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	Not yet assigned
Filing Date	Herewith
First Named Inventor	Duncan P. Bathe
Art Unit	Not Yet Assigned
Examiner Name	Unknown

Submitted: May 15, 2012

Sheet	1	of	1

Attorney Docket No: 3000-US-0026(IKA0011-00US)

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 RelevantFigures 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 RelevantFigures 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

PRAXAIR 1016

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

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

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)

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

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, Fascimile 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

---

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2011/020319

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

1

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 notifed the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:	Date of completion of this opinion	Authorized Officer
European Patent Office 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

PTO-1390 (09-11)
Approved for use through 4/30/2013. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	
3000-US-0026 (IKA0011-00US)	
U.S. APPLICATION NO. (If known, see 37 CFR 1.5)	

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US11/20319	January 6, 2011	January 6, 2011

TITLE OF INVENTION
Gas Delivery Device And System

APPLICANT(S) FOR DO/EO/US
Duncan P. Bathe, John Klaus, David Christensen

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☑ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☑ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☐ has been communicated by the International Bureau.
   c. ☑ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☑ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☑ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☑ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A preliminary amendment.
14. ☑ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13*ter*.3 and 37 CFR 1.821- 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

PTO-1390 (09-11)
Approved for use through 4/30/2013. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
	PCT/US11/20319	3000-US-0026 (IKA0011-00US)

20. Other items or information:

The following fees have been submitted	CALCULATIONS	PTO USE ONLY
21. ☑ Basic national fee (37 CFR 1.492(a))..... **$380**	$ 380.00	
22. ☑ Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... **$0** All other situations..... **$250**	$250.00	
23. ☑ Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... **$0** Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... **$120** International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... **$490** All other situations..... **$620**	$ 620.00	
TOTAL OF 21, 22 and 23 =		
☐ Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) in an electronic medium or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is **$310** for each additional 50 sheets of paper or fraction thereof.		

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round **up** to a whole number)	RATE	
- 100 =	/50 =		x $**310**	$

Surcharge of **$130.00** for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).	$	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	$	
Total claims	18 - 20 =	0	x $ **60**	$0	
Independent claims	3 - 3 =	0	x **$250**	$0	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$450**	$	
			TOTAL OF ABOVE CALCULATIONS =	$1250.00	
☑ Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.				625.00	
			SUBTOTAL =	$	
Processing fee of **$130.00** for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). +				$	
			TOTAL NATIONAL FEE =	$ 625.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$	
			TOTAL FEES ENCLOSED =	$ 625.00	
			Amount to be refunded:	$ 0	
			Amount to be charged	$625.00	

a. ☐ A check in the amount of $ _____ to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees.

c. ☑ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-3329.

d. ☑ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038. The PTO-2038 should only be mailed or faxed to the USPTO. However, when paying the basic national fee, the PTO-2038 may NOT be faxed to the USPTO.

ADVISORY: If filing by EFS-Web, do **NOT** attach the PTO-2038 form as a PDF along with your EFS-Web submission. Please be advised that this is **not** recommended and by doing so your **credit card information may be displayed via PAIR**. To protect your information, it is recommended paying fees online by using the electronic payment method.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Diehl Servilla LLC
33 Wood Avenue South
Second Floor, Suite 210
Iselin, New Jersey 08830
USA

/Sunil Raval, Reg. No. 47,886/
SIGNATURE

Sunil Raval
NAME

47,886
REGISTRATION NUMBER

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.

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:	Sunil Raval/Jessica Escobar
Attorney Docket Number:	3000-US-0026(IKA0011-00US

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Basic National Stage Fee	2631	1	190	190
Natl Stage Search Fee - all other cases	2632	1	310	310
Natl Stage Exam Fee - all other cases	2633	1	125	125
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**625**

Electronic Acknowledgement Receipt	
EFS ID:	12781890
Application Number:	13509873
International Application Number:	PCT/US11/20319
Confirmation Number:	8620
Title of Invention:	Gas Delivery Device And System
First Named Inventor/Applicant Name:	Duncan P. Bathe
Customer Number:	48394
Filer:	Sunil Raval/Jessica Escobar
Filer Authorized By:	Sunil Raval
Attorney Docket Number:	3000-US-0026(IKA0011-00US
Receipt Date:	15-MAY-2012
Filing Date:	
Time Stamp:	14:43:11
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$625
RAM confirmation Number	1185
Deposit Account	
Authorized User	

File Listing:

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

1	Application Data Sheet	00270955.PDF	62060 446f2a293b0fb03b9f015d9dafbb2bc2dcfeeee3	no	5
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
2	Transmittal Letter	00270958.PDF	18438 dd16aa16ece235e700077a49260a1166fbfaf371	no	1
Warnings:					
Information:					
3	Information Disclosure Statement (IDS) Form (SB08)	00270957.PDF	29194 42bc217ee8f7b69fc2641a7ae6b79ba4bb5332cb	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					
4	Non Patent Literature	00270843.PDF	2292666 505ccb91ae60a5ed31a2330ee59724da582568a2	no	19
Warnings:					
Information:					
5	Documents submitted with 371 Applications	00262956.PDF	246841 7fa5aa7a35f3ece2ced84f736073eeb441ec90be	no	4
Warnings:					
Information:					
6	Fee Worksheet (SB06)	fee-info.pdf	32788 6fc708ac31ffe2c87663fc3d91fb7e21b31d78cb	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2681987		

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/14 (07-07)
Approved for use through 06/30/2010. 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 contains a valid OMB control number

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3000-US-0026(IKA0011-00US)
	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					
Applicant Authority	☒ Inventor	☐ Legal Representative under 35 U.S.C. 117	☐ Party of Interest under 35 U.S.C. 118		
Prefix	**Given Name**	**Middle Name**	**Family Name**	**Suffix**	
	Duncan	P.	Bathe		
Residence Information (Select One)	☒ US Residency	☐ Non US Residency	☐ Active US military Service		
City	Fitchburg	**State**	WI	**Country of Residence**	US
Citizenship under 37 CFR 1.41(b)	GB				

Mailing Address of Applicant:

Address 1	5699 Nutone Street		
Address 2			
City	Fitchburg	**State/Province**	WI
Postal Code	53711	**Country**	United States of America

Applicant Information

Applicant 2			
Applicant Authority	☒ Inventor	☐ Legal Representative under 35	☐ Party of Interest under 35 U.S.C.

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. 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 contains a valid OMB control number

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3000-US-0026(IKA0011-00US)
	Application Number	
Title of Invention	Gas Delivery Device And System	

		U.S.C. 117	118

Prefix	Given Name	Middle Name	Family Name	Suffix
	John		Klaus	

Residence Information (Select One)	[X] US Residency	[ ] Non US Residency	[ ] Active US military Service

City	Cottage Grove	State	WI	Country of Residence	US

Citizenship under 37 CFR 1.41(b)	US

Mailing Address of Applicant:

Address 1	2730 Gaston Road		
Address 2			
City	Cottage Grove	State/Province	WI
Postal Code	53527	Country	United States of America

Applicant Information

Applicant 3

Applicant Authority	[X] Inventor	[ ] Legal Representative under 35 U.S.C. 117	[ ] Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	David		Christensen	

Residence Information (Select One)	[X] US Residency	[ ] Non US Residency	[ ] Active US military Service

City	Cambridge	State	WI	Country of Residence	US

Citizenship under 37 CFR 1.41(b)	US

Mailing Address of Applicant:

Address 1	N4398 Wolff Road

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3000-US-0026(IKA0011-00US)
	Application Number	
Title of Invention	Gas Delivery Device And System	

Address 2			
City	Cambridge	State/Province	WI
Postal Code	53523	Country	United States of America

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).	
[X] An Address is being provided for the correspondence Information of this application	
Customer Number	48394
Email Address	

Application Information:

Title of Invention	Gas Delivery Device And System		
Attorney Docket Number	3000-US-0026(IKA0011-00US)	[X]	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.

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. 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 contains a valid OMB control number

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3000-US-0026(IKA0011-00US)
	Application Number	
Title of Invention	Gas Delivery Device And System	

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing

Please Select One:	[X] Customer Number	[ ] US Patent Practitioner	[ ] Limited Recognition (37 CFR 11.9)
Customer Number	48394		

Domestic Benefit/National Stage Information:

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**
	a 371 of International	PCT/US11/20319	January 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:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

If the Assignee is an Organization check here. [X]	
Organization Name	Ikaria, Inc.

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3000-US-0026(IKA0011-00US)
	Application Number	
Title of Invention	Gas Delivery Device And System	

Mailing Address Information:			
Address 1	53 Frontage Road, Third Floor		
Address 2	P.O. Box 9001		
City	Hampton	**State/Province**	N.J.
Country	United States of America	**Postal Code**	08827
Phone Number		**Fax Number**	
Email Address			

Signature:

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	/Sunil Raval, Reg. No. 47,886/			**Date**	2012-05-15
First Name	Sunil	**Last Name**	Raval	**Registration Number**	47,886

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.

S/N Not Yet Assigned **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Duncan P. Bathe et al.	Examiner:	Unknown
Serial No.:	Not Yet Assigned	Group Art Unit:	Not Yet Assigned
Filed:	Herewith	Docket:	3000-US-0026 (IKA0011-00US)
Title:	Gas Delivery Device And System		

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. Pursuant to 37 C.F.R. 1.98(a)(2), Applicant believes that copies of cited U.S. Patents and Published Applications are no longer required to be provided to the Office.

Pursuant to 37 C.F.R. §1.97(b), it is believed that no fee or statement is required with the Information Disclosure Statement. 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 May 15, 2012

By /Sunil Raval, Reg. No. 47,886/
Sunil Raval
Reg. No. 47,886

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

1

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

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.

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

---

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	

Form PCT/ISA/210 (patent family annex) (April 2005)

WO 2012/094008
PCT/US2011/020319

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

FIRST NOTICE INFORMING THE APPLICANT OF THE COMMUNICATION OF THE INTERNATIONAL APPLICATION (TO DESIGNATED OFFICES WHICH DO NOT APPLY THE 30 MONTH TIME LIMIT UNDER ARTICLE 22(1))

(PCT Rule 47.1(c))

To:

PATEL, Payal A.
Diehl Servilla LLC
33 Wood Avenue South
Second Floor, Suite 210
Iselin, New Jersey 08830
ETATS-UNIS D'AMERIQUE

Date of mailing *(day/month/year)*	
09 August 2012 (09.08.2012)	
Applicant's or agent's file reference	IMPORTANT NOTICE
IKA0011-00WO	

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2011/020319	06 January 2011 (06.01.2011)	

Applicant: IKARIA, INC. et al

1. **ATTENTION**: For any designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002 (30 months from the priority date), **does apply**, please see Form PCT/IB/308(Second and Supplementary Notice) (to be issued promptly after the expiration of 28 months from the priority date).

2. Notice is hereby given that the following designated Office(s), for which the time limit under Article 22(1), as in force from 1 April 2002, **does not apply**, has/have requested that the communication of the international application, as provided for in Article 20, be effected under Rule 93*bis*.1. The International Bureau has effected that communication on the date indicated below:
12 July 2012 (12.07.2012)

   None

   In accordance with Rule 47.1(c-*bis*)(i), those Offices will accept the present notice as conclusive evidence that the communication of the international application has duly taken place on the date of mailing indicated above and no copy of the international application is required to be furnished by the applicant to the designated Office(s).

3. The following designated Offices, for which the time limit under Article 22(1), as in force from 1 April 2002, **does not apply**, have not requested, as at the time of mailing of the present notice, that the communication of the international application be effected under Rule 93*bis*.1 :

   LU, TZ, UG

   In accordance with Rule 47.1(c-*bis*)(ii), those Offices accept the present notice as conclusive evidence that the Contracting State for which that Office acts as a designated Office does not require the furnishing, under Article 22, by the applicant of a copy of the international application.

4. **TIME LIMITS for entry into the national phase**

   For the designated Office(s) listed above, and unless a demand for international preliminary examination has been filed before the expiration of **19 months** from the priority date (see Article 39(1)), the applicable time limit for entering the national phase will, **subject to what is said in the following paragraph,** be **20 MONTHS** from the priority date.

   In practice, **time limits other than the 20-month time limit** will continue to apply, for various periods of time, in respect of certain of the designated Offices listed above. For **regular updates on the applicable time limits** (20 or 21 months, or other time limit), Office by Office, refer to the *PCT Gazette*, the *PCT Newsletter* and the *PCT Applicant's Guide*, Volume II, National Chapters, all available from WIPO's Internet site, at http://www.wipo.int/pct/en/index.html.

   It is the applicant's **sole responsibility** to monitor all these time limits.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No. +41 22 338 82 70

Authorized officer
Nora Lindner

e-mail: pt03.pct@wipo.int

Form PCT/IB/308(First Notice) (January 2004)

PCT REQUEST

Original (for **SUBMISSION**)

0	**For receiving Office use only**	
0-1	International Application No.	PCT/US11/20319
0-2	International Filing Date	06 JAN 2011 (06.01.11)
0-3	Name of receiving Office and "PCT International Application"	PCT INTERNATIONAL APPLICATION RO/US
0-4	**Form PCT/RO/101 PCT Request**	
0-4-1	Prepared Using	PCT-SAFE [EASY/EFS-Web mode] Version 3.51.047.223 MT/FOP 20101001/0.20.5.18
0-5	**Petition**	
	The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty	
0-6	**Receiving Office (specified by the applicant)**	United States Patent and Trademark Office (USPTO) (RO/US)
0-7	**Applicant's or agent's file reference**	IKA0011-00WO
I	**Title of Invention**	GAS DELIVERY DEVICE AND SYSTEM
II	**Applicant**	
II-1	This person is	Applicant only
II-2	Applicant for	All designated States except US
II-4	Name	IKARIA, INC.
II-5	Address	6 Route 173 Clinton, New Jersey 08809 United States of America
II-6	State of nationality	US
II-7	State of residence	US
III-1	**Applicant and/or inventor**	
III-1-1	This person is	Applicant and inventor
III-1-2	Applicant for	US only
III-1-4	Name (LAST, First)	BATHE, Duncan P.
III-1-5	Address	5699 Nutone Street Fitchburg, Wisconsin 53711 United States of America
III-1-6	State of nationality	GB
III-1-7	State of residence	US

PCT REQUEST

Original (for **SUBMISSION**)

III-2	**Applicant and/or inventor**	
III-2-1	This person is	Applicant and inventor
III-2-2	Applicant for	US only
III-2-4	Name (LAST, First)	KLAUS, John
III-2-5	Address	2730 Gaston Road Cottage Grove, Wisconsin 53527 United States of America
III-2-6	State of nationality	US
III-2-7	State of residence	US
III-3	**Applicant and/or inventor**	
III-3-1	This person is	Applicant and inventor
III-3-2	Applicant for	US only
III-3-4	Name (LAST, First)	CHRISTENSEN, David
III-3-5	Address	N4398 Wolff Road Cambridge, Wisconsin 53523 United States of America
III-3-6	State of nationality	US
III-3-7	State of residence	US
IV-1	**Agent or common representative; or address for correspondence** The person identified below is hereby/ has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:	Agent
IV-1-1	Name (LAST, First)	PATEL, Payal A.
IV-1-2	Address	Diehl Servilla LLC 33 Wood Avenue South Second Floor, Suite 210 Iselin, New Jersey 08830 United States of America
IV-1-3	Telephone No.	732-815-0404
IV-1-4	Facsimile No.	732-815-1330
IV-1-5	e-mail	docket@dsiplaw.com
IV-1-5(a)	E-mail authorization The receiving Office, the International Searching Authority, the International Bureau and the International Preliminary Examining Authority are authorized to use this e-mail address, if the Office or Authority so wishes, to send notifications issued in respect of this international application:	exclusively in electronic form (no paper notifications will be sent)
IV-1-6	Agent's registration No.	60,672

PCT REQUEST

Original (for **SUBMISSION**)

V	**DESIGNATIONS**		
V-1	**The filing of this request constitutes under Rule 4.9(a), the designation of all Contracting States bound by the PCT on the international filing date, for the grant of every kind of protection available and, where applicable, for the grant of both regional and national patents.**		
VI-1	**Priority Claim**	NONE	
VII-1	**International Searching Authority Chosen**	European Patent Office (EPO) (ISA/EP)	
VIII	**Declarations**	Number of declarations	
VIII-1	Declaration as to the identity of the inventor	–	
VIII-2	Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent	–	
VIII-3	Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application	–	
VIII-4	Declaration of inventorship (only for the purposes of the designation of the United States of America)	–	
VIII-5	Declaration as to non-prejudicial disclosures or exceptions to lack of novelty	–	
IX	**Check list**	Number of sheets	Electronic file(s) attached
IX-1	Request (including declaration sheets)	4	✓
IX-2	Description	22	–
IX-3	Claims	4	–
IX-4	Abstract	1	✓
IX-5	Drawings	12	–
IX-7	TOTAL	43	
	Accompanying Items	Paper document(s) attached	Electronic file(s) attached
IX-8	Fee calculation sheet	✓	–
IX-20	**Figure of the drawings which should accompany the abstract**	1	
IX-21	**Language of filing of the international application**	English	
X-1	**Signature of applicant, agent or common representative**	/Payal A. Patel, Reg. No. 60,672/	
X-1-1	Name (LAST, First)	PATEL, Payal A.	
X-1-2	Name of signatory		
X-1-3	Capacity		

FOR RECEIVING OFFICE USE ONLY

10-1	Date of actual receipt of the purported international application	06 JAN 2011 (06.01.11)
10-2	Drawings:	
10-2-1	Received	
10-2-2	Not received	
10-3	Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application	
10-4	Date of timely receipt of the required corrections under PCT Article 11(2)	
10-5	International Searching Authority	ISA/EP
10-6	Transmittal of search copy delayed until search fee is paid	

FOR INTERNATIONAL BUREAU USE ONLY

11-1	Date of receipt of the record copy by the International Bureau	

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

Form PCT/ISA/210 (first sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/020319

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	

Form PCT/ISA/210 (patent family annex) (April 2005)

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

---

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 July 2012 (12.07.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/094008 A1

(51) International Patent Classification:
A61M 16/10 (2006.01) *A61M 16/20* (2006.01)

(21) International Application Number:
PCT/US2011/020319

(22) International Filing Date:
6 January 2011 (06.01.2011)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant *(for all designated States except US)*: **IKARIA, INC.** [US/US]; 6 Route 173, Clinton, New Jersey 08809 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BATHE, Duncan P.** [GB/US]; 5699 Nutone Street, Fitchburg, Wisconsin 53711 (US). **KLAUS, John** [US/US]; 2730 Gaston Road, Cottage Grove, Wisconsin 53527 (US). **CHRISTENSEN, David** [US/US]; N4398 Wolff Road, Cambridge, Wisconsin 53523 (US).

