912
1940
1512
1936
1928
1916
1944
1932
1936
1920
1924
1900
2040
1908
2056
2052

Fig. 19

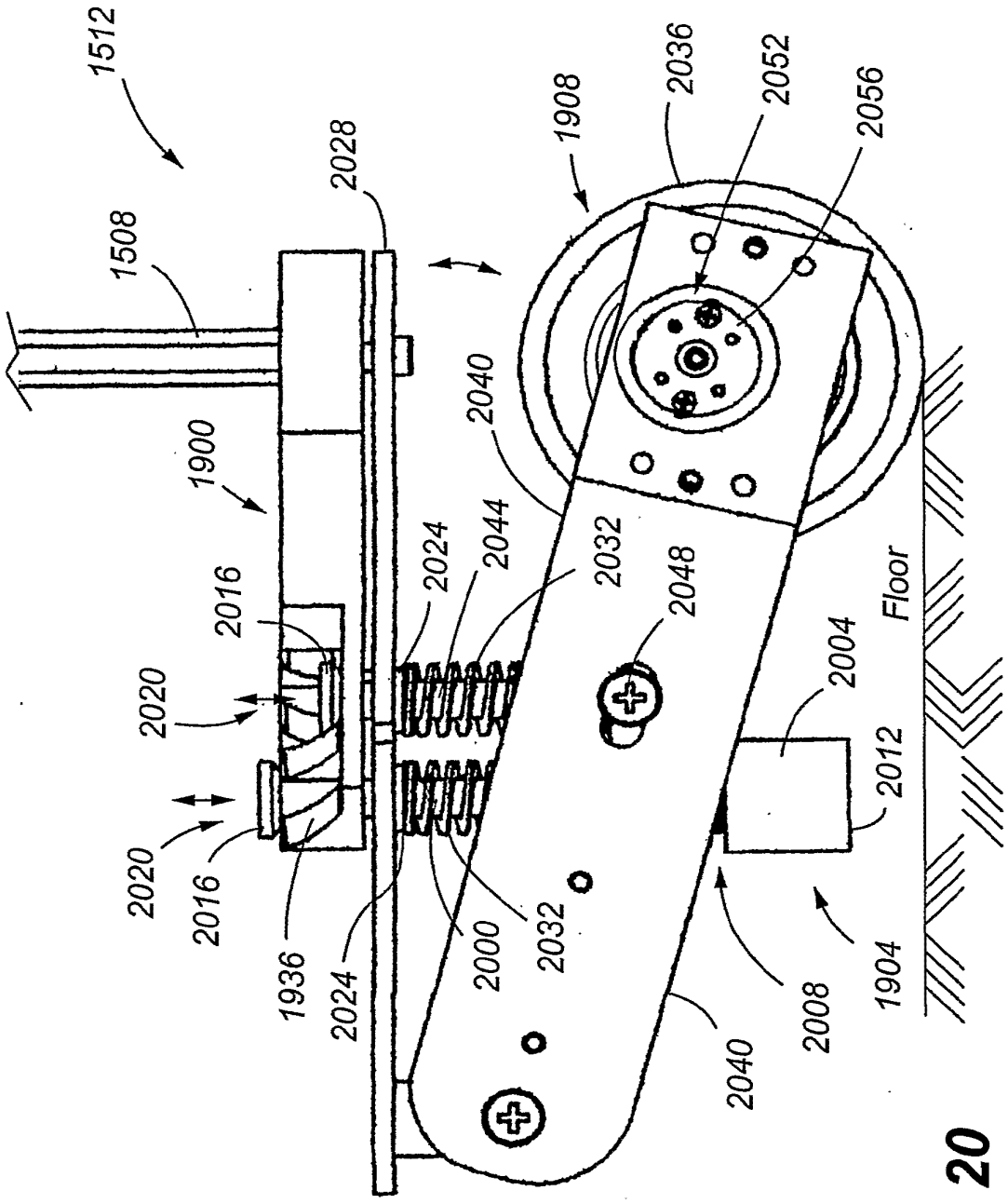

1512
1508
2028
1908
2036
2052
2056
1900
2040
2016
2024
2044
2032
2048
2020
2004
Floor
2012
2020
2016
1936
2024
2000
2032
2008
1904
2040

Fig. 20

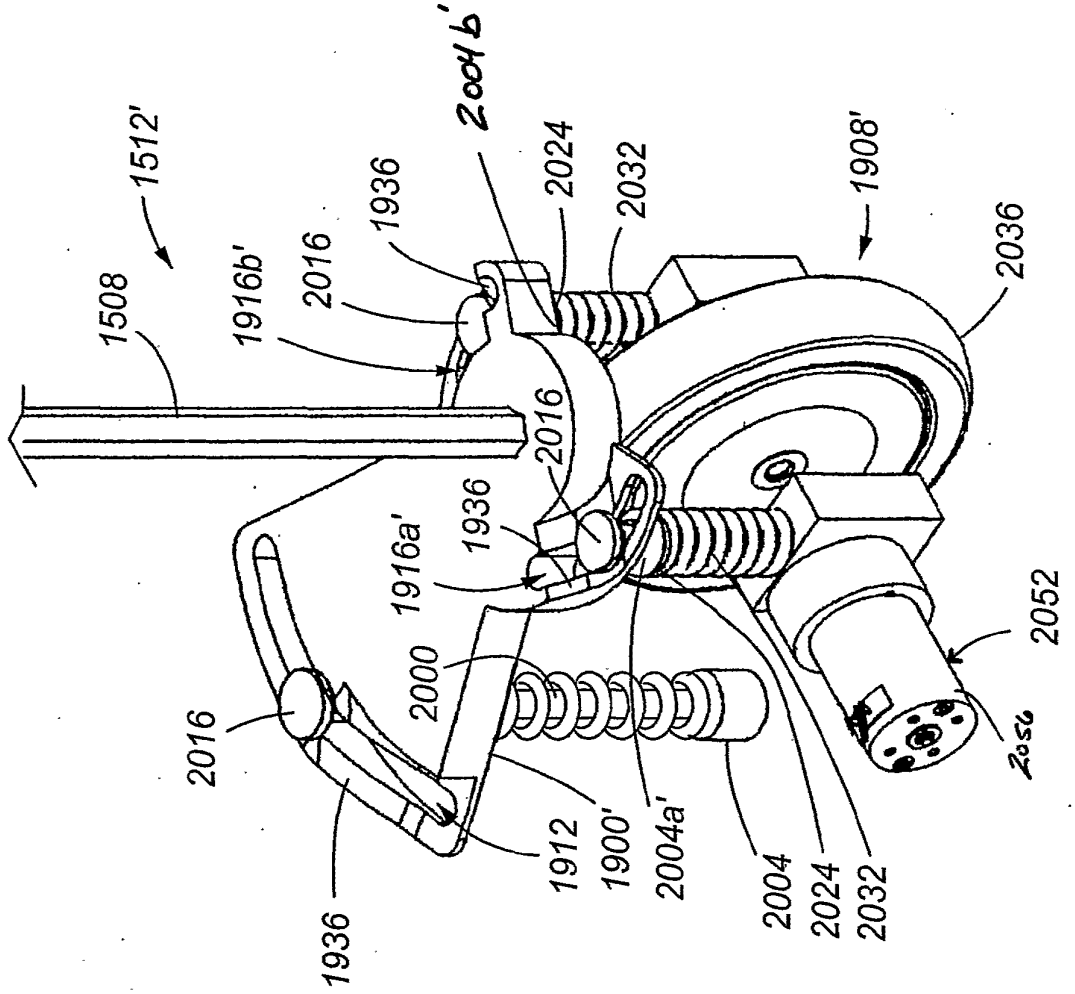
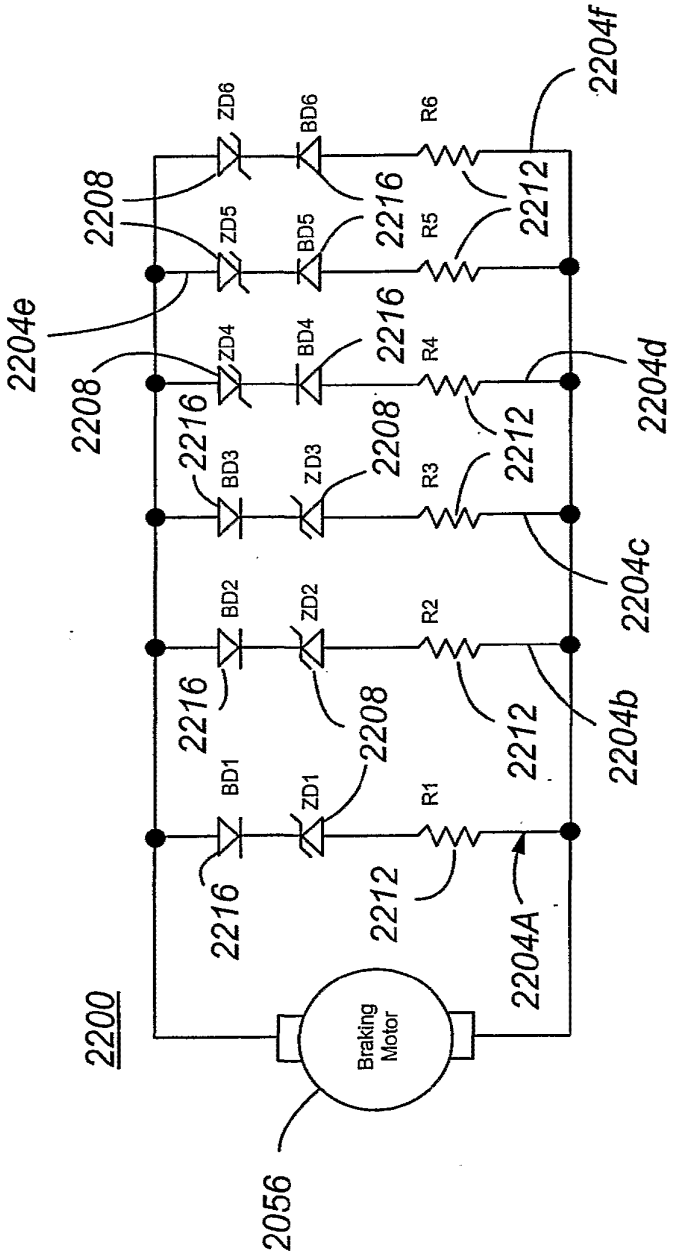

1512'
1508
1916b'
2016
1936
2004b'
2024
2032
1908'
2036
2016
1936
1916a'
2000
2016
1912
1900'
2004a'
2004
2024
2032
1936
2052
2050

Fig. 21

Fig. 22


2200
2056
Braking Motor
2204A
2204b
2204c
2204d
2204e
2204f
2208
2212
2216
BD1
BD2
BD3
BD4
BD5
BD6
ZD1
ZD2
ZD3
ZD4
ZD5
ZD6
R1
R2
R3
R4
R5
R6

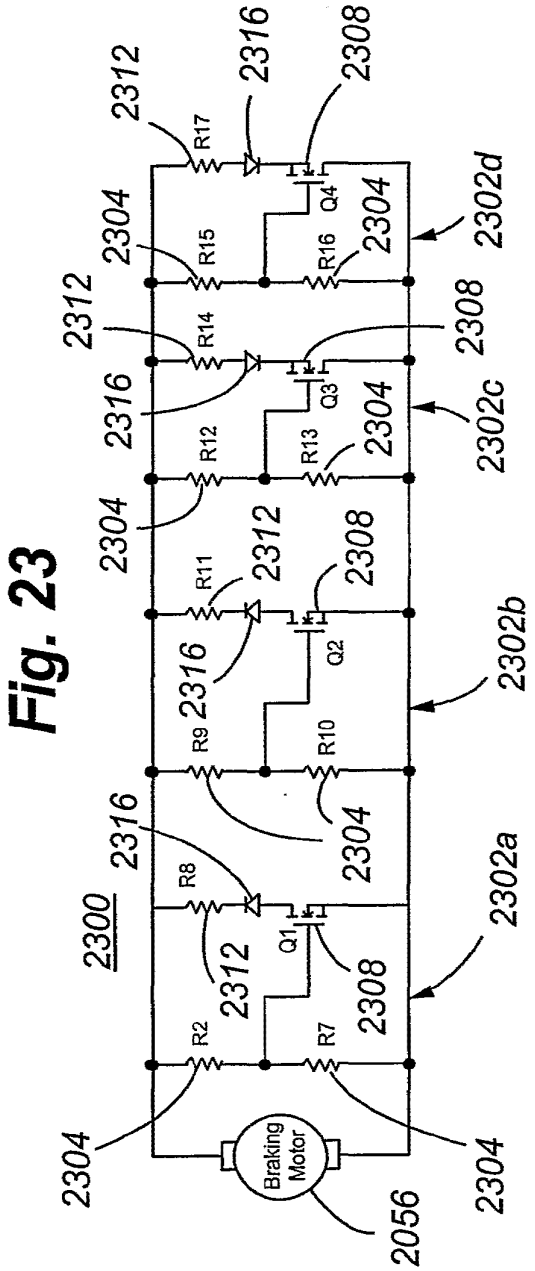



Fig. 23

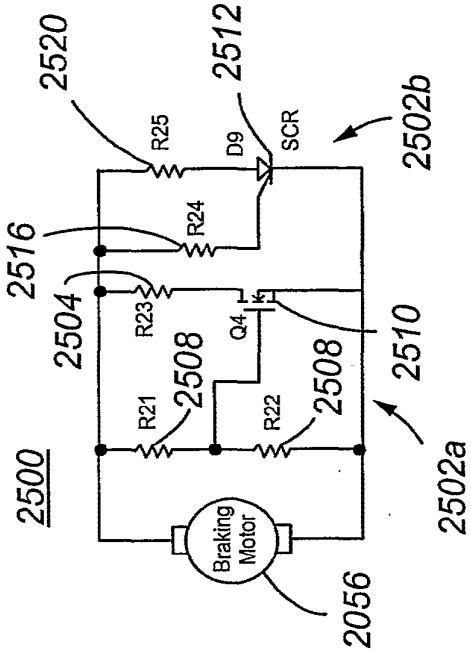



Fig. 25

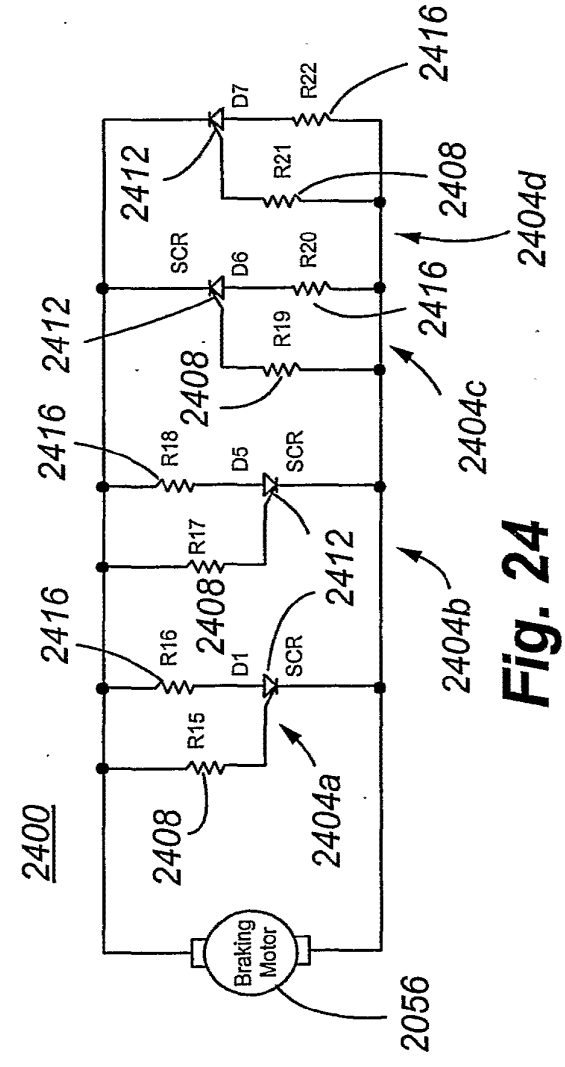



Fig. 24

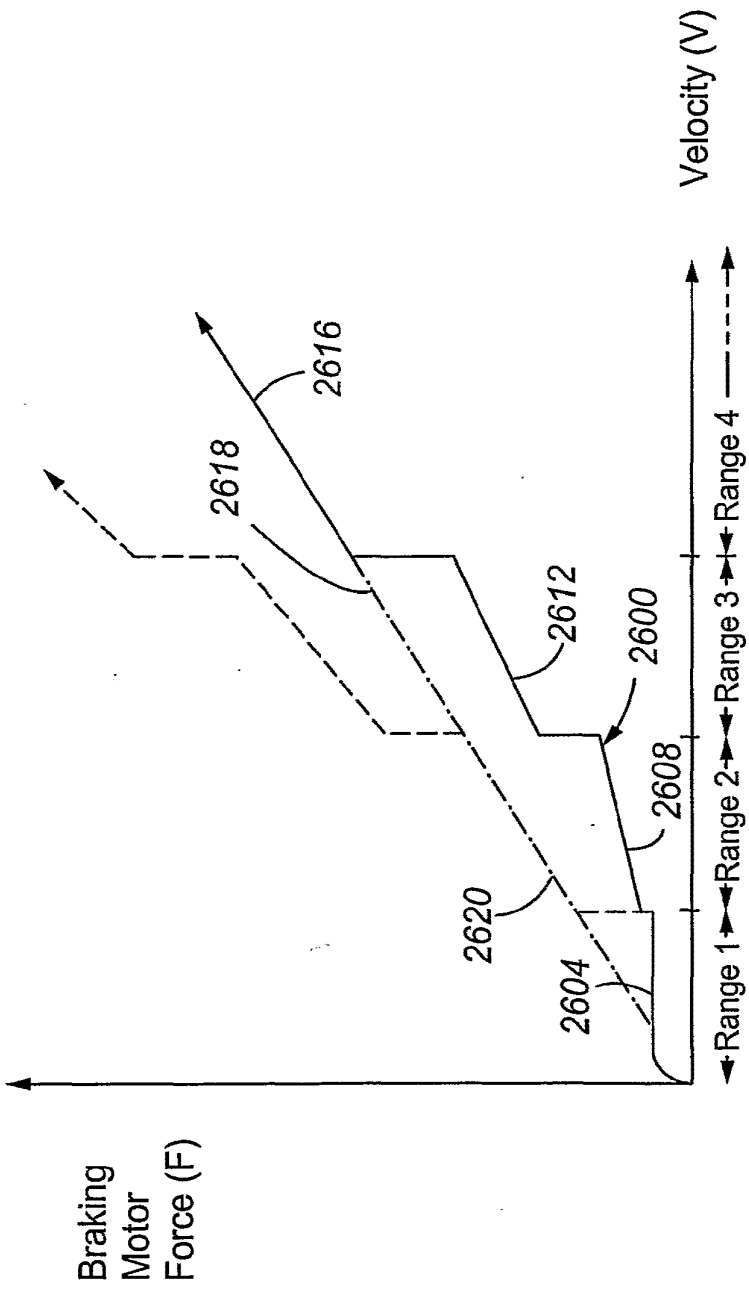

Braking Motor Force (F)
Velocity (V)
Range 1
Range 2
Range 3
Range 4
2604
2620
2608
2600
2612
2618
2616

Fig. 26

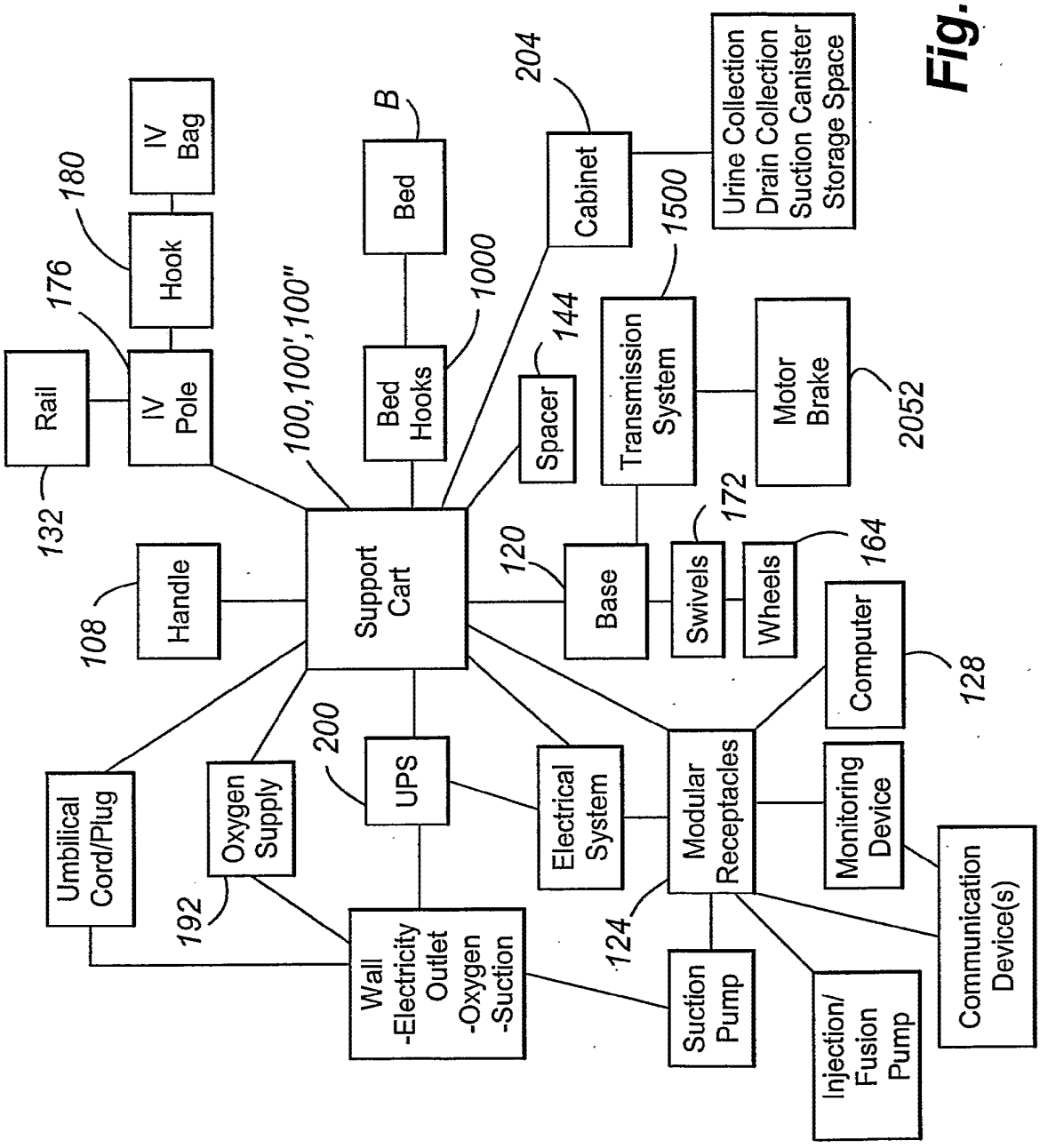

Support Cart
100,100',100"
Handle
108
Rail
132
IV Pole
176
Hook
180
IV Bag
Bed Hooks
1000
Bed
B
Spacer
144
Cabinet
204
Urine Collection
Drain Collection
Suction Canister
Storage Space
1500
Transmission System
Motor Brake
2052
Base
120
Swivels
172
Wheels
164
Computer
128
Modular Receptacles
124
Monitoring Device
Communication Device(s)
Electrical System
UPS
200
Oxygen Supply
192
Umbilical Cord/Plug
Wall -Electricity Outlet -Oxygen -Suction
Suction Pump
Injection/ Fusion Pump

Fig. 27

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 March 2008 (06.03.2008)

PCT

(10) International Publication Number
WO 2008/028165 A2

(51) International Patent Classification:
*A61M 5/20* (2006.01)

(21) International Application Number:
PCT/US2007/077460

(22) International Filing Date: 31 August 2007 (31.08.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/824,222 31 August 2006 (31.08.2006) US

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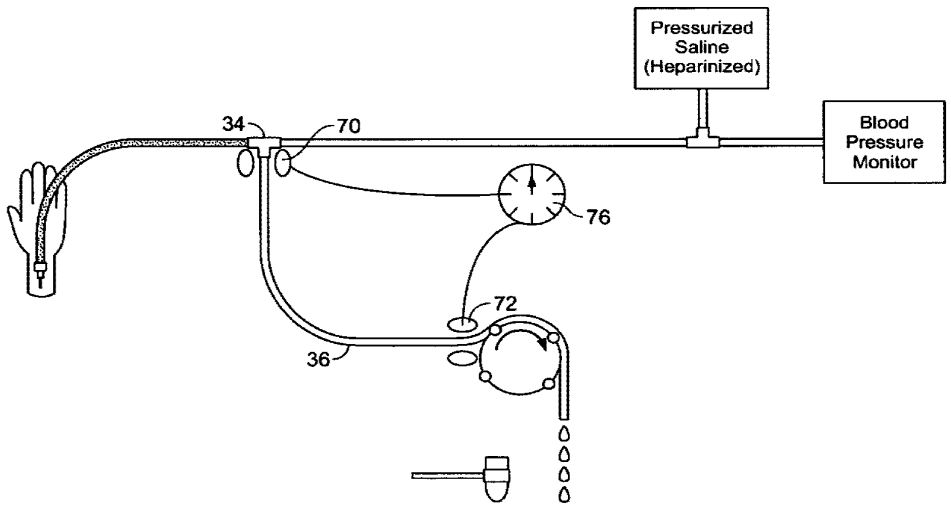
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**
— *without international search report and to be republished upon receipt of that report*

(54) Title: AUTOMATED BLOOD DRAW SYSTEM




(57) Abstract: An automated blood draw system operates in conjunction with an arterial or venous line. The aspiration mechanism allows the rate of aspiration, volume of aspirate, and the time interval of aspiration to be predetermined. Blood can be collected in sequential collection vials for subsequent analysis of a given laboratory parameter, or delivered directly to integrated analysis devices. While a predetermined volume of aspirate can be wasted, excessive aspiration is prevented by monitoring waste obtained in a collection receptacle. A flush system maintains the patency of the line without contamination of the specimen.

WO 2008/028165 A2

# TITLE OF THE INVENTION

# AUTOMATED BLOOD DRAW SYSTEM

## FIELD OF THE INVENTION

(0001) The invention relates to devices used to secure blood samples from humans and animals for purposes of medical studies and patient care. More specifically the invention relates to automated blood drawing devices.

## BACKGROUND OF THE INVENTION

(0002) Periodic sampling of blood is important in a number of applications including applications related to medical studies and in monitoring patient progress and/ or overall health. For example, it is often desirable to determine blood glucose levels over time after a meal in order to determine the efficacy of the body in metabolizing glucose, especially as it relates to diabetic care. Traditionally, blood drawn for the purposes of monitoring blood parameters has been done manually. In a hospital or other research or medical environment, a phlebotomist will manually draw blood by accessing a port on an existing venous or arterial line by inserting a needle in a shunt and drawing blood out using a syringe. In order to best assess the patient's health and/or to make the best study of blood and the body systems being analyzed, blood is often drawn at particular intervals known as time-points. When the blood sampling time-points are spread out, it is possible to manually draw blood,

with a needle and syringe, without the need to pre-establish a blood line with an access port.

(0003) In many applications, the time-points needed for periodic blood sampling is large and blood is sampled frequently. In these cases, manual sampling of blood has numerous disadvantages. Often, manual sampling relies on a healthcare professional that has additional responsibilities besides sampling blood from the patient. In these cases the risk that a time-point sampling could be delayed or missed entirely is high. However, to avoid missing a time-point sample one or more full time attendants are required. This is an expensive and labor intensive requirement.

(0004) Even where the blood drawing technician timely arrives to sample blood, the temporal resolution of the time-point sampling is low. It is difficult for the technician to accurately determine the exact time that the blood was drawn, and in some cases the difference between the actual time-point sampling versus the desired time-point sampling may vary, for example, by tens of seconds to several minutes. With frequent sampling, such variance is counterproductive to the tests being performed.

(0005) It is therefore an object of the present invention to provide an improved system for obtaining periodic time-point sampling of blood so as to, for example, ease the labor requirements of time-point blood sampling and to significantly reduce or eliminate inherent error in manual blood sampling performed according to the current methodology.

## SUMMARY OF THE INVENTION

(0006) It is an object of the present invention to provide for an improved automated blood drawing apparatus. The improved automated blood drawing system allows for accurate and efficient sequential sampling of blood with reduced risk of contamination and ease of use.

(0007) For the purposes of obtaining periodic blood sampling from a patient or research participant, in a first embodiment of the device of the present invention, a 3-way valve assembly is incorporated into a venous or arterial line in close proximity to a patient. The valve assembly is comprised of a first, second and third port. The venous or arterial line is connected to a first port of the valve assembly and an isotonic saline source is connected via a fluid line to the second port of the valve assembly. The first and second ports are thereby configured as fluid entry points into the valve assembly. The third port is attached to aspiration tubing for the purpose of draining the valve assembly into, either a sample collecting receptacle or into a waste receptacle, as will be described below. Arterial or venous blood or saline solution may pass through the valve assembly and enter a fluid line connected to the third port of the valve assembly. The valve assembly is configured to alternatively inhibit the flow of blood or the saline solution depending on the valve assembly setting.

(0008) In one embodiment of the invention, the valve assembly is a commercially available 3-way stopcock assembly. The 3-way stopcock assembly may be

manually controlled; however, automated control is preferred and provided for in embodiments of the present invention. Automated control may be accomplished, in one embodiment, by a rotary servo motor clamped to a stopcock assembly comprised of the 3-way stopcock and a durable holding device or base. The 3-way stopcock is used to control the flow of fluids from a set of tubes attached, respectively, to the source of blood and to a source of flushing solution.

(0009) As will be understood by those having ordinary skill in the art, the automated or manual control of the valve assembly as configured in one embodiment will allow for the valve be used to open and/or close, alternatively, two separate positions (blood and flushing solution) in the system. Therefore, when the valve assembly is connected to tubing as described above and the stopcock is turned to a first position, either manually or through automation, saline solution will be drawn from its source, through the stopcock from the fluid line attached at the second port and into aspiration tubing attached at the third port of the valve assembly. Alternatively, when the stopcock is in a second position, saline solution is prohibited from flowing through the valve body and into the aspiration tubing. Instead, blood will flow from the arterial or venous line, though the valve body and into the aspiration tubing. It will be understood by persons having ordinary skill in the art that a stop position can be included in the valve assembly or that a separate valve can be installed

upstream of the main valve assembly in the saline solution line such that the flow of fluid can be stopped completely as needed.

(00010) Fluid flow through the plurality of fluid lines is controlled by an infusion pump. Activation of the infusion pump results in fluid flow from the venous or arterial line or from the saline source depending on the setting of the valve assembly. In a preferred embodiment of the invention, the infusion pump is pre-programmed for a specific fluid flow rate, to allow for a specific volume of fluid and/or to operate for a specific period of time. In this way, the healthcare professional can predetermine the volume of blood to be drawn from a patient at a specific blood sampling time-point.

(00011) The infusion pump used in such embodiments acts in coordination with an automated control system for the valve assembly. Coordination of the infusion pump and automated valve assembly may be accomplished via serial port programming of the infusion pump and valve assembly control. For example, PC based systems used to control anesthetic drug infusions have been adapted for use with a variety of commercially available medical infusion pumps. Alternatively, the infusion pump may be independently operated by a relay switch controlling power to the infusion pump while the valve assembly is manually or independently automatically operated.

(00012) For example, when a sampling of blood is desired, the valve assembly is automatically set to allow blood from the venous or arterial line to flow through the valve assembly and into the aspiration tubing. When the desired

amount of blood has been obtained, the valve assembly may be automatically programmed to inhibit flow from the arterial or venous line and to allow fluid flow from the saline source into the aspiration tubing. Flushing of the aspiration tubing following blood sampling is desired. Once flushing of the aspiration tubing has been obtained, the infusion pump is programmed to shut off until the next scheduled blood sampling time-point.

(00013) Blood flowing into the aspiration tubing is collected for simultaneous or subsequent analysis of a given blood parameter or for blood drug concentration. Blood may be collected upon exit from the aspiration tubing in a blood collecting vial. Placement of the blood vial in the stream of the blood exiting the aspiration tubing is accomplished automatically via a commercially available fraction collector suitable for the purpose. Alternatively, blood may be collected in a bolus in heat sealable tubing. Date and time stamping of the bolus identifies the samples for subsequent analysis.

(00014) Appropriate safety features are preferably incorporated into the blood drawing apparatus. In those applications where blood exiting the aspiration tubing flows into an open vial, introduction of air into the arterial or venous line is of particular concern. To avoid the unwanted introduction of air, prior flushing of the aspiration tubing prior to a given sampling may be accomplished. Alternatively, an infusion pump may be incorporated with an internal sensor able to detect air entering the fluid lines. Other safety features, such as

pressurized expulsion of blood from the aspiration tubing may be used independently or in coordination with other safety features of the system.

(00015) Malfunction and erroneous programming of the automated blood drawing apparatus is of particular concern as it may result in excessive pumping of venous or arterial blood from the a patient, or infusion of excessive saline into the venous or arterial line attached to the patient. A float sensor may be incorporated into an overflow tank so as to monitor excessive wasting of blood or saline flowing from the aspiration tubing. An alarm may be activated when the waste tank contents reach a predetermined level and power from the infusion pump may be automatically cut. Alternatively, an optical sensor may be incorporated at a desired location in at least one of the plurality of fluid lines so as to detect and calculate the volume of blood flowing through the tubing at a given sampling time. Once the volume exceeds a predetermined limit the user is notified or the system may be programmed to automatically shut off. Other sensing devices may be used independently or in addition to the safety features already described, such as mechanical, ultrasonic, or other acceptable flow sensing technologies.

(00016) An automated blood drawing apparatus consistent with the present invention may be adapted for use in systems currently established for manual blood drawing and monitoring. For example, manual systems have been developed for simultaneous monitoring of blood pressure in between blood sampling.

These systems may be successfully adapted utilizing the automated features described herein.

(00017) Other modifications and improvements of currently available and described devices will become apparent to those skilled in the art from the detailed description of the invention below. The current invention is not limited by the specific and preferred embodiments described herein.

## BRIEF DESCRIPTION OF THE DRAWINGS

(00018) Further objects of the invention, together with additional features contributing thereto and advantages occurring therefrom, will be apparent from the following description of the invention when read in conjunction with the accompanying drawings; wherein:

(00019) FIG. **1** depicts a schematic representation of a single time-point sampling of blood by an automated blood drawing apparatus according to a specific embodiment of the present invention;

(00020) FIG. **2** depicts a schematic representation of the blood collection vials on a carousel-type device and a waste collector all used in association with a specific embodiment of the present invention;

(00021) FIG. **3** depicts a specific embodiment of the automated blood draw device incorporated into an arterial line pre-established to monitor blood pressure;

(00022) FIG. **4** depicts a specific embodiment of the automated blood draw device utilizing optical sensors and a timing element to improve efficiency of the device;

(00023) FIG. **5** depicts a specific embodiment of the automated blood draw device wherein coordination of apparatus components is accomplished via a single computer;

(00024) FIG. **6** depicts a specific embodiment of the automated blood draw device wherein sampled blood is collected in a bolus of pliable material;

(00025) FIG. **7** depicts another specific embodiment of the automated blood draw device wherein sampled blood is collected in a bolus of pliable material.

## DETAILED DESCRIPTION OF THE INVENTION

(00026) While the present invention is susceptible of embodiment in various forms, there is shown in the drawings and will hereinafter be described a presently preferred embodiment with the understanding that the present disclosure is to be considered an exemplification of the invention and is not intended to limit the invention to the specific embodiments illustrated. It should be further understood that the title of this section of the specification, namely "Detailed Description of the Invention", relates to a requirement of the United States Patent Office, and does not imply, nor should be inferred to limit the subject matter disclosed herein.

(00027) Referring to **FIG. 1**, In a particular embodiment of the present invention a valve assembly is comprised of a 3-way stopcock **8**, a solid base and a rotary servo motor, all of which are known to persons having ordinary skill in the art. Disposable 3-way stopcocks appropriate for the patient environment are commercially available and preferred for their ease of use. The 3-way

stopcock is provided with means for selectively determining the position of an internal valve within the stopcock body to allow fluid flow through the stopcock body from one of two input ports and out of a third port.

(00028) A solid base, such as of metal or hard plastic, is provided to receive and securely clamp the stopcock body. Ideally, placement of the stopcock valve assembly at the base is accomplished without tools. For example, the stopcock assembly may be placed by press fitting the assembly to the base. The solid base may also be associated with means providing easy access by a health care professional to the 3-way stopcock. Additionally, a rotary servo motor may be clamped to the stopcock body and base to allow automated operation of the internal valve so as to determine at least two positions of the valve. The rotary servo motor in conjunction with the 3-way stopcock and solid base comprises the valve assembly.

(00029) It will be apparent to one skilled in the art that the invention is not limited to the specific valve assembly described. For example, the 3-way stopcock may be replaced in appropriate applications with a 1-way or 4-way stopcock incorporated into the previously described valve assembly. Alternatively, T-branches as commonly known in the art may be used to interconnect tubing. A T-branch is comprised of a first, second and third port that can accept the blood line **2**, flushing line **4** and aspiration line **6** of **FIG. 1** respectively. In lieu of the valve apparatus of the stopcock, multiple blunt pinchers may be used to facilitate or inhibit fluid flow in the plurality of fluid lines. Before

use, the interconnected tubing would be pressed into the jaws of the pinchers. In one embodiment of the invention, servo motors may be used to control the pinchers, enabling one or more sections of tubing to be pinched closed while simultaneously releasing one or more sections of tubing, thereby facilitating fluid flow. Other modifications of the valve assembly consistent with the spirit and scope of the present invention will be obvious to those skilled in the art. The preceding is included for completeness of the description and while numerous elements described are not shown in the illustration, persons having ordinary skill in the art will understand the use and placement of such elements.

(00030) Referring now to **FIG. 1**, in one particular embodiment of the invention utilizing a valve assembly with a 3-way stopcock, the 3-way stopcock **8** valve assembly is associated with a patient blood line **2**. The blood line **2** is connected at an origin position to a patient, in a manner well known to medical and research professionals, and at a terminal position to a first port **10** of the 3-way stopcock **8**. Preferably, the length of the blood line **2** is kept small so the total volume of blood required to fill the blood line is minimized and excessive blood waste from the patient is avoided. In an alternative embodiment of the invention, the blood line is a previously established venous or arterial line wherein the valve assembly is incorporated into the venous or arterial line at a position in close proximity to the patient.

(00031) A fluid line **4** is connected at an origin position to a flushing solution source **16** and at a terminal position to a second port **12** of the 3-way stopcock **8** valve assembly. It will be understood by persons having ordinary skill in the art that the flushing solution will be utilized to cleanse the valve and aspiration tubing preceding each blood sampling as will be described in detail below. In a specific embodiment of the invention, the flushing solution source **16** attached to the origin of the fluid line **4** is comprised of an isotonic saline solution. In some applications it may be desirable to utilize an isotonic flushing solution with additives, such as heparin, to better effectuate clearing of the automated blood apparatus of blood in between sampling. The flushing solution is utilized in applications according to the invention so as to flush the stopcock valve and the aspiration tubing after a given sampling of blood and to further ensure fluid flow through the stopcock valve and the plurality of fluid lines does not become obstructed.

(00032) Finally, aspiration tubing **6** is connected at an origin position to a third and final port **14** of the 3-way stopcock **8** valve assembly. The terminus of the aspiration tubing allows for elimination of fluid originating from either the blood line **2** or the fluid line **4** into appropriate collecting means or into a waste collection tub **26** (see **FIG. 2**). Where it is desired to incorporate the valve assembly into a pre-existing venous or arterial line, the pre-existing line is cut and the cut termini of the venous or arterial line are attached at the first and third ports of a 3-way stopcock as previously described, forming the

blood line and the aspiration tubing respectively. The flushing line **4** is then established as previously described.

(00033) Referring now to **FIG. 1A**, when the 3-way stopcock is manually or automatically set to a first position the flushing solution **16** is drawn into the flushing line **4**, through the stopcock **8** and into the aspiration tubing **6** attached at the third port of the stopcock. Flushing solution is prohibited from entering the blood line **2** attached to the first port of the stopcock. Alternatively, as shown in **FIG. 1B**, when the 3-way stopcock is set to a second position blood is drawn into the blood line **2**, through the stopcock **8** and into the aspiration tubing **6**. Blood is prohibited from flowing into the fluid line **4** attached to the second port of the stopcock when the stopcock is in either the first or second position. Flushing solution and blood passing through the stopcock body and into the aspiration tubing is collected, wasted and/or analyzed as described in detail herein.

(00034) Referring generally to **FIG. 1**, fluid flow from the flushing solution source **16** or from the blood line **2** is controlled by an infusion pump **18**. When the infusion pump is inactive, fluid flow through the stopcock body **8** is inhibited. Upon activation of the infusion pump, fluid flows through the stopcock body **8** and into the aspiration tubing **6**. Activation of the infusion pump may be manually effectuated. Alternatively, in a preferred embodiment of the invention, activation of the infusion pump **18**, the rate of fluid flow into the aspiration tubing **6**, the volume of aspirate, and/or the time interval of

aspiration are pre-programmed and automated. In one embodiment of the invention, an analog infusion pump operable by a relay switch controls power to the infusion pump. Alternatively, serial port programming of the infusion pump **18** can be used to control fluid flow through the stopcock body **8** and into the aspiration tubing **6**. For example, PC based systems used to control anesthetic drug infusions have been adapted for use with a variety of commercially available medical infusion pumps and may be successfully adapted for use with the present invention.

(00035) According to one embodiment of the invention, blood is collected upon exit from the aspiration tubing **6** in a vial **20** of an appropriate size for the application. Preferably, vial placement in the blood stream is accomplished automatically. For example, **FIG. 1** depicts a linear actuator **28** that may be used to place a vial **20** in one of two positions. A first position, shown in **FIG. 1A**, places the vial **20** out of the stream of fluid flowing from the aspiration tubing **6**. When the linear actuator **28** is in this position, fluid flowing from the aspiration tubing **6** is collected in a waste receptacle. A second position of the linear actuator **28**, shown for example in **FIG. 1D**, places a collection vial **20** in the path of blood flow and allows for the collection of blood exiting from the aspiration tubing **6**.

