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CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Duncan P. Bathe	Nonprovisional Application Number (if known):	Unknown
Title of Invention:	Gas Delivery Device And System		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i), the prioritized examination fee set forth in 37 CFR 1.17(c), and if not already paid, the publication fee set forth in 37 CFR 1.18(d) have been filed with the request. The basic filing fee, search fee, examination fee, and any required excess claims and application size fees are filed with the request or have been already been paid.

2. The application contains or is amended to contain no more than four independent claims and no more than thirty total claims, and no multiple dependent claims.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed oath or declaration under 37 CFR 1.63 is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Rory P. Alegria, Reg. No. 66,947/	Date 6/11/12
Name (Print/Typed) Rory P. Alegria	Practitioner Registration Number 66,947

Note: *Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below*.*

☑ *Total of 1 forms are submitted.

GAS DELIVERY DEVICE AND SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation application of U.S. Patent Application Serial No. 13/509,873 filed on May 15, 2012, which is the National Phase entry of PCT/US2011/020319, filed January 6, 2011, the entire content of which are incorporated herein by reference in their entirety.

TECHNICAL FIELD

[0002] Embodiments of the present invention relate to gas delivery device for use in a gas delivery system for administering therapy gas and methods of administering therapy gas.

BACKGROUND

[0003] Certain medical treatments include the use of gases that are inhaled by the patient. Gas delivery devices are often utilized by hospitals to deliver the necessary gas to patients in need. It is important when administering gas therapy to these patients to verify the correct type of gas and the correct concentration are being used. It is also important to verify dosage information and administration.

[0004] Known gas delivery devices may include a computerized system for tracking patient information, including information regarding the type of gas therapy, concentration of gas to be administered and dosage information for a particular patient. However, these computerized systems often do not communicate with other components of gas delivery devices, for example, the valve that controls the flow of the gas to the computerized system and/or ventilator for administration to the patient. In addition, in known systems, the amount of gas utilized by a single patient is often difficult or impossible to discern, leading to possible overbilling for usage.

[0005] There is a need for a gas delivery device that integrates a computerized system to ensure that patient information contained within the computerized system matches the gas that is to be delivered by the gas delivery device. There is also a need for such an integrated device that does not rely on repeated manual set-ups or connections and which can also track individual patient usage accurately and simply.

SUMMARY

[0006] Aspects of the present invention pertain to a gas delivery device that may be utilized with a gas delivery system and methods for administering therapy gas to a patient. The therapy gas may comprise nitric oxide (NO). One or more embodiments of the gas delivery devices described herein may include a valve and a circuit with a valve memory in communication with a valve processor and a valve transceiver. One or more embodiments of the gas delivery systems described herein incorporate the gas delivery devices described herein with a control module including a control processing unit (CPU) in communication with a CPU memory and CPU transceiver. As will be described herein, the valve transceiver and the CPU transceiver may be in communication such that information or data from the valve memory and the CPU memory may be communicated to one another. The information communicated between the valve memory and the CPU memory may be utilized for selecting a therapy for delivery to a patient and controlling delivery of the selected therapy to the patient. The gas delivery devices and systems described herein may be utilized with medical devices such as ventilators and the like to delivery gas to a patient.

[0007] A first aspect of the present invention pertains to a gas delivery device. In one or more embodiments, the gas delivery device administers therapy gas from a gas source containing NO under the control of a control module. In one variant, the gas delivery device may include a valve attachable to the gas source and a circuit. The valve may include an inlet and an outlet in fluid communication and a valve actuator to open and close the valve to allow the gas to flow through the valve to a control module. The circuit of one or more embodiments includes a memory, a processor and a transceiver in communication with the memory to send wireless optical line-of-sight signals to communicate information stored or retained within the memory to the control module that controls gas delivery to a subject. In one or more alternative embodiments, the signals to communicate information stored or retained within the memory to the control module that controls gas delivery to a subject may be communicated via a wire. Examples of such wired signals may incorporate or utilize an optical cable, wired pair and/or coaxial cable. The circuit may include a memory to store gas data, which may include one or more of gas identification, gas expiration date and gas concentration. The transceiver may communicate to send the gas data to the control module via wireless optical line-of-sight signals.

[0008] In one or more embodiments, the valve may include a data input in communication with said memory, to permit a user to enter the gas data into the memory.

The gas data may be provided in a bar code that may be disposed on the gas source. In such embodiments, the gas data may be entered into the data input of the valve for storage in the memory by a user-operated scanning device in communication with the data input. Specifically, the user may scan the bar code to communicate the gas data stored therein to the valve memory via the data input.

[0009] In one or more embodiments, the valve may include a power source. In such embodiments, the power source may include a battery or other portable power source. In one or more embodiments, the valve transceiver may periodically send the wireless optical line-of-sight signals to the control module, wherein the signals are interrupted by a duration of time at which no signal is sent. In one or more specific embodiments, the duration of time at which no signal is sent comprises about 10 seconds.

[0010] A second aspect of the present invention pertains to a gas delivery device, as described herein, and a control module in fluid communication with the outlet of the valve of the gas delivery device and with a gas delivery mechanism, such as a ventilator. In one or more embodiments, the control module may include a CPU transceiver to receive line-of-sight signals from the transceiver and a CPU in communication with the CPU transceiver. The CPU carries out the instructions of a computer program or algorithm. As used herein the phrase "wireless optical line-of-sight signal" includes infrared signal and other signals that require a transmitter and receiver or two transceivers to be in aligned such that the signal may be transmitted in a straight line. The CPU may include a CPU memory that stores the gas data that is communicated by the valve transceiver of the gas delivery device to the CPU transceiver.

[0011] In one or more embodiments, the gas delivery system may incorporate a valve with a timer including a calendar timer and an event timer for determining or marking the date and time that the valve is opened and closed and the duration of time the valve is opened.. In such embodiments, the valve memory stores the date and time of opening and closing of the valve and the duration of time that the valve is open and the valve transceiver communicates the date and time of opening and closing of the valve to the CPU transceiver for storage in the CPU memory.

[0012] In one or more variants, the gas delivery system may incorporate a control module that further includes an input means to enter patient information into the CPU memory. The control module may also have a real time clock built into the CPU module such that the

control module knows what the current time and date is and can compare that to the expiration date stored in the gas delivery device. If the expiration date is passed the current date then the control module can cause an alarm and not deliver drug to the patient. When the term "patient information" is used, it is meant to include both patient information entered by the user and information that is set during manufacturing, such as the gas identification and the gas concentration that the control module is setup to deliver. The control module may also include a display. In one or more embodiments, the display incorporates an input means for entering patient information into the CPU memory. In one or more embodiments, the CPU of the control module compares the patient information entered into the CPU memory via the input means and the gas data from the transceiver. The CPU or control module may include comprises an alarm that is triggered when the patient information entered into the CPU memory and the gas data from the transceiver do not match or conflict. As used herein the phrase "do not match," includes the phrase "are not identical," "are not substantially identical," "do conflict" and/or "do substantially conflict." The CPU determines whether the patient information and additional data, or other data set matches by performing a matching algorithm which includes criteria for establishing whether one set of data (i.e. patient information) and another set of data match. The algorithm may be configured to determine a match where every parameter of the data sets match or selected parameters of the data sets match. The algorithm may be configured to include a margin of error. For example, where the patient information require a gas concentration of 800 ppm, and the additional data includes a gas concentration of 805 ppm, the algorithm may be configured to include a margin of error of ± 5ppm such it determines that the patient information and the additional data match. It will be understood that determining whether the patient information and additional data match will vary depending on the circumstances, such as variables in measuring gas concentration due to temperature and pressure considerations.

[0013] A third aspect of the present invention pertains to a control module memory comprising instructions that cause a control module processor to receive gas data from a valve via a wireless optical line-of-sight signal. The valve may be connected to a gas source containing NO and may include a memory for storing the gas data. The control module memory may include instructions that cause the control module processor to compare the gas data with user-inputted patient information. The user-inputted patient information may be stored within the control module memory. Gas data may be selected from one or more of gas

identification, gas expiration date and gas concentration. In one or more embodiments, the control module memory may include instructions to cause the control module processor to coordinate delivery of therapy to the patient with a medical device, such as a ventilator and the like for delivering gas to a patient, via the wireless optical line-of-sight signal. The control module memory may also include instructions to cause the control module processor to select a therapy for delivery to a patient based on the received patient information and control delivery of the selected therapy to the patient.

[0014] In one or more embodiments, the memory may include instructions to cause the processor to detect the presence of more than one valve and whether more than one valve is open at the same time. In accordance with one or more specific embodiments, the memory includes instructions to cause the processor to receive a first valve status selected from a first open position and a first closed position from a first valve via a first wireless optical line-of-sight signal with the first valve connected to a first gas source, receive a second valve status selected from a second open position and a second closed position from a second valve via a second wireless optical line-of-sight signal with the second valve connected to a second gas source, compare the first valve status and the second valve status, and emit an alarm if the first valve status comprises the first open position and the second valve status comprises the second open position. In one or more alternative embodiments, the first valve status and the second valve status may be communicated to the processor via a single wireless optical line-of-sight signal, instead of separate wireless optical line-of-sight signals. In a more specific embodiment, the memory of one or more embodiments may include instructions to cause the processor to terminate delivery of therapy if the first valve status comprises the first open position and the second valve status comprises the second open position.

[0015] In one or more embodiments, the memory may include instructions to cause the processor to emit an alarm when a desired dose has been delivered through a valve. In such embodiments, the processor may include a memory to store the desired dose or dosage information. In such embodiments, the memory may include instructions to cause the processor to receive gas delivery information or information regarding the amount of gas delivered and compare the gas delivery information to the dosage information and emit an alarm when the gas delivery information and the dosage information match. As used herein, the term "dosage information" may be expressed in units of parts per million (ppm), milligrams of the drug per kilograms of the patient (mg/kg), millimeters per breath, and other units known

for measuring and administering a dose. In one or more embodiments, the dosage information may include various dosage regimes which may include administering a standard or constant concentration of gas to the patient, administering a gas using a pulsed method. Such pulsing methods includes a method of administering a therapy gas to a patient during an inspiratory cycle of the patient, where the gas is administered over a single breath or over a plurality of breaths and is delivery independent of the respiratory pattern of the patient.

[0016] A fourth aspect of the present invention pertains to a method for administering a therapy gas to a patient. The therapy gas may comprise NO. In one or more embodiments, the method includes establishing communication between the patient and a gas delivery device via a transceiver, wherein the gas delivery device comprises a first memory including gas data, comparing the gas data with patient information stored within a second memory. The second memory may be included within a control module in communication with the gas delivery device. After comparing the gas data and the patient information, the method may further include coordinating delivery of therapy to a patient with the gas delivery device via a wireless optical line-of-sight signal, selecting a therapy for delivery to the patient based on the comparison of the gas data and the patient information and controlling delivery of the selected therapy to the patient. In one or more specific embodiments, the method may include entering the gas data into the first memory of the gas delivery device and/or entering the patient information into the second memory. In embodiments in which the method includes entering the patient information into the second memory, the control module may include input means by which patient information may be entered into the second memory. In one or more variants, the method includes ceasing delivery of the selected therapy to the patient based on the comparison of the gas data and the patient information. The method may include emitting an alert based on the comparison of the gas data and the patient information.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] Figure 1 is a diagram of a gas delivery system including a gas delivery device, a gas source, a control module and a gas delivery mechanism, according to one or more embodiments;

[0018] Figure 2 illustrates a valve assembly of the gas delivery device according to one or more embodiments attached to a gas source;

[0019] Figure 3 illustrates a disassembled view of the valve assembly shown in Figure 2;

[0020] Figure 4 is a diagram showing a circuit supported in the valve assembly shown in Figure 2, according to one or more embodiments;

[0021] Figure 5 illustrates an exemplary gas source for use with the valve assembly shown in Figure 2;

[0022] Figure 6 is an operational flow diagram of the communication between the circuit of the gas delivery device shown in Figure 1 with a control module regarding the establishment of communication between the circuit and the control module

[0023] Figure 7 illustrates a front view of an exemplary gas delivery system;

[0024] Figure 8 illustrates a back view of the gas delivery system shown in Figure 7;

[0025] Figure 9 illustrates a partial side view of the gas delivery system shown in Figure 7;

[0026] Figure 10 illustrates a front view of a control module according to one or more embodiments;

[0027] Figure 11 illustrates a back view of the control module shown in Figure 10;

[0028] Figure 12 is an operational flow diagram of the communication between the circuit of the gas delivery device and the control module shown in Figure 1 regarding the gas contained within a gas source; and

[0029] Figure 13 is an operational flow diagram of the preparation of a gas delivery device and use within the gas delivery system according to one or more embodiments.

DETAILED DESCRIPTION

[0030] Before describing several exemplary embodiments of the invention, it is to be understood that the invention is not limited to the details of construction or process steps set forth in the following description. The invention is capable of other embodiments and of being practiced or being carried out in various ways.

[0031] A system for the administration of therapy gas is described. A first aspect of the present invention pertains to a gas delivery device. The gas delivery device may include a valve assembly including at least one valve with a circuit. The gas delivery system may include the gas delivery device (e.g. valve assembly, including a valve and a circuit) in communication with a control module to control the delivery of gas from a gas source to a

ventilator or other device used to introduce the gas into the patient, for example, a nasal cannula, endotracheal tube, face mask or the like. Gas source, as used herein, may include a gas source, gas tank or other pressured vessel used to store gases at above atmospheric pressure. The gas delivery system 10 is shown in Figure 1. In Figure 1, the valve assembly 100, including a valve 107 or valve actuator and a circuit 150, is in communication with a control module 200 via a wireless line-of-sight connection 300. In one or more alternative embodiments, communication between the valve assembly 100 and the control module 200 may be established via a wired signal. The gas delivery system 10 also includes a gas source 50 including a gas attached to the valve assembly 100 and a gas delivery mechanism, which includes a ventilator 400 and a breathing circuit 410, in communication with the control module 200.

[0032] Figures 2-4 illustrate the components of the valve assembly 100. The valve assembly 100 includes a valve 107 and a circuit 150 supported in the valve assembly. Figure 3 illustrates a disassembled view of the valve assembly 100, showing components of the physical circuit 150 and the valve 107. As shown in Figure 4, which will be described in more detail below, the circuit 150 of the gas delivery device includes a valve transceiver 120 for establishing communication with the control module 200, which will also be discussed in greater detail below.

[0033] Referring to Figure 2, the valve 107 includes an attachment portion 102 for attaching the valve assembly 100 to the gas source 50, an inlet 104 and an outlet 106 in fluid communication with the inlet 104, as more clearly shown in Figure 2.

[0034] Figure 3 illustrates a disassembled view of the valve assembly 100 and illustrates an actuator 114 is disposed on the valve 107 and is rotatable around the valve 107 for opening and closing the valve 107. The actuator 114 includes a cap 112 mounted thereto. As shown in Figure 3, the circuit 150 may include a data input 108 disposed on the actuator 114. The data input 108 may be disposed at other locations on the valve 107. In one or more variants, the data input may include a port such as a USB port, a receiver for receiving electronic signals from a transmitted or other known input means known in the art for entering information or data into a memory.

[0035] Figure 4 illustrates a block diagram of the circuit 150. The circuit 150 shown in Figure 4 includes a valve processor 122, a valve memory 134, a reset 128, a valve transceiver 120 and a power source 130. The circuit 150 may also include support circuits a timer 124, a

sensor 126 and/or other sensors. Referring to Figure 3, the circuit 150 is supported within the valve assembly 100, with the physical components of the circuit 150 specifically disposed between actuator 114 and the cap 112. As shown in Figure 3, the valve display 132 and the valve transceiver 120 are disposed adjacent to the cap 112, such that the valve display 132 is visible through a window 113. The sensor 126 and the valve processor 122 are disposed beneath the valve display 132 and the valve transceiver 120, within the actuator 114.

[0036] The valve processor 122 may be one of any form of computer processor that can be used in an industrial setting for controlling various actions and sub-processors. The valve memory 134, or computer-readable medium, may be one or more of readily available memory such as electrically erasable programmable read only memory (EEPROM), random access memory (RAM), read only memory (ROM), floppy disk, hard disk, or any other form of digital storage, local or remote, and is typically coupled to the valve processor 122. The support circuits may be coupled to the valve processor 122 for supporting the circuit 150 in a conventional manner. These circuits include cache, power supplies, clock circuits, input/output circuitry, subsystems, and the like.

[0037] In the embodiment shown, the valve memory 134 communicates with a data input 108 disposed on the side of the actuator 114. The data input 108 shown in Figures 3-4 is used to transfer data from the valve memory 134 to other devices or to input data into the valve memory 134. For example, gas data, which includes information regarding the gas contained within the gas source, may be entered into the valve memory 134 via the data input 108. In one or more alternative embodiments, the gas data may be programmed or directly entered into the valve memory 134 by the gas supplier. In one or more embodiments, the gas data may be provided in the form of a bar code 610 that is disposed on a label 600 that is affixed on a to the side of the gas source, as shown in Figure 5. The bar code 610 may be disposed directly on the gas source. An external scanning device in communication with the electronic data input 108 may be provided and may be used to scan the bar code 610 and convey the information from the bar code 610 to the valve memory 134. Gas data may include information regarding the gas composition (e.g., NO, O_2, NO_2, CO, etc.), concentration, expiration date, batch and lot number, date of manufacturing and other information. Gas data may be configured to include one or more types of information. The valve processor 122 may include instructions to convey all or a pre-determined portion of the gas data via the valve transceiver 120 to another transceiver.

[0038] In embodiments that utilize a timer 124, the timer 124 may include two sub-timers, one of which is a calendar timer and the other of which is an event timer. The reset 128 may be located inside the actuator 114 and may be depressed to reset the event timer. The cap 112 also includes a window 113 that allows the user to see the valve display 132 disposed within the cap 112 that displays information regarding whether the actuator 114 is opened or closed and the duration the valve 107 was opened or closed. In one or more embodiments, the valve display 132 may alternate flashing of two different numbers, a first number may be accumulated open time, and the second number may be the time at which the valve 107 was opened for the current event. The time at which the valve 107 was opened for a current event may be preceded by other indicators.

[0039] The sensor 126 disposed within the actuator 114 may include a proximity switch model MK20-B-100-W manufactured by Meder Inc. The sensor 126 utilized in one or more embodiments may cooperate with a magnet (not shown) to sense whether the actuator 114 is turned on or turned off. Such sensors are described in U.S. Patent No. 7,114,510, which is incorporated by reference in its entirety.

[0040] For example, the sensor 126 and a corresponding magnet (not shown) may be disposed on a stationary portion of the valve 107. When the actuator 114 is rotated to the closed position, the sensor 126 is adjacent to the magnet that is in a fixed position on the valve 107. When the sensor 126 is adjacent to the magnet, it sends no signal to the valve processor 122, thereby indicating that the actuator 114 is in the "closed" position or has a valve status that includes an open position or a closed position. When the actuator 114 is rotated to open the valve 107, the sensor 126 senses that it has been moved away from the magnet and sends a signal to the valve processor 122, indicating an "open" position. The valve processor 122 instructs the valve memory 134 to record the event of opening the valve 107 and to record the time and date of the event as indicated by the calendar timer. The valve processor 122 instructs the valve memory 134 to continue checking the position of the valve 107 as long as the valve 107 is open. When the valve 107 is closed, the valve processor 122 uses the logged open and close times to calculate the amount of time the valve 107 was open and instructs the valve memory 134 to record that duration and the accumulated open time duration. Thus, every time the valve 107 is opened, the time and date of the event is recorded, the closing time and date is recorded, the duration of time during which the valve 107 is open is calculated and recorded, and the accumulated open time is calculated and recorded.

[0041] In one or more embodiments in which the power source 130 includes a battery, the valve transceiver 120 may be configured to communicate with the CPU transceiver 220 to preserve the life of the battery. In this embodiment the valve transceiver 120 is only turned on to receive a signal from the Control Module CPU transceiver 220 for 20msec every second. The control module CPU transceiver 220 sends out a short transmit signal continuously and if the valve transceiver 120 is present it responds in the 20msec interval. This conserves battery power as the valve transceiver 120 is only powered on for 20 msec every second. When the valve transceiver 120 responds it includes in its signal information regarding whether the communication from the control module CPU transceiver 220 was early or late within this 20msec window. This ensures that once communications has been established it is synchronized with the 20msec window that the valve transceiver 120 is powered on and able to receive communications. For example, as shown in Figure 6, the valve transceiver 120 sends a wireless optical line-of-sight signal during a pre-determined interval in response to a signal from the control module CPU transceiver 220. The wireless optical line-of-sight signals sent by the valve transceiver 120 are a series of on off cycles where the transmitter is either transmitting light or is not and these correspond to digital binary signals. The mechanism by which the valve transceiver sends a wireless optical line-of-sight signal may be construed as a series of digital on off signals that correspond to data being transmitted. Once communications has been established between the control module CPU transceiver 220 and the valve transceiver 120, the interval between communication signals may be in the range from about 20 seconds to about 5 seconds. In one or more specific embodiments, the interval or duration between transceiver signals may be about 10 seconds.

[0042] As will be described in more detail below, the control module 200 includes a CPU 210 which is connected to a CPU transceiver 220 which can send and receive wireless optical line-of-sight signals. The CPU transceiver 220 sends out a signal and waits for a response from the valve transceiver 120 when communication or more specifically, line-of-sight communication is established between the CPU transceiver 220 and the valve transceiver 120. If no response is sent by the valve transceiver 120, the CPU transceiver 220 sends another signal after a period of time. This configuration preserves battery life because the valve transceiver 120 does not continuously send a signal unless requested to by the CPU 210. This is important as the gas delivery device and gas source spends most of its time in shipping and storage prior to being placed on the gas delivery system, if it was transmitting all this time

trying to establish communications with the control module it would be consuming the battery life significantly.

[0043] The valve processor 122 may include link maintenance instructions to determine whether the interval should be increased or decreased. As shown in Figure 6, when a valid link is established between the valve transceiver 120 and CPU transceiver 121, the valve processor 122 executes the link maintenance instructions to increase the interval or decrease the interval.

[0044] As shown more clearly in Figure 1, valve assembly 100 and gas source 50 is in communication with a control module 200, which is in communication with a gas delivery mechanism. The gas delivery mechanism shown in Figure 1 includes a ventilator 400 with associated breathing circuit 410. The control module 200 may include a CPU 210and a CPU transceiver 220 in communication with the circuit 150 via the valve transceiver 120. The control module 200 also includes a CPU memory 212 in communication with the CPU transceiver 220 to store patient information, information or data received from the valve transceiver 120 and other information. The control module 200 may also include support circuits. The CPU 210 may be one of any form of computer processor that can be used in an industrial setting for controlling various actions and sub-processors. The CPU memory 212, or computer-readable medium, may be one or more of readily available memory such as random access memory (RAM), read only memory (ROM), floppy disk, hard disk, or any other form of digital storage, local or remote, and is typically coupled to the CPU 210. The support circuits may be coupled to the CPU 210 for supporting the control module 200 in a conventional manner. These circuits include cache, power supplies, clock circuits, input/output circuitry, subsystems, and the like. The CPU 210 may also include a speaker 214 for emitting alarms. Alternatively, alarms may also be displayed visually on a display. As shown in Figure 1, the control module 200 may also include a regulator 110 and, optionally, pressure gauges and flow meters for determining and/or controlling the gas flow from the gas source 50.

[0045] In one or more embodiments, the CPU transceiver 220 is disposed on a cover portion 225 (shown more clearly in Figure 7), that is part of a cart 500 (show more clearly in Figure 7) onto which the control module 200 is disposed. The cover portion 225 in one or more embodiments is in communication with the control module 200. Communication between the cover portion 225 and the control module 200 may be established wirelessly or via a cable. As will be discussed in greater detail below, the valve assembly 100, including the

valve 107, the circuit 150 and a gas source 50 attached to the valve 107, are placed on the cart 500 in proximity and in a light-of-sight path with the CPU transceiver 220. When properly configured such that communication is established between the valve transceiver 120 and the CPU transceiver 220, the CPU transceiver 220 is positioned directly above the valve transceiver 120, as shown more clearly in Figure 9. In one or more alternative embodiments, the CPU transceiver 220 may be disposed on the CPU 210.

[0046] The CPU 210 may be in communication with a plurality of gas sensors 230 for determining the concentration of a sample of gas drawn via a sample line 232 and a sample line inlet 280 (shown more clearly in Figure 1) disposed on the control module 200. As will be discussed in greater detail, the sample line 232 draws a sample of gas from a breathing circuit 410 of a ventilator 400 when the ventilator is in fluid communication with the control module 200 and gas is being delivered to the ventilator. The CPU 210 may also be in communication with a sample flow sensor 234 for sensing the flow of the sample drawn via sample line 232, a pump 236 for drawing the sample via the sample line 232 to the flow sensor 234 and zero valve 238 controlling the flow of the sample via the sample line 232 to the sample pump 236, sample flow sensor 234 and the plurality of CPU sensors. The sample line 232 may include a water trap 233 for collecting any water or liquid from the sample.

[0047] The control module 200 may also include a delivery module 260 for regulating the flow of gas from the gas source 50 to the ventilator 400. The delivery module 260 may include a pressure switch 262 for determining a gas supply pressure is present, a pressure shut-off valve 264, a proportional valve 266 and a delivery flow sensor 268. The delivery module 260 may also include a backup on/off switch 269. The detailed method of how the delivery module delivers the gas to the ventilator circuit is described in US Patent No. 5,558,083 which is incorporated here by reference in its entirety.

[0048] The ventilator 400 shown in Figure 1 is in fluid communication with the control module 200 via an injector tubing 440 and in electrical communication via an injector module cable 450. The control module 200 and more specifically, the CPU 210, is in fluid communication with the ventilator 400 via the sample line 232. The ventilator 400 may include a breathing circuit 410 with an inspiratory limb 412 and an expiratory limb 414 in fluid communication with the ventilator 400. The inspiratory limb 412 may be in fluid communication with a humidifier 420, which is in fluid communication with the ventilator 400 via an injector module 430. The inspiratory limb 412 carries gas to the patient and the

expiratory limb 414 carries gas exhaled by the patient to the ventilator 400. The injector module 430 shown in Figure 1 is in fluid communication with the gas source 50 via the injector tubing 440 and in electronic communication with the delivery module 260 via the injector module cable 450 such that the delivery module 260 can detect and regulate the flow of gas from the gas source 50 to the ventilator 400. Specifically, the injector module 430 is in fluid communication with the gas source 50 via an injector tubing 440, which is in fluid communication with one or more of the pressure switch 262, pressure shut-off valve 246, proportional valve 266, flow sensor 268 and the backup switch 269 of the delivery module 260. The injector module 430 may also be in electronic communication with the delivery module 260 via the injector module cable 450. The inspiratory limb 412 of the ventilator 400 may include a sample tee 416 for facilitating fluid communication between the inspiratory limb 412 of the breathing circuit and the sample line 232.