(74) Agent: **PATEL, Payal A.**; Diehl Servilla LLC, 33 Wood Avenue South, Second Floor, Suite 210, Iselin, New Jersey 08830 (US).

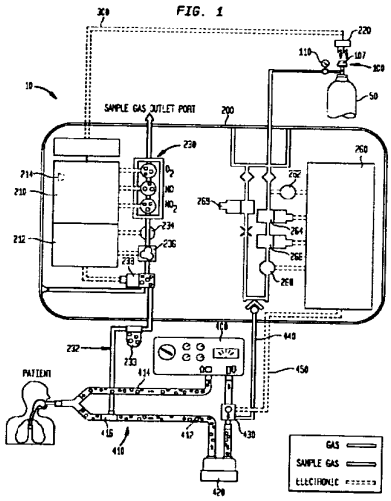
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG,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

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

Published:

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

(54) Title: GAS DELIVERY DEVICE AND SYSTEM



(57) Abstract: 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.

WO 2012/094008 A1

GAS DELIVERY DEVICE AND SYSTEM

TECHNICAL FIELD

[0001] 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

[0002] 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.

[0003] 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.

[0004] 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

[0005] 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. 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.

[0006] 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 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.

[0007] 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.

[0008] 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.

[0009] 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.

[0010] 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.

[0011] 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.

[0012] 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 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.

[0013] 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.

[0014] 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.

[0015] A fourth aspect of the present invention pertains to a method for administering a therapy gas to a patient. 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

[0016] 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;

[0017] Figure 2 illustrates a valve assembly of the gas delivery device according to one or more embodiments attached to a gas source;

[0018] Figure 3 illustrates a disassembled view of the valve assembly shown in Figure 2;

[0019] Figure 4 is a diagram showing a circuit supported in the valve assembly shown in Figure 2, according to one or more embodiments;

[0020] Figure 5 illustrates an exemplary gas source for use with the valve assembly shown in Figure 2;

[0021] 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

[0022] Figure 7 illustrates a front view of an exemplary gas delivery system;

[0023] Figure 8 illustrates a back view of the gas delivery system shown in Figure 7;

[0024] Figure 9 illustrates a partial side view of the gas delivery system shown in Figure 7;

[0025] Figure 10 illustrates a front view of a control module according to one or more embodiments;

[0026] Figure 11 illustrates a back view of the control module shown in Figure 10;

[0027] 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

[0028] 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

[0029] 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.

[0030] 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.

[0031] 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.

[0032] 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.

[0033] 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.

[0034] 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.

[0035] 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.

[0036] 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.

[0037] 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.

[0038] 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.

[0039] 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.

[0040] 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.

[0041] 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.

[0042] 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.

[0043] 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.

[0044] 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.

[0045] 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.

[0046] 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.

[0047] 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.

[0048] 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.

[0049] 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.

[0050] 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.

[0051] 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.

[0052] 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.

[0053] 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.

[0054] 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.

[0055] 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.

[0056] 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.

[0057] 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.

[0058] 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.

[0059] 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.

[0060] 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.

[0061] 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.

[0062] 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.

[0063] 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.

[0064] 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.

[0065] 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.

[0066] 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.

[0067] 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 from a gas source, the gas delivery device comprising:

a valve 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 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; 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 to a patient 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.

FIG. 1

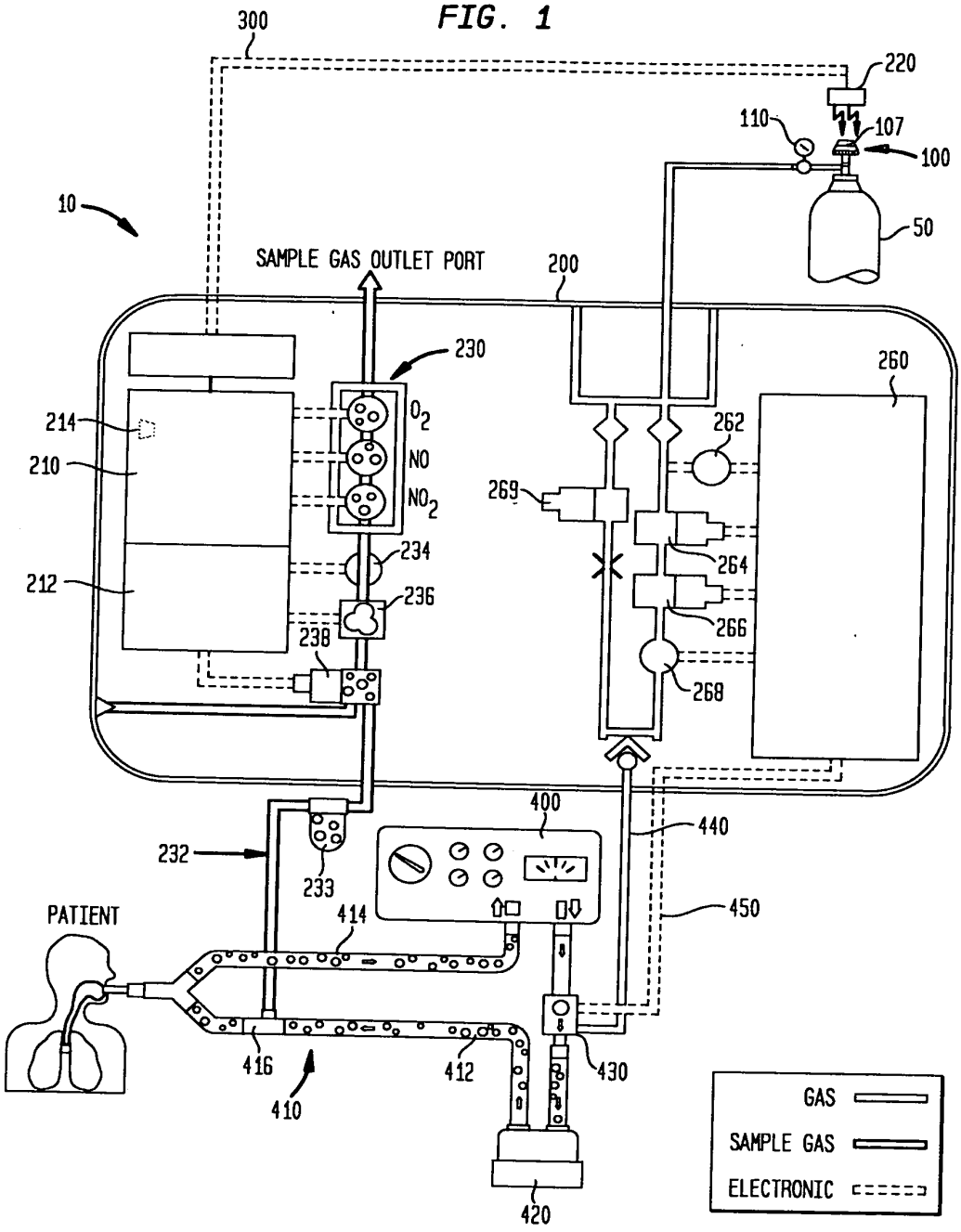

300
220
110
107
100
10
50
SAMPLE GAS OUTLET PORT
200
230
260
214
O_2
262
210
NO
269
NO_2
234
264
212
236
266
238
268
400
440
232
233
450
PATIENT
414
416
412
430
410
420
GAS
SAMPLE GAS
ELECTRONIC

FIG. 2

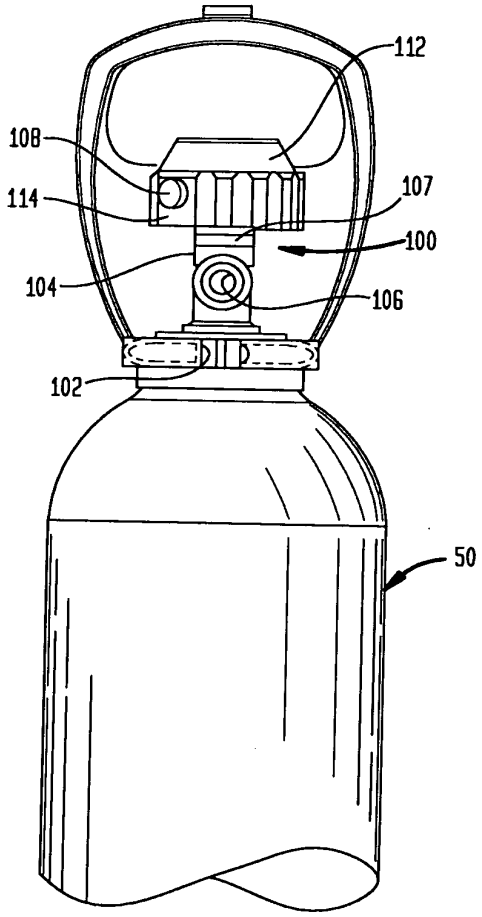


FIG. 3

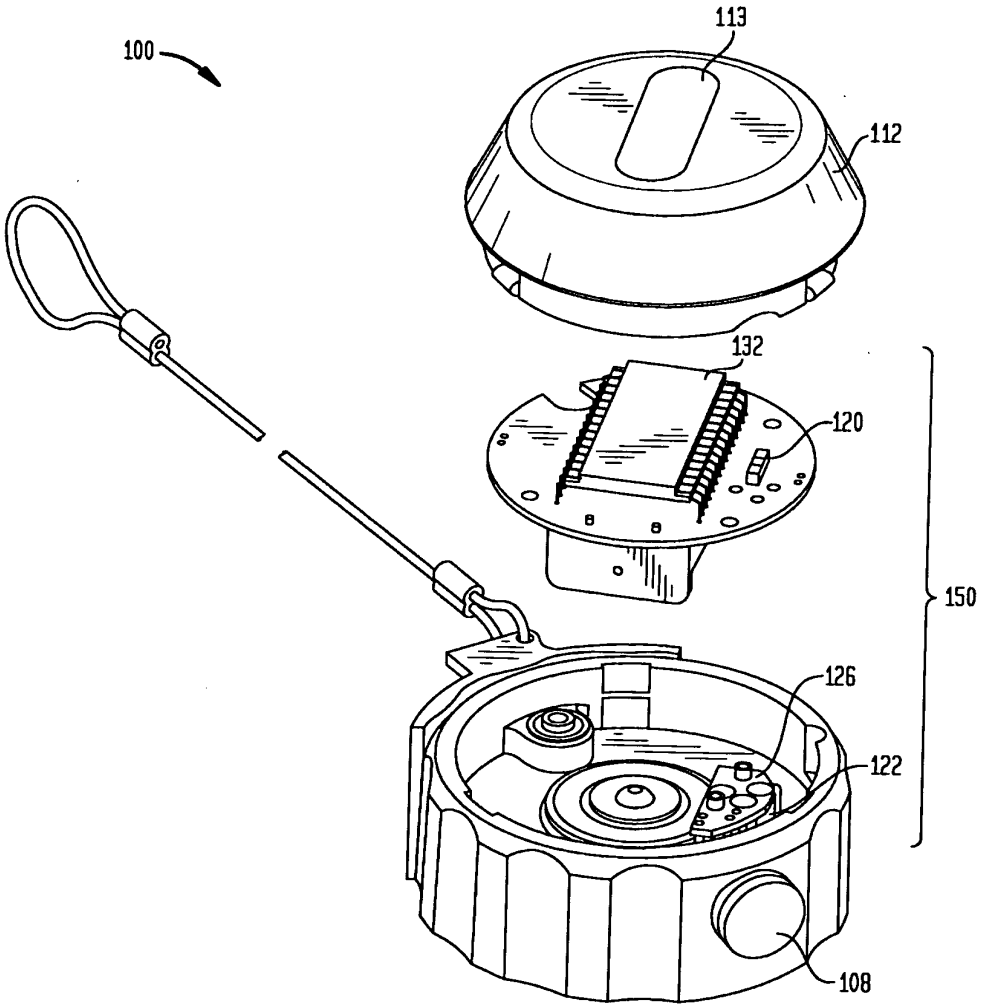


FIG. 4

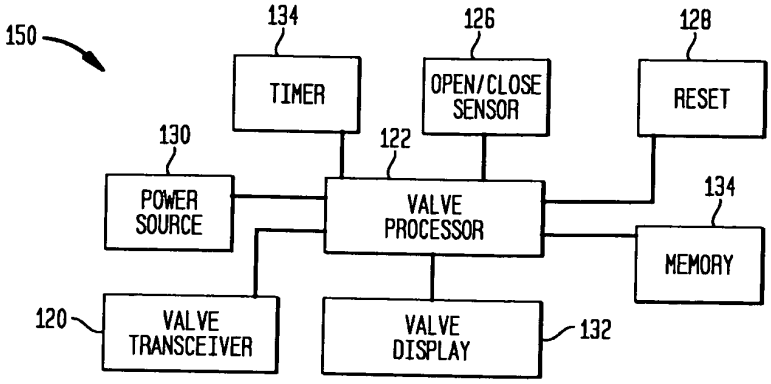

150
134
TIMER
126
OPEN/CLOSE SENSOR
128
RESET
130
POWER SOURCE
122
VALVE PROCESSOR
134
MEMORY
120
VALVE TRANSCEIVER
VALVE DISPLAY
132