(00036) Alternatively, it may be desirable to sequentially obtain blood from the aspiration tubing **6** in multiple collection vials. An apparatus, such as a fraction collector able to hold multiple vials and sequentially place them in a

stream of blood flowing from the aspiration tubing may be used. In one embodiment of the invention demonstrated at **FIG. 2**, a rotating tray **22** capable of holding a plurality of vials **24** is used for the purposes of obtaining sequential blood samples automatically and without manual intervention. Flushing solution and stagnant blood exiting the aspiration tubing **6** is collected in a waste tub **26** located beneath the rotating tray **22**. When the waste fluid has been fully cleared from the aspiration line **6**, the rotating tray automatically places the next available collection vial **24** into the blood stream thereby collecting the desired time-point blood sample. In one specific embodiment of the invention, the rotating tray may be coupled with a point-of-care analyzer such as an ACT monitor to analyze blood parameters in the collected sample. While the sample is being analyzed, the adjacent vial is positioned to gather the next sample. This system allows for automation of several samples sequentially. The ACT analysis cartridge may be changed by the health care provider at change of shift or at set intervals.

(00037) Referring again to **FIG. 1**, a time-point sampling of blood from a patient according to one embodiment of the invention is shown. The 3-way stopcock **8** valve is manually or automatically set to a first position to allow flushing solution **16** to flow into the aspiration tubing **6**. The infusion pump **18** is activated manually or automatically to completely flush the stopcock body **8** and the aspiration line **6**, as shown at **FIG. 1A**. Flushing solution exits from the aspiration tubing **6** into a waste receptacle. Adequate flushing of the

aspiration tubing allows for accurate blood sampling and prevents contamination of the aspiration line.

(00038) Referring now to **FIG. 1B** and **1C**, once the aspiration line **6** has been adequately flushed, the stopcock valve is manually or automatically set to a second position, thereby allowing blood to flow through the stopcock body **8** and into the aspiration tubing **6**. The infusion pump **18** is activated manually or automatically to allow blood from the blood line **2** to enter the aspiration tubing **6**. The blood line **2** will be filled with stagnant blood left over from the previous time-point blood sampling and must be eliminated from the system before the time-point blood sample is collected, as shown in **FIG. 1C**. Likewise, flushing solution filling the stopcock body and the aspiration tubing must be eliminated from the system, as shown in **FIG. 1B**. Stagnant blood and flushing solution are eliminated from the system and collected in a waste container. The linear actuator **28** may be manually operated or automated in conjunction with the infusion pump **18** to ensure the vial **20** remains in a first position out of the stream of fluid exiting the aspiration tubing **6** until such time that the flushing solution and stagnant blood have cleared the system.

(00039) In one embodiment of the invention, a second infusion pump may be placed along the blood line **2** between the stopcock **8** and the patient to allow for flushing of the blood line **2** in between blood sampling. The infusion pump is activated at the end of a time-point blood sampling either before or after the aspiration tubing **6** has been flushed. Appropriate flushing solution **16** flows

through the valve body and into the blood line **2**, and toward the patient. The infusion pump may be manually or automatically operated to ensure excessive flushing solution does not enter the blood line **2** and thereby the patient. An appropriate valve assembly is selected in systems calling for flushing of the blood line between time-point blood sampling and other modifications apparent to one skilled in the art are within the scope of the invention.

(00040) Referring now to **FIG. 1D**, the linear actuator **28** is manually or automatically activated to move the collection vial **20** into the stream of blood exiting the aspiration tubing **6**. A time-point sampling of blood is collected manually or automatically. In a preferred embodiment of the invention, the blood sample is collected automatically. The system is pre-programmed to calculate the amount of blood flowing into the aspiration tubing from the patient. System dependent parameters that may be entered by a technician include the length of the blood line **2**, the length of the aspiration tubing **6**, the infusion pump **18** speed or the volume rate of fluid flowing through the aspiration tubing **6** and/ or the volume of blood to be sampled at each time-point. In certain applications, it may be desirable to deliver a quantity of flushing solution to the collection vial, for example, to deliver an additive such as heparin present in the flushing solution. In this manner, vials pre-packaged containing heparin or any other desired additive may be obviated.

(00041) Once the desired volume of blood for a time-point sample has entered the aspiration tubing **6**, the stopcock **8** valve is set to a first position to allow

flushing solution **16** to enter the stopcock body and flow into the aspiration tubing **6**. In this manner, the total volume of blood drawn from the patient at each time-point sampling is carefully calculated and the system may be programmed to minimize wasting. Minimization of wasting is particularly important where a number of time-point blood samples are required over a relatively short period of time.

(00042) After the desired volume of blood has been collected in the collection vial **20**, the linear actuator **28** moves the collection vial out of the stream of blood exiting the aspiration tubing **6**, as shown in **FIG. 1E** and **1F**. To provide for accurate blood sampling and to prevent contamination the aspiration tubing must be flushed between sequential blood draws. The stopcock **8** and aspiration tubing **6** are completely flushed with flushing solution **16**. In one embodiment of the invention, the automated blood draw system is programmed to allow the residual blood and a predetermined amount of flushing solution to pass through the aspiration tubing **6** and into the waste collection container. Flushing is coordinated to avoid collection of flushing solution in the blood collection vials and to minimize blood waste.

(00043) Once the aspiration tubing **6** has been completely flushed, the infusion pump **18** is manually or automatically shut off to inhibit the flow of fluid through the system. The automated blood draw system is inactive until the next scheduled time-point blood sampling is desired. Blood collected in the collection vial **20**

is manually or automatically stored or processed and a new collection vial prepared for the next sampling.

(00044) A specific embodiment of the invention has been described whereby time-point blood samples are collected in collection vials **20**. Alternatively, a time-point blood sample may be collected as a bolus within a heat-sealable sheath of pliable tubing as shown in **FIGS. 6** and **7**. Referring to **FIG. 7**, blood exiting the aspiration tubing is introduced into the pliable collection tubing material **164**. Once the desired volume of blood has entered the collection tubing, heating and pressure means, for example heated wires and pressure rollers, are provided for heat-sealing at a first **182** and second **184** position along the tubing length, thereby creating a bolus **176** of blood of the desired volume. A time-point sample identifying stamp may be pressed into a crimped portion **178** of the pliable material. Air may be evacuated from the bolus prior to heat sealing to ensure the integrity of the sample prior to processing. The heat sealed bolus is then cut from the remaining tubing utilizing, for example, a plurality of cutting elements **170** and **172** adjacent the heating elements **160**, **162**. Flushing of the aspiration tubing may then proceed as previously described and the tubing material advanced for a subsequent sampling.

(00045) In one embodiment of the invention, referring to **FIG. 6**, an automated device for pinching, cutting, and advancement of the pliable collection tubing containing a bolus of blood may utilize first **202** and second **200** rolling

elements positioned adjacent heated wires **204**, **206**. The heated wires may be pre-spaced to an appropriate separation to achieve the desired bolus volume. The heated wires **204**, **206** are capable of pressing in on the pliable tubing **212** while heating the material so as to seal the tubing material upon cooling. A guillotine **208** for cutting the heat sealed bolus is provided adjacent the second roller means. Preferably, when the collected bolus has been sealed from the unused collection tubing, means are provided **210** for time marking either directly to the tubing or to a label attached to the tubing the time at which the blood sample was sealed and any other identifying information that may be helpful when later handling the bolus. Collection tubing used in accordance with the invention should be supplied with sufficient excess material to allow for collection of the desired number of blood samples without the risk of running out of the pliable collection tubing.

(00046) In some applications, it may be desirable to further automate the device to allow for immediate analysis of one or more blood parameters. For example, it is often necessary to perform real-time evaluation of the Activated Clotting Time (ACT) of a given blood sample. In current practice, a health care provider is often required to manually recover a collected sample of blood so as to perform real-time ACT analysis. The present invention may be successfully practiced to automate the ACT analysis so as to provide faster and more efficient blood parameter readings.

(00047) An automated blood sampling device according to a specific embodiment of the present invention may be pre-programmed to periodically determine the Activated Clotting Time of an aspirated volume of blood. Automated means known in the art are adapted to perform ACT analysis of a blood volume collected in a collection vial as previously described and to provide real-time display of ACT. Alternatively, blood may be delivered automatically to a testing apparatus that is moved into the stream of blood exiting the aspiration tubing after a blood sample has been obtained in a collection vial. The testing apparatus is adapted to perform ACT analysis on the sample in the usual way. It will be obvious to one skilled in the art that further automation of the invention to allow for blood parameter analysis is not limited to the specific embodiments described.

(00048) The invention may also be successfully adapted for practice with an arterial line that has been established to monitor blood pressure and to allow the delivery of pressurized saline. In these applications it is possible to allow for the periodic sampling of blood while maintaining the functionality of the blood pressure monitoring system.

(00049) Referring to **FIG. 3**, a normal arterial line **30** is provided with access means in the form of a port **32** adjacent the insertion of the arterial line **30** into a patient. The port **32** provides access to the patient's bloodstream for delivery of medication. Upstream of the port **32**, a 3-way stopcock **34** is inserted by cutting the pre-existing arterial line and attaching the cut termini to a first **50**

and third **52** port of the stopcock body. Aspiration tubing **36** is attached to a second **54** port of the stopcock body. The stopcock **34** is inserted such that the pressurized saline source **38** and blood pressure monitoring means **40** are located upstream.

(00050) Fluid lines incorporating the pressurized saline source **38** and blood pressure monitoring means **40** into the automated blood drawing device are set up in the usual manner. For example, a second 3-way stopcock **46** receives fluid lines from the saline source **38** and blood pressure monitoring means **40** at a second **56** and third **58** port of the stopcock **46** body respectively. The transmission line **60** is attached at an origin to the third port **52** of the stopcock **34** and at a terminus to the third port **62** of the stopcock **46** receiving fluid lines from the saline source **38** and blood pressure monitoring device **40**. The first **34** and second **46** stopcocks may be manually or automatically controlled, for example, utilizing rotary servo motors.

(00051) The saline source **38** connected via the upstream stopcock **46** may be used to flush the aspiration tubing **36** and optionally the arterial line **30** in between time-point blood sampling. The stopcock valves, infusion pump, and linear actuator **44** used to collect sample blood may be manually or automatically controlled. System flushing, blood collection, and wasting of flushing fluid and stagnant blood is accomplished in the manner previously described. The pressurized saline source **38** acts similarly to the flushing solution **16** of **FIG.**

**1** when the stopcock **46** valve is set in a first position allowing pressurized saline to flow through the stopcock body and into the transmission line **60**.

(00052) It will be readily apparent to one skilled in the art that pre-programming of the automated blood draw system is preferred. In one embodiment of the invention, multiple programming interfaces may be used to independently control an infusion pump, a stopcock valve assembly comprised of a servo motor and a blood fraction collecting device. User interfaces are commonly associated with commercially available servo motors, infusion pumps and fraction collectors.

(00053) Alternatively, referring to **FIG. 5**, in a preferred embodiment of the invention, a single user interface **104** is provided for programming a computer **106**. For example, a single computer interface **104** may be used to accept programming input to control a servo motor **100**, an infusion pump **18** and vial carousel **102** according to the present invention. Appropriate system parameters are entered into the computer and a microprocessor coordinates the operation of the component parts to achieve the desired result by generating output signals **108**, **110**, **112**. While systems with a single user interface are preferred, the present invention is not limited to single user interface systems or to systems designed for automated operation.

(00054) The computer **106** may also be adapted to receive output signals **114**, **116**, **118** generated by monitoring devices. Monitoring devices may include, for example, a fluid waste container **120** or fluid sensors **122**, **124**. The present

invention is not limited to the specific monitoring devices described herein, and one skilled in the art will recognize obvious modifications that are within the scope of the present invention.

(00055) The automated blood drawing system according to the present invention may be further automated to provide for more precise measuring of blood flow through the stopcock body and into the aspiration tubing. In one embodiment of the present inventions, referring to **FIG. 4**, optical sensor switches are provided in cooperation with timing means and together are adapted to measure the quantity of blood passing through the aspiration tubing at a given sampling. A first optical sensor **70** is placed along the aspiration tubing **36** adjacent the valve body **34**. A second optical sensor **72** is placed along the aspiration tubing **36** at a position downstream of the valve body **34** and before the open end of the aspiration tubing **36**. The optical sensors are able to detect whether blood or flushing solution is flowing through the aspiration tubing **36** adjacent the respective sensor based on the absorption properties of the liquid.

(00056) The first **70** and second **72** optical sensors are provided with means for communicating with a timer **76**. The timer **76** may be, for example, a mechanical timer, a digital recorder, or a computer. In a preferred embodiment of the invention, when blood enters the aspiration tubing **36** from the valve body **34** the first optical sensor **70** sends a signal to a timing computer **76**, resulting in the initiation of the timing clock. When the blood reaches the second sensor **72**, a signal is sent to the timing computer **76**. The

computer then calculates the rate of blood flow through the aspiration tubing **36** based on pre-programmed system parameters and the timing between activation of the first and second optical sensors. This information may be used by the computer to coordinate other system components resulting in efficient blood sampling. Likewise, the optical sensors are able to calculate the rate of flushing solution passing through the aspiration tubing so as to ensure adequate flushing of the line.

(00057) The information obtained from the optical sensors and delivered to the computer may also be used to generate a time stamp for a given time-point blood sampling. The exact timing of the blood draw, the volume of blood obtained, and other pertinent system parameters may be recorded to a database for future reference. Other modifications of the system utilizing optical sensors to coordinate functionality of various components within the scope of the present invention will be apparent to those skilled in the art.

(00058) Consistent with the scope of the invention, appropriate safety features may be incorporated into particular embodiments of the invention. For example, in those applications where collection blood is delivered directly into an open vial, accidental introduction of air into the arterial or venous line is a particular safety concern. Referring to **FIG. 1A**, to prevent unwanted introduction of air into the plurality of fluid lines, isotonic saline solution may be run through the aspiration tubing **6** before the stopcock **8** valve is set to a second position, thereby allowing blood to enter the aspiration tubing **6**. In

addition, the infusion pump **18** may be adapted with an internal alarm programmed to sound when air enters the aspiration tubing **6**.

(00059) In another embodiment of the invention adapted to prevent air from entering the system, blood and saline may be pressure forced through the stopcock body and aspiration tubing rather than allowing sample or waste fluid to drip freely from the terminus of the aspiration tubing and into the desired collection receptacle or waste collector. A valve that opens only after exceeding a minimum pressure may be used since the infusion pump creates pressure downstream of the valve.

(00060) An additional safety consideration is a potential malfunction or erroneous programming of the automated blood draw system that may result in excessive pumping of arterial or venous blood through the aspiration tubing and into the collection container. A fluid float, such as those commonly used to indicate gas level in a closed tank may be used to monitor the level of waste collected in a waste container. An alarm may be programmed to activate when excessive fluid is collected. In an alternative embodiment of the invention, power to the infusion pumps may be cut when the fluid level in the waste container has passed a pre-determined level indicating excessive fluid waste by the system.

(00061) In another embodiment of the invention, an optical system sensitive to the difference in light absorption between clear flushing solution and opaque blood may be used to monitor when blood is being aspirated. Such a device

may be placed at a point along the aspiration tubing before or after the infusion pump. The volume of aspirated blood may be calculated, based for example on the length of time the infusion pump has been operational, volume of through-flow per second for the tubing and infusion pump used, and/or on whether blood or saline was being pumped through the system during the infusion pumps operation. If this blood volume exceeds a pre-set limit of aspiration, the user would be notified and/or power to the infusion pump would be cut.

(00062) In yet another embodiment of the invention, a flow sensor may be placed around or in series with the section of tubing coming from the patient's blood line, before the intersection of the blood line with the saline line, to monitor the amount of blood flowing out of the patient. This flow sensor could be mechanical (e.g., paddle wheel), ultrasonic (e.g., Doppler), or be comprised of other accepted flow sensing technology. When total volume of blood outflow exceeds a pre-set limit of aspiration, the user would be notified and/or power to the infusion pump would be cut. Additional safety features within the scope of the present invention will be apparent to one skilled in the art.

(00063) A specific embodiment of an automated blood drawing apparatus according to the present invention has been described for the purpose of illustrating the manner in which the invention is made and used. It should be understood that the implementation of other variations and modifications of the invention and its various aspects will be apparent to one skilled in the art, and that the

invention is not limited by the specific embodiments described. Therefore, it is contemplated to cover the present invention and any and all modifications, variations, or equivalents that fall within the true spirit and scope of the basic underlying principles disclosed and claimed herein.

CLAIMS

1. An automated blood drawing apparatus for drawing blood samples at scheduled time intervals from a human or animal, comprising:

a branching element capable of transmitting fluid and engaging at least three fluid lines;

the first fluid line being capable of transmitting blood from a human or animal to the branching element;

the second fluid line being capable of delivering a flushing solution from a flushing solution source to the branching element;

the third fluid line being capable of transmitting fluid arriving at the branching element from either the first or second fluid line to collection means located at the terminus of the third fluid line;

the collection means comprising at least one collection receptacle and a waste container;

the collection means being capable of moving the collection receptacle to a first position to allow fluid exiting the third fluid line to empty into the collection receptacle or to a second position to allow the fluid exiting the third fluid line to empty into the waste container, wherein the collection receptacle is moved to a first or second position in response to an input signal;

at least one pumping means capable of initiating fluid flow through the branching element and the plurality of fluid lines upon activation, the pumping means being selectively activated or deactivated in response to an input signal;

at least one selection means for selectively inhibiting fluid flow in at least one of the fluid lines while the pumping means is activated, the selection means being capable of selective activation in response to an input signal;

wherein activation of one or more selection means allows blood to flow from the first fluid line through the branching element and into the third fluid line or allows flushing solution to flow from the second fluid line through the branching element and into either the first or third fluid line;

computer means capable of providing an input signal to the pumping means, the selection means, and the collecting means in response to system generated information;

the system generated information being produced by the computer means in response to programming information entering the computer means from at least one user interface and from at least one monitoring device;

the system generated information resulting in output signals allowing for coordination of the pumping means, selection means, and the collecting means such that efficient blood sampling occurs at scheduled time intervals without excessive blood waste.

2. An automated blood drawing apparatus according to claim **1**, wherein the collection means is comprised of a fraction collector and a waste receptacle;

the fraction collector being comprised of a carousel tray and a plurality of collection receptacles;

wherein in response to an input signal, the carousel tray is moved to a first position whereby one of a plurality of collection receptacles is placed into a stream of fluid exiting the third fluid line;

wherein in response to a second input signal, the carousel tray is moved to a second position whereby the first collection receptacle is moved out of the stream of fluid exiting the third fluid line, fluid exiting the fluid line thereby being collected in a waste container located beneath the carousel tray;

wherein subsequent input signals result in the carousel tray being moved so as to place additional collection vials sequentially in and out of the stream of fluid exiting the third fluid line.

3. An automated blood drawing apparatus according to claim **1**, wherein a monitoring device determines the volume of fluid in the waste receptacle;

said monitoring device being capable of generating an output signal to the computer means when the fluid level in the waste container exceeds a pre-determined level;

said output signal resulting in sounding of an alarm and deactivation of the pumping means, thereby preventing excessive blood or flushing solution aspiration.

4. An automated blood drawing apparatus according to claim **1**, wherein the blood is captured in a bolus of pliable tubing.

5. An automated blood drawing apparatus according to claim **4**, wherein the pliable tubing is sealed at one end and the collection means is further comprised of sealing means, cutting means and advancement means;

the pliable tubing material being capable of softening in response to an application of a specific temperature stimulus, whereby removal of the temperature stimulus results in the pliable material hardening relative to its softened state;

the sealing means being comprised of at least two heating elements, each capable of applying heat or pressure at two positions tangent to the pliable tubing, said tangents being parallel one to the other;

the advancement means being capable of advancing a section of pliable tubing into a position relative to the sealing means such that the first heating element is located at a position adjacent a cut end of the pliable tubing and the second heating element is located at position below the first heating element;

the second heating element is capable of applying heat and pressure to the pliable tubing in response to an input signal, whereby application of heat and pressure to the pliable tubing results in melting of the pliable tubing and a sealing of the tubing upon cooling;

the collection receptacle formed by sealing at the second heating element is capable of accepting fluid from the open end of the third fluid line when placed in the stream of fluid;

the first heating element is capable of applying heat and pressure to the pliable tubing of the collection receptacle in response to an input signal generated once fluid has been introduced into the receptacle, whereby application of heat and pressure to the open end of the collection receptacle results in melting of the pliable tubing and sealing of the collection receptacle, thereby creating a bolus of fluid;

the cutting means is capable of cutting the sealed bolus from the remainder of the pliable tubing;

after cutting, the advancement means is capable moving the bolus out of proximity of the sealing means and advancing additional pliable tubing into a position relative to the sealing means.

6. An automated blood drawing apparatus according to claim **4**, wherein fluid exiting the third fluid tube enters a length of pliable tubing and exits into a waste receptacle;

the pliable tubing being positioned along a surface;

first and second heat sealing elements are positioned along a length of pliable tubing,

the heat sealing elements being capable of pressing the pliable tubing down on the flat surface, thereby heating the pliable material and adhering it to itself upon cooling;

the pliable tubing is sealed so as to obtain a bolus of blood in the tubing between the first and second sealed portion;

cutting means cutting the pliable tubing adjacent the sealed portion so as to free the bolus of blood from the remaining tubing material;

a cutting means further cutting the pliable tubing so as to allow fluid to flow through the remaining pliable tubing and into a waste container.

7. An automated blood drawing apparatus according to either of claims **5** and **6**, wherein system generated information is affixed or stamped to the bolus.

8. An automated blood drawing apparatus according to claim **1**, wherein a monitoring device is comprised of at least two optical sensors in communication with a timing means;

the first optical sensor being located at a position along the third fluid line and adjacent the branching means;

the second optical sensor being located at a position along the third fluid line downstream of the first optical sensor;

the timing means being capable of monitoring time;

the first and second optical sensors being capable of generating an output signal to the timing means in response to changes in the opacity of fluid flowing through the third fluid line;

the first output signal being generated when a change in opacity indicates either blood or flushing solution has entered the third fluid line, said output signal resulting in the timing means polling time;

the second output signal being generated when a change in opacity indicates either blood or flushing solution has reached a position along the third fluid line corresponding to the location of the second optical sensor, said output signal resulting in the cessation of time polling by the timing means, whereby the polled time may be used by the computer to generate system generated information.

9. An automated blood drawing apparatus for drawing blood samples at scheduled time intervals from a human or animal, comprising:

at least two branching elements each capable of transmitting fluid and engaging at least three fluid lines;

the first fluid line of the first branching element is comprised of a blood line being capable of transmitting blood from a human or animal to the first branching element;

the second fluid line of the first branching element being capable of delivering a flushing solution from a flushing solution source to the first branching element;

the third fluid line of the first branching element being comprised of an aspiration line being capable of transmitting fluid arriving at the first branching element from either the blood or second fluid line to collection means located at the terminus of the aspiration line;

the second branching element being incorporated upstream of the second fluid line, such that the second branching element also engages the second fluid line;

the first fluid line of the second branching element is comprised of a flushing line capable of delivering a flushing solution from a flushing solution source through the second branching element to the second fluid line;

the third fluid line of the second branching element is comprised of a monitoring line attached to a blood pressure monitoring device capable of monitoring the blood pressure of a human or animal;

the collection means comprising at least one collection receptacle and a waste container;

the collection means being capable of moving the collection receptacle to a first position to allow fluid exiting the third fluid line to empty into the collection receptacle or to a second position to allow the fluid exiting the third fluid line to empty into the waste container, wherein the collection receptacle is moved to a first or second position in response to an input signal;

at least one pumping means capable of initiating fluid flow through the branching elements and the plurality of fluid lines upon activation, the pumping means being selectively activated or deactivated in response to an input signal;

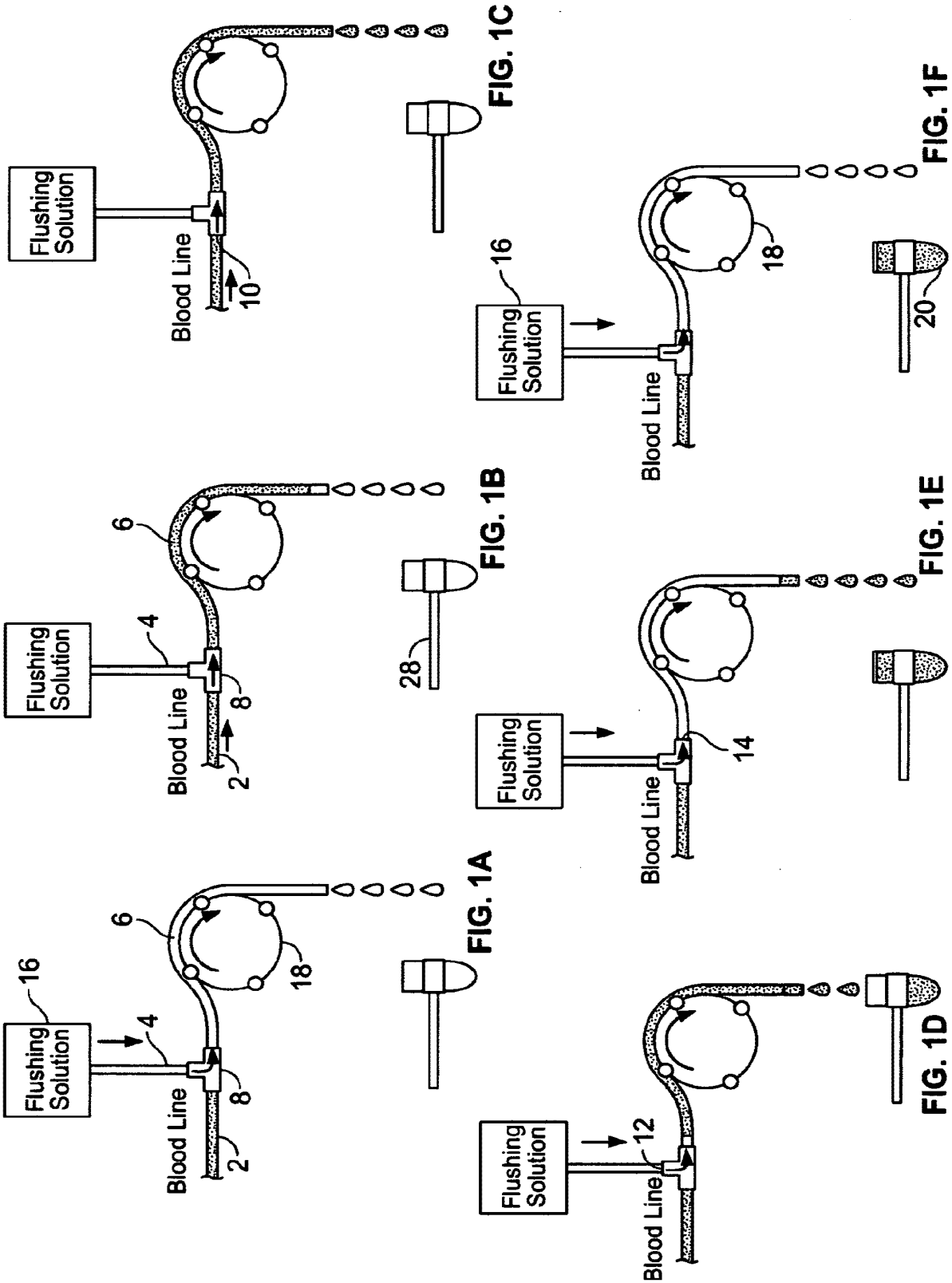
at least two selection means for selectively inhibiting fluid flow in at least two of the fluid lines while the pumping means is activated, the selection means being capable of selective activation in response to an input signal;

wherein activation of one or more selection means allows blood to flow from the blood fluid line through the first branching element and into the aspiration line or allows flushing solution to flow from the flushing line, through the second branching element, into the second fluid line, through the first branching element and into either the blood or third aspiration line, or allows the blood pressure monitoring device to monitor the blood pressure of a human or animal, the blood line, second fluid line, and monitor line forming a continuous fluid line when the blood pressure monitoring device is active;

computer means capable of providing an input signal to the pumping means, the selection means, and the collecting means in response to system generated information;

the system generated information being produced by the computer means in response to programming information entering the computer means from at least one user interface and from at least one monitoring device;

the system generated information resulting in output signals allowing for coordination of the pumping means, selection means, and the collecting means such that efficient blood sampling occurs at scheduled time intervals without excessive blood waste.


Flushing Solution
Blood Line
10
FIG. 1C
16
Flushing Solution
Blood Line
18
20
FIG. 1F
6
Flushing Solution
4
Blood Line
8
2
28
FIG. 1B
Flushing Solution
Blood Line
14
FIG. 1E
16
Flushing Solution
4
6
18
Blood Line
8
2
FIG. 1A
Flushing Solution
12
Blood Line
FIG. 1D

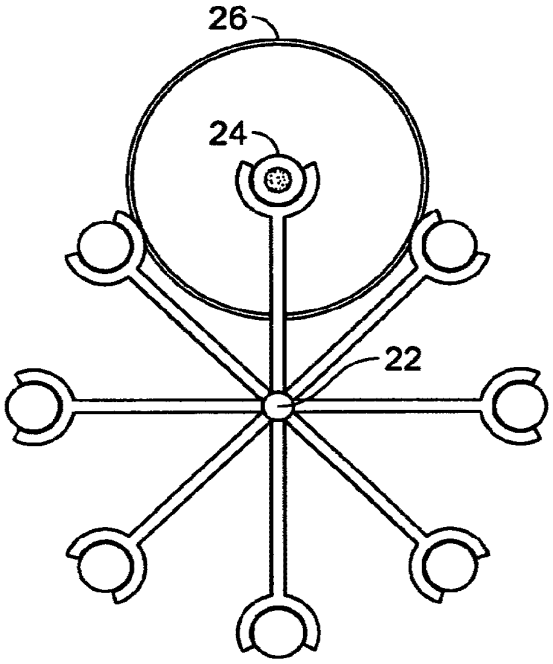



FIG. 2A

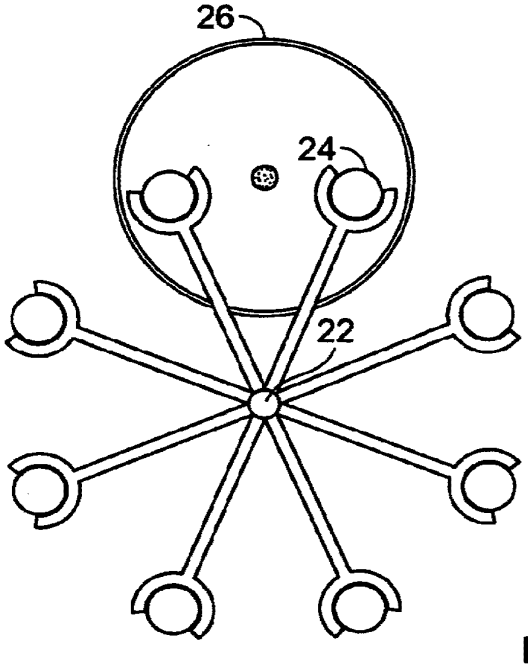



FIG. 2B

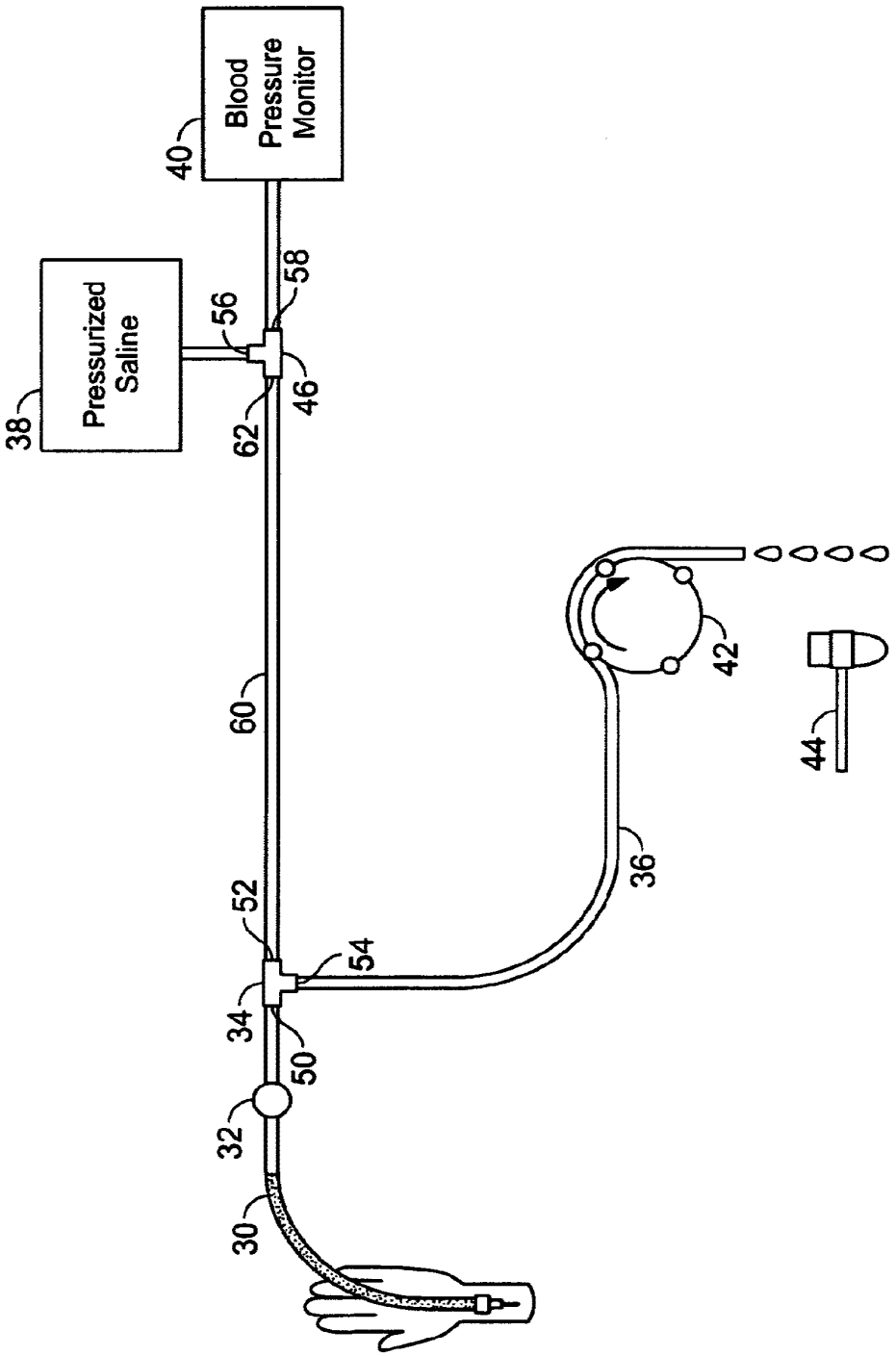

Blood Pressure Monitor
40
Pressurized Saline
38
56
58
46
62
60
52
54
34
50
32
30
36
42
44