[0049] As discussed above, the control module 200 may be disposed or attached on a cart 500, as shown in Figures 7-9 to facilitate movement of the gas source 50 and the gas delivery device to a patient in need of gas therapy. The gas source 50 and the valve assembly 100 attached thereto may be placed on the cart 500 in proximity to the control module 200. More specifically, as shown in Figure 7, the gas source 50 is placed on the cart 500 such that the valve transceiver 120 is in proximity of the CPU transceiver 220 and a line-of-sight path is established between the valve transceiver 120 and the CPU transceiver 220. In this configuration, the CPU 210 detects the presence of the circuit 150 and thus the gas source 50 via the CPU transceiver 220.

[0050] As shown in Figures 7-9, the gas delivery device may include more than one valve, with each valve being attached to a single gas source. In such embodiments which utilize a second gas source 60 with a second valve assembly 101, the second valve assembly 101 is positioned in proximity and in a light-of-sight path with a second CPU transceiver as the gas source 60 is loaded onto the cart. The second CPU transceiver 222 establishes communication with the second valve assembly 101 and thus detects the presence of a second gas source 60. In the embodiment shown in Figures 7-9, the second CPU transceiver 222 may also be disposed on the cover portion 225 of a cart. In one or more alternative embodiments, the second CPU transceiver 222 may be disposed on the CPU 210.

[0051] As shown in Figure 8, the cart 500 may include an optional small bin 510, a mount 512 for supporting the control module 200 on the cart 500, at least one a holding bracket

520, at least one mounting strap 530, an auxiliary bracket 540, for holding an auxiliary gas source, a plurality of casters 550 and a caster lock lever 560 disposed on each of the plurality of casters 550. The cart 500 may include a mount 570 for mounting the control module 200 on to the cart.

[0052] An exemplary control module 200 is shown in Figures 10-12 includes a display 270 for providing visual indication to the user the components of the gas being delivered from the gas source 50 to the ventilator 400 (e.g., NO, O_2, NO_2), the concentration of each component and whether communication has been established with one or more gas sources. Other information may also be displayed to the user. In addition, visual alarms may also be displayed on the display 270. The control module 200 may also include a main power indicator 272 indicating whether the control module is connected to a power source, such as an AC/DC power source and/or a battery. The control module 200 may also include a control wheel 274 allowing the user to navigate through various displays or information displayed on the display. An injection module tubing outlet 276 may be disposed on the control module for providing fluid communication between the delivery module 260 and the injector module 430. An injection module cable port 278 may also be provided on the control module to provide electronic communication between the delivery module 260 and the injector module 430. The control module 200 shown in Figures 10-12 also includes the sample line inlet 280 in fluid communication with the sample line 232 and the inspiratory limb 412 of the ventilator 400. In the embodiment shown in Figures 10-12, the water trap 233 is disposed on the control module, adjacent to the sample line inlet 280.

[0053] Figure 11 illustrates a back view of the control module 200 and shows a plurality of inlets. In the embodiment shown, two gas inlets 282, 284 for connecting the control module 200 to the gas source 50 are provided and one auxiliary inlet 286 for connecting the control module 200 to an auxiliary gas source, which may include oxygen or other gas. A power port 288 is also provided on the back of the control module to connect the control module to an AC/DC power source.

[0054] The control module 200 may also include an input means 290 for allowing the user to enter patient information, for example the identity of the patient, the type and concentration of the gas and dose of the gas to be administered to the patient, the patient's disease or condition to be treated by the gas or reason for treatment, gestational age of the patient and patient weight. The input means 290 shown in Figure 12 includes a keyboard

integrated with the display. In one or more alternative embodiments, the input means may include a USB port or other port for the connection of an external keyboard or other input mechanism known in the art. The information entered via the input means 290 is stored within the CPU memory 212.

[0055] The control module 200 and the valve assembly 100 may be utilized in the gas delivery system 10 to improve patient safety. Specifically, the safety benefits of the gas delivery system described herein include detecting a non-confirming drug or gas source, an expired drug or gas, incorrect gas type, incorrect gas concentration and the like. In addition, embodiments of the gas delivery system described herein also improve efficiency of gas therapy.

[0056] Figure 13 is a block diagram showing the sequence of how gas delivery device, including the valve assembly 100, may be provided and its use within the gas delivery system 10, according to one or more embodiments. As shown in Figure 13, the gas delivery device 10 is prepared for use by providing a gas source 50 in the form of a gas cylinder or other container for holding a gas and filling the gas source 50 with a gas (700) and attaching a valve assembly 100 as described herein, to assemble the gas delivery device 10 (710). These steps may be performed by a gas supplier or manufacturer. The gas data regarding the gas filled within the gas source 50 is entered into the valve memory 134 as described herein (720). The gas data may be entered into the valve memory 134 by the gas supplier or manufacturer that provides the gas source 50 and assembles the gas delivery device 10. Alternatively, the hospital or other medical facility may enter the gas data into the valve memory 134 after the gas delivery device has been transported to the hospital or medical facility (730). The gas delivery device 10 is positioned on a cart 500 (740) and communication between the CPU transceiver 220 and the valve transceiver 120 is established (750). The gas data stored within the valve memory 134 is conveyed to the control module 200 (760) via the wireless optical line-of-sight communication between valve transceiver 120 and the CPU transceiver 220. The CPU 210 compares the gas data to patient information entered into the CPU memory 212 (770). The patient information may be entered into the CPU memory after the gas data is entered into the CPU memory 212. The patient information may be entered into the CPU memory before the gas delivery device 10 is positioned in the cart or before communication between the CPU transceiver 220 and the valve transceiver is established. In one or more alternative embodiments, the patient information may be entered into the CPU memory 212 before the gas delivery device 10 is

prepared or transported to the hospital or facility. The CPU 210 then compares whether the gas data and the patient information match (780). If the gas data and the patient information match, then gas is administered to the patient (790), for example through a ventilator or other gas delivery mechanism. If the gas data and the patient information do not match, then an alarm is emitted (800). As described otherwise herein, the alarm may be audible and emitted through the speaker 214 and/or may be visual and displayed on the display 270.

[0057] The gas delivery system described herein simplifies set-up procedures by utilizing wireless line-of-sight signals to establish communication. The user does not need to ensure all the cables are correct connected and can freely load new gas sources onto a cart without disconnecting cables linking the control module 200 and the valve assembly 100 or circuit 150. This reduces set-up time and any time spent correcting errors that may have occurred during the set-up process. The control module 200 and the circuit 150 are further designed to automatically send and detect information to establish delivery of a correct gas having the correct concentration and that is not expired. In one or more specific embodiments, such automated actions prevent the use of the gas delivery system by preventing gas flow to a patient, without user intervention.

[0058] In one or more embodiments, after communication between the valve transceiver 120 and the CPU transceiver 220 is established, the valve processor 122 includes instructions to convey the gas data stored in the valve memory 134 via the valve transceiver 120 to the CPU transceiver 220. The CPU 210 includes instructions to store the gas data received from the CPU transceiver 220 in the CPU memory. The CPU 210 also includes an algorithm that compares the gas data with patient information that is entered into the CPU memory 212. If the gas data and the patient information do not match, the CPU 210 includes instructions to emit an alarm, which may be audible, visual or both, alerting the user that the gas contained within the gas source is different from the gas to be administered to the patient. For example, as illustrated in Figure 12, if the gas data includes gas expiration date, the CPU memory 212 includes information regarding the current date and the CPU 210 compares the gas expiration date with the current date. If the gas expiration date is earlier than the current date, the CPU 210 emits an alarm. The alarm may be emitted through one or both the speaker 214 and display 270. In one or more embodiments, the CPU 210 may include instructions that the delivery module 260 cease or prevent delivery of the gas. In one or more embodiments, the CPU 210 includes instructions to turn the backup on/off switch 269 off if the delivery module

260 commences or continues delivery of the gas. The detection of an expired gas by the CPU 210 may be stored within the CPU memory 212.

[0059] If the gas data includes gas concentration information or data, the CPU memory 212 includes information regarding the desired concentration of gas to be administered to the patient. The control module 200 may be configured to alert the user that the gas contained within a gas source has incorrect concentration or a concentration that does not match the desired gas concentration. For example, a user may enter a concentration of 800 ppm into the CPU memory 212 and this concentration is compared to the gas concentration conveyed from the valve memory 134 to the CPU memory 212. As illustrated in Figure 12, the CPU 210 includes instructions to compare the gas concentration of the gas with the concentration entered by the user. If the gas concentration does not match the concentration entered by the user, the CPU 210 emits an alarm, which may be audible and/or visual. In one or more embodiments, the CPU 210 may include instructions that the delivery module 260 cease or prevent delivery of the gas. In one or more embodiments, the CPU 210 includes instructions to turn the backup on/off switch 269 off if the delivery module 260 commences or continues delivery of the gas. The detection of a gas with incorrect concentration may be stored within the CPU memory 212.

[0060] In one or more embodiments, the control module 200 may be configured to detect more than one valve and to detect whether more than one valve is turned on. This configuration eliminates waste because it alerts a user that both valves are turned on and thus unnecessary gas is being delivered to via the delivery module 260. In addition, such a configuration improves safety because it avoids the issues related to having two regulators pressurized at the same time and connected to the delivery module 260. In one or more embodiments, the cover portion 225 of the control module 200 may include a second CPU transceiver 222 and the CPU 210 may include instructions for the second CPU transceiver 222 to detect wireless optical line-of-sight signals from a second valve assembly 101, and more specifically, a second valve transceiver 121. The CPU 210 may also include instructions that once a second valve assembly 101 is detected by the CPU transceiver 222, whether both valve assemblies 100, 101 are opened or have a valve status that includes an open position. In operation, a first valve assembly 100 includes a circuit with a valve processor with instructions to covey an open or closed position via the first valve transceiver 120. The circuit of the second valve assembly similarly includes a valve processor with instructions to convey an

open or closed position via a second valve transceiver 121. The first CPU transceiver 220 and the second CPU transceiver 222 detect the valve statuses for each respective valve assembly from the first valve transceiver 120 and the second valve transceiver 121 via the wireless optical line-of-sight signals sent by both transceivers. The CPU 210 instructs the CPU transceivers 220, 222 to collect the valve statuses for both valve assemblies 100, 101 and the memory to store the valve statuses. The CPU 210 then compares the valve status information from the first valve assembly 100 and the second valve assembly 101 and, if the valve statuses both comprise an open position, the CPU 210 emits an alarm. The alarm may be audible and/or visual. In one or more embodiments, the CPU 210 may include instructions that the delivery module 260 cease or prevent further delivery of gas through either the first valve assembly or the second valve assembly. In one or more embodiments, the CPU 210 includes instructions to turn the backup on/off switch 269 off if the delivery module 260 commences or continues delivery of gas. The detection that more than one valve assembly had a valve that was turned on or had a valve status including an open position may be stored within the CPU memory.

[0061] In one or more embodiments, the control module 200 may be configured to alert a user when the desired dose has been delivered. In such embodiments, the patient information entered into the CPU memory 212 may include dosage information or the dose to be delivered to a patient. The valve processor 122 may include instructions to convey gas usage information from the valve memory 134, including the amount of gas delivered, to the CPU memory 212 via the valve transceiver 120. Alternatively, the valve processor 122 may include instructions to covey the duration of time the valve 170 has been turned on or has a valve status including an open position to the CPU memory 212 via the valve transceiver 120. The CPU 210 may include instructions to compare the dosage information entered by the user and stored within the CPU memory 212 with the gas usage information. The CPU 210 may include instructions to emit an alarm when the dosage information and the gas usage information match. The CPU 210 may include instructions to emit the same or different alarm to alert the user to turn off the valve or, more specifically, the actuator 114 when the dose has been delivered. In one or more embodiments, the CPU 210 may include instructions that the delivery module 260 cease or prevent further delivery of gas. In one or more embodiments, the CPU 210 includes instructions to turn the backup on/off switch 269 off if the delivery module 260 commences or continues delivery of gas.

[0062] In addition, the control module 200 may be configured to alert the user that a detected valve is and remains closed and no gas is being delivered to the patient. This configuration expedites treatment time and increases efficiency for the hospital. In such embodiments, the valve processor 122 may include instructions for the valve transceiver 120 to convey the valve status to the CPU 210 via a wireless optical line-of-sight signal. The CPU 210 includes instructions to collect the valve status information and emit an alert if the dosage information is set or other input has been entered into the CPU memory 212 to commence treatment and the valve status includes a closed position.

[0063] The control module 200 may be configured to alert the user that no valve assembly or gas source has been detected. In such embodiments, the CPU 210 includes instructions to detect the presence of a wireless optical line-of-sight signal from another transceiver, for example, the valve transceiver 120. The CPU 210 may include instructions to emit an alarm if the dosage information or other input to commence delivery of the gas has been entered into the CPU memory 212 and no signal from another transceiver has been detected. Similarly, the control module 200 may be configured to emit an alarm if communication between one or both of the CPU transceiver(s) 220, 222 and one or both of the valve transceivers 120, 121 has been lost during gas delivery. In such embodiments, the CPU 210 may include instructions to continuously detect the presence of a signal from another transceiver and emit an alarm if the dosage information or other input to commence delivery of the gas has been entered into the CPU memory 212 and no signal from another transceiver has been detected.

[0064] The CPU 210 may include instructions to alert a user when sensors in the control module 200 must be calibrated to ensure accurate delivery of gas to a patient. In addition, the CPU 210 may include instructions to correlate gas usage information from the circuit 150 of the valve assembly 100 to the patient information entered into the CPU memory 212. The CPU 210 may also have instructions to store the correlated gas usage information and the patient information in the CPU memory 212. The valve processor 122 may also include instructions detect patient information from the CPU memory 212. Specifically, the valve processor 122 may include instructions to collect patient information via the valve transceiver 120 from the CPU transceiver 220 and store the collected patient information in the valve memory 134. In such embodiments in which information from the CPU 210 is collected and stored in the valve memory 134, the CPU 210 may include instructions that the patient

information and/or correlated patient information and gas usage information be conveyed from the CPU memory 212 via the CPU transceiver 220 to the valve transceiver 120. The valve processor 122 may also include instructions to correlate gas usage information with the collected patient information and store the correlated gas usage information and collected patient information in the valve memory 134. Alternatively, the valve processor 122 may include instructions to collect the correlated patient information and gas usage information from the CPU 210. The correlated information may be utilized to bill the user according to patient. In addition, the correlated information may be utilized as patient demographic data, which can assist hospitals or other facilities to generate budget reports, determine usage per department, determine usage per patient diagnosis and link usage of multiple gas sources to individual patients.

[0065] A second aspect of the present invention pertains to a method for administering a therapy gas to a patient. The method includes providing a gas in a gas source. The gas source may be prepared by a supplier to contain a gas having a predetermined composition, concentration and expiration date. The method may include providing a valve assembly 100 attached to a gas source 50 to dispense the gas contained within the gas source 50 to a patient. The method may include entering gas data, which may include gas composition, gas concentration and gas expiration date, into the valve memory 134. In one or more embodiments, the supplier may enter the gas data directly into the valve memory 134. In another variant, the gas data is provided in the form of a bar code disposed on the gas source. In such embodiments, the method includes providing a scanner in communication with the data input 108, scanning the bar code to collect the gas data information and conveying the gas data to the valve memory 134 via the data input 108. These steps may be repeated for a second gas source. The gas source(s), with the valve assembly mounted thereon may be transported to a hospital or other facility for administration to a patient. The gas source(s) are then mounted onto the cart 500 and secured by the holding bracket 520 and mounting strap 530. The method includes establishing communication between the valve transceivers disposed on each valve and the CPU transceivers 220, 222. Establishing communication may include positioning the valve assembly 100 in a line-of-sight path with at least one of the CPU transceivers 220, 222. As otherwise described herein, communication may be established by instructing the valve transceivers to send a wireless optical line-of-sight signal to the CPU transceivers 220, 222.

The method may include instructing the valve transceiver 120 to send a wireless optical line-of-sight signal at pre-determined intervals, as otherwise described herein.

[0066] The method may include entering patient information into the CPU memory 212. This step may be performed before or after the gas source(s) are mounted onto the cart. The method may specifically include entering patient information such as dosage information into the valve memory 134. The method includes coordinating delivery of the gas to the patient by collecting gas data from the valve memory 134 and comparing the gas data with the patient information according to an algorithm and determining if the gas data and patient information match, according to the algorithm. Coordinating delivery of the gas may include turning on the actuator 114 of the valve 107 such that gas can flow from the inlet 104 to the outlet 106. After the dose has been delivered, the method may include correlating the gas usage information and the patient information. The method may also include recording the patient information, gas usage information and/or the correlated patient information and gas usage information in the CPU memory 212 and/or the valve memory 134. In one or more variants, the method may include utilizing the patient information, gas usage information and/or correlated patient information and gas usage information to generate invoices identifying the use of the gas by individual patients.

[0067] Reference throughout this specification to “one embodiment,” “certain embodiments,” “one or more embodiments” or "an embodiment" means that a particular feature, structure, material, or characteristic described in connection with the embodiment is included in at least one embodiment of the invention. Thus, the appearances of the phrases such as “in one or more embodiments,” “in certain embodiments,” “in one embodiment” or “in an embodiment” in various places throughout this specification are not necessarily referring to the same embodiment of the invention. Furthermore, the particular features, structures, materials, or characteristics may be combined in any suitable manner in one or more embodiments.

[0068] Although the invention herein has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the principles and applications of the present invention. It will be apparent to those skilled in the art that various modifications and variations can be made to the method and apparatus of the present invention without departing from the spirit and scope of the invention. Thus, it is

intended that the present invention include modifications and variations that are within the scope of the appended claims and their equivalents.

What is claimed is:

1. A gas delivery device to administer therapy gas comprising NO from a gas source comprising NO, the gas delivery device comprising:

a valve attachable to the gas source comprising NO, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas comprising NO through the valve to a control module; and

a circuit including:

memory to store gas data comprising one or more of gas identification, gas expiration date and gas concentration and

a processor and a transceiver in communication with the memory to send wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject.

2. The device of claim 1, wherein the valve further comprises a data input in communication with said memory, to permit a user to enter the gas data into the memory.

3. The device of claim 2, wherein the gas data is provided in a bar code disposed on the gas source and is entered into the data input by a user-operated scanning device in communication with the data input.

4. The device of claim 1, wherein the valve comprises a power source; and the transceiver periodically sends the wireless optical line-of-sight signals to the control module, wherein the signals are interrupted by a duration of time at which no signal is sent.

5. The device of claim 4, wherein the duration of time at which no signal is sent comprises about 10 seconds.

6. A gas delivery system comprising:

the gas delivery device of claim 1; and

a control module in fluid communication with the outlet of the valve and a ventilator, the control module comprising:

a CPU transceiver to receive line-of-sight signals from the transceiver; and

a CPU in communication with the CPU transceiver and including a CPU memory,

wherein the transceiver communicates the gas data to the CPU transceiver for storage in the CPU memory.

7. The system of claim 6, wherein the valve comprises a timer including a calendar timer and an event timer, wherein the memory stores the date and time of opening and closing of the valve and the duration of time that the valve is open and the transceiver communicates the date and time of opening and closing of the valve to the CPU transceiver for storage in the CPU memory.

8. The system of claim 6, wherein the control module further comprises an input means to enter patient information into the CPU memory; and a display.

9. The system of claim 8, wherein the CPU compares the patient information entered into the CPU memory via the input means and the gas data from the transceiver.

10. The system of claim 9, wherein the CPU comprises an alarm that is triggered when the patient information entered into the CPU memory and the gas data from the transceiver do not match.

11. A memory comprising instructions that cause a processor to: receive gas data selected from one or more of gas identification, gas expiration date and gas concentration from a valve via a wireless optical line-of-sight signal with the valve connected to a gas source comprising NO; compare the gas data with user-inputted patient information; coordinate delivery of therapy to the patient with a medical device via the wireless optical line-of-sight signal; select a therapy for delivery to a patient based on the received patient information; and control delivery of the selected therapy to the patient.

12. The memory of claim 11, wherein the memory comprises instructions that cause the processor to:

receive a first valve status selected from a first open position and a first closed position from a first valve via a first wireless optical line-of-sight signal with the first valve connected to a first gas source;

receive a second valve status selected from a second open position and a second closed position from a second valve via a second wireless optical line-of-sight signal with the second valve connected to a second gas source;

compare the first valve status and the second valve status; and

emit an alarm if the first valve status comprises the first open position and the second valve status comprises the second open position.

13. The memory of claim 12, wherein the memory comprises instructions that causes the processor to:

terminate delivery of therapy if the first valve status comprises the first open position and the second valve status comprises the second open position.

14. A method for administering a therapy gas comprising NO to a patient, the method comprising:

establishing communication via a transceiver with a gas delivery device comprising a first memory including gas data;

comparing the gas data with patient information stored within a second memory;

coordinating delivery of therapy to a patient with the gas delivery device via a wireless optical line-of-sight signal;

selecting a therapy for delivery to the patient based on the comparison of the gas data and the patient information; and

controlling delivery of the selected therapy to the patient.

15. The method of claim 14, further comprising ceasing delivery of the selected therapy to the patient based on the comparison of the gas data and the patient information.

16. The method of claim 14, further comprising emitting an alert based on the comparison of the gas data and the patient information.

17. The method of claim 14, further comprising entering the gas data into the first memory.

18. The method of claim 14, further comprising entering the patient information into the second memory.

ABSTRACT

GAS DELIVERY DEVICE

A gas delivery system including a gas delivery device, a control module and a gas delivery mechanism is described. An exemplary gas delivery device includes a valve assembly with a valve and circuit including a memory, a processor and a transceiver in communication with the memory. The memory may include gas data such as gas identification, gas expiration and gas concentration. The transceiver on the circuit of the valve assembly may send wireless optical line-of-sight signals to communicate the gas data to a control module. Exemplary gas delivery mechanisms include a ventilator and a breathing circuit. Methods of administering gas are also described.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3000-US-0026CON
	Application Number	
Title of Invention	Gas Delivery Device And System	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2

☐	Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Applicant Information

Applicant 1					
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Title of Invention	Gas Delivery Device And System	

		U.S.C. 117	118

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Title of Invention	Gas Delivery Device And System	

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Application Information:

Title of Invention	Gas Delivery Device And System		
Attorney Docket Number	3000-US-0026CON	☒	Small Entity Status Claimed
Application Type	Non provisional		
Subject Matter	Utility		
Suggested Class (if any)		Sub Class (if any)	
Suggested Technology Center (if any)			
Total Number of Drawing Sheets (if any)	12	Selected Figure for Publication (if any)	1

Publication Information:

☐	Request Early Publication (Fee required at time of Request 37 CFR 1.219)
☐	**Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S. C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3000-US-0026CON
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This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, or 365(c) or indicate National Stage entry from a PCT application. Providing this information in the application data sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78(a) (2) or CFR 1.78(a) (4), and need not otherwise be made part of the specification.

Prior Application Status	Pending		
Application Number	**Continuity Type**	**Prior Application Number**	**Filing Date**
	Is a continuation of	13/509,873	May 15, 2012
Prior Application Status	Pending		
Application Number	**Continuity Type**	**Prior Application Number**	**Filing Date**
13/509,873	Is a 371	PCT/US2011/020319	Jan. 6, 2011

Foreign Priority Information:

This section allows for the applicant to claim benefit of foreign priority and to identify any prior foreign application for which priority is not claimed. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55(a).

Application Number	**Country**	**Parent Filing Date**	**Priority Claimed**
			[ ] Yes [ ] No

Assignee Information:

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3000-US-0026CON
	Application Number	
Title of Invention	Gas Delivery Device And System	

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A signature of the applicant or representative is required in accordance with 37 CFR 1.33 and 10.18. Please see 37 CFR 1.4(d) for the form of the signature.					
Signature	/Rory P. Alegria, Reg. #66947/			**Date**	2012-06-11
First Name	Rory P.	**Last Name**	Alegria	**Registration Number**	66947

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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.

Doc Code: OATH

Document Description: Oath or declaration filed

PTO/SB/01 (10-08)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted With Initial Filing *OR* ☑ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (f)) required)

Attorney Docket Number	3000-US-0026 (IKA0011-00US)
First Named Inventor	Duncan P. Bathe
COMPLETE IF KNOWN	
Application Number	13/509,873
Filing Date	January 6, 2011
Art Unit	Unknown
Examiner Name	Unknown

I hereby declare that: (1) Each inventor's residence, mailing address, and citizenship are as stated below next to their name; and (2) I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Gas Delivery Device And System

(Title of the Invention)

the application of which

☐ is attached hereto

OR

☑ was filed on (MM/DD/YYYY) 05/15/2012 as United States Application Number or PCT International Application Number 13/509,873 and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified application, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Authorization To Permit Access To Application by Participating Offices

☑ If checked, the undersigned hereby grants the USPTO authority to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), and any other intellectual property offices in which a foreign application claiming priority to the above-identified application is filed access to the above-identified patent application. See 37 CFR 1.14(c) and (h). This box should not be checked if the applicant does not wish the EPO, JPO, KIPO, or other intellectual property office in which a foreign application claiming priority to the above-identified application is filed to have access to the application.

In accordance with 37 CFR 1.14(h)(3), access will be provided to a copy of the application-as-filed with respect to: 1) the above-identified application, 2) any foreign application to which the above-identified application claims priority under 35 USC 119(a)-(d) if a copy of the foreign application that satisfies the certified copy requirement of 37 CFR 1.55 has been filed in the above-identified US application, and 3) any U.S. application from which benefit is sought in the above-identified application.

In accordance with 37 CFR 1.14(c), access may be provided to information concerning the date of filing the Authorization to Permit Access to Application by Participating Offices.

PTO/SB/01 (10-08)
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DECLARATION — Utility or Design Patent Application

Claim of Foreign Priority Benefits

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	NO
PCT/US11/20319	PCT	01/06/2011	☐	☐	☑
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

PTO/SB/01 (10-08)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

DECLARATION — Utility or Design Patent Application

Direct all correspondence to:	☑ The address associated with Customer Number:	48394	OR ☐	Correspondence address below

Name		
Address		
City	State	ZIP
Country	Telephone	Email

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available. Petitioner/applicant is advised that documents which form the record of a patent application (such as the PTO/SB/01) are placed into the Privacy Act system of records DEPARTMENT OF COMMERCE, COMMERCE-PAT-7, System name: *Patent Application Files*. Documents not retained in an application file (such as the PTO-2038) are placed into the Privacy Act system of COMMERCE/PAT-TM-10, System name: *Deposit Accounts and Electronic Funds Transfer Profiles*.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle (if any)): Duncan P.	Family Name or Surname: Bathe
Inventor's Signature: DPBathe	Date: 6/13/2012

Residence: City	State	Country	Citizenship
Fitchburg	WI	US	GB

Mailing Address: 5899 Nutone Street			
City: Fitchburg	State: WI	Zip: 53711	Country: US

☑ Additional inventors or a legal representative are being named on the 1 supplemental sheet(s) PTO/SB/02A or 02LR attached hereto.