FIG. 5

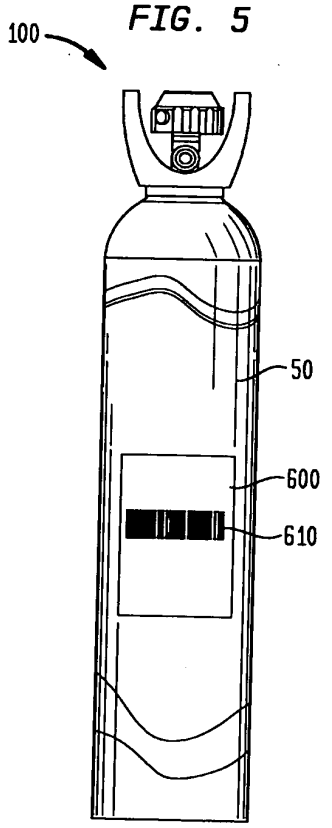

100
50
600
610

FIG. 6

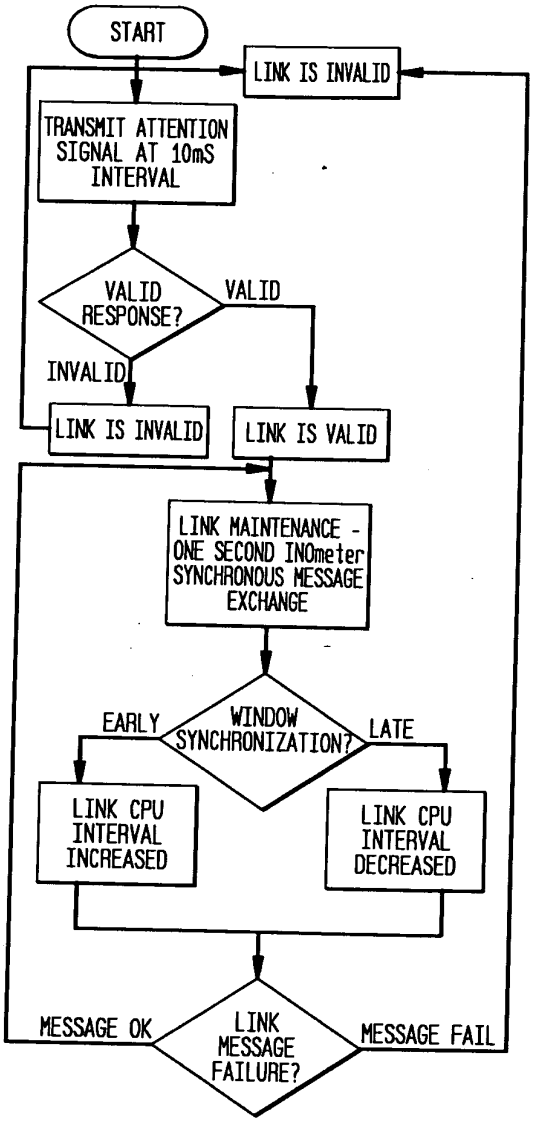

START
LINK IS INVALID
TRANSMIT ATTENTION SIGNAL AT 10mS INTERVAL
VALID RESPONSE?
VALID
INVALID
LINK IS INVALID
LINK IS VALID
LINK MAINTENANCE - ONE SECOND INOmeter SYNCHRONOUS MESSAGE EXCHANGE
WINDOW SYNCHRONIZATION?
EARLY
LATE
LINK CPU INTERVAL INCREASED
LINK CPU INTERVAL DECREASED
LINK MESSAGE FAILURE?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

FIG. 7

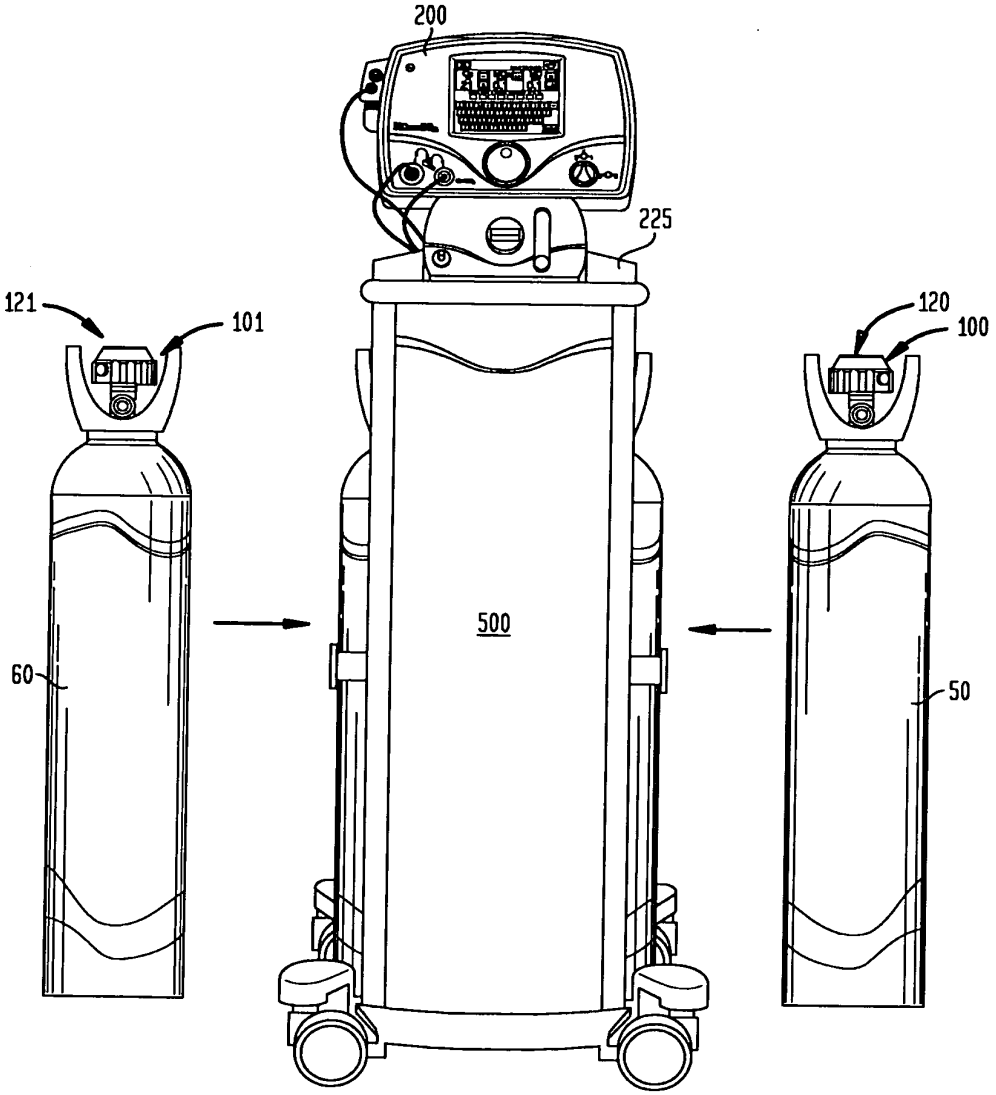


FIG. 8

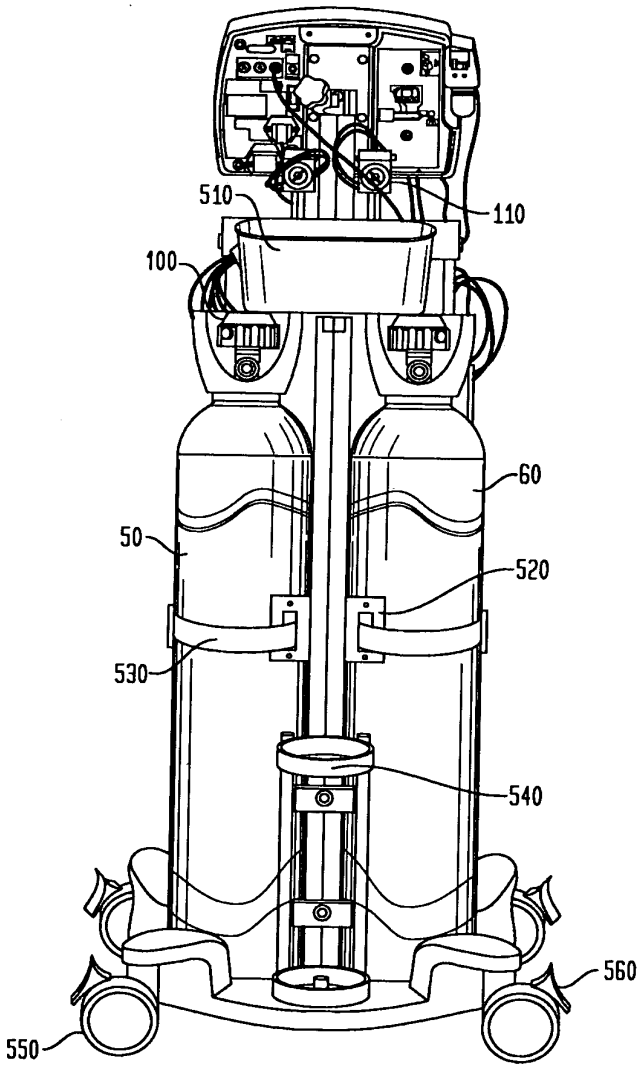


FIG. 9

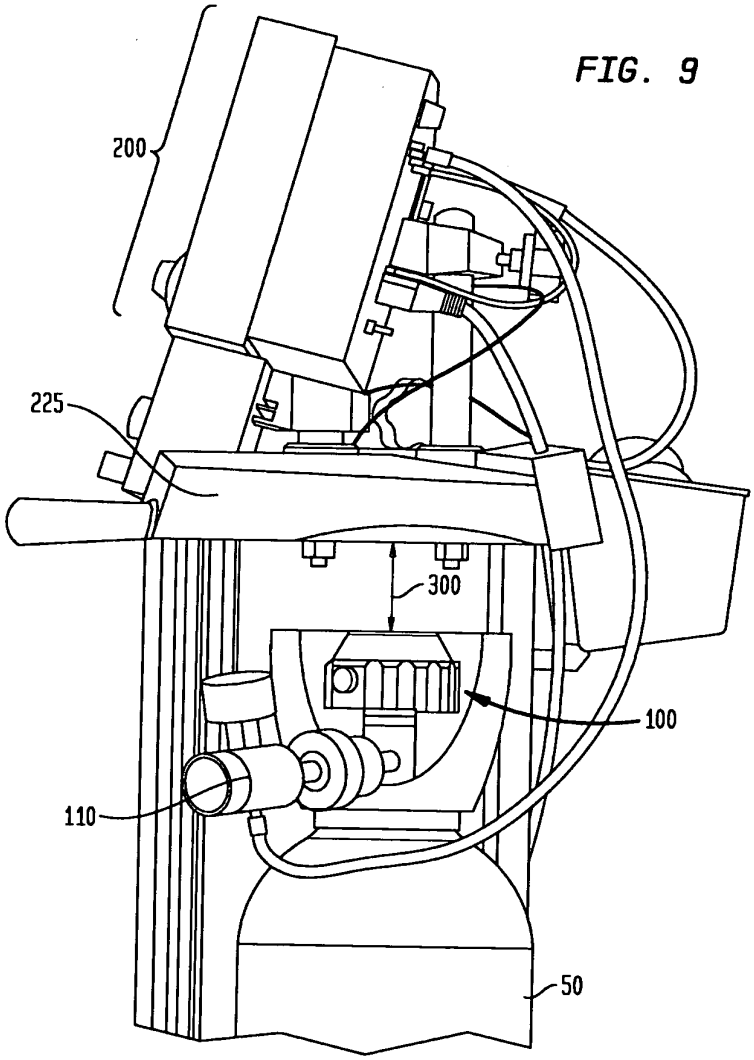


FIG. 10

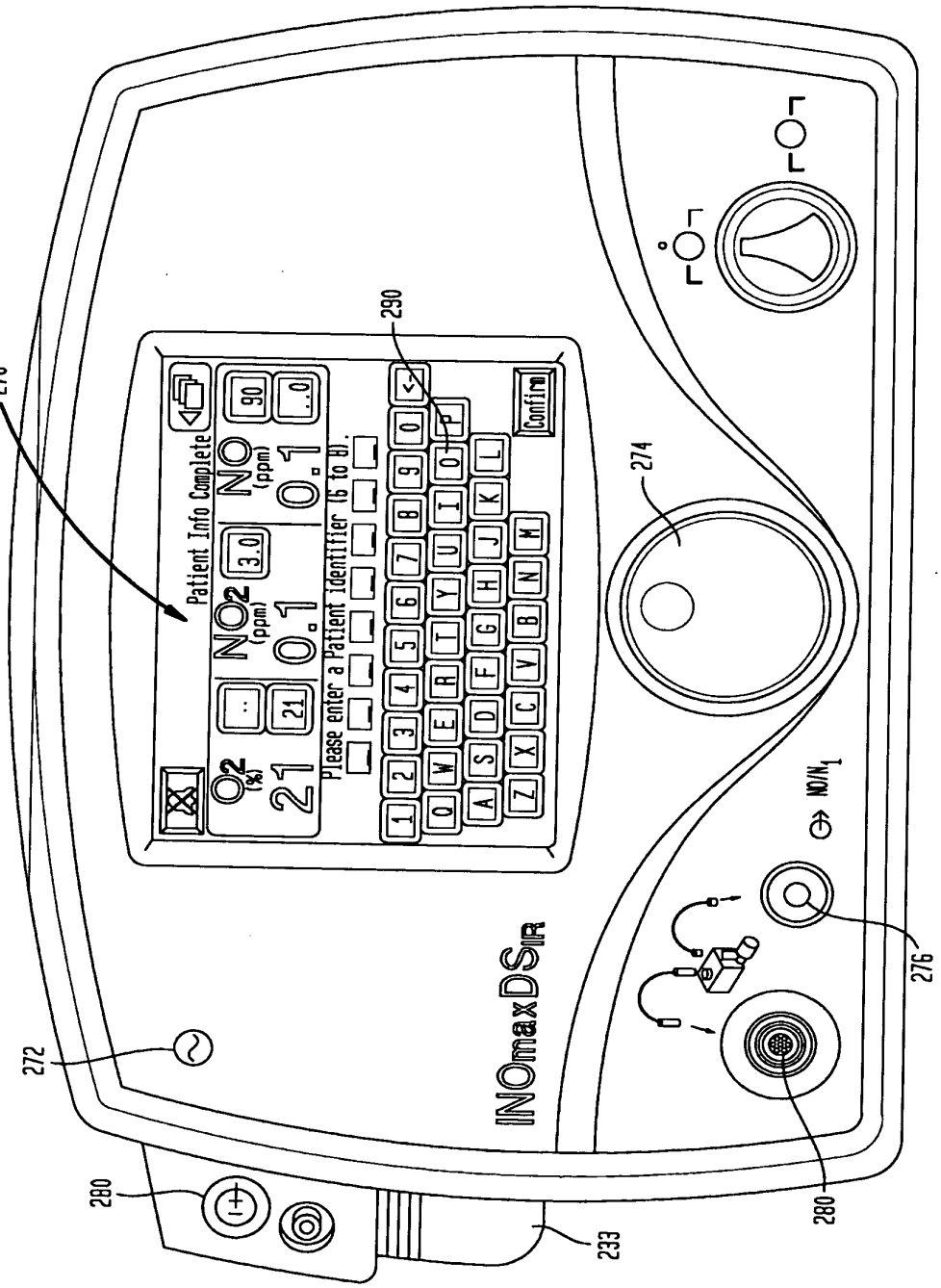

270
290
274
272
280
233
276
280
Patient Info Complete
NO (ppm)
0.1
NO2 (ppm)
0.1
O2 (%)
21
Please enter a Patient Identifier 16 to 0.
Confirm
INOmaxDSIR
NO/N1