FIG. 3

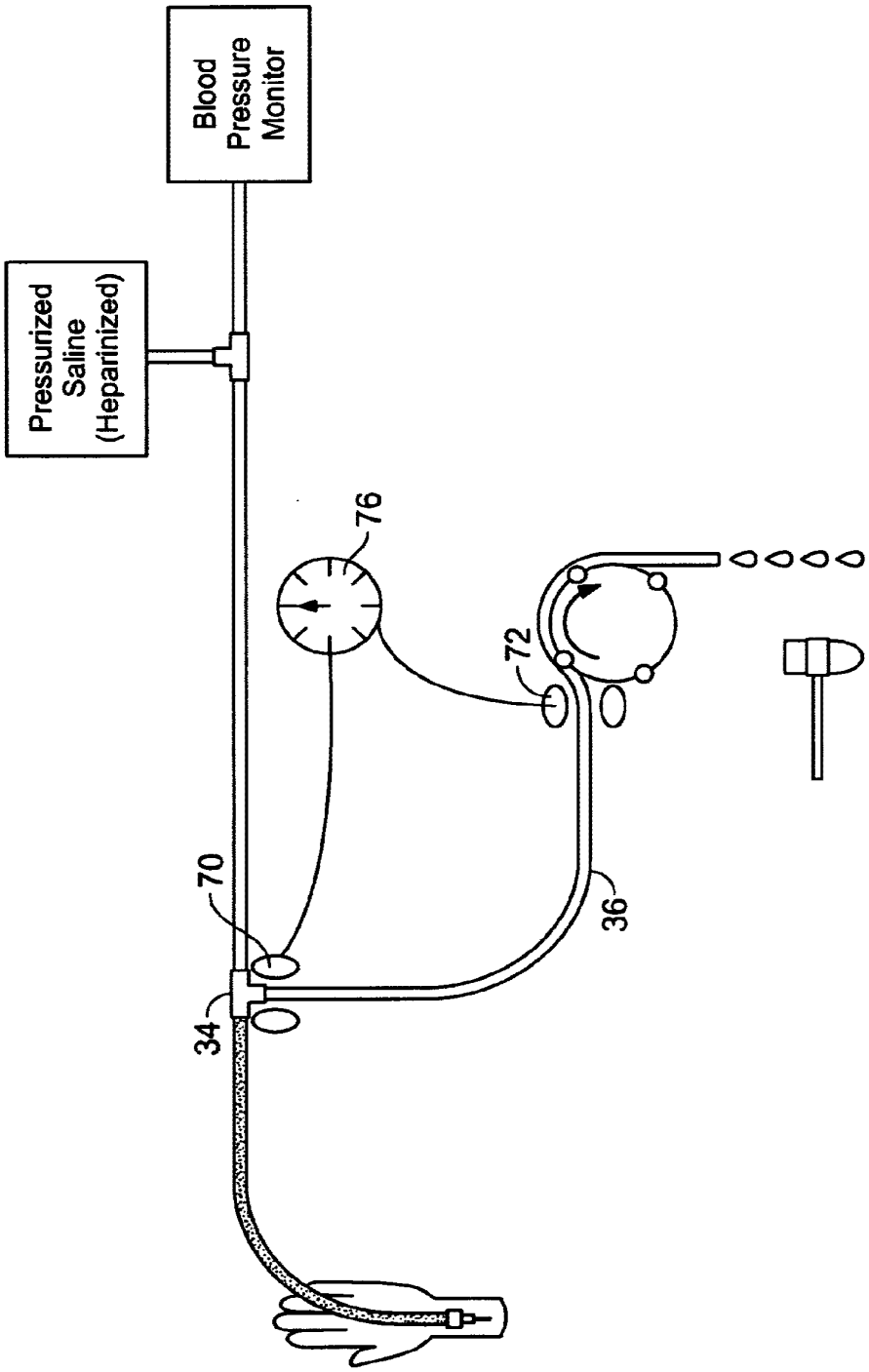

Blood Pressure Monitor
Pressurized Saline (Heparinized)
76
72
70
36
34

FIG. 4

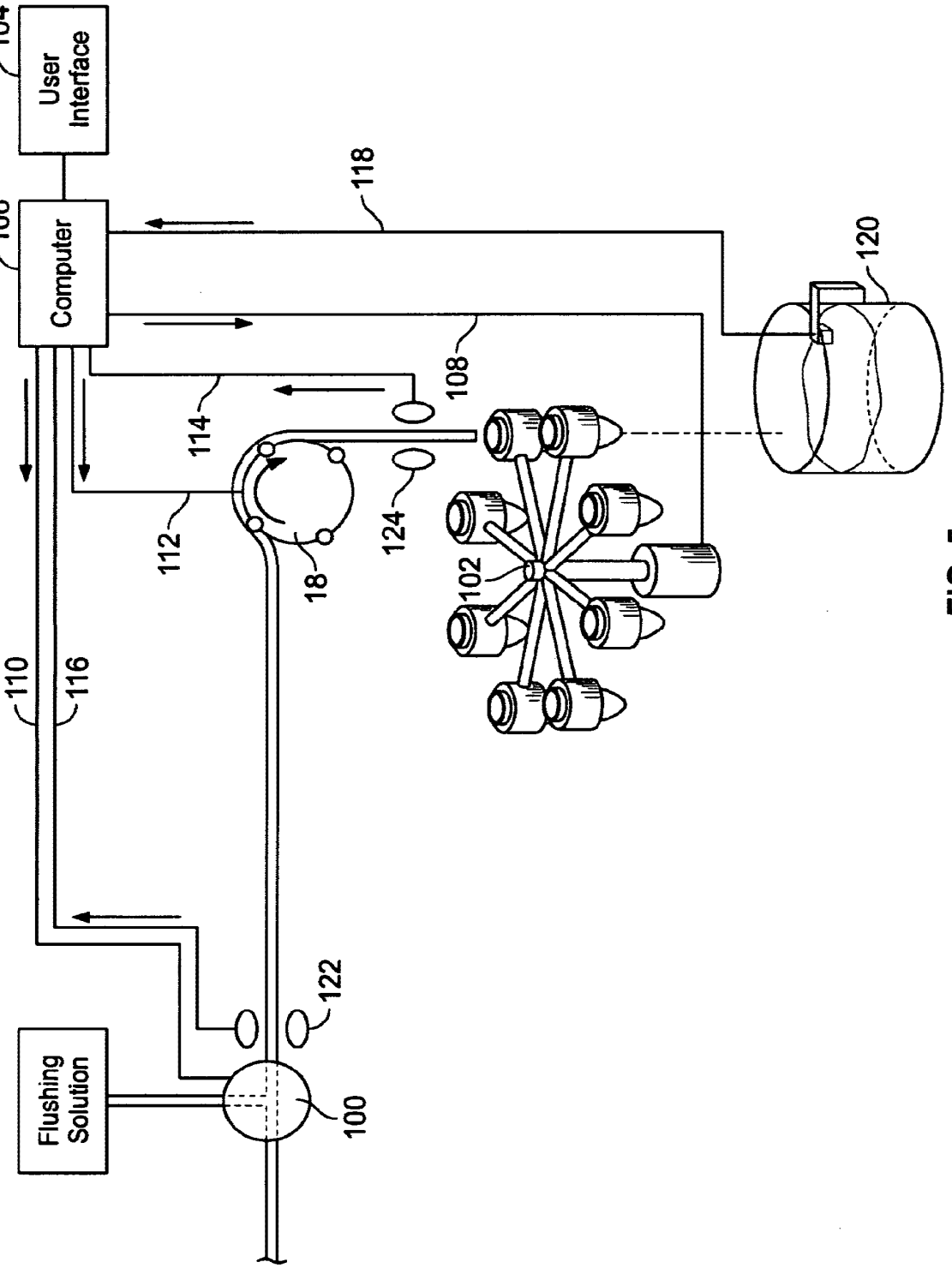

104
User Interface
106
Computer
118
120
108
114
112
124
18
102
110
116
122
Flushing Solution
100

FIG. 5

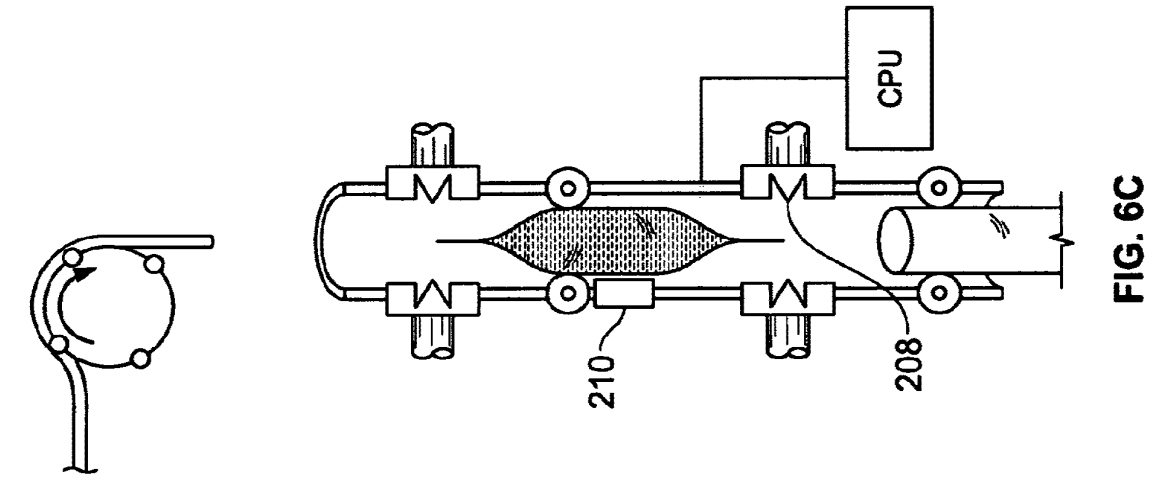



FIG. 6C

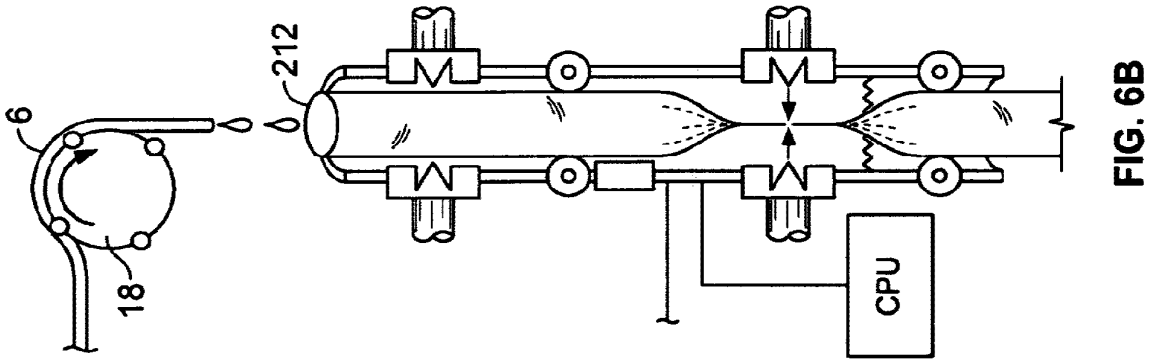



FIG. 6B

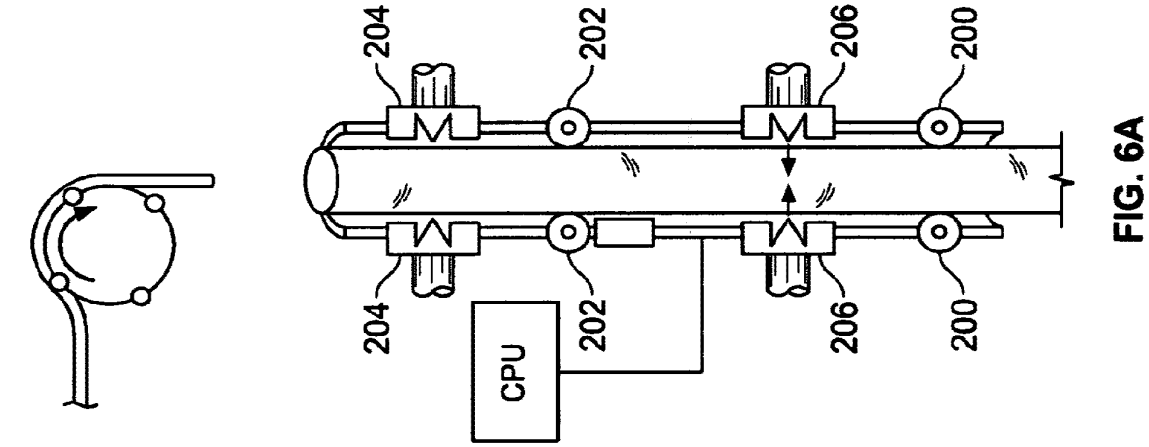



FIG. 6A

FIG 7A

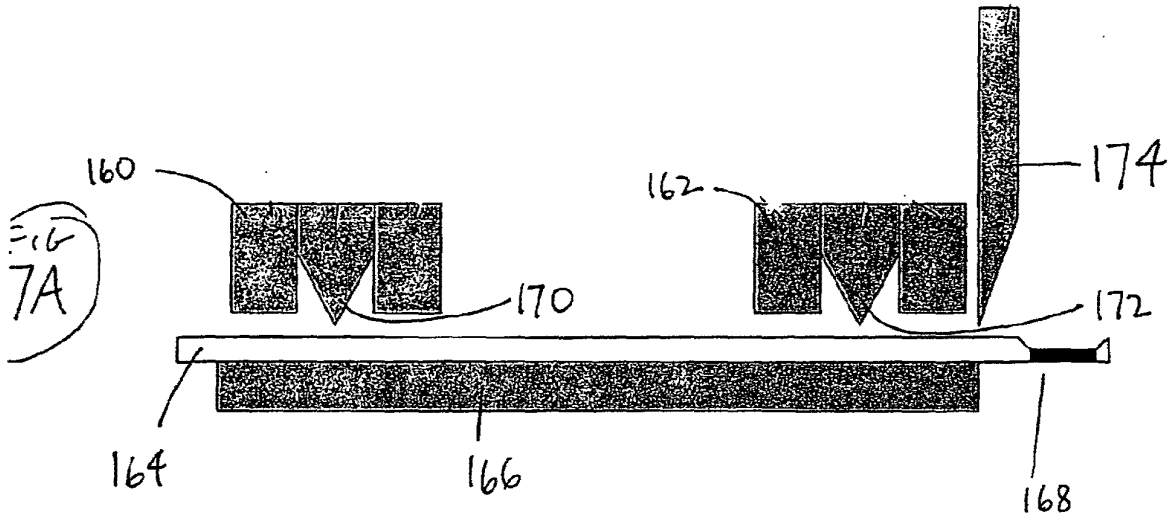



FIG 7C

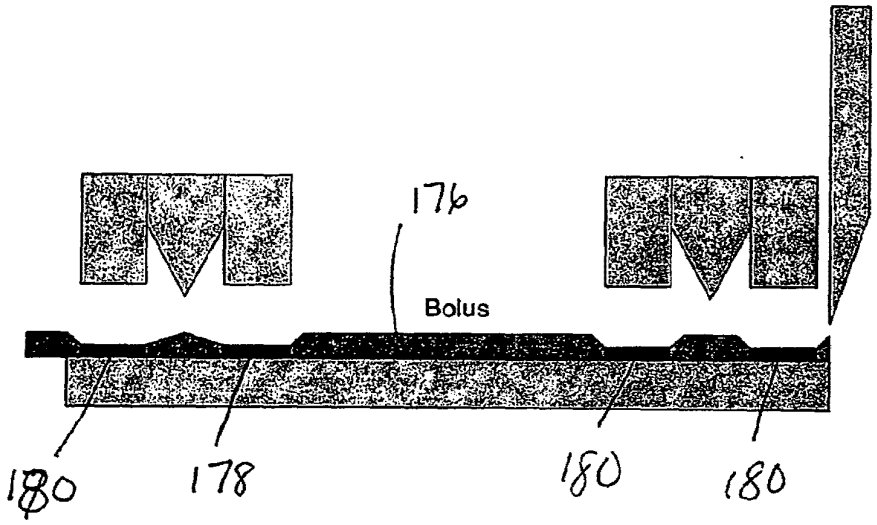
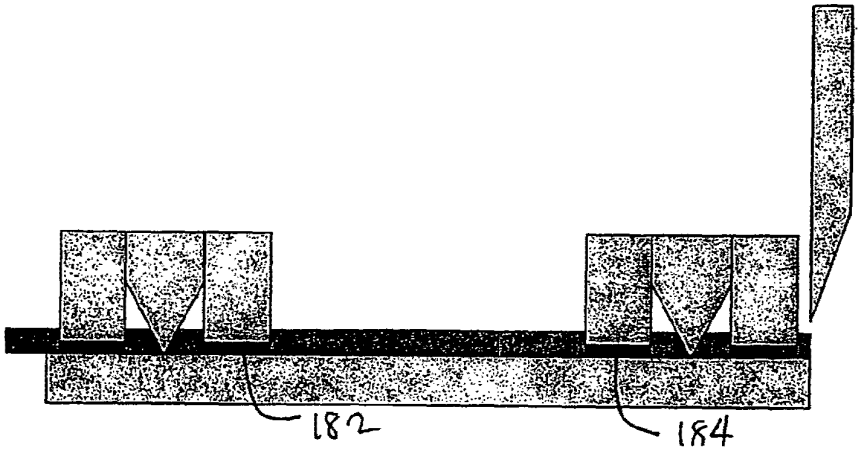



FIG 7B



# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| Applicant's or agent's file reference | **FOR FURTHER ACTION** | see Form PCT/ISA/220 as well as, where applicable, item 5 below. |
|---|---|---|
| 56782.1.5.1 | | |
| International application No. | International filing date *(day/month/year)* | (Earliest) Priority Date *(day/month/year)* |
| PCT/US2009/047027 | 11/06/2009 | 11/06/2008 |
| Applicant | | |
| BRACCO DIAGNOSTICS INC. | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 8 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language,** the international search was carried out on the basis of:
      [X] the international application in the language in which it was filed
      [ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [X] **Certain claims were found unsearchable** (See Box No. II)

3. [X] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1c
      [ ] as suggested by the applicant
      [X] as selected by this Authority, because the applicant failed to suggest a figure
      [ ] as selected by this Authority, because this figure better characterizes the invention
   b. [ ] none of the figures is to be published with the abstract

Form PCT/ISA/210 (first sheet) (April 2007)

International application No
PCT/US2009/047027

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/14 G21F5/015
ADD. A61M36/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M G21F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | WO 2005/002971 A1 (IPHASE TECHNOLOGIES PTY LTD [AU]; TOCHON-DANGUY HENRI-JACQUES [AU]; PO) 13 January 2005 (2005-01-13) figures 1-4 page 5, paragraph 4 - page 11, paragraph 3 | 1-15, 34-37 |
| X | US 2003/004463 A1 (REILLY DAVID M [US] ET AL) 2 January 2003 (2003-01-02) figures 1-4 paragraph [0049] - paragraph [0072] | 1-15, 34-37 |
| X | JP 2000 350783 A (SUMITOMO HEAVY INDUSTRIES) 19 December 2000 (2000-12-19) figures 1-5 paragraph [0014] - paragraph [0033] | 1-15, 22-37 |

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 15 February 2010 | 25/02/2010 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Reinbold, Sylvie |

3

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br><br><br>Y<br>A | WO 2008/037939 A2 (LEMER PROT ANTI X PAR ABREVIAT [FR]; LEMER PIERRE-MARIE [FR]) 3 April 2008 (2008-04-03)<br>the whole document | 22-27<br><br><br>28-33<br>1-15 |
| X,P | WO 2008/082966 A2 (MEDRAD INC [US]) 10 July 2008 (2008-07-10)<br>figures 1-45<br>paragraph [0068] - paragraph [0273] | 1,22,27,<br>34 |
| X | EP 0 102 121 A1 (BYK MALLINCKRODT CIL BV [NL]) 7 March 1984 (1984-03-07)<br>figures 1-4<br>page 9, line 6 - page 12, line 11 | 22-36 |
| Y | JP 2006 325826 A (UNIVERSAL GIKEN KK; SD GIKEN KK) 7 December 2006 (2006-12-07)<br>figures 1-10<br>paragraph [0020] - paragraph [0072] | 28-33 |

3

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

Continuation of Box II.1

Claims Nos.: 16-21

The methods of claims 16 to 21 for setting up an infusion device is carried out within a human body. It is implicit that the methods are during a medical therapy because the infusion tubing is connected to a patient. The application does not meet the requirement of Rule 39.1(iv), because these claims are methods of treatment of the human body.

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/047027

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 16-21
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[X] No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-15, 37

These claims disclose a shielding assembly for an infusion system comprising:
- a first compartment sized to contain more radioisotope generators and enclosed by a first sidewall including an opening extending therethrough and including an opening and lid, the opening being oriented upward and located at a first elevation
- a second compartment sized to contain a portion of an infusion tubing circuit and being enlosed by a second sidewall and including a base portion and a lid
- a third compartment sized to contain a waste bottle of the infusion system and being enclosed by a third sidewall that forms a barrier to ratioactive radiation, including an opening and a lid, the opening of the third sidewall being oriented upward and located at a second elevation, the second elevation being greater than the first elevation of the opening of the first sidewall (technical problem: to facilitate an ergonomic stance for technical personnel to lift generator out from the compartment)

---

2. claims: 22-26

These claims disclose a shielding assembly for an infusion system comprising:
- a first door to contain one or more radioisotope generators
- a second door to provide access to a second compartment being sized to contain an infusion tubing
- the second door, when enclosing the second compartment preventing the first door from the opening to provide access to the first compartment
(technical problem: provide access to the corresponding compartments)

---

3. claims: 27-33

These claims disclose an infusion system comprising:
- a cabinet structure including a shell and an access panel
- a lock engaging the access panel
- an eluant source
- a shielding assembly comprising a plurality of compartments and including a corresponding plurality of doors
(technical problem: to provide a relatively ergonomic and organized work area to operate the infusion system)

---

4. claims: 34-36

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

These claims disclose a shielding assembly for an infusion system comprising:
- a plurality of compartments
- a corresponding plurality of doors
- a first compartment sized to contain a radioisotope generator including a first sidewall with a first sidewall opening oriented upward and alignet with a first upper opening through a shell of the cabinet structure,
- wherein an upper surface of the shell is located at an elevation which is substantially greater that of the first sidewall opening and the first upper opening
(technical problem: to provide an alternative access to the compartment)

---

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| WO 2005002971 A1 | 13-01-2005 | EP 1644247 A1 | 12-04-2006 |
| | | US 2006151048 A1 | 13-07-2006 |
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| | | US 2010030009 A1 | 04-02-2010 |
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# PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

# PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43*bis*.1)

Date of mailing
*(day/month/year)* see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

**FOR FURTHER ACTION**
See paragraph 2 below

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/US2009/047027 | 11.06.2009 | 11.06.2008 |

International Patent Classification (IPC) or both national classification and IPC
INV. A61M5/14 G21F5/015
ADD. A61M36/00

Applicant
BRACCO DIAGNOSTICS INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| Name and mailing address of the ISA: | Date of completion of this opinion | Authorized Officer |
|---|---|---|
| European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0<br>Fax: +49 89 2399 - 4465 | see form PCT/ISA/210 | Reinbold, Sylvie<br>Telephone No. +49 89 2399-7918 |

Form PCT/ISA/237 (Cover Sheet) (April 2005)

**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 16-21

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 16-21

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

**Box No. IV Lack of unity of invention**

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☒ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   **see separate sheet**

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-15, 22-37

**Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 2-15, 23-26, 28-33, 35-36 |
| | No: | Claims | 1, 22, 27, 34, 37 |
| Inventive step (IS) | Yes: | Claims | |
| | No: | Claims | 1-15, 22-37 |
| Industrial applicability (IA) | Yes: | Claims | 1-15, 22-37 |
| | No: | Claims | |

2. Citations and explanations

**see separate sheet**

**Box No. VI Certain documents cited**

1. Certain published documents (Rules 43*bis*.1 and 70.10)

   and / or

2. Non-written disclosures (Rules 43*bis*.1 and 70.9)

   **see form 210**

## Re Item III

### Non- establishment of opinion with regard to novelty, inventive step and industrial applicability

The methods of **claims 16 to 21** for setting up an infusion device is carried out within a human body. It is implicit that the methods are during a medical therapy because the infusion tubing is connected to a patient. The application does not meet the requirement of Rule 39.1 (iv), because these claims are methods of treatment of the human body.

Consequently, no opinion will be formulated with respect to the industrial applicability of the subject matter of theses claims. (Article 34(4)(a)(i)PCT)

## Re Item IV

### Lack of unity of invention

The inventions in this international application, as follows:

**1. Claims 1-15.37**

These claims disclose a shielding assembly for an infusion system comprising:

- a first compartment sized to contain more radioisotope generators and enclosed by a first sidewall including an opening extending therethrough and including an opening and lid, the opening being oriented upward and located at a first elevation

- a second compartment sized to contain a portion of an infusion tubing circuit and being enclosed by a second sidewall and including a base portion and a lid

- a third compartment sized to contain a wast bottle of the infusion system and being enclosed by a third sidewall that forms a barrier to radioactive radiation, including an opening and a lid, the opening of the third sidewall being oriented upward and located at a second elevation, the second elevation being greater than the first elevation of the opening of the first sidewall (technical problem: to facilitate an ergonomic stance for technical personnel to lift generator out from the compartment)

**2. Claims 22-26:**

These claims disclose a shielding assembly for an infusion system comprising:

- a first door to contain one or more radioisotope generators

- a second door provide access to a second compartment being sized to contain an infusion tubing

- the second door, when enclosing the second compartment preventing the first door from the opening to provide access to the first compartment

(technical problem: provide access to the corresponding compartments)

**3. Claims 27-33:**

These claims disclose an infusion system comprising:

- a cabinet structure including a shell and an access panel

- a lock engaging the access panel, an eluant source

- a shielding assembly comprising a plurality of compartments and including a corresponding plurality of doors

(technical problem: to provide a relatively ergonomic and organized work area to operate the infusion system)

**4. Claims 34-36:**

These claims disclose a shielding assembly for an infusion system comprising:

- a plurality of compartments, a corresponding plurality of doors

- a first compartment sized to contain a radioisotope generator including a first sidewall with a first sidewall opening oriented upward and aligned with a first upper opening through a shell of the cabinet structure,

- wherein an upper surface of the shell is located at an elevation which is substantially greater that of the first sidewall opening and the first upper opening

(technical problem: to provide an alternative access to the compartment)

The differences between the disclosure of Document D1 (WO2005002971) and the 4 inventions can be defined as follows:

**claim 1**: all the features of claim 1 are disclosed in D1

**claim 22**: the difference between the subject matter of claim 22 and D1 is the second door, when enclosing the second compartment, preventing the first door from opening to provide access to the first compartment. In D1 there is no such a door.

**claim 27**: the difference between the subject matter of claim 27 and D1 is a lock for an access panel, an infusion system with an eluant source. In D1 there is no such a lock.

**claim 34**: the difference between the subject matter of claim 34 and D1 is wherein an upper surface of the shell is located at an elevation which is substantially greater that of the first sidewall opening and the first upper opening. In D1 there is no such a technical feature.

The special technical features are not identical. The effects of three compounds are different.

The use of the shielding assembly for an infusion device in claim 22 provides access to the corresponding compartments.

The use of the infusion system in claim 27 permits to provide a relatively ergonomic and organized work area to operate the infusion system.

The use of the shielding assembly in claim 34 permits to provide in an alternative way an access to the compartment.

In conclusion, the groups of claims are not linked by common or corresponding special technical features and define 4 different inventions not linked by a single general inventive concept. Therefore the application claims 4 inventions not so linked to form a single general inventive concept. The requirement of unity is not fulfilled, according to Rule 13 PCT.

## Re Item V

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1 Reference is made to the following documents:

D1 WO 2005/002971 A1

D2 US 2003/004463 A1

D3 JP 2000 350783 A

D4 WO 2008/037939 A2

D5 WO 2008/082966 A2

D6 EP 0 102 121 A1

D7 JP 2006 325826 A

## Novelty Article 33(2) PCT

**Invention 1: Claims 1 - 15,37**

2 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of **claim 1** is not new in the sense of Article 33(2) PCT.

2.1 The document D1 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) discloses a shielding assembly for an infusion system, the shielding assembly being mounted within a cabinet structure comprising (figure 1-4):

- a first compartment (30) sized to contain one or more radioisotope generators (34) of the infusion system, the first compartment being enclosed by a first sidewall (sidewall 31) that forms a barrier to radioactive radiation, the first sidewall including an opening extending therethrough and a lid (32), the lid mating with the opening to alternately enclose the first compartment and

provide access to the first compartment, via the opening, and the opening being oriented upward and located at a first elevation, with respect to a lowermost portion of the cabinet structure;

- a second compartment (2) sized to contain a portion of an infusion tubing circuit (tubing 57) of the infusion system that is downstream of the one or more generators, the second compartment being enclosed by a second sidewall that forms a barrier to radioactive radiation, the second sidewall including a base portion and a lid portion (9), the lid portion mating with the base portion to alternately enclose the second compartment and provide access to the second compartment; and

- a third compartment (52) sized to contain a waste bottle (53) of the infusion system, the third compartment being enclosed by a third sidewall that forms a barrier to radioactive radiation, the third sidewall including an opening, extending through the third sidewall, and a lid (41), the lid of the third sidewall mating with the opening of the third sidewall to alternately enclose the third compartment and provide access to the third compartment, via the opening of the third sidewall, the opening of the third sidewall being oriented upward and located at a second elevation, with respect to the lowermost portion of the cabinet structure, and the second elevation being greater than the first elevation of the opening of the first sidewall.

The subject matter of claim 1 is not novel document D1.

2.2 The technical feature of claim 37 is also disclosed in Document D1.

2.3 The technical feature of claims 1 and 37 is shown in Documents D2 and D3.

**Invention 2: Claims 22-26**

3 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of **claim 22** is not new in the sense of Article 33(2) PCT.

3.1 The document D4 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) discloses a shielding assembly for an infusion system (6) comprising (figure 1-2):

- a plurality of compartments (2a,2b,2c) and providing a radioactive radiation barrier for the compartments, the assembly further comprising:

- a first door (2b) to alternately enclose and provide access to a first compartment of the plurality of compartments, the first compartment sized to contain one or more radioisotope generators (11) of the infusion system; and

- second door (41) to alternately enclose and provide access to a second compartment (2) of the plurality of compartments, the second compartment being separate from, and outside of, the first compartment, the second

compartment being sized to contain a portion of an infusion tubing circuit (22) of the infusion system that is downstream of the one or more generators, and the second door, when enclosing the second compartment, preventing the first door from opening to provide access to the first compartment.

The subject matter of claim 22 is not new over document D4.

3.2 The technical feature of claim 1 is revealed in Document D3.

**Invention 3: Claims 27-33**

4 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of **claim 27** is not new in the sense of Article 33(2) PCT.

4.1 The document D4 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) discloses an infusion system comprising (figure 1-2):

- a cabinet structure (figure 2) including a shell defining an interior space thereof, the shell including a first opening (21), a second opening (2b) and an access panel (41), the access panel mating with the second opening and being removable therefrom;

- a lock reversibly (it is implicit that the access panel has a lock) engaging the access panel to secure access to the interior space of the cabinet structure;

- an eluant source (16);

- a shielding assembly located within the interior space of the cabinet structure, the shielding assembly including a sidewall defining a plurality of compartments and providing a barrier to radioactive radiation for the compartments, the shielding assembly further including a corresponding plurality of doors (41,2b), each door, when open, providing access to the corresponding compartment via an opening in the sidewall, and, when closed, providing further barrier to radioactive radiation for the corresponding compartment;

- one or more radioisotope generators (11) contained within a first compartment of the plurality of compartments (2c) of the shielding assembly and being accessible through the second opening (2b) of the shell of the cabinet structure, when the access panel (41) is unlocked, and when a first door (2b) of the plurality of doors, which corresponds to the first compartment, is open;

- an eluant line (23) coupled to the eluant source and to the one or more generators; an eluate line coupled to the one or more generators; and a patient line (17) coupled to the eluate line and extending out from the interior space of the cabinet structure through the first opening of the shell.

The subject matter of claim 27 is not new over Document D4.

4.2 The technical feature of claim 27 is disclosed in Document D3.

**Invention 4: Claims 34-36**

5 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of **claim 34** is not new in the sense of Article 33(2) PCT.

5.1 The document D1 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) discloses a shielding assembly comprising (figure 1-4):

- a plurality of compartments (2,30) having sidewalls providing barriers to radioactive radiation for the compartments;

- a corresponding plurality of doors (9,32), each door, when open, providing access to the corresponding compartment via an opening in its sidewall, and, when closed, providing further barrier to radioactive radiation for the corresponding compartment;

-a first compartment (2) of the plurality of compartments enclosed by a first sidewall of the sidewalls and sized to contain one or more radioisotope generators (62) of the infusion system, the first sidewall including a first sidewall opening oriented upward and aligned with a first upper opening through a shell of the cabinet structure;

- wherein an upper surface of the shell is located at an elevation, with respect to a lowermost portion of the cabinet structure, such that the elevation of the upper surface is substantially greater than that of the first sidewall opening and the first upper opening (see figure 1)

The subject matter of claim 34 is not new over Document D1.

5.2 Furthermore the technical features of claims 34 are revealed by documents D2,D3 and D6.

**Inventive step Article 33(3) PCT**

**Invention 1: Claims 1 - 15,37**

6 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of **claims 2 to 15** does not seem to involve an inventive step in the sense of Article 33(3) PCT. Document D1 is the closest prior art.

In claims 2 to 15 a slight constructional change in the shielding assembly is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of these claims also lacks an inventive step.

**Invention 2: Claims 22-26**

7 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of **claims 23 to 26** does not seem to involve an inventive step in the sense of Article 33(3) PCT. Document D4 is the closest prior art.

In claims 23 to 26 a slight constructional change in the shielding assembly is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of these claims also lacks an inventive step.

**Invention 3: Claims 27-33**

8 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of **claims 28 to 33** does not seem to involve an inventive step in the sense of Article 33(3) PCT. Document D4 is the closest prior art.

The features of claims 28 to 33 are merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed. (see Document D7 for using a latch component) Consequently, the subject-matter of these claims also lacks an inventive step.

**Invention 4: Claims 34-36**

9 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of **claims 35 and 36** does not seem to involve an inventive step in the sense of Article 33(3) PCT. Document D1 is the closest prior art.

In claims 35 and 36 a slight constructional change in the shielding assembly (elevation) is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of these claims also lacks an inventive step.

**Further comments**

**Invention 1: Claims 1 - 15,37**

10 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D1-D4 are not mentioned in the description, nor are these documents identified therein.

11 Independent claim 1 is not in the **two-part form** in accordance with Rule 6.3 (b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

12 The features of the claims are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).

13 The unit employed in claims 4 and 5 and in description is not recognised in international practice, contrary to the requirements of Rule 10.1(d) PCT.

**Invention 2: Claims 22-26**

14 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D3,D4 and D6 are not mentioned in the description, nor are these documents identified therein.

15 Independent claim 22 is not in the **two-part form** in accordance with Rule 6.3 (b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D4) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

16 The features of the claims are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).

**Invention 3: Claim 27-33**

17 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D3,D4 and D7 are not mentioned in the description, nor are these documents identified therein.

18 Independent claim 27 is not in the **two-part form** in accordance with Rule 6.3 (b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D4) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

19 The features of the claims are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).

**Invention 4: Claim 34-36**

20 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D1,D2,D3 and D6 are not mentioned in the description, nor are these documents identified therein.

21 Independent claim 34 is not in the **two-part form** in accordance with Rule 6.3 (b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

22 The features of the claims are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).

23 The unit employed in claims 35 and 36 and in description is not recognised in international practice, contrary to the requirements of Rule 10.1(d) PCT.

## Re Item VI

### Certain documents cited

Certain published documents

| Application No<br>Patent No | Publication date<br>*(day/month/year)* | Filing date<br>*(day/month/year)* | Priority date *(valid claim)*<br>*(day/month/year)* |
|---|---|---|---|
| WO2008082966 | 10.07.2008 | 20.12.2007 | 31.10.2007 |

Document D5 discloses the technical feature of claims 1,22,27 and 34. This document will be considered during the European phase.

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| Applicant's or agent's file reference | **FOR FURTHER ACTION** | see Form PCT/ISA/220 as well as, where applicable, item 5 below. |
|---|---|---|
| 56782.1.6.1 | | |
| International application No. | International filing date *(day/month/year)* | (Earliest) Priority Date *(day/month/year)* |
| PCT/US2009/047030 | 11/06/2009 | 11/06/2008 |
| Applicant | | |
| BRACCO DIAGNOSTICS INC. | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 6 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language,** the international search was carried out on the basis of:
      [X] the international application in the language in which it was filed
      [ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] **Certain claims were found unsearchable** (See Box No. II)

3. [X] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1d
      [ ] as suggested by the applicant
      [X] as selected by this Authority, because the applicant failed to suggest a figure
      [ ] as selected by this Authority, because this figure better characterizes the invention
   b. [ ] none of the figures is to be published with the abstract

Form PCT/ISA/210 (first sheet) (April 2007)

International application No
PCT/US2009/047030

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/00
ADD. A61M5/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | FR 2 867 084 A1 (GEN ELECTRIC [US])<br>9 September 2005 (2005-09-09)<br>figures 1-12<br>page 6, line 16 - page 30, line 11 | 1-2,5-9 |
| X | EP 0 102 121 A1 (BYK MALLINCKRODT CIL BV [NL]) 7 March 1984 (1984-03-07)<br>figures 1-4<br>page 9, line 15 - page 12, line 11 | 1,5-9,<br>17-25,<br>27-32,<br>36-38 |
| X | WO 99/56117 A1 (GEN HOSPITAL CORP [US]; LAYFIELD DOMINICK [US]; VENEGAS JOSE [US])<br>4 November 1999 (1999-11-04)<br>page 4, line 20 - page 16, line 13;<br>figures 1-6 | 1-3,<br>15-17,<br>31-38 |

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 10 February 2010 | 17/02/2010 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Reinbold, Sylvie |

2

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | EP 0 160 303 A2 (SQUIBB & SONS INC [US]) 6 November 1985 (1985-11-06) figures 1-12 page 7, line 28 - line 15 | 1-2 |
| X | JP 2000 350783 A (SUMITOMO HEAVY INDUSTRIES) 19 December 2000 (2000-12-19) paragraph [0014] - paragraph [0032]; figures 1-5 | 18-25, 27-30 |
| X | US 2008/093564 A1 (TARTAGLIA DANIEL [CA] ET AL) 24 April 2008 (2008-04-24) figures 1-7 paragraph [0023] - paragraph [0035] | 18-30 |
| X | WO 2007/149108 A2 (MALLINCKRODT INC [US]; POLLARD RALPH E JR [US]) 27 December 2007 (2007-12-27) figures 1-18 paragraph [0031] - paragraph [0053] | 18-30 |
| X | US 2003/004463 A1 (REILLY DAVID M [US] ET AL) 2 January 2003 (2003-01-02) paragraph [0049] - paragraph [0072]; figures 1-4 | 31-38 |

2

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/047030

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-17

These claims essentially define an infusion system comprising an eluant source, a shielding assembly having a plurality of compartments and plurality of doors, a radioisotope generator, a eluate line and a patient line.
(technical effect: to provide an infusion system to infuse an radioactive eluate)

---

2. claims: 18-30

These claims essentially define a shielding assembly comprising a sidewall defining a plurality of compartments, a first passageway formed in an upper surface of a first portion of the sidewall and defining a first compartment sized to contain a radioisotope and a second passageway with a second compartment.
(technical effect: to provide a shielding assembly to permit a more effective operation)

---

3. claims: 31-38

These claims essentially define a disposable infusion circuit subassembly comprising: an eluate line, a patient line, a waste line, a valve member and a support frame.
(technical effect: to facilitate the positioning of the components of a portion of infusion circuit in an infusion system)

---

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| FR 2867084 A1 | 09-09-2005 | DE 102005010152 A1 | 15-09-2005 |
| | | DE 102005010154 A1 | 15-09-2005 |
| | | FR 2867294 A1 | 09-09-2005 |
| | | JP 2005326398 A | 24-11-2005 |
| | | JP 2005324007 A | 24-11-2005 |
| | | US 2008242915 A1 | 02-10-2008 |
| EP 0102121 A1 | 07-03-1984 | NONE | |
| WO 9956117 A1 | 04-11-1999 | EP 1075654 A1 | 14-02-2001 |
| | | US 6773673 B1 | 10-08-2004 |
| EP 0160303 A2 | 06-11-1985 | AU 581218 B2 | 16-02-1989 |
| | | CA 1250504 A1 | 28-02-1989 |
| | | CA 1233274 A2 | 23-02-1988 |
| | | DE 3581653 D1 | 14-03-1991 |
| | | JP 2568169 B2 | 25-12-1996 |
| | | JP 60241454 A | 30-11-1985 |
| | | US 4562829 A | 07-01-1986 |
| JP 2000350783 A | 19-12-2000 | NONE | |
| US 2008093564 A1 | 24-04-2008 | WO 2009003290 A1 | 08-01-2009 |
| WO 2007149108 A2 | 27-12-2007 | CA 2627429 A1 | 27-12-2007 |
| | | CN 101253577 A | 27-08-2008 |
| | | EP 1938339 A2 | 02-07-2008 |
| | | JP 2009506343 T | 12-02-2009 |
| | | US 2008224065 A1 | 18-09-2008 |
| US 2003004463 A1 | 02-01-2003 | US 2005238576 A1 | 27-10-2005 |
| | | US 2003216609 A1 | 20-11-2003 |

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

# PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

| | |
|---|---|
| Date of mailing *(day/month/year)* see form PCT/ISA/210 (second sheet) | |
| Applicant's or agent's file reference<br>see form PCT/ISA/220 | **FOR FURTHER ACTION**<br>See paragraph 2 below |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/US2009/047030 | 11.06.2009 | 11.06.2008 |

International Patent Classification (IPC) or both national classification and IPC
INV. A61M5/00
ADD. A61M5/14

Applicant
BRACCO DIAGNOSTICS INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| Name and mailing address of the ISA: | Date of completion of this opinion | Authorized Officer |
|---|---|---|
| European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0<br>Fax: +49 89 2399 - 4465 | see form PCT/ISA/210 | Reinbold, Sylvie<br>Telephone No. +49 89 2399-7918 |

Form PCT/ISA/237 (Cover Sheet) (April 2005)

**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

**Box No. IV Lack of unity of invention**

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☒ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   **see separate sheet**

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-38

**Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 4, 10-14, 24-26, 29-30, 33, 35 |
| | No: | Claims | 1-3, 5-9, 15-23, 27-28, 31-32, 34, 36-38 |
| Inventive step (IS) | Yes: | Claims | 4, 10-14 |
| | No: | Claims | 1-3, 5-9, 15-38 |
| Industrial applicability (IA) | Yes: | Claims | 1-38 |
| | No: | Claims | |

2. Citations and explanations

**see separate sheet**

**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item IV**

**Lack of unity of invention**

The inventions in this international application, as follows:

**1. Claims 1 - 17**

These claims essentially define an infusion system comprising an eluant source, a shielding assembly having a plurality of compartments and plurality of doors, a radioisotope generator, a eluate line and a patient line.

(technical effect: to provide an infusion system to infuse an radioactive eluate)

**2. Claims 18-30:**

These claims essentially define a shielding assembly comprising a sidewall defining a plurality of compartments, a first passageway formed in an upper surface of a first portion of the sidewall and defining a first compartment sized to contain a radioisotope and a second passageway with a second compartment.

(technical effect: to provide a shielding assembly to permit a more effective operation)

**3. Claims 31-38:**

These claims essentially define a disposable infusion circuit subassembly comprising: an eluate line, a patient line, a waste line, a valve member and a support frame.

(technical effect: to facilitate the positioning of the components of a portion of infusion circuit in an infusion system)

The only common concept between the invention 1 and 2 is a shielding assembly having a plurality of compartments. This is already known from the person skilled in the art. (FR2867084)

The only common concept between the invention 1 and 3 is an eluate line and a patient line. This is already know from the person skilled in the art. (FR2867084)

There is no common concept between the invention 2 and 3.

The special technical features are not identical. The effects of both compounds are different. The problems posed when using a shielding assembly and a disposable infusion circuit subassembly are also quite different. Consequently the special technical features cannot be regarded as being corresponding. Therefore the application claims 3 inventions not so linked to form a single general inventive concept. The requirement of unity is not fulfilled, according to Rule 13PCT.

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1 Reference is made to the following documents:

D1 FR 2 867 084 A1

D2 EP 0 102 121 A1

D3 WO 99/56117 A1

D4 EP 0 160 303 A2

D5 JP 2000 350783 A

D6 US 2008/093564 A1

D7 WO 2007/149108 A2

D8 US 2003/004463 A1

**Novelty Article 33(2) PCT**

**Invention 1: Claims 1 - 17**

2 The present application does not meet the criteria of Article 33 (1) PCT, because the subject- matter of claims **1-3,5-9 and 15-17** is not new in the sense of Article 33(2) PCT.

2.1 The document D1 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) discloses an infusion system comprising:

- a cabinet structure (page 20 line 25-30) including a shell defining an interior space thereof;

- an eluant source (412)

- a shielding assembly (509+404) located within the interior space of the cabinet structure, the shielding assembly including a sidewall defining a plurality of compartments (509,404,418) and providing a barrier to radioactive radiation for the compartments, the shielding assembly further including a corresponding plurality of doors, each door, when open, providing access to the corresponding compartment via an opening in the sidewall, and, when closed, providing further barrier to radioactive radiation for the corresponding compartment;

- radioisotope generator (502)contained within a first compartment (509) of the plurality of compartments of the shielding assembly;

- an eluant line (figure 6)coupled to the eluant source (412) and to the generator (104,502), the eluant line extending from the eluant source to the generator, through the shielding assembly, at a first location between the sidewall and a first door of the plurality of doors, which first door corresponds to the first compartment;

- an eluate line coupled to the generator and extending out from the first compartment and into a second compartment (418) of the plurality of compartments of the shielding assembly, at a second location between the sidewall and both the first door and a second door of the plurality of doors, which corresponds to the second compartment, the second compartment being located immediately adjacent the first compartment;

- a patient line (428) coupled to the eluate line, within the second compartment, the patient line extending out from the second compartment at a third location between the sidewall and the second door, and out from the interior space through an opening in the shell of the cabinet structure.

The subject matter of claim 1 is not novel document D1.

2.2 Document D1 shows the technical features of claims 2 and 5 to 9.

2.3 Furthermore document D2 reveals the technical features of claims 1,5-9 and 17. (figure 1 to 4)

2.4 The technical features of claims 1-3 and 15-17 are disclosed in document D3.

2.5 Finally document D4 shows the technical features of claims 1 and 2.

**Invention 2: Claims 18-30**

3 Furthermore, the above-mentioned lack of clarity notwithstanding, the subject-matter of **claim 18-23 and 27-28** is not new in the sense of Article 33(2) PCT, and therefore the criteria of Article 33(1) PCT are not met.

3.1 The document D5 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) discloses a shielding assembly (40+84) comprising:

- a sidewall defining a plurality of compartments and providing a radioactive radiation barrier for the compartments;

- a first passageway (bore between wagon (40) and casing (52)) formed in an upper surface of a first portion of the sidewall, the first portion of the sidewall defining a first compartment (62) of the plurality of compartments, the first compartment being sized to contain a radioisotope generator (30) of the infusion system, and the first passageway (bore) being sized to accommodate routing of an eluate line (see figure 2) from the generator;

- a second passageway (passage for the tube 80) formed along a second portion of the sidewall, the second portion of the sidewall extending upward relative to the first portion of the sidewall and defining a second compartment (84) of the plurality of compartments, the second compartment (84) being sized to accommodate a waste bottle (82) of the infusion system and the second compartment being located on a side of the second portion of the

sidewall that is opposite the second passageway, and the second passageway being sized to accommodate routing of at least one extension of the eluate line (see figure 5) from the generator.

The subject matter of claim 18 is not novel document D5.

3.2 Document D5 shows the technical features of claims 18-23,27 and 28.

3.3 The document D2 discloses a shielding assembly (41+26) comprising:

- a sidewall defining a plurality of compartments and providing a radioactive radiation barrier for the compartments;

- a first passageway (bore 32) formed in an upper surface of a first portion of the sidewall, the first portion of the sidewall defining a first compartment (26) of the plurality of compartments, the first compartment being sized to contain a radioisotope generator (31) of the infusion system, and the first passageway (32) being sized to accommodate routing of an eluate line (see figure 1) from the generator;

- a second passageway (passage between the shield (26) and cover (43)) formed along a second portion of the sidewall, the second portion of the sidewall extending upward relative to the first portion of the sidewall and defining a second compartment (41) of the plurality of compartments, the second compartment (41) being sized to accommodate a waste bottle (12a) of the infusion system and the second compartment being located on a side of the second portion of the sidewall that is opposite the second passageway, and the second passageway being sized to accommodate routing of at least one extension of the eluate line (see figure 1) from the generator.

The subject matter of claim 18 is not novel document D2.

3.4 Document D2 shows the technical features of claims 18-21,27 and 28.

3.5 Furthermore documents D6 and D7 reveal the technical features of claim 18.

**Invention 3: Claims 31-38**

4 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of **claims 31,32,34 and 36-38** is not new in the sense of Article 33(2) PCT.

4.1 The document D8 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) discloses a disposable infusion circuit comprising (figures 1-5):

- an eluate line (line from the syringe (20)) ;

- a patient line (100);

- a waste line (line in connection with waste (161));

- a valve member (171) coupling the patient line and the waste line to the eluate line; and

- a support frame (15) including a perimeter edge, the support frame holding the valve member (16) and a portion of each of: the eluate line, the patient line and the waste line in approximately fixed relation with respect to the perimeter edge;

- wherein the perimeter edge of the support frame is sized to fit within a compartment of a shielding assembly (18) of the infusion system; and

- an end of each of the eluate line, the patient line and the waste line extends out from the perimeter edge.

Therefore the subject matter of claim 31 is not novel over document D8.

4.2 Document D8 shows the technical features of claims 32,34 and 36-38.

4.3 Furthermore documents D2 and D3 reveal the technical features of claims 31,32 and 36-38.

Document D2: (figures 1 to 5), eluate line (6), patient line (line next to the valve 4b), waste line (11a), valve member (4b), support frame (operating block 46)

Document D3: (figures 1 to 56, eluate line (saline), patient line (to patient), waste line (dump), valve member (27), support frame (figure 5a-5c)

## Inventive step Article 33(3) PCT

### Invention 1: Claims 1 - 17

5 The present application does not meet the criteria of Article 33 (1) PCT, because the subject- matter of **claims 4 and 10 to 14** does not seem to involve an inventive step in the sense of Article 33(3) PCT. Document D1 is the closest prior art. In claims 4 and 10 to 14 a slight constructional change in the infusion system is defined which comes within the scope of the customary practise followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of these claims also lacks an inventive step.