PTO/SB/02A (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle (if any))	Family Name or Surname
John	Klaus
Inventor's Signature	Date 06/11/2012
Cottage Grove Residence: City	WI State	United States of America Country	US Citizenship
2730 Gaston Road Mailing Address			
Cottage Grove City	WI State	53527 Zip	United States of America Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle (if any))	Family Name or Surname
David	Christensen
Inventor's Signature	Date 06/11/2012
Cambridge Residence: City	WI State	United States o Country	US Citizenship
N4398 Wolff Road Mailing Address			
Cambridge City	WI State	53523 Zip	United States of America Country

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor
Given Name (first and middle (if any))	Family Name or Surname
Inventor's Signature	Date
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	Zip	Country

FIG. 1

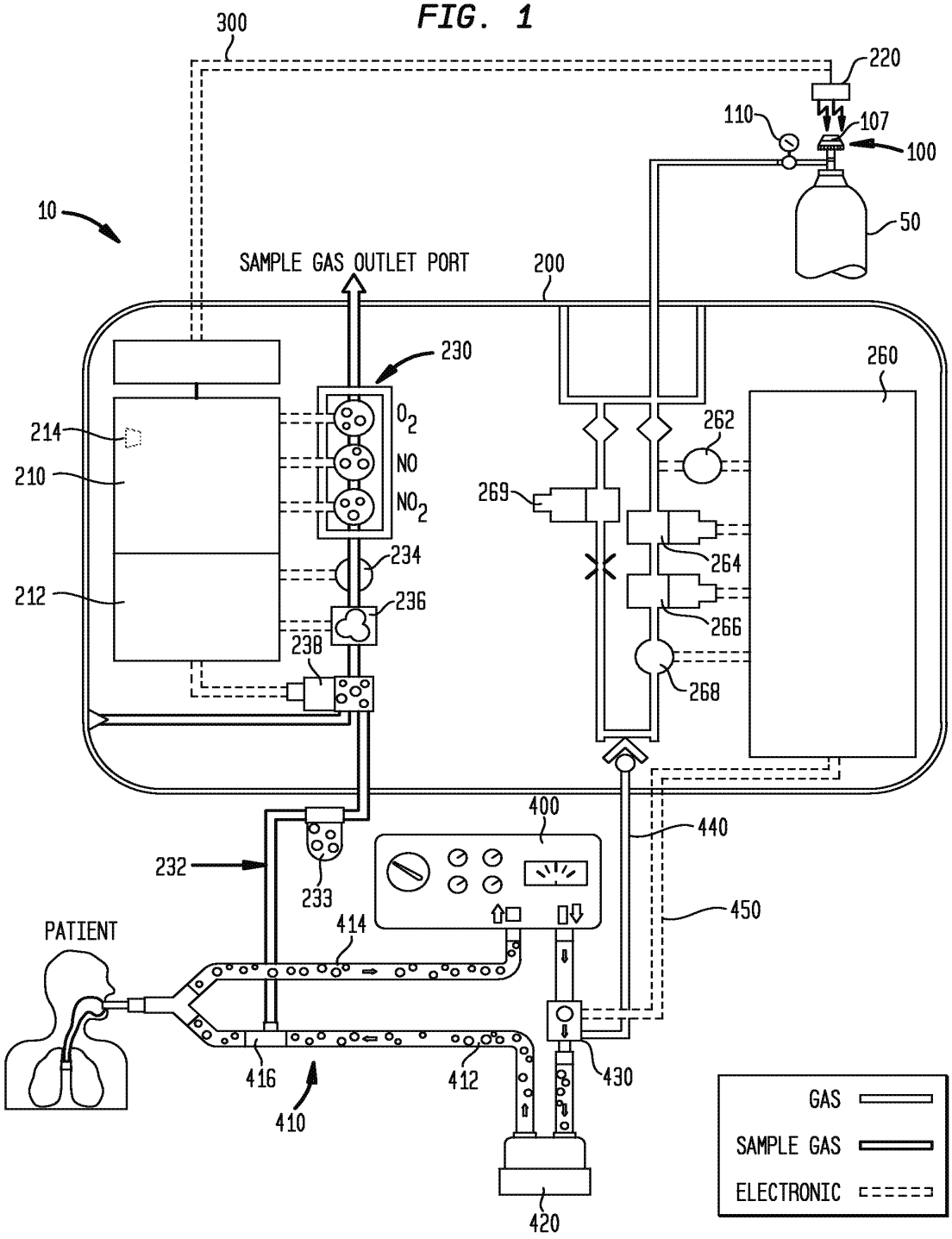

300
220
110
107
100
10
50
SAMPLE GAS OUTLET PORT
200
230
260
214
O_2
262
210
NO
269
NO_2
234
264
212
236
266
238
268
400
440
232
233
450
PATIENT
414
416
412
430
410
420
GAS
SAMPLE GAS
ELECTRONIC

FIG. 2

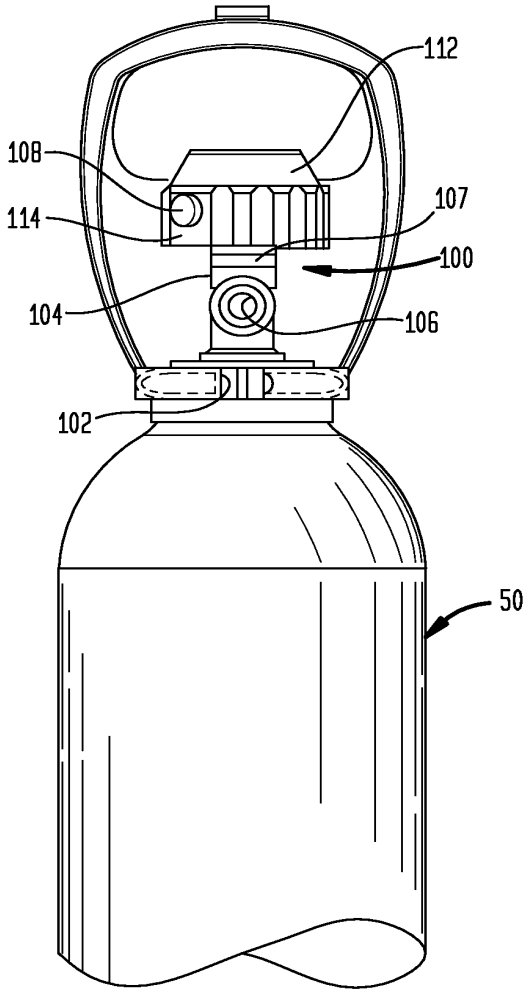


FIG. 3

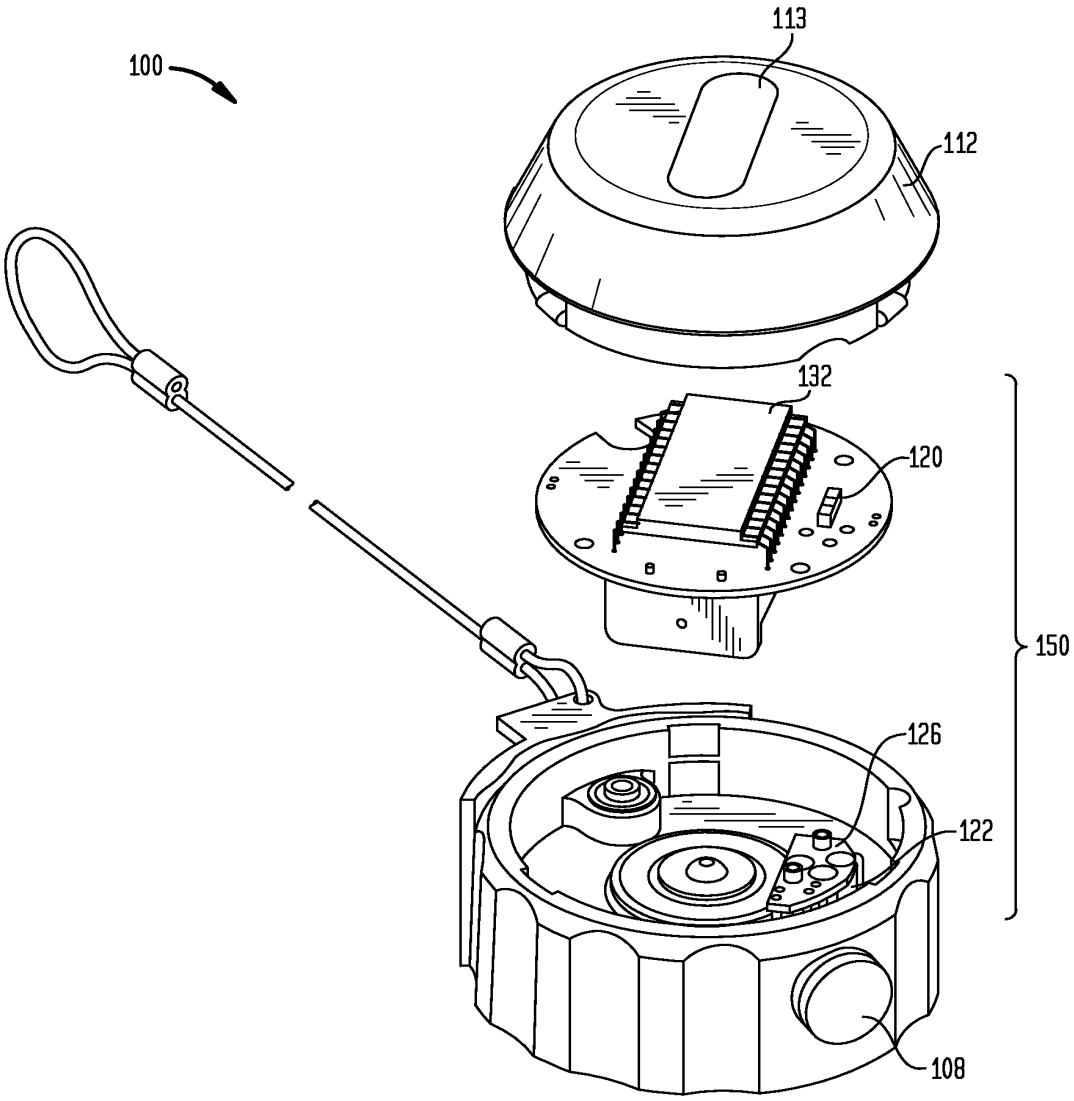


FIG. 4

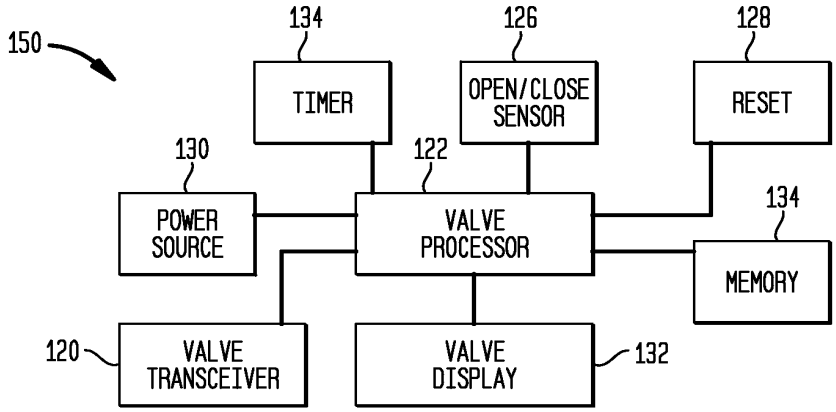

150
134
TIMER
126
OPEN/CLOSE SENSOR
128
RESET
130
POWER SOURCE
122
VALVE PROCESSOR
134
MEMORY
120
VALVE TRANSCEIVER
VALVE DISPLAY
132

FIG. 5

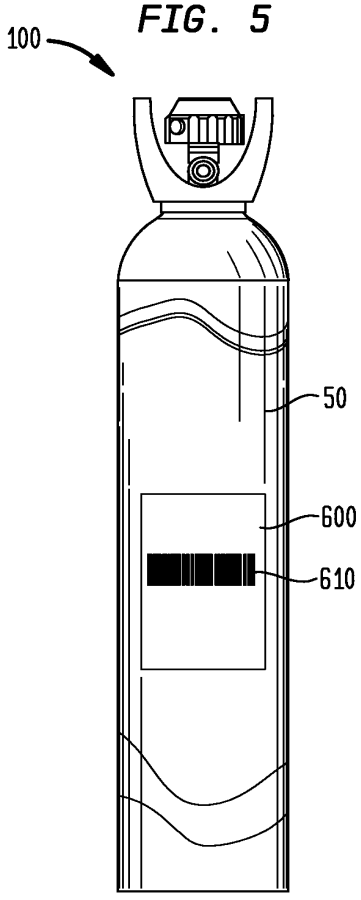

100
50
600
610

FIG. 6

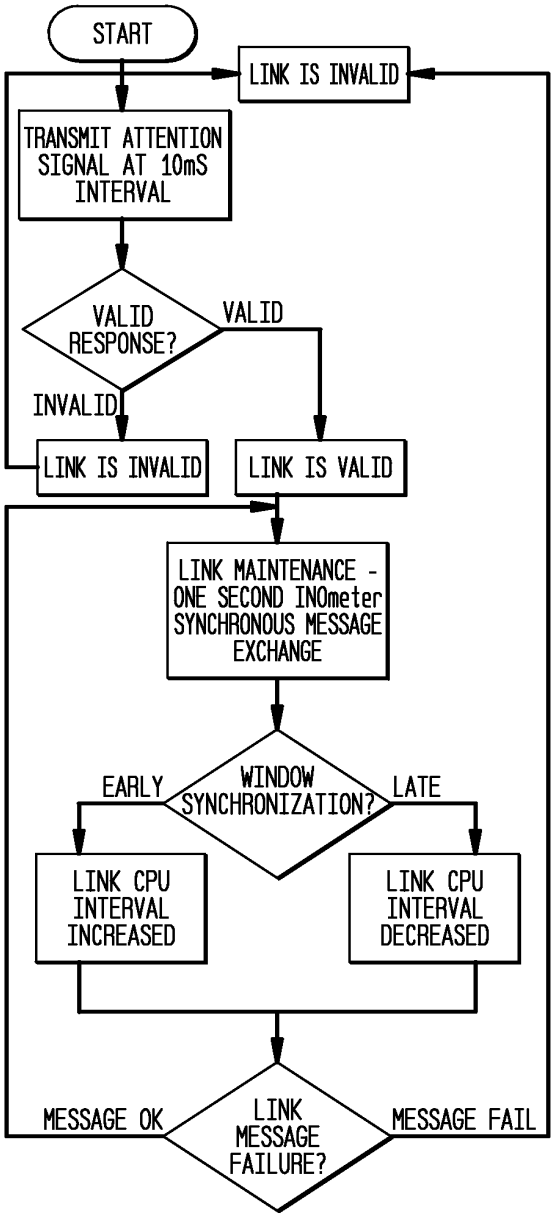

START
LINK IS INVALID
TRANSMIT ATTENTION SIGNAL AT 10mS INTERVAL
VALID RESPONSE?
VALID
INVALID
LINK IS INVALID
LINK IS VALID
LINK MAINTENANCE - ONE SECOND INOmeter SYNCHRONOUS MESSAGE EXCHANGE
WINDOW SYNCHRONIZATION?
EARLY
LATE
LINK CPU INTERVAL INCREASED
LINK CPU INTERVAL DECREASED
LINK MESSAGE FAILURE?
MESSAGE OK
MESSAGE FAIL

FIG. 7

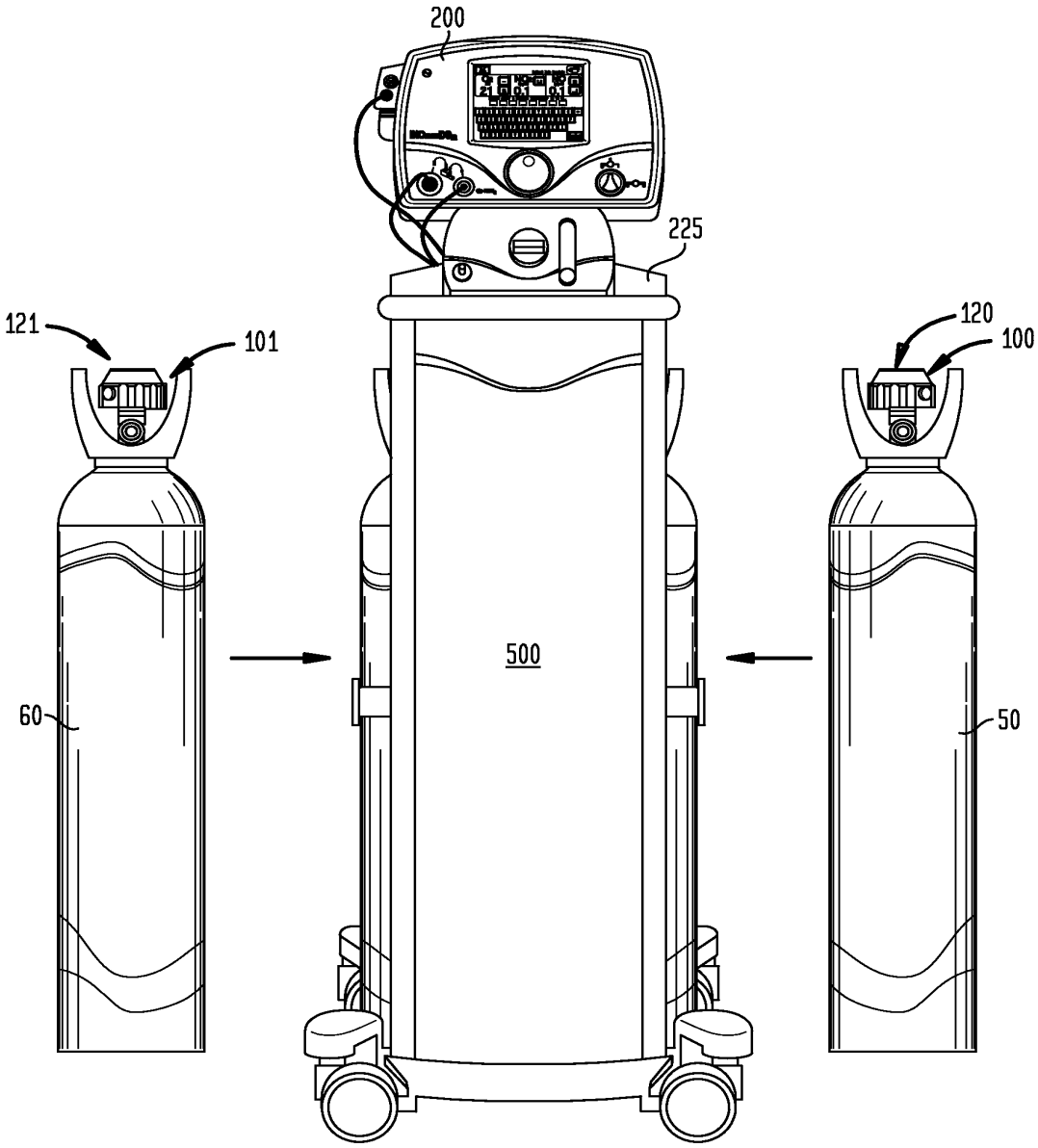


FIG. 8

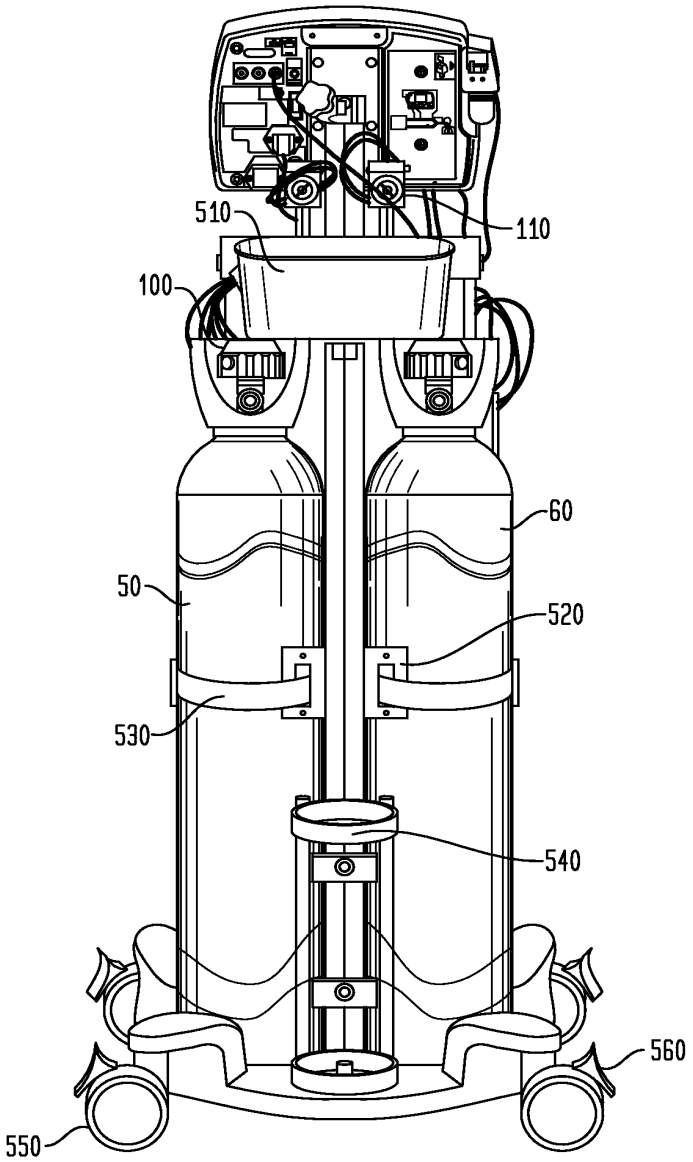


FIG. 9

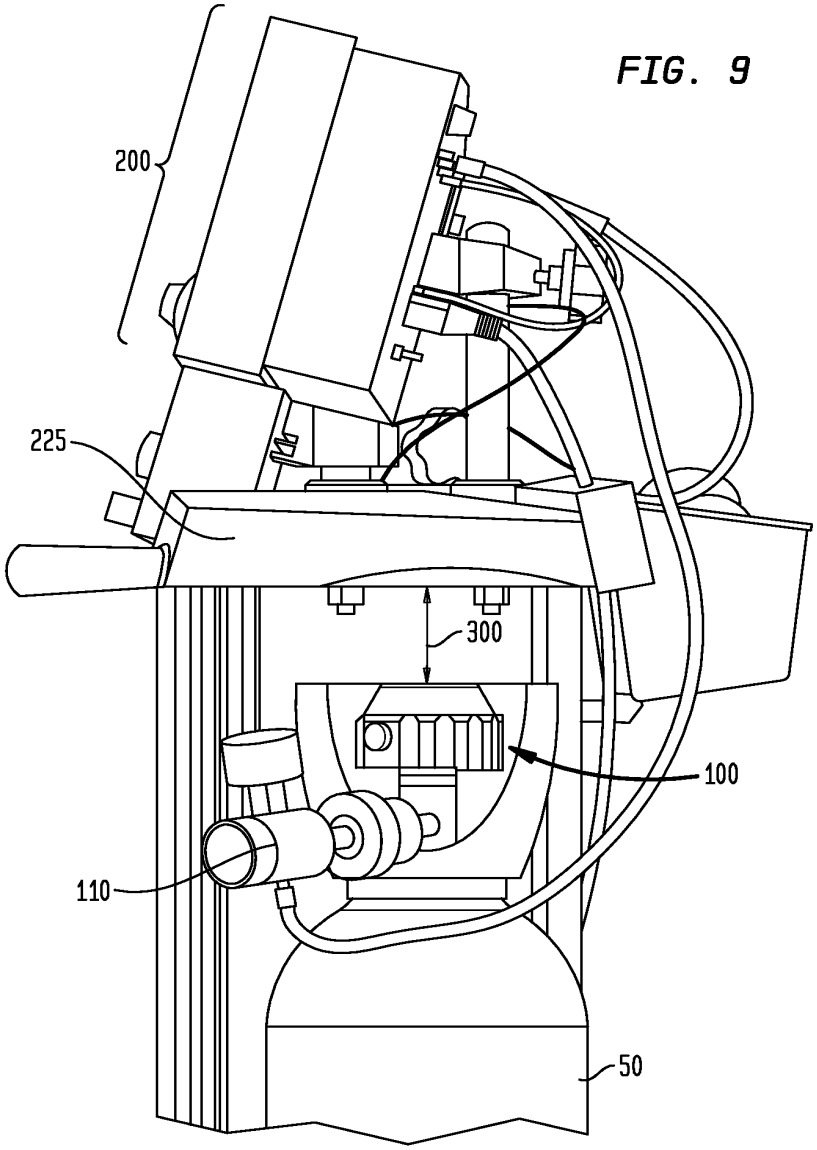


FIG. 10

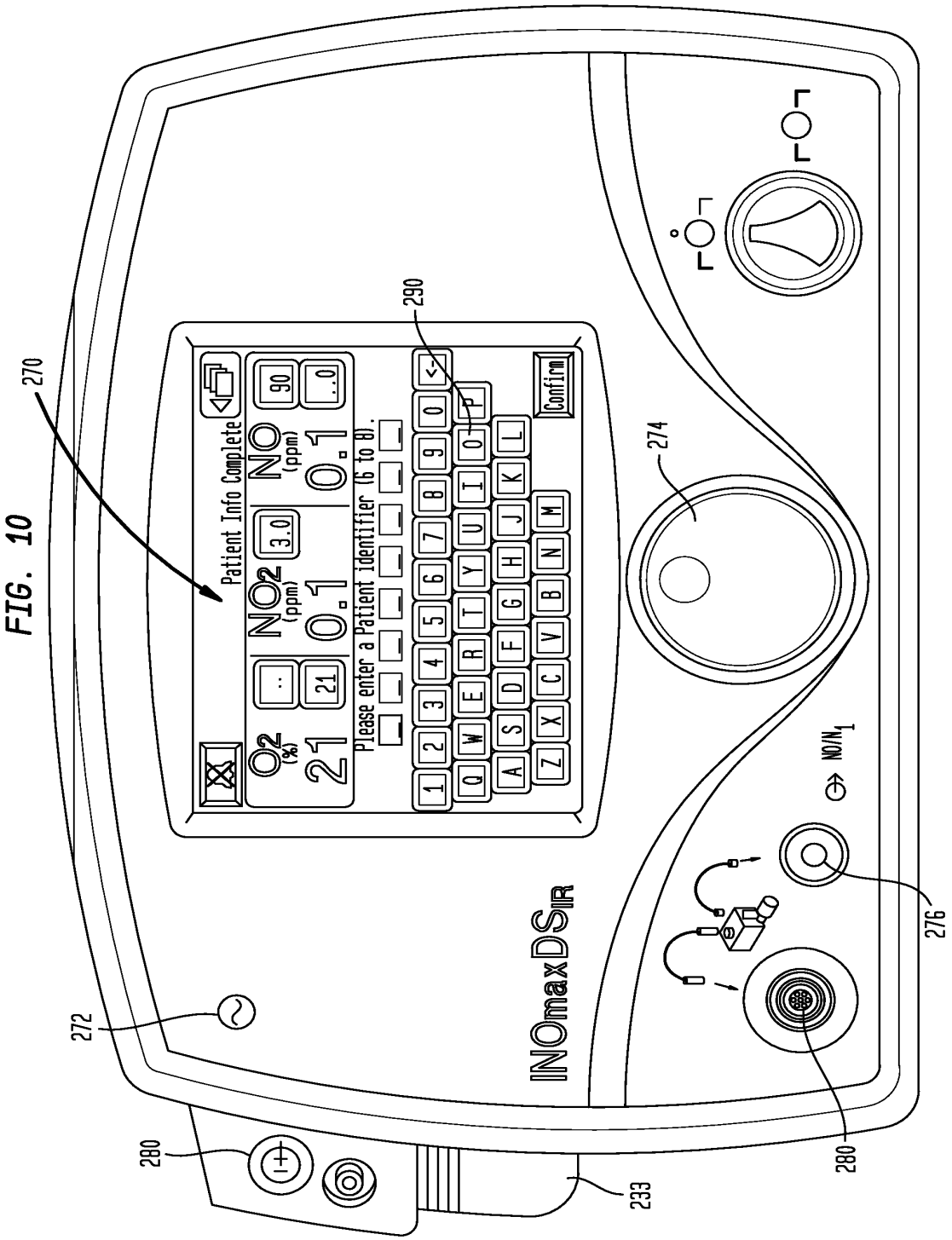

270
290
272
280
233
280
276
274
INOmaxDS IR
NO/N2
Patient Info Complete
Please enter a Patient identifier (6 to 8).
Confirm