FIG. 11

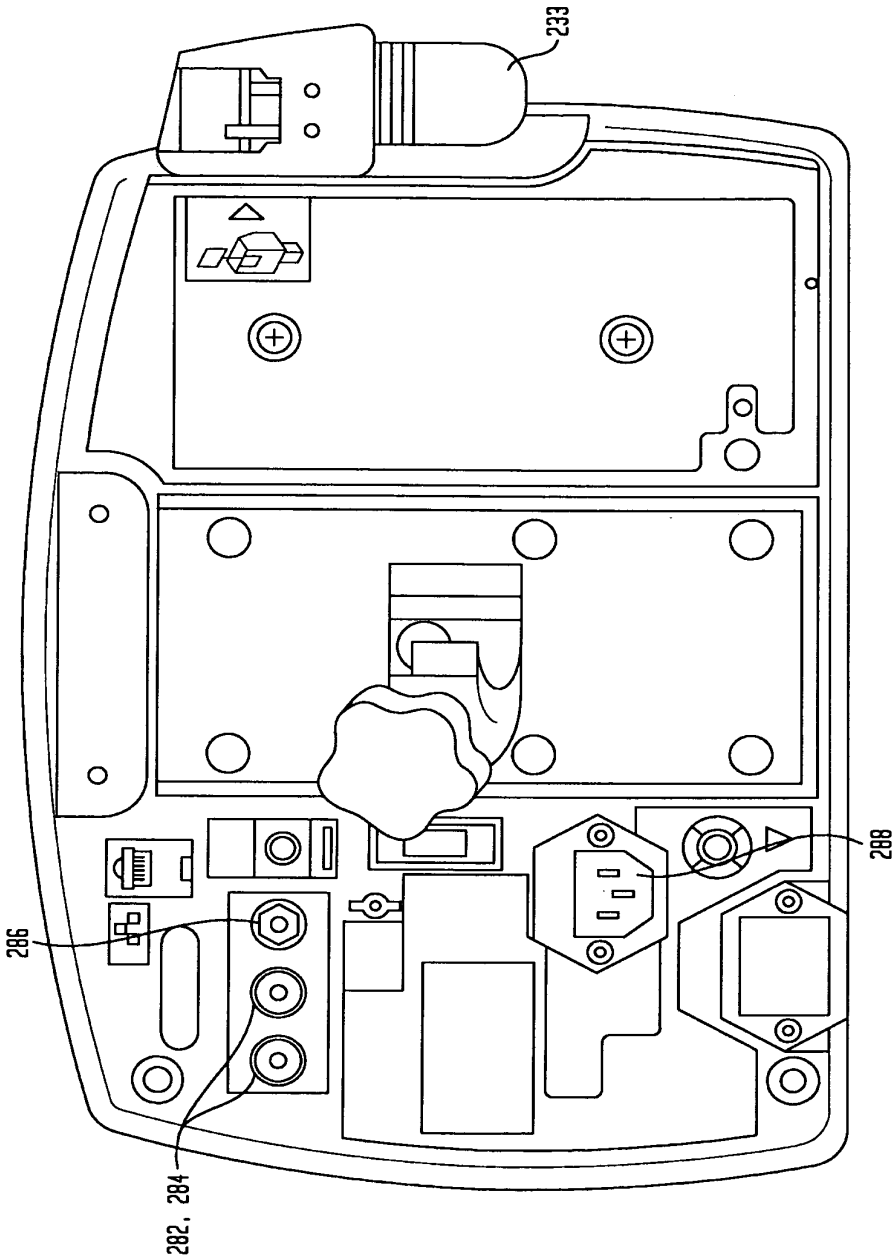


FIG. 12

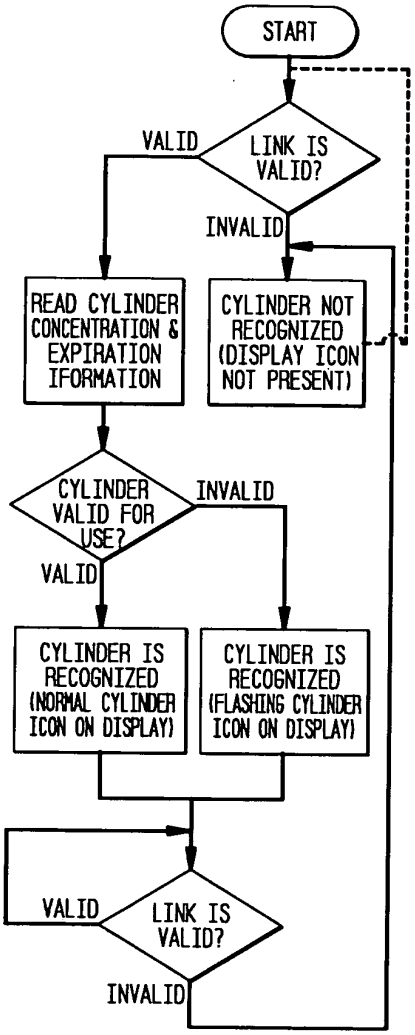
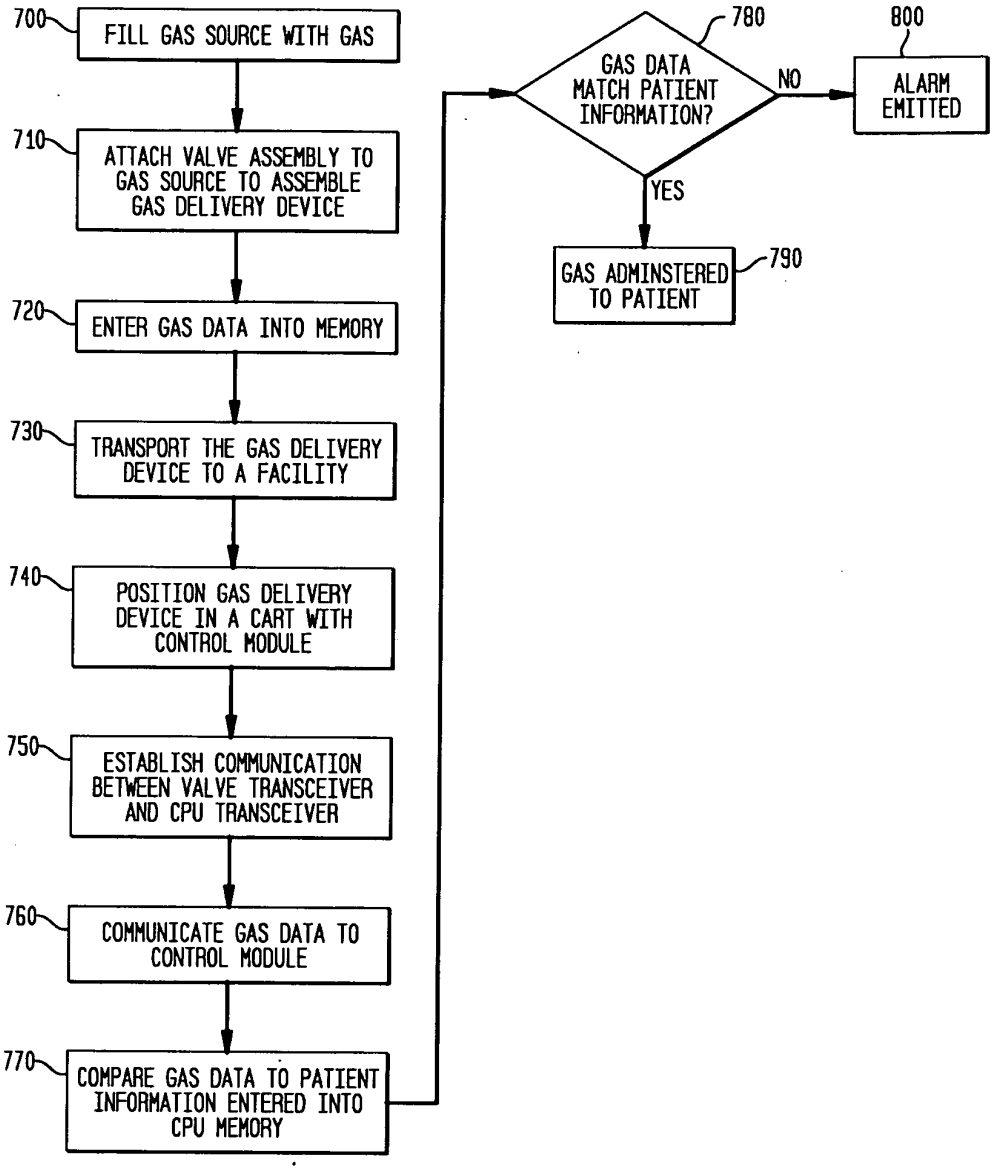

START
LINK IS VALID?
VALID
INVALID
READ CYLINDER CONCENTRATION & EXPIRATION IFORMATION
CYLINDER NOT RECOGNIZED (DISPLAY ICON NOT PRESENT)
CYLINDER VALID FOR USE?
INVALID
VALID
CYLINDER IS RECOGNIZED (NORMAL CYLINDER ICON ON DISPLAY)
CYLINDER IS RECOGNIZED (FLASHING CYLINDER ICON ON DISPLAY)
LINK IS VALID?
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
GAS ADMINSTERED TO PATIENT
790

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

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.

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: Fitchburg | State: WI | Country: US | Citizenship: 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

Electronic Patent Application Fee Transmittal

Application Number:	13509873
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-0026(IKA0011-00US

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Oath/decl > 30 mo. from priority date	2617	1	65	65
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**65**

Electronic Acknowledgement Receipt	
EFS ID:	12983394
Application Number:	13509873
International Application Number:	
Confirmation Number:	8620
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-0026(IKA0011-00US
Receipt Date:	11-JUN-2012
Filing Date:	
Time Stamp:	16:15:39
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$65
RAM confirmation Number	3215
Deposit Account	
Authorized User	

File Listing:

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

1	Oath or Declaration filed	00276815.PDF	1775772 7f1be1cadb08b2cc8dc49e081d2275c9fb900097	no	4
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30161 1321bec49b09003ede7f8da6ed4114f7d6dac43c	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1805933		

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Duncan P. Bathe	Examiner	Unknown
Serial No.:	13/509,873	Group Art Unit	Unknown
Filed:	January 6, 2011	Docket No.:	3000-US-0026 (IKA0011-00US)
		Confirmation No.:	8620

Title: Gas Delivery Device And System

PRELIMINARY AMENDMENT

Prior to examination of the captioned application, please enter the following amendments and consider the attached remarks.

IN THE CLAIMS

Please amend the claims as follows:

1. (Canceled)

2. (Currently amended) ~~The device of claim 1~~A gas delivery device to administer therapy gas from a gas source, the gas delivery device comprising:

a valve 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 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,

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. (Original) 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. (Currently amended) ~~The device of claim 1~~A gas delivery device to administer therapy gas from a gas source, the gas delivery device comprising:

a valve 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 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,

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

6. (Canceled)

7. (Currently amended) ~~The system of claim 6~~A gas delivery system comprising:

a gas delivery device to administer therapy gas from a gas source, the gas delivery device comprising:

a valve 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 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; and

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

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, and

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. (Canceled)

9. (Currently amended) ~~The system of claim 8~~A gas delivery system comprising:

a gas delivery device to administer therapy gas from a gas source, the gas delivery device comprising:

a valve 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 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; and

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

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,

wherein the control module further comprises an input means to enter patient information into the CPU memory; and a display, and

wherein the CPU compares the patient information entered into the CPU memory via the input means and the gas data from the transceiver.

10. (Original) 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. - 18. (Canceled)

REMARKS

Prior to examination of this application, please enter the foregoing amendments to the claims. Claims 1, 6, 8 and 11-18 are canceled without prejudice. Claims 2, 4, 7 and 9 have been rewritten in independent form. After entry of this amendment, claims 2-5, 7 and 9-10 are presented for further examination.

No new matter has been added by this amendment.

It is believed that no fees are due with this submission. If any fees are due at this time, the Commissioner is authorized to charge Deposit Account No. 50-3329.

Respectfully submitted,

Dated: June 12, 2012

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

Rory P. Alegria
Reg. No. 66,947
Diehl Servilla LLC
33 Wood Ave S
Second Floor, Suite 210
Iselin, NJ 08830

Telephone: (732) 815-0404
Attorney for Applicant

Electronic Acknowledgement Receipt	
EFS ID:	12993385
Application Number:	13509873
International Application Number:	
Confirmation Number:	8620
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-0026(IKA0011-00US
Receipt Date:	12-JUN-2012
Filing Date:	
Time Stamp:	15:24:30
Application Type:	U.S. National Stage under 35 USC 371

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	Petition to make Special under PCT-Patent Pros Hwy	00277147.PDF	101573 4ef20643d743d0a6ba51abbc86b24b58a95b5ed0	no	2
Warnings:					
Information:					

2		00277149.PDF	32806 ac12acda87893f24562b6c0a72741d3f312194fc	yes	6

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	6

Warnings:	
Information:	
Total Files Size (in bytes):	134379

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/20PCT-EP (05-10)
Approved for use through 01/31/2015. OMB 0651-0058
U.S. Patent and Trademark Office; U.S DEPARTMENT OF COMMERCE

REQUEST FOR PARTICIPATION IN THE PATENT COOPERATION TREATY – PATENT PROSECUTION HIGHWAY (PCT-PPH) PILOT PROGRAM BETWEEN THE EUROPEAN PATENT OFFICE (EPO) AND THE USPTO

Application No.:	13/509,873	First Named Inventor:	Duncan P. Bathe
Filing Date:	05-15-2012	Attorney Docket No.:	3000-US-0026 (IKA0011-00US)
Title of the Invention:	Gas Delivery Device And System		

THIS REQUEST FOR PARTICIPATION IN THE PCT-PPH PILOT PROGRAM ALONG WITH THE REQUIRED DOCUMENTS MUST BE SUBMITTED VIA EFS-WEB. INFORMATION REGARDING EFS-WEB IS AVAILABLE AT HTTP://WWW.USPTO.GOV/EBC/EFS_HELP.HTML.

APPLICANT HEREBY REQUESTS PARTICIPATION IN THE PCT-PPH PILOT PROGRAM AND PETITIONS TO MAKE THE ABOVE-IDENTIFIED APPLICATION SPECIAL UNDER THE PCT-PPH PILOT PROGRAM.

The above-identified application is (1) a national stage entry of the corresponding PCT application, or (2) a national stage entry of another PCT application which claims priority to the corresponding PCT application, or (3) a national application that claims domestic/ foreign priority to the corresponding PCT application, or (4) a national application which forms the basis for the priority claim in the corresponding PCT application, or (5) a continuing application of a U.S. application that satisfies one of (1) to (4) above, or (6) a U.S. application that claims domestic benefit to a U.S. provisional application which forms the basis for the priority claim in the corresponding PCT application.

The corresponding PCT application number(s) is/are: PCT/US2011/020319

The international filing date of the corresponding PCT application(s) is/are: 01-06-2011

I. List of Required Documents:

a. **A copy of the latest international work product (WO/ISA, WO/IPEA, or IPER) in the above-identified corresponding PCT application(s)**

☐ is attached.

☑ is not attached because the document is already in the U.S. application.

b. **A copy of all claims which were indicated as having novelty, inventive step and industrial applicability in the above-identified corresponding PCT application(s)**

☐ is attached.

☑ is not attached because the document is already in the U.S. application.

c. **English translations of the documents in a. and b. above are attached (if the documents are not in the English language). A statement that the English translation is accurate is attached for the document in b. above.**

d. **(1) An information disclosure statement listing the documents cited in the international work products (ISR, WO/ISA, WO/IPEA, IPER) of the corresponding PCT application.**

☐ is attached.

☑ has already been filed in the above-identified U.S. application on 05-15-2012

(2) Copies of all documents (except for U.S. patents or U.S. patent application publications)

☐ are attached.

☑ have already been filed in the above-identified U.S. application on 05-15-2012

REQUEST FOR PARTICIPATION IN THE PCT-PPH PILOT PROGRAM BETWEEN THE EPO AND THE USPTO
(continued)

Application No.:	13/509,873	First Named Inventor:	Duncan P. Bathe

II. Claims Correspondence Table:

Claims in US Application	Patentable Claims in the corresponding PCT application	Explanation regarding the correspondence
2	2	Claims are the same; claim 2 in US application rewritten in independent form
3	3	Claims are the same
4	4	Claims are the same; claim 4 in US application rewritten in independent form
5	5	Claims are the same
7	7	Claims are the same; claim 7 in US application rewritten in independent form
9	9	Claims are the same; claim 9 in US application rewritten in independent form
10	10	Claims are the same

III. All the claims in the US application sufficiently correspond to the patentable claims in the corresponding PCT application.

Signature /Rory P. Alegria, Reg. No 66,947/	Date 06/12/12
Name (Print/Typed) Rory P. Alegria	Registration Number 66,947

Electronic Patent Application Fee Transmittal	
Application Number:	13509873
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-0026(IKA0011-00US
Filed as Small Entity	

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Independent claims in excess of 3	2614	1	125	125
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**125**

Electronic Acknowledgement Receipt	
EFS ID:	12993601
Application Number:	13509873
International Application Number:	
Confirmation Number:	8620
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-0026(IKA0011-00US
Receipt Date:	12-JUN-2012
Filing Date:	
Time Stamp:	15:32:03
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$125
RAM confirmation Number	2463
Deposit Account	
Authorized User	

File Listing:

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

1	Fee Worksheet (SB06)	fee-info.pdf	30148 dc3caf3e63574d4cbbdebffb333a2bd0102e3dcb	no	2

Warnings:	
Information:	
Total Files Size (in bytes):	30148

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Duncan P. Bathe et al.	Examiner:	Unknown
Serial No.:	13/509,873	Group Art Unit:	Not Yet Assigned
Filed:	January 6, 2011	Docket:	3000-US-0026 (IKA0011-00US)
Conf. No.:	8620		
Title:	Gas Delivery Device And System		

SECOND SUBMISSION OF ITEMS CONCERNING A SUBMISSION UNDER 35 U.S.C. § 371

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

Please see the attached transmittal letter for a second submission of items concerning a submission under 35 U.S.C. § 371. A first submission was previously filed on May 15, 2012, but Box 3 was inadvertently not checked to indicate an express request to begin national examination procedures under 35 U.S.C. § 371(f). Please treat this second submission as an express request to begin U.S. national examination procedures under 35 U.S.C. § 371(f).

Please note that the inventors' declaration was previously submitted on June 11, 2012 and the basic national fee, examination fee and search fee were paid on May 15, 2012. A preliminary amendment and a petition to make special under the PCT-Patent Prosecution Highway Program were filed on June 12, 2012.

It is believed that no fees are due with this submission. If any fees are due at this time, the Commissioner is authorized to charge Deposit Account No. 50-3329.