### Invention 2: Claims 18-30

6 The present application does not meet the criteria of Article 33 (1) PCT, because the subject- matter of **claims 24-26,29 and 30** does not seem to involve an inventive step in the sense of Article 33(3) PCT. Document D2 is the closest prior art. In claims 24-26,29 and 30 a slight constructional change in the shielding assembly is defined which comes within the scope of the

customary practise followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of these claims also lacks an inventive step.

**Invention 3: Claims 31-38**

7 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of **claims 33 and 35** does not seem to involve an inventive step in the sense of Article 33(3) PCT. Document D8 is the closest prior art. In claims 33 and 35 a slight constructional change in the disposable infusion circuit (eluant line extends out from a third side of the perimeter edge) is defined which comes within the scope of the customary practise followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject- matter of these claims also lacks an inventive step.

**Further comments**

**Invention 1: Claims 1 - 17**

8 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D1- D4 are not mentioned in the description, nor are these documents identified therein.

9 Independent claim 1 is not in the **two-part form** in accordance with Rule 6.3 (b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

10 The features of the claims are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).

**Invention 2: Claims 18-30**

11 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D2,D5-D7 are not mentioned in the description, nor are these documents identified therein.

12 Independent claim 18 is not in the **two-part form** in accordance with Rule 6.3 (b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D5) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

13 The features of the claims are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).

**Invention 3: Claims 31-38**

14 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D2,D3 and D8 are not mentioned in the description, nor are these documents identified therein.

15 Independent claim 31 is not in the **two-part form** in accordance with Rule 6.3 (b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D8) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

16 The features of the claims are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).

## Re Item VIII

### Certain observations on the international application

### Invention 2: Claims 18-30

## Clarity Article 6 PCT

17 Although **claims 18 and 27** have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought.

The aforementioned claims therefore lack conciseness. Moreover, lack of clarity ofthe claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, these claims do not appear to meet the requirements of Article 6 PCT.

It appears to be appropriate to file an amended set of claims taking account of the above comments and Article 34(2)(b) PCT. The revelant subjecr-matter should be defined in **a single independent claim** followed by dependent claims covering features which are merely optional (Rules 6.3 and 6.4 PCT)

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| Applicant's or agent's file reference | **FOR FURTHER ACTION** | see Form PCT/ISA/220 as well as, where applicable, item 5 below. |
|---|---|---|
| 56782.1.7.1 | | |
| International application No. | International filing date *(day/month/year)* | (Earliest) Priority Date *(day/month/year)* |
| PCT/US2009/047031 | 11/06/2009 | 11/06/2008 |
| Applicant | | |
| BRACCO DIAGNOSTICS INC. | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 7 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language,** the international search was carried out on the basis of:
      [X] the international application in the language in which it was filed
      [ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [X] **Certain claims were found unsearchable** (See Box No. II)

3. [X] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**
   [ ] the text is approved as submitted by the applicant
   [X] the text has been established by this Authority to read as follows:

INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION

5. With regard to the **abstract,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1d
      [ ] as suggested by the applicant
      [X] as selected by this Authority, because the applicant failed to suggest a figure
      [ ] as selected by this Authority, because this figure better characterizes the invention
   b. [ ] none of the figures is to be published with the abstract

International application No
PCT/US2009/047031

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/00
ADD. A61M5/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | EP 0 310 148 A2 (SQUIBB & SONS INC [US])<br>5 April 1989 (1989-04-05)<br>figures 1-6<br>column 3, line 37 - column 15, line 43 | 1-5 |
| X | US 2007/140958 A1 (DEKEMP ROBERT A [CA])<br>21 June 2007 (2007-06-21)<br>figures 1-5<br>paragraph [0003]<br>paragraph [0018] - paragraph [0035] | 1-5 |
| X | WO 2006/129301 A2 (SPECTRUM DYNAMICS [IL];<br>ROUSSO BENNY [IL]; BEN-HAIM SHLOMO [GB];<br>BRONS) 7 December 2006 (2006-12-07)<br>figures 1-14<br>page 40, line 3 - page 41, line 16<br>page 90, line 10 - page 97, line 26 | 1 |

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 12 February 2010 | 01/03/2010 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Reinbold, Sylvie |

2

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 2007/213848 A1 (DEKEMP ROBERT A [CA] ET AL) 13 September 2007 (2007-09-13) figures 1-8 paragraph [0006] paragraph [0024] - paragraph [0056] | 1-7, 32-35 |
| X | NEIL J. EPSTEIN, AHMED BENELFASSI, ROB S.B. BEANLANDS, ROBERT A. DEKEMP: "A Rb82 infusion system for quantitative perfusion imaging with 3D PET" APPLIED RADIATION AND ISOTOPES, vol. 60, 9 February 2004 (2004-02-09), pages 921-927, XP002557544 DOI: 10.1016/j.apradiso.2004.02.002 the whole document | 1-7, 32-35 |
| X | R KLEIN, A ADLER, R S BEANLANFS AND R A DEKEMP: "Precision controlled elution of a Sr82/Rb82 generator for cardiac perfusion imaging with positron emission tomography" PHYSICS IN MEDICINE AND BIOLOGY, vol. 52, 11 January 2007 (2007-01-11), pages 659-673, XP002557545 DOI: 10.1088/0031-9155/52/3/009 the whole document | 1-7, 32-35 |
| X | WO 2008/028165 A2 (CATHOLIC HEALTHCARE WEST D B A [US]; DESHMUKH VIVEK R [US]; CRAWFORD N) 6 March 2008 (2008-03-06) paragraph [0060]; figures 1-5 | 30-31 |

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

Continuation of Box II.1

Claims Nos.: 8-29, 36

The methods of claims 8 to 29 for operating an infusion system is carried out within a human body. As stated in the claims, the method is during a medical therapy. Furthermore the method of claim 36 for purging a tubing circuit of an infusion system with air is carried out within a human body. As stated in the claim, the method is during a medical therapy. These methods are forming part of a therapeutic procedure and can therefore not be regarded as an invention which is susceptible of industrial application. The application does not meet the requirement of Rule 39.1 (iv), because these claims are a method of treatment of the human body.

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/047031

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 8-29, 36
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[X] No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-5

These claims essentially define an infusion system with an eluant reservoir, a pump, a radioisotope generator, an activity detector, a waste bottle, a computer,an eluant line and an user interface.
(technical effect: to provide an infusion pump which permits a quality control of a dose)

---

2. claims: 6-7

These claims essentially define an infusion system with an eluate line, a pump, an activity sensor, a waste bottle, a computer, a patient line, a by pass line coupled to the eluant line via a divergence valve and a radiosotope generator.
(technical effect: to provide an infusion system which permits to flush or to push any eluate remaining in patient line)

---

3. claims: 30-35

These claims essentially define a computer readable medium.
(technical effect: to execute computer instructions)

---

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| EP 0310148 A2 | 05-04-1989 | AT 53305 T | 15-06-1990 |
| | | AU 570429 B2 | 17-03-1988 |
| | | CA 1237539 A1 | 31-05-1988 |
| | | DE 3482410 D1 | 12-07-1990 |
| | | EP 0117752 A2 | 05-09-1984 |
| | | JP 5249245 A | 28-09-1993 |
| | | JP 1856747 C | 07-07-1994 |
| | | JP 5062314 B | 08-09-1993 |
| | | JP 59163584 A | 14-09-1984 |
| | | US 4585941 A | 29-04-1986 |
| | | US 4585009 A | 29-04-1986 |
| US 2007140958 A1 | 21-06-2007 | AU 2006326814 A1 | 28-06-2007 |
| | | CA 2562340 A1 | 21-06-2007 |
| | | WO 2007071022 A1 | 28-06-2007 |
| | | EP 1973624 A1 | 01-10-2008 |
| | | JP 2009520953 T | 28-05-2009 |
| WO 2006129301 A2 | 07-12-2006 | CA 2610256 A1 | 07-12-2006 |
| | | EP 1891597 A2 | 27-02-2008 |
| US 2007213848 A1 | 13-09-2007 | AU 2007224955 A1 | 20-09-2007 |
| | | CA 2562453 A1 | 10-09-2007 |
| | | WO 2007104133 A1 | 20-09-2007 |
| | | EP 1996276 A1 | 03-12-2008 |
| | | JP 2009529682 T | 20-08-2009 |
| | | KR 20090071512 A | 01-07-2009 |
| WO 2008028165 A2 | 06-03-2008 | NONE | |

# PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

# PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
*(day/month/year)* see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

**FOR FURTHER ACTION**
See paragraph 2 below

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/US2009/047031 | 11.06.2009 | 11.06.2008 |

International Patent Classification (IPC) or both national classification and IPC
INV. A61M5/00
ADD. A61M5/14

Applicant
BRACCO DIAGNOSTICS INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| Name and mailing address of the ISA: | Date of completion of this opinion | Authorized Officer |
|---|---|---|
| European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0<br>Fax: +49 89 2399 - 4465 | see form PCT/ISA/210 | Reinbold, Sylvie<br>Telephone No. +49 89 2399-7918 |

Form PCT/ISA/237 (Cover Sheet) (April 2005)

**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

☐ the entire international application

☒ claims Nos. 8-29, 36

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☒ no international search report has been established for the whole application or for said claims Nos. 8-29, 36

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b).

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

**Box No. IV Lack of unity of invention**

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☒ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   **see separate sheet**

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☒ all parts.

   ☐ the parts relating to claims Nos. 1-5

**Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 7, 35 |
| | No: | Claims | 1-6, 30-34 |
| Inventive step (IS) | Yes: | Claims | |
| | No: | Claims | 1-7, 30-35 |
| Industrial applicability (IA) | Yes: | Claims | 1-7, 30-35 |
| | No: | Claims | |

2. Citations and explanations

**see separate sheet**

**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

## Re Item III

**Non- establishment of opinion with regard to novelty, inventive step and industrial applicability**

The methods of **claims 8 to 29** for operating an infusion system is carried out within a human body. As stated in the claims, the method is during a medical therapy.

Furthermore the method of **claim 36** for purging a tubing circuit of an infusion system with air is carried out within a human body. As stated in the claim, the method is during a medical therapy.

These methods are forming part of a therapeutic procedure and can therefore not be regarded as an invention which is susceptible of industrial application. The application does not meet the requirement of Rule 39.1 (iv), because these claims are a method of treatment of the human body. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject matter of theses claims. (Article 34 (4)(a)(i)PCT)

## Re Item IV

**Lack of unity of invention**

The inventions in this international application, as follows:

### 1. Claims 1-5

These claims essentially define an infusion system with an eluant reservoir, a pump, a radioisotope generator, an activity detector, a waste bottle, a computer,an eluant line and an user interface. (technical effect: to provide an infusion pump which permits a quality control of a dose)

### 2. Claims 6-7

These claims essentially define an infusion system with an eluate line, a pump, an activity sensor, a waste bottle, a computer, a patient line, a by pass line coupled to the eluant line via a divergence valve and a radioisotope generator. (technical effect: to provide an infusion system which permits to flush or to push any eluate remaining in patient line)

### 3. Claims 30-35:

These claims essentially define a computer readable medium. ( technical effect: to execute computer instructions)

The only common concept between the invention 1 and 2 is an infusion system comprising an eluant reservoir, a pump, a radioisotope generator, an activity detector, a waste bottle, a computer and an eluant line. This is already known from the person skilled in the art. (EP0310148)

There is no common concept between the invention 1 and 3 and 2 and 3.

The special technical features are not identical. The effects of both compounds are different. The use of the infusion system in claim 6 is to flush or push any eluate remaining in the patient line. The use of a computer readable medium is to execute computer instructions.

The groups of claims are not linked by common or corresponding special technical features and define 3 different inventions not linked by a single general inventive concept. Therefore the application claims 3 inventions not so linked to form a single general inventive concept. The requirement of unity is not fulfilled, according to Rule 13 PCT.

## Re Item V

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1 Reference is made to the following documents:

D1 EP 0 310 148

D2 US 2007/140958

D3 WO 2006/129301

D4 US 2007/213848

D5 NEIL J. EPSTEIN "A Rb82 infusion system for quantitative perfusion imaging with 3D PET"

D6 R KLEIN "Precision controlled elution of a Sr82/Rb82 generator for cardiac perfusion imaging with positron emission tomography"

D7 WO2008/028165

## Novelty Article 33(2) PCT

**Invention 1: Claims 1 - 5**

2 Furthermore, the above-mentioned lack of clarity notwithstanding, the subject-matter of **claims 1 to 5** is not new in the sense of Article 33(2) PCT, and therefore the criteria of Article 33(1) PCT are not met.

2.1 The document D1 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) an infusion system comprising (figure 1-6):

-an eluant reservoir (10) , a pump (64) coupled to the reservoir, an infusion tubing circuit (26,30,44,38), a radioisotope generator (28), an activity detector (58), a waste bottle (42) and a computer (60);

- the infusion tubing circuit including an eluant line (26) coupled to the pump and to the generator and an eluate line (30) coupled to the generator and to the activity detector; and the computer being coupled to a user interface (figure 2), to the pump and to the activity detector and being preprogrammed to receive input from a user of the system, via the user interface, to collect information, from the pump and the activity detector, and to provide output to the user, via the user interface (column 6 line 12 to 42), according to a method, the method comprising

- activating the pump to pump a volume of eluant from the reservoir, through the eluant line and through the generator, in order to generate a sample or a dose of eluate in the eluate line, via an elution within the generator, the sample (probe 58) being intended for a quality control measurement, and the dose being intended for diagnostic imaging;

- providing an indication, via the computer interface, that the elution is completed, when the pump has completed pumping the volume of eluant through the generator; and

- providing an indication, via the computer interface, of a time lapse since the elution was completed.

The subject matter of claim 1 is not novel document D1.

2.2 Document D1 shows the technical features of claims 2 to 5.

2.3 The technical features of claims 1 to 5 are also disclosed in Documents D2 to D6.

**Invention 2: Claims 6-7**

3 Furthermore, the above-mentioned lack of clarity notwithstanding, the subject-matter of **claim 6** is not new in the sense of Article 33(2) PCT, and therefore the criteria of Article 33(1) PCT are not met.

3.1 The document D4 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) an infusion system comprising (figure 1-8):

- an eluant reservoir (4), a pump (6) coupled to the reservoir, an infusion tubing circuit, a radioisotope generator (8), an activity detector (20), a waste bottle (26) and a computer (28); the infusion tubing circuit including an eluant line coupled to the pump and to the generator (figure 6), an eluate line coupled to the generator and to the activity detector, a patient line coupled to the eluate line, a by-pass line (18) coupled to the eluant line, via a divergence valve (16), and to the patient line, the by-pass line (18) accommodating flow of eluant to the patient line, when the divergence valve is set to direct the flow to by-pass the generator; and the computer being coupled to the pump and to

the activity detector and being pre-programmed to collect information, from the pump and the activity detector and to control the divergence valve and the pump (paragraph 29 to 32) according to a method, the method comprising:

- activating the pump a first time to pump a portion of a volume of eluant from the reservoir, through the eluant line and through the generator at a first flow rate, in order to generate eluate in the eluate line, via an elution within the generator, and to push a dose of the eluate into the patient line (figure 6c);

- setting the divergence valve (16) to direct flow through the by-pass line, once the dose has been pushed into the patient line (figure 6d); and

- activating the pump a second time to pump a second portion of the volume of eluant from the reservoir, through the eluant line, through the by-pass line and into the patient line to inject the dose out from the patient line (figure 6d);

- wherein the pump, when activated the second time, is controlled to pump the second portion of the volume of eluant at a second flow rate, the second flow rate being higher than the first flow rate, in order to increase a flow rate of the injection of the dose. (the flow rate can be variable: desired flow)

The subject matter of claim 6 is not novel document D4.

3.2 The technical feature of claim 6 is also disclosed in Documents D5 (figure 1) and D6. (figure 1)

**Invention 3: Claims 30-35**

4 Furthermore, the above-mentioned lack of clarity notwithstanding, the subject-matter of **claims 30-34** is not new in the sense of Article 33 (2) PCT, and therefore the criteria of Article 33(1) PCT are not met.

4.1 The document D7 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) a computer readable medium (106) comprising (figure 1-5):

- having computer executable instructions for executing a method for maintaining an infusion system (18), the method comprising:

- tracking a portion of a volume of eluant (saline) that is pumped from a reservoir (38) of the system and through a generator of the system, in order to generate, via elution, an eluate; providing an indication of the volume of eluant within the reservoir to a user of the system; tracking a volume of the eluate that is diverted from the generator to a waste bottle (120) of the system; and providing an indication to the user that the waste bottle needs to be emptied (paragraph 60).

The subject matter of claim 30 is not novel document D7.

4.2 Document D7 also reveals the technical feature of claim 31.

4.3 The document D4 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) a computer readable medium (28) comprising (figure 1-8) computer executable instructions for executing a method of calibrating an activity detector (20) of an infusion system. (see paragraph 29-32 and paragraph 55). The subject matter of claim 32 is not novel over document D4.

4.4 Moreover Document D4 shows the technical features of claims 33 and 34.

4.5 Finally the technical features of claims 32 to 34 are also disclosed in Documents D5 and D6.

## Inventive Step Article 33(3) PCT

### Invention 2: Claims 6-7

5 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of **claim 7** does not seem to involve an inventive step in the sense of Article 33(3) PCT. Document D4 is the prior art. In **claim 7** a slight constructional change (flow rate) in device of D4 is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of this claim also lacks an inventive step.

### Invention 3: Claims 30-35

6 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of **claim 35** does not seem to involve an inventive step in the sense of Article 33(3) PCT. Document D4 is the prior art. In **claim 35** a slight constructional change (time period) in device of D4 is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of this claim also lacks an inventive step.

## Further comments

### Invention 1: Claims 1 - 5

7 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D1- D3 are not mentioned in the description, nor are these documents identified therein.

8 Independent claim 1 is not in the **two-part form** in accordance with Rule 6.3 (b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

9 The features of the claims are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).

**Invention 2: Claims 6-7**

10 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D4- D6 are not mentioned in the description, nor are these documents identified therein.

11 Independent claim 6 is not in the **two-part form** in accordance with Rule 6.3 (b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D4) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

12 The features of the claims are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).

**Invention 3: Claims 30-35**

13 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D4- D7 are not mentioned in the description, nor are these documents identified therein.

14 Independent claim 30 is not in the **two-part form** in accordance with Rule 6.3 (b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D7) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

15 The features of the claims are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).

**Re Item VIII**

**Certain observations on the international application**

**Clarity Article 6 PCT**

**Invention 1: Claims 1 - 5**

16 Some of the features in the apparatus **claim 1** relate to a method of using the apparatus (method comprising activating the pump, providing an indication and providing an indication) rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.

Furthermore such a method of using an infusion system is not allowed because this is a method of treatment of the human body. (Rule 39.1 (iv))

**Invention 2: Claims 6-7**

17 Some of the features in the infusion system **claim 6** relate to a method of using the apparatus (method comprising activating the pump, setting the valve and providing an indication) rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.

Furthermore such a method of using an infusion system is not allowed because this is a method of treatment of the human body. (Rule 39.1 (iv)). The method is carried out within a human body, because a dose of eluate is injected to the patient line into the patient.

**Invention 3: Claims 30-35**

18 Although **claims 30,32 and 33** have been drafted as separate independent claims, they appear to relate effectively to the **same subject-matter** and to differ from each other only with regard to the definition of the subject-matter for which protection is sought.

The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection. Hence, these claims do not meet the requirements of Article 6 PCT.

19 Some of the features in the computer readable medium of **claim 30** relate to a method for maintaining an infusion system rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.

Furthermore such a method for maintaining an infusion system is not allowed because this is during a method of treatment of the human body. (Rule 39.1 (iv)). It is implicit that to generate an eluate, the infusion pump is activated and is during a method of treatment of the human body.

20 Some of the features in the computer readable medium of **claim 32** relate to a method for calibrating an activity detector of an infusion system, rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.

Furthermore such a method for calibrating an activity detector of an infusion system is not allowed because this is during a method of treatment of the human body. (Rule 39.1 (iv)). It is implicit that to generate an eluate, the infusion pump is activated and is during a method of treatment of the human body.

21 Some of the features in the computer readable medium of **claim 33** relate to a method for conducting a breakthrough test of a radioisotope generator of an infusion system rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.

Furthermore such a method for conducting a breakthrough test of a radioisotope generator of an infusion system is not allowed because this is during a method of treatment of the human body. (Rule 39.1 (iv)). It is implicit that to generate an eluate, the infusion pump is activated and is during a method of treatment of the human body.

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

| Applicant's or agent's file reference | **FOR FURTHER ACTION** | see Form PCT/ISA/220 as well as, where applicable, item 5 below. |
|---|---|---|
| 56782.1.8.1 | | |
| International application No. | International filing date *(day/month/year)* | (Earliest) Priority Date *(day/month/year)* |
| PCT/US2009/047034 | 11/06/2009 | 11/06/2008 |
| Applicant | | |
| BRACCO DIAGNOSTICS INC. | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 6 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
   a. With regard to the **language,** the international search was carried out on the basis of:
      [X] the international application in the language in which it was filed
      [ ] a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))
   b. [ ] This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).
   c. [ ] With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. [ ] **Certain claims were found unsearchable** (See Box No. II)

3. [X] **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**
   [X] the text is approved as submitted by the applicant
   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings,**
   a. the figure of the **drawings** to be published with the abstract is Figure No. 1c
      [ ] as suggested by the applicant
      [X] as selected by this Authority, because the applicant failed to suggest a figure
      [ ] as selected by this Authority, because this figure better characterizes the invention
   b. [ ] none of the figures is to be published with the abstract

Form PCT/ISA/210 (first sheet) (April 2007)

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/14 A61G12/00
ADD. A61M5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M G21F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, INSPEC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | JP 2000 350783 A (SUMITOMO HEAVY INDUSTRIES) 19 December 2000 (2000-12-19) figures 1-5 paragraph [0013] - paragraph [0032] | 1-35 |
| X | WO 2008/037939 A2 (LEMER PROT ANTI X PAR ABREVIAT [FR]; LEMER PIERRE-MARIE [FR]) 3 April 2008 (2008-04-03) figures 1-2 page 5, line 27 - page 11, line 19 | 1-23 |
| X | EP 0 102 121 A1 (BYK MALLINCKRODT CIL BV [NL]) 7 March 1984 (1984-03-07) figures 1-4 page 9, line 16 - page 12, line 11 | 1,8-10, 12, 14-16, 19,22-23 |

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 11 February 2010 | 25/02/2010 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL – 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Reinbold, Sylvie |

3

Form PCT/ISA/210 (second sheet) (April 2005)

International application No
PCT/US2009/047034

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | JP 2006 325826 A (UNIVERSAL GIKEN KK; SD GIKEN KK) 7 December 2006 (2006-12-07)<br>figures 1-10<br>paragraph [0020] - paragraph [0069] | 1-23 |
| X | FR 2 867 084 A1 (GEN ELECTRIC [US])<br>9 September 2005 (2005-09-09)<br>figures 1-12<br>page 13, line 23 - page 27, line 9 | 1,8-12,<br>14-15,<br>17,19 |
| X | WO 2006/074473 A2 (ATLAS SYSTEMS INC [US]; LIVENGOOD AMY L [US]; LIVENGOOD JOSEPH C [US];) 13 July 2006 (2006-07-13)<br>figures 1-6<br>page 16, line 4 - page 27, line 4 | 24-35 |
| X | US 5 590 648 A (MITCHELL ANDREW [US] ET AL) 7 January 1997 (1997-01-07)<br>figures 1-9<br>column 3, line 65 - column 8, line 5 | 24,28-35 |
| X<br><br>A | WO 02/096335 A2 (HILL ROM SERVICES INC [US]; GALLANT DENNIS J [US]; LANCI DENNIS M [US]) 5 December 2002 (2002-12-05)<br>figure 18<br>page 22, line 6 - page 23, line 3 | 24,<br>28-29,<br>33-34<br>35 |
| X | WO 96/15337 A1 (NILSSON AGNE [CY])<br>23 May 1996 (1996-05-23)<br>figures 1-26<br>page 4, line 4 - page 12, line 34 | 28-35 |

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2009/047034

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-23

These claims essentially define a cabinet structure for an infusion system comprising:
- a platform
- a shell, wherein the shell comprises a first upper opening, a second upper opening and an access panel
- the access panel mating with the upper opening and being removable therefrom
- the upper opening is sized and oriented to allow a lowering of one or more radioisotope generators
- the upper opening being located at an elevation which is substantially lower than an elevation of an uppermost portion of the upper surface
(technical problem: to provide a better ergonomic)

---

2. claims: 24-35

These claims essentially define a cabinet structure for an infusion system comprising:
- a platform
- a shell
- at least one external recess
(technical problem: to provide a cabinet structure to hold articles pertaining to operation of the infusion system)

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| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| JP 2000350783 A | 19-12-2000 | NONE | |
| WO 2008037939 A2 | 03-04-2008 | AU 2007301772 A1 | 03-04-2008 |
| | | CA 2664760 A1 | 03-04-2008 |
| | | CN 101516420 A | 26-08-2009 |
| | | EP 2077873 A2 | 15-07-2009 |
| | | FR 2906475 A1 | 04-04-2008 |
| | | KR 20090057979 A | 08-06-2009 |
| | | US 2010030009 A1 | 04-02-2010 |
| EP 0102121 A1 | 07-03-1984 | NONE | |
| JP 2006325826 A | 07-12-2006 | NONE | |
| FR 2867084 A1 | 09-09-2005 | DE 102005010152 A1 | 15-09-2005 |
| | | DE 102005010154 A1 | 15-09-2005 |
| | | FR 2867294 A1 | 09-09-2005 |
| | | JP 2005326398 A | 24-11-2005 |
| | | JP 2005324007 A | 24-11-2005 |
| | | US 2008242915 A1 | 02-10-2008 |
| WO 2006074473 A2 | 13-07-2006 | US 2006163829 A1 | 27-07-2006 |
| US 5590648 A | 07-01-1997 | NONE | |
| WO 02096335 A2 | 05-12-2002 | AU 2002305689 A1 | 09-12-2002 |
| | | AU 2002309987 A1 | 09-12-2002 |
| | | AU 2002310044 A1 | 09-12-2002 |
| | | CA 2447655 A1 | 05-12-2002 |
| | | CA 2447656 A1 | 05-12-2002 |
| | | CA 2447661 A1 | 05-12-2002 |
| | | EP 1389995 A2 | 25-02-2004 |
| | | EP 1395220 A1 | 10-03-2004 |
| | | EP 1397103 A2 | 17-03-2004 |
| | | JP 2005515800 T | 02-06-2005 |
| | | JP 2005516635 T | 09-06-2005 |
| | | JP 2005514080 T | 19-05-2005 |
| | | WO 02096339 A1 | 05-12-2002 |
| | | WO 02096338 A2 | 05-12-2002 |
| | | US 2008236054 A1 | 02-10-2008 |
| | | US 2003014817 A1 | 23-01-2003 |
| | | US 2007068089 A1 | 29-03-2007 |
| | | US 2004237202 A1 | 02-12-2004 |
| WO 9615337 A1 | 23-05-1996 | AT 288000 T | 15-02-2005 |
| | | AU 3943695 A | 06-06-1996 |
| WO 9615337 A1 | | CN 1173211 A | 11-02-1998 |
| | | DE 69533965 D1 | 03-03-2005 |
| | | EP 0797712 A1 | 01-10-1997 |
| | | JP 10508770 T | 02-09-1998 |
| | | JP 4061657 B2 | 19-03-2008 |
| | | US 6089518 A | 18-07-2000 |

# PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

# PCT

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
*(day/month/year)* see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

**FOR FURTHER ACTION**
See paragraph 2 below

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/US2009/047034 | 11.06.2009 | 11.06.2008 |

International Patent Classification (IPC) or both national classification and IPC
INV. A61M5/14 A61G12/00
ADD. A61M5/00

Applicant
BRACCO DIAGNOSTICS INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

| Name and mailing address of the ISA: | Date of completion of this opinion | Authorized Officer |
|---|---|---|
| European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0<br>Fax: +49 89 2399 - 4465 | see form PCT/ISA/210 | Reinbold, Sylvie<br>Telephone No. +49 89 2399-7918 |

Form PCT/ISA/237 (Cover Sheet) (April 2005)

**Box No. I Basis of the opinion**

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).

2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material:

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing:

      ☐ contained in the international application as filed.

      ☐ filed together with the international application in electronic form.

      ☐ furnished subsequently to this Authority for the purposes of search.

4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

**Box No. IV Lack of unity of invention**

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit:

   ☒ paid additional fees

   ☐ paid additional fees under protest and, where applicable, the protest fee

   ☐ paid additional fees under protest but the applicable protest fee was not paid

   ☐ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

   **see separate sheet**

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☒ all parts.

   ☐ the parts relating to claims Nos. 1-23

**Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 2-7, 13, 20-21, 26-27 |
| | No: | Claims | 1, 8-12, 14-19, 22-25, 28-35 |
| Inventive step (IS) | Yes: | Claims | |
| | No: | Claims | 1-35 |
| Industrial applicability (IA) | Yes: | Claims | 1-35 |
| | No: | Claims | |

2. Citations and explanations

   **see separate sheet**

**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

## Re Item IV

**Lack of unity of invention**

The inventions in this international application, as follows:

**1. Claims 1 - 23**

These claims essentially define a cabinet structure for an infusion system comprising:

- a platform, a shell, wherein the shell comprises a first upper opening, a second upper opening and an access panel

- the access panel mating with the upper opening and being removable therefrom

- the upper opening is sized and oriented to allow a lowering of one or more radioisotope generators

- the upper opening being located at an elevation which is substantially lower than an elevation of an uppermost portion of the upper surface

(technical problem: to provide a better ergonomic)

**2. Claims 24-35:**

These claims essentially define a cabinet structure for an infusion system comprising:

- a platform, a shell

- at least one external recess

(technical problem: to provide a cabinet structure to hold articles pertaining to operation of the infusion system)

The only common concept between the invention 1 and 2 is a cabinet structure for an infusion system having a platform and a shell. This is already known from the person skilled in the art. (see JP200350783).

The special technical features are not identical. The effects of both compounds are different. The use of the cabinet structure in claim 24 or 28 permit to hold articles pertaining to operation of the infusion system.

In conclusion, the groups of claims are not linked by common or corresponding special technical features and define 2 different inventions not linked by a single general inventive concept. Therefore the application claims 2 inventions not so linked to form a single general inventive concept. The requirement of unity is not fulfilled, according to Rule 13 PCT.

## Re Item V

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1 Reference is made to the following documents:

D1 JP 2000 350783

D2 WO 2008/037939

D3 EP 0 102 121

D4 JP 2006 325826

D5 FR 2 867 084

D6 WO 2006/074473

D7 US 5 590 648

D8 WO 02/096335

D9 WO 96/15337

**Novelty Article 33(2) PCT**

**Invention 1: claims 1 - 23**

2 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of claims **1,8-12,14-19,22 and 23** is not new in the sense of Article 33(2) PCT.

2.1 The document D1 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) discloses a cabinet structure for an infusion system comprising (figure 1-5):

- a platform on which the infusion system is mounted; and

- a shell (40+74) surrounding an interior space of the structure, the interior space containing at least a portion of the infusion system;

- wherein the shell comprises a first upper opening (84) into the interior space, a second upper opening (opening where the panel (64) is fixed) into the interior space and an access panel;

- the access panel (64) mates with the second upper opening and is removable therefrom;

- the first upper opening is sized to provide access to a waste bottle (syringe) of the infusion system within the interior space; and

- the second upper opening is sized and oriented to allow a lowering of one or more radioisotope generators, for the system, into the interior space, and a lifting of the one or more generators out from the interior space, the second upper opening being located at an elevation, with respect to a lowermost

portion of the cabinet structure, which is lower than an elevation, with respect to the lowermost portion of the cabinet structure, of the first upper opening (see figure 2).

The subject matter of claim 1 is not novel over document D1.

2.2 Document D1 shows the technical features of claims 8,10,11,12,14,15,17-19, 22 and 23.

2.3 The technical feature of claims 1,8-12,14-19,22 and 23 is disclosed in Documents D2,D3,D4 and D5.

**Invention 2: claims 24 - 35**

3 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of claims **24,25 and 28-35** is not new in the sense of Article 33(2) PCT.

3.1 The document D6 is regarded as being the closest prior art and discloses (the references in parentheses applying to this document) discloses a cabinet structure (100) for an infusion system (124, page 16 line 21), the structure comprising (figures 1-15):

- a platform (120) on which the infusion system is mounted; and

- a shell (204) surrounding an interior space of the structure and including an upper surface (112) in which at least one opening (138,124) and an external recess (192) is formed;

- wherein the interior space contains at least a portion of the infusion system (IV pump);

- the at least one opening provides a passageway (138) for a tubing line of the infusion system to extend out from the interior space; and the external recess (192) is sized to contain a spill from the infusion system.

Therefore the subject matter of claim 24 is not novel over document D6.

3.2 Document D6 also shows the technical features of claims 25 and 28 to 35.

3.3 Moreover the technical feature of **claims 24,25 and 28-35** is disclosed in Documents D1,D7,D8 and D9.

**Inventive step Article 33(3) PCT**

**Invention 1: claims 1 - 23**

4 The present application does not meet the criteria of Article 33 (1) PCT, because the subject- matter of **claims 2-7,13 and 20-21** does not seem to involve an inventive step in the sense of Article 33(3) PCT. Document D1 is the closest prior art.

In claims 2-7,9,13 and 20-21 a slight constructional change in the cabinet structure is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject-matter of these claims also lacks an inventive step.

**Invention 2: claims 24 - 35**

5 The present application does not meet the criteria of Article 33 (1) PCT, because the subject-matter of **claims 26 and 27** does not seem to involve an inventive step in the sense of Article 33(3) PCT. Document D6 is the closest prior art.

In claims 26 and 27 a slight constructional change in the cabinet structure is defined which comes within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen. Consequently, the subject- matter of these claims also lacks an inventive step.

**Further comments**

**Invention 1: claims 1 - 23**

6 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D1- D4 are not mentioned in the description, nor are these documents identified therein.

7 Independent claim 1 is not in the **two-part form** in accordance with Rule 6.3 (b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

8 The features of the claims are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).

**Invention 2: claims 24 - 35**

9 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the **relevant background** art disclosed in the documents D1, D6 to D9 are not mentioned in the description, nor are these documents identified therein.

10 Independent claim 24 is not in the **two-part form** in accordance with Rule 6.3 (b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

11 The features of the claims are not provided with **reference signs** placed in parentheses (Rule 6.2(b) PCT).

**Re Item VIII**

**Certain observations on the international application**

**Clarity Article 6 PCT**

**Invention 1: claims 1 - 23**

12 Although **claims 1 and 19** have been drafted as separate independent claims, they appear to relate effectively to the **same subject-matter** and to differ from each other only with regard to the definition of the subject-matter for which protection is sought.

The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, these claims do not meet the requirements of Article 6 PCT.

It appears to be appropriate to file an amended set of claims taking account of the above comments and Article 34(2)(b) PCT. The relevant subject-matter should be defined in **a single independent claim** followed by dependent claims covering features which are merely optional (Rules 6.3 and 6.4 PCT).

**Invention 2: claims 24 - 35**

13 Although **claims 24 and 28** have been drafted as separate independent claims, they appear to relate effectively to the **same subject-matter** and to differ from each other only with regard to the definition of the subject-matter for which protection is sought.

The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises, since the plurality of independent claims makes it difficult, if not impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

Hence, these claims do not meet the requirements of Article 6 PCT.

It appears to be appropriate to file an amended set of claims taking account of the above comments and Article 34(2)(b) PCT. The relevant subject-matter should be defined in **a single independent claim** followed by dependent claims covering features which are merely optional (Rules 6.3 and 6.4 PCT).

# Electronic Acknowledgement Receipt

| | |
|---|---|
| **EFS ID:** | 7196882 |
| **Application Number:** | 12137364 |
| **International Application Number:** | |
| **Confirmation Number:** | 7377 |
| **Title of Invention:** | INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE |
| **First Named Inventor/Applicant Name:** | Stephen E. Hidem |
| **Customer Number:** | 22859 |
| **Filer:** | Elisabeth Lacy Belden |
| **Filer Authorized By:** | |
| **Attorney Docket Number:** | 56782.1.7 |
| **Receipt Date:** | 12-MAR-2010 |
| **Filing Date:** | 11-JUN-2008 |
| **Time Stamp:** | 12:36:02 |
| **Application Type:** | Utility under 35 USC 111(a) |

## Payment information:

| | |
|---|---|
| Submitted with Payment | no |

## File Listing:

| Document Number | Document Description | File Name | File Size(Bytes)/ Message Digest | Multi Part /.zip | Pages (if appl.) |
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| 1 | | 5thSIDS_56782-1-7.pdf | 858263<br>8e25b62944274bd441fa0df48cf6d20ab35f daae | yes | 5 |

| | Multipart Description/PDF files in .zip description | | | |
|---|---|---|---|---|
| | Document Description | | Start | End |
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| | Transmittal Letter | | 4 | 5 |
| **Warnings:** | | | | |
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| 2 | Foreign Reference | WO9615337A1.pdf | 1486044<br>3f0a489957d75fe17b634665cba1dca9a555959d | no | 36 |
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| 3 | Foreign Reference | WO02096335A2.pdf | 2874922<br>0123b0873d007d1e9c2963ddeec35337455e36de | no | 57 |
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| 6 | NPL Documents | Article-Epstein.pdf | 1242548<br>4d1ae76a39290b7146438b33486c7d98821ec552 | no | 7 |
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| 7 | NPL Documents | Article-Klein.pdf | 2007175<br>3e644852e664ae035f2776e9ac7322fa45a539c5 | no | 15 |
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| 8 | NPL Documents | ISR-WO_56782_1_5_1.pdf | 3081572<br>773bbb06586bc6dbfbafe2f645d6b37ceaebe442 | no | 22 |
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| 9 | NPL Documents | ISR-WO_56782_1_6_1.pdf | 2732881<br>70698277b5883d4af6d71695b799561e78095ddb | no | 17 |
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| 10 | NPL Documents | ISR-WO_56782_1_7_1.pdf | 3013153<br>08067db8c7b81d3142e5ad89e5ab72e32d751231 | no | 20 |
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| 12/137,364 | 06/11/2008 | Stephen E. Hidem | 56782.1.7 |

**CONFIRMATION NO. 7377**

22859
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**PUBLICATION NOTICE**

*OC000000039286488*

**Title:**INFUSION SYSTEMS INCLUDING COMPUTER-FACILITATED MAINTENANCE AND/OR OPERATION AND METHODS OF USE

**Publication No.**US-2009-0312630-A1
**Publication Date:**12/17/2009

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| First Named Inventor | Stephen E. Hidem |
| Art Unit | 3737 |
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(51) International Patent Classification 6 : G01N 24/00, 37/00

A1

(11) International Publication Number: **WO 99/56117**

(43) International Publication Date: 4 November 1999 (04.11.99)

(21) International Application Number: PCT/US99/08981

(22) International Filing Date: 26 April 1999 (26.04.99)

(30) Priority Data:
60/083,133 27 April 1998 (27.04.98) US

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application
US 60/083,133 (CON)
Filed on 27 April 1998 (27.04.98)

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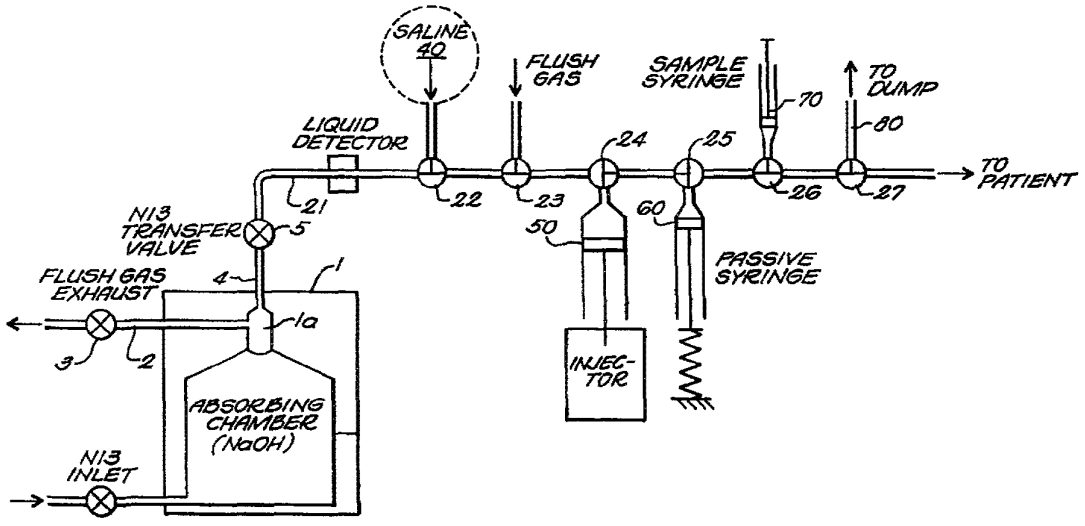
(81) Designated States: JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

**Published**
*With international search report.*

(54) Title: RADIATION HANDLING SYSTEM AND SET




(57) Abstract

A radioactive material such as an unstable isotopic gas is provided to a receiving chamber (1) directly from a source to form a purified or enriched bubble. The bubble is passed to a fluid handling set for preparation of the reagent or other delivery system. In an exemplary embodiment trace amounts of nitrogen–13 are concentrated in a receiving chamber and passed into a small bubble of carrier gas. The carrier gas is then delivered into a fluid handling set. The fluid handling set connects to a pressure syringe (50) and a passive syringe (60), and further includes a plurality of flushable valves (22–27) interconnected as a closed unit by tubing (21) to form a switchable or finite state flow network in which the pressure syringe may back flush the tubing, mix the isotope in a delivery liquid, and transfer the mixed liquid to an output for diagnostic imaging or other use.

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# RADIATION HANDLING SYSTEM AND SET

## CROSS-REFERENCE TO RELATED APPLICATIONS

Not Applicable.

## STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH

Not Applicable.