FIG. 11

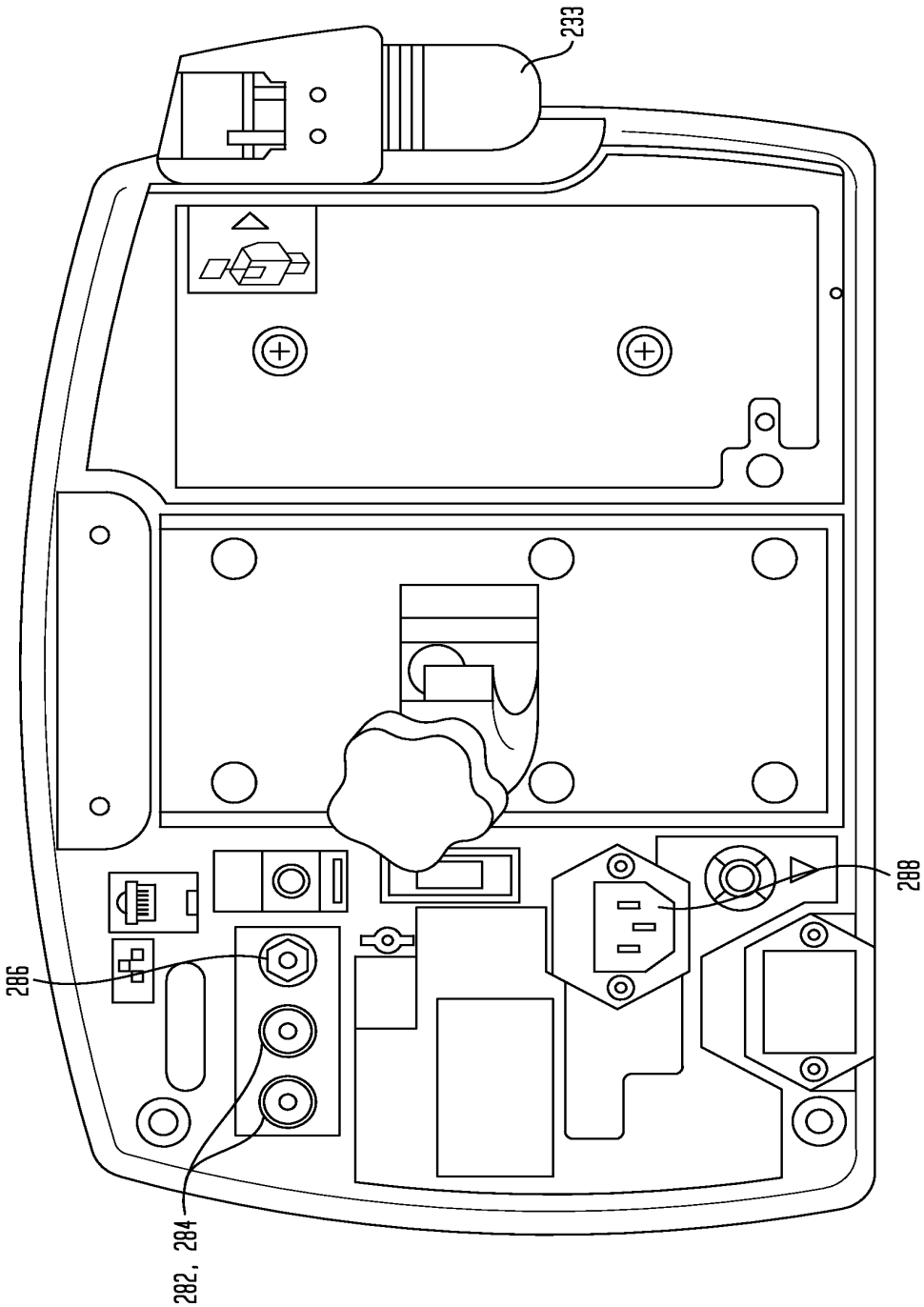


FIG. 12

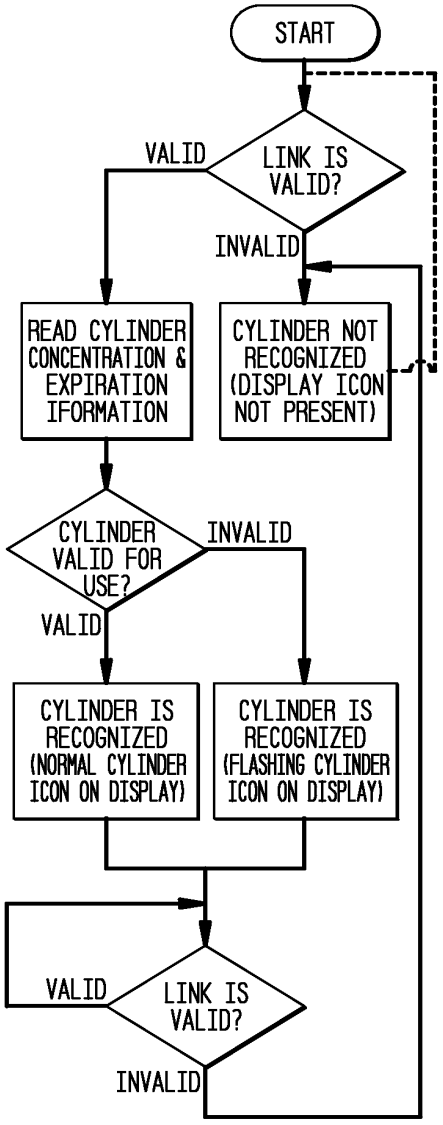
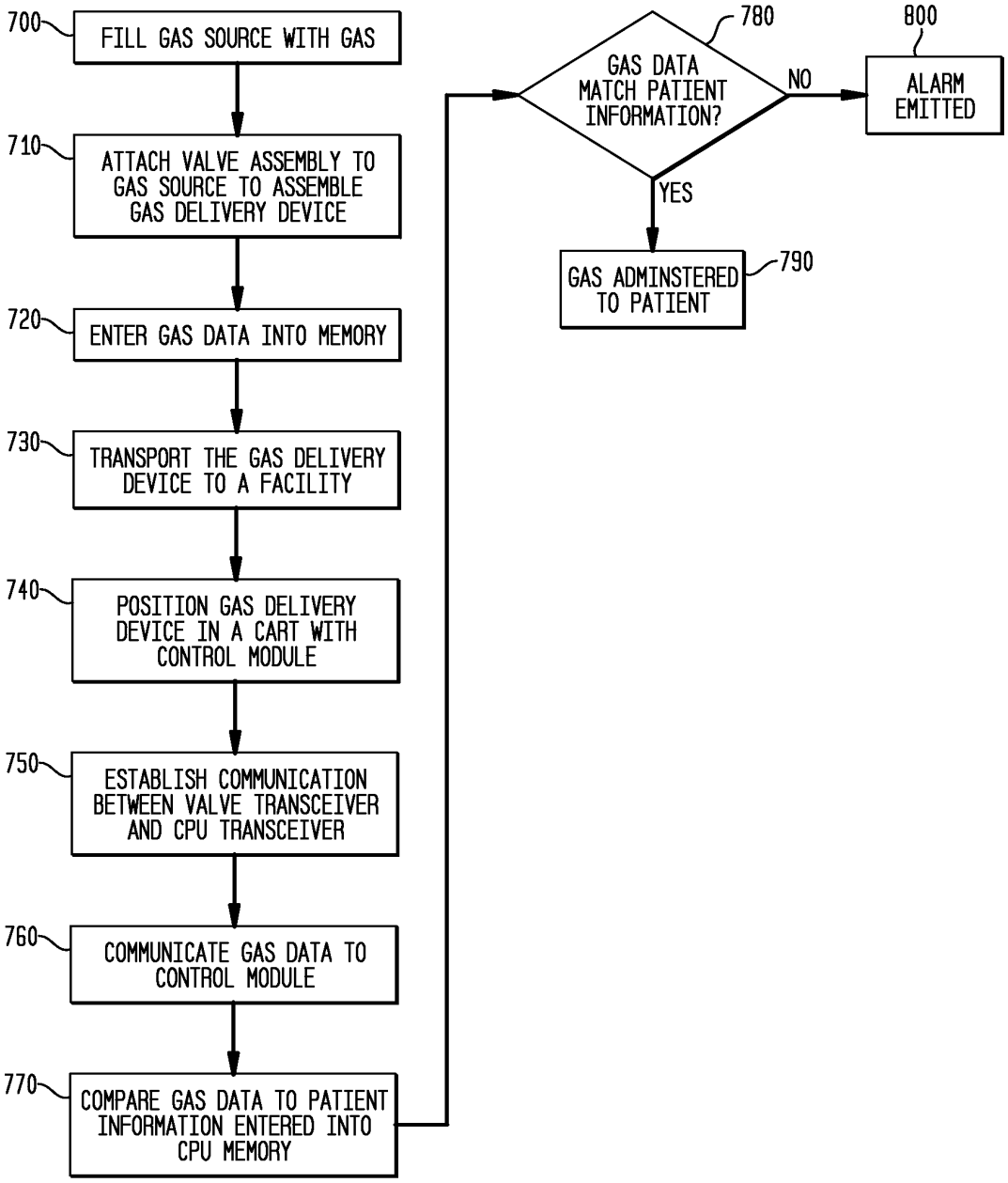

START
LINK IS VALID?
VALID
INVALID
READ CYLINDER CONCENTRATION & EXPIRATION IFORMATION
CYLINDER NOT RECOGNIZED (DISPLAY ICON NOT PRESENT)
CYLINDER VALID FOR USE?
INVALID
VALID
CYLINDER IS RECOGNIZED (NORMAL CYLINDER ICON ON DISPLAY)
CYLINDER IS RECOGNIZED (FLASHING CYLINDER ICON ON DISPLAY)
LINK IS VALID?
VALID
INVALID

FIG. 13


700
FILL GAS SOURCE WITH GAS
710
ATTACH VALVE ASSEMBLY TO GAS SOURCE TO ASSEMBLE GAS DELIVERY DEVICE
720
ENTER GAS DATA INTO MEMORY
730
TRANSPORT THE GAS DELIVERY DEVICE TO A FACILITY
740
POSITION GAS DELIVERY DEVICE IN A CART WITH CONTROL MODULE
750
ESTABLISH COMMUNICATION BETWEEN VALVE TRANSCEIVER AND CPU TRANSCEIVER
760
COMMUNICATE GAS DATA TO CONTROL MODULE
770
COMPARE GAS DATA TO PATIENT INFORMATION ENTERED INTO CPU MEMORY
780
GAS DATA MATCH PATIENT INFORMATION?
NO
800
ALARM EMITTED
YES
790
GAS ADMINSTERED TO PATIENT

Electronic Patent Application Fee Transmittal	
Application Number:	
Filing Date:	
Title of Invention:	Gas Delivery Device And System
First Named Inventor/Applicant Name:	Duncan P. Bathe
Filer:	Rory P. Alegria/Linda Murphy
Attorney Docket Number:	3000-US-0026CON
Filed as Small Entity	

Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Utility filing Fee (Electronic filing)	4011	1	95	95
Utility Search Fee	2111	1	310	310
Utility Examination Fee	2311	1	125	125
Request for Prioritized Examination	2817	1	2400	2400
Pages:				
Claims:				
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Publ. Fee- early, voluntary, or normal	1504	1	300	300
Processing Fee, except for Provis. apps	1808	1	130	130
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**3360**

Electronic Acknowledgement Receipt	
EFS ID:	12983209
Application Number:	13493493
International Application Number:	
Confirmation Number:	6133
Title of Invention:	Gas Delivery Device And System
First Named Inventor/Applicant Name:	Duncan P. Bathe
Customer Number:	48394
Filer:	Rory P. Alegria/Linda Murphy
Filer Authorized By:	Rory P. Alegria
Attorney Docket Number:	3000-US-0026CON
Receipt Date:	11-JUN-2012
Filing Date:	
Time Stamp:	16:07:45
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$3360
RAM confirmation Number	3030
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	TrackOne Request	00276828.PDF	67398 0dfce61dd4d4066535946e995356c84748e724ed	no	1
Warnings:					
Information:					
2		00276859.PDF	158873 ec317bade53bf31783d66fe35bbb7f759e496ed5	yes	28
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Specification		1	23	
	Claims		24	27	
	Abstract		28	28	
Warnings:					
Information:					
3	Application Data Sheet	00276857.PDF	62484 b9d028e4ab065fc35d2671d6c651406f4d0844bf	no	5
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
4	Oath or Declaration filed	00276821.PDF	1775772 7f1be1cadb08b2cc8dc49e081d2275c9fb900097	no	4
Warnings:					
Information:					
5	Drawings-only black and white line drawings	00276827.PDF	158914 9a4f15995c663c9b249213db4cf7c8d123d691b9	no	12
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	40083 2e9e78748ee4bce4c52eee9051aee4ee859bcdf3	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2263524		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 13/493,493

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	95		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	310		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	125		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	18 minus 20 =	*	x 30 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	3 minus 3 =	*	x 125 =	0.00			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	530		TOTAL	

APPLICATION AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
13/493,493	06/11/2012	3771	830	3000-US-0026CON	18	3

CONFIRMATION NO. 6133

48394
DIEHL SERVILLA LLC
33 WOOD AVE SOUTH
SECOND FLOOR, SUITE 210
ISELIN, NJ 08830

FILING RECEIPT

OC000000054933490

Date Mailed: 06/21/2012

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Duncan P. Bathe, Fitchburg, WI;
John Klaus, Cottage Grove, WI;
David Christensen, Cambridge, WI;

Assignment For Published Patent Application

INO Therapeutics LLC, Hampton, NJ

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 13/509,873
which is a 371 of PCT/US11/20319 01/06/2011

Foreign Applications (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.)

Permission to Access - A proper **Authorization to Permit Access to Application by Participating Offices** (PTO/SB/39 or its equivalent) has been received by the USPTO.

If Required, Foreign Filing License Granted: 06/19/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/493,493**

Projected Publication Date: 09/27/2012

Non-Publication Request: No

Early Publication Request: No

** **SMALL ENTITY** **

Title

Gas Delivery Device And System

Preliminary Class

128

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as

set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MAILED

JUL 24 2012

OFFICE OF PETITIONS

DIEHL SERVILLA LLC
33 WOOD AVE SOUTH
SECOND FLOOR, SUITE 210
ISELIN NJ 08830

Doc Code: TRACK1.GRANT

Decision Granting Request for Prioritized Examination (Track I or After RCE)	Application No.: 13/493,493

1. THE REQUEST FILED June 11, 2012 IS **GRANTED**.

The above-identified application has met the requirements for prioritized examination

A. ☒ for an original nonprovisional application (Track I).
B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination.** The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:

A. filing a **petition for extension of time** to extend the time period for filing a reply;
B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims**, or a multiple dependent claim;
C. filing a **request for continued examination**;
D. filing a notice of appeal;
E. filing a request for suspension of action;
F. mailing of a notice of allowance;
G. mailing of a final Office action;
H. completion of examination as defined in 37 CFR 41.102; or
I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to Irvin Dingle at (571)272-3210, Office of Petitions.

Irvin Dingle
/Irvin Dingle/
[*Signature*]

Petitions Examiner
(Title)

Doc Code: FAI.REQ
Document Description: Request First Action Interview

PTO/SB/413C (05-11)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REQUEST FOR FIRST ACTION INTERVIEW (FULL PILOT PROGRAM)

Attorney Docket Number: 3000-US-0026CON (IKA0011-01CT)	Application Number (if known): 13/493,493	Filing date: 06-11-2012
First Named Inventor: Duncan P. Bathe	Title: Gas Delivery Device And System	

APPLICANT HEREBY REQUESTS A FIRST ACTION INTERVIEW IN THE ABOVE-IDENTIFIED APPLICATION. See Instruction Sheet on page 2.

1. The application must contain three (3) or fewer independent claims and twenty (20) or fewer total claims.

2. The application must not contain any multiple dependent claims.

3. By filing this request:

   Applicant is agreeing to make an election without traverse if the Office determines that the claims are not obviously directed to a single invention; and

   Applicant is agreeing not to request for a refund of the search fee and any excess claims fee paid in the application after the mailing or notification of the pre-interview communication prepared by the examiner.

4. Other attachments: _____

Signature /Rory P. Alegria, Reg. No. 66,947/	Date 08-02-2012
Name (Print/Typed) Rory P. Alegria	Registration Number 66,947

Note: *Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below*.*

[x] *Total of 1 forms are submitted.

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 1.11 and 1.14. This collection is estimated to take 12 hours 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Doc Code: FAI.REQ
Document Description: Request First Action Interview

PTO/SB/413C (05-11)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

REQUEST FOR FIRST ACTION INTERVIEW (FULL PILOT PROGRAM)

Attorney Docket Number: 3000-US-0026CON (IKA0011-01CT)	Application Number (if known): 13/493,493	Filing date: 06-11-2012
First Named Inventor: Duncan P. Bathe	Title: Gas Delivery Device And System	

APPLICANT HEREBY REQUESTS A FIRST ACTION INTERVIEW IN THE ABOVE-IDENTIFIED APPLICATION. See Instruction Sheet on page 2.

1. The application must contain three (3) or fewer independent claims and twenty (20) or fewer total claims.

2. The application must not contain any multiple dependent claims.

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   Applicant is agreeing to make an election without traverse if the Office determines that the claims are not obviously directed to a single invention; and

   Applicant is agreeing not to request for a refund of the search fee and any excess claims fee paid in the application after the mailing or notification of the pre-interview communication prepared by the examiner.

4. Other attachments: _____

Signature /Rory P. Alegria, Reg. No. 66,947/	Date 08-02-2012
Name (Print/Typed) Rory P. Alegria	Registration Number 66,947

Note: *Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below*.*

[x] *Total of 1 forms are submitted.

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 1.11 and 1.14. This collection is estimated to take 12 hours 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Acknowledgement Receipt	
EFS ID:	13402446
Application Number:	13493493
International Application Number:	
Confirmation Number:	6133
Title of Invention:	Gas Delivery Device And System
First Named Inventor/Applicant Name:	Duncan P. Bathe
Customer Number:	48394
Filer:	Rory P. Alegria/Linda Murphy
Filer Authorized By:	Rory P. Alegria
Attorney Docket Number:	3000-US-0026CON
Receipt Date:	02-AUG-2012
Filing Date:	11-JUN-2012
Time Stamp:	13:35:18
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	First Action Interview - Enrollment Request	00288308.PDF	30484 f0bca6a876c281b0c3d927c4b1f38653b3e2b4de	no	1

Warnings:
Information:

Total Files Size (in bytes):	30484

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PTO/SB/08a (01-08)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

	Complete if Known
Application Number	13/493,493
Filing Date	Jun 11, 2012
First Named Inventor	Duncan P. Bathe
Art Unit	3778
Examiner Name	Matter, Kristen Clarette
	Submitted: August 7, 2012
Sheet 1 of 1	Attorney Docket No: 3000-US-0026CON

US PATENT DOCUMENTS

Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2005/0172966	Aug 11, 2005	Blaise, Gilbert et al.	
		2009/0266358	Oct 29, 2009	Rock, Emilio S., et al.	
		6109260	Aug 29, 2000	Bathe, Duncan P.	
		6125846	Oct 3, 2000	Bathe, Duncan P., et al.	
		6164276	Dec 26, 2000	Bathe, Duncan P., et al.	
		6581592	Jun 24, 2003	Bathe, Duncan P., et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[2]

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		"PCT International Search Report and Written Opinion for PCT/US2011/020319",Jan. 31, 2012, 19 pages	

EXAMINER **DATE CONSIDERED**

Substitute Disclosure Statement Form (PTO-1449)
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional) [2] Applicant is to place a check mark here if English language Translation is attached

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Duncan P. Bathe et al.	Examiner:	Matter, Kristen Clarette
Serial No.:	13/493,493	Group Art Unit:	3778
Filed:	June 11, 2012	Docket:	3000-US-0026CON
Title:	Gas Delivery Device And System	Conf. No.:	6133

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with 37 C.F.R. §§ 1.97 *et. seq.*, the referenced materials are brought to the attention of the Examiner for consideration in connection with the above-identified patent application. Applicants respectfully request that this Information Disclosure Statement be entered and the documents listed on the attached Form 1449 be considered by the Examiner and made of record. Pursuant to the provisions of MPEP 609, Applicants request that a copy of the 1449 form, initialed as being considered by the Examiner, be returned to the Applicants with the next official communication. Applicant acknowledges the requirement to submit copies of foreign patent documents and non-patent literature in accordance with 37 C.F.R. 1.98(a)(2).

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Information Disclosure Statement. However, if an Office Action on the merits has been mailed, the Commissioner is hereby authorized to charge the required fees to Deposit Account No. 50-3329 in order to have this Information Disclosure Statement considered. The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this communication.

Respectfully submitted,

Diehl Servilla LLC
33 Wood Avenue South
Second Floor, Suite 210
Iselin, New Jersey 08830
732-815-0404

Date August 7, 2012

By /Rory P. Alegria, Reg. No. 66,947/
Rory P. Alegria
Reg. No. 66,947

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

To:
Patel, Payal A.
DIEHL SERVILLA LLC
33 Wood Ave South, Suite 210
Iselin, NJ 08830
ETATS-UNIS D'AMERIQUE

Applicant's or agent's file reference IKA0011-00WO	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No. PCT/US2011/020319	International filing date *(day/month/year)* 6 January 2011 (06-01-2011)
Applicant IKARIA, INC.	

Date of mailing *(day/month/year)*
31 January 2012 (31-01-2012)

1. [X] The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes 1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 - 9.011.

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. [ ] **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Name and mailing address of the International Searching Authority	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax: (+31-70) 340-3016	FLANTER, Gerda Tel: +49 (0)89 2399-7024

Form PCT/ISA/220 (July 2010)

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.
IKA0011-00WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2011/020319	06/01/2011	
Applicant		
IKARIA, 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.

☐ 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:
      ☒ 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. ☒ **Unity of invention is lacking** (see Box No III)

4. With regard to the **title,**
   ☒ 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,**
   ☐ 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. 1
      ☒ as suggested by the applicant
      ☐ 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 SEARCH REPORT

International application No.
PCT/US2011/020319

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.: 14-18
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

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. [X] 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.:

1-10

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.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/020319

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/10 A61M16/20
ADD.

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/266358 A1 (SACRISTAN ROCK EMILIO [MX] ET AL) 29 October 2009 (2009-10-29)	1,6,8
A	paragraphs [0131], [0132], [0142] - [0148]; figures 3,4	2-4,7,9, 10
A	US 2005/172966 A1 (BLAISE GILBERT [CA] ET AL) 11 August 2005 (2005-08-11) paragraphs [0049] - [0061]; figure 5	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 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
17 October 2011	31/01/2012

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

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2011/020319

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009266358 A1	29-10-2009	CN 102046234 A	04-05-2011
		EP 2266653 A1	29-12-2010
		JP 2011515184 A	19-05-2011
		US 2009266358 A1	29-10-2009
		WO 2009120057 A1	01-10-2009
US 2005172966 A1	11-08-2005	NONE	

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-10

A gas delivery device comprising a valve, a memory to store gas data and a processor and a transceiver to send wireless signals to a control module.
Problem to be solved: Simplifying the set-up procedure when new gas sources are loaded onto a cart.

---

2. claims: 11-13

A memory comprising instructions that cause a processor to receive gas data, compare the gas data with user inputted patient information, coordinate, select and control a therapy to the patient.
Problem to be solved: Enhancing accuracy and safety of the therapy

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Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

A gas delivery system including a gas delivery device (100), a control module (200) and a gas delivery mechanism is described. An exemplary gas delivery device includes a valve (107) assembly with a valve and circuit including a memory (134), a processor (122) and a transceiver (120)in communication with the memory. The memory may include gas data such as gas identification, gas expiration and gas concentration. The transceiver on the circuit of the valve assembly may send wireless optical line-of-sight signals to communicate the gas data to a control module. Exemplary gas delivery mechanisms include a ventilator (400) and a breathing circuit (410). Methods of administering gas are also described.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/020319

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.: 14-18
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

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. [X] 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.:

1-10

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.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/020319

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M16/10 A61M16/20
ADD.

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2009/266358 A1 (SACRISTAN ROCK EMILIO [MX] ET AL) 29 October 2009 (2009-10-29)	1,6,8
A	paragraphs [0131], [0132], [0142] - [0148]; figures 3,4	2-4,7,9, 10
A	US 2005/172966 A1 (BLAISE GILBERT [CA] ET AL) 11 August 2005 (2005-08-11) paragraphs [0049] - [0061]; figure 5	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 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
17 October 2011	31/01/2012

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

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2011/020319

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2009266358 A1	29-10-2009	CN 102046234 A	04-05-2011
		EP 2266653 A1	29-12-2010
		JP 2011515184 A	19-05-2011
		US 2009266358 A1	29-10-2009
		WO 2009120057 A1	01-10-2009
US 2005172966 A1	11-08-2005	NONE	

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-10

A gas delivery device comprising a valve, a memory to store gas data and a processor and a transceiver to send wireless signals to a control module.
Problem to be solved: Simplifying the set-up procedure when new gas sources are loaded onto a cart.