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

PTO-1390 (09-11)
Approved for use through 4/30/2013. OMB 0651-0021
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	U.S. APPLICATION NO. (If known, see 37 CFR 1.5)
3000-US-0026 (IKA0011-00US)	13/509,873

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US11/20319	January 6, 2011	January 6, 2011

TITLE OF INVENTION
Gas Delivery Device And System

APPLICANT(S) FOR DO/EO/US
Duncan P. Bathe, John Klaus, David Christensen

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☑ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☑ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☑ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is attached hereto (required only if not communicated by the International Bureau).
   b. ☐ has been communicated by the International Bureau.
   c. ☑ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☐ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☑ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☑ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☑ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☑ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A preliminary amendment.
14. ☑ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13*ter*.3 and 37 CFR 1.821- 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).

PTO-1390 (09-11)
Approved for use through 4/30/2013. OMB 0651-0021
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.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
13/509,873	PCT/US11/20319	3000-US-0026 (IKA0011-00US)

20. Other items or information:
Please note that the Basic National Fee, Examination Fee and Search Fee were previously submitted with the first submission on May 15, 2012.

The following fees have been submitted	CALCULATIONS	PTO USE ONLY
21. ☑ Basic national fee (37 CFR 1.492(a))..... **$380**	$ 380.00	
22. ☑ Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... **$0** All other situations..... **$250**	$250.00	
23. ☑ Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)..... **$0** Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... **$120** International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB..... **$490** All other situations..... **$620**	$ 620.00	
TOTAL OF 21, 22 and 23 =		
☐ Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) in an electronic medium or computer program listing in an electronic medium) (37 CFR 1.492(j)). The fee is **$310** for each additional 50 sheets of paper or fraction thereof.		

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round **up** to a whole number)	RATE	
- 100 =	/50 =		x $**310**	$

Surcharge of **$130.00** for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).	$	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	$	
Total claims	18 - 20 =	0	x $ **60**	$0	
Independent claims	3 - 3 =	0	x **$250**	$0	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$450**	$	
			TOTAL OF ABOVE CALCULATIONS =	$1250.00	
☑ Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by ½.				625.00	
			SUBTOTAL =	$	
Processing fee of **$130.00** for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)). +				$	
			TOTAL NATIONAL FEE =	$ 625.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$	
			TOTAL FEES ENCLOSED =	$ 625.00	
			Amount to be refunded:	$ 0	
			Amount to be charged	$625.00	

a. ☐ A check in the amount of $ _____ to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $ _____ to cover the above fees.

c. ☑ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-3329.

d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038. The PTO-2038 should only be mailed or faxed to the USPTO. However, when paying the basic national fee, the PTO-2038 may NOT be faxed to the USPTO.

ADVISORY: If filing by EFS-Web, do **NOT** attach the PTO-2038 form as a PDF along with your EFS-Web submission. Please be advised that this is **not** recommended and by doing so your **credit card information may be displayed via PAIR**. To protect your information, it is recommended paying fees online by using the electronic payment method.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Diehl Servilla LLC
33 Wood Avenue South
Second Floor, Suite 210
Iselin, New Jersey 08830
USA

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

Rory P. Alegria
NAME

66,947
REGISTRATION NUMBER

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.

Electronic Acknowledgement Receipt	
EFS ID:	13438979
Application Number:	13509873
International Application Number:	
Confirmation Number:	8620
Title of Invention:	Gas Delivery Device And System
First Named Inventor/Applicant Name:	Duncan P. Bathe
Customer Number:	48394
Filer:	Rory P. Alegria/Jessica Escobar
Filer Authorized By:	Rory P. Alegria
Attorney Docket Number:	3000-US-0026(IKA0011-00US
Receipt Date:	07-AUG-2012
Filing Date:	
Time Stamp:	16:25:03
Application Type:	U.S. National Stage under 35 USC 371

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	Miscellaneous Incoming Letter	00289316.PDF	17015 5da0d5e925e62997537087d25cefbabe3f37596a	no	1
Warnings:					
Information:					

2	Documents submitted with 371 Applications	00289278.PDF	249060 96d8272dda91b799376e8e577ea3822829dc40fc	no	4

Warnings:	
Information:	
Total Files Size (in bytes):	266075

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.

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

1

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

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.

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

---

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	

Form PCT/ISA/210 (patent family annex) (April 2005)

13508873

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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 July 2012 (12.07.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/094008 A1

(51) International Patent Classification:
A61M 16/10 (2006.01) *A61M 16/20* (2006.01)

(21) International Application Number:
PCT/US2011/020319

(22) International Filing Date:
6 January 2011 (06.01.2011)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicant *(for all designated States except US)*: **IKARIA, INC.** [US/US]; 6 Route 173, Clinton, New Jersey 08809 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BATHE, Duncan P.** [GB/US]; 5699 Nutone Street, Fitchburg, Wisconsin 53711 (US). **KLAUS, John** [US/US]; 2730 Gaston Road, Cottage Grove, Wisconsin 53527 (US). **CHRISTENSEN, David** [US/US]; N4398 Wolff Road, Cambridge, Wisconsin 53523 (US).

(74) Agent: **PATEL, Payal A.**; Diehl Servilla LLC, 33 Wood Avenue South, Second Floor, Suite 210, Iselin, New Jersey 08830 (US).

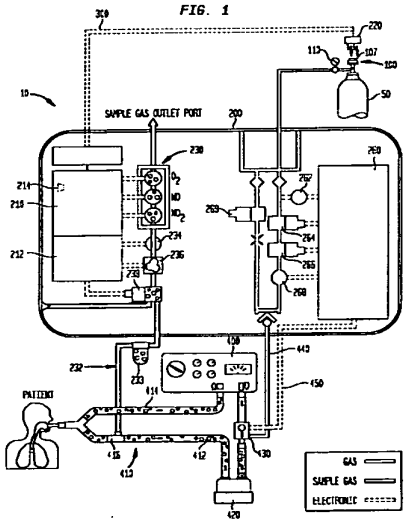
(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG,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

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

Published:

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

(54) **Title**: GAS DELIVERY DEVICE AND SYSTEM



(57) **Abstract**: 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.

WO 2012/094008 A1

GAS DELIVERY DEVICE AND SYSTEM

TECHNICAL FIELD

[0001] 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

[0002] 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.

[0003] 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.

[0004] 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

[0005] 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. 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.

[0006] 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 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.

[0007] 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.

[0008] 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.

[0009] 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.

[0010] 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.

[0011] 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.

[0012] 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 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.

[0013] 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.

[0014] 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.

[0015] A fourth aspect of the present invention pertains to a method for administering a therapy gas to a patient. 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

[0016] 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;

[0017] Figure 2 illustrates a valve assembly of the gas delivery device according to one or more embodiments attached to a gas source;

[0018] Figure 3 illustrates a disassembled view of the valve assembly shown in Figure 2;

[0019] Figure 4 is a diagram showing a circuit supported in the valve assembly shown in Figure 2, according to one or more embodiments;

[0020] Figure 5 illustrates an exemplary gas source for use with the valve assembly shown in Figure 2;

[0021] 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

[0022] Figure 7 illustrates a front view of an exemplary gas delivery system;

[0023] Figure 8 illustrates a back view of the gas delivery system shown in Figure 7;

[0024] Figure 9 illustrates a partial side view of the gas delivery system shown in Figure 7;

[0025] Figure 10 illustrates a front view of a control module according to one or more embodiments;

[0026] Figure 11 illustrates a back view of the control module shown in Figure 10;

[0027] 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

[0028] 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

[0029] 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.

[0030] 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.

[0031] 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.

[0032] 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.

[0033] 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.

[0034] 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.

[0035] 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.

[0036] 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.

[0037] 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.

[0038] 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.

[0039] 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.

[0040] 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.

[0041] 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.

[0042] 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.

[0043] 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.

[0044] 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.

[0045] 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.

[0046] 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.

[0047] 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.

[0048] 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.

[0049] 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.

[0050] 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.

[0051] 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.

[0052] 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.

[0053] 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.

[0054] 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.

[0055] 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.

[0056] 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.

[0057] 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.

[0058] 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.

[0059] 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.

[0060] 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.

[0061] 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.

[0062] 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.

[0063] 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.

[0064] 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.

[0065] 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.

[0066] 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.

[0067] 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 from a gas source, the gas delivery device comprising:

a valve 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 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; 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 to a patient 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.

FIG. 1

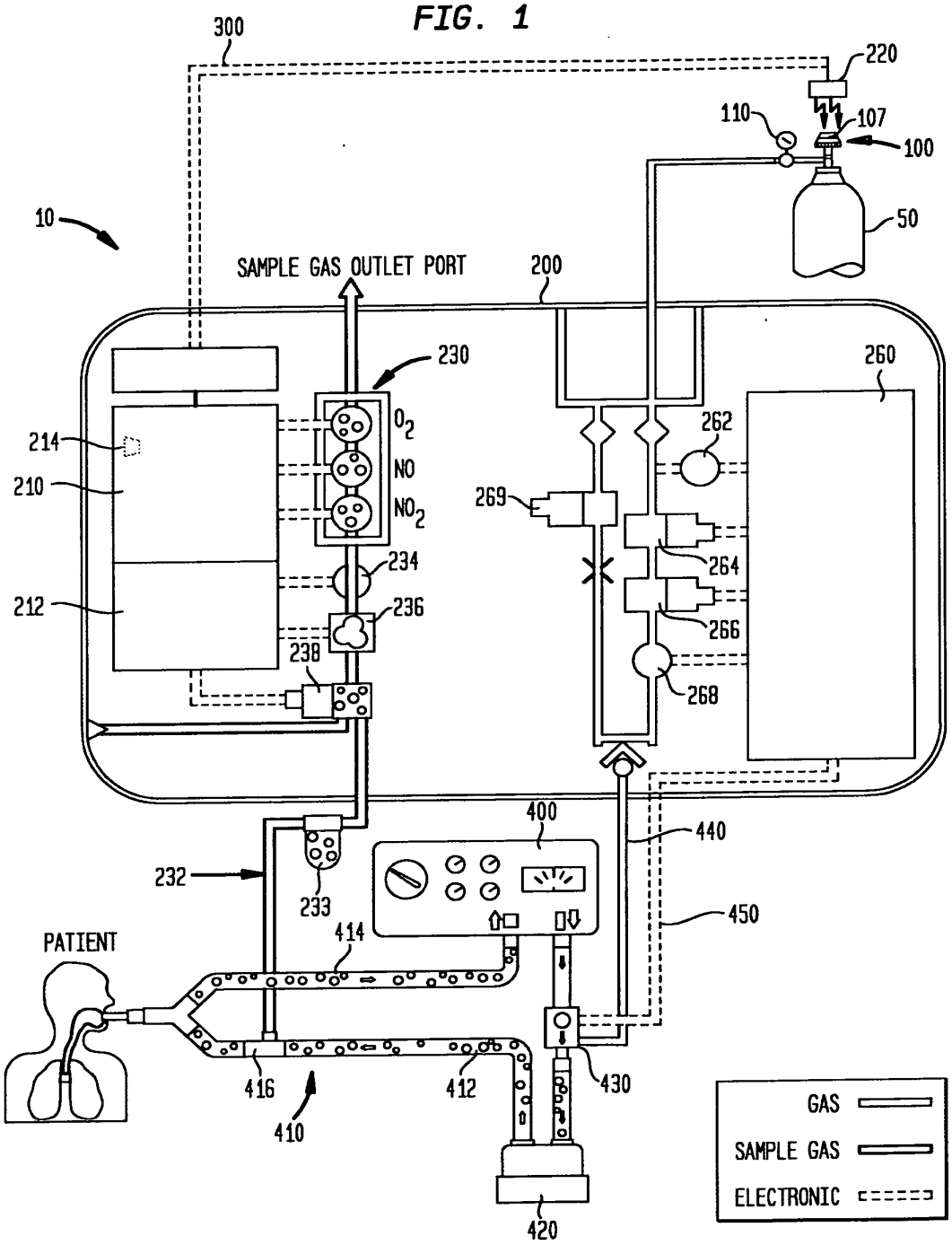

300
220
110
107
100
10
50
SAMPLE GAS OUTLET PORT
200
230
260
214
210
212
O_2
NO
NO_2
234
236
238
262
269
264
266
268
400
440
232
233
450
PATIENT
414
416
412
410
430
420
GAS
SAMPLE GAS
ELECTRONIC

FIG. 2

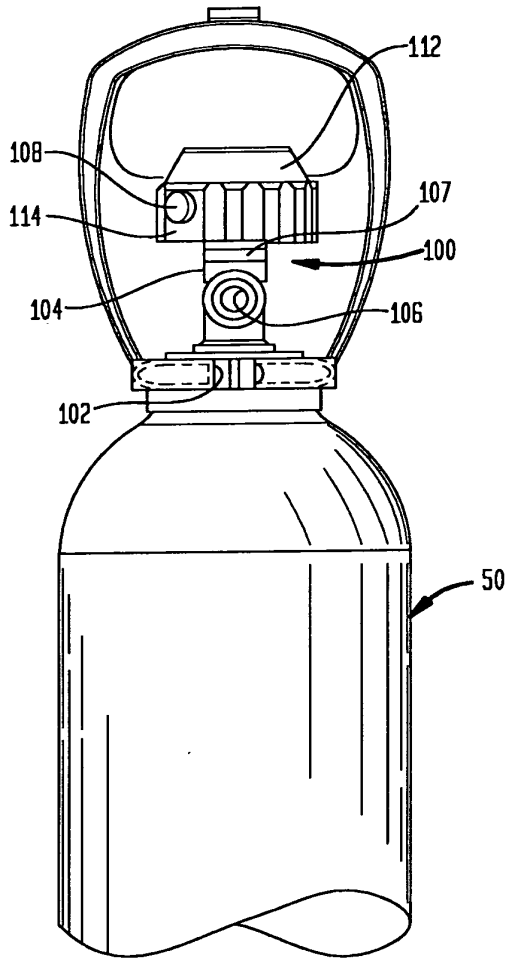


FIG. 3

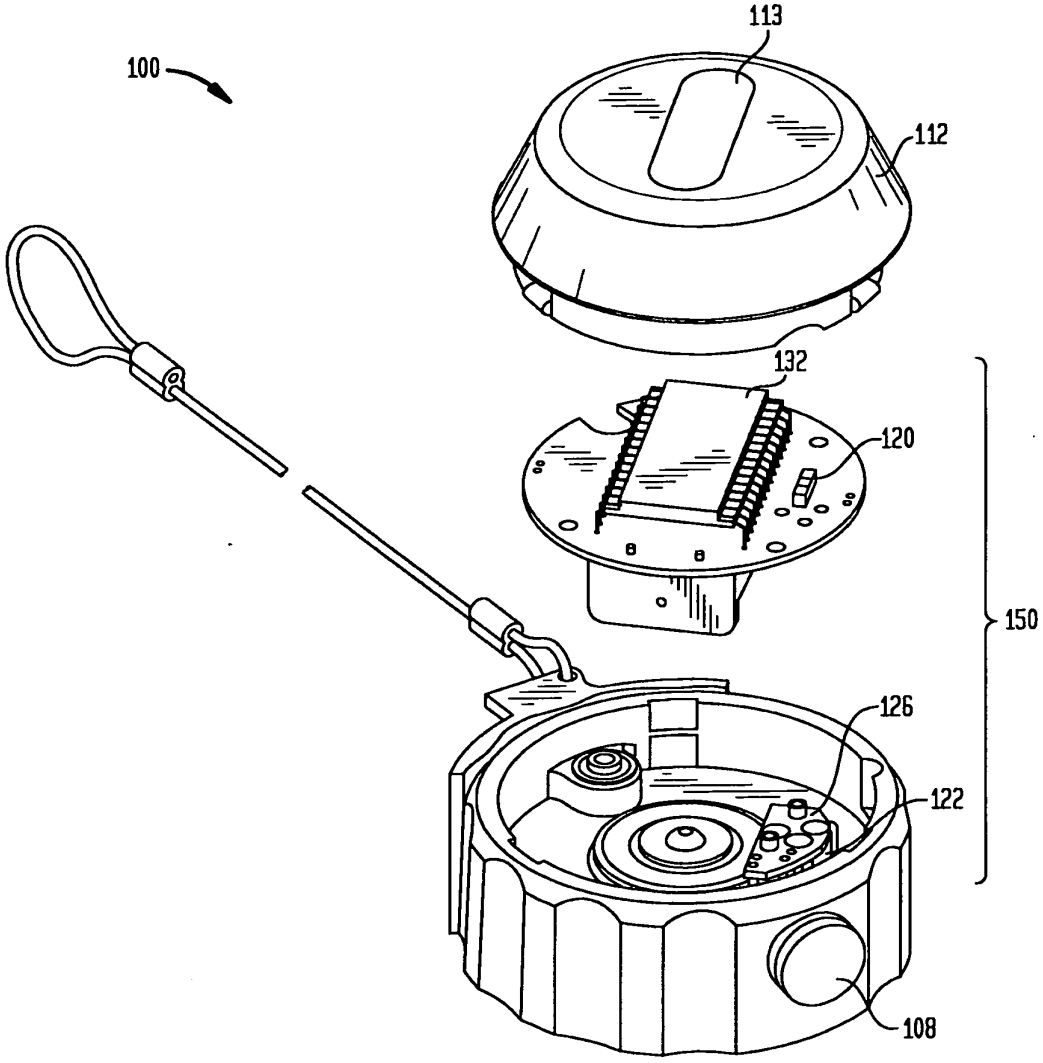


FIG. 4

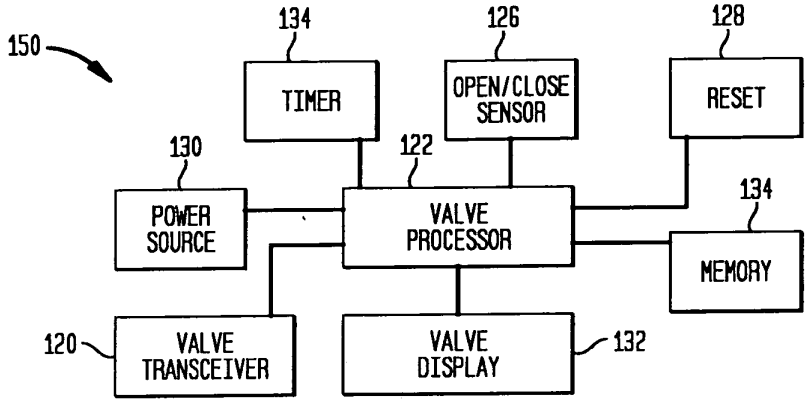

150
134
TIMER
126
OPEN/CLOSE SENSOR
128
RESET
130
POWER SOURCE
122
VALVE PROCESSOR
134
MEMORY
120
VALVE TRANSCEIVER
VALVE DISPLAY
132