## BACKGROUND OF THE INVENTION

The present invention relates to the preparation and use of radioactive isotopes for biological purposes such as labeling, marking, imaging and diagnostics. Such applications generally utilize a single element containing minor amounts of an unstable isotope, which must be generally formed into a simple compound that is incorporated into a solution or reagent which undergoes a known or predictable interaction with the biological system being studied. Thus, for example, radionuclides are often added as labels to a substance that binds to a nucleic acid to indicate the presence of a particular substrate, termination or functional group. Similarly, materials which are taken up by particular biological systems may be labeled for treatment or imaging purposes. Aerosols or radio-labeled fluids may also be used for blood flow or lung function diagnostic imaging studies.

In general, it is necessary that radioactive materials be handled in such a way as to not expose the operator to radiation. Thus they are preferably handled under robotic control or automated conditions. It is desirable that the radioisotopes involved have a short half life, so as to automatically limit the exposure of the subject to radiation, and to facilitate proper disposal. However, materials with a short half life cannot be compounded in advance or stored for lengthy times. Such radionuclides must therefore be manufactured at or near to the site of intended use. In these cases the purification and preparation of the radionuclide in a suitable delivery system must also be accomplished locally. The brevity of the nuclide half life may further complicate its handling and processing. These factors have sometimes prevented the acceptance or use of otherwise worthwhile radionuclide-based procedures.

It would therefore be desirable to provide a convenient system for preparing radionuclides for biological use.

It would also be desirable to provide such a system for handling a radionuclide in an automated fashion without exposing the operator to radiation.

It would further be desirable to provide such a system useful for short-lived materials or small batches to enable the routine use of such materials in individual procedures.

## SUMMARY OF THE INVENTION

These and other desirable features are achieved in a system in accordance with the present invention by providing a radioactive marker material such as an unstable isotopic gas to a receiving chamber directly from a source to undergo initial cleansing or concentration, and passing the material into a fluid handling set for automated preparation of the reagent or actual delivery system. In an exemplary embodiment, trace amounts of $^{13}N$, created by proton bombardment of a target at a cyclotron, pass to a receiving chamber, are cleansed and pass into a small bubble of carrier gas. The carrier gas is then delivered into a fluid handling set. The fluid handling set includes or connects to a pressure syringe and a passive syringe, and further includes a plurality of flushable valves interconnected by tubing in a closed unit to form a flow network in which the pressure syringe may back-flush the tubing, mix the isotope in a delivery liquid, and transfer the mixed liquid to an output for diagnostic imaging or other use. The fluid handling set, which is a closed and preferably sterile unit, may include the receiving chamber 1, and it mounts in a fixed console of operating motors and condition sensors to control the various steps of fluid handling and delivery, and to effect safety functions which enable the system to connect directly to a catheter or to a vascular injection system for use on human beings.

In a preferred embodiment, the receiving chamber 1 is substantially rigid, but has a region of limited or unidirectional compliance. The chamber receives a flow of trace

isotope in a bulk gas, operating to remove the bulk gas while the radionuclide accumulates in a bubble at the outlet port of the chamber. Compliance of the receiving chamber may be effected by means of an elastic wall tensioned against a rigid support such that the wall flexes outwardly under pressure to accommodate the inflow of carrier gas but may not bow inwardly. This maintains the chamber volume above a fixed minimum, and prevents liquid from leaving the chamber when suction is applied at the top. In an illustrative system, nitrogen-13 is generated by cyclotron bombardment of a target with accelerated particles, and when the target has attained a sufficient level of radioactivity, the sample is passed to the receiving chamber and the $CO_2$ with trace $^{13}NN$ is bubbled into a sodium hydroxide solution. The one-way compliant wall allows a large flow to be received and maintained under pressure to accommodate the different rates of carrier delivery and carrier removal effected at this stage. The $CO_2$ reacts with and is effectively taken up by the sodium hydroxide solution, while the desired nuclide concentrates at a gas-filled plenum at the top of the receiving chamber, where it is accessed at the outlet port using a closed sterile set to effect transfer, mixing and delivery in a form useful for medical imaging. The fluid handling set includes a plurality of three way valves or medical infusion stopcocks that are preconnected together via small bore tubing to form a flow path. Two of the stopcocks each have a third port, which are attached to syringe bodies. One operates as an active bidirectional pump, while various motors and sensors in the console operate and control the position of the stopcock handles to achieve transfer, mixing and delivery of the radionuclide.

## BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which:

Figure 1 is a flow chart illustrating major steps of the preparation process of the present system:

Figure 1A illustrates the system showing representative components in use for positron emission tomography;

Figure 2 illustrates system architecture as applied to a nitrogen 13 radionuclide;

Figure 3 illustrates a preferred construction of a receiving chamber for the system of Figure 2;

Figures 4A through 4D illustrate details of valve operation and flow for transfer of the radionuclide into a fluid handling set of the present invention;

Figure 5 illustrates an operating console for the set of the invention;

Figures 5A-5C illustrate stopcock mounting and control blocks of the console for use with a closed sterile set; and

Figure 6 illustrates another embodiment of the system and set.

DETAILED DESCRIPTION OF THE DRAWINGS

In accordance with a principal aspect of the present invention, there is provided a system for automated and isolated handling of a hazardous material, such as a radionuclide, for biological or medical use. The system includes a sterile set defining the path of the nuclide from a source or process chamber to its end use which, in the illustrated embodiment, involves injection into a patient. Other potential end uses may include specialized labeling, microanalytic or synthesis applications. As shown in Figure 1 for a representative system, the radionuclide, which in this case is nitrogen-13, passes from a source to a conditioning or purification chamber 1 which produces a small mass or bubble of the concentrated radionuclide for delivery to the preparation portion 10 of the system. The preparation portion 10 dissolves the nuclide in

a saline solution for injection in a patient, and may directly inject the prepared solution into the patient.

By way of technical background for this embodiment, the use of nitrogen-13 in gaseous form for medical imaging procedures was pioneered at the Hammersmith Hospital, in London, several decades ago. The radionuclide is produced by bombardment in a cyclotron using a number of possible target systems and sweep gases. Further details may be found in the text Short-lived Radioactive Gases for Clinical Use of J. C. Clark and P. D. Buckingham (Butterworth, London and Boston) pp 190-200. That text is hereby incorporated herein by reference. Nitrogen-13 is only very slightly soluble in blood, and when injected in solution in the blood stream, quickly leaves the blood and accumulates at the blood-air exchange interface in the lung. Its decay creates positrons which may provide excellent three dimensional PET images of the lung, for evaluation of both perfusion and ventilation. However, the difficulties of using this radionuclide have effectively prevented its adoption in hospital settings. Much of the discussion below is applicable to other gaseous radionuclides such as oxygen-15, or radionuclides incorporated in a gaseous medium, or in a liquid with appropriate modifications. However, the preparation and use of nitrogen-13 presents a number of technical difficulties and will therefore be discussed more fully to illustrate aspects of a system and components of the present invention.

In accordance with a principal aspect of the present invention the source radionuclide is provided in a relatively crude or bulk form, for example in a sweep gas or target fluid from a cyclotron, or in other primitive or intermediate form, and flows through the system to directly enter the patient or be applied to some other sterile or purified application such as marking, analysis or synthesis of a pure product. As shown in Figure 1A it is generally contemplated that the system 20 will be a small cabinet, desktop or other stand-alone unit containing the sub-assemblies 1, 10 (Figure 1), and which attaches to the source and to the patient either directly or via a small intermediate assembly. For example, the unit 20 may connect to the source through a filtration unit or the like, and to the patient via an infusion line, port or pressurized timed injector or the

like. However, most preferably the connection to the source and to the patient are as direct as possible so that little dead space, wasted volume, delay time or regions of radiation exposure are interposed between the source and the patient.

As further shown in Figure 1A, the invention generally contemplates that the unit 20 will be controlled as to several parameters discussed below by a connection to a keyboard/processor assembly 21. Also the specific nitrogen-13 embodiment is used in conjunction with an imaging or detection assembly 25. The assembly 25 of Figure 1A is a detector array which encircles the patient and is configured for positron emission tomography, to simultaneously detect the pair of annihilation photons emitted in opposite directions by positron-electron annihilations as the radionuclide decays. The detector 25 provides its detection signals to a processor for construction of a three dimensional image of the distribution of the positron-emitting radionuclide. Other suitable detectors include single-sided detector arrays, or even photographic plate cameras which register and record the received annihilation photons on a plate of film. However, a positron emission tomography (PET) instrument is the preferred detection instrument for the illustrated process.

Figure 2 illustrates functional component of the units 1, 10 of Figure 1. As shown, the unit 1 for carrying out preliminary cleansing or refinement of the radionuclide in this case includes an absorbing chamber through which the nitrogen-13 bubbles to remove the $CO_2$ sweep or residual target gas as the material arrives from the cyclotron source. The absorbing chamber 1 is filled with sodium hydroxide solution and is shaped with an inverted funnel cap that channels unabsorbed gas upward to a plenum 1a at the top of the chamber. Plenum 1a connects on the one hand to an exhaust port 2 controlled by an exhaust valve 3 and, on the other hand, to an outlet port 4 controlled by transfer valve 5. The outlet port connects to the main process line 21 of the sub-assembly 10, which as noted above resides within the preparation console 20 (Figure 1A) forming an inlet thereof and extending therethrough to the patient or end use. As described further below, chamber 1 may also be located within the console 20.

As further shown in Figure 2, the functional flow control and handling units appearing in the preparation console 20 include in addition to the flow line 21 a plurality of sterile three-way valves or stopcocks 22,... 27 each of which has two of its three ports connected to the line 21, and its third port connected to an inlet, outlet or syringe. The distal end of line 21 forms the output path from console 20. Each of the stopcocks 22-27 may be identical, and advantageously the stopcocks together with tube 21 are connected together and initially provided as a closed and sterile unit packaged in a manner similar, for example, to a medical infusion set. Each stopcock thus has one "free" port which is connected to allow material to enter, leave, or be moved along line 21. These third ports are attached to a source of sterile saline fluid 40, an active injector syringe 50, a source of flush fluid, and a passive holding syringe 60. In addition, a sample syringe 70 connects at stopcock 26, and an outlet line 80 to a dump, or waste vessel, extends from stopcock 27. These elements may also be connected as part of the set, although, as will be understood from the discussion below, variations are possible. The function of the sample syringe may be implemented instead by providing a small plenum with a pierceable septum connected to the third port of stopcock 26, and the line 80 may simply terminate with a spike port for attaching to a suitable collection vessel or transfer mechanism.

As further illustrated in Figure 2, the passive syringe is spring loaded so that it is normally biased to a non-extended, closed or minimal volume configuration. Thus, when a pressurized flow appears along line 21 and is directed into the syringe 60 by stopcock 25, its piston moves outwardly to form an adaptive chamber that changes volume under pressure for receiving the fluid in the line 21.

In accordance with a principal aspect of the present invention, the sterile set 21 includes a set of connected stopcocks and a syringe 50 all configured to fit within the control console (described further below) and to be manipulated by servomotor elements therein to carry out the radionuclide preparation and delivery to the patient. In a representative preparation and delivery protocol, the stopcocks are set to positions such that one or more stopcocks block the inlet, outlet or intermediate portion of the set, while

one or more stopcocks are open to interconnect various portions of the path for receiving, preparing or delivering the radionuclide. In particular, the set 21 defines a finite state flow path formed of sterile single use disposable elements that fit within a console adapted to secure and control both sets of elements. Advantageously, the console 20 may be configured as a cabinet having separate compartments and which may, for example, be hinged to open for inserting and changing the set. In the prototype, the receiving chamber 1 is housed in the back half with its outlet line 4 (Figure 1A) connecting through the middle wall of the cabinet so that the fluid line 21 (Figure 2), runs through an array of stopcock or syringe receiving recesses and control elements laid out along a path in the front half of the cabinet.

In this embodiment, the apparatus is conveniently divided into those parts that do not contact the sterile solution, and those parts which do. The parts which contact the saline directly are sterile, and are assembled from disposable medical components. These include all of the tubing downstream of the liquid detector, the stopcocks, and the three syringes 50, 60, 70 which are disposable, and are to be replaced for each patient. These components are mounted on the front panel of the main unit, so that they can be changed quickly. The remaining parts of the system do not contact the saline, and may advantageously be made of reusable components. Thus the absorbing chamber 1, and the various solenoid valves and tubing that connect to it may be permanently installed. Preferably, the system is enclosed in a cabinet which is connected to a high flow-rate vacuum to maintain a steady flow into the cabinet through its small openings, so that any leaks of radioactivity within the system are contained and the radioactive material is removed.

The cabinet is divided into three compartments. The rear compartment, accessible via a rear door, contains the absorbing chamber and a dump tank. This compartment is watertight so that a catastrophic failure of the absorbing chamber will not result in escape of sodium hydroxide. A central compartment houses all of the electronics of the apparatus, and is protected from contact with any liquid that may leak from a failing component or connection. The front of the cabinet forms a door which

encloses the front panel, allowing easy access to components of the system that need to be changed frequently. Preferably the syringes mount on this panel.

Figure 3 shows a preferred construction for the receiving chamber 1, which may be formed of a strong medical grade polymer. As shown, the receiving vessel 1 is configured with a rigid housing 101 which may for example be formed of a hard plastic and having an interior with a major lower portion configured with a sloped roof leading to a chimney-like upper portion or outlet plenum 109 of defined volume. The vessel 101 is configured to fit on a magnetic base such as a stand having an internally mounted rotating permanent magnet driver mechanism positioned below the chamber support surface, and a magnetic stirring rod 107 is positioned in the bottom of the vessel 1. The main chamber communicates through a passage 102 to a secondary chamber 101a bounded by a flexible elastic membrane or wall 104 positioned over the passage 102. This serves as a compliant chamber; the membrane 104 bends outwardly as pressure increases in the chamber 1 and fluid flows through the passage into the secondary chamber. However, housing 101 is rigid and the passage 102 is relatively small, or else may consist of a number of small passages such that the wall below the flexible sheet 104 forms a perforated plate that supports the sheet and effectively prevents the sheet 104 from moving inwardly in response to negative pressure. This arrangement provides a stable volume within chamber 1, and accommodates a large influx of fluid so that when radioactive material from the cyclotron enters the inlet, a large bolus of material may be received, increasing the pressure and allowing the material to more effectively react in the absorbing chamber at the slower process rate of absorption therein. As discussed briefly above for the illustrated $CO_2$/nitrogen-13 material, chamber 1 is filled with a sodium hydroxide solution and is gently stirred by a magnetic stirring rod, so the solution quickly reacts with and effectively removes all the $CO_2$ while the unreactive nitrogen tracer rises into the outlet plenum 109 at the top of the chamber.

Preferably, for this process, the plenum 109 is initially loaded with a small volume, e.g. a few cubic centimeters, of a carrier gas in which the nitrogen-13 is soluble. This carrier may, for example, be nitrous oxide or other suitable biocompatible

gas. It is also advantageous that the carrier be highly soluble in blood or aqueous solutions, so that as discussed further below, problems of bubble formation or potential danger of bends are avoided. Thus, operation of the receiving chamber 1 is such that the sweep gas or target predecessor material from the source is removed, and the cleansed or concentrated radionuclide resides in the plenum 109 with a carrier gas for transfer through the transfer valve to the flow path 21. The architecture of vessel 1 therefore retains the pocket of gas at the top of the chamber intact. In this way, no liquid infiltrates the tubing leading to the rest of the apparatus, where small droplets of liquid might cause false triggering of the liquid detector or blocking of the hydrophobic filter.

An important aspect of the design of the compliant compartment is that it is only compliant to positive volumes. That is, volume can be added to the chamber, but not withdrawn. Once the carbon dioxide is absorbed, and the bubble of nitrogen withdrawn, the membrane wall lies flat against the side wall of the chamber, and the chamber becomes rigid. Thus it is impossible to suck significant volumes of sodium hydroxide out of the absorbing chamber and into the rest of the system.

Skipping ahead to Figure 5, there is shown a representative front panel of the console assembly 20 with the radionuclide entry port and elements of the flow path 21 laid out thereon. As shown, the flow line 21 first passes through a liquid detector which detects the arrival of liquid in the flow line from the chamber 1 and provides a control signal used, as described further below, for switching the states of the various stopcocks and transporting the bubble of radionuclide through the processing stages of the preparation assembly 10.

As further shown in Figure 5 a hydrophobic filter 29b is placed in the flow line 21 as a barrier to entry of liquid from chamber 1 into the system 10. As shown, the fluid preparation line 21 or set, is positioned in the console 20 such that each of the stopcocks 22-27 fits within a corresponding receiving block 22a through 27a, and the injection syringe 50 and passive syringe 60 fit within a driver mounting 50a and a syringe support 60a, respectively. By way of example, the driver assembly for the injector syringe may be that of, or similar to, a manual or programmed contrast agent injector system capable

of operation to drive a standard disposable syringe at high pressures through one or more precisely timed and controlled displacements to inject preset doses or volumes into the vascular system of a patient. The mounting 60a for the passive syringe may include a spring-loaded or counter-weighted platform or pushing member against which the distal end of the plunger of the injection syringe rides, so that the biased member returns the piston to its upper position (as shown) when the state of the stopcocks allows flow and the pressure in line 21 drops below the spring bias threshold.

In the prototype embodiment, the injector drive consisted of a MedRad radiographic contrast injection instrument, and the remainder of the cabinet and control mechanism of unit 20 was built atop the injector mount so that the active syringe was conveniently located in immediate proximity to the other elements shown in Figure 2. The stopcock mounting assemblies were prepared as shown in Figures 5A through 5C, by constructing shaped plastic receiving blocks having recesses each shaped to accept a standard disposable stopcock assembly therein and to mount on a plate so that each stopcock engages a position reporting actuator mechanism, which turns the handle of the stopcock. The stopcock was placed into the housing with the handle facing forward and the housing was designed to grip the three fluid connecting stubs of the stopcock, thus securely holding the stopcock body in a fixed position that allowed stopcock position to be controlled to within about one degree. A molded coupling was used to connect the stopcock handle to a standard servomotor, which in turn was controlled by a microcontroller board connected via a serial line to a computer used to control the apparatus. The computer was programmed to control operation of the stopcocks to define different segments for receiving, transferring, mixing and delivering the material. It was also programmed to control the injection regimen of the syringe for delivery of prepared doses to the patient.

In the prototype embodiment, the servomotor assemblies were modified so that the output of an internal potentiometer was passed to an A/D converter on the microcontroller board, and this output was used to calibrate the stopcock positions and then continuously monitor the position of each stopcock. Control software in the

microprocessor with a graphical user interface allowed the user to set the position of the stopcock and displayed the position on the screen, signaling an alarm if a motor fails to drive a stopcock element to the programmed position. For preparing the nitrogen-13 tracer, the program was written to effect a sequence of control steps as described below, and delivery steps were controlled by using the injector both to control the preparation of the solution and the injection into the patient.

Figure 4 illustrates a particular sequence for transfer of the tracer bubble from the absorbing chamber 1 into the mixing syringe, which is performed by encapsulating the tracer bubble with a saline solution. In broad terms, the operating sequence proceeded as follows. Before gas is received from the cyclotron the system is readied for production. The tubing from the absorbing chamber is flushed with a gas and the remainder of the apparatus is flushed and filled with de-gassed saline solution. One suitable flush gas is nitrous oxide but many other gases may be used. The chief requirements are that the gas be biologically safe, soluble in water and be non-reactive with the reagents used (sodium hydroxide, in this case). The radioactive gas is then admitted to the absorbing chamber and is stirred with a magnetic stirrer until all carbon dioxide is absorbed. Stirring is performed gently to avoid generation of droplets which might clog the hydrophobic filter 29b (Figure 5). The bubble of remaining gas at the top of the absorbing chamber is then transferred to the injector syringe which is otherwise filled with an appropriate amount of de-gassed saline for the contemplated infusion regiment or for the amount or available radionuclide. The mixture in the injector is next dissolved by repeatedly ejecting it into the passive syringe allowing its return and again ejecting it, so that by the vigorous flow and atomizing action of ejection the tracer is quickly dissolved in the saline solution. This process of vigorous atomization mixing by repeated passage through a flow segment between syringes in a closed set thus effectively addresses the difficult problem of preparing the radionuclide solution in a manner that is both safe and quick.

Next, with the stopcocks reset to define a different flow segment, a sample of the injectate so prepared is expelled from the syringe into the sampling syringe 80. Preferably a pH sensor is also present in the apparatus downstream of the injector

syringe to detect any sodium hydroxide contamination which may have occurred, and to actuate a shutdown in that event. The strength of the prepared solution is determined and this data is entered in suitable program for the injection control or image processing. The stopcock configurations are again changed, and the injector then gives a rapid bolus of tracer solution along its output line into the patient.

Returning now to Figure 4, there is shown a representative sequence of states of the finite state flow segment operating sequence of the device, illustrating in this case the initial radionuclide transfer from the receiving chamber 1 into the preparation set 10. After the initial system preparation and cleansing in chamber 1 are completed, the state of the apparatus is as depicted in Figure 4A. The upstream tubing (on the left) of stopcock 22 is filled with flush gas and the downstream tubing (to the right) is filled with degassed saline. The syringe 50 is then operated to draw along line 21 so that, as shown in Figure 4B the bubble of radioactive gas is drawn out of the pocket 109 (Figure 3), and toward the injector syringe 50. Sodium hydroxide solution is also drawn out of the absorbing chamber 1 at the trailing edge of the bubble of carrier/tracer gas. A liquid detector 29a is installed in the assembly 10 about the line 21 just upstream of the first stopcock 22 to provide a signal when the sodium hydroxide reaches this point. The transfer valve (Figure 3) is then closed, and the controller moves the first stopcock (Figure 4C) to connect the saline reservoir and fill in behind the bubble with saline solution from the reservoir. The bubble of tracer is thus "encapsulated" by saline solution as shown in Figure 4D. This allows controlled transfer through the apparatus by operation of the injector syringe. A slight amount of tracer gas still residing in the first stopcock and liquid detector is wasted. However, it will be understood that all tubing interconnecting the various components in the processing section 10 is of small size (under one millimeter), of the type customarily used for transfer of small volumes of fluid, and thus the wasted tracer represents a very small proportion of the carrier/tracer bubble being processed.

After the bubble of gas is completely drawn into the injector syringe, the stopcocks are moved to define a new flow/transfer segment such that the injector outlet

communicates only with the adjacent passive syringe. The mixture is then vigorously expelled into the passive syringe, then again drawn back into the active syringe and re-expelled. This process of repeated ejection promotes dissolution of the gas in several ways. Firstly, the surface area of the interface is increased exponentially by atomizing the fluid and in subsequent ejections breaking bubbles of gas into many smaller bubbles. Secondly, the ejection occurs at elevated pressure, thus enhancing the mechanisms of diffusion. Finally, the strong current and highly turbulent flow during ejection mixes the liquid very well, reducing any concentration gradients that might otherwise limit the process.

After the mixing process is complete, the stopcocks are again repositioned and the syringe 50 is operated to expel to the dump a volume equal to the volume of gas originally drawn into the syringe. This assures that any undissolved gas is ejected from the system. The lines to the patient are then flushed with the prepared tracer solution, and a small (1 ml) sample is taken. For the illustrated system, the sample is used primarily to assess the activity of the solution, but it could be additionally analyzed to check the composition of the injectate, or when applied to other radionuclide systems could determine other relevant conditions or parameters.

The pH of the solution is preferably measured by a sensor installed on the line to the dump tank. Any sodium hydroxide contamination is detected at this point, before injection to a patient.

In the foregoing system, it is important that the solution injected into the patient not be super-saturated and not contain any gas bubbles. If the solution were super-saturated, there would be a risk that bubbles could spontaneously appear in the solution before infusion or that microbubbles of nitrogen would form in the bloodstream causing an artificially-induced form of decompression sickness ('the bends'). To assure that supersaturation does not occur, the volume of nitrogen withdrawn from the absorbing chamber is limited to that volume which is known to dissolve in the volume of saline being prepared, and following dissolution, the mixture is allowed to equilibrate at atmospheric pressure. Thus, even if the solution is super-saturated, excess gas will

diffuse out of the solution. Further, when, following the mixing described above, the volume at least as great as the volume of gas originally drawn in from the absorbing chamber is ejected from the top of the injector syringe to dump, both the excess undissolved gas and the gas that has come out of solution are expelled.

Preferably, an ultrasonic bubble detector is also installed on the line to the patient, as well as a bubble-trap filter. Prior to injection, the lines are flushed, and a final, visual check for microbubbles is performed.

Figure 6 illustrates another embodiment of the system and set of the present invention. In this embodiment, the compliance chamber or flexible-walled side chamber may be actively pressed. This may be done to assure complete return of the flexible wall, and thus further guard against expulsion of the sodium hydroxide solution. Furthermore, the stopcocks are located somewhat differently to provide a short direct infusion path to the patient, and to separate or shift other paths or path segments. As in the first embodiment, the pressure syringe is centrally located, and serves as a hub for drawing, expelling or moving fluid along the various segment defined by the states of the stopcock valves. Advantageously, the pressure syringe mounts vertically, so that it initially receives and segregates the gas, and subsequently expels residual bubbles to the dump.

For operation of the system, the saline may be drawn from a USP-standard infusion bag, and all parts of the apparatus that contact the solution are assembled using aseptic technique from sterile, disposable medical components. Microporous filters are installed on the line entering the system from the saline bag, and on the line out of the system to the patient. Preferably a batch of tracer solution is prepared before the batch intended for infusion, and a sample is assayed.

Preferably, the bolus infusion of tracer is given by the injector under computer control, with the computer programmed to accurately control the infusate volume and rate, to effectively synchronize with a PET camera, and to automatically adjust dosage as the tracer decays. However, preferably the hardware is designed so that if necessary, the injector can be disconnected and operated manually. In the prototype embodiment using

an existing, manually-operated contrast media injector, the addition of a microprocessor-based controller and other modifications made to the injector were such that all of its safety-features function normally, and when manually-operated, the injector was fundamentally the same device as an unmodified, FDA-approved original. The series architecture of the treatment vessel and mixing assembly, together with the unique bubble transfer mechanism and multiple redundant stops and operation safety checks thus forms a system that is safely interposed between a cyclotron target and the patient's vasculature. Repetitive ejection between syringes produces a highly effective mixing/solution mechanism using fungible disposables. Moreover, the provision of a closed, disposable set for handling and compounding the radionuclide in an automated negative pressure safety cabinet allows the operator to maintain a safe distance from radiation, and provides a convenient system for the remote handling and preparation of diverse medicines, reagents and tracer materials.

The invention has been described above in a particular application for receiving, preparing and injecting a gaseous radionuclide for pulmonary PET imaging. However, the unique remote handling, sterile mixing, and volumetric control achieved by the set and the operating console are applicable with slight changes to compounding and delivering medications, marking and synthesizing materials and other radiation-handling tasks. Thus, it should be understood that the invention is not to be limited by the particular embodiments shown and discussed above, but may take other forms and be embodied in diverse systems for preparing, reacting, formulating or delivering radionuclides or biologically active materials. The invention and its principals of operation being thus disclosed, one skilled in the art will appreciate further features and advantages of the invention, and will be lead to further variations and modifications of the invention. Accordingly, all such variations and modifications are considered to be within the spirit and scope of applicant's invention as defined by claims appended hereto and equivalents thereof. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

## Claims

1. A system for preparation and delivery of a biologically active, hazardous or radioactive fluid, the system comprising

a receiving system having a first port for receiving said fluid and a second port positioned for delivering said fluid

a fluid handling set including a syringe and a plurality of flushable valves interconnected as a closed unit by tubing extending to an outlet

the syringe connecting via said fluid handling set to said second port and to said outlet for drawing the fluid into the tubing and transferring said fluid to the outlet as a prepared liquid

and the fluid handling set being configured for operation of said valves to define a finite set of flow segments at different times in said set such that the syringe flushes, fills, prepares and delivers the prepared fluid without exposing the operator to radiation.

2. A system for preparation and delivery of a biologically active, hazardous or radioactive material such as a gas, the system comprising

a receiving chamber having a first port for receiving said fluid and a second port positioned for accessing an active gas present in said material

an operating assembly for mounting a fluid handling set including a pressure syringe, a passive syringe and a plurality of flushable valves interconnected as a closed unit by tubing such that the tubing connects to said second port, and the operating assembly being configured to secure and operate the pressure syringe and the plurality of valves in sequence such that the pressure syringe draws the material into the pressure syringe and transfers the material with liquid to said passive syringe so as to form a prepared liquid, and furtheroperating said valves to define a finite set of flow segments at different times in said set for flushing, filling, preparing and delivering the prepared liquid, to receive the material from a source and provide the prepared liquid to a patient.

3. A system for preparation and delivery of a biologically active, hazardous or radioactive material, the system comprising

a receiving chamber having a first port for receiving said material and a second port positioned for accumulating a desired portion of the material

a fluid handling set including a plurality of flushable valves interconnected as a closed unit by tubing and configured for automated remote operation of said valves to form a finite state flow path effective to receive and encapsulate said desired portion as a bubble, prepare said portion in a delivery liquid and transfer the delivery liquid to an output.

4. The system of claim 3, wherein said valves define flow segments at different times in said set for flushing, filling, preparing and delivering the material such that the set receives the material as a gas from a source and safely delivers the delivery liquid to the bloodstream of a patient.

5. The system of claim 4, wherein the fluid handling set includes a pressure syringe operable for drawing the material into the set, mixing the delivery liquid, and delivering the delivery liquid into the bloodstream of a patient.

6. The system of claim 3 or 4, wherein the system prepares a gaseous radionuclide for injection to perform positron emission tomographic images of the patient.

7. The system of claim 3, wherein the fluid handling set is sterile assembly and further comprises and active syringe connected to one of said valves, and a passive syringe connected to another of said valves for receiving liquid such that the set is operable to prepare said portion in said delivery liquid by ejecting said portion and delivery liquid from the active syringe into the passive syringe.

8. A system for sterile preparation of a fluid radionuclide for use, such system comprising a sterile flow set including an inlet, an outlet, a plurality of stopcocks arranged in a sequence along a flow line to define a plurality of fluid transport segments, and first

and second syringes connected to the flow line being operable to form a sterile liquid solution of said radionuclide while it remains in the flow set by repeated ejection from said first syringe to said second syringe and return to said first syringe.

9. A system according to claim 8, wherein the sterile flow set includes at least five stopcocks.

10. A system according to claim 8, wherein at least one of said syringes attaches directly to a port of one of the stopcocks.

11. A fluid handling set for use in receiving a hazardous fluid material and forming a delivery liquid, such set comprising a plurality of at least five stopcocks and tubing interconnecting said plurality of stopcocks to form a closed transport path for handling the hazardous fluid material, each stopcock further having a port for admitting material to or expelling material from said closed transport path.

12. A device for receiving a hazardous fluid material and forming a delivery liquid such as a reagent, medicine or imaging agent containing said fluid material, such device comprising

a plurality of stopcock receptacles arranged along a path,

a corresponding plurality of servomotors positioned and configured for individually controlling a stopcock each being positioned in one of the receptacles,

a syringe driver, and

a controller operative to control said servomotors to form a set of flow segments along a closed transport path for handling the hazardous fluid material, and to control said syringe driver to drive a syringe so that the syringe draws said fluid material into the transport path and moves the fluid material along ones of said flow segments so as to prepare and deliver the delivery fluid.

13. The device of claim 12, further comprising a flow set including a plurality of stopcocks interconnected by tubing to form a sterile flow path, an active syringe connected to said flow path, and a passive syringe connected to said flow path.

14. The device of claim 13, wherein the controller is operative to control said servomotors to define a path between the active syringe and the passive syringe, and to prepare the fluid material by repeated ejection of the material from the active syringe to the passive syringe.

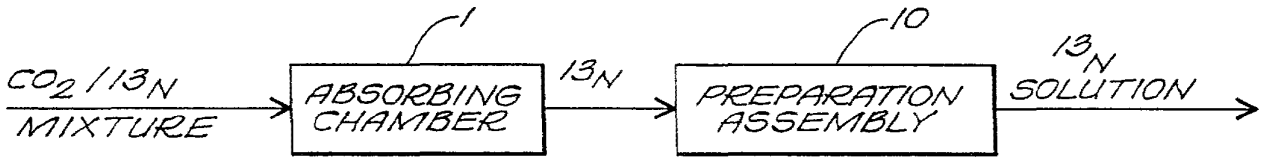
$CO_2$ / $^{13}N$
MIXTURE
1
ABSORBING CHAMBER
$^{13}N$
10
PREPARATION ASSEMBLY
$^{13}N$
SOLUTION

FIG. 1

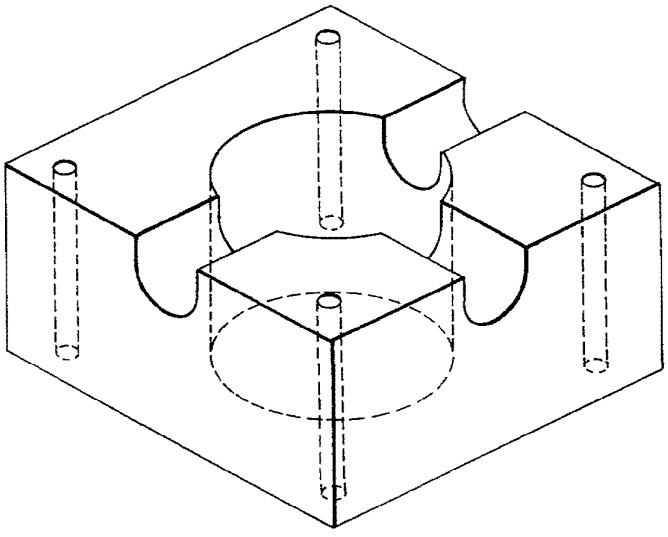

FIG. 5A

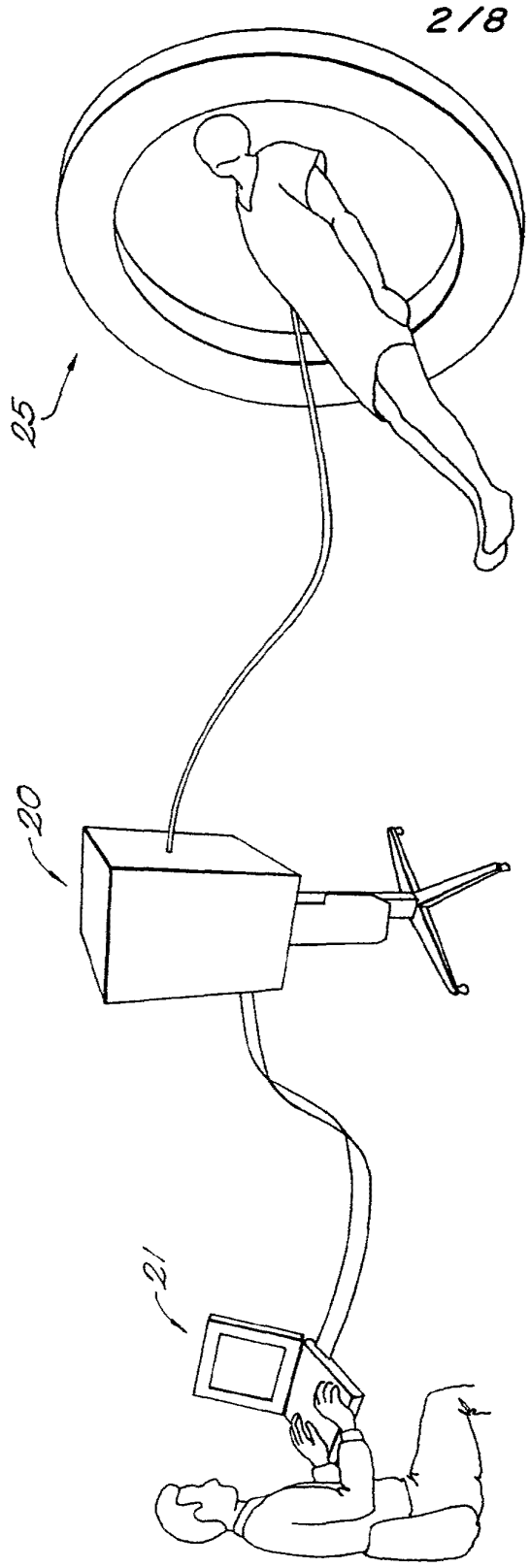


FIG. 1A

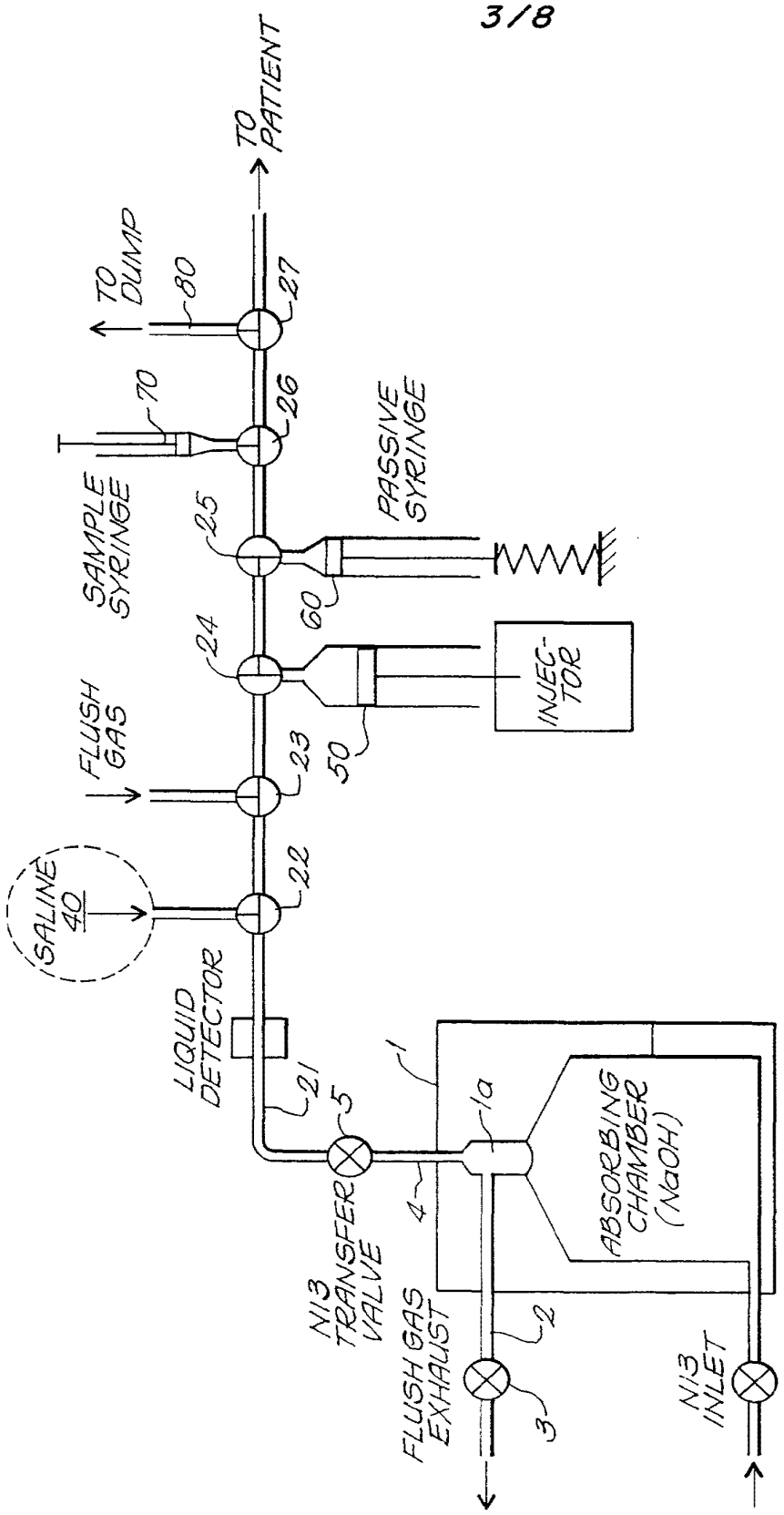
TO PATIENT
TO DUMP
80
27
70
26
SAMPLE SYRINGE
PASSIVE SYRINGE
25
60
24
INJEC-TOR
FLUSH GAS
23
50
SALINE 40
22
LIQUID DETECTOR
21
5
1
1a
ABSORBING CHAMBER (NaOH)
4
N13 TRANSFER VALVE
2
FLUSH GAS EXHAUST
3
N13 INLET

FIG. 2

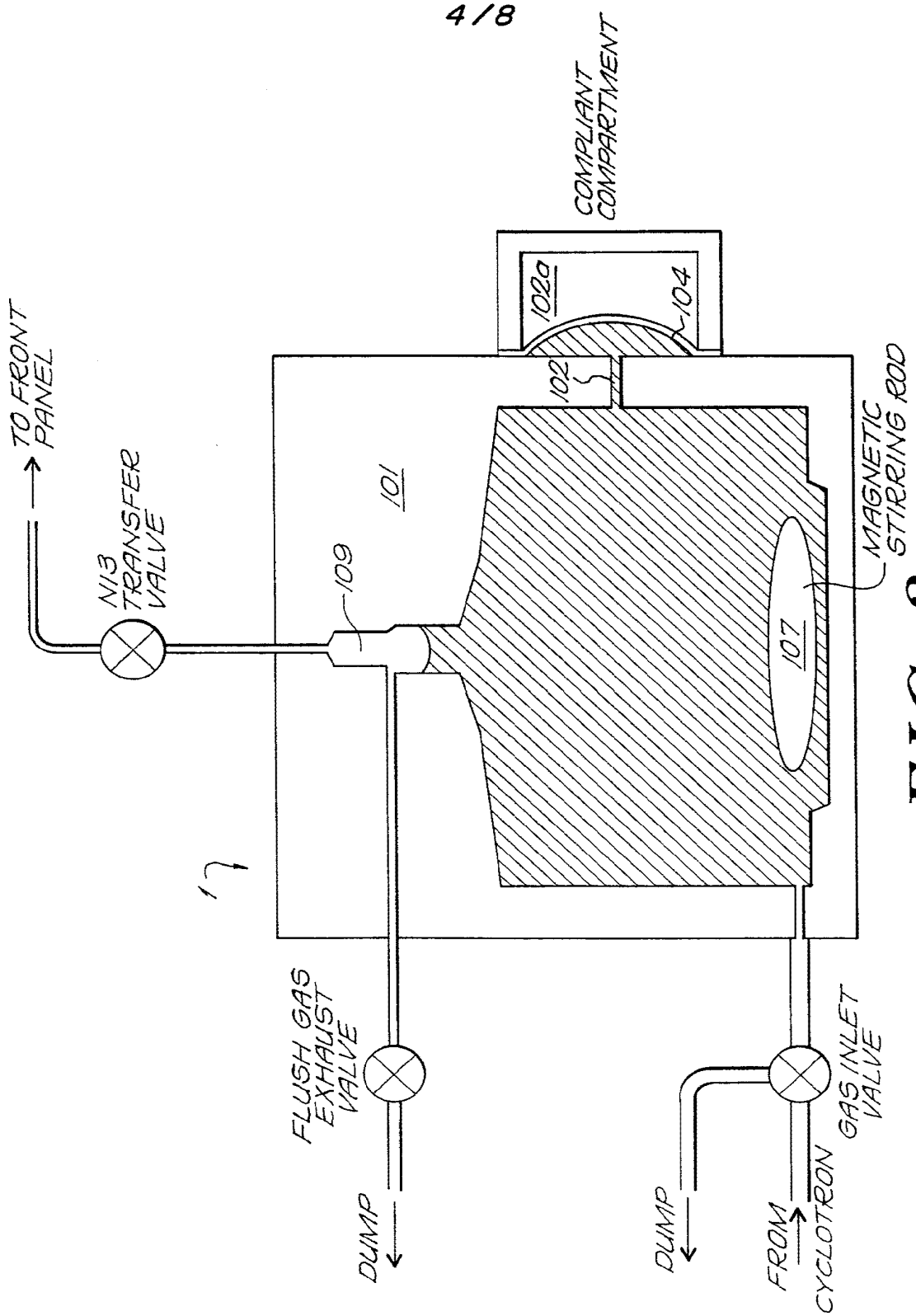
COMPLIANT COMPARTMENT
102a
104
102
TO FRONT PANEL
N13 TRANSFER VALVE
101
109
MAGNETIC STIRRING ROD
107
17
FLUSH GAS EXHAUST VALVE
DUMP
DUMP
FROM CYCLOTRON
GAS INLET VALVE