---

2. claims: 11-13

A memory comprising instructions that cause a processor to receive gas data, compare the gas data with user inputted patient information, coordinate, select and control a therapy to the patient.
Problem to be solved: Enhancing accuracy and safety of the therapy

---

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/US2011/020319	06.01.2011	

International Patent Classification (IPC) or both national classification and IPC
INV. A61M16/10 A61M16/20

Applicant
IKARIA, 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 and 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 notified 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 D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	see form PCT/ISA/210	Böttcher, Stephanie Telephone No. +49 89 2399-2875

Form PCT/ISA/237 (Cover Sheet) (July 2009)

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, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. (means)

      ☐ on paper

      ☐ in electronic form

   b. (time)

      ☐ in the international application as filed

      ☐ together with the international application in electronic form

      ☐ 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 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. 11-18

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. 11-18

☐ 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).

☐ 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. 1-10

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	2-5, 7, 9, 10
	No:	Claims	1, 6, 8
Inventive step (IS)	Yes:	Claims	2-5, 7, 9, 10
	No:	Claims	1, 6, 8
Industrial applicability (IA)	Yes:	Claims	1-10
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Rule 39.1(iv) PCT - Claims 14-18 relate to a method for treatment of the human or animal body by therapy.

Re Item IV

Lack of unity of invention

This Authority considers that the application does not meet the requirements of unity of invention and that there are two inventions covered by the claims indicated as follows:

1. claims: 1-10

   A gas delivery device comprising a valve, a memory to store gas data and a processor and a transceiver to send wireless signals to a control module.

   Problem to be solved: Simplifying the set-up procedure when new gas sources are loaded onto a cart.

2. claims: 11-13

   A memory comprising instructions that cause a processor to receive gas data, compare the gas data with user inputted patient information and coordinate, select and control a therapy to the patient.

   Problem to be solved: Enhancing accuracy and safety of the therapy

The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

The above-mentioned groups of claims relate to different devices and the technical problems which they pretend to solve are different (see above). Thus, they are not linked by common or corresponding special technical features and define two different inventions not linked by a single general inventive concept.

The application, hence does not meet the requirements of unity of invention as defined in Rules 13.1 and 13.2 PCT.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1 US 2009/266358 A1 (SACRISTAN ROCK EMILIO) 29 October 2009

D2 US 2005/172966 A1 (BLAISE GILBERT [CA] ET AL) 11 August 2005

2 The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claim 1 is not new.

Document D1 discloses (see paragraphs [0131], [0132], [0142] - [0148]; figures 3,4) a gas delivery device (400) to administer therapy gas from a gas source, the gas delivery device comprising:
a valve (518) attachable to the gas source, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas through the valve to a control module; and
a circuit including:
memory (812) to store gas data comprising one or more of gas identification, gas expiration date and gas concentration and
a processor and a transceiver in communication with the memory to send wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject.

3 Dependent claims 6 and 8 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (see D1, paragraphs [0131], [0132], [0142] - [0148]; figures 3,4).

4 The combination of the features of dependent claims 2-5, 7 and 9-10 is neither known from nor rendered obvious by the available prior art.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.
Amending claims under Art. 19 PCT	Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.
Filing a demand for international preliminary examination	In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT). If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).
Filing informal comments	After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.
End of the international phase	At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPER (international preliminary examination report).
Relevant PCT Rules and more information	Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, OJ 11/2003, OJ 12/2003

Electronic Acknowledgement Receipt	
EFS ID:	13434863
Application Number:	13493493
International Application Number:	
Confirmation Number:	6133
Title of Invention:	Gas Delivery Device And System
First Named Inventor/Applicant Name:	Duncan P. Bathe
Customer Number:	48394
Filer:	Rory P. Alegria/Christine Danelson
Filer Authorized By:	Rory P. Alegria
Attorney Docket Number:	3000-US-0026CON
Receipt Date:	07-AUG-2012
Filing Date:	11-JUN-2012
Time Stamp:	13:16:33
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) Form (SB08)	00289162.PDF	29110 e4374917d5e81d720056a2e71ef9afecc8f25c86	no	1
Warnings:					
Information:					

This is not an USPTO supplied IDS fillable form					
2	Transmittal Letter	00289161.PDF	18163 1350d0d733adfe2e3839e8e4a0139499590 97f43	no	1
Warnings:					
Information:					
3	Non Patent Literature	00289163.PDF	13693525 d3829aec491ef6ee6780eb58d8a0d2a97af2 d29f	no	19
Warnings:					
Information:					
			Total Files Size (in bytes):	13740798	

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

First Action Interview Pilot Program Pre-Interview Communication	Application No. 13/493,493	Applicant(s) BATHE ET AL.	
	Examiner KRISTEN MATTER	Art Unit 3778	Page 1 of

-The MAILING OR NOTIFICATION DATE of this communication appears on the cover sheet with the correspondence address -

THE SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE **ONE MONTH OR THIRTY (30) DAYS,** WHICHEVER IS LONGER, FROM THE MAILING OR NOTIFICATION DATE OF THIS COMMUNICATION.

This time period for reply is extendable under 37 CFR 1.136(a) for only ONE additional MONTH.
This communication constitutes notice under 37 CFR 1.136(a)(1)(i).

Applicant must, within the time period for reply, file: (1) A letter requesting not to have a first action interview; (2) A reply under 37 CFR 1.111 waiving the first action interview and First Action Interview Office Action; or (3) An Applicant Initiated Interview Request Form (PTOL-413A) electronically via EFS-Web, accompanied by a proposed amendment or arguments, and schedule the interview within 2 months from the filing of the request. A failure to respond to this communication will be treated as a request not to have an interview. If applicant waives the First Action Interview Office Action, the instant Pre-Interview Communication is deemed the first Office Action on the Merits. The next subsequent Office action may be made final if appropriate. See MPEP 706.07(a).

Disposition of Claims

3)☒ Claim(s) *1-18* is/are pending in the application.
3a) Of the above claim(s) _____ is/are withdrawn from consideration.
4)☐ Claim(s) _____ is/are allowed.
5)☒ Claim(s) *1-18* is/are rejected.
6)☐ Claim(s) _____ is/are objected to.
7)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

8)☐ The specification is objected to by the Examiner.
9)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
10)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

11)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.

Contact Information

Examiner's Telephone Number: (571)272-5270
Examiner's Typical Work Schedule: Monday - Friday 9-5
Supervisor's Name: Jackie Ho
Supervisor's Telephone Number: (571) 272-4696

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/7/12*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

First Action Interview Pilot Program Pre-Interview Communication	Application No. 13493493	Applicant(s) BATHE ET AL.	
	Examiner KRISTEN MATTER	Art Unit 3778	Page 2 of

Notification of Rejection(s) and/or Objection(s)

#	Claim(s)	Reference(s) (if applicable)	Rejection Statutory Basis	Brief Explanation of Rejection
1	6-10		112	It is unclear if the "control module" mentioned in line 3 of claim 6 is the same control module or a different one because of use of the term "a" before the element that has already been introduced in the claims.
2	1-18	B	Double Patenting	Copending claim 1 is the same as instant claim 1 except for that the copending claim 1 does not specify NO gas. However, use of NO gas is considered an obvious modificaiton that does not patentably distinguish the two inventions (see below)
3	1, 2, 4-7	A, B	103	A discloses all of the limitations of the claims, including a gas delivery device comprising a valve actuator to open and close a valve [83] and a circuit with memory to store gas data [41, 50, 56, 57-65] and a processor/transciever to (see below)
4	3	A, B, C	103	The modified A/B device does not mention a bar code. However, use of a bar code for scanning is obvious in light of C (see [6] for example).
5	8-18	A, B, D	103	The modified A/B device does not specifically mention entering patient data for comparing against the delivery. However, D has a similar gas delivery system that allows the entry of patent information for setting threshold ranges and (see below)

Expanded Discussion/Commentary

2		(see also reference B). Similar arguments exist for the remaining claims.
3		periodically communicate the data to a CPU/control module that stores the info and uses it to control a ventilator [42-45, 68, 77, 83, 88, 94]. A does not mention NO but use of such gas is obvious in view of B (see abstract of B).
5		control of ventilator settings [35] to increase patient safety.

DATE:		
15 August, 2012	/Kristen C. Matter/ Primary Examiner, Art Unit 3778	

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

BIB DATA SHEET

CONFIRMATION NO. 6133

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/493,493	06/11/2012	128	3778	3000-US-0026CON

APPLICANTS

Duncan P. Bathe, Fitchburg, WI;
John Klaus, Cottage Grove, WI;
David Christensen, Cambridge, WI;

** **CONTINUING DATA** ********** /KCM/

This application is a CON of 13/509,873
which is a 371 of PCT/US11/20319 01/06/2011

** **FOREIGN APPLICATIONS** ********** None /KCM/

** **IF REQUIRED, FOREIGN FILING LICENSE GRANTED** ** ** SMALL ENTITY **
06/19/2012

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /KRISTEN CLARETTE MATTER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		WI	12	18	3

ADDRESS

DIEHL SERVILLA LLC
33 WOOD AVE SOUTH
SECOND FLOOR, SUITE 210
ISELIN, NJ 08830
UNITED STATES

TITLE

Gas Delivery Device And System

FILING FEE RECEIVED		
830	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

BIB (Rev. 05/07).

Inventor Information for 13/493493

Inventor Name	City	State/Country
BATHE, DUNCAN P.	FITCHBURG	WISCONSIN
KLAUS, JOHN	COTTAGE GROVE	WISCONSIN
CHRISTENSEN, DAVID	CAMBRIDGE	WISCONSIN

Appln Info | Contents | Petition Info | Atty/Agent Info | Continuity Data | Foreign Data | **Inventors** | Address | Fees | Post Info | Pre

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PCT / / Search **or PG PUBS #** Search

Attorney Docket # Search

Bar Code # Search

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Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13493493	BATHE ET AL.
	Examiner	Art Unit
	KRISTEN MATTER	3778

SEARCHED			
Class	Subclass	Date	Examiner
128	204.18, 204.21-204.23, 205.24, 203.12, 203.14	8/15/12	KCM

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor name search, see attached EAST text search	8/15/12	KCM

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/493,493	06/11/2012	Duncan P. Bathe	3000-US-0026CON	6133

48394 7590 08/21/2012

DIEHL SERVILLA LLC
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ISELIN, NJ 08830

EXAMINER	
MATTER, KRISTEN CLARETTE	
ART UNIT	PAPER NUMBER
3778	

NOTIFICATION DATE	DELIVERY MODE
08/21/2012	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@dsiplaw.com
jescobar@dsiplaw.com
lmurphy@dsiplaw.com

Notice of References Cited	Application/Control No. 13/493,493	Applicant(s)/Patent Under Reexamination BATHE ET AL.	
	Examiner KRISTEN MATTER	Art Unit 3778	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2009/0266358	10-2009	Sacristan Rock et al.	128/203.26
*	B	US-2011/0240019	10-2011	Fine et al.	128/202.26
*	C	US-2002/0044059	04-2002	Reeder et al.	340/573.1
*	D	US-2011/0041849	02-2011	Chen et al.	128/204.23
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	8	(("20090266358") or ("20110240019") or ("20020044059") or ("20110041849")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/08/15 10:02
S1	249	valve and ventilator and (NO (nitric adj oxide)) with gas with (identify indentification concentration)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 09:22
S2	59	valve and ventilator and (NO (nitric adj oxide)) with gas with (identify indentification concentration) and infrared	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 09:23
S3	133	S1 and "128"/.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 09:25
S4	118	S3 not S2	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 09:26
S5	28	(US-20110168177-$ or US-20090090359-$ or US-20090054798-$ or US-20080202526-$ or US-20120199123-$ or US-20120180790-$ or US-20120042876-$ or US-20110240019-$ or US-20110220103-$ or US-20110082380-$ or US-20110041847-$ or US-20110017211-$ or US-20100030091-$ or US-20090107497-$ or US-20080289628-$ or US-20080178882-$ or US-20070144515-$ or US-20060207594-$ or US-20050172966-$ or US-20030131848-$).did. or (US-6305212-$ or US-5778874-$ or US-5615669-$ or US-4188946-$ or US-6032665-$ or US-5918596-$ or US-5752504-$ or US-5732693-$).did.	US-PGPUB; USPAT	OR	ON	2012/08/13 09:56

S6	8	S5 and (CPU computer) and (memory store storing record$3)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 09:57
S7	8	S5 and infrared	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 09:58
S8	14	S5 and (CPU computer) and control$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 10:00
S9	7	S5 and concentration with signal with control$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 10:13
S10	8	gas with (identify indentif$4 indentification) with (barcode bar code) with scan$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 11:22
S11	214	gas with (barcode bar code) with scan$3	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 11:23
S12	1	S11 and ventilator	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 11:24
S13	14	gas with (identify indentif$4 indentification type) with (barcode bar code) and ventilator	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 11:24
S14	28	(identify indentif$4 indentification type) with (barcode bar code) with scan$3 and ventilator	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	ON	2012/08/13 11:25

			DERWENT; IBM_TDB			
S15	43	"128"/.ccls. and ventilator and wireless with infrared	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 11:32
S16	8	"128"/.ccls. and signals with control$3 with wireless with infrared	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 11:33
S17	7	(("20090266358") or ("20050172966") or ("3581592")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/08/13 11:50
S18	6	(("20090266358") or ("20050172966") or ("6581592")).PN.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2012/08/13 11:55
S19	34919	microphone.ti.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 18:09
S20	514	microphone.ti. and mask	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 18:09
S21	45	(nitric adj oxide) with liquid and "128"/.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 19:04
S22	4	Patient with information with range with anesthesia	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 19:16
S23	1	Patient with information with threshold with anesthesia	US-PGPUB; USPAT; USOCR;	OR	ON	2012/08/13 19:17

			FPRS; EPO; JPO; DERWENT; IBM_TDB			
S24	244	Patient with information with (threshold range) and "128"/.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 19:17
S25	162	(bathe with duncan).in. (klaus with john).in. (david with christensen).in.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 19:29
S26	0	S25 and (valve and signals and memory and gas).clm.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2012/08/13 19:30

EAST Search History (Interference)

<This search history is empty>

8/15/2012 10:36:37 AM
C:\Users\kmatter\Documents\EAST\Workspaces\13493493 NO controller.wsp

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13493493	BATHE ET AL.
	Examiner	**Art Unit**
	KRISTEN MATTER	3778

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/15/2012								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
	8	✓								
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	12	✓								
	13	✓								
	14	✓								
	15	✓								
	16	✓								
	17	✓								
	18	✓								

PTO/SB/08a (01-08)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	1

Complete if Known	
Application Number	13/493,493
Filing Date	Jun 11, 2012
First Named Inventor	Duncan P. Bathe
Art Unit	3778
Examiner Name	Matter, Kristen Clarette
Submitted: August 7, 2012	
Attorney Docket No: 3000-US-0026CON	

US PATENT DOCUMENTS

Examiner Initial *	Cite No	Document Number	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		2005/0172966	Aug 11, 2005	Blaise, Gilbert et al.	
		2009/0266358	Oct 29, 2009	Rock, Emilio S., et al.	
		6109260	Aug 29, 2000	Bathe, Duncan P.	
		6125846	Oct 3, 2000	Bathe, Duncan P., et al.	
		6164276	Dec 26, 2000	Bathe, Duncan P., et al.	
		6581592	Jun 24, 2003	Bathe, Duncan P., et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[2]

OTHER DOCUMENTS -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No [1]	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, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		"PCT International Search Report and Written Opinion for PCT/US2011/020319",Jan. 31, 2012, 19 pages	

EXAMINER	/Kristen Matter/	DATE CONSIDERED	08/15/2012

Substitute Disclosure Statement Form (PTO-1449)
[1] EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional) [2] Applicant is to place a check mark here if English language Translation is attached

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /K.M./

PTO/SB/80 (11-08)
Approved for use through 11/30/2011. OMB 0651-0035
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(b).

I hereby appoint:

☑ Practitioners associated with the Customer Number: 48394

OR

☐ Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

as attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(b).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(b) to:

☑ The address associated with Customer Number: 48394

OR

☐ Firm or Individual Name			
Address			
City		State	Zip
Country			
Telephone		Email	

Assignee Name and Address:

INO THERAPEUTICS LLC
6 STATE ROUTE 173
CLINTON, NEW JERSEY 08809

A copy of this form, together with a statement under 37 CFR 3.73(b) (Form PTO/SB/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(b) may be completed by one of the practitioners appointed in this form if the appointed practitioner is authorized to act on behalf of the assignee, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee

Signature		Date	08 Nov 11
Name	Jonathan Provoost	Telephone	908-238-6600
Title	Associate General Counsel		

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: INO Therapeutics LLC

Application No./Patent No.: 13/493,493 Filed/Issue Date: June 11, 2012

Titled: Gas Delivery Device And System

INO Therapeutics LLC ,a Limited Liability Company

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.

states that it is:

1. ☑ the assignee of the entire right, title, and interest in;

2. ☐ **an assignee of less than the entire right, title, and interest in (The extent (by percentage) of its ownership interest is** _____%); or

3. ☐ the assignee of an undivided interest in the entirety of (a complete assignment from one of the joint inventors was made)

the patent application/patent identified above, by virtue of either:

A. ☑ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 028383 , Frame 0403 , or for which a copy therefore is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

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3. From: _____ To: _____

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Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☐ As required by 37 CFR 3.73(b)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/Rory P. Alegria, Reg. #66947/ August 21, 2012

Signature Date

Rory P. Alegria Attorney or Agent

Printed or Typed Name Title

Electronic Acknowledgement Receipt	
EFS ID:	13544444
Application Number:	13493493
International Application Number:	
Confirmation Number:	6133
Title of Invention:	Gas Delivery Device And System
First Named Inventor/Applicant Name:	Duncan P. Bathe
Customer Number:	48394
Filer:	Rory P. Alegria/Linda Murphy
Filer Authorized By:	Rory P. Alegria
Attorney Docket Number:	3000-US-0026CON
Receipt Date:	21-AUG-2012
Filing Date:	11-JUN-2012
Time Stamp:	15:19:52
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	Power of Attorney	00298633.PDF	582610 08d0b6c3cc2dba46d9681e858afb18e07f8fb13a	no	1
Warnings:					
Information:					

2	Assignee showing of ownership per 37 CFR 3.73(b).	00298671.PDF	95554 d8c58450e0482df6f177690991a16e54d71ee339	no	1

Warnings:	
Information:	
Total Files Size (in bytes):	678164

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

PROPOSED

S/N 13/493,493 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Bathe, Duncan P.	Examiner	Kristen Matter
Serial No.:	13/493,493	Group Art Unit	3778
Filed:	Jun 11, 2012	Docket No.:	3000-US-0026CON (IKA0011-01CT)
		Confirmation No.:	6133

Title: Gas Delivery Device And System

PROPOSED AMENDMENT AND RESPONSE TO PRE-INTERVIEW COMMUNICATION

This paper is being submitted in response to the Pre-Interview Communication dated August 21, 2012, in the above-identified patent application. The one month period for reply to the Communication expires on September 21, 2012. Accordingly, this paper is being timely filed.

PROPOSED

IN THE CLAIMS

1. (Currently amended) A ~~gas delivery device~~ valve assembly to deliver ~~administer therapy~~ gas comprising NO from a gas ~~source~~ container containing gas comprising NO, the ~~gas delivery device~~ valve assembly comprising:

a valve ~~attachable~~ adapted to attach to the gas ~~source~~ container containing gas comprising NO, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas comprising NO through the valve to a control module; and

a circuit including:

a valve memory to store gas data comprising ~~one or more of gas identification, gas expiration date and~~ gas concentration in the gas container and

a valve processor and a valve transceiver in communication with the valve memory to send wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject.

2. (Currently amended) The ~~device~~ valve assembly of claim 1, wherein the valve further comprises a data input in communication with said valve memory, to permit a user to enter the gas data into the valve memory.

3. (Currently amended) The ~~device~~ valve assembly of claim 2, wherein the gas data is provided in a bar code disposed on the gas ~~source~~ container and is entered into the data input by a user-operated scanning device in communication with the data input.

4. (Currently amended) The ~~device~~ valve assembly of claim 1, wherein the valve comprises a power source; and the valve transceiver periodically sends the wireless optical line-of-sight signals to the control module, wherein the signals are interrupted by a duration of time at which no signal is sent.

PROPOSED

5. (Currently amended) The ~~device~~ valve assembly of claim 4, wherein the duration of time at which no signal is sent comprises about 10 seconds.

6. (Currently amended) A gas delivery system comprising:

the ~~gas delivery device~~ valve assembly of claim 1; and

[[a]] the control module in fluid communication with the outlet of the valve ~~and a ventilator~~, the control module comprising:

a CPU transceiver to receive line-of-sight signals from the valve transceiver; ~~and~~

a CPU in communication with the CPU transceiver and including a CPU memory; and

a display to enter patient information into the CPU memory,

wherein the valve transceiver communicates the gas data comprising gas concentration to the CPU transceiver for storage in the CPU memory, and wherein the CPU compares the patient information entered into the CPU memory via the display and the gas concentration from the valve transceiver.

7. (Currently amended) The system of claim 6, wherein the valve comprises a timer including a calendar timer and an event timer, wherein the valve memory stores the date and time of opening and closing of the valve and the duration of time that the valve is open and the valve transceiver communicates the date and time of opening and closing of the valve to the CPU transceiver for storage in the CPU memory.

8 – 9. (Canceled)

10. (Currently amended) The system of claim [[9]] 6, wherein the CPU comprises an alarm that is triggered when the patient information entered into the CPU memory and the gas data from the valve transceiver do not match.

PROPOSED

11. (Currently amended) The system of claim 6, wherein [[A]] the CPU memory ~~comprising~~ comprises instructions that cause [[a]] the CPU processor to: receive gas data comprising ~~selected from one or more of gas identification, gas expiration date and~~ gas concentration from [[a]] the valve via a wireless optical line-of-sight signal with the valve connected to [[a]] the gas ~~source~~ container containing gas comprising NO; compare the gas data with user-inputted patient information; coordinate delivery of therapy to the patient with a medical device via the wireless optical line-of-sight signal between the CPU transceiver and the valve transceiver; select a therapy for delivery to a patient based on the received patient information; and control delivery of the selected therapy to the patient.

12. (Currently amended) The ~~memory~~ system of claim 11, wherein the memory further comprises instructions that cause the CPU processor to:

receive a first valve status selected from a first open position and a first closed position from a first valve via a first wireless optical line-of-sight signal with the first valve connected to a first gas ~~source~~ container;

receive a second valve status selected from a second open position and a second closed position from a second valve via a second wireless optical line-of-sight signal with the second valve connected to a second gas ~~source~~ container;

compare the first valve status and the second valve status; and

emit an alarm if the first valve status comprises the first open position and the second valve status comprises the second open position.

13. (Currently amended) The ~~memory~~ system of claim 12, wherein the memory further comprises instructions that causes the CPU processor to:

terminate delivery of therapy if the first valve status comprises the first open position and the second valve status comprises the second open position.

14. (Currently amended) A method for administering a therapy gas comprising NO to a patient, the method comprising:

establishing communication via a CPU transceiver with a ~~gas delivery device~~ valve assembly comprising a valve processor and a valve transceiver in communication with a ~~first~~ valve memory including gas data, wherein the gas data comprises a concentration of NO in a gas source;

comparing the gas data with patient information stored within a ~~second~~ CPU memory;

coordinating delivery of therapy to a patient with the gas delivery device via a wireless optical line-of-sight signal between the CPU transceiver and the valve transceiver;

selecting a therapy for delivery to the patient based on the comparison of the gas data and the patient information; and

controlling delivery of the selected therapy to the patient.

15. (Original) The method of claim 14, further comprising ceasing delivery of the selected therapy to the patient based on the comparison of the gas data and the patient information.

16. (Original) The method of claim 14, further comprising emitting an alert based on the comparison of the gas data and the patient information.

17. (Currently amended) The method of claim 14, further comprising entering the gas data into the ~~first~~ valve memory.

18. (Currently amended) The method of claim 14, further comprising entering the patient information into the ~~second~~ CPU memory.

19. (New) A gas delivery device comprising:

the valve assembly of claim 1; and

the gas container containing gas comprising NO attached to the valve assembly, wherein a bar code disposed on the gas container provides the gas data.

PROPOSED

REMARKS

Claims 1-18 are pending in the application. Claims 1-18 are rejected. No claims are allowed.

Claims 1-14 and 17-18 include proposed amendments to more clearly describe and distinctly claim the subject matter the Applicants consider their invention. Specifically, the proposed amendments to claim 1 recite a "valve assembly" instead of a "gas delivery device". The proposed amendments to claim 1 also replace the "gas source comprising NO" with a "container containing gas comprising NO", and the various components (memory, transceiver and processor) now more clearly recite that these components are part of the valve assembly. Claim 1 also now recites that the gas data comprises gas concentration. Claims 2-5 include minor proposed amendments to use the same terminology as amended claim 1.

The proposed amendments to claim 6 incorporate the subject matter of claims 8 and 9. Accordingly, claims 8 and 9 are canceled. The proposed amendments to claim 6 also remove the phrase "and [in fluid communication with] a ventilator". Claims 7 and 10 include proposed amendments to correct dependency and specify that the memory and transceiver are the valve memory and valve transceiver, respectively.

Claim 11 is proposed to be dependent from claim 6 and specify that the memory is the CPU memory. Claims 11-13 include proposed amendments to use the same terminology as claim 6. The proposed amendments to claim 14 recite that the communication is between a CPU transceiver and a valve transceiver, as well as specify that the gas data comprises a concentration of NO in a gas source. Proposed amendments to claims 17 and 18 specify that the first memory and second memory are the valve memory and CPU memory, respectively.

New claim 19 has been added.

Support for the amendments can be found at least at paragraphs [0019], [0035] and [0056], and Figures 1 and 3 of the specification as originally filed, as well as the as-filed claims.

No new matter has been added by this amendment.

Claim Rejections – 35 U.S.C. § 112

Claims 6-10 are rejected under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. According to the Examiner, it is unclear whether the control module of claim 6 is the same control module as in claim 1. The proposed amendment to claim 6 replaces "a control module" with "the control module", and Applicants respectfully request that this rejection be withdrawn.