FIG. 5

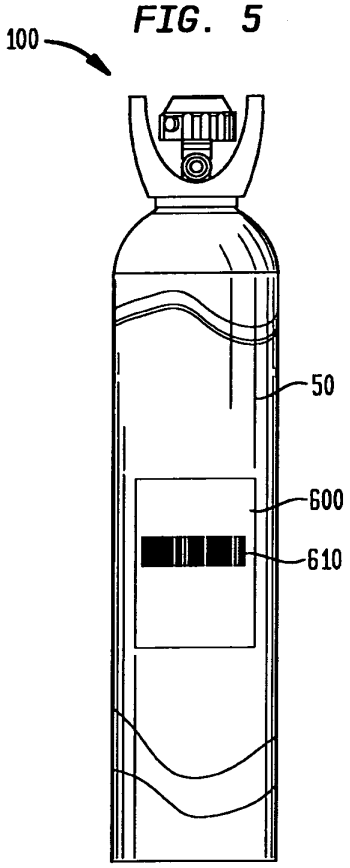

100
50
600
610

FIG. 6

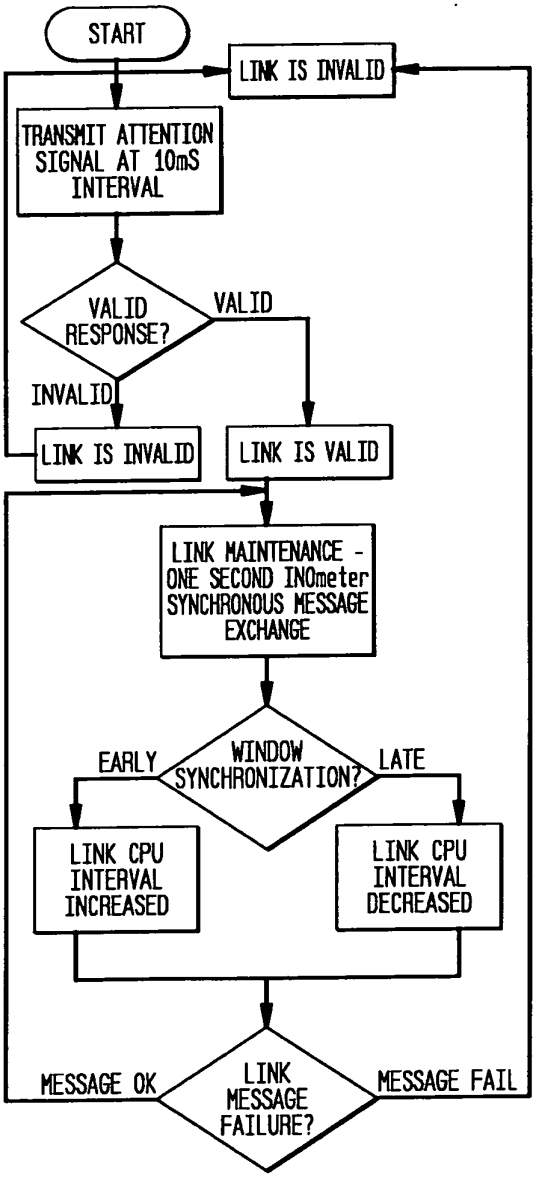

START
LINK IS INVALID
TRANSMIT ATTENTION SIGNAL AT 10mS INTERVAL
VALID RESPONSE?
VALID
INVALID
LINK IS INVALID
LINK IS VALID
LINK MAINTENANCE - ONE SECOND INOmeter SYNCHRONOUS MESSAGE EXCHANGE
WINDOW SYNCHRONIZATION?
EARLY
LATE
LINK CPU INTERVAL INCREASED
LINK CPU INTERVAL DECREASED
LINK MESSAGE FAILURE?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

FIG. 7

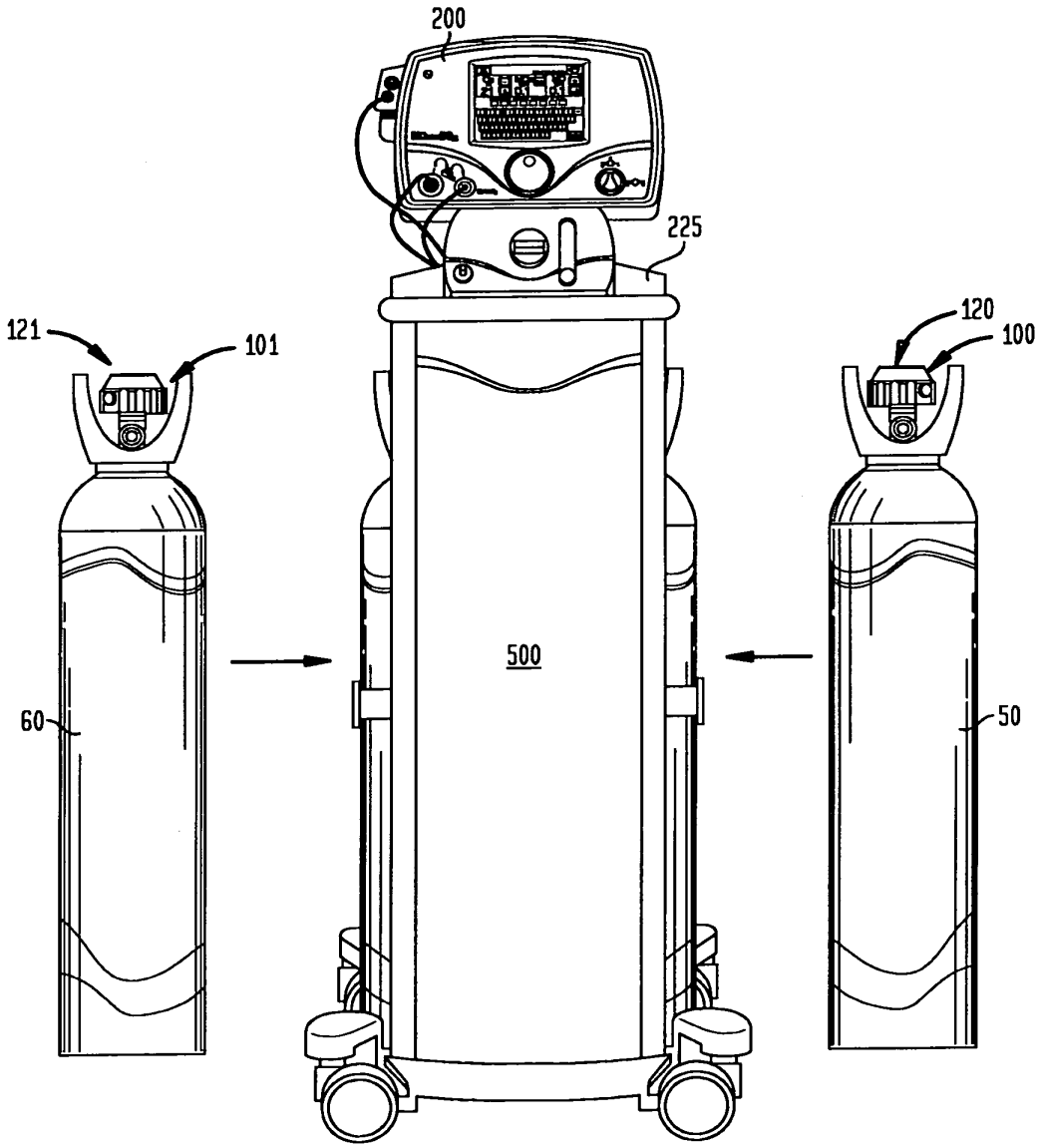


FIG. 8

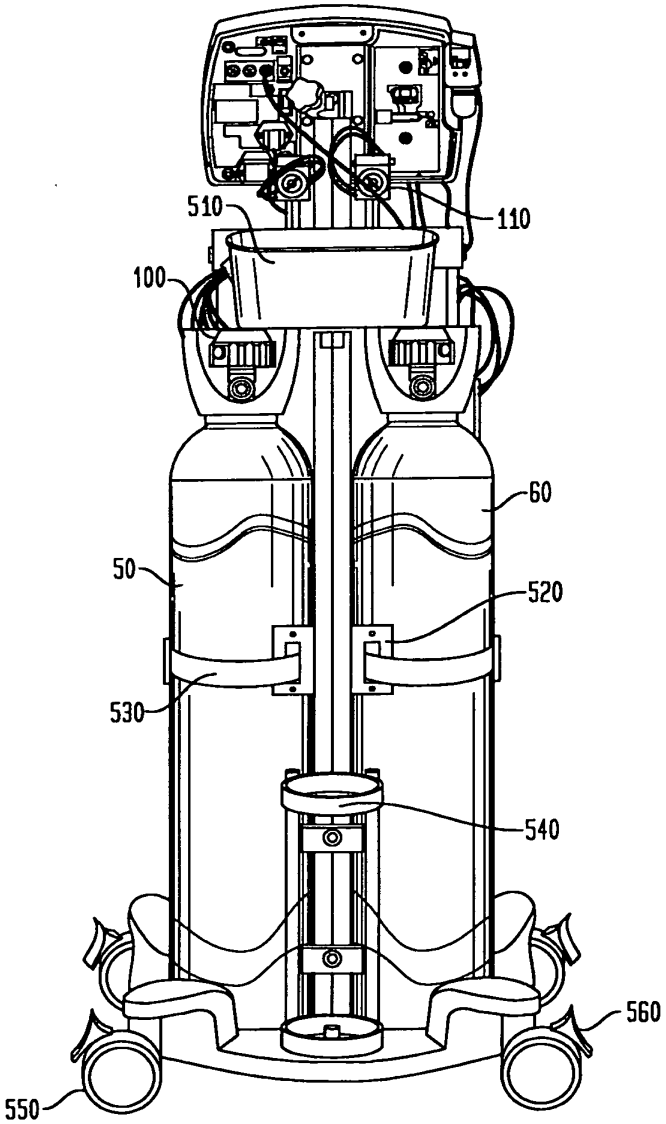


FIG. 9

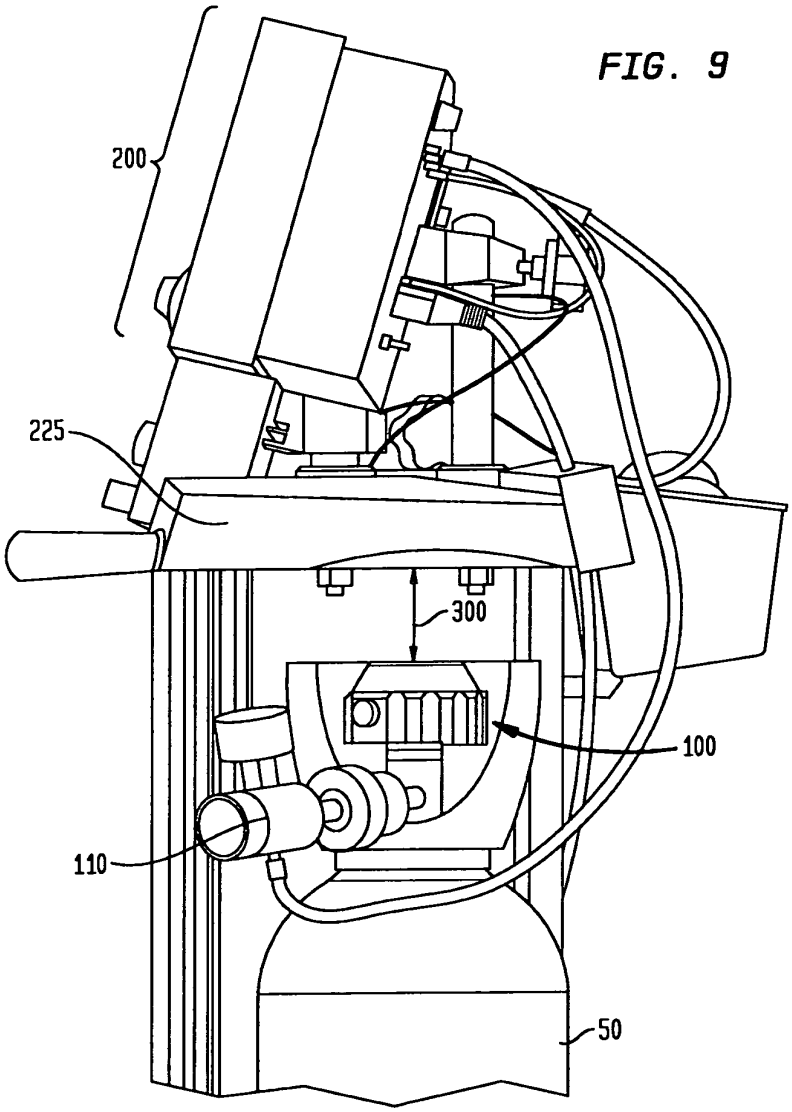


FIG. 10

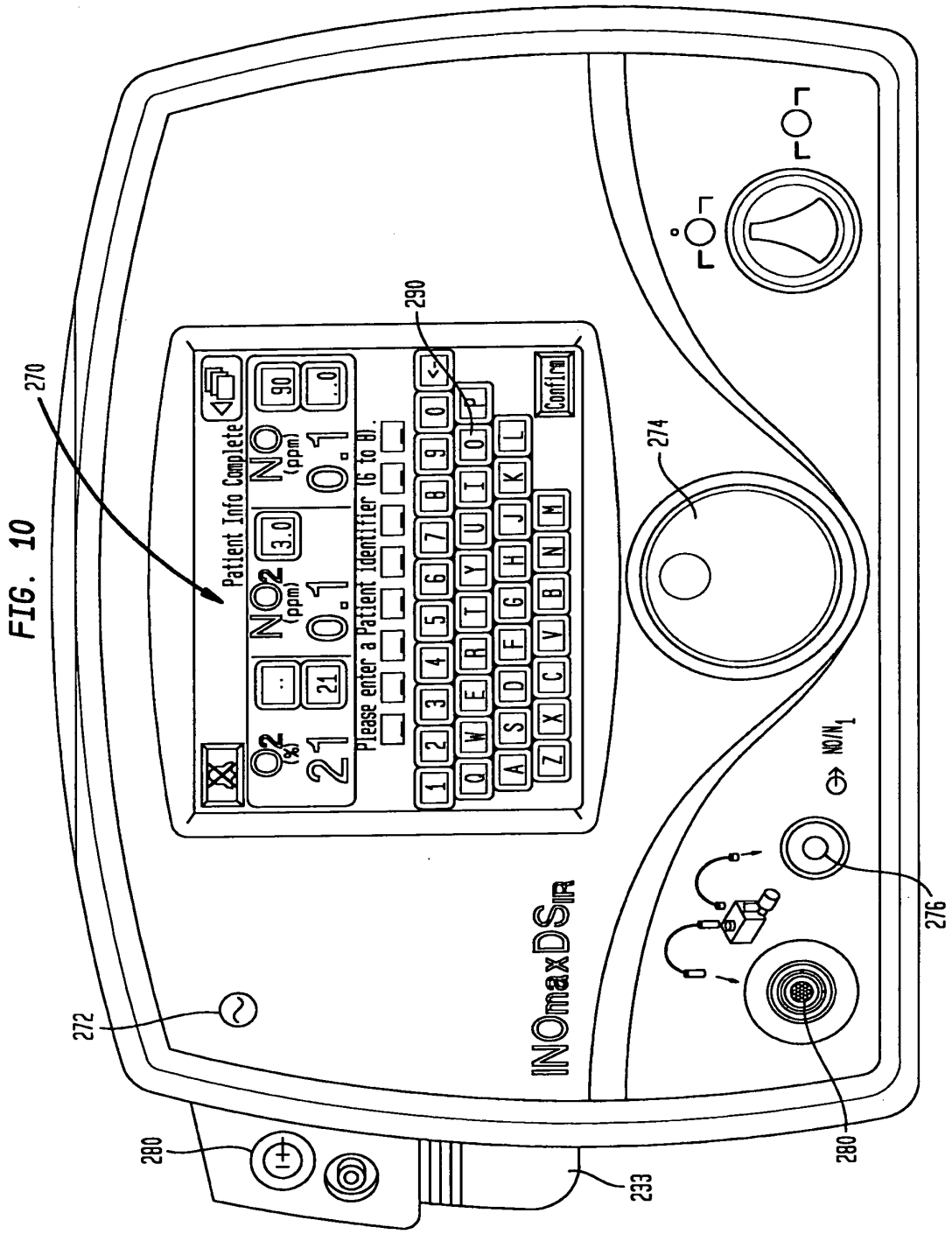

270
290
274
272
280
280
276
233
Patient Info Complete
Please enter a Patient Identifier (6 to 8).
Confirm
INOmaxDS