FIG. 3

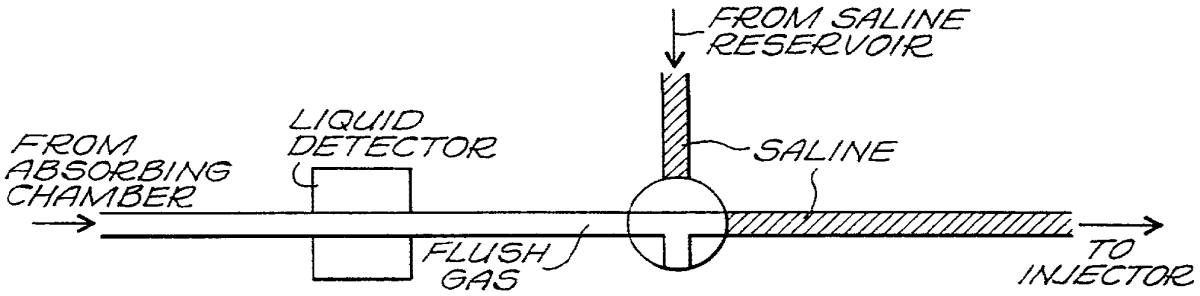


FIG. 4A

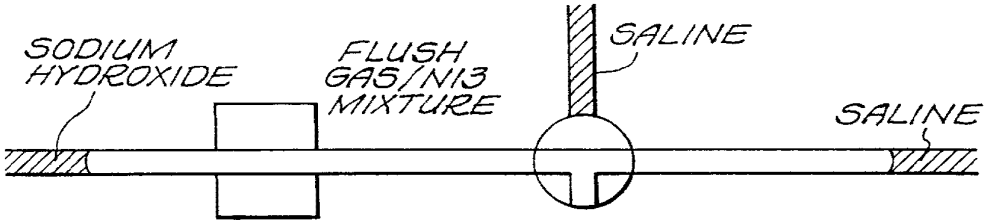


FIG. 4B

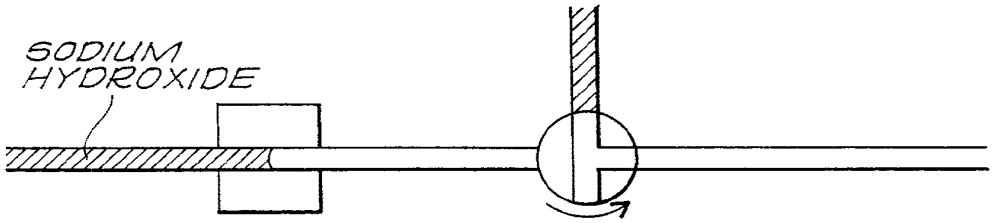


FIG. 4C

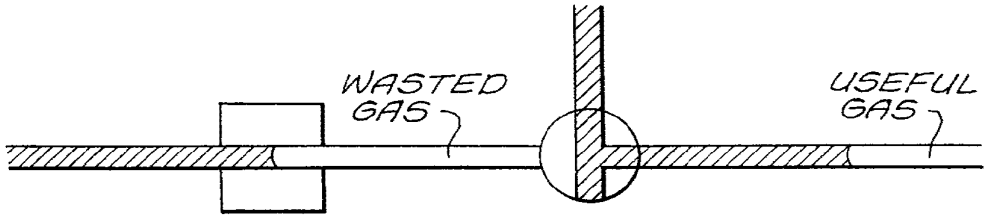


FIG. 4D

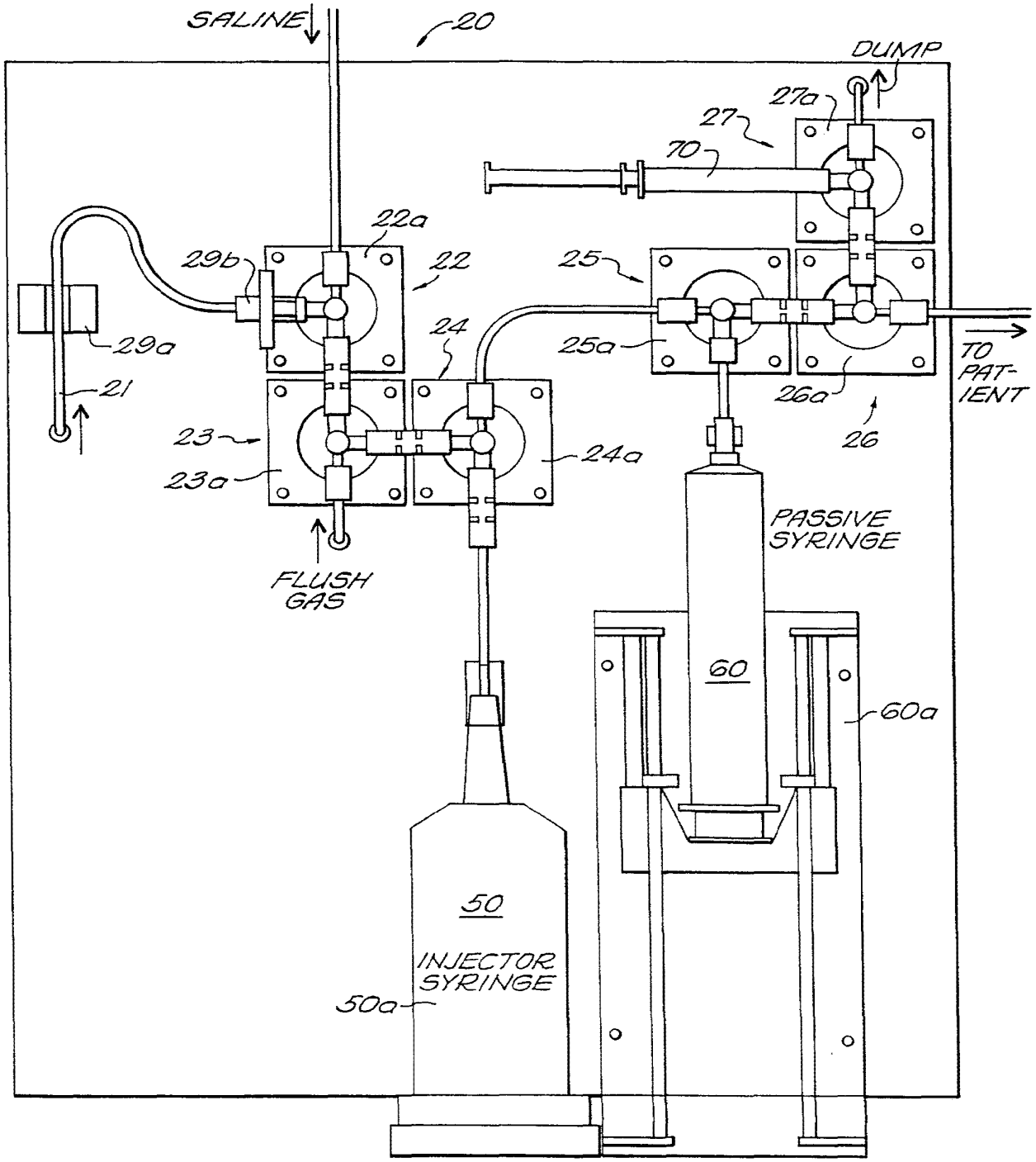
SALINE
20
DUMP
27a
27
70
22a
29b
22
25
29a
24
25a
TO PAT-IENT
21
26a
26
23
24a
23a
PASSIVE SYRINGE
FLUSH GAS
60
60a
50
INJECTOR SYRINGE
50a

FIG. 5

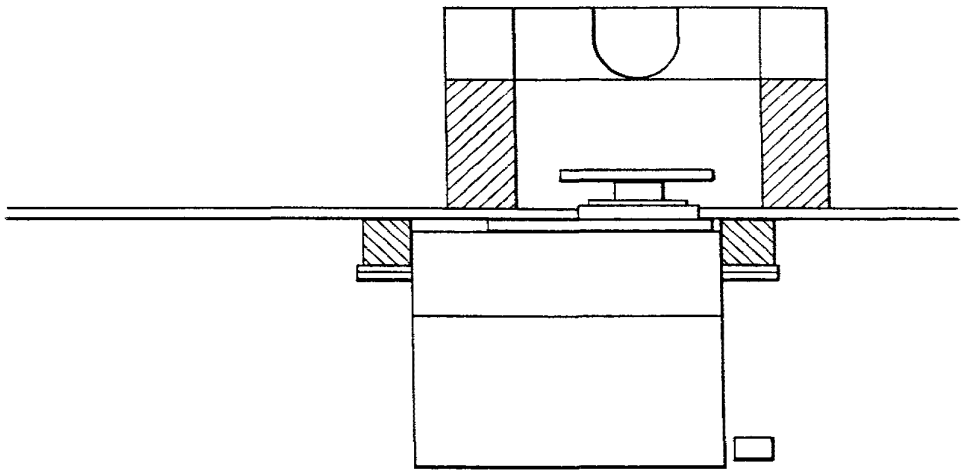

FIG. 5B

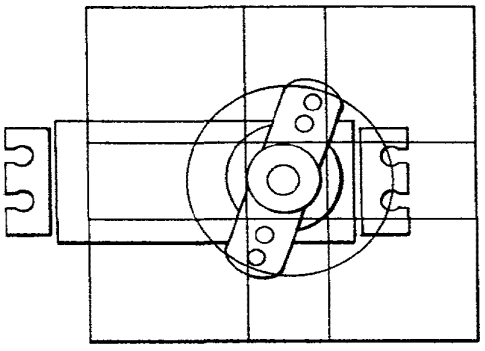

FIG. 5C

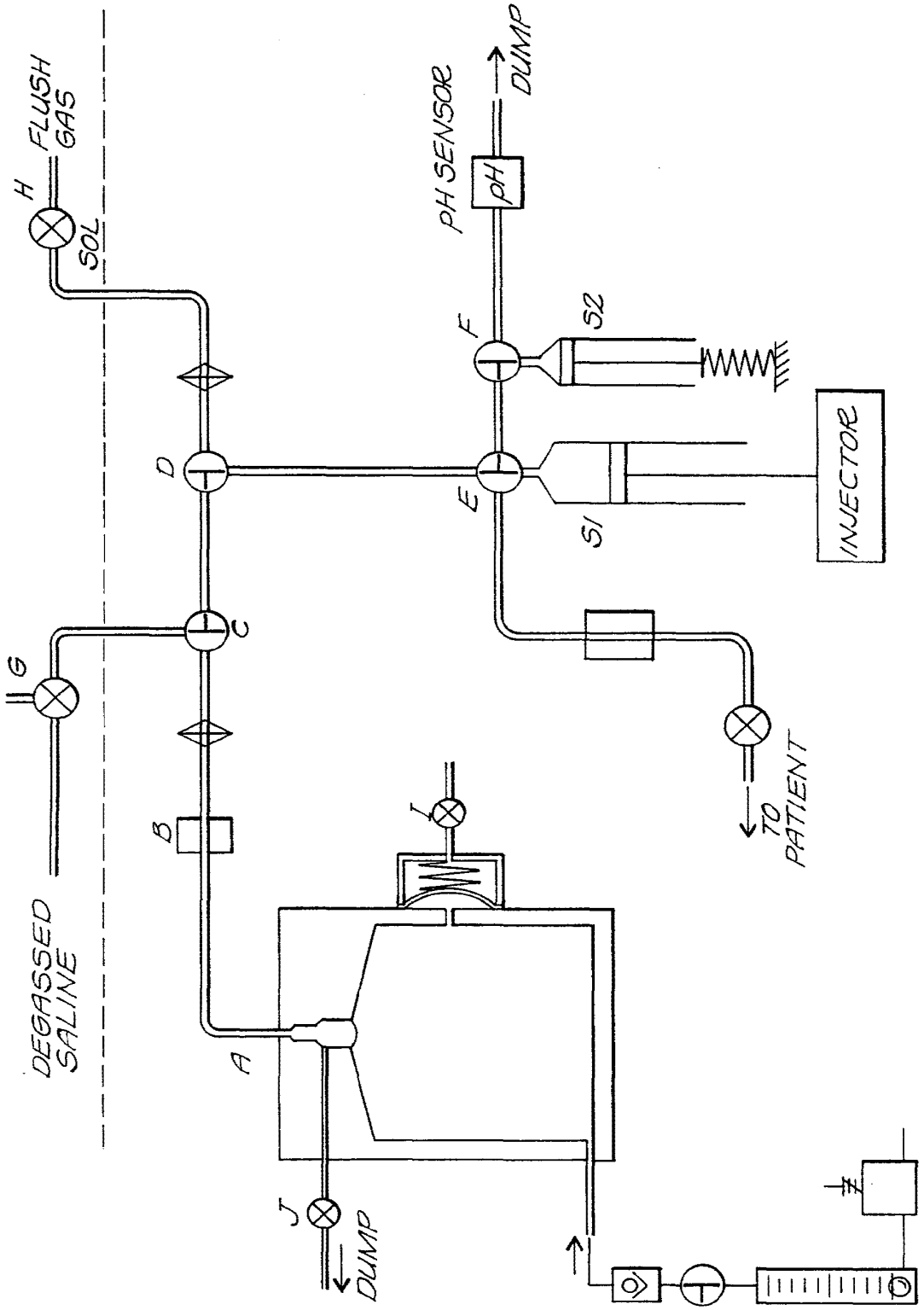
H
FLUSH GAS
SOL
PH SENSOR
pH
DUMP
F
S2
D
E
S1
INJECTOR
C
G
B
I
TO PATIENT
DEGASSED SALINE
A
J
DUMP

FIG. 6

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/08981

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :G01N 24/00, 37/00
US CL :436/57, 174, 180; 422/81, 100, 903

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 436/57, 174, 180; 422/81, 100, 903

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | US 5,482,865 A (FERRIERI et al) 09 January 1996, entire document. | 1-14 |
| A | US 5,514,071 A (SIELAFF, JR. et al) 07 May 1996, entire document. | 1-14 |
| A | US 5,468,355 A (SHEFER et al) 21 November 1995, entire document. | 1-14 |
| A | US 5,223,434 A (KANNO et al) 29 June 1993, entire document. | 1-14 |

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

| | | | |
|---|---|---|---|
| * | Special categories of cited documents: | "T" | later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention |
| "A" | document defining the general state of the art which is not considered to be of particular relevance | "X" | document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone |
| "E" | earlier document published on or after the international filing date | "Y" | document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art |
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Date of the actual completion of the international search
19 JULY 1999

Date of mailing of the international search report
19 AUG 1999

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
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Washington, D.C. 20231
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Form PCT/ISA/210 (second sheet)(July 1992)★

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 January 2005 (13.01.2005)

PCT

(10) International Publication Number
WO 2005/002971 A1

(51) International Patent Classification[7]: B65B 3/30

(21) International Application Number: PCT/AU2004/000897

(22) International Filing Date: 2 July 2004 (02.07.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2003903404 2 July 2003 (02.07.2003) AU

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

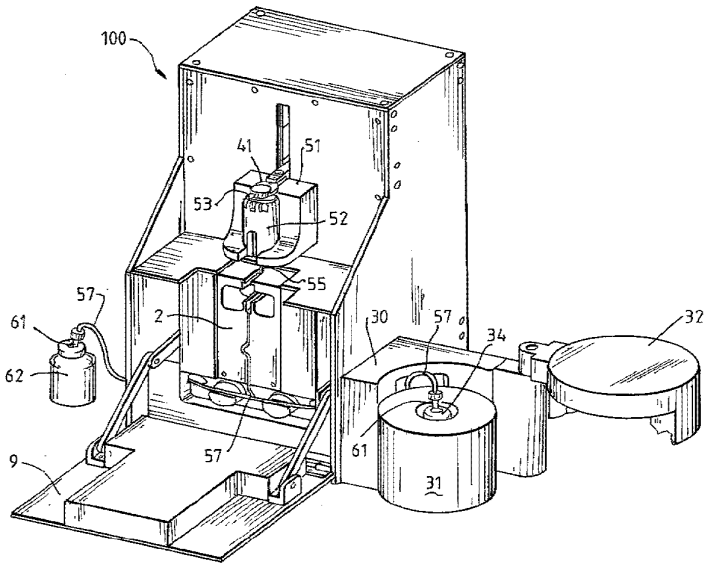
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Declarations under Rule 4.17:**

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS,*

*[Continued on next page]*

(54) Title: PROCESS AND DEVICE FOR THE DOSE DISPENSING OF A RADIOACTIVE SOLUTION




(57) Abstract: A method of and a device (100) for automatically dispensing radioactive doses by filling a container (53), being a vial or disposable syringe, with a required radioactive dose in a sterile environment, the device (100) being stand alone and radiation shielded. The device (100) further includes control means to accurately dispense and dilute the requested radioactive dose using an on-line radioactivity measurement without any need for knowledge of the volumetric radioactivity of the stock solution.

WO 2005/002971 A1

*JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)*

— *of inventorship (Rule 4.17(iv)) for US only*

**Published:**

— *with international search report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# PROCESS AND DEVICE FOR THE DOSE DISPENSING OF A RADIOACTIVE SOLUTION

## Area Of The Invention

This invention relates to apparatus used in nuclear medicine and in particular to a means whereby a radioactive dose required can be provided to a syringe in an automated fashion which obviates the need for a person to actually handle the radioactive material.

## Background To The Invention

Radioactive solutions called radiotracers or radiopharmaceuticals, have found applications in various medical fields, in particular in medical diagnostic and therapeutic fields. In recent years the advance of Positron Emission Tomography (PET), which use radionuclides (radioisotopes) of significant higher radiation energy than more conventional nuclear medicine isotopes, has raised some concerns about hand and body radiation exposure received by the persons preparing the dose.

The dangers of ionising radiation are well known and apply to all persons being exposed to radiation, including the staff involved in the preparation of radioactive solutions. Dose fractionation of the radioactive solutions is usually a manual process, performed behind a lead shielded screen to minimal exposure to radiation. However, the performance of this task is time consuming, as the operator needs to withdraw

by successive iterations, small volumes of the radiotracer, until he reaches the targeted dose.

After each withdrawal the needle needs to be re-capped and the syringe placed in a dose calibrator to determine if more or less of the radioactive solution should be processed in or out of the syringe. When the targeted dose has been achieved (within ± 10%), the syringe may be topped up with saline to obtain a reasonable volume.

Before being released or dispatched for clinical use, the syringe is placed again in the dose calibrator to print out the accurate dose record. To date, very little attempt has been made by manufacturers to design automated equipment capable of withdrawing a dedicated radioactive dose into a disposable sterile syringe or vial.

The very few systems currently on the market are expensive and bulky and are not widely available. Other more affordable systems are either not technically practical or do not achieve efficient radiation protection and need to be operated in a shielded environment. In addition, most of these apparatus rely on the pre-requisite knowledge of the volumetric radioactivity (Ci/mL or Bq/mL) of the stock solution to determine the corresponding volume and hence the radioactive dose to be dispensed.

**Outline of The Invention**

It is an object of this invention to provide an accurate means of automatically dispensing individual doses of a radioactive solution into vials or syringes under

aseptically controlled conditions while minimising the exposure to radiation of an operator which would otherwise be associated with the manipulation of radioactive solutions.

The invention in one aspect is a radioactive dose dispensing device for automatically filling a container with a required radioactive dose in a sterile environment, said device being stand alone and radiation shielded and including control means to control a mix of radioactive stock solution and dilution stock solution, the radioactivity of which mix is monitored by radiation detection means.

The invention in a second aspect is a method of automatically dispensing a dose of a radioactive solution using a software controlled lead shielded device which includes the steps of

- providing the device with a radioactive stock solution and a dilution stock solution
- using a computer software interface to the device to control the dose dispensed automatically into a syringe or vial in the device.

It is preferred that the radioactive dose dispensing device be used for filling a disposable syringe. It is further preferred that a shielded receptacle be provided to receive the syringe.

It is also preferred that a fork shaped arm be provided to actuate the plunger of the disposable shielded syringe. It is further preferred that a high precision linear drive mechanism to move either the syringe or its plunger in a vertical direction.

It is preferred that a customised disposable T shaped tubing assembly be used to provide a sterile fluid pathway. It is further preferred that pinch valves be provided to switch between the radioactive stock solution and the dilution stock solution.

It is also preferred that the automation of the device be controlled by a programmable logic controller (PLC) in association with a radiation detector which monitors on-line the radioactive dose passing through the tubing and being dispensed into the syringe.

It is further preferred that the PLC controls the automation tasks and relevant mathematical calculations for dispensing a requisite dose and that this be operable by computer means with an associated printer although any desired arrangement could be used.

In order that the invention may be more readily understood an embodiment of it will be described herein by way of non limiting example with reference to the accompanying drawings

**Brief Description Of The Drawing Figures**

Fig. 1 Shows a perspective view of the components of the radioactive dose dispensing device of the invention in its "open" orientation;

Fig. 2 Shows a cross-section though the device of the invention as shown in Figure 1.;

Fig. 3 Shows the pre assembled sterile disposable tubing kit used in the device;

Fig. 4 Shows the device of the invention in its "closed" orientation;

**Brief Description of an Embodiment of the Invention**

The invention 100 in one embodiment is a device for the automatic filling of disposable syringes with a radioactive solution (radiopharmaceutical) for injection or infusion into a patient.

The device 100 is a stand alone equipment that does not require any additional lead shielding and can be directly used on a bench or inside a conventional, unshielded, laminar flow cabinet.

The device includes a concave lead block 30 and a swinging lead lid 32 designed to accommodate standard lead shielded pots 31 commonly used for the transport of radioactive solutions. It also includes a receptacle 51 that can accommodate various shapes of commercially available tungsten syringe shields and provides an easy and safe installation of the syringe shield 52.

The device further includes a fork-shape arm 41 that can hold or release the plunger of the syringe and an electro-actuator that can link the linear drive 36 to the receptacle 51, and drive up/down the syringe and its needle 55 to pierce the Luer Slip Injection Site 59.

The device provides a permanent link between the linear drive 36 and the fork-shape arm 41 and allows both the radioactive solution and the diluting solution to be drawn at a constant fluid flow rate through the tubing and into the syringe.

The Luer Slip Injection Site 59 is attached to the upper tubing assembly and two Luer-lock fittings 61 (with needles) are attached to the lower tubes assembly (see Fig.3 for view of the pre-assembled sterile disposable kit).

The tubing assembly is held in its appropriate position by a small groove and a dedicated shaped recess 2 to accurately position the Luer Slip Injection Site 59, in regard to the needle 55.

The device is provided with both radioactive and diluting stock solutions which are dispensed from their respective vials 34 and 62, up to the syringe by passing through a disposable, sterile and non-pyrogenic fluid pathway with the radioactive amount controlled by a radiation detector 63, which in this embodiment of the invention is a Geiger-Muller tube or PIN photodiode and located behind a portion of the tube assembly leading to the injection site (behind the plate holder 2).

The device is automated via a programmable PLC and is connected to a computer serving as a user interface, and preferably is provided with a printer to print the syringe or vial label showing the activity, date, time, batch, patient name, etc. or whatever may be required.

The dispensing of the radioactive dose is done on-line by measuring the true amount of radioactivity passing in front of the radiation detector 63 and the total volume required into the syringe is automatically adjusted by dilution.

The device also includes a safety cross-evaluation of the delivered radioactive dose which is automatically performed using the traditional volumetric dispensing method, and the volumetric method can also be used as the main dispensing method.

It is further envisaged that the device of the invention may include a built-in sterile air flow, designed to allow the device to be operated on a bench in a conventional room but still maintaining full compliance with a 3.5 class (A class) dispensing environment, characterized by a sterile air flow directed towards the Luer Slip Injection Site 59 and needle 55.

It is also envisaged that in another embodiment of the invention a sterile disposable double check-valve could be located between the syringe 53 and needle 55, or underneath the Luer Slip Injection Site 59 to allow the transfer of an accurate dose of radioactive solution through a tube, to externally located vials or containers.

## Operation of the device

When the device is being operated the user opens the door 9 of the device and installs a new tubing kit 57 onto the tubing holder 2. The Luer Slip Injection Site 59 attached to the upper T-shape tube is slid into the appropriate recess and both needles 61 attached to the lower T-shape tubes are fed through each lead channel and connected to the radioactive stock solution 34 and the dilution stock solution 62.

The user then rotates the lid 32 and closes the door 9 and introduces a disposable syringe 53 with its appropriate needle 55 into a tungsten syringe shield 52. At this point the needle is un-capped and the tungsten syringe shield is placed onto the receptacle 51 on the front face of the device. The operator then enters on the computer the requested radioactive dose and total volume.

The device lowers the receptacle 51 enabling the syringe to pierce the Luer Slip Injection Site with the needle. The filling sequence will automatically dispense the desired radioactive dose into the syringe and dilute it to match the requested volume by actuation of the syringe plunger. Once the syringe has been filled (less than one minute), the syringe and syringe shield are lifted away from the Luer Slip Injection Site, and the syringe and syringe shield is removed from the device and needle re-capped. At the end of the process, a syringe label is printed with the appropriate dose data.

## Summary of the embodiment of invention

Traditionally the accurate knowledge of the volumetric radioactivity (specific activity: Ci/mL or Bq/mL) of a radioactive stock solution is required for the accurate dispensing of any radioactive dose.

For example, a dose of 3mCi (111MBq) of a radioactive solution with a volumetric radioactivity of 50 mCi/mL (1850MBq/mL) will be precisely achieved by dispensing a volume of 0.06mL. However, volumetric radioactivity of solutions is not always determined with great accuracy at the time of the manufacturing of the product, and post measurement of the volumetric radioactivity at the customer site is regarded as a critical operation.

The invention has the novel feature in that it can accurately dispense a requested radioactive dose without any knowledge of the volumetric radioactivity of the stock solution by an on-line radioactivity measurement and without exposing an operator to the radiation.

In the invention, a radiation detector 63 being a Geiger-Muller tube, a PIN photodiode or other fast measuring device is located behind a portion of the tubing leading to the injection site 59 and then to the syringe 53. The radiation detector continuously monitors the radioactive dose passing through the tube and into the syringe at a very constant liquid flow rate and the PLC 11 determines the appropriate switching sequence of the valves to dispense the requested dose and volume.

The program also calculates online the corresponding radioactivity contained in the dead volume of the tubing which will be inevitably added-on during the dilution phase of the syringe filling. That corresponding radioactivity is subtracted from the required dose by the PLC 11 to identify the amount of radioactivity allowed to pass the radiation detector 63. At the end of the filling process, the sum of the amount of activity allowed to pass by the detector before the dilution phase and the resultant activity gained during the dilution phase due to the dead volume of the tubing kit, translates to the required dose.

Below is the formula used to determine how much of the stock solution needs to be drawn-up into the syringe to achieve the desired dose (this calculation is performed continuously during the filling process):

Let RD = Requested dose

ADV = Activity contained in the dead volume of the tubing

RMT = Radioactivity measured passing through the tubing

VA = Volumetric activity of the stock solution

DV = Dead volume of the tubing

SA = Volumetric radioactivity

VSW = Volume of stock solution withdrawn from vial

Therefore the radioactive amount of stock solution to draw-up into syringe:

= RD – ADV

= RD – (DV x SA)

$$= RD - (DV \times (RMT/(VSW-DV))$$

Using the above method of filling a syringe with a radioactive solution, it is not necessary to know the specific activity of the stock solution prior to the filling process, as it is calculated during the filling process.

The accuracy of the dose dispensed is a function of the volumetric radioactivity of the radioactive stock solution, and experiments have shown accuracy better than 5% for volumetric radioactivity in the range of 0-50 mCi/mL (0-1850MBq/mL) and better than 10% for volumetric radioactivity in the range of 50-100 mCi/mL (0-3700MBq/mL).

The invention lies in an automated means of preparing a dose of a radiopharmaceutical into a disposable syringe under computer control by means of a radiation detector to determine the radioactive dosage and dilution by a non radioactive solution to achieve a desired volume. By this means such a dose can be prepared without unnecessary radiation exposure occurring to the person preparing the dose.

The precise components of the apparatus of the invention may be varied provided they achieve the method of the invention as described. It is further envisaged that other embodiments of the invention will exhibit any number of and any combination of the features of those previously described and whilst we have described herein one specific embodiment of the invention it is to be understood that variations and modifications in this can be made without departing from the spirit and scope thereof.

The claims defining the invention are as follows:

1. A radioactive dose dispensing device for automatically filling a container with a required radioactive dose in a sterile environment, said device being stand alone and radiation shielded and including control means to control a mix of radioactive stock solution and dilution stock solution, the radioactivity of which mix is monitored by radiation detection means.

2. A radioactive dose dispensing device as claimed in claim 1 wherein the container is a plunger operated disposable syringe.

3. A radioactive dose dispensing device as claimed in claim 2 wherein a shielded receptacle is provided in the device to receive the syringe.

4. A radioactive dose dispensing device as claimed in claim 3 wherein drive means are provided to actuate the plunger of the syringe.

5. A radioactive dose dispensing device as claimed in claim 4 wherein the drive means is a linear drive mechanism adapted to move either the syringe or its plunger relative to one and other.

6. A radioactive dose dispenser device as claimed in any one of claims 1 to 5 wherein a disposable tubing assembly is used to provide a sterile fluid pathway for the stock solutions.

7. A radioactive dose dispenser device as claimed in claim 6 wherein pinch valves are provided to switch between the radioactive stock solution and the dilution stock solution.

8. A radioactive dose dispenser device as claimed in any one of claims 1 to 7 wherein the automation of the device and its calculation of a requisite dose is controlled by a programmable logic controller (PLC) in association with a radiation detector which controls the radioactive dose passing through the tubing and being dispensed into the syringe.

9. A radioactive dose dispenser device as claimed in claim 8 wherein the device and its PLC are operable by means of a computer interface.

10. A method of automatically dispensing a dose of a radioactive solution using a software controlled lead shielded device which includes the steps of

- providing the device with a radioactive stock solution and a dilution stock solution
- using a computer software interface to the device to control the dose dispensed automatically into a syringe or vial in the device.

FIG. 1.

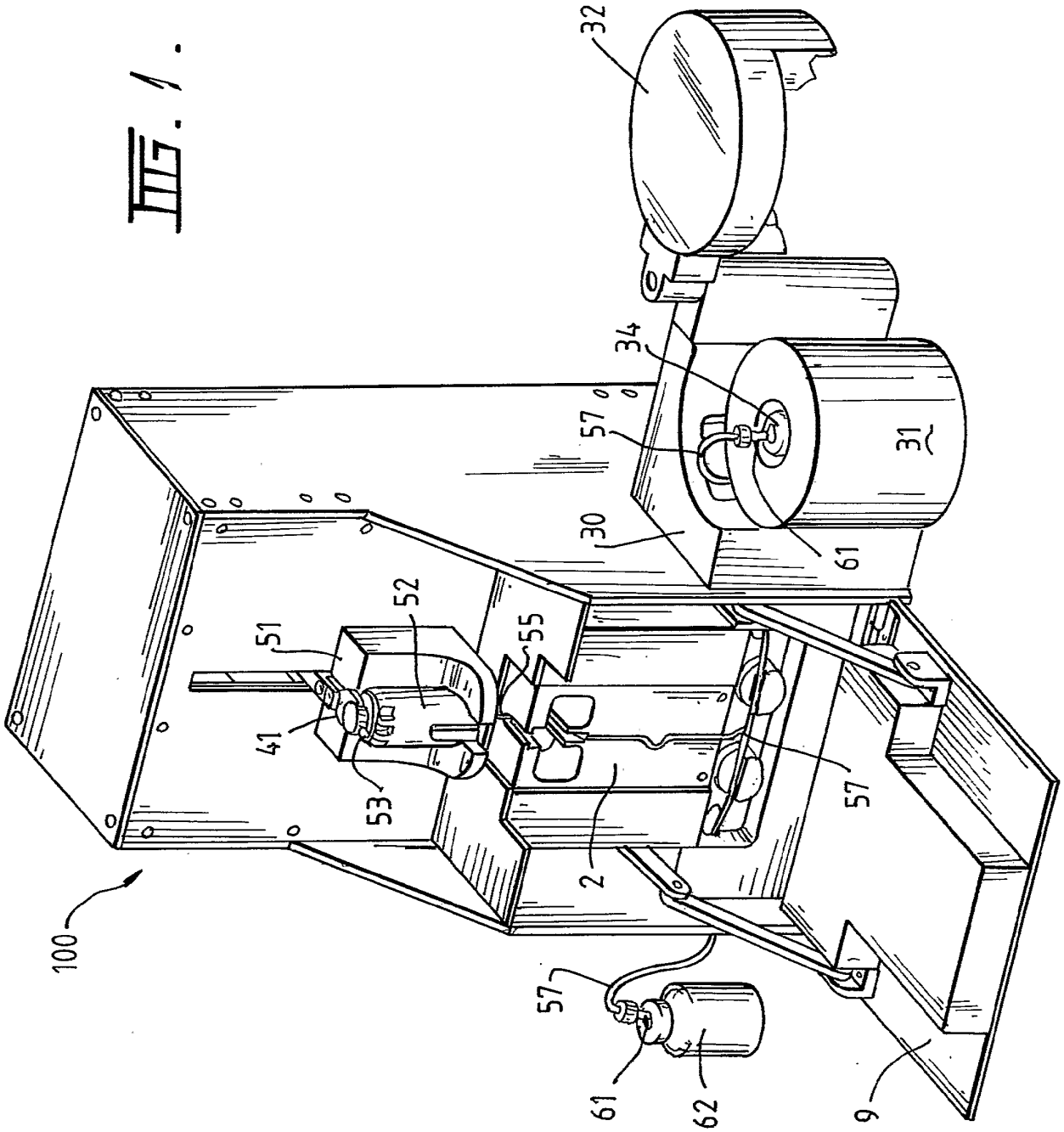
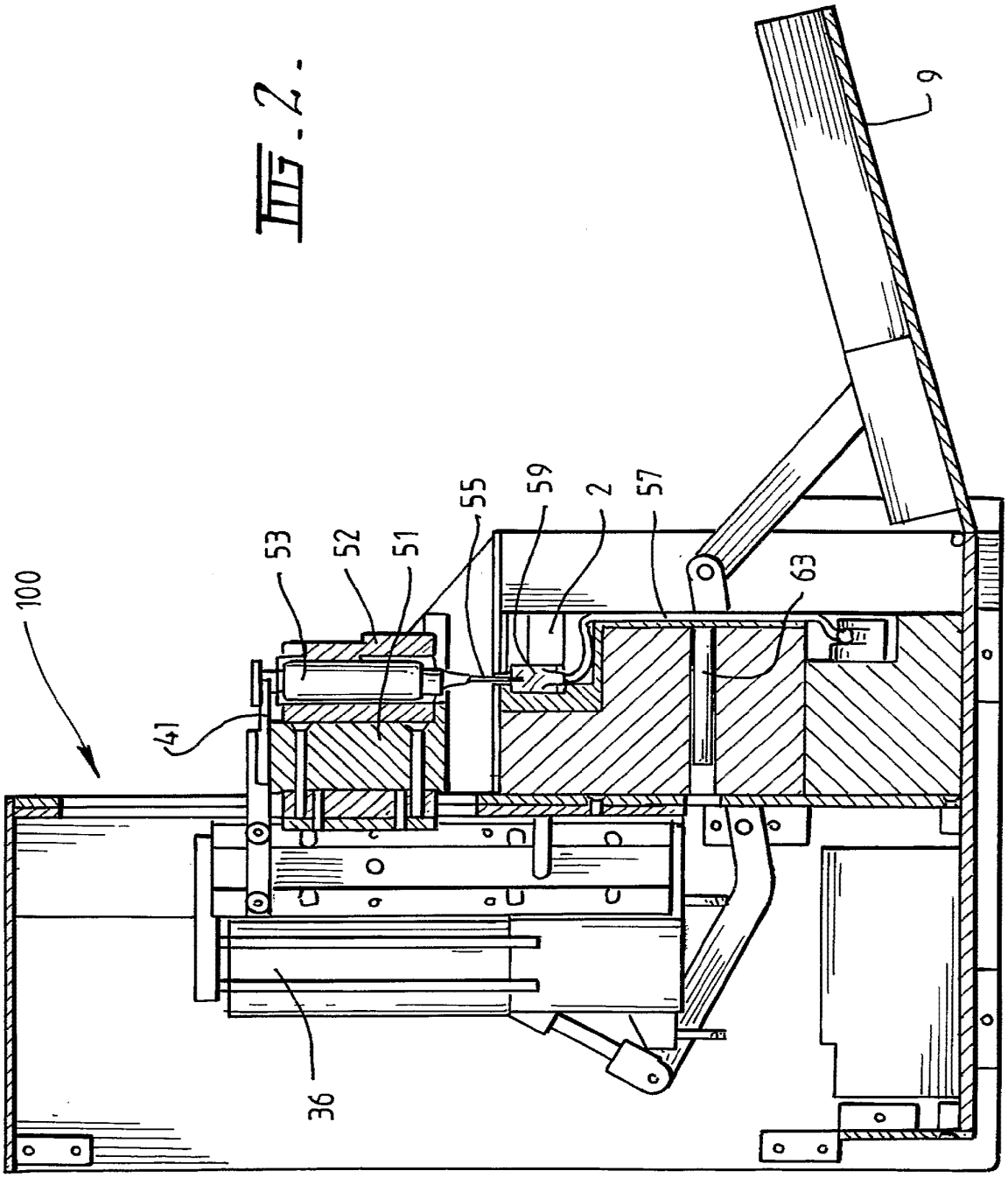


Fig. 2.



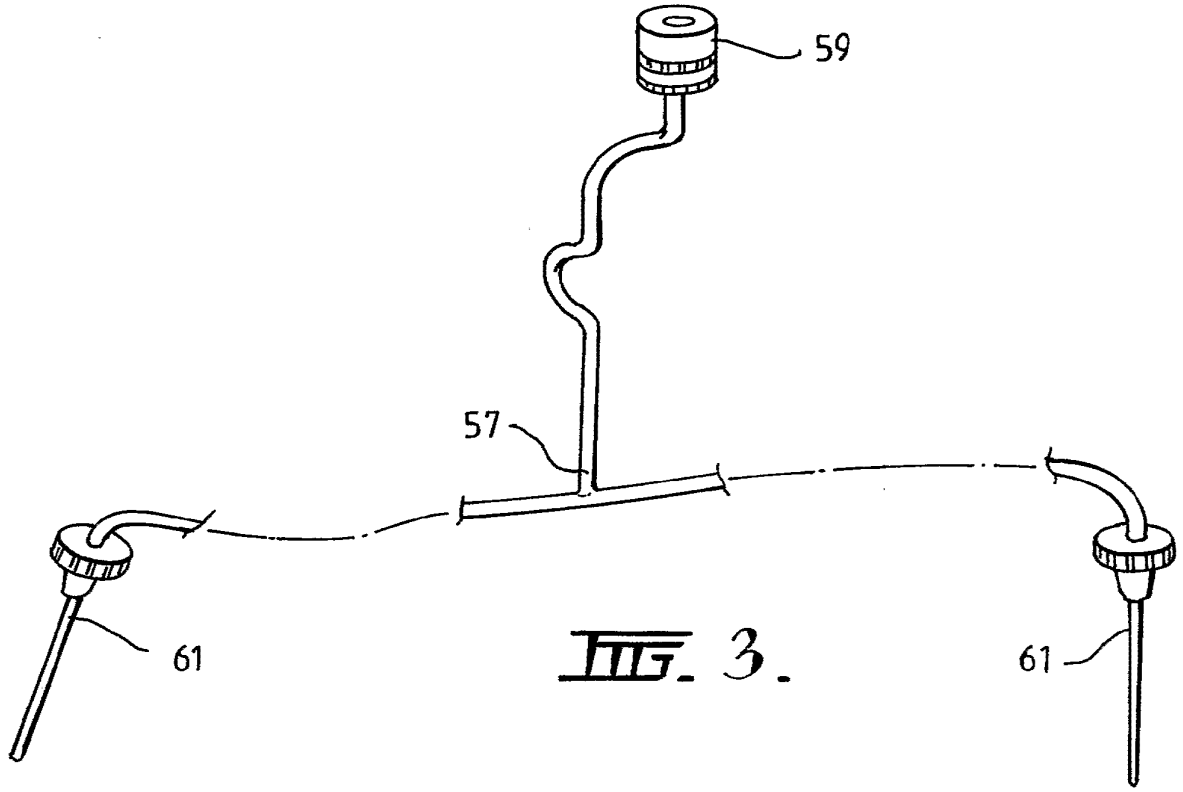



FIG. 3.