Obviousness-Type Double Patenting

Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims of the co-pending U.S. Patent Application Number 13/509,873. As this is a provisional rejection, upon an indication of allowable subject matter in the present application, Applicants will consider whether filing a terminal disclaimer is appropriate.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 2 and 4-7

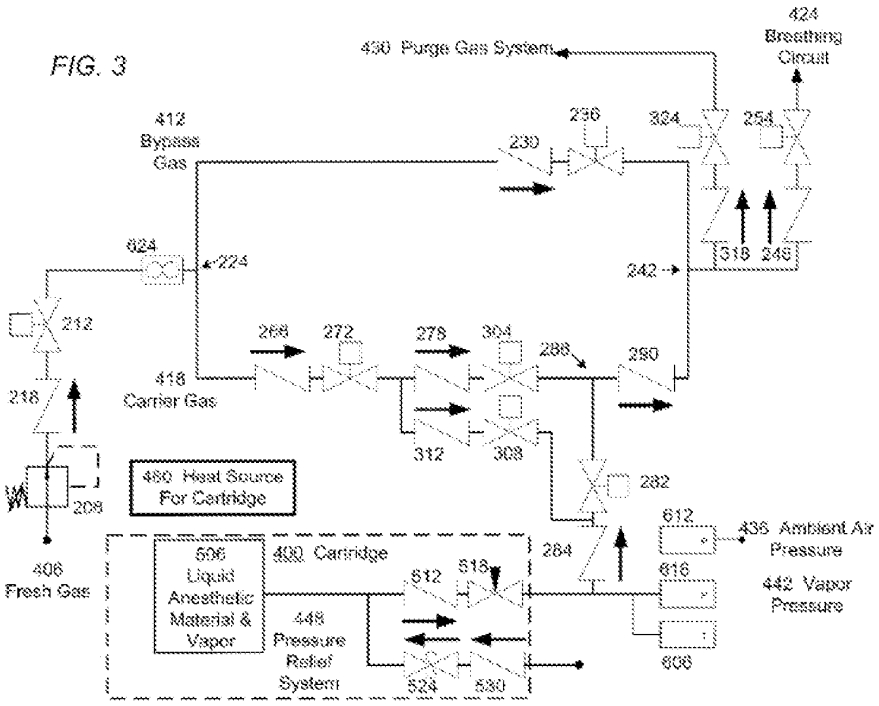
Claims 1, 2 and 4-7 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over US 2009/0266358 (Rock) in view of US 2011/0240019 (Fine). According to the Examiner, Rock discloses all of the limitations of the claims, including a gas delivery device comprising a valve actuator to open and close a valve, a circuit with memory to store gas data, a processor/transceiver to periodically communicate the data to a CPU/control module that stores the information and uses it to control a ventilator, but does not mention NO. The Examiner concludes that the use of NO is obvious in view Fine. Applicants respectfully traverse this basis for rejection.

In rejecting claims under 35 U.S.C. § 103, there must be a factual basis to support the legal conclusion of obviousness. Although the analysis need not identify explicit teachings directed to the claimed subject matter, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the

claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). As such, "'there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Applicants respectfully submit that the required reason to combine the references is absent and that even if the references were combined, all claims elements are not disclosed, taught or suggested.

Claim 1

Rock is directed to a vaporizer and cartridge system that utilizes liquid anesthetic materials. *See* Rock abstract. The vaporizer and cartridge system of Rock can be best understood with reference to FIG. 3, which is reproduced below:



The cartridge is preloaded with a particular liquid anesthetic material, which is heated by the vaporizer to provide an anesthesia vapor. *See* Rock ¶¶ [0035]-[0037]. The saturated vapor

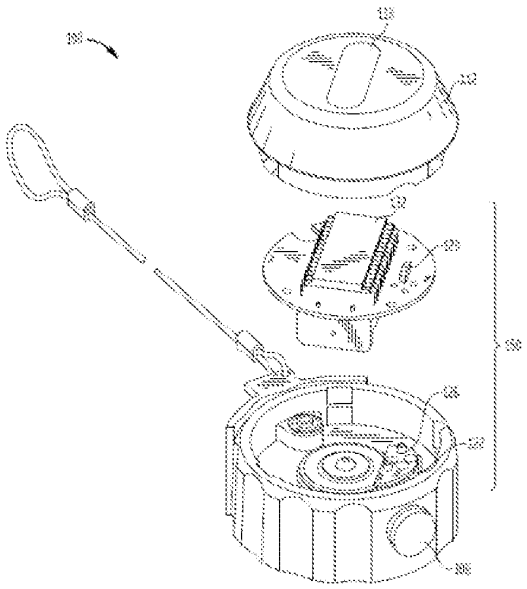
pressure of the anesthesia material is predictable depending on the liquid material used, the ambient air pressure, and the heated temperature of the liquid. *See* Rock ¶ [0035].

The cartridge may communicate information from the cartridge to the vaporizer, including the specific liquid anesthetic material within the cartridge, lot number, expiration date, and volume of liquid anesthetic material in the cartridge. *See* Rock ¶ [0041]. However, Rock does not disclose communicating gas concentration from the cartridge to the vaporizer. Indeed, as the anesthetic material of Rock is stored as a liquid, not a gas, there is no gas concentration in the cartridge. Furthermore, there is no "concentration" for the vaporized liquid, other than a concentration of 100% anesthesia vapor.

Accordingly, there is no reason to communicate a gas concentration from the cartridge to the vaporizer in Rock because this parameter is nonexistent for the vaporizer/cartridge system. As such, a person of ordinary skill in the art would have no motivation to communicate the gas concentration as recited in claim 1.

Rock also fails to disclose, teach or suggest a circuit within the valve assembly that includes a valve memory, valve transceiver and valve processor. FIG. 3 of the present application shows a valve assembly having the circuit 150.

FIG. 3



As described in the paragraph [0035] of the present application, the circuit 150 includes a valve memory, a valve processor, and a valve transceiver. Amended claim 1 specifically recites that the valve assembly itself comprises the valve and the circuit (including the circuit's individual components). However, Rock fails to disclose a transceiver, memory and a processor within the valve assembly.

Fine does not cure the deficiencies of Rock described above. Fine pertains to methods and systems for delivering nitric oxide using N_2O_4 as a liquid nitrogen dioxide source. *See* Fine abstract. In Fine, a liquid source containing pure N_2O_4 is vaporized to produce NO_2, which in turn is converted to NO by passing it through a cartridge containing a surface-activated material saturated with an aqueous solution of an antioxidant. *See* Fine ¶¶ [0018] and [0026]. The NO is then passed through a second cartridge before being administered to the patient. *See* Fine ¶ [0026]. As with Rock, the liquid source is vaporized to produce a pure vapor, and thus there is no relevant gas concentration. Although Fine also describes using NO_2 gas bottles, this is not the drug that is ultimately administered to the patient. The NO_2 itself is highly toxic if inhaled and can form nitric acid and nitrous acid in the lungs. *See* Fine ¶ [0003]. As the drug that is ultimately administered to the patient is NO, not NO_2, the NO_2 bottle of Fine does not have a concentration of the relevant NO gas. Thus, there is no motivation to communicate a gas concentration from the N_2O_4 reservoir or NO_2 bottle of Fine to the vaporizer.

Fine also does not disclose any communication elements in the reservoir/bottle, and therefore does not disclose a valve assembly having a valve transceiver, a valve memory and a valve processor. Accordingly, even if a person of ordinary skill in the art were to combine Rock and Fine, the combination of references does not disclose all of the elements of amended claim 1. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Claims 2 and 4-7

Applicants respectfully submit that the combination of Rock and Fine do not teach the further limitations of claims 2 and 4-7. Regarding claim 2, Rock does not disclose a data input for a valve memory. Instead, Rock only discloses data input for the vaporizer delivery device. *See* Rock ¶ [0056]. Rock also does not teach the further limitations of claims 4 and 5, which

relate to an intermittent signal from the valve transceiver to the control module. Rock also does not disclose comparing patient information entered into the CPU memory via the display and the gas concentration from the valve receiver as recited in claim 6. Rock also fails to disclose a timer for storing the duration that the valve is open as recited in claim 7. Applicants note that the cartridge valve 518 of Rock is actuated and opened upon insertion of the cartridge 400 into the vaporizer, and the valve does not close until the cartridge is removed. *See* Rock ¶¶ [0039], [0132]-[0133] and [0140]. Thus, there is no need to time the duration that the cartridge valve is open because this will only indicate how long the cartridge was attached to the vaporizer.

Fine does not teach any communication elements in the reservoir/bottle, so it does not cure these deficiencies of Rock.

Claim 3

Claim 3 is rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Rock in view of Fine and US 2002/0044059 (Reeder). According to the Examiner, use of a bar code in a modified system based on Rock and Fine is obvious in view of Reeder. Applicants respectfully traverse this basis for rejection.

Reeder is directed to a patient monitoring system comprising a computer, an input device coupled to the computer and configured to input patient information, and first and second display screens coupled to the computer. *See* Reeder abstract. Reeder discusses a bar code reader in paragraph [0006] in which "[t]he computer system also includes an input device such as, for example, a keyboard or a bar code reader to capture costs of medication or other treatment or articles used by the patient." However, this bar code reader is for providing information to the central computer 12. This is not the same as having a bar code reader to input gas data from the gas container to the valve memory, which is then further communicated to the CPU memory via the wireless communication between the valve transceiver and the CPU transceiver. Accordingly, Applicants respectfully submit that this limitation is not disclosed, taught or suggested in the references and request that the rejection be withdrawn.

New claim 19 recites that a bar code disposed on the gas container provides the gas data. Applicants respectfully submit that there is no motivation in the references to have gas data

provided by a bar code on the gas container, in addition to gas data stored in the valve memory. The gas container and valve assembly combination of claim 19 includes two distinct locations that provide gas data, which is not taught or suggested in the references.

Claims 8-18

Claims 8-18 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Rock in view of Fine and US 2011/0041849 (Chen). According to the Examiner, Chen includes a similar gas delivery system that allows patient information for setting threshold ranges and control of ventilator settings to increase patient safety. Applicants respectfully traverse this basis for rejection.

Chen relates to a method and system for controlling a ventilator, which may use oxygen saturation values from pulse oximeters to adjust the settings of a ventilator. *See* Chen abstract. Although Chen describes calculating the difference between two S_pO_2 readings and comparing to a threshold, there is no suggestion of comparing user-inputted patient information and a NO concentration in a container to determine if they substantially match. Chen is describing a system that changes ventilator settings in response to S_pO_2 readings, not comparing drug information to a patient's information to determine if the drug is appropriate for therapy.

Chen also does not describe any of the steps recited in claim 14, which require establishing communication via a CPU transceiver with a valve assembly comprising a valve processor and a valve transceiver in communication with a valve memory including gas data, wherein the gas data comprises a concentration of NO in a gas source; comparing the gas data with patient information stored within a CPU memory; coordinating delivery of therapy to a patient with the gas delivery device via a wireless optical line-of-sight signal between the CPU transceiver and the valve transceiver; selecting a therapy for delivery to the patient based on the comparison of the gas data and the patient information; and controlling delivery of the selected therapy to the patient. Indeed, as Chen does not disclose any valves for communicating with the delivery system, there is no reason to perform many of these steps. Accordingly, Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

It is believed that claims 1-7 and 10-19 are now in condition for allowance, early notice of which would be appreciated. No fees are believed due with this submission. If any fees are due at this time, the Commissioner is authorized to charge Deposit Account No. 50-3329. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

Respectfully submitted,

Dated: August 23, 2012

By: /Rory P. Alegria, Reg. No. 66,947/

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Bathe, Duncan P.	Examiner	Kristen Matter
Serial No.:	13/493,493	Group Art Unit	3778
Filed:	Jun 11, 2012	Docket No.:	3000-US-0026CON (IKA0011-01CT)
		Confirmation No.:	6133

Title: Gas Delivery Device And System

CONTINUATION OF APPLICANT INITIATED INTERVIEW REQUEST FORM PTOL-413A

Continuation of "Issues To Be Discussed"

(5) 103 rejection of claims 8-18 based on Rock, Fine and Chen

Electronic Acknowledgement Receipt	
EFS ID:	13567942
Application Number:	13493493
International Application Number:	
Confirmation Number:	6133
Title of Invention:	Gas Delivery Device And System
First Named Inventor/Applicant Name:	Duncan P. Bathe
Customer Number:	48394
Filer:	Rory P. Alegria/Linda Murphy
Filer Authorized By:	Rory P. Alegria
Attorney Docket Number:	3000-US-0026CON
Receipt Date:	23-AUG-2012
Filing Date:	11-JUN-2012
Time Stamp:	11:00:55
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	First Action Interview - Enrollment Request	00299340.PDF	442020 0d6574e706617201cc7410c8e13b2fd06de3dfa4	no	1
Warnings:					
Information:					

2		00299343.PDF	233257 6ac37bb40ab9b3a4cc1a20043acd3a5c3d167660	yes	13

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Preliminary Amendment	1	1
	Claims	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	13

Warnings:

Information:

3	Miscellaneous Incoming Letter	00299339.PDF	20400 6269a4c26667fb98a9a75866a1697d568cf985b3	no	1

Warnings:

Information:

Total Files Size (in bytes):	695677

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Doc Code: M865 or FAI.REQ.INTV

PTOL-413A (08-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Applicant Initiated Interview Request Form

Application No.: 13/493,493 First Named Applicant: Duncan P. Bathe
Examiner: Kristen Clarette Matter Art Unit: 3778 Status of Application: Pending

Tentative Participants:
(1) Rory Alegria (2) Erika Senska
(3) Jaron Acker (4)

Proposed Date of Interview: 08/23/12 **Proposed Time:** 2:00 PM **(AM/PM)**

Type of Interview Requested:
(1) [✓] Telephonic (2) [ ] Personal (3) [ ] Video Conference

Exhibit To Be Shown or Demonstrated: [ ] YES [✓] NO
If yes, provide brief description:

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) 112	6-10		[ ]	[ ]	[ ]
(2) OTDP	1-18	13/509,873, Fine	[ ]	[ ]	[ ]
(3) 103	1,2,4-7	Rock, Fine	[ ]	[ ]	[ ]
(4) 103	3	Rock, Fine, Reeder	[ ]	[ ]	[ ]

[✓] Continuation Sheet Attached [✓] Proposed Amendment or Arguments Attached

Brief Description of Arguments to be Presented: see attached

An interview was conducted on the above-identified application on

NOTE: This form should be completed and filed by applicant in advance of the interview (see MPEP § 713.01). If this form is signed by a registered practitioner not of record, the Office will accept this as an indication that he or she is authorized to conduct an interview on behalf of the principal (37 CFR 1.32(a)(3)) pursuant to 37 CFR 1.34. This is not a power of attorney to any above named practitioner. See the Instruction Sheet for this form, which is incorporated by reference. By signing this form, applicant or practitioner is certifying that he or she has read the Instruction Sheet. After the interview is conducted, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible. This application will not be delayed from issue because of applicant's failure to submit a written record of this interview.

/Rory P. Alegria, Reg. No 66,947/
Applicant/Applicant's Representative Signature

Examiner/SPE Signature

Rory P. Alegria
Typed/Printed Name of Applicant or Representative

66,947
Registration Number, if applicable

Doc Code: M865 or FAI.REQ.INTV

PTOL-413A (08-10)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Type of Interview Requested:
(1) [✓] Telephonic (2) [ ] Personal (3) [ ] Video Conference

Exhibit To Be Shown or Demonstrated: [ ] YES [✓] NO
If yes, provide brief description:

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) 112	6-10		[ ]	[ ]	[ ]
(2) OTDP	1-18	13/509,873, Fine	[ ]	[ ]	[ ]
(3) 103	1,2,4-7	Rock, Fine	[ ]	[ ]	[ ]
(4) 103	3	Rock, Fine, Reeder	[ ]	[ ]	[ ]

[✓] Continuation Sheet Attached [✓] Proposed Amendment or Arguments Attached

Brief Description of Arguments to be Presented: see attached

An interview was conducted on the above-identified application on

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/Rory P. Alegria, Reg. No 66,947/
Applicant/Applicant's Representative Signature

Examiner/SPE Signature

Rory P. Alegria
Typed/Printed Name of Applicant or Representative

66,947
Registration Number, if applicable

PTO/SB/06 (07-06)
Approved for use through 1/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number	Filing Date	☐ To be Mailed
13/493,493	06/11/2012	

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)	SMALL ENTITY ☒		OR	OTHER THAN SMALL ENTITY	
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)		RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =		OR	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X $ =			X $ =	
☐ APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).						
☐ MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))							
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL			TOTAL	

APPLICATION AS AMENDED – PART II

AMENDMENT 08/23/2012	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)	OR	OTHER THAN SMALL ENTITY RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	* 17	Minus	** 20	= 0	X $30 =	0	OR	X $ =	
Independent (37 CFR 1.16(h))	* 3	Minus	***3	= 0	X $125 =	0	OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE	

AMENDMENT	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)		RATE ($)	ADDITIONAL FEE ($)
Total (37 CFR 1.16(i))	*	Minus	**	=	X $ =		OR	X $ =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	X $ =		OR	X $ =	
☐ Application Size Fee (37 CFR 1.16(s))									
☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.

** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".

*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".

The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

Legal Instrument Examiner:
/CAROLYN THOMAS/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/493,493	06/11/2012	Duncan P. Bathe	3000-US-0026CON

CONFIRMATION NO. 6133

48394
DIEHL SERVILLA LLC
33 WOOD AVE SOUTH
SECOND FLOOR, SUITE 210
ISELIN, NJ 08830

POA ACCEPTANCE LETTER

OC000000056198603

Date Mailed: 08/30/2012

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 08/21/2012.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

/fstephanos/

Office of Data Management, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

PROPOSED

S/N 13/493,493 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Bathe, Duncan P.	Examiner	Kristen Matter
Serial No.:	13/493,493	Group Art Unit	3778
Filed:	Jun 11, 2012	Docket No.:	3000-US-0026CON (IKA0011-01CT)
		Confirmation No.:	6133

Title: Gas Delivery Device And System

PROPOSED AMENDMENT AND RESPONSE TO PRE-INTERVIEW COMMUNICATION

This paper is being submitted in response to the Pre-Interview Communication dated August 21, 2012, in the above-identified patent application. The one month period for reply to the Communication expires on September 21, 2012. Accordingly, this paper is being timely filed.

PROPOSED

IN THE CLAIMS

1. (Currently amended) A ~~gas delivery device~~ valve assembly to deliver a ~~administer therapy~~ gas comprising NO from a gas ~~source~~ container containing the gas comprising NO, the ~~gas delivery device~~ valve assembly comprising:

a valve attachable to the gas ~~source~~ container containing the gas comprising NO, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas comprising NO through the valve to a control module; ~~and~~

a circuit supported within the valve assembly and disposed between the actuator and a cap, the circuit including:

a valve memory to store gas data comprising ~~one or more of gas identification, gas expiration date and~~ gas concentration in the gas container and

a valve processor and a valve transceiver in communication with the valve memory to send wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject; and

a data input disposed on the actuator and in communication with said valve memory, to permit a user to enter the gas data into the valve memory.

2. (Canceled)

3. (Currently amended) The ~~device~~ valve assembly of claim [[2]] 1, wherein the gas data is provided in a bar code disposed on the gas ~~source~~ container and is entered into the data input by a user-operated scanning device in communication with the data input.

4. (Currently amended) The ~~device~~ valve assembly of claim 1, wherein the valve comprises a power source; and the valve transceiver periodically sends the wireless optical line-of-sight signals to the control module, wherein the signals are interrupted by a duration of time at which no signal is sent.

PROPOSED

5. (Currently amended) The ~~device~~ valve assembly of claim 4, wherein the duration of time at which no signal is sent comprises about 10 seconds.

6. (Currently amended) A gas delivery system comprising:

the ~~gas delivery device~~ valve assembly of claim 1; and

[[a]] the control module, wherein the control module is in fluid communication with the outlet of the valve ~~and a ventilator~~, the control module comprising:

a CPU transceiver to receive line-of-sight signals from the valve transceiver; ~~and~~

a CPU in communication with the CPU transceiver and including a CPU memory; and

a display to enter patient information into the CPU memory,

wherein the valve transceiver communicates the gas data comprising gas concentration to the CPU transceiver for storage in the CPU memory, and wherein the CPU compares the patient information entered into the CPU memory via the display and the gas concentration from the valve transceiver.

7. (Currently amended) The system of claim 6, wherein the valve comprises a timer including a calendar timer and an event timer, wherein the valve memory stores the date and time of opening and closing of the valve and the duration of time that the valve is open and the valve transceiver communicates the date and time of opening and closing of the valve to the CPU transceiver for storage in the CPU memory.

8 – 9. (Canceled)

10. (Currently amended) The system of claim [[9]] 6, wherein the CPU comprises an alarm that is triggered when the patient information entered into the CPU memory and the gas data from the valve transceiver do not match.

PROPOSED

11. (Currently amended) The system of claim 6, wherein [[A]] the CPU memory ~~comprising~~ comprises instructions that cause [[a]] the CPU processor to: receive gas data comprising ~~selected from one or more of gas identification, gas expiration date and~~ gas concentration from [[a]] the valve via a wireless optical line-of-sight signal with the valve connected to [[a]] the gas ~~source~~ container containing gas comprising NO; compare the gas data with user-inputted patient information; coordinate delivery of therapy to the patient with a medical device via the wireless optical line-of-sight signal between the CPU transceiver and the valve transceiver; select a therapy for delivery to a patient based on the received patient information; and control delivery of the selected therapy to the patient.

12. (Currently amended) The ~~memory~~ system of claim 11, wherein the memory further comprises instructions that cause the CPU processor to:

receive a first valve status selected from a first open position and a first closed position from a first valve via a first wireless optical line-of-sight signal with the first valve connected to a first gas ~~source~~ container;

receive a second valve status selected from a second open position and a second closed position from a second valve via a second wireless optical line-of-sight signal with the second valve connected to a second gas ~~source~~ container;

compare the first valve status and the second valve status; and

emit an alarm if the first valve status comprises the first open position and the second valve status comprises the second open position.

13. (Currently amended) The ~~memory~~ system of claim 12, wherein the memory further comprises instructions that causes the CPU processor to:

terminate delivery of therapy if the first valve status comprises the first open position and the second valve status comprises the second open position.

14. (Currently amended) A method for administering a therapy gas comprising NO to a patient, the method comprising:

establishing communication via a CPU transceiver with ~~a gas delivery device~~ the valve assembly of claim 1 and communicating the gas data from the valve transceiver to the CPU transceiver ~~comprising a first memory including gas data~~,

comparing the gas data communicated from the valve transceiver with patient information stored within a ~~second~~ CPU memory;

coordinating delivery of therapy to a patient with the gas delivery device via a wireless optical line-of-sight signal between the CPU transceiver and the valve transceiver;

selecting a therapy for delivery to the patient based on the comparison of the gas data and the patient information; and

controlling delivery of the selected therapy to the patient.

15. (Original) The method of claim 14, further comprising ceasing delivery of the selected therapy to the patient based on the comparison of the gas data and the patient information.

16. (Original) The method of claim 14, further comprising emitting an alert based on the comparison of the gas data and the patient information.

17. (Currently amended) The method of claim 14, further comprising entering the gas data into the ~~first~~ valve memory.

18. (Currently amended) The method of claim 14, further comprising entering the patient information into the ~~second~~ CPU memory.

19. (New) A gas delivery device comprising:

the valve assembly of claim 1; and

the gas container containing gas comprising NO attached to the valve assembly, wherein a bar code disposed on the gas container provides the gas data.

PROPOSED

REMARKS

Claims 1-18 are pending in the application. Claims 1-18 are rejected. No claims are allowed.

Claims 1, 3-7, 10-14 and 17-18 include proposed amendments to more clearly describe and distinctly claim the subject matter the Applicants consider their invention. Specifically, the proposed amendments to claim 1 recite a "valve assembly" instead of a "gas delivery device". The proposed amendments to claim 1 also replace the "gas source comprising NO" with a "container containing gas comprising NO", and claim 1 now recites that the circuit components (memory, transceiver and processor) are supported within the valve assembly and disposed between the actuator and the cap. Claim 1 also now recites that the gas data comprises gas concentration. The proposed amendments to claim 1 also incorporate the subject matter of claim 2, as well as specify that the data input is disposed on the actuator. Accordingly, claim 2 is canceled. Claims 3-5 include minor proposed amendments to use the same terminology as amended claim 1.

The proposed amendments to claim 6 incorporate the subject matter of claims 8 and 9. Accordingly, claims 8 and 9 are canceled. The proposed amendments to claim 6 also remove the phrase "and [in fluid communication with] a ventilator". Claims 7 and 10 include proposed amendments to correct dependency and specify that the memory and transceiver are the valve memory and valve transceiver, respectively.

Claim 11 is proposed to be dependent from claim 6 and specify that the memory is the CPU memory. Claims 11-13 include proposed amendments to use the same terminology as claim 6. Claim 14 is proposed to be dependent from claim 1. The proposed amendments to claim 14 also recite that the communication is between a CPU transceiver and a valve transceiver and the gas data is communicated from the valve transceiver to the CPU transceiver. Proposed amendments to claims 17 and 18 specify that the first memory and second memory are the valve memory and CPU memory, respectively.

New claim 19 has been added.

Support for the amendments can be found at least at paragraphs [0019], [0035], [0037] and [0056], and Figures 1 and 3 of the specification as originally filed, as well as the as-filed claims.

No new matter has been added by this amendment.

Claim Rejections – 35 U.S.C. § 112

Claims 6-10 are rejected under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. According to the Examiner, it is unclear whether the control module of claim 6 is the same control module as in claim 1. The proposed amendment to claim 6 replaces "a control module" with "the control module", and Applicants respectfully request that this rejection be withdrawn.