FIG. 11

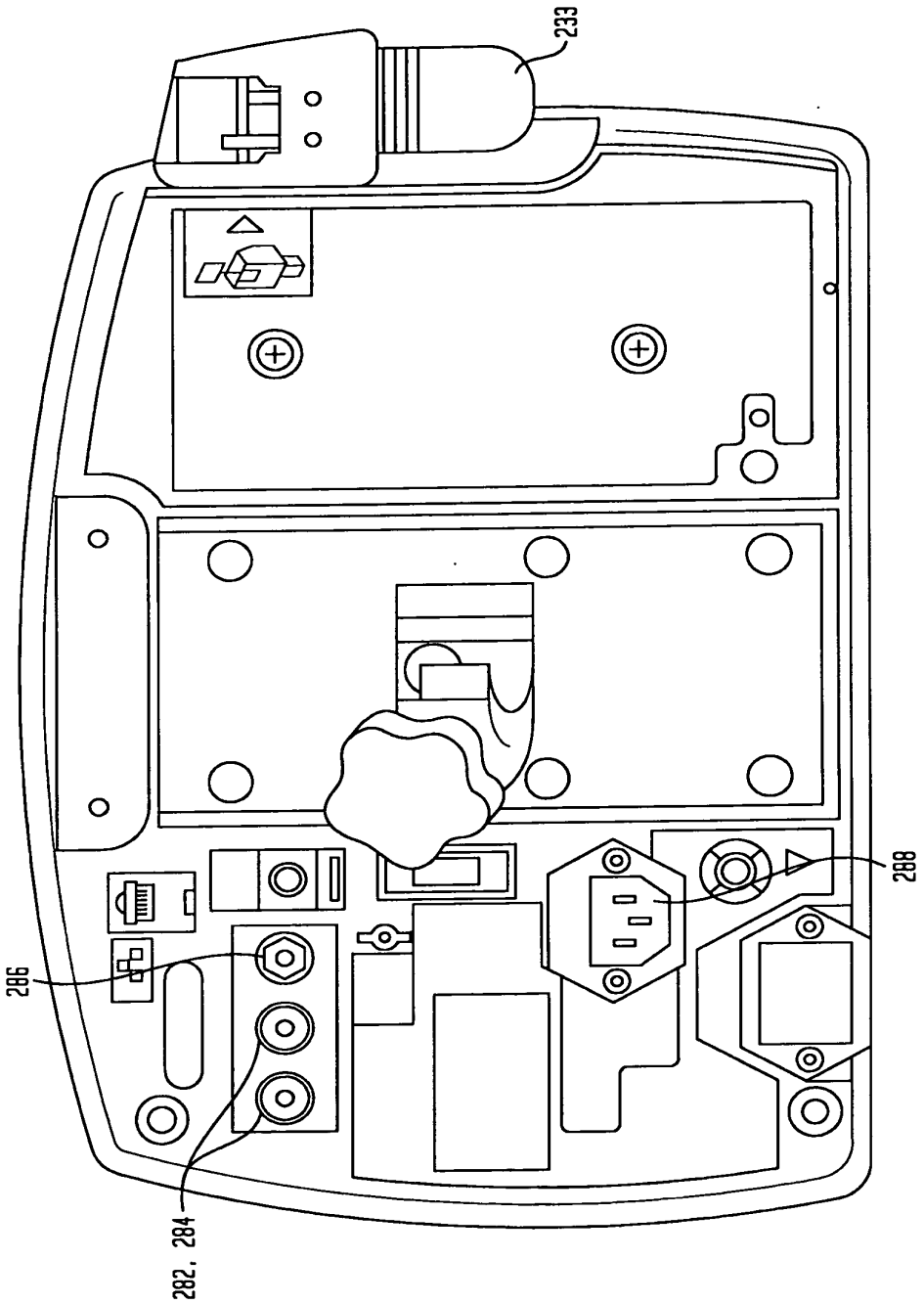


FIG. 12

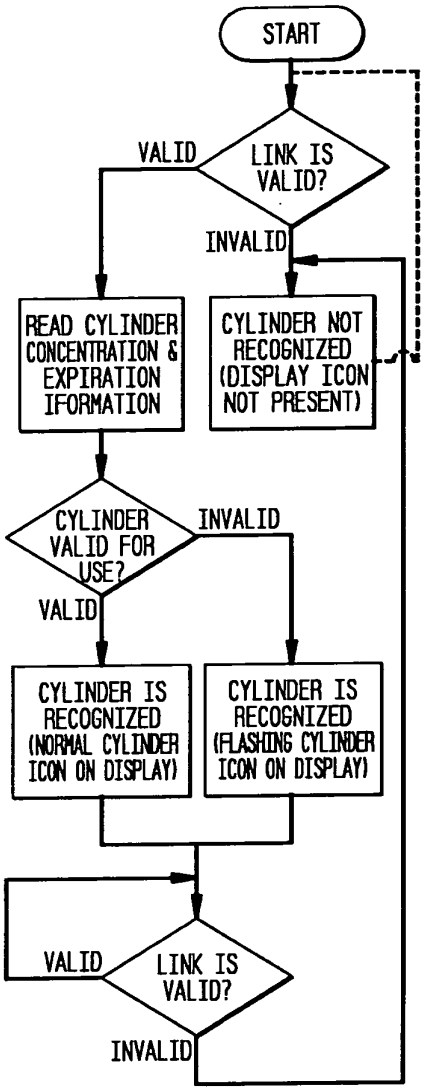
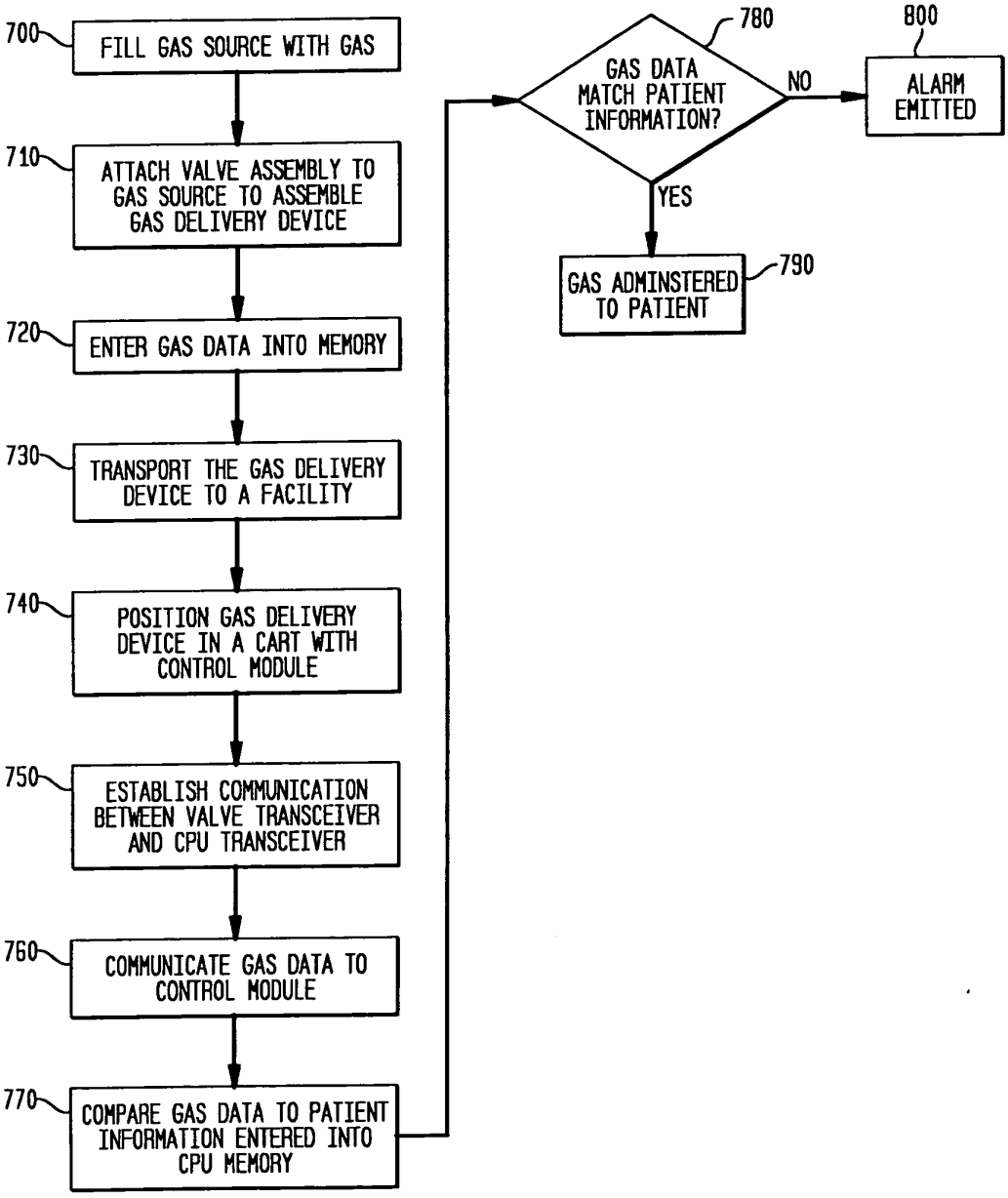

START
LINK IS VALID?
VALID
INVALID
READ CYLINDER CONCENTRATION & EXPIRATION IFORMATION
CYLINDER NOT RECOGNIZED (DISPLAY ICON NOT PRESENT)
CYLINDER VALID FOR USE?
INVALID
VALID
CYLINDER IS RECOGNIZED (NORMAL CYLINDER ICON ON DISPLAY)
CYLINDER IS RECOGNIZED (FLASHING CYLINDER ICON ON DISPLAY)
LINK IS VALID?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

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

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

MAILED
AUG 13 2012
OFFICE OF PETITIONS

In re Application of
Duncan P. Bathe
Application No.: 13/509,873
Effective Date: May 15, 2012
Attorney Docket No.: 3000-US-0026(IKA0011-00US
For: GAS DELIVERY DEVICE AND SYSTEM

: DECISION ON REQUEST TO
: PARTICIPATE IN THE PATENT
: PROSECUTION HIGHWAY
: PROGRAM AND PETITION
: TO MAKE SPECIAL UNDER
: 37 CFR 1.102(a)

This is a decision on the request to participate in the PCT Patent Prosecution Highway (PCT-PPH) pilot program and the petition under 37 CFR 1.102(a), filed on June 12, 2012, to make the above-identified application special.

The request and petition are **GRANTED**.

Discussion

A grantable request to participate in the PCT-PPH pilot program and petition to make special require:

(1) The U.S. application must have an eligible relationship to one or more PCT applications where the ISA or IPEA are the JPO, EPO, KIPO, NPI, NBPR, or USPTO;

(2) At least one claim in the PCT application has novelty, inventive step, and industrial applicability and must be free of any observations in Box VIII in the latest work product in the international stage or applicant must identify and explain why the claim(s) is/are not subject to the observation in Box VIII;

(3) Applicant must submit a copy of the claim(s) from the PCT application(s) that have novelty, inventive step, and industrial applicability along with an English translation thereof and a statement that the English translation is accurate, if the claims are not in the English language;

(4) All the claims in the U.S. application must sufficiently correspond or be amended to sufficiently correspond to the claim(s) that have novelty, inventive step, and industrial applicability in the PCT application(s);

(5) Examination of the U.S. application has not begun;

(6) Applicant must submit a copy of the latest international work product from the PCT application indicating that the claim(s) have novelty, inventive step, and industrial applicability along with an English translation thereof and a statement that the English translation is accurate if the latest international work product is not in the English language;

(7) Applicant must submit an IDS listing the documents cited by the PCT examiner in the international work product along with copies of documents except U.S. patents or U.S. patent application publications.

The request to participate in the PCT-PPH pilot program and petition comply with the above requirements. Accordingly, the above-identified application has been accorded "special" status.

Telephone inquiries concerning this decision should be directed to Terri Johnson at 571-272-2991.

All other inquiries concerning the examination or status of the application is accessible in the PAIR system at http://www.uspto.gov/ebc.index.html.

This application will be forwarded to the examiner for action on the merits commensurate with this decision after the formalities review has been completed.

/Terri Johnson/
Terri Johnson
Petitions Examiner
Office of Petitions

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

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
13/509,873	Duncan P. Bathe	3000-US-0026(IKA0011-00US

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

INTERNATIONAL APPLICATION NO.	
PCT/US11/20319	
I.A. FILING DATE	PRIORITY DATE
01/06/2011	

CONFIRMATION NO. 8620
371 ACCEPTANCE LETTER

OC00000005666981 9

Date Mailed: 09/25/2012

NOTICE OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C 371 AND 37 CFR 1.495

The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as a Designated / Elected Office (37 CFR 1.495), has determined that the above identified international application has met the requirements of 35 U.S.C. 371, and is ACCEPTED for national patentability examination in the United States Patent and Trademark Office.

The United States Application Number assigned to the application is shown above and the relevant dates are:

06/11/2012	08/07/2012
DATE OF RECEIPT OF 35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTS	DATE OF COMPLETION OF ALL 35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE " FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 (c)(1), (c)(2) and (c)(4) REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** *The filing date of the above identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363).* Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

The following items have been received:

- Indication of Small Entity Status
- Copy of the International Application filed on 05/15/2012
- Copy of the International Search Report filed on 05/15/2012
- Preliminary Amendments filed on 06/12/2012
- Information Disclosure Statements filed on 05/15/2012
- Oath or Declaration filed on 06/11/2012
- Request for Immediate Examination filed on 08/07/2012
- U.S. Basic National Fees filed on 05/15/2012
- Authorization to Permit Access filed on 06/11/2012

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

TONI M HOOD

Telephone: (571) 272-3654

FORM PCT/DO/EO/903 (371 Acceptance Notice)

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
13/509,873	06/11/2012		750	3000-US-0026(IKA0011-00US	7	4

CONFIRMATION NO. 8620

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

FILING RECEIPT

OC000000056669818

Date Mailed: 09/25/2012

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**

Inventor(s)
Duncan P. Bathe, Fitchburg, WI;
John Klaus, Cottage Grove, WI;
David Christensen, Cambridge, WI;

Applicant(s)
Duncan P. Bathe, Fitchburg, WI;
John Klaus, Cottage Grove, WI;
David Christensen, Cambridge, WI;

Assignment For Published Patent Application
Ikaria, Inc., Hampton, NJ

Power of Attorney: The patent practitioners associated with Customer Number 48394

Domestic Priority data as claimed by applicant
This application 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: 09/20/2012
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/509,873**
Projected Publication Date: 01/03/2013

Non-Publication Request: No

Early Publication Request: No
**** SMALL ENTITY ****
Title

Gas Delivery Device And System

Preliminary Class

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).