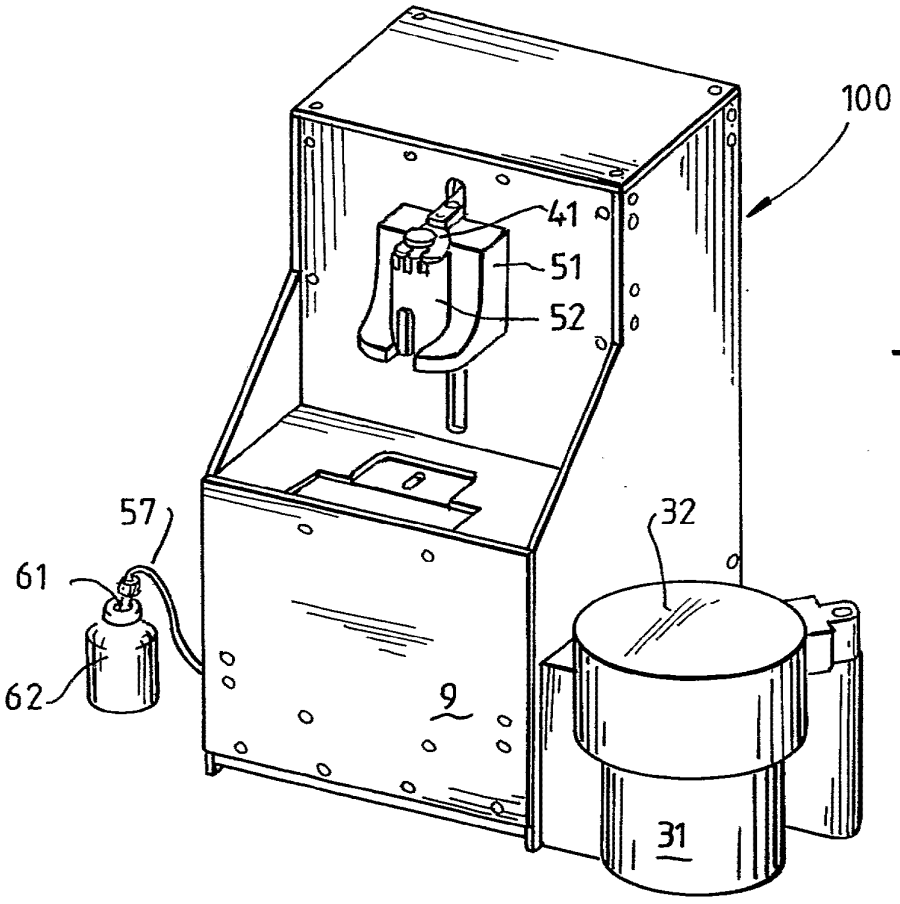



FIG. 4.

# INTERNATIONAL SEARCH REPORT

International application No.
**PCT/AU2004/000897**

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: B65B 3/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
See below under "Electronic database consulted"

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPTO

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI: IPC : B65B 3/- with keywords: radioactive, nuclear

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| | US 5911252A (CASSEL) 15 June 1999 | |
| X | The whole document | 10 |
| Y | The whole document | 1-9 |
| | US 4041994A (HORWITZ et al.) 16 August 1977 | |
| Y | The whole document | 1-9 |
| A | US 4662231A (SCHAARSCHMIDT et al.) 5 May 1987 | 1-10 |
| A | GB 1415804A (COMMISSARIAT A L'ENERGIE ATOMIQUE) 26 November 1975 | 1-10 |

☐ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 22 July 2004 | - 3 AUG 2004 |

| Name and mailing address of the ISA/AU | Authorized officer |
|---|---|
| AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaustralia.gov.au<br>Facsimile No. (02) 6285 3929 | **ASANKA PERERA**<br>Telephone No : (02) 6283 2373 |

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/000897

**Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)**

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:
See the Supplemental Box

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2004/000897

**Supplemental Box**
(To be used when the space in any of Boxes I to VIII is not sufficient)

**Continuation of Box No: III**

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-9 is directed to a radioactive dose dispensing device including control means to control a mix of radioactive stock solution and dilution solution. It is considered that the monitoring the radioactivity of a mix by radiation detection means comprises a first "special technical feature".

2. Claim 10 is directed to a method of automatically dispensing a dose of radioactive solution. It is considered that the steps providing the device with a radioactive stock solution and dilution solution and using a computer software interface to control the dispensed dose comprises a second "special technical feature".

These groups are not so linked as to form a single general inventive concept, that is, they do not have any common inventive features, which define a contribution over the prior art. The common concept linking together these groups of claims is controlling a mix of radioactive stock solution and dilution solution in a dispensing device. However this concept is not novel in the light of US 5911252A. Therefore these claims lack unity a posteriori.

## INTERNATIONAL SEARCH REPORT

International application No.
**PCT/AU2004/000897**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in Search Report | | Patent Family Member | | | | | |
|---|---|---|---|---|---|---|---|
| US | 5911252 | | | | | | |
| US | 4041994 | | | | | | |
| US | 4662231 | BE | 900719 | BE | 902407 | BR | 8405970 |
| | | BR | 8505220 | DE | 3342470 | DE | 3438303 |
| | | FR | 2555746 | FR | 2572179 | GB | 2151780 |
| | | GB | 2167736 | JP | 60179624 | JP | 61099836 |
| | | US | 4665758 | | | | |
| GB | 1415804 | BE | 805777 | CH | 576845 | FR | 2205038 |

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
7 December 2006 (07.12.2006)

PCT

(10) International Publication Number
WO 2006/129301 A2

(51) International Patent Classification: Not classified

(21) International Application Number:
PCT/IL2006/000562

(22) International Filing Date: 11 May 2006 (11.05.2006)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

| | | |
|---|---|---|
| PCT/IL2005/000572 | 1 June 2005 (01.06.2005) | IL |
| PCT/IL2005/000575 | 1 June 2005 (01.06.2005) | IL |
| 60/691,780 | 20 June 2005 (20.06.2005) | US |
| 60/700,318 | 19 July 2005 (19.07.2005) | US |
| 60/700,299 | 19 July 2005 (19.07.2005) | US |
| 60/700,317 | 19 July 2005 (19.07.2005) | US |
| 60/700,753 | 20 July 2005 (20.07.2005) | US |
| 60/700,752 | 20 July 2005 (20.07.2005) | US |
| 60/702,979 | 28 July 2005 (28.07.2005) | US |
| 60/720,034 | 26 September 2005 (26.09.2005) | US |
| 60/720,652 | 27 September 2005 (27.09.2005) | US |
| 60/720,541 | 27 September 2005 (27.09.2005) | US |
| 171346 | 10 October 2005 (10.10.2005) | IL |
| PCT/IL2005/001173 | 9 November 2005 (09.11.2005) | IL |
| PCT/IL2005/001215 | 16 November 2005 (16.11.2005) | IL |
| 172349 | 27 November 2005 (27.11.2005) | IL |
| 60/741,440 | 2 December 2005 (02.12.2005) | US |
| 60/750,287 | 13 December 2005 (13.12.2005) | US |
| 60/750,294 | 13 December 2005 (13.12.2005) | US |
| 60/750,597 | 15 December 2005 (15.12.2005) | US |
| 60/750,334 | 15 December 2005 (15.12.2005) | US |
| PCT/IL2006/000059 | 15 January 2006 (15.01.2006) | IL |
| 67/763,458 | 31 January 2006 (31.01.2006) | US |

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(74) Agents: **SANFORD T. COLB & CO.** et al.; P.o. Box 2273, 76122 Rehovot (IL).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

**Published:**

— *without international search report and to be republished upon receipt of that report*

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: UNIFIED MANAGEMENT OF RADIOPHARMACEUTICAL DISPENSING, ADMINISTRATION, AND IMAGING

(57) Abstract: Apparatus is provided for use with at least one labeled radiopharmaceutical agent, the apparatus including a container (22) containing the at least one labeled radiopharmaceutical agent, and a portable computer-communicatable data carrier (120, 24) associated with the container (22), the data carrier (120, 24) containing imaging protocol information for use with the at least one labeled radiopharmaceutical agent. Other embodiments are also described.

WO 2006/129301 A2

# UNIFIED MANAGEMENT OF RADIOPHARMACEUTICAL DISPENSING, ADMINISTRATION, AND IMAGING

## CROSS-REFERENCES TO RELATED APPLICATIONS

The present patent application is a continuation-in-part of:

(i) International Application PCT/IL2005/001215, filed November 16, 2005; and

(ii) International Application PCT/IL2005/001173, filed November 9, 2005, which:

(a) claims the benefit of the following US Provisional Patent Applications:

- 60/625,971, filed November 9, 2004;
- 60/628,105, filed November 17, 2004;
- 60/630,561, filed November 26, 2004;
- 60/632,236, filed December 2, 2004;
- 60/632,515, filed December 3, 2004;
- 60/635,630, filed December 14, 2004;
- 60/636,088, filed December 16, 2004;
- 60/640,215, filed January 3, 2005;
- 60/648,385, filed February 1, 2005;
- 60/648,690, filed February 2, 2005;
- 60/675,892, filed April 29, 2005;
- 60/691,780, filed June 20, 2005;
- 60/700,318, filed July 19, 2005;
- 60/700,299, filed July 19, 2005;
- 60/700,317, filed July 19, 2005;
- 60/700,753, filed July 20, 2005;
- 60/700,752, filed July 20, 2005;

- 60/702,979, filed July 28, 2005;
- 60/720,034, filed September 26, 2005;
- 60/720,652, filed September 27, 2005; and
- 60/720,541, filed September 27, 2005, and

(b) is a continuation-in-part of the following International Patent Applications:

- PCT/IL2005/000572, filed June 1, 2005; and
- PCT/IL2005/000575, filed June 1, 2005.

The present patent application claims the benefit of the following US Provisional Applications:

- 60/750,287, filed December 13, 2005;
- 60/750,334, filed December 15, 2005; and
- 60/750,597, filed December 15, 2005.

The present patent application is related to a US provisional patent application filed on even date herewith, entitled, "Imaging protocols."

All of the above-mentioned applications are assigned to the assignee of the present application and are incorporated herein by reference.

## FIELD OF THE INVENTION

The present invention relates generally to pharmaceutical management and control, and specifically to systems and methods for radiopharmaceutical dispensing, administration, and imaging.

## BACKGROUND OF THE INVENTION

US Patent Application Publication 2005/0277833 to Williams, Jr., which is incorporated herein by reference, describes techniques for handling, mixing, dispensing and/or injecting a mixture into an individual during a medical procedure. The mixture contains pharmaceutical agents and/or radiopharmaceutical agents. Also described is a mixing device capable of diluting a radiopharmaceutical agent with, for instance, a diluent, for altering a radiation dose emitted by the radiopharmaceutical agent.

US Patent Application Publication 2005/0203389 to Williams, Jr., which is incorporated herein by reference, describes techniques for an operator to control an injection device and imaging equipment from a common control console. The injection device may be used to administer a contrast medium into a patient so that imaging equipment can acquire internal images of the patient. An injection system is bundled with software and/or hardware that is used to modify an existing imaging control console so that it can be used to operate both the injection device and imaging device. In one embodiment, the common control console can access stored protocols that can contain operational parameters for the injection device, the imaging device, or both.

US Patent 4,679,142 to Lee, which is incorporated herein by reference, describes techniques for dispersing quantities of radioactive material at a user location. Billing is accomplished by monitoring the decay of material and the degree of activity following each user withdrawal.

US Patent Application Publication 2005/0261938 to Silverbrook et al., which is incorporated herein by reference, describes a method for authenticating a pharmaceutical product, the pharmaceutical product being associated with packaging having disposed thereon or therein coded data including a number of coded data portions, each coded data portion being indicative of an identity of the pharmaceutical product and at least part of a digital signature of at least part of the identity. The method includes having a computer system receive indicating data from a sensing device, the sensing device being responsive to sensing of the coded data to generate indicating data at least partially indicative of the identity of the pharmaceutical product and the signature part. The computer system determines the identity at least one determined signature part and uses these to authenticate the pharmaceutical product.

US Patent Application Publication 2005/0261936 to Silverbrook et al., which is incorporated herein by reference, describes a method for allowing a user to interact with a pharmaceutical product, the pharmaceutical product associated with packaging having disposed thereon or therein coded data, at least some of the coded data being indicative of at least an identity. The method includes having a computer system receive indicating data from a sensing device, in response to sensing of the coded data, and determine, using the indicating data, at least one action. The computer system then performs the action associated with the pharmaceutical product, the action including at least one of providing

information to a user; updating tracking information relating to the pharmaceutical product; performing a transaction relating to the pharmaceutical product; authenticating the pharmaceutical product; and receiving feedback from the user.

US Patents 5,882,338 and 6,019,745 to Gray, which are incorporated herein by reference, describe a medical syringe comprising a cylindrical barrel having therein a plunger which can be axially driven by a plunger rod. The plunger rod passes through an aperture in the center of a finger grip having two finger grip projections at opposite sides thereof. A data carrier means in the form of an electrically or magnetically operable device is mounted near the end of one of the two finger grip projections, with preferably a device mounted near the end of each finger grip projection. The device carries data relating to the medicament contained or to be contained within the syringe, and can be read by a suitably adapted syringe pump when the syringe is mounted thereon to be driven by the syringe pump.

US Patent 6,970,735 to Uber, III et al., which is incorporated herein by reference, describes a system for producing a contrast-enhanced medical image of a patient, including a source of a contrast or enhancement medium, a pressurizing unit in fluid connection with the source of contrast or enhancement medium, an energy source operable to apply energy to a region of the patient, an imaging unit providing a visual display of an internal view of the patient based upon a signal resulting from the energy applied to the region of the patient, and a control unit. In an embodiment, the signal is affected by a condition of the contrast or enhancement medium in the patient. To control an imaging procedure, the control unit adjusts the condition of the contrast or enhancement medium in the patient based upon the signal. A communication interface preferably enables information between an injector subsystem and an imaging subsystem.

US Patents 5,781,442, 6,671,563, 6,915,170, and 6,731,989 to Engleson et al., which are incorporated herein by reference, describe a care management system in which the management of the administration of care for patients is automated. Hospital information systems are monitored and the information from those systems is used in verifying the administrations of care to patients. The care management system monitors ongoing administrations for progress and automatically updates records and provides alarms when necessary. The care management system is modular in nature but is fully integrated among its modules. Particular lists of data, such as the termination times of all

ongoing infusions, provide hospital staff current information for increased accuracy and efficiency in planning. Features include the automatic provision of infusion parameters to pumps for accurate and efficient configuration of the pump, and providing an alarm when an unscheduled suspension of an infusion exceeds a predetermined length of time. A passive recognition system for identifying patients and care givers is described.

US Patent Application Publication 2003/0055685 to Cobb et al., which is incorporated herein by reference, describes techniques for monitoring administration of a medical product within a delivery device using a medicine data storage device attached to the delivery device, which includes a product identifier identifying the medical product and an intended patient identifier identifying a patient intended to receive the medical product. Before administering the medical product to an individual patient, the product identifier and the intended patient identifier are uploaded into a reader, and a patient identifier is accessed from the reader's memory or uploaded from a patient identification device associated with the individual patient into the reader. The patient identifier is compared with the intended patient identifier to determine whether the individual patient is intended to receive the medical product. Once it is confirmed that the individual patient is intended to receive the medical product, the medical product is administered to the individual patient.

US Patent Application Publication 2005/0131270 to Weil et al., which is incorporated herein by reference, describes a system including a radiation treatment agent to treat tissue in response to received X-ray radiation and an identifier associated with the radiation treatment agent. The identifier may be usable to identify a radiation treatment plan. In some embodiments, a radiation treatment plan associated with a patient is generated, the radiation treatment plan is associated with an identifier and a patient identifier identifying the patient, a radiation treatment agent is prepared for delivery to the patient according to the radiation treatment plan, and the radiation treatment agent is associated with the identifier.

US Patent 6,985,870 to Martucci et al., which is incorporated herein by reference, describes a medication delivery system comprising a medical container holding a prescribed medication to be delivered to a patient, a tag adapted to be worn by the patient, a handheld computing device, and an electronic medication delivery device. Data on the medication is contained in a first label on the medication container. The first label also

contains the instruction on how the medication is delivered to the patient, including the appropriate settings for an electronic medication delivery device for delivering the medication to the patient. Patient data is contained in a second label on the tag worn by the patient. The medication data, medication delivery instruction, and patient data are provided in machine readable formats. The handheld computing device reads the medication data and the medication delivery instruction on the medication container and the patient data on the patient tag. The handheld computing device stores the information obtained and performs a matching check to confirm that the medication data matches with the patient data. Upon a confirmed match, it transmits the medication delivery instruction to the electronic medication delivery device, which downloads the instruction, programs the delivery device, and prompts an operator to begin delivering the medication to the patient according to the downloaded instruction.

US Patent Application Publication 2005/0029277 to Tachibana, which is incorporated herein by reference, describes a drug container having an identification tag fixed or detachably provided at a predetermined position of the container, the tag having recorded thereon drug data on a kind and a concentration of a drug, and upper and/or lower limits of a flow rate for continuous infusion, or time and flow rate for one-shot administration.

US Patent Application Publication 2005/0277911 to Stewart et al., which is incorporated herein by reference, describes techniques for programming a medical therapy in a medical device. The medical device has a controller, a memory, a processor, and an input device. The memory is preloaded with at least one of a plurality of patient profiles and condition profiles. The memory is further preloaded with an associated medication therapy for a plurality of the profiles. The input device receives profile data, comprising at least one of a patient profile data and a condition profile data for a specific patient, and the processor processes the received profile data and provides as output one of the preloaded medication therapies based on the processed profile data.

US Patent 6,506,155 to Sluis, which is incorporated herein by reference, describes an ultrasound imaging system including a data entry device that reads storage media that is assigned to each patient on which the system is to be used or the operator of the system to obtain ultrasound images. The storage media, which comprises a barcode, smartcard, or personal digital assistant, contains patient identifying information. The patient or

procedure identifying information is used to access a digital requisition that is referenced by the patient identifying information. The digital requisition is stored in a disk drive included in the ultrasound imaging system or in a clinical information system accessed through a communication link included in the ultrasound imaging system. The digital requisition includes information pertaining to an ultrasound examination procedure that is to be performed on the patient, which is used to automatically set up the ultrasound imaging system. The digital requisition may also include the patient's medical history or information about the patient that can be associated with ultrasound images obtained from the patient.

US Patent Application Publication 2005/0121505 to Metz et al., which is incorporated herein by reference, describes patient-centric data acquisition protocol selection systems and methods, and identification tags therefor. A patient-centric data acquisition protocol selection system comprises a programmable identification tag capable of allowing predetermined information about a patient to be stored therein and retrieved therefrom; a medical imaging system capable of communicating with the programmable identification tag; and programming associated with the medical imaging system for selecting an optimal data acquisition protocol. The medical imaging system reads information from the programmable identification tag and then the programming selects an optimal data acquisition protocol based, at least in part, on the predetermined information about the patient that is stored in the programmable identification tag.

PCT Publication WO 04/004787 to Van Naemen et al., which is incorporated herein by reference, describes a method for dispensing individual doses of a radiopharmaceutical solution, which consists of a radioactive parent solution diluted with a diluting solution. Also described is a computer-generated dose dispenser for dispensing individual doses of a radiopharmaceutical solution at a specified speed. The method and device are described as being particularly suitable for use in the field of nuclear medicine, and more in particular for use for PET scan applications.

US Patent 6,032,155 to de la Huerga, which is incorporated herein by reference, describes techniques for administering a prescribed medication to a patient. A medication administration system and apparatus dispense the prescribed medication, verify that the medication is given to a correct patient by an authorized healthcare worker, and track and record the administration of the medication. The system utilizes a workstation connected

to a database containing prescribed medication dose information for various patients. A healthcare worker uses the workstation to manually or automatically dispenses the medication the portable container. An information device is secured to the portable container during transport and administration of the medication to the intended patient. The information device prevents access to the medication or warns the healthcare worker of a potential error if the medication is delivered to the wrong patient or administered by an unauthorized healthcare worker. The information device records actual consumption information, and delivers this information back the workstation database or to a hospital or pharmacy database.

US Patent 5,317,506 to Coutre et al., which is incorporated herein by reference, describes an infusion management and pumping system. Infusion prescriptions are generated and monitored by a pharmacy management system. Labels for each infusion to be given to a patient are generated and printed in a barcode format. Each label contains data regarding a prescribed infusion program, including the drug or drugs to be infused, the infusion regimen, the expiration date, and the patient to whom the infusion is to be administered. The management system checks for incompatibilities between drugs that are being prescribed for simultaneous infusion. Each label generated by the management system is attached to the container which holds the infusion solution. The data on the label is transferred to an infusion pumping system by a barcode reader at the infusion pumping system. The pumping system checks that all necessary data has been entered. During operation, the pumping system checks for a variety of alarm conditions and stores any alarms in a ranking according to urgency. The infusion pumping system is responsive to remote or biofeedback instructions to alter the planned infusion program. Central computer records processing receives infusion data and provides infusion, inventory, and use analysis.

US Patent 5,039,863 to Matsuno et al., which is incorporated herein by reference, describes an automatic radioisotope filling apparatus, which is equipped with a radioisotope vial containing a radioisotope solution, a saline vial containing a physiological saline solution, a dilution vial to which a predetermined amount of the radioisotope solution and a predetermined amount of the physiological saline solution are to be transferred to prepare a diluted radioisotope solution, a radiation detector for measuring the radioactive intensity of the diluted radioisotope solution prepared in the dilution vial, and a plurality of label vials containing a drug to be labeled.

US Patent Application Publication 2004/0051368 to Caputo et al., which is incorporated herein by reference, describes a system for delivering medical fluid to a patient. The system includes a medical container including a Radio Frequency Identification (RFID) tag storing data related to the medical fluid therein. A RF reader receives data signals transmitted from the RFID tag that include a desired flow rate for delivering the fluid to the intended patient. A pump coupled to the reader includes a pumping mechanism for pumping the medical fluid from the container, and a pump controller for receiving the data including the desired flow rate from the reader. The pump controller automatically controls the pumping mechanism to pump the medical fluid from the medical container at the desired flow rate based upon the data.

US Patent Application Publication 2005/0171815 to Vanderveen, which is incorporated herein by reference, describes a centralized medication management system for monitoring, managing and controlling medication delivery from a central location. A central computer displays medication orders and ongoing medication administrations for a health care facility. The central computer checks medication delivery against a database of medication administration guidelines, including guidelines for medication interactions with other medications and with patient conditions, and provides an indication of any detected incompatibilities. A clinician at the central location may adjust the medication administration parameters in response to detected incompatibilities and communicate with a caregiver at the point of care to provide decision support. In an embodiment, the central location is a pharmacy at the healthcare facility.

US Patent Application Publication 2005/0240441 to Suzuki, which is incorporated herein by reference, describes a hospital information system. The system enables an RF reader, comprising a personal digital assistant (PDA), to read tag information recorded by RF tags either attached to, or embedded in, various types of a patient wrist bands, injection medicine bottles, patient charts, and medical instrument cases. The PDA transmits a query to a server via a wireless LAN for confirmation from the server. The server collates the query with the content of a medical practice order recorded in its data base, and registers a completion of instructed operation for an instructed item in the database, and replies with a notification if the transmitted readout data from the PDA is correct. If the readout data is incorrect, the PDA is notified and instructed to perform another reading.

US Patent Application Publication 2001/0049608 to Hochman, which is incorporated herein by reference, describes an automated drug administering system such an injection device or infusion pump, which is provided with means for reading information from a container holding the drug. The information is then checked for accuracy before the administration of the drug. Optionally, an ID tag on the patient and/or the health care professional providing the drug may also be scanned and checked. The information thus gathered is sent to another station where it is logged for future use and analyzed.

US Patent 6,743,202 to Hirschman et al., which is incorporated herein by reference, describes apparatus for sharing information on syringe configuration between syringes and injector systems, comprising a storage system to store encoded information on syringe configuration. The encoded information is readable by a detection circuit in an injector. In one embodiment, the storage system is an electronic storage system in which information relevant to the syringe configuration is encoded. A method comprises the step of conveying syringe configuration information to a detector in an injector for use with the syringe.

US Patent Application Publication 2005/0148869 to Masuda, which is incorporated herein by reference, describes a liquid syringe having various kinds of data items recorded in a two-dimensional code format. A liquid injector optically reads the two-dimensional codes, decodes them, and executes a predetermined operations corresponding to the decoded results. Recording, for example, a variable pattern for the liquid of interest in the two-dimensional code format on the liquid syringe makes it possible for the liquid injector to inject the liquid in accordance with the predetermined variable pattern.

US Patent 6,346,886 de la Huerga, which is incorporated herein by reference, describes an electronic identification apparatus having data storage memory on board a removable transceiver device. The transceiver device also includes a processor and a transponder for receiving information pertaining to the object/person to which it is attached and storing the information in memory. The transceiver also transmits stored data to a control computer or the external devices. The transceiver is mounted on a base, such as a wristband, and the apparatus includes an attachment sensor indicating whether the transceiver is attached to the base. If the transceiver has been removed from the base,

the processor performs one or more lockdown operations to prevent the stored data from being used in connection with another object or person. The lockdown operations include clearing the contents of the memory, disabling access to the memory, suppressing the display of stored data and activating an alarm.

US Patent Application Publication 2004/0156081 to Bril et al., which is incorporated herein by reference, describes a color-coded signature, for securing documents or encrypting images. The encrypted image comprises an array of printed positions formed using a group of inks each of which has a predetermined spectrum. The positions are selected to form a predetermined image, either real or virtual, when the image is viewed through an optical processor. The optical processor may further use a distorted grating or a distorted lens. The correct image is the spectrum, as distorted by the optical processor. An image formed using inks having the same colors as experienced by the human eye, or even by a standard spectrometer will fail to form the correct predetermined image.

The following patents and patent application publications, all of which are incorporated herein by reference, may be of interest:

US Patent Applications 2005/0131579 and 2005/0088306, and US Patent 6,935,560, all to Andreasson

US Patent 6,851,615 to Jones

US Patent application 2005/0131397 and US Patent 6,861,954 to Levin

US Patent 6,519,569 to White et al.

US Patent 5,692,640 to Caulfield et al.

US Patents 6,475,192 and 6,733,478 to Reilly et al.

US Patent 6,958,053 to Reilly

US Patent Application Publications 2005/0261937 and 2005/0261938 to Silverbrook et al.

US Patent 6,994,249 to Peterka et al.

US Patent 6,843,357 to Bybee et al.

US Patent 6,425,174 to Reich

US Patent 6,722,499 to Reich

US Patent 5,536,945 to Reich

US Patent RE36,693 to Reich

US Patent 5,519,931 to Reich

US Patent Application Publication 2005/0198800 to Reich

US Patent 6,576,918 to Fu et al.

US Patent Application Publication 2005/0247893 to Fu et al.

US Patent 5,927,351 to Zhu et al.

US Patent 5,828,073 to Zhu et al.

US Patent 6,162,198 to Coffey et al.

US Patents 6,338,007 and 6,116,461 to Broadfield et al.

US Patent 5,944,190 to Edelen

PCT Publication WO 04/032151 to Besing et al.

US Patent Application Publication 2005/0234424 to Besing et al.

US Patent 4,296,785 to Vitello et al.

US Patent 3,446,965 to Ogier et al.

US Patent 6,355,024 to Small et al.

US Patent 6,468,261 to Small et al.

US Patent 5,580,541 to Wells et al.

US Patent 3,535,085 to Shumate

US Patent 4,853,546 to Abe et al.

US Patent 5,329,976 to Haber et al.

US Patent 5,304,165 to Haber et al.

US Patent 5,911,252 to Cassel

US Patent 5,475,232 to Powers et al.

PCT Publication WO 05/002971 to Tochon-Danguy et al.

US Patent Application Publication 2005/0278066 to Graves

US Patent 5,479,969 to Hardie et al.

US Patent 5,309,959 to Shaw et al.

US Patent 6,870,175 to Dell et al.

US Patent 6,767,319 to Reilly et al.

US Patent 6,976,349 to Baldwin et al.

US Patent 6,957,522 to Baldwin et al.

US Patent 6,915,619 to Baldwin

US Patent 6,813,868 to Baldwin et al.

US Patent 5,893,397 to Peterson et al.

US Patents 5,885,216, 5,806,519, and 6,901,283 to Evans, III et al.

US Patent Application Publication 2004/0084340 to Morelle et al.

US Patent 6,269,340 to Ford et al.

US Patent Application Publication 2004/0193453 to Butterfield et al.

US Patent 4,476,381 to Rubin

US Patent 6,643,537 to Zatezalo et al.

US Patent Application Publication 2005/0108044 to Koster

US Patent 6,851,615 to Jones

US Patent 5,840,026 to Uber, III et al.

US Patent 6,685,678 to Evans et al.

US Patent Application Publication 2003/0183226 to Brand et al.

US Patent Application Publications 2005/0107914 and 2005/0113945 to Engleson et al.

US Patent Application Publication 2002/0198738 to Osborne

US Patent Application Publication 2002/0099334 to Hanson et al.

US Patents 6,317,648 and 6,522,945 to Sleep et al.

US Patent 6,155,485 and 6,318,630 to Coughlin et al.

US Patent 6,202,923 to Boyer et al.

US Patent 6,915,823 to Osborne et al.

US Patent Application Publication 2004/0205343 to Forth et al.

US Patent 5,493,805 to Penuela et al.

US Patent 5,973,598 to Beigel

US Patent Application Publication 2005/0149350 to Kerr et al.

US Patent 5,884,457 to Ortiz et al.

The following patents and patent application publications, which describe gamma cameras and imaging processing techniques, and which are incorporated herein by reference, may be of interest:

US Patent Application Publication 2005/0205792 to Rousso et al.

PCT Publication WO 05/118659 to Dichterman et al.

PCT Publication WO 05/119025 to Nagler et al.

US Patent Application Publication 2004/0204646 to Nagler et al.

PCT Publication WO 04/042546 to Kimchy et al.

US Patent Application Publication 2004/0054248 to Kimchy et al.

US Patent Application Publication 2004/0015075 to Kimchy et al.

US Patent Application Publication 2004/0054278 to Kimchy et al.

US Patent Application Publication 2005/0266074 to Zilberstein et al.

US Patents 5,939,724, 5,587,585, and 5,365,069 to Eisen et al.

US Patent 6,943,355 to Shwartz et al.

US Patents 6,242,743 and 5,757,006 to DeVito et al.

US Patent 6,137,109 to Hayes

US Patent 6,388,258 to Berlad et al.

US Patent 6,429,431 to Wilk

US Patent 6,838,672 to Wagenaar et al.

US Patents 6,740,882, 6,545,280, 6,229,145, 5,519,221, and 5,252,830 to Weinberg

US Patent 6,713,766 to Garrard et al.

US Patent 6,765,981 to Heumann

US Patent 6,664,542 to Ye et al.

US Patent 6,080,984 to Friesenhahn

US Patent 5,818,050 to Dilmanian et al.

US Patent 6,728,583 to Hallett

US Patent 5,481,115 to Hsieh et al.

US Patent 6,723,988 to Wainer

US Patent 6,940,070 to Tumer

US Patent 6,635,879 to Jimbo et al.

US Patent 6,353,227 to Boxen

US Patent 6,184,530 to Hines et al.

US Patent Application Publication 2005/0145797 to Oaknin et al.

US Patent Application Publication 2004/0251419 to Nelson et al.

US Patent Application Publication 2003/0001098 to Stoddart et al.

PCT Publication WO 98/16852 to DeVito et al.

PCT Publication WO 05/059840 to Nielsen et al.

## SUMMARY OF THE INVENTION

In some embodiments of the present invention, an end-to-end automated system for medical imaging comprises a plurality of integrated elements that are configured to electronically exchange information among one another. The elements include an automated radiopharmaceutical dispensing system, a portable information-bearing radiopharmaceutical agent container, a patient management system, a portable patient-specific data carrier, an automated administration system, and an automated

imaging system. The systems perform their respective automated functions at least in part responsively to the exchanged information. The elements typically authenticate one another via the exchanged information, in order to ensure that only authorized elements participate in the system, and that the systems perform only authorized and appropriate functions.

The exchanged information typically includes patient-specific data, radiopharmaceutical agent-specific data, and/or patient- or radiopharmaceutical agent-specific imaging protocol data. Such data enable the systems to customize their respective automated functions for specific patients, radiopharmaceutical agents, indications, and/or imaging procedures. For some applications, the exchanged information includes commercial license information relating to the use of a specific protocol with a specific radiopharmaceutical agent, and one or more of the systems are configured to verify the license information before performing their respective functions.

In some embodiments of the present invention, the information-bearing radiopharmaceutical agent container and/or the patient-specific data carrier is configured to contain protocol information for performing an imaging procedure using the labeled radiopharmaceutical agent held by the container. For some applications, the protocol information includes SPECT imaging protocol information, and the imaging system uses the protocol information to perform a SPECT imaging procedure using the labeled radiopharmaceutical agent contained in the container. For some applications, the agent container contains a single dose of the labeled radiopharmaceutical agent, which dose is appropriate for use with the imaging protocol.

In some embodiments of the present invention, the information-bearing radiopharmaceutical agent container or the patient-specific data carrier is configured to contain at least one kinetic parameter of the labeled radiopharmaceutical agent contained in the container. The imaging system uses the kinetic parameter to perform a dynamic SPECT imaging procedure.

In some embodiments of the present invention, the information-bearing radiopharmaceutical agent container contains radiopharmaceutical information regarding the labeled radiopharmaceutical agent contained in the container. The portable patient-specific data carrier is configured to contain patient information regarding the patient, and imaging protocol information for use with the labeled radiopharmaceutical

agent, such as SPECT imaging protocol information. The imaging system uses the protocol information to perform an imaging procedure, such as a dynamic SPECT imaging procedure. For some applications, the patient-specific data carrier comprises a coupling mechanism configured to be coupled to the patient. For example, the coupling mechanism may comprise a bracelet, a watch, a necklace, or another wearable article.

In some embodiments of the present invention, the information-bearing radiopharmaceutical agent container contains a first identifier value, and the patient-specific data carrier contains a second identifier value. The imaging system is configured to perform an imaging procedure responsively to a detection of a correspondence between the first and second identifier values. For some applications, the first identifier value equals the second identifier value, while for other applications the values do not equal one another, but instead correspond to one another based on information provided by an element of the end-to-end system. For some applications, the first and/or second identifier values are arbitrarily assigned, or pre-loaded into the data carrier my a manufacturer or distributor, while for other applications at least one of the identifier values comprises a patient identifier, or another meaningful value. For some applications, at least one of the information-bearing agent container and the patient-specific data carrier performs the detection of the correspondence, while for other applications the imaging system or another element of the end-to-end system performs the detection of the correspondence.

In some embodiments of the present invention, the imaging system comprises a SPECT imaging system configured to utilize the information contained in the labeled radiopharmaceutical agent container and/or the patient-specific data carrier to customize at least one function of the system selected from the group consisting of: administration of the labeled radiopharmaceutical agent, acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered, reconstruction of the SPECT image, analysis of the SPECT image, and diagnosis of a condition of the patient based at least in part on the analysis.

The integration of the elements of the end-to-end system, and the exchange of authenticatable information among the elements generally increase patient safety, by ensuring that each patient receives the prescribed labeled radiopharmaceutical agent and dosage, and undergoes the desired imaging protocol. For some applications, one or more

elements of the end-to-end system are configured to perform their respective function only upon being triggered by another element of the system. For example, the administration or imaging system may perform its function only upon being triggered by the information-bearing radiopharmaceutical agent container, by the patient-specific data carrier, and/or, in the case of the administration system, by the imaging system.

In some embodiments of the present invention, the automated radiopharmaceutical dispensing system comprises an information manager that is configured to receive radiopharmaceutical information regarding a labeled radiopharmaceutical agent and patient information regarding a patient. Responsively to the information, the dispensing system automatically dispenses a dose of the labeled radiopharmaceutical agent to an agent container, and stores the radiopharmaceutical information and at least a portion of the patient information in a data carrier associated with the container. For some applications, the radiopharmaceutical information is selected from the group consisting of: imaging protocol information for use with the labeled radiopharmaceutical agent, such as a SPECT imaging protocol; at least one kinetic parameter useful for performing a dynamic SPECT imaging procedure using the at least one labeled radiopharmaceutical agent; and authenticatable information regarding a commercial license for use of a SPECT imaging protocol with the at least one labeled radiopharmaceutical agent.

In some embodiments of the present invention, the dispensing system is configured to receive a mother vial containing a labeled radiopharmaceutical agent in a quantity sufficient for preparation of a plurality of doses of the labeled radiopharmaceutical agent. Associated with the mother vial is a data carrier containing information regarding the labeled radiopharmaceutical agent, such as the formulation, radioactivity information, and protocol information. The information manager of the dispensing system receives at least a portion of the labeled radiopharmaceutical agent information from the data carrier.

In some embodiments of the present invention, use of the end-to-end automated system enables customization of one or more aspects of the imaging process, from dispensing to diagnosis. Customization typically includes one or more of the following:

- The dispensing system customizes the dispensed dose for a specific patient, based on radiopharmaceutical information and patient-specific information. Typically, the dispensing system customizes the dispensed

dose (e.g., the radioactivity level thereof) based in part on the scheduled time of the scheduled time of administration of the dose, and/or the scheduled time of the imaging procedure to be performed using the dose.

- The administration system customizes the administered dose for a specific patient, based on radiopharmaceutical information and patient-specific information. For some applications in which the administration system customizes the administered dose, the radiopharmaceutical agent container contains a standard, non-customized dose.

- The imaging system customizes image acquisition, image reconstruction, image analysis, and/or diagnosis, based on radiopharmaceutical information and patient-specific information, such as patient physiology and/or known and/or suspected disease of the patient.

Such customization is typically based at least in part on information provided by the manufacturer or distributor of the radiopharmaceutical agent. Such information may be in the form of lookup tables and/or expert system rules.

As used in the present application, including in the claims, "labeled" means radiolabeled, and "unlabeled" means not radiolabeled.

There is therefore provided, in accordance with an embodiment of the present invention, apparatus for use with at least one labeled radiopharmaceutical agent, the apparatus comprising:

a container containing the at least one labeled radiopharmaceutical agent; and

a portable computer-communicatable data carrier associated with the container, the data carrier containing imaging protocol information for use with the at least one labeled radiopharmaceutical agent.

For some applications, the apparatus comprises a device configured to write the imaging protocol information to the data carrier.

For some applications, the data carrier additionally contains administration protocol information useful for administering the at least one labeled radiopharmaceutical agent.

In an embodiment, the imaging protocol information comprises instructions for performing an imaging procedure using the at least one labeled radiopharmaceutical agent. Alternatively or additionally, the imaging protocol information comprises an identifier of an imaging protocol. Further alternatively or additionally, the imaging protocol information comprises a parameter of the at least one labeled radiopharmaceutical agent. Still further alternatively or additionally, the imaging protocol information comprises a parameter useful for configuring at least one aspect of an imaging procedure performed using the at least one labeled radiopharmaceutical agent.

In an embodiment, the container contains a single dose of the radiopharmaceutical agent, which dose is appropriate for use with the imaging protocol information. Alternatively, the container contains a plurality of labeled radiopharmaceutical agents mixed together. For some applications, the container is shaped so as to define a plurality of chambers, each of which contains a respective one of a plurality of labeled radiopharmaceutical agents.

In an embodiment, the data carrier comprises a first data carrier, which contains a first identifier value, the apparatus further comprises a second computer-communicatable data carrier, which contains a second identifier value, and the apparatus is configured to operate responsively to a detection of a correspondence between the first and second identifier values. For some applications, at least one of the first and second data carriers is configured to perform the detection of the correspondence. Alternatively or additionally, the apparatus comprises a correspondence-detection element configured to perform the detection of the correspondence.

In an embodiment, at least one of the first and second data carriers contains an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.

For some applications, at least one of the first and second identifier values comprises an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.

In an embodiment, exactly one of the first and second data carriers comprises a coupling mechanism configured to be coupled to a patient to whom the labeled radiopharmaceutical agent is to be administered.

In an embodiment, the apparatus comprises an imaging system comprising imaging functionality, the imaging system configured, responsively to the detection of the correspondence, to drive the imaging functionality to perform an imaging procedure using the at least one labeled radiopharmaceutical agent.

In an embodiment, the data carrier is physically coupled to the container. For some applications, the data carrier contains an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered, and the imaging protocol information comprises imaging protocol information selected for the patient. For some applications, the imaging protocol information comprises an identifier of an imaging protocol.

For some applications, the imaging protocol information comprises imaging protocol information customized for the patient.

In an embodiment, the imaging protocol information comprises SPECT imaging protocol information, such as dynamic SPECT imaging protocol information. For some applications, the SPECT imaging protocol information comprises at least one kinetic parameter of the at least one labeled radiopharmaceutical agent, the at least one kinetic parameter useful for performing a dynamic SPECT imaging procedure using the at least one labeled radiopharmaceutical agent.

In an embodiment, the apparatus comprises an imaging system, which comprises a communication element, configured to read the imaging protocol information from the data carrier; and a control unit, comprising imaging functionality, which is configured to perform an imaging procedure, and to configure the procedure at least in part responsively to the imaging protocol information read from the data carrier by the communication element.

In an embodiment, the imaging system comprises a camera, wherein the imaging functionality comprises image acquisition functionality, and wherein the image acquisition functionality is configured to perform an image acquisition procedure using the camera, and to configure the procedure at least in part responsively to the imaging protocol information read from the data carrier by the communication element. For some applications, the image acquisition functionality configures a total acquisition time of the image acquisition procedure at least in part responsively to the imaging protocol information. Alternatively or additionally, the camera comprises a plurality of detectors, and wherein the image acquisition functionality is configured to configure, at least in part

responsively to the imaging protocol information, at least one motion of at least one of the detectors during the image acquisition procedure. For some applications, the control unit is configured to configure, at least in part responsively to the imaging protocol information, a waiting time between administration of the labeled radiopharmaceutical agent and commencement of the image acquisition procedure. For some applications, the image acquisition functionality is configured to perform a gated image acquisition procedure at least in part responsively to the imaging protocol information.

In an embodiment, the imaging functionality comprises image reconstruction functionality, and wherein the image reconstruction functionality is configured to perform an image reconstruction procedure, and to configure the procedure at least in part responsively to the imaging protocol information read from the data carrier by the communication element.

In an embodiment, the imaging functionality comprises image analysis functionality, and wherein the image analysis functionality is configured to perform an image analysis procedure, and to configure the procedure at least in part responsively to the imaging protocol information read from the data carrier by the communication element.

In an embodiment, the imaging functionality comprises diagnosis functionality, and wherein the diagnosis functionality is configured to perform a diagnostic procedure, and to configure the procedure at least in part responsively to the imaging protocol information read from the data carrier by the communication element.

In an embodiment, the imaging procedure includes a three-dimensional dynamic imaging study, and wherein the imaging functionality is configured to perform the three-dimensional dynamic imaging study, and to configure the study at least in part responsively to the imaging protocol information read from the data carrier by the communication element.

In an embodiment, the data carrier is not physically coupled to the container, and wherein the data carrier contains an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered. For some applications, the data carrier comprises a coupling mechanism configured to be coupled to the patient. In an embodiment, the data carrier comprises a first data carrier, and wherein the apparatus further comprises a second computer-communicatable data carrier physically coupled to

the container, the second data carrier containing radiopharmaceutical information regarding the at least one labeled radiopharmaceutical agent.