Obviousness-Type Double Patenting

Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims of the co-pending U.S. Patent Application Number 13/509,873. While Applicants do not necessarily agree with this conclusion, in the interest of furthering prosecution, a timely filed terminal disclaimer accompanies this response. Therefore, it is respectfully requested that this rejection be reconsidered and withdrawn.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 2 and 4-7

Claims 1, 2 and 4-7 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over US 2009/0266358 (Rock) in view of US 2011/0240019 (Fine). According to the Examiner, Rock discloses all of the limitations of the claims, including a gas delivery device comprising a valve actuator to open and close a valve, a circuit with memory to store gas data, a processor/transceiver to periodically communicate the data to a CPU/control module that stores the information and uses it to control a ventilator, but does not mention NO. The Examiner

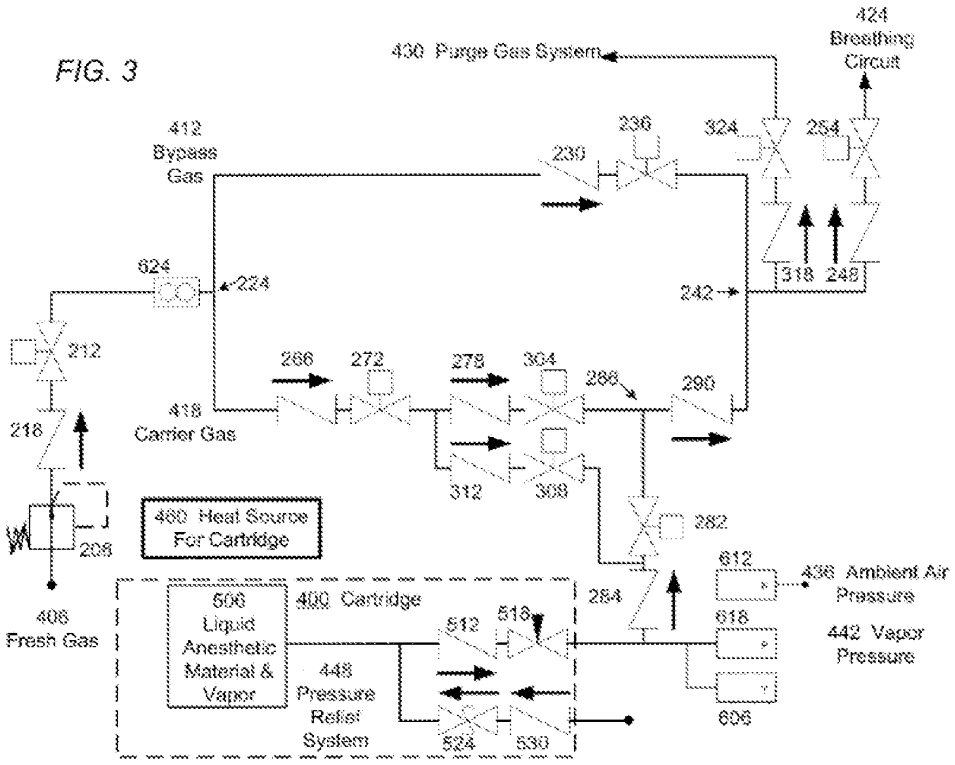
concludes that the use of NO is obvious in view Fine. Applicants respectfully traverse this basis for rejection.

In rejecting claims under 35 U.S.C. § 103, there must be a factual basis to support the legal conclusion of obviousness. Although the analysis need not identify explicit teachings directed to the claimed subject matter, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). As such, "'there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Applicants respectfully submit that the required reason to combine the references is absent and that even if the references were combined, all claims elements are not disclosed, taught or suggested.

Claim 1

Rock is directed to a vaporizer and cartridge system that utilizes liquid anesthetic materials. *See* Rock abstract. The vaporizer and cartridge system of Rock can be best understood with reference to FIG. 3, which is reproduced below:

PROPOSED



The cartridge is preloaded with a particular liquid anesthetic material, which is heated by the vaporizer to provide an anesthesia vapor. *See* Rock ¶¶ [0035]-[0037]. The saturated vapor pressure of the anesthesia material is predictable depending on the liquid material used, the ambient air pressure, and the heated temperature of the liquid. *See* Rock ¶ [0035].

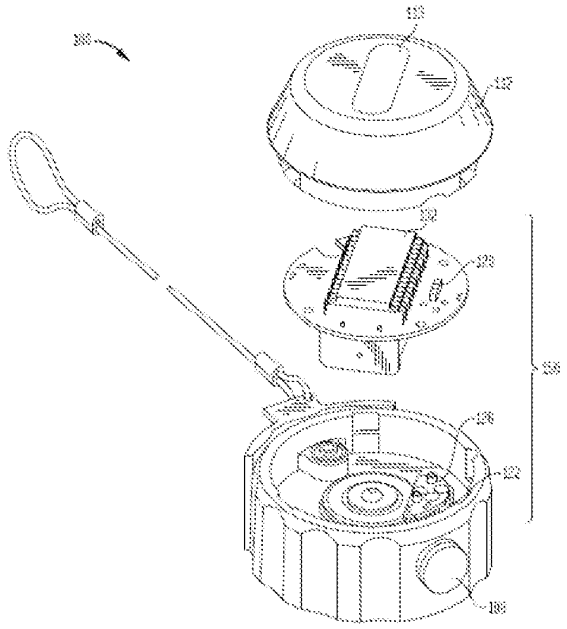
The cartridge may communicate information from the cartridge to the vaporizer, including the specific liquid anesthetic material within the cartridge, lot number, expiration date, and volume of liquid anesthetic material in the cartridge. *See* Rock ¶ [0041]. However, Rock does not disclose communicating gas concentration from the cartridge to the vaporizer. Indeed, as the anesthetic material of Rock is stored as a liquid, not a gas, there is no gas concentration in the cartridge. Furthermore, there is no "concentration" for the vaporized liquid, other than a concentration of 100% anesthesia vapor.

PROPOSED

Accordingly, there is no reason to communicate a gas concentration from the cartridge to the vaporizer in Rock because this parameter is nonexistent for the vaporizer/cartridge system. Additionally, because no gas concentration is taught, a person of ordinary skill in the art would have no motivation to communicate a gas concentration as recited in claim 1.

Rock also fails to disclose, teach or suggest a circuit **within the valve assembly** that includes a valve memory, valve transceiver and valve processor. FIG. 3 of the present application shows a valve assembly having the circuit 150.

FIG. 3



As described in the paragraph [0035] of the present application, the circuit 150 includes a valve memory, a valve processor, and a valve transceiver within the valve assembly. Amended claim 1 specifically recites that the valve assembly itself comprises the valve and the circuit (including the circuit's individual components), as well specify that the circuit is disposed between the valve actuator and cap as shown in FIG. 3. However, Rock fails to disclose a transceiver, memory and a processor **within the valve assembly**. Instead, the memory of Rock (and presumably any other circuit components that are not specifically disclosed) is located **within the cartridge**.

PROPOSED

Accordingly, Rock does not provide that all of the communication components are located within a single unit or housing that is distinct from the drug source. As recited in claim 1, the valve is attachable to the gas container having the NO gas. By comparing FIGS. 2 and 3 of the instant application, it is clear that the gas container is not integral to the valve assembly and that the valve assembly and the gas container may be attached or detached from each other. However, the cartridge of Rock includes the reservoir of anesthesia liquid **and** the memory device. *See* Rock claim 1. There is no indication in Rock that the reservoir may be separate from a valve assembly having the memory. Therefore, Rock does not disclose a valve assembly having the components as claimed.

Rock also does not disclose a data input for a valve memory. Instead, Rock only discloses data input for the vaporizer delivery device. *See* Rock ¶ [0056]. Accordingly, Rock does not provide a data input in communication with the valve memory and disposed on the actuator as recited in claim 1.

Fine does not cure the deficiencies of Rock described above. Fine pertains to methods and systems for delivering nitric oxide using N_2O_4 as a liquid nitrogen dioxide source. *See* Fine abstract. In Fine, a liquid source containing pure N_2O_4 is vaporized to produce NO_2, which in turn is converted to NO by passing it through a cartridge containing a surface-activated material saturated with an aqueous solution of an antioxidant. *See* Fine ¶¶ [0018] and [0026]. The NO is then passed through a second cartridge before being administered to the patient. *See* Fine ¶ [0026]. As with Rock, the liquid source is vaporized to produce a pure vapor, and thus there is no relevant gas concentration. Although Fine also describes using NO_2 gas bottles, this is not the drug that is ultimately administered to the patient. Fine teaches that the NO_2 itself is highly toxic if inhaled and can form nitric acid and nitrous acid in the lungs. *See* Fine ¶ [0003]. As the drug that is ultimately administered to the patient is NO, not NO_2, the NO_2 bottle of Fine does not have a concentration of the relevant NO gas. Thus, there is no motivation to communicate a gas concentration from the N_2O_4 reservoir or NO_2 bottle of Fine to the vaporizer.

Fine also does not disclose any communication elements in the reservoir/bottle, and therefore does not disclose a valve assembly having a valve transceiver, a valve memory and a valve processor. Fine also fails to disclose a data input disposed on an actuator and in

communication with a valve memory. Accordingly, even if a person of ordinary skill in the art were to combine Rock and Fine, the combination of references does not disclose all of the elements of amended claim 1. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Claims 4-7

Applicants respectfully submit that in addition to the above arguments with respect to claim 1, the combination of Rock and Fine do not teach the further limitations of claims 4-7. Regarding claims 4 and 5, Rock does not disclose an intermittent signal from the valve transceiver to the control module. Rock also does not disclose comparing patient information entered into the CPU memory via the display and the gas concentration from the valve receiver as recited in claim 6. Rock also fails to disclose a timer for storing the duration that the valve is open as recited in claim 7. Applicants note that the cartridge valve 518 of Rock is actuated and opened upon insertion of the cartridge 400 into the vaporizer, and the valve does not close until the cartridge is removed. *See* Rock ¶¶ [0039], [0132]-[0133] and [0140]. Thus, there is no need to time the duration that the cartridge valve is open because this will only indicate how long the cartridge was attached to the vaporizer.

Fine does not teach any communication elements in the reservoir/bottle, so it does not cure these deficiencies of Rock.

Claim 3

Claim 3 is rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Rock in view of Fine and US 2002/0044059 (Reeder). According to the Examiner, use of a bar code in a modified system based on Rock and Fine is obvious in view of Reeder. Applicants respectfully traverse this basis for rejection.

Reeder is directed to a patient monitoring system comprising a computer, an input device coupled to the computer and configured to input patient information, and first and second display screens coupled to the computer. *See* Reeder abstract. Reeder discusses a bar code reader in paragraph [0006] in which "[t]he computer system also includes an input device such as, for

example, a keyboard or a bar code reader to capture costs of medication or other treatment or articles used by the patient." However, this bar code reader is for providing information to the central computer 12. This is not the same as having a bar code reader to input gas data from the gas container to the valve memory, which is then further communicated to the CPU memory via the wireless communication between the valve transceiver and the CPU transceiver, as in the instant application. Accordingly, Applicants respectfully submit that this limitation is not disclosed, taught or suggested in the references and request that the rejection be withdrawn.

New claim 19 recites that a bar code disposed on the gas container provides the gas data. Applicants respectfully submit that there is no motivation in the references to have gas data provided by a bar code on the gas container, in addition to gas data stored in the valve memory. The gas container and valve assembly combination of claim 19 includes two distinct locations that provide gas data, which is not taught or suggested in the references.

Claims 8-18

Claims 8-18 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Rock in view of Fine and US 2011/0041849 (Chen). According to the Examiner, Chen includes a similar gas delivery system that allows patient information for setting threshold ranges and control of ventilator settings to increase patient safety. Applicants respectfully traverse this basis for rejection.

Chen does not remedy the deficiencies of Rock and Fine as described above. As such, claims 8-18 are not obvious over Rock in view of Fine and Chen for at least the reasons provided above.

Furthermore, Chen relates to a method and system for controlling a ventilator, which may use oxygen saturation values from pulse oximeters to adjust the settings of a ventilator. *See* Chen abstract. Although Chen describes calculating the difference between two S_pO_2 readings and comparing to a threshold, there is no suggestion of comparing user-inputted patient information and a NO concentration in a container to determine if they substantially match. Chen describes a system that changes ventilator settings in response to S_pO_2 readings, not

comparing drug information to a patient's information to determine if the drug is appropriate for therapy.

Chen also does not describe any of the steps recited in claim 14, which require establishing communication via a CPU transceiver with the valve assembly and communicating gas data from the valve transceiver to the CPU transceiver; comparing the gas data communicated from the valve transceiver with patient information stored within a CPU memory; coordinating delivery of therapy to a patient with the gas delivery device via a wireless optical line-of-sight signal between the CPU transceiver and the valve transceiver; selecting a therapy for delivery to the patient based on the comparison of the gas data and the patient information; and controlling delivery of the selected therapy to the patient. Indeed, as Chen does not disclose any valves for communicating with the delivery system, there is no reason to perform many of these steps. Accordingly, Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

It is believed that claims 1, 3-7 and 10-19 are now in condition for allowance, early notice of which would be appreciated. No fees are believed due with this submission. If any fees are due at this time, the Commissioner is authorized to charge Deposit Account No. 50-3329. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

Respectfully submitted,

Dated: August 30, 2012

By: /Rory P. Alegria, Reg. No. 66,947/

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Electronic Acknowledgement Receipt	
EFS ID:	13624226
Application Number:	13493493
International Application Number:	
Confirmation Number:	6133
Title of Invention:	Gas Delivery Device And System
First Named Inventor/Applicant Name:	Duncan P. Bathe
Customer Number:	48394
Filer:	Rory P. Alegria/Linda Murphy
Filer Authorized By:	Rory P. Alegria
Attorney Docket Number:	3000-US-0026CON
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Time Stamp:	11:36:08
Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		00300906.PDF	268981 ed1265eaf7081d1a7e2446ec7fe69f5e7669bbad	yes	14

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Reply under 1.111 to Pre-Interview Communication	1	1
	Claims	2	5
	Applicant Arguments/Remarks Made in an Amendment	6	14
Warnings:			
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TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION

Docket Number (Optional): 3000-US-0026CON

In re Application of: Duncan P. Bathe

Application No.: 13/493,493

Filed: June 11, 2012

For: Gas Delivery Device And System

The owner*, INO Therapeutics LLC, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending **reference** Application Number 13/509,873, filed on January 6, 2011, as such term is defined in 35 U.S.C. 154 and 173, and as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the **reference** application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of any patent granted on said **reference** application, "as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application," in the event that: any such patent: granted on the pending **reference** application: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☑ The undersigned is an attorney or agent of record. Reg. No. 66947

/Rory P. Alegria, Reg. #66947/ — Signature

August 30, 2012 — Date

Rory P. Alegria — Typed or printed name

732 815 0404 — Telephone Number

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Electronic Patent Application Fee Transmittal					
Application Number:	13493493				
Filing Date:	11-Jun-2012				
Title of Invention:	Gas Delivery Device And System				
First Named Inventor/Applicant Name:	Duncan P. Bathe				
Filer:	Rory P. Alegria/Linda Murphy				
Attorney Docket Number:	3000-US-0026CON				
Filed as Small Entity					
Utility under 35 USC 111(a) Filing Fees					
Description		**Fee Code**	**Quantity**	**Amount**	**Sub-Total in USD($)**
Basic Filing:					
Pages:					
Claims:					
Miscellaneous-Filing:					
Petition:					
Patent-Appeals-and-Interference:					
Post-Allowance-and-Post-Issuance:					
Extension-of-Time:					

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
Statutory or terminal disclaimer	2814	1	80	80
		Total in USD ($)		**80**

Electronic Acknowledgement Receipt	
EFS ID:	13625704
Application Number:	13493493
International Application Number:	
Confirmation Number:	6133
Title of Invention:	Gas Delivery Device And System
First Named Inventor/Applicant Name:	Duncan P. Bathe
Customer Number:	48394
Filer:	Rory P. Alegria/Linda Murphy
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Attorney Docket Number:	3000-US-0026CON
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RAM confirmation Number	13488
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Terminal Disclaimer Filed	00300973.PDF	56553 0e650fb16d6082d067ad798019554931135 05349	no	1
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Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	13/493,493	BATHE ET AL.	

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TERMINAL DISCLAIMER	☐ APPROVED	☒ DISAPPROVED
Date Filed : 8/30/12	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:

Td disapproved.

Improper e-signature on terminal disclaimer (td). Resubmit td with proper signature. 37 CFR 1.4(d)2(i).

Lawana Hixon

U.S. Patent and Trademark Office

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TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION	Docket Number (Optional) 3000-US-0026CON

In re Application of: Duncan P. Bathe

Application No.: 13/493,493

Filed: June 11, 2012

For: Gas Delivery Device And System

The owner*, INO Therapeutics LLC, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending **reference** Application Number 13/509,873, filed on January 6, 2011, as such term is defined in 35 U.S.C. 154 and 173, and as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the **reference** application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☑ The undersigned is an attorney or agent of record. Reg. No. 66947

/Rory P. Alegria/ — Signature

August 31, 2012 — Date

Rory P. Alegria, Reg. No. 66947 — Typed or printed name

732 815 0404 — Telephone Number

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Electronic Acknowledgement Receipt	
EFS ID:	13634885
Application Number:	13493493
International Application Number:	
Confirmation Number:	6133
Title of Invention:	Gas Delivery Device And System
First Named Inventor/Applicant Name:	Duncan P. Bathe
Customer Number:	48394
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Attorney Docket Number:	3000-US-0026CON
Receipt Date:	31-AUG-2012
Filing Date:	11-JUN-2012
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Application Type:	Utility under 35 USC 111(a)

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Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Terminal Disclaimer Filed	00301193.PDF	56459 7b6eaae542625f68f4a40959e0f00b6e862ad3be	no	1
Warnings:					
Information:					

Total Files Size (in bytes):	56459

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New Applications Under 35 U.S.C. 111
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

National Stage of an International Application under 35 U.S.C. 371
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	13/493,493	BATHE ET AL.	

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 8/31/12	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
Lawan Hixon

U.S. Patent and Trademark Office

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

48394 7590 09/11/2012

DIEHL SERVILLA LLC
33 WOOD AVE SOUTH
SECOND FLOOR, SUITE 210
ISELIN, NJ 08830

EXAMINER
MATTER, KRISTEN CLARETTE

ART UNIT	PAPER NUMBER
3778	

DATE MAILED: 09/11/2012

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/493,493	06/11/2012	Duncan P. Bathe	3000-US-0026CON	6133

TITLE OF INVENTION: GAS DELIVERY DEVICE AND SYSTEM

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$870	$0	$0	$870	12/11/2012

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

48394 7590 09/11/2012

DIEHL SERVILLA LLC
33 WOOD AVE SOUTH
SECOND FLOOR, SUITE 210
ISELIN, NJ 08830

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/493,493	06/11/2012	Duncan P. Bathe	3000-US-0026CON	6133

TITLE OF INVENTION: GAS DELIVERY DEVICE AND SYSTEM

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$870	$0	$0	$870	12/11/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS
MATTER, KRISTEN CLARETTE	3778	128-202120

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. 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 12 minutes 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/493,493	06/11/2012	Duncan P. Bathe	3000-US-0026CON	6133

48394 7590 09/11/2012

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ISELIN, NJ 08830

EXAMINER	
MATTER, KRISTEN CLARETTE	
ART UNIT	PAPER NUMBER
3778	

DATE MAILED: 09/11/2012

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 0 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 0 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No.	Applicant(s)	
	13/493,493	BATHE ET AL.	
	Examiner	Art Unit	
	KRISTEN MATTER	3778	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed 8/30/12*.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☒ The allowed claim(s) is/are *1,3-7 and 10-19*.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20120830* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Kristen C. Matter/
Primary Examiner, Art Unit 3778

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	13/493,493	BATHE ET AL.	
	Examiner	Art Unit	
	KRISTEN MATTER	3778	

All participants (applicant, applicant's representative, PTO personnel):

(1) *KRISTEN MATTER*.

(2) *RORY ALEGRIA*.

(3) *ERIKA SENSKA*.

(4) *JARON ACKER*.

Date of Interview: *30 August 2012*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☒ Yes ☐ No.
If Yes, brief description: *Proposed amendments and arguments*.

Issues Discussed ☐101 ☐112 ☐102 ☒103 ☐Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *1-19*.

Identification of prior art discussed: *US 2009/0266358 and US 6,089,229*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

See Continuation Sheet.

Applicant recordation instructions: The formal written reply to the last Office action must include the substance of the interview. (See MPEP section 713.04). If a reply to the last Office action has already been filed, applicant is given a non-extendable period of the longer of one month or thirty days from this interview date, or the mailing date of this interview summary form, whichever is later, to file a statement of the substance of the interview

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☒ Attachment

/Kristen C. Matter/ Primary Examiner, Art Unit 3778	

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: On 8/29/12, applicants noted the importance of the invention for treating premature infants and closely and accurately monitoring that concentration of NO provided to them. Examiner indicated that the proposed amendments of 8/23/12 were sufficient to overcome the Rock reference but that Bathe as combined with Rock might still read on the invention as claimed. Examiner suggested making it clear in the claims that 1) the circuit was physically contained within the valve assembly and 2) that the gas data is somehow inputted into the system to overcome Bathe as well. Applicants agreed to make such changes and file a terminal disclaimer to move the case towards allowance. Examiner agreed to let applicants file another set of proposed claims making the agreed upon changes at which time examiner would do an updated search and if found allowable, the second set of proposed claims would be entered and a notice of allowance mailed. If the claims were not found allowable after the updated search the examiner indicated she would sent out the FAI Office Action and not enter any of the proposed claim amendments.

An updated search on the claims submitted 8/30/12 did not yield any additional art that the claims were not patentably distinguished from. Accordingly, the claims have been entered and the attached Examiner's Amendment was discussed and agreed upon on 8/30/12.

EXAMINER'S AMENDMENT

Terminal Disclaimer

The terminal disclaimer filed on 8/31/12 has been reviewed and is accepted. The terminal disclaimer has been recorded.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Rory Alegria on 8/30/12.

The application has been amended as follows:

In claim 6, lines 2-3, "and the control module," has been deleted.

The following is an examiner's statement of reasons for allowance: The prior art of record does not disclose the combination of limitations found in claim 1, particularly including a valve assembly for attachment to a NO gas container comprising a circuit supported within the valve assembly and disposed between an actuator for opening/closing the valve and a cap, the circuit including a valve memory to store inputted gas concentration data, a valve processor, and a valve transceiver to send wireless signals to a control module that controls gas delivery to a user through the valve assembly.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTEN MATTER whose telephone number is (571)272-5270. The examiner can normally be reached on Monday - Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kristen C. Matter/
Primary Examiner, Art Unit 3778

Notice of References Cited	Application/Control No. 13/493,493	Applicant(s)/Patent Under Reexamination BATHE ET AL.	
	Examiner KRISTEN MATTER	Art Unit 3778	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,089,229	07-2000	Bathe et al.	128/204.21
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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PROPOSED

IN THE CLAIMS

1. (Currently amended) A ~~gas delivery device~~ valve assembly to deliver a ~~administer therapy~~ gas comprising NO from a gas ~~source~~ container containing the gas comprising NO, the ~~gas delivery device~~ valve assembly comprising:

a valve attachable to the gas ~~source~~ container containing the gas comprising NO, the valve including an inlet and an outlet in fluid communication and a valve actuator to open or close the valve to allow the gas comprising NO through the valve to a control module; ~~and~~

a circuit supported within the valve assembly and disposed between the actuator and a cap, the circuit including:

a valve memory to store gas data comprising ~~one or more of gas identification, gas expiration date and~~ gas concentration in the gas container and

a valve processor and a valve transceiver in communication with the valve memory to send wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject; and

a data input disposed on the actuator and in communication with said valve memory, to permit a user to enter the gas data into the valve memory.

2. (Canceled)

3. (Currently amended) The ~~device~~ valve assembly of claim [[2]] 1, wherein the gas data is provided in a bar code disposed on the gas ~~source~~ container and is entered into the data input by a user-operated scanning device in communication with the data input.

4. (Currently amended) The ~~device~~ valve assembly of claim 1, wherein the valve comprises a power source; and the valve transceiver periodically sends the wireless optical line-of-sight signals to the control module, wherein the signals are interrupted by a duration of time at which no signal is sent.

PROPOSED

5. (Currently amended) The ~~device~~ valve assembly of claim 4, wherein the duration of time at which no signal is sent comprises about 10 seconds.

6. (Currently amended) A gas delivery system comprising:

the ~~gas delivery device~~ valve assembly of claim 1; and

[[a]] the control module, wherein the control module is in fluid communication with the outlet of the valve ~~and a ventilator~~, the control module comprising:

a CPU transceiver to receive line-of-sight signals from the valve transceiver; ~~and~~

a CPU in communication with the CPU transceiver and including a CPU memory; and

a display to enter patient information into the CPU memory,

wherein the valve transceiver communicates the gas data comprising gas concentration to the CPU transceiver for storage in the CPU memory, and wherein the CPU compares the patient information entered into the CPU memory via the display and the gas concentration from the valve transceiver.

7. (Currently amended) The system of claim 6, wherein the valve comprises a timer including a calendar timer and an event timer, wherein the valve memory stores the date and time of opening and closing of the valve and the duration of time that the valve is open and the valve transceiver communicates the date and time of opening and closing of the valve to the CPU transceiver for storage in the CPU memory.

8 – 9. (Canceled)

10. (Currently amended) The system of claim [[9]] 6, wherein the CPU comprises an alarm that is triggered when the patient information entered into the CPU memory and the gas data from the valve transceiver do not match.

PROPOSED

11. (Currently amended) The system of claim 6, wherein [[A]] the CPU memory ~~comprising~~ comprises instructions that cause [[a]] the CPU processor to: receive gas data comprising ~~selected from one or more of gas identification, gas expiration date and~~ gas concentration from [[a]] the valve via a wireless optical line-of-sight signal with the valve connected to [[a]] the gas ~~source~~ container containing gas comprising NO; compare the gas data with user-inputted patient information; coordinate delivery of therapy to the patient with a medical device via the wireless optical line-of-sight signal between the CPU transceiver and the valve transceiver; select a therapy for delivery to a patient based on the received patient information; and control delivery of the selected therapy to the patient.

12. (Currently amended) The ~~memory~~ system of claim 11, wherein the memory further comprises instructions that cause the CPU processor to:

receive a first valve status selected from a first open position and a first closed position from a first valve via a first wireless optical line-of-sight signal with the first valve connected to a first gas ~~source~~ container;

receive a second valve status selected from a second open position and a second closed position from a second valve via a second wireless optical line-of-sight signal with the second valve connected to a second gas ~~source~~ container;

compare the first valve status and the second valve status; and

emit an alarm if the first valve status comprises the first open position and the second valve status comprises the second open position.

13. (Currently amended) The ~~memory~~ system of claim 12, wherein the memory further comprises instructions that causes the CPU processor to:

terminate delivery of therapy if the first valve status comprises the first open position and the second valve status comprises the second open position.

14. (Currently amended) A method for administering a therapy gas comprising NO to a patient, the method comprising:

establishing communication via a CPU transceiver with ~~a gas delivery device~~ the valve assembly of claim 1 and communicating the gas data from the valve transceiver to the CPU transceiver ~~comprising a first memory including gas data~~,

comparing the gas data communicated from the valve transceiver with patient information stored within a ~~second~~ CPU memory;

coordinating delivery of therapy to a patient with the gas delivery device via a wireless optical line-of-sight signal between the CPU transceiver and the valve transceiver;

selecting a therapy for delivery to the patient based on the comparison of the gas data and the patient information; and

controlling delivery of the selected therapy to the patient.

15. (Original) The method of claim 14, further comprising ceasing delivery of the selected therapy to the patient based on the comparison of the gas data and the patient information.

16. (Original) The method of claim 14, further comprising emitting an alert based on the comparison of the gas data and the patient information.

17. (Currently amended) The method of claim 14, further comprising entering the gas data into the ~~first~~ valve memory.

18. (Currently amended) The method of claim 14, further comprising entering the patient information into the ~~second~~ CPU memory.

19. (New) A gas delivery device comprising:

the valve assembly of claim 1; and

the gas container containing gas comprising NO attached to the valve assembly, wherein a bar code disposed on the gas container provides the gas data.

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PROPOSED

REMARKS

Claims 1-18 are pending in the application. Claims 1-18 are rejected. No claims are allowed.

Claims 1, 3-7, 10-14 and 17-18 include proposed amendments to more clearly describe and distinctly claim the subject matter the Applicants consider their invention. Specifically, the proposed amendments to claim 1 recite a "valve assembly" instead of a "gas delivery device". The proposed amendments to claim 1 also replace the "gas source comprising NO" with a "container containing gas comprising NO", and claim 1 now recites that the circuit components (memory, transceiver and processor) are supported within the valve assembly and disposed between the actuator and the cap. Claim 1 also now recites that the gas data comprises gas concentration. The proposed amendments to claim 1 also incorporate the subject matter of claim 2, as well as specify that the data input is disposed on the actuator. Accordingly, claim 2 is canceled. Claims 3-5 include minor proposed amendments to use the same terminology as amended claim 1.

The proposed amendments to claim 6 incorporate the subject matter of claims 8 and 9. Accordingly, claims 8 and 9 are canceled. The proposed amendments to claim 6 also remove the phrase "and [in fluid communication with] a ventilator". Claims 7 and 10 include proposed amendments to correct dependency and specify that the memory and transceiver are the valve memory and valve transceiver, respectively.

Claim 11 is proposed to be dependent from claim 6 and specify that the memory is the CPU memory. Claims 11-13 include proposed amendments to use the same terminology as claim 6. Claim 14 is proposed to be dependent from claim 1. The proposed amendments to claim 14 also recite that the communication is between a CPU transceiver and a valve transceiver and the gas data is communicated from the valve transceiver to the CPU transceiver. Proposed amendments to claims 17 and 18 specify that the first memory and second memory are the valve memory and CPU memory, respectively.

New claim 19 has been added.

Support for the amendments can be found at least at paragraphs [0019], [0035], [0037] and [0056], and Figures 1 and 3 of the specification as originally filed, as well as the as-filed claims.

No new matter has been added by this amendment.

Claim Rejections – 35 U.S.C. § 112

Claims 6-10 are rejected under 35 U.S.C. § 112, second paragraph for allegedly being indefinite. According to the Examiner, it is unclear whether the control module of claim 6 is the same control module as in claim 1. The proposed amendment to claim 6 replaces "a control module" with "the control module", and Applicants respectfully request that this rejection be withdrawn.

Obviousness-Type Double Patenting

Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims of the co-pending U.S. Patent Application Number 13/509,873. While Applicants do not necessarily agree with this conclusion, in the interest of furthering prosecution, a timely filed terminal disclaimer accompanies this response. Therefore, it is respectfully requested that this rejection be reconsidered and withdrawn.

Claim Rejections – 35 U.S.C. § 103

Claims 1, 2 and 4-7

Claims 1, 2 and 4-7 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over US 2009/0266358 (Rock) in view of US 2011/0240019 (Fine). According to the Examiner, Rock discloses all of the limitations of the claims, including a gas delivery device comprising a valve actuator to open and close a valve, a circuit with memory to store gas data, a processor/transceiver to periodically communicate the data to a CPU/control module that stores the information and uses it to control a ventilator, but does not mention NO. The Examiner

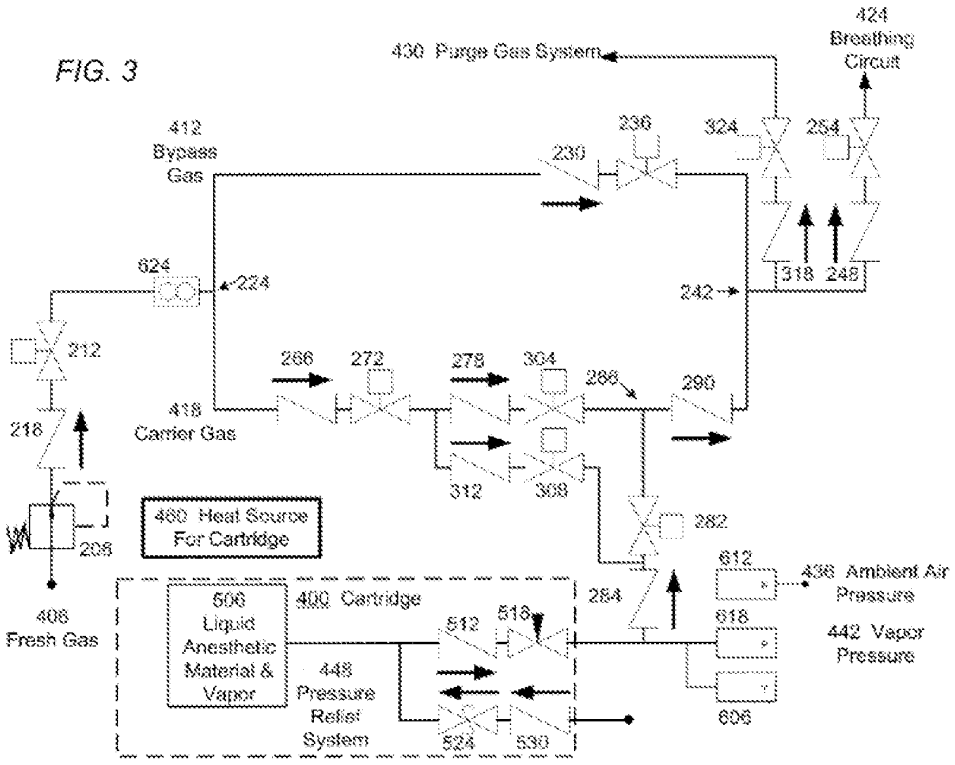
concludes that the use of NO is obvious in view Fine. Applicants respectfully traverse this basis for rejection.

In rejecting claims under 35 U.S.C. § 103, there must be a factual basis to support the legal conclusion of obviousness. Although the analysis need not identify explicit teachings directed to the claimed subject matter, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). As such, "'there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Applicants respectfully submit that the required reason to combine the references is absent and that even if the references were combined, all claims elements are not disclosed, taught or suggested.

Claim 1

Rock is directed to a vaporizer and cartridge system that utilizes liquid anesthetic materials. *See* Rock abstract. The vaporizer and cartridge system of Rock can be best understood with reference to FIG. 3, which is reproduced below:

PROPOSED



The cartridge is preloaded with a particular liquid anesthetic material, which is heated by the vaporizer to provide an anesthesia vapor. *See* Rock ¶¶ [0035]-[0037]. The saturated vapor pressure of the anesthesia material is predictable depending on the liquid material used, the ambient air pressure, and the heated temperature of the liquid. *See* Rock ¶ [0035].

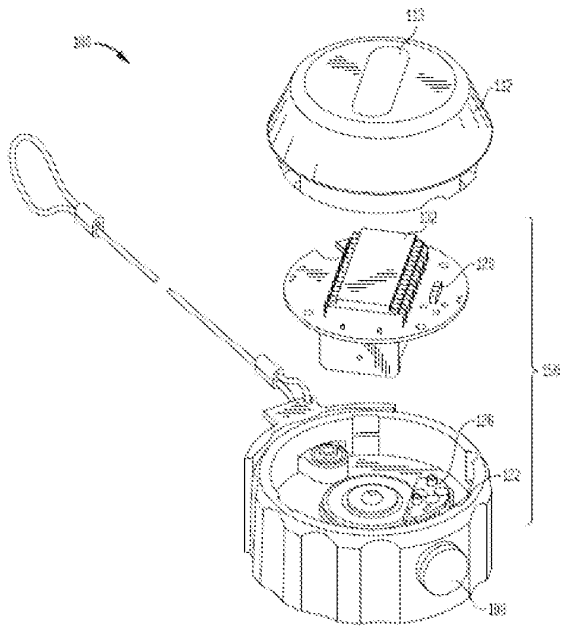
The cartridge may communicate information from the cartridge to the vaporizer, including the specific liquid anesthetic material within the cartridge, lot number, expiration date, and volume of liquid anesthetic material in the cartridge. *See* Rock ¶ [0041]. However, Rock does not disclose communicating gas concentration from the cartridge to the vaporizer. Indeed, as the anesthetic material of Rock is stored as a liquid, not a gas, there is no gas concentration in the cartridge. Furthermore, there is no "concentration" for the vaporized liquid, other than a concentration of 100% anesthesia vapor.

PROPOSED

Accordingly, there is no reason to communicate a gas concentration from the cartridge to the vaporizer in Rock because this parameter is nonexistent for the vaporizer/cartridge system. Additionally, because no gas concentration is taught, a person of ordinary skill in the art would have no motivation to communicate a gas concentration as recited in claim 1.

Rock also fails to disclose, teach or suggest a circuit **within the valve assembly** that includes a valve memory, valve transceiver and valve processor. FIG. 3 of the present application shows a valve assembly having the circuit 150.

FIG. 3



As described in the paragraph [0035] of the present application, the circuit 150 includes a valve memory, a valve processor, and a valve transceiver within the valve assembly. Amended claim 1 specifically recites that the valve assembly itself comprises the valve and the circuit (including the circuit's individual components), as well specify that the circuit is disposed between the valve actuator and cap as shown in FIG. 3. However, Rock fails to disclose a transceiver, memory and a processor **within the valve assembly**. Instead, the memory of Rock (and presumably any other circuit components that are not specifically disclosed) is located **within the cartridge**.

Accordingly, Rock does not provide that all of the communication components are located within a single unit or housing that is distinct from the drug source. As recited in claim 1, the valve is attachable to the gas container having the NO gas. By comparing FIGS. 2 and 3 of the instant application, it is clear that the gas container is not integral to the valve assembly and that the valve assembly and the gas container may be attached or detached from each other. However, the cartridge of Rock includes the reservoir of anesthesia liquid **and** the memory device. *See* Rock claim 1. There is no indication in Rock that the reservoir may be separate from a valve assembly having the memory. Therefore, Rock does not disclose a valve assembly having the components as claimed.

Rock also does not disclose a data input for a valve memory. Instead, Rock only discloses data input for the vaporizer delivery device. *See* Rock ¶ [0056]. Accordingly, Rock does not provide a data input in communication with the valve memory and disposed on the actuator as recited in claim 1.

Fine does not cure the deficiencies of Rock described above. Fine pertains to methods and systems for delivering nitric oxide using N_2O_4 as a liquid nitrogen dioxide source. *See* Fine abstract. In Fine, a liquid source containing pure N_2O_4 is vaporized to produce NO_2, which in turn is converted to NO by passing it through a cartridge containing a surface-activated material saturated with an aqueous solution of an antioxidant. *See* Fine ¶¶ [0018] and [0026]. The NO is then passed through a second cartridge before being administered to the patient. *See* Fine ¶ [0026]. As with Rock, the liquid source is vaporized to produce a pure vapor, and thus there is no relevant gas concentration. Although Fine also describes using NO_2 gas bottles, this is not the drug that is ultimately administered to the patient. Fine teaches that the NO_2 itself is highly toxic if inhaled and can form nitric acid and nitrous acid in the lungs. *See* Fine ¶ [0003]. As the drug that is ultimately administered to the patient is NO, not NO_2, the NO_2 bottle of Fine does not have a concentration of the relevant NO gas. Thus, there is no motivation to communicate a gas concentration from the N_2O_4 reservoir or NO_2 bottle of Fine to the vaporizer.

Fine also does not disclose any communication elements in the reservoir/bottle, and therefore does not disclose a valve assembly having a valve transceiver, a valve memory and a valve processor. Fine also fails to disclose a data input disposed on an actuator and in

communication with a valve memory. Accordingly, even if a person of ordinary skill in the art were to combine Rock and Fine, the combination of references does not disclose all of the elements of amended claim 1. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Claims 4-7

Applicants respectfully submit that in addition to the above arguments with respect to claim 1, the combination of Rock and Fine do not teach the further limitations of claims 4-7. Regarding claims 4 and 5, Rock does not disclose an intermittent signal from the valve transceiver to the control module. Rock also does not disclose comparing patient information entered into the CPU memory via the display and the gas concentration from the valve receiver as recited in claim 6. Rock also fails to disclose a timer for storing the duration that the valve is open as recited in claim 7. Applicants note that the cartridge valve 518 of Rock is actuated and opened upon insertion of the cartridge 400 into the vaporizer, and the valve does not close until the cartridge is removed. *See* Rock ¶¶ [0039], [0132]-[0133] and [0140]. Thus, there is no need to time the duration that the cartridge valve is open because this will only indicate how long the cartridge was attached to the vaporizer.

Fine does not teach any communication elements in the reservoir/bottle, so it does not cure these deficiencies of Rock.

Claim 3

Claim 3 is rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Rock in view of Fine and US 2002/0044059 (Reeder). According to the Examiner, use of a bar code in a modified system based on Rock and Fine is obvious in view of Reeder. Applicants respectfully traverse this basis for rejection.

Reeder is directed to a patient monitoring system comprising a computer, an input device coupled to the computer and configured to input patient information, and first and second display screens coupled to the computer. *See* Reeder abstract. Reeder discusses a bar code reader in paragraph [0006] in which "[t]he computer system also includes an input device such as, for

example, a keyboard or a bar code reader to capture costs of medication or other treatment or articles used by the patient." However, this bar code reader is for providing information to the central computer 12. This is not the same as having a bar code reader to input gas data from the gas container to the valve memory, which is then further communicated to the CPU memory via the wireless communication between the valve transceiver and the CPU transceiver, as in the instant application. Accordingly, Applicants respectfully submit that this limitation is not disclosed, taught or suggested in the references and request that the rejection be withdrawn.

New claim 19 recites that a bar code disposed on the gas container provides the gas data. Applicants respectfully submit that there is no motivation in the references to have gas data provided by a bar code on the gas container, in addition to gas data stored in the valve memory. The gas container and valve assembly combination of claim 19 includes two distinct locations that provide gas data, which is not taught or suggested in the references.

Claims 8-18

Claims 8-18 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Rock in view of Fine and US 2011/0041849 (Chen). According to the Examiner, Chen includes a similar gas delivery system that allows patient information for setting threshold ranges and control of ventilator settings to increase patient safety. Applicants respectfully traverse this basis for rejection.

Chen does not remedy the deficiencies of Rock and Fine as described above. As such, claims 8-18 are not obvious over Rock in view of Fine and Chen for at least the reasons provided above.

Furthermore, Chen relates to a method and system for controlling a ventilator, which may use oxygen saturation values from pulse oximeters to adjust the settings of a ventilator. *See* Chen abstract. Although Chen describes calculating the difference between two S_pO_2 readings and comparing to a threshold, there is no suggestion of comparing user-inputted patient information and a NO concentration in a container to determine if they substantially match. Chen describes a system that changes ventilator settings in response to S_pO_2 readings, not

comparing drug information to a patient's information to determine if the drug is appropriate for therapy.

Chen also does not describe any of the steps recited in claim 14, which require establishing communication via a CPU transceiver with the valve assembly and communicating gas data from the valve transceiver to the CPU transceiver; comparing the gas data communicated from the valve transceiver with patient information stored within a CPU memory; coordinating delivery of therapy to a patient with the gas delivery device via a wireless optical line-of-sight signal between the CPU transceiver and the valve transceiver; selecting a therapy for delivery to the patient based on the comparison of the gas data and the patient information; and controlling delivery of the selected therapy to the patient. Indeed, as Chen does not disclose any valves for communicating with the delivery system, there is no reason to perform many of these steps. Accordingly, Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

It is believed that claims 1, 3-7 and 10-19 are now in condition for allowance, early notice of which would be appreciated. No fees are believed due with this submission. If any fees are due at this time, the Commissioner is authorized to charge Deposit Account No. 50-3329. Please contact the undersigned if any further issues remain to be addressed in connection with this submission.

Respectfully submitted,

Dated: August 30, 2012

By: /Rory P. Alegria, Reg. No. 66,947/

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BIB DATA SHEET

CONFIRMATION NO. 6133

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/493,493	06/11/2012	128	3778	3000-US-0026CON

APPLICANTS

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John Klaus, Cottage Grove, WI;
David Christensen, Cambridge, WI;

** **CONTINUING DATA** ********** /KCM/

This application is a CON of 13/509,873
which is a 371 of PCT/US11/20319 01/06/2011

** **FOREIGN APPLICATIONS** ********** None /KCM/

** **IF REQUIRED, FOREIGN FILING LICENSE GRANTED** ** ** SMALL ENTITY **
06/19/2012

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☑ No Verified and Acknowledged /KRISTEN CLARETTE MATTER/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		WI	12	~~18~~ 19 /KCM/	~~3~~ 4 /KCM/

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TITLE

Gas Delivery Device And System

FILING FEE RECEIVED		
830	FEES: Authority has been given in Paper No._____ to charge/credit DEPOSIT ACCOUNT No._____ for following:	☐ All Fees ☐ 1.16 Fees (Filing) ☐ 1.17 Fees (Processing Ext. of time) ☐ 1.18 Fees (Issue) ☐ Other _____ ☐ Credit

BIB (Rev. 05/07).

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13493493	BATHE ET AL.
	Examiner	**Art Unit**
	KRISTEN MATTER	3778

ORIGINAL		INTERNATIONAL CLASSIFICATION																	
CLASS	SUBCLASS	CLAIMED										NON-CLAIMED							
128	205.24	A	6	1	M	15 / 00 (2006.0)													
CROSS REFERENCE(S)		F	1	6	K	31 / 02 (2006.0)													
		A	6	2	B	9 / 02 (2006.01.01)													
CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)																		
128	203.14	204.22																	

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
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13	16														

NONE		Total Claims Allowed:	
(Assistant Examiner)	(Date)	16	
/KRISTEN MATTER/ Primary Examiner.Art Unit 3778	8/30/12	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	3

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13493493	BATHE ET AL.
	Examiner	**Art Unit**
	KRISTEN MATTER	3778

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☒ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	08/15/2012	08/30/2012							
1	1	✓	=							
	2	✓	-							
2	3	✓	=							
3	4	✓	=							
4	5	✓	=							
5	6	✓	=							
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8	11	✓	=							
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14	17	✓	=							
15	18	✓	=							
16	19		=							

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	1	(NO and valve and memory and processor and concentration and control and input and data).clm.	US-PGPUB	OR	ON	2012/08/30 14:31

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	2	(NO and valve and memory and processor and concentration and control and input and data).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2012/08/30 14:32

8/30/2012 2:33:40 PM

COPY /KCM/ 8/30/12

Doc Code: M865 or FAI.REQ.INTV

PTOL-413A (08-10)
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Applicant Initiated Interview Request Form

Application No.: 13/493,493 First Named Applicant: Duncan P. Bathe
Examiner: Kristen Clarette Matter Art Unit: 3778 Status of Application: Pending

Tentative Participants:
(1) Rory Alegria (2) Erika Senska

(3) Jaron Acker (4)

Proposed Date of Interview: 08/23/12 **Proposed Time:** 2:00 PM **(AM/PM)**

Type of Interview Requested:
(1) [✓] Telephonic (2) [ ] Personal (3) [ ] Video Conference

Exhibit To Be Shown or Demonstrated: [ ] YES [✓] NO
If yes, provide brief description:

Issues To Be Discussed

Issues (Rej., Obj., etc)	Claims/ Fig. #s	Prior Art	Discussed	Agreed	Not Agreed
(1) 112	6-10		[ ]	[ ]	[ ]
(2) OTDP	1-18	13/509,873, Fine	[ ]	[ ]	[ ]
(3) 103	1,2,4-7	Rock, Fine	[ ]	[ ]	[ ]
(4) 103	3	Rock, Fine, Reeder	[ ]	[ ]	[ ]

[✓] Continuation Sheet Attached [✓] Proposed Amendment or Arguments Attached

Brief Description of Arguments to be Presented: see attached

An interview was conducted on the above-identified application on

NOTE: This form should be completed and filed by applicant in advance of the interview (see MPEP § 713.01). If this form is signed by a registered practitioner not of record, the Office will accept this as an indication that he or she is authorized to conduct an interview on behalf of the principal (37 CFR 1.32(a)(3)) pursuant to 37 CFR 1.34. This is not a power of attorney to any above named practitioner. See the Instruction Sheet for this form, which is incorporated by reference. By signing this form, applicant or practitioner is certifying that he or she has read the Instruction Sheet. After the interview is conducted, applicant is advised to file a statement of the substance of this interview (37 CFR 1.133(b)) as soon as possible. This application will not be delayed from issue because of applicant's failure to submit a written record of this interview.

/Rory P. Alegria, Reg. No 66,947/
Applicant/Applicant's Representative Signature

Examiner/SPE Signature

Rory P. Alegria
Typed/Printed Name of Applicant or Representative

66,947
Registration Number, if applicable

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13493493	BATHE ET AL.
	Examiner	Art Unit
	KRISTEN MATTER	3778

SEARCHED			
Class	Subclass	Date	Examiner
128	204.18, 204.21-204.23, 205.24, 203.12, 203.14	8/15/12	KCM
128	200.24, 205.11, 205.23	8/30/12	KCM
	Updated Search	8/30/12	KCM

SEARCH NOTES		
Search Notes	Date	Examiner
Inventor name search, see attached EAST text search	8/15/12	KCM

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner
	See attached EAST search	8/30/12	KCM

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Diehl Servilla LLC
33 Wood Avenue South
Second Floor, Suite 210
Iselin, NJ 08830

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

N/A (Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/493,493	06/11/2012	Duncan P. Bathe	3000-US-0026CON	6133

TITLE OF INVENTION:

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$870	$0	$0	$870	12/11/2012

EXAMINER	ART UNIT	CLASS-SUBCLASS

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 Diehl Servilla LLC
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE: INO Therapeutics LLC

(B) RESIDENCE: (CITY and STATE OR COUNTRY): Hampton, NJ

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ■ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

☑ Issue Fee

☐ Publication Fee (No small entity discount permitted)

☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

☐ A check is enclosed.

☑ Payment by credit card. ~~Form PTO-2038 is attached.~~

☑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 50-3329 (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature /Rory P. Alegria, Reg. #66947/ Date September 11, 2012

Typed or printed name Rory P. Alegria Registration No. 66947

This collection of information is required by 37 CFR 1.311. 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 12 minutes 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, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PTO/SB/47 (09-06)
Approved for use through 04/30/2009. OMB 0651-0016
U.S. Patent and Trademark Office; U. S. DEPARTMENT OF COMMERCE

"FEE ADDRESS" INDICATION FORM

Address to:
Mail Stop M Correspondence
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

- OR -

Fax to:
571-273-6500

INSTRUCTIONS: The issue fee must have been paid for application(s) listed on this form. In addition, only an address represented by a Customer Number can be established as the fee address for maintenance fee purposes (hereafter, fee address). A fee address should be established when correspondence related to maintenance fees should be mailed to a different address than the correspondence address for the application. **When to check the first box below:** If you have a Customer Number to represent the fee address. **When to check the second box below:** If you have no Customer Number representing the desired fee address, in which case a completed Request for Customer Number (PTO/SB/125) must be attached to this form. For more information on Customer Numbers, see the Manual of Patent Examining Procedure (MPEP) § 403.

For the following listed application(s), please recognize as the "Fee Address" under the provisions of 37 CFR 1.363 the address associated with:

☑ Customer Number: 13918

OR

☐ The attached Request for Customer Number (PTO/SB/125) form.

PATENT NUMBER (if known)	APPLICATION NUMBER
	13/493.493

Completed by (check one):

☐ Applicant/Inventor

/Rory P. Alegria, Reg. #66947/
Signature

☑ Attorney or Agent of record 66947 (Reg. No.)

Rory P. Alegria
Typed or printed name

☐ Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)

732 815 0404
Requester's telephone number

☐ Assignee recorded at Reel _____ Frame_____

September 11, 2011
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more that one signature is required, see below*.

☑ * **Total of** 1 **forms are submitted.**

Electronic Patent Application Fee Transmittal

Application Number:	13493493
Filing Date:	11-Jun-2012
Title of Invention:	GAS DELIVERY DEVICE AND SYSTEM
First Named Inventor/Applicant Name:	Duncan P. Bathe
Filer:	Rory P. Alegria/Linda Murphy
Attorney Docket Number:	3000-US-0026CON

Filed as Small Entity

Utility under 35 USC 111(a) Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Utility Appl issue fee	2501	1	870	870
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**870**

Electronic Acknowledgement Receipt	
EFS ID:	13707885
Application Number:	13493493
International Application Number:	
Confirmation Number:	6133
Title of Invention:	GAS DELIVERY DEVICE AND SYSTEM
First Named Inventor/Applicant Name:	Duncan P. Bathe
Customer Number:	48394
Filer:	Rory P. Alegria/Linda Murphy
Filer Authorized By:	Rory P. Alegria
Attorney Docket Number:	3000-US-0026CON
Receipt Date:	11-SEP-2012
Filing Date:	11-JUN-2012
Time Stamp:	11:35:10
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$870
RAM confirmation Number	10893
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)

1	Issue Fee Payment (PTO-85B)	00303258.PDF	74324 b6f54f827ce77673774007946a82d5d2dbf7a38c	no	1
Warnings:					
Information:					
2	Miscellaneous Incoming Letter	00303255.PDF	34652 b1f43662a1ec4fde43b4472d4e18a838879fd72c	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	30529 a30079bcb0dfc52251ea6e347efca8c2b22dbce6	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	139505		

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.

<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/493,493	06/11/2012	Duncan P. Bathe	3000-US-0026CON

CONFIRMATION NO. 6133

48394
DIEHL SERVILLA LLC
33 WOOD AVE SOUTH
SECOND FLOOR, SUITE 210
ISELIN, NJ 08830

PUBLICATION NOTICE

Title:GAS DELIVERY DEVICE AND SYSTEM

Publication No.US-2012-0240927-A1
Publication Date:09/27/2012

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Office of Public Records. The Office of Public Records can be reached by telephone at (703) 308-9726 or (800) 972-6382, by facsimile at (703) 305-8759, by mail addressed to the United States Patent and Trademark Office, Office of Public Records, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently http://pair.uspto.gov/. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

Further assistance in electronically accessing the publication, or about PAIR, is available by calling the Patent Electronic Business Center at 1-866-217-9197.

Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

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United States Patent and Trademark Office
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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/493,493	10/23/2012	8291904	3000-US-0026CON	6133

48394 7590 10/03/2012

DIEHL SERVILLA LLC
33 WOOD AVE SOUTH
SECOND FLOOR, SUITE 210
ISELIN, NJ 08830

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 0 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Duncan P. Bathe, Fitchburg, WI;
John Klaus, Cottage Grove, WI;
David Christensen, Cambridge, WI;