MULTIPLE DEPENDENT CLAIM FEE CALCULATION SHEET

Substitute for Form PTO-1360
(For use with Form PTO/SB/06)

Application Number	Filing Date
13509873	

Applicant(s) Duncan Bathe

* May be used for additional claims or amendments

CLAIMS	AS FILED		AFTER FIRST AMENDMENT		AFTER SECOND AMENDMENT	
	Indep	Depend	Indep	Depend	Indep	Depend
1	1		---	---		
2		1	1			
3		1		1		
4		1	1			
5		1		1		
6		1	---	---		
7		1	1			
8		1	---	---		
9		1	1			
10		1		1		
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
31						
32						
33						
34						
35						
36						
37						
38						
39						
40						
41						
42						
43						
44						
45						
46						
47						
48						
49						
50						
Total Indep	1		4		0	
Total Depend	9	↵	3	↵	0	↵
Total Claims	10		7		0	

	*		*		*	
	Indep	Depend	Indep	Depend	Indep	Depend
51						
52						
53						
54						
55						
56						
57						
58						
59						
60						
61						
62						
63						
64						
65						
66						
67						
68						
69						
70						
71						
72						
73						
74						
75						
76						
77						
78						
79						
80						
81						
82						
83						
84						
85						
86						
87						
88						
89						
90						
91						
92						
93						
94						
95						
96						
97						
98						
99						
100						

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 13/509,873

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	190		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	245		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))	7 minus 20 =	*	x 30 =	0.00	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	4 minus 3 =	* 1	x 125 =	125			
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	685		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($)	ADDITIONAL FEE($)	OR	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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Duncan P. Bathe et al.	Examiner: Unknown
Serial No.:	13/509,873	Group Art Unit: Unknown
Filed:	January 6, 2011	Docket: 3000-US-0026
Title:	Gas Delivery Device And System	Conf. No.: 8620

COMMUNICATION RE: INCORRECT FILING RECEIPT

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

Applicants hereby request correction of the Filing Receipt with respect to the above-identified patent application. In the Filing Receipt received September 25, 2012, (copy enclosed), please correct the Assignee under "Assignment For Published Patent Application" to "INO Therapeutics LLC, Hampton, NJ" as reflected in the attached Supplemental Application Data Sheet.

Applicants would appreciate the above-identified error be corrected and that a new "corrected" filing receipt be sent to Applicants' representatives at the address given below.

Respectfully submitted,

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

Date September 28, 2012

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

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
13/509,873	06/11/2012		750	3000-US-0026(IKA0011-00US	7	4

CONFIRMATION NO. 8620

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

FILING RECEIPT

Date Mailed: 09/25/2012

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**

Inventor(s)

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

Applicant(s)

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

Assignment For Published Patent Application

~~Ikaria, Inc., Hampton, NJ~~ INO Therapeutics LLC, Hampton, NJ

Power of Attorney: The patent practitioners associated with Customer Number 48394

Domestic Priority data as claimed by applicant

This application 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: 09/20/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/509,873**

Projected Publication Date: 01/03/2013

Non-Publication Request: No

Early Publication Request: No
** SMALL ENTITY **
Title

Gas Delivery Device And System

Preliminary Class

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).

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. 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 contains a valid OMB control number

Supplemental Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3000-US-0026(IKA0011-00US)
	Application Number	13/509,873
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					
Applicant Authority	☒ Inventor	☐ Legal Representative under 35 U.S.C. 117	☐ Party of Interest under 35 U.S.C. 118		
Prefix	**Given Name**	**Middle Name**	**Family Name**	**Suffix**	
	Duncan	P.	Bathe		
Residence Information (Select One)	☒ US Residency	☐ Non US Residency	☐ Active US military Service		
City	Fitchburg	**State**	WI	**Country of Residence**	US
Citizenship under 37 CFR 1.41(b)	GB				

Mailing Address of Applicant:

Address 1	5699 Nutone Street		
Address 2			
City	Fitchburg	**State/Province**	WI
Postal Code	53711	**Country**	United States of America

Applicant Information

Applicant 2

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. 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 contains a valid OMB control number

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3000-US-0026(IKA0011-00US)
	Application Number	
Title of Invention	Gas Delivery Device And System	

Applicant Authority	[X] Inventor	[ ] Legal Representative under 35 U.S.C. 117	[ ] Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	John		Klaus	

Residence Information (Select One)	[X] US Residency	[ ] Non US Residency	[ ] Active US military Service

City	Cottage Grove	State	WI	Country of Residence	US
Citizenship under 37 CFR 1.41(b)	US				

Mailing Address of Applicant:

Address 1	2730 Gaston Road		
Address 2			
City	Cottage Grove	State/Province	WI
Postal Code	53527	Country	United States of America

Applicant Information

Applicant 3

Applicant Authority	[X] Inventor	[ ] Legal Representative under 35 U.S.C. 117	[ ] Party of Interest under 35 U.S.C. 118

Prefix	Given Name	Middle Name	Family Name	Suffix
	David		Christensen	

Residence Information (Select One)	[X] US Residency	[ ] Non US Residency	[ ] Active US military Service

City	Cambridge	State	WI	Country of Residence	US
Citizenship under 37 CFR 1.41(b)	US				

Mailing Address of Applicant:

Address 1	N4398 Wolff Road

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3000-US-0026(IKA0011-00US)
	Application Number	
Title of Invention	Gas Delivery Device And System	

Address 2			
City	Cambridge	**State/Province**	WI
Postal Code	53523	**Country**	United States of America

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below. For further information see 37 CFR 1.33(a).	
[X] **An Address is being provided for the correspondence Information of this application**	
Customer Number	48394
Email Address	

Application Information:

Title of Invention	Gas Delivery Device And System		
Attorney Docket Number	3000-US-0026(IKA0011-00US)	[X] **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.

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3000-US-0026(IKA0011-00US)
	Application Number	
Title of Invention	Gas Delivery Device And System	

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32). Enter either Customer Number or complete the Representative Name section below. If both sections are completed the Customer Number will be used for the Representative Information during processing

Please Select One:	[X] Customer Number	[ ] US Patent Practitioner	[ ] Limited Recognition (37 CFR 11.9)
Customer Number	48394		

Domestic Benefit/National Stage Information:

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**
	a 371 of International	PCT/US11/20319	January 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:

Providing this information in the application data sheet does not substitute for compliance with any requirement of part 3 of Title 37 of the CFR to have an assignment recorded in the Office.

If the Assignee is an Organization check here. [X]	
Organization Name	~~Ikaria, Inc.~~ INO Therapeutics LLC

PTO/SB/14 (07-07)
Approved for use through 06/30/2010. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	3000-US-0026(IKA0011-00US)
	Application Number	
Title of Invention	Gas Delivery Device And System	

Mailing Address Information:			
Address 1	~~53 Frontage Road,~~ Third Floor ~~53~~ 53 Frontage Road		
Address 2	~~P.O. Box 9001~~ Perryville III Corporate Park		
City	Hampton	**State/Province**	N.J.
Country United States of America		**Postal Code**	08827
Phone Number		**Fax Number**	
Email Address			

Signature:

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. No. 66,947/			**Date**	2012-09-28
First Name	Rory	**Last Name**	Alegria	**Registration Number**	66,947

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.

Electronic Acknowledgement Receipt	
EFS ID:	13861466
Application Number:	13509873
International Application Number:	
Confirmation Number:	8620
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-0026(IKA0011-00US
Receipt Date:	28-SEP-2012
Filing Date:	11-JUN-2012
Time Stamp:	13:11:39
Application Type:	U.S. National Stage under 35 USC 371

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	Request for Corrected Filing Receipt	00308421.PDF	15548 622297e6501887086ca8c7c29da11810f4c39977	no	1
Warnings:					
Information:					

2	Miscellaneous Incoming Letter	00308422.PDF	400264 d964a461069f98ec1dd3f6759ade96e339a154cc	no	3
Warnings:					
Information:					
3	Application Data Sheet	00308424.PDF	63609 d4e80ae3738a62419523b74f20fba3f335e3994d	no	5
Warnings:					
Information:					
This is not an USPTO supplied ADS fillable form					
			Total Files Size (in bytes):	479421	

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.

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
13/509,873	06/11/2012		750	3000-US-0026(IKA0011-00US	7	4

CONFIRMATION NO. 8620

CORRECTED FILING RECEIPT

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

OC000000056851458

Date Mailed: 10/02/2012

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**

Inventor(s)

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

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: The patent practitioners associated with Customer Number 48394

Domestic Priority data as claimed by applicant

This application 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: 09/20/2012

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 13/509,873**

Projected Publication Date: 01/03/2013

Non-Publication Request: No

Early Publication Request: No
** **SMALL ENTITY** **
Title

Gas Delivery Device And System

Preliminary Class

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

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	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/509,873	06/11/2012	Duncan P. Bathe	3000-US-0026(IKA0011-00US

CONFIRMATION NO. 8620

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-2013-0000643-A1
Publication Date:01/03/2013

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

PLUS Search Results for S/N 13509873, Searched Tue Feb 26 09:21:15 EST 2013

The Patent Linguistics Utility System (PLUS) is a USPTO automated search system for U.S. Patents from 1971 to the present PLUS is a query-by-example search system which produces a list of patents that are most closely related linguistically to the application searched. This search was prepared by the staff of the Scientific and Technical Information Center, SIRA.

4911379 99
5407647 91
4425757 87
4865817 87
5192517 87
5362464 87
5727538 87
6196056 87
4255926 83
4333764 83
4448751 83
4567916 83
4821524 83
4944496 83
5565180 83
6009900 83
6210464 83
6210464 83
4273025 79
4317540 79
4452898 79
4509456 79
4560042 79
4563982 79
4583319 79
4764085 79
4779355 79
4919826 79
4960708 79
4963329 79
4978367 79
4992301 79
5023064 79
5326835 79
5450899 79
5520858 79
5662838 79
5707424 79
5824271 79
5950572 79
6228146 79
6236894 79
4265670 75
RE30935 75
4341651 75
4350665 75
4363443 75
4364753 75
4381898 75
4382908 75
4391860 75
4409301 75
4410041 75
4416332 75
4445846 75
4474612 75
4528337 75
4548765 75
4557816 75
4566565 75
4582254 75
4609541 75
4774152 75
4808534 75
4818640 75
4849191 75
4871580 75
4976685 75
4991423 75
5017348 75
5231991 75
5242564 75
5259456 75
5271725 75
5282739 75

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 NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/509,873	06/11/2012	Duncan P. Bathe	3000-US-0026(IKA0011-00US	8620

48394 7590 03/15/2013

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

EXAMINER	
TSAI, MICHAEL JASPER	
ART UNIT	**PAPER NUMBER**
3771	

NOTIFICATION DATE	DELIVERY MODE
03/15/2013	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

Office Action Summary	Application No.	Applicant(s)	
	13/509,873	BATHE ET AL.	
	Examiner	Art Unit	
	Michael Tsai	3771	

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

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/15/2012, 6/12/2012, and 8/7/2012*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ 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.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *2-5,7,9 and 10* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *2-5, 7, 9, and 10* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☒ The drawing(s) filed on *07 August 2012* 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).

Priority under 35 U.S.C. § 119

12)☐ 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.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/15/2012*.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

4) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

2. The references Peters et al. (US 7,114,510) and Bathe et al. (US 5,558,083) have been cited on pages 10 and 13 of the specifications.

Drawings

3. The drawings are objected to because of the unlabeled rectangular box(es) shown in figure. The drawings should be provided with suitable descriptive legends. See: 37 CFR 1.84 (n) and (o).

4. The drawings are objected to because the drawings contain blank boxes and other shapes, which are not widely, recognized engineering symbols. Applicant must supply a suitable legend. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

> 37 CFR 1.84(n) and (o) permit use of symbols which are not universally recognized, subject to approval by the Office, if they are not likely to be confused with existing conventional symbols, and if they are readily identifiable. In addition, **suitable descriptive legends may be used subject to approval by the Office,**

> **or may be required by the examiner where necessary for understanding of the drawing.** (Emphasis added). Thus the examiner may require, on a case-by-case basis, the use of descriptive legends where it is believed that such will facilitate a clear understanding of the drawings without undue reliance on the specification for understanding of the subject matter depicted therein. "When possible, a drawing should be so complete that the purpose and operation of the invention may be readily understood by one skilled in the art by means of a mere inspection of said drawing. The necessity of reading the specification in connection with the drawing should be avoided, if possible." See Ex Parte Hartley, 1901 C.D. 247 (Comm'r Pat. 1901).

5. In the instant case, the figure has boxes and other shapes and the use of descriptive legends is necessary because it is believed that such will facilitate a clear understanding of the drawings without undue reliance on the specification for understanding of the subject matter depicted therein. It is clear that the figure is not “so complete that the purpose and operation of the invention may be readily understood by one skilled in the art by means of a mere inspection of said drawing” and that undue reliance on the specification is required for understanding of the subject matter depicted therein. For example, in FIG. 1, the box labeled with the reference numeral 212 should be labeled with "CPU memory”.

6. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

7. The following is a quotation of 35 U.S.C. 112(b):

(B) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 7, 9, and 10 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention.

Regarding claim 7, the limitation “a control module” recited on lines 6 and 13. It is unclear as to whether or not these control modules are the same control modules or a different one. It seems the control module is being redefined on line 13.

Regarding claim 9, the limitation "a control module" recited on lines 6 and 13. It is unclear as to whether or not these control modules are the same control modules or a different one. It seems the control module is being redefined on line 13.

Claim 10 is included in the rejection for depending either directly or indirectly upon a rejected claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Peters et al. (7,114,510).

Regarding claim 2, Peters discloses a gas delivery device to administer therapy gas from a gas source, the gas delivery device comprising a valve 10 attachable to the gas source 12 (gas cylinder), the valve 10 including an inlet 18 (inlet port) and an outlet 20 (outlet port) in fluid communication and a valve actuator 16 (handle) to open or close the valve to allow the gas through the valve to a control module (to open and close the flow of gas from the cylinder to the gas dispensing device) (Peters, col. 2, lines 39-57). Peters also discloses a circuit (several electronic devices) including a memory 22 (electronic memory device), a processor 23 (Peters, col. 2, lines 68-67), and a transceiver (transmitter) (Peters, col. 7, lines 1-10). Peters also discloses the memory to

store gas data comprising gas identification (initialization parameter data to the memory; initial parameter such as: cylinder serial number, gas lot number) (Peters, col. 5, line 45 - col. 6, lines 15). Peters also discloses the processor and the transceiver in communication with the memory (processor instructs the memory; transmitter; transfer data from the memory device) (Peters, col. 3, lines 30-45; col. 7, lines 1-10) to send wireless optical line-of-sight signals to communicate gas data to the control module that controls the gas delivery to a subject (transfer data from memory device to main computer; develop therapy protocol) (Peters, col. 7, lines 10-51). Peters also discloses the valve comprising a data input 22' (ports on handle) in communication with the memory 22 (memory device communicates with a one-wire port) to permit a user to enter gas data into the memory (distributer inputs the initialization parameters) (Peters, col. 2, lines 58-65; col. 5, lines 43-57).

Regarding claim 4, Peters has everything as claimed (see rejection to claim 2). Peters also discloses that the valve comprises a power source 25 (battery) (Peters, col. 2, lines 58-67), 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 (handle to include a transmitter to transmit the data to a remote recording device at intervals) (Peters, col. 7, lines 1-20).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. (7,114,510).

Regarding claim 5, Peters has everything as claimed including the transceiver (Peters, col. 7, lines 1-20), but does not specifically mention that the duration of time at which no signal is sent comprises of about 10 seconds. However, since the circuit and transceiver of Peters is the same as claimed, one of ordinary skill in the art at the time the invention would looked at the Peters reference and considered the duration of time at which no signal is sent to be a matter of design consideration depending on the interval in which the user chooses to update the data of the control module.

13. Claims 3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. (7,114,510) as applied to claim 2 above, and in further view of Zaitsu et al. (2002/0013551).

Regarding claim 3, Peters has everything as claimed including the gas data, but does not specifically disclose that the gas data is provided in a bar code disposed on the gas source.

Zaitsu teaches data (identification information) is provided in bar codes disposed on sources (medical pumps) (Zaitsu, para. 0057, lines 10-20).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add to the gas sources of Peters bar codes as taught by Zaitsu in order to provide product identification to ensure proper distribution of product.

The now modified Peters reference also discloses the data is inputted by a user-operated scanning device 102a (scanner) in communication with the data input (reads information to the system) (Zaitsu, para. 0057, lines 10-20).

Regarding claim 7, Peters has everything as claimed (see rejection to claim 2). Peters also discloses that the control module (gas dispensing device) is in fluid communication with the outlet of the valve (flow of gas from the cylinder to other gas dispensing devices) and also discloses a ventilator, but does not specifically disclose the control module being in fluid communication with a ventilator. However, one of ordinary skill in the art at the time the invention was made would have looked at the Peters reference and recognize that it would have been obvious