There is also provided, in accordance with an embodiment of the present invention, apparatus for use with at least one labeled radiopharmaceutical agent, the apparatus comprising:

a container containing the at least one labeled radiopharmaceutical agent; and

a computer-communicatable data carrier associated with the container, the data carrier containing authenticatable information regarding a commercial license for use of SPECT imaging protocol information with the at least one labeled radiopharmaceutical agent.

In an embodiment, the apparatus comprises an imaging system, which comprises:

a communication element, configured to read the authenticatable license information from the data carrier;

a control unit, comprising imaging functionality, the control unit configured to:

authenticate the authenticatable license information, and

only upon authentication, drive the imaging functionality to perform an imaging procedure using the SPECT imaging protocol information.

For some applications, the apparatus comprises a device configured to write the authenticatable license information to the data carrier.

For some applications, the data carrier is physically coupled to the container.

There is further provided, in accordance with an embodiment of the present invention, apparatus comprising a portable computer-communicatable data carrier containing authenticatable information regarding a commercial license for use of SPECT imaging protocol information.

For some applications, the data carrier additionally contains patient information regarding a patient upon whom an imaging procedure using the SPECT imaging protocol information is to be performed.

For some applications, the authenticatable license information is encrypted.

In an embodiment, the apparatus comprises an imaging system, which comprises:

a communication element, configured to read the authenticatable license

information from the data carrier;

a control unit, comprising imaging functionality, the control unit configured to:

authenticate the authenticatable license information, and

only upon authentication, drive the imaging functionality to perform an imaging procedure using the SPECT imaging protocol information.

For some applications, the apparatus comprises a device configured to write the authenticatable license information to the data carrier.

For some applications, the data carrier comprises a coupling mechanism configured to be coupled to a patient upon whom an imaging procedure using the SPECT imaging protocol information is to be performed.

There is still further provided, in accordance with an embodiment of the present invention, apparatus comprising:

a first portable computer-communicatable data carrier containing a first identifier value;

a second portable computer-communicatable data carrier containing a second identifier value; and

an imaging system comprising imaging functionality, the imaging system configured, responsively to a detection of a correspondence between the first and second identifier values, to drive the imaging functionality to perform an imaging procedure on a patient.

For some applications, at least one of the first and second data carriers is configured to perform the detection of the correspondence. Alternatively or additionally, the imaging system comprises a correspondence-detection element configured to perform the detection of the correspondence.

For some applications, at least one of the first and second data carriers contains an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.

For some applications, at least one of the first and second identifier values comprises an identifier of a patient to whom the labeled radiopharmaceutical agent is to be administered.

In an embodiment, one of the first and second data carriers comprises a coupling

mechanism configured to be coupled to a patient to whom the labeled radiopharmaceutical agent is to be administered.

For some applications, the apparatus comprises a device configured to write at least one of the first and second identifier values to the respective first and second data carriers.

In an embodiment, at least one of the first and second data carriers contains radiopharmaceutical information regarding at least one labeled radiopharmaceutical agent, the imaging system comprises a communication element, configured to read the radiopharmaceutical information from the at least one of the data carriers, and the imaging system is configured to configure the imaging procedure at least in part responsively to the read radiopharmaceutical information. For some applications, the apparatus comprises a container containing the at least one labeled radiopharmaceutical agent. For some applications, one of the first and second data carriers is physically coupled to the container.

In an embodiment, the imaging functionality comprises a nuclear camera. For some applications, the nuclear camera comprises a SPECT camera.

There is yet further provided, in accordance with an embodiment of the present invention, apparatus for use with first and second portable computer-communicatable data carriers containing first and second identifier values, respectively, the apparatus comprising an imaging system, which comprises:

imaging functionality; and

a control unit configured to drive the imaging functionality to perform an imaging procedure on a patient, responsively to a detection of a correspondence between the first and second identifier values.

For some applications, the imaging system comprises a correspondence-detection element configured to perform the detection of the correspondence.

There is additionally provided, in accordance with an embodiment of the present invention, apparatus for use with at least one labeled radiopharmaceutical agent for administration to a patient, the apparatus comprising:

a container containing the at least one labeled radiopharmaceutical agent;

a first computer-communicatable data carrier physically coupled to the container,

the first data carrier containing radiopharmaceutical information regarding the at least one labeled radiopharmaceutical agent; and

a second portable computer-communicatable data carrier containing patient information regarding the patient, and imaging protocol information for use with the at least one labeled radiopharmaceutical agent.

For some applications, the imaging protocol information comprises SPECT imaging protocol information.

For some applications, the patient information comprises an identifier of the patient.

For some applications, the second data carrier comprises a coupling mechanism configured to be coupled to the patient.

For some applications, the first data carrier contains a first patient identifier, the patient information contained in the second data carrier comprises a second patient identifier, and the apparatus comprises an administration system, which comprises:

a first communication element, configured to read the first patient identifier from the first data carrier;

a second communication element, configure to read the second patient identifier from the second data carrier; and

a control unit, configured to compare the first patient identifier to the second patient identifier, and, upon detecting a match, generate an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container.

For some applications, the first data carrier contains a first protocol identifier, the imaging protocol information contained in the second data carrier comprises a second protocol identifier, and the apparatus comprises an administration system, which comprises:

a communication element, configured to read the first and second protocol identifiers from the first and second data carriers, respectively; and

a control unit, configured to compare the first protocol identifier to the second protocol identifier, and, upon detecting a match, generate an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container.

For some applications, the first data carrier contains a first protocol identifier, the imaging protocol information contained in the second data carrier comprises a second protocol identifier, and the apparatus comprises an administration system, which comprises:

a first communication element, configured to read the first protocol identifier from the first data carrier;

a second communication element, configured to read the second protocol identifier from the second data carrier; and

a control unit, configured to compare the first protocol identifier to the second protocol identifier, and, upon detecting a match, generate an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container.

In an embodiment, the apparatus comprises an administration system, which comprises:

a communication element; and

a control unit, configured to:

generate an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container, and

drive the communication element to transmit information regarding the administration to the second data carrier.

For some applications, the apparatus comprises a device configured to write the imaging protocol information to the first data carrier. Alternatively or additionally, the apparatus comprises a device configured to write the patient information to the second data carrier.

In an embodiment, the imaging protocol information comprises imaging protocol information selected for the patient. For some applications, the imaging protocol information comprises an identifier of an imaging protocol. For some applications, the imaging protocol information comprises imaging protocol information customized for the patient.

In an embodiment, the first data carrier contains a first patient identifier, the patient information contained in the second data carrier includes a second patient identifier, and the apparatus comprises an administration system, which comprises:

a communication element, configured to read the first and second patient identifiers from the first and second data carriers, respectively; and

a control unit, configured to compare the first patient identifier to the second patient identifier, and, upon detecting a match, generate an administration signal that triggers administration to the patient of the at least one labeled radiopharmaceutical agent contained in the container.

For some applications, the administration system comprises an automated administration device, configured to administer the at least one labeled radiopharmaceutical agent to the patient upon being triggered by the administration signal.

For some applications, the control unit is configured to generate the administration signal to trigger the administration of the at least one labeled radiopharmaceutical agent by instructing a healthcare worker to administer the at least one labeled radiopharmaceutical agent to the patient.

There is yet additionally provided, in accordance with an embodiment of the present invention, apparatus for use with at least one labeled radiopharmaceutical agent for administration to a patient, the apparatus comprising:

a container containing the at least one labeled radiopharmaceutical agent;

a computer-communicatable data carrier associated with the container, the data carrier containing data regarding at least one of: the labeled radiopharmaceutical agent and the patient; and

a SPECT imaging system comprising:

a communication element, configured to read the data; and

a control unit, configured to utilize the read data to customize at least one function of the system selected from the group consisting of: administration of the labeled radiopharmaceutical agent, acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered, reconstruction of the SPECT image, analysis of the SPECT image, and diagnosis of a condition of the patient based at least in part on the analysis.

For some applications, the data carrier contains the data regarding the labeled radiopharmaceutical agent. Alternatively or additionally, the data carrier contains the data regarding the patient.

For some applications, the control unit is configured to utilize the read data to customize the administration of the labeled radiopharmaceutical agent. Alternatively or additionally, the control unit is configured to utilize the read data to customize the acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered. Further alternatively or additionally, control unit is configured to utilize the read data to customize the reconstruction of the SPECT image. Still further alternatively or additionally, the control unit is configured to utilize the read data to customize the analysis of the SPECT image. Alternatively or additionally, the control unit is configured to utilize the read data to customize the diagnosis of a condition of the patient based at least in part on the analysis.

For some applications, the apparatus comprises a device configured to write the data to the data carrier.

There is also provided, in accordance with an embodiment of the present invention, a SPECT imaging system for use with a container containing at least one labeled radiopharmaceutical agent for administration to a patient, and data regarding at least one of: the labeled radiopharmaceutical agent and the patient, the system comprising:

a communication element, configured to read the data; and

a control unit, configured to utilize the read data to customize at least one function of the system selected from the group consisting of: administration of the labeled radiopharmaceutical agent, acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered, reconstruction of the SPECT image, analysis of the SPECT image, and diagnosis of a condition of the patient based at least in part on the analysis.

For some applications, the system comprises a device configured to write the data to the container.

There is further provided, in accordance with an embodiment of the present invention, an automated radiopharmaceutical dispensing system for use with a container and a computer-communicatable container data carrier associated with the container, the system comprising:

a robot, configured to manipulate the container;

a communication element; and

a control unit, configured to:

receive radiopharmaceutical information regarding at least one labeled radiopharmaceutical agent, the radiopharmaceutical information selected from the group consisting of: imaging protocol information for use with the at least one labeled radiopharmaceutical agent, and authenticatable information regarding a commercial license for use of an imaging protocol with the at least one labeled radiopharmaceutical agent,

receive patient information regarding a patient,

drive the robot to automatically dispense a dose of the labeled radiopharmaceutical agent to the container, and

drive the communication element to transmit to the container data carrier at least a portion of the radiopharmaceutical information and at least a portion of the patient information.

For some applications, the control unit is configured to receive the radiopharmaceutical information regarding a plurality of labeled radiopharmaceutical agents, and drive the robot to automatically dispense respective doses of the labeled radiopharmaceutical agents to the container.

For some applications, the patient information includes an identifier of an imaging protocol assigned to the patient for performance using the dose, and wherein the control unit is configured to drive the communication element to transmit the imaging protocol identifier to the container data carrier.

For some applications, the control unit is configured to drive the communication element to transmit to the container data carrier at least one of: a time of dispensing of the labeled radiopharmaceutical agent to the container, and information regarding a radioactivity of the dose at the time of dispensing.

In an embodiment, the apparatus comprises:

a mother vial that contains the labeled radiopharmaceutical agent prior to dispensing thereof; and

a computer-communicatable mother vial data carrier associated with the mother vial, which mother vial data carrier contains the radiopharmaceutical information,

wherein the control unit is configured to receive the radiopharmaceutical

information from the mother vial data carrier.

For some applications, the radiopharmaceutical information comprises the imaging protocol information. For some applications, the imaging protocol information comprises SPECT imaging protocol information, which may comprise at least one kinetic parameter of the at least one labeled radiopharmaceutical agent.

In an embodiment, the radiopharmaceutical information comprises the authenticatable information regarding the commercial license. For some applications, the information regarding the commercial license comprises information regarding the commercial license for use of a SPECT imaging protocol with the at least one labeled radiopharmaceutical agent. For some applications, the control unit is configured to authenticate the authenticatable license information, and to drive the robot to automatically dispense the dose only upon authentication.

There is still further provided, in accordance with an embodiment of the present invention, apparatus for use with a container, the apparatus comprising:

a mother vial having a volume of at least 10 ml, which contains at least 5 ml of a non-diluted labeled radiopharmaceutical agent, and at least 5 ml of saline solution; and

an automated radiopharmaceutical dispensing system, configured to contain the mother vial, and to dispense at least one dose from the mother vial to the container.

There is additionally provided, in accordance with an embodiment of the present invention, a method comprising:

placing at least one labeled radiopharmaceutical agent in a container;

associating a portable computer-communicatable data carrier with the container; and

writing, to the data carrier, imaging protocol information for use with the at least one labeled radiopharmaceutical agent.

There is yet additionally provided, in accordance with an embodiment of the present invention, a method comprising:

placing at least one labeled radiopharmaceutical agent in a container;

associating a computer-communicatable data carrier with the container; and

writing, to the data carrier, authenticatable information regarding a commercial license for use of SPECT imaging protocol information with the at least one labeled

radiopharmaceutical agent.

There is also provided, in accordance with an embodiment of the present invention, a method comprising:

providing a portable computer-communicatable data carrier; and

writing, to the data carrier, authenticatable information regarding a commercial license for use of SPECT imaging protocol information.

There is further provided, in accordance with an embodiment of the present invention, a method comprising:

writing first and second identifier values to first and second computer-communicatable data carriers, respectively;

detecting a correspondence between the first and second identifier values; and

perform an imaging procedure on a patient responsively to the detecting.

There is still further provided, in accordance with an embodiment of the present invention, a method for use with at least one labeled radiopharmaceutical agent for administration to a patient, the method comprising:

placing at least one labeled radiopharmaceutical agent in a container;

physically coupling a first computer-communicatable data carrier to the container;

writing, to the first data carrier, radiopharmaceutical information regarding the at least one labeled radiopharmaceutical agent; and

writing, to a second portable computer-communicatable data carrier, patient information regarding the patient, and imaging protocol information for use with the at least one labeled radiopharmaceutical agent.

There is additionally provided, in accordance with an embodiment of the present invention, a method comprising:

placing, in a container, at least one labeled radiopharmaceutical agent for administration to a patient;

associating a computer-communicatable data carrier with the container;

writing data to the data carrier regarding at least one of: the labeled radiopharmaceutical agent and the patient;

reading the data from the data carrier at a SPECT imaging system;

utilizing the read data to customize at least one function of the system selected

from the group consisting of: administration of the labeled radiopharmaceutical agent, acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered, reconstruction of the SPECT image, analysis of the SPECT image, and diagnosis of a condition of the patient based at least in part on the analysis.

There is yet additionally provided, in accordance with an embodiment of the present invention, a method for use with a container containing at least one labeled radiopharmaceutical agent for administration to a patient, and data regarding at least one of: the labeled radiopharmaceutical agent and the patient, the method comprising:

reading the data at a SPECT imaging system; and

utilizing the read data to customize at least one function of the system selected from the group consisting of: administration of the labeled radiopharmaceutical agent, acquisition of a SPECT image of the patient to whom the labeled radiopharmaceutical agent is administered, reconstruction of the SPECT image, analysis of the SPECT image, and diagnosis of a condition of the patient based at least in part on the analysis.

There is also provided, in accordance with an embodiment of the present invention, a method for use with a container and a computer-communicatable container data carrier associated with the container, the method comprising:

receiving, by an automated radiopharmaceutical dispensing system, radiopharmaceutical information regarding at least one labeled radiopharmaceutical agent, the radiopharmaceutical information selected from the group consisting of: imaging protocol information for use with the at least one labeled radiopharmaceutical agent, and authenticatable information regarding a commercial license for use of an imaging protocol with the at least one labeled radiopharmaceutical agent;

receiving, by the dispensing system, patient information regarding a patient;

automatically robotically dispensing, by the dispensing system, a dose of the labeled radiopharmaceutical agent to the container; and

transmitting to the container data carrier, by the dispensing system, at least a portion of the radiopharmaceutical information and at least a portion of the patient information.

There is further provided, in accordance with an embodiment of the present invention, a method for automatically dispensing a labeled radiopharmaceutical agent to a

container, comprising:

providing a mother vial having a volume of at least 10 ml;

filling the mother vial with at least 5 ml of a non-diluted labeled radiopharmaceutical agent, and with at least 5 ml of saline solution;

placing the mother vial in an automated radiopharmaceutical dispensing system; and

dispensing at least one dose from the mother vial to the container.

There is also provided, in accordance with an embodiment of the present invention, a method for setting a dose of a labeled radiopharmaceutical agent for use for performing an imaging procedure on a patient for studying a physiological characteristic of the patient, the method including:

selecting the radiopharmaceutical agent;

receiving information regarding a medical parameter of the patient not directly related to the physiological characteristic of the patient; and

setting the dose at least in part responsively to the received information.

There is further provided, in accordance with an embodiment of the present invention, a substance associated with a time-dependent substance intake program generated by a computer controlled functionality employing a machine readable multi-parameter human physiological profile including at least one of a kinetic and intra-body location dependent parameter and a machine readable multi-parameter substance profile, including at least one kinetic parameter.

There is still further provided, in accordance with an embodiment of the present invention, a computer controlled functionality employing a machine readable multi-parameter human physiological profile including at least one of a kinetic and intra-body location dependent parameter and a machine readable multi-parameter substance profile, including at least one kinetic parameter, for indicating a time-dependent substance intake program.

There is yet further provided, in accordance with an embodiment of the present invention, a substance associated with a time-dependent substance intake program generated by a computer controlled functionality employing a machine readable multi-parameter human physiological profile including at least one of a kinetic and

intra-body location dependent parameter and a machine readable multi-parameter substance profile, including at least one kinetic parameter.

There is also provided, in accordance with an embodiment of the present invention, a time-dependent substance intake program generated by a computer controlled functionality employing a machine readable multi-parameter human physiological profile including at least one of a kinetic and intra-body location dependent parameter and a machine readable multi-parameter substance profile, including at least one kinetic parameter.

There is further provided, in accordance with an embodiment of the present invention, a substance formulated in accordance with a time-dependent substance intake program generated by a computer controlled functionality employing a machine readable multi-parameter human physiological profile including at least one of a kinetic and intra-body location dependent parameter and a machine readable multi-parameter substance profile, including at least one kinetic parameter.

There is still further provided, in accordance with an embodiment of the present invention, an apparatus, method, and/or functionality for generation of a machine readable multi-parameter human physiological profile including at least one of a kinetic and intra-body location dependent parameter, including providing a time-dependent substance intake program; a data acquisition system which acquires data from the patient passing through the intake program; and a computerized analysis using a machine readable multi-parameter substance profile, including at least one kinetic parameter.

There is yet further provided, in accordance with an embodiment of the present invention, an apparatus, method, and/or functionality for generation of a human physiological profile, including providing a substance intake program; a data acquisition system which acquires data from the patient passing through the intake program; and a computerized analysis using a substance profile, including at least one kinetic parameter.

There is also provided, in accordance with an embodiment of the present invention, an interactive pharmaceutical-containing, machine-readable information-bearing, customized medicine module suitable for use in computerized customized medicine, said customized medicine module including a computerized

customized medicine machine-interfaceable pharmaceutical-containing delivery module and a computerized individualized medicine machine-readable information-containing carrier containing at least data regarding said pharmaceutical which is required for use of said pharmaceutical in computerized customized medicine, said data being useful in computerized customized medicine machine actuation of said pharmaceutical-containing delivery module.

There is additionally provided, in accordance with an embodiment of the present invention, a computerized customized medicine machine including:

a computerized patient imager;

a computerized pharmaceutical deliverer employing a pharmaceutical-containing, machine-readable information-bearing, customized medicine module; and

a customized medicine protocol controller including:

an interactive patient imager interface including patient information receiving functionality and patient imaging actuation functionality; and

an interactive pharmaceutical deliverer interface including patient information receiving functionality and patient information-responsive pharmaceutical delivery actuation functionality.

There is also provided, in accordance with an embodiment of the present invention, an interactive pharmaceutical-containing, machine-readable authenticated, authenticated customized medicine module suitable for use in computerized customized medicine, said customized medicine module including a computerized customized medicine machine-interfaceable pharmaceutical-containing module and a computerized individualized medicine machine-readable authentication-containing carrier containing at least authentication data regarding said pharmaceutical which is required for use of said pharmaceutical in computerized customized medicine, said data being useful in said computerized customized medicine machine.

There is further provided, in accordance with an embodiment of the present invention, a computerized customized medicine preparation machine including:

a computerized patient information manager;

a computerized customized medicine pharmaceutical information manager;

a computerized authenticated customized medicine module authenticator; and

a computerized pharmaceutical-containing, machine-readable information-bearing, customized medicine module generator including:

a computerized generator protocol manager operative to receive patient information from said patient information manager, to receive authentication of an authenticated customized medicine module from said authenticator, to receive customized medicine pharmaceutical information relating to at least one pharmaceutical contained in said authenticated customized medicine module from said pharmaceutical information manager and to prepare customized medicine information to be included in said customized medicine module; and

a computerized pharmaceutical-containing, machine-readable information-bearing, customized medicine module preparer operative to associate said customized medicine information prepared by said protocol manager in an authenticatable machine readable form with a quantity of said pharmaceutical contained in said authenticated customized medicine module, thereby providing a pharmaceutical-containing, machine-readable information-bearing, customized medicine module.

There is still further provided, in accordance with an embodiment of the present invention, an interactive pharmaceutical-containing, machine-readable information-bearing, individualized medicine module suitable for use in computerized individualized medicine, said individualized medicine module including a computerized individualized medicine machine actuable pharmaceutical-containing delivery module and a computerized individualized medicine machine-readable information-containing carrier containing at least data regarding said pharmaceutical which is required for use of said pharmaceutical in computerized individualized medicine, said data being useful in computerized individualized medicine machine actuation of said pharmaceutical-containing delivery module.

For some applications, said data is in an encrypted format, readable by said computerized individualized medicine machine upon receipt of a predetermined authentication.

There is also provided, in accordance with an embodiment of the present invention, a computerized individualized medicine machine including:

a computerized patient imager;

a computerized pharmaceutical deliverer employing a pharmaceutical-containing, machine-readable information-bearing, individualized medicine module; and

an individualized medicine protocol controller including:

an interactive patient imager interface including patient image receiving functionality and patient imaging actuation functionality; and

an interactive pharmaceutical deliverer interface including patient image receiving functionality and patient image-responsive pharmaceutical delivery actuation functionality.

There is further provided, in accordance with an embodiment of the present invention, use of a high definition, high sensitivity camera for determination of an optimal parameter for a labeled radiopharmaceutical agent, the optimal parameter selected from the group consisting of: optimal dose, optimal mode of administration, optimal mode of acquisition of data with respect to the labeled radiopharmaceutical agent, optimal mode of data processing with respect to the labeled radiopharmaceutical agent, and optimal mode of presentation of information acquired with respect to the labeled radiopharmaceutical agent.

There is still further provided, in accordance with an embodiment of the present invention, a labeled radiopharmaceutical agent that is manufactured or designed or indicated for use with or sold with any one of the above techniques.

The present invention will be more fully understood from the following detailed description of embodiments thereof, taken together with the drawings, in which:

## BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic illustration of an end-to-end automated system for medical imaging, in accordance with an embodiment of the present invention;

Fig. 2 is a flow chart showing an end-to-end method for medical imaging, in accordance with an embodiment of the present invention;

Fig. 3 is a schematic illustration of a patient-specific data carrier, in accordance with an embodiment of the present invention;

Fig. 4 is a schematic illustration of a patient management system, in accordance with an embodiment of the present invention;

Fig. 5 is a schematic illustration of a radiopharmaceutical dose calculation system, in accordance with an embodiment of the present invention;

Figs. 6A-E are tables showing exemplary preconfigured SPECT protocols and parameters thereof, in accordance with respective embodiments of the present invention;

Fig. 7 is a schematic illustration of a mother vial and attached data carrier, in accordance with an embodiment of the present invention;

Fig. 8 is a schematic illustration of a data carrier coupled to a radiopharmaceutical agent container, in accordance with an embodiment of the present invention;

Figs. 9A-H are schematic illustrations of respective embodiments of a radiopharmaceutical agent container and data carrier coupled thereto, in accordance with respective embodiments of the present invention;

Fig. 10 is a schematic illustration of an administration system, in accordance with an embodiment of the present invention;

Fig. 11 is a schematic illustration of an imaging system, in accordance with an embodiment of the present invention;

Fig. 12 is a schematic illustration of an automated radiopharmaceutical dispensing system, in accordance with an embodiment of the present invention;

Figs. 13A-C are schematic illustrations of a system for carrying out a data transfer process, in accordance with an embodiment of the present invention;

Fig. 14 is a schematic illustration of a radioisotope automatic elution system, in accordance with an embodiment of the present invention;

Fig. 15 is a schematic illustration of a mother vial preparation system, in accordance with an embodiment of the present invention;

Figs. 16A-B are illustrations of color spectra and a color-coded signature, respectively, in accordance with an embodiment of the present invention;

Fig. 17 is a schematic illustration of a computer-readable medium, a portion of which is shaped so as to define a physical key, in accordance with an embodiment of the present invention; and

Fig. 18 is a graph showing particle energy vs. photon count at a detector of a

camera, in accordance with an embodiment of the present invention.

## DETAILED DESCRIPTION OF EMBODIMENTS

Fig. 1 is a schematic illustration of an end-to-end automated system 10 for medical imaging, in accordance with an embodiment of the present invention. System 10 comprises a plurality of integrated elements that are configured to electronically exchange information among one another. The elements include an automated radiopharmaceutical dispensing system 20, a portable information-bearing radiopharmaceutical agent container 22, a portable patient-specific data carrier 24, an automated administration system 26, and an automated imaging system 28. The systems perform their respective automated functions at least in part responsively to the exchanged information. The elements typically authenticate one another via the exchanged information, in order to ensure that only authorized elements participate in the system, and that only authorized and appropriate functions are performed. Each of the elements is described in detail hereinbelow.

*End-to-end imaging method*

Fig. 2 is a flow chart showing an end-to-end method for medical imaging, in accordance with an embodiment of the present invention. At a radiopharmaceutical provisioning step 100, a manufacturer 102 (Fig. 1) or distributor provides a mother vial 104 (Fig. 1) containing an unlabeled radiopharmaceutical agent, and information associated with the radiopharmaceutical agent. Such an unlabeled radiopharmaceutical agent typically comprises a pharmaceutical substance, for example an antibody such as Capromab Pendetide marketed by Cytogen Corp. under the name ProstaScint and used in the detection of prostate cancer metastases, or sestamibi used in cardiac perfusion studies and marketed under the name of Cardiolite by Bristol Meyers Squibb Corporation, an ion, or another biological metabolized substance, or a substance which is not metabolized but nevertheless undergoes an interaction with the body. The information is stored in a mother vial data carrier 106 associated with mother vial 104, as described hereinbelow with reference to Fig. 7. For some applications, data carrier 106 is physically coupled to mother vial 104, while for other applications the data carrier is provided as a separate element associated with the mother vial. As described hereinbelow with reference to Fig. 7, the information stored in data carrier 106 typically includes information regarding the

radiopharmaceutical agent, such as the formulation, pharmacologic kinetic parameters, radioactivity information, and/or protocol information.

At a labeling step 110, the unlabeled radiopharmaceutical agent is labeled with an appropriate radioisotope, to produce a labeled radiopharmaceutical agent. Such labeling is typically performed using conventional methods, including mixing the agent with a solution containing the radioisotope, heating the mixture, and performing quality testing on the labeled radiopharmaceutical agent. For some applications, step 110 is performed using conventional radiopharmacy labeling techniques, while for other applications system 10 comprises a mother vial preparation system 700, which automatically performs all or a portion of the labeling, as described hereinbelow with reference to Fig. 15. The radioisotopes are provided by a radioisotope supplier 111, such as a conventional radiopharmacy or an automatic elution system 600, described hereinbelow with reference to Fig. 14. Data carrier 106 is typically updated with radioactivity-related information, including the time of labeling, the radioactivity of the radioisotope at the time of labeling, and the volume of the labeled radiopharmaceutical agent, as described hereinbelow with reference to Fig. 7.

For some applications, the only active constituent of the labeled radiopharmaceutical agent is the radioisotope; in other words, the radioisotope is not bound to a biologically active substance. For example, the labeled radiopharmaceutical agent may consist essentially of thallium (as well as pH-balancing constituents, salt ions, and preservatives). As used in the present application, including in the claims, a "labeled radiopharmaceutical agent" means either: (a) an agent comprising a diagnostic radioisotope, such as thallium, or (b) an agent comprising a radioisotope bound to a biologically active substance, such as an antibody, a pharmaceutical compound, an ion, or another biological metabolized substance, or a substance which is not metabolized but nevertheless undergoes an interaction with the body.

At a patient registration and imaging protocol assignment step 112, a healthcare worker 206 uses a patient management system 160 to register a patient into system 10, and to assign appropriate administration and imaging protocols for the patient, as described in detail hereinbelow with reference to Fig. 4. At an information transfer step 114, patient management system 160 assigns a portable patient-specific data carrier 24 to the patient, and transmits information to data carrier 24, including at least a patient

identifier (typically, the patient's identification code and/or name), and the assigned administration and imaging protocols. Additional patient data parameters recorded may include physiological data such as girth, height and weight. The patient management system additionally transmits an order for one or more patient-specific doses of the appropriate labeled radiopharmaceutical agent(s) to dispensing system 20 or a conventional radiopharmacy.

At a dose dispensing step 116, dispensing system 20 dispenses the ordered customized dose of the labeled radiopharmaceutical agent from mother vial 104, as described in detail hereinbelow with reference to Fig. 12. Prior to dispensing the dose, dispensing system 20 typically authenticates the mother vial using information stored in mother vial data carrier 106. For some applications, dispensing system 20 verifies the authenticity of a commercial license contained in data carrier 106. Typically, all or a portion of the information used for such verification is encrypted, and dispensing system 20 decrypts the information during the verification procedure. Alternatively or additionally, dispensing system 20 accesses, over a network, information stored at a remote site, and utilizes the information for such verification. The dispensing system dispenses the dose based on patient-specific prescription information, radiopharmaceutical agent-related information stored in data carrier 106, and/or patient-specific information provided by an element of system 10. Such patient-specific information may include, for example, age, weight, Body Mass Index (BMI), body dimensions, metabolic rate, hemodynamic state, and/or kinetic parameters of the labeled radiopharmaceutical agent as determined during previous imaging procedures performed on the patient. For some applications, dosage information is provided directly or indirectly by patient management system 160 and/or a radiopharmaceutical dose calculation system 152, which are described hereinbelow with reference to Figs. 4 and 5, respectively.

At an information transfer step 118, dispensing system 20 transfers patient-specific information and radiopharmaceutical-related information to a data carrier 120 physically coupled to container 22, as described hereinbelow with reference to Figs. 9A-H and 10. "Physically coupled," as used in the present application, including the claims, includes both direct and indirect physical coupling. For example, data carrier 120 may be indirectly physically coupled to container 22 via shielding of container 22, or shielding of a cylinder in which container 22 is stored during transport and handling

thereof. The patient-specific information includes the patient's identification code and/or name, and the assigned administration and imaging protocols. The radiopharmaceutical-related information typically includes: (a) all or a portion of the information provided by the manufacturer in data carrier 106, such as described hereinbelow with reference to Fig. 7, e.g., intended use, formulation, pharmacologic kinetic parameters, and protocol information; (b) information regarding the radioactivity and volume of the dose; and (c) time of dispensing, as described in detail hereinbelow with reference to Fig. 8. In addition, the dispensing system typically prints and attaches a conventional information label to container 22, such as in order to comply with regulatory labeling requirements. For applications in which the labeled radiopharmaceutical agent(s) is dispensed using conventional radiopharmacy techniques, dispensing system 20, or another element of system 10, such as dose calculation system 152, typically transfers the radiopharmaceutical-related information to data carrier 120. Alternatively, all or a portion of the information is transferred directly from mother vial data carrier 106 to container data carrier 120.

At an administration step 122, administration system 26 receives radiopharmaceutical agent container 22, and administers the labeled radiopharmaceutical agent contained therein to the appropriate patient. As described hereinbelow with reference to Fig. 10, for some applications, administration system 26 comprises an automated administration device, which is configured to administer the labeled radiopharmaceutical agent, while for other applications, a healthcare worker manually administers the agent upon receiving a signal to do so from system 26. Prior to administration, system 26 authenticates container 22 and verifies the identity of the patient, using information provided by patient-specific data carrier 24 and container data carrier 120, and, optionally, another element of system 10, such as a physician station 115. Typically, all or a portion of the information used for such verification is encrypted, and administration system 26 decrypts the information during the verification procedure. Alternatively or additionally, administration system 26 accesses, over a network, information stored at a remote site, and utilizes the information for such verification. Administration system 26 verifies that the patient identification codes contained in patient-specific data carrier 24 and container data carrier 120 match one another, and, typically, verifies that the administration and/or imaging protocols contained in the data carriers match one another. Typically, at least a portion of the information stored in data

carrier 120 of container 22 is transferred to data carrier 24, either directly, via administration system 26, or via a communication element. For some applications, system 26 generates a signal for a healthcare worker confirming that a proper match has been made between agent container 22 and the patient. The system also typically verifies that the current time is the proper administration time, as per the administration protocol, and that container 22 contains the proper dose, as per the selected protocol. Optionally, system 26 is configured to administer the labeled radiopharmaceutical agent only if such matches are confirmed by the system. For some applications, administration system 26 verifies the authenticity of a commercial license contained in data carrier 120, and performs the administration only upon verification of the authenticity.

For some applications, administration system 26 customizes the administration of the labeled radiopharmaceutical agent using information provided by data carrier 24, data carrier 120, physician station 115, and/or patient management system 160. For example, system 26 may customize a time-dependent administration profile of the labeled radiopharmaceutical agent, such as a rate of administration. Alternatively or additionally, system 26 may administer less than the entire dose of the labeled radiopharmaceutical agent, e.g., based on feedback from imaging system 28 during an imaging procedure.

For some applications, such as dynamic studies, administration system 26 administers the labeled radiopharmaceutical agent during an imaging procedure performed by imaging system 28. For these applications, the administration system is in communication with the imaging system during the administration, in order to assure information regarding time-dependent administration is accurately communicated between the administration system and the imaging system. For some applications, imaging system 28 reads information from patient-specific data carrier 24, and transmits at least a portion of the information to administration system 26, thereby obviating the need for the administration system to directly read such information from the data carrier. For some applications, imaging system 28 triggers the commencement of administration. (It is to be understood that although the imaging system triggers administration of the agent, for some applications the agent is not administered until a healthcare worker provides a final authorization to do so, such as to comply with regulatory safety requirements.) For some applications, the labeled radiopharmaceutical agent(s) is administered in a closed loop with an imaging procedure performed by imaging system 28; administration system 28 modifies one or more parameters of the administration in

real time based on feedback received from imaging system 28, and/or based on real-time measurements of physiological parameters of the patient (e.g., systemic blood concentrations) during the imaging procedure. For some protocols, the administration system administers a preliminary bolus injection, and, based on feedback from imaging system 28 and/or on physiological parameters of the patient, configures one or more parameters of a subsequent administration of the same or a different labeled radiopharmaceutical agent.

At an information transfer step 123, before, during and/or after administration of the labeled radiopharmaceutical agent, system 26 electronically updates patient-specific data carrier 24 with details of the administration, such as:

- an identification code of container 22 and/or an administration device;
- an identification code of the patient to which the labeled radiopharmaceutical agent was dispensed, which should match the patient code already stored in data carrier 24;
- the administered labeled radiopharmaceutical agent;
- the volume of the labeled radiopharmaceutical agent administered;
- the time of administration;
- the time profile of administration;
- the radioactivity of the labeled radiopharmaceutical agent at the time of administration;
- the radioactivity of the labeled radiopharmaceutical agent when dispensed to container 22;
- the time of measurement of the radioactivity when dispensed to container 22; and/or
- at least a portion of the radiopharmaceutical information provided by data carrier 106 of mother vial 104.

For some applications, data carrier 120 of container 22 communicates administration information to patient-specific data carrier 24, either directly or via administration system 26. For some applications, system 26 provides similar updates to

other elements of system 10, such as patient management system 160, management control component 150, physician station 115, and/or imaging system 28. Alternatively or additionally, a healthcare worker manually updates one or more of the data carrier and/or system elements. Typically, for safety purposes, after administration system 26 has read all necessary information from data carrier 120, administration system 26 permanently disables data carrier 120 of container 22, in order to ensure that the data carrier is not accidentally reused for another patient.

Reference is still made to Fig. 2. After or during administration of the labeled radiopharmaceutical agent, imaging system 28 performs an imaging procedure on the patient, at an imaging step 124. Imaging system 28 is described hereinbelow with reference to Fig. 11. Prior to performing the imaging procedure, system 28 verifies one or more of the following:

- the identity of the patient, using information provided by patient-specific data carrier 24;
- the authenticity of patient-specific data carrier 24, typically using information provided by the data carrier itself, a coded signature 256, as described hereinbelow in the section entitled "Signature," and/or a key 852, as described hereinbelow with reference to Fig. 17;
- that patient-specific data carrier 24 has been brought within a certain distance of imaging system 28, e.g., within about 30 cm;
- the identity of the manufacturer or distributor of the radiopharmaceutical agent, using information stored in data carrier 120;
- that a selected camera of imaging system 28, imaging protocol, and patient identification code, as provided to imaging system 28 by one or more elements of system 10, match those stored in patient-specific data carrier 24;
- the authenticity of a commercial license contained in patient-specific data carrier 24. For some applications, system 28 verifies that the license has not been previously used, for example by verifying that a registration code associated with the license has not been previously received by system 28 and/or system 10; and/or

- that administration system 26 used (or is about to use, for procedures in which administration occurs during imaging) the correct container 22 and associated data carrier 120 for the prescribed imaging procedure, and administered (or is about to administer) the appropriate dose of the labeled radiopharmaceutical agent(s) at time(s) appropriate for performance of the imaging procedure.

Typically, all or a portion of the information used for such verification is encrypted, and imaging system 28 decrypts the information during the verification procedure. Alternatively or additionally, imaging system 28 accesses, over a network, information stored at a remote site, and utilizes the information for such verification.

For some applications, system 28 generates a signal for a healthcare worker confirming that a proper match has been made between the patient and one or more of the components described above. Optionally, system 28 is configured to perform the imaging procedure only if such a match is confirmed by the system.

Typically, system 28 customizes the imaging procedure using information provided by administration system 26, data carrier 24, and/or physician station 115. Such information typically includes information regarding the time of labeled radiopharmaceutical administration, the labeled radiopharmaceutical agent (e.g., radioactive strength, time of preparation, and/or kinetic parameters), patient-specific physiological information, and/or imaging protocol information. Parameters of the imaging procedure that are typically customized include, but are not limited to: total acquisition time; detector motions, such as detector angular and translational motions, detector step size (i.e., the density of the step size, typically expressed in degrees), and detector dwell time at each view; type of study, such as standard, active vision (as described in the above-mentioned International Application PCT/IL2005/001173), or gated; definition of the region of interest (ROI), for example, based on the size of the heart; and/or attenuation correction parameters, which are typically based on physiological parameters such as body mass, BMI, and girth.

At an image reconstruction step 126, imaging system 28 uses the acquired imaging data for image reconstruction. For some applications, system 28 customizes the image reconstruction procedure using information provided by administration system 26, data carrier 24, and/or physician station 115.

Imaging system 28 analyzes the reconstructed image, at an analysis step 128. For some applications, system 28 customizes the analysis procedure using information provided by administration system 26, data carrier 24, and/or physician station 115.

The imaging system, or a separate diagnostic system of system 10, assists with developing a diagnosis based on the analysis, at a diagnosis step 130. Typically, system 28 customizes the diagnostic procedure using information provided by administration system 26, data carrier 24, and/or physician station 115. For some applications, authentication is performed to verify that the imaging was performed as intended. Reconstruction and analysis are preferably based on lookup tables and expert system rules, for example, as provided by the radiopharmaceutical manufacturer, and may be patient customized, taking into account known patient physiology and/or suspected disease. Alternatively or additionally, the lookup tables and/or expert system diagnostic rules are configured to provide such customization. For some applications, customization and/or diagnostic techniques are performed that are described in the above-mentioned International Application PCT/IL2005/001173.

The diagnosis and/or the results of the imaging procedure are typically transmitted to physician station 115, for use by an attending healthcare worker 206. Alternatively or additionally, the diagnosis and/or the results of the imaging procedure are transmitted to a database 132 (Fig. 1). The accumulated results of a number of such imaging procedures for a large population are analyzed in order to develop, optimize, update, or otherwise re-evaluate imaging protocols, and update appropriate lookup tables and/or expert system rules for the use of the radiopharmaceutical agent. For example, the database may contain quantitative data regarding absolute blood flow measurements from healthy patients and patients with varying level of diseases. For some applications, such data is used to obtain disease-specific tissue signatures by performing quantitative analysis of normal and diseased tissue. Alternatively or additionally, the information in database 132 is used for: (a) comparing the results of an imaging procedure (images, and/or quantitative information and/or analyses) with historical results of the patient, in order to classify disease state and/or (b) comparing the results of an imaging procedure with similar results from a patient population, in order to classify disease state.

Typically, physician station 115 comprises one or more standard personal computers or servers with appropriate memory, communication interfaces and software

for carrying out the functions prescribed by relevant embodiments of the present invention. This software may be downloaded to the physician station in electronic form over a network, for example, or it may alternatively be supplied on tangible media, such as CD-ROM.

During or after steps 124 through 128, imaging system 28 updates the data stored in patient-specific data carrier 24 and/or other elements of system 10, such as patient information system 160, and/or physician station 115, to reflect details of the imaging procedure performed. In addition, for some applications, imaging system 28 transfers data to the specific camera used for the procedure, such as patient details, radiopharmaceutical information, and/or administration information, which information is received from data carrier 24, or from other elements of system 10.

*The patient-specific data carrier*

Reference is made to Fig. 3, which is a schematic illustration of patient-specific data carrier 24, in accordance with an embodiment of the present invention. Data carrier 24 is configured to be held or worn by the patient, and, for some applications, comprises a coupling mechanism configured to be coupled to the patient, which coupling mechanism, comprises, for example, a bracelet, watch, or necklace (Fig. 3A shows the data carrier integrated into a watch or bracelet 170). Data carrier 24 is computer-communicatable, and typically comprises an RFID tag, smart card, disk-on-key (e.g., a USB key), or other electronic memory, as described below. Data carrier 24 is configured to hold information regarding the patient and a selected imaging procedure, as described immediately hereinbelow with reference to Fig. 4.

One or more communication elements 240 are provided for reading data from and transmitting data to data carrier 24 e.g., using a proprietary or standard wireless protocol, e.g., Bluetooth, WiFi, W-LAN, or IEEE 802.11. Alternatively, the communication element is brought into physical contact with data carrier 24, and reads and/or writes the information using an electrical contact, or other coupling technique, such as inductive coupling. Respective communication elements 240 are typically in data communication with patient management system 160, physician station 115, dispensing system 20, administration system 26, and/or imaging system 28. For some applications, communication elements 240 comprise one or more coils for transmitting and receiving electromagnetic radiation. Typically, the communication elements are configured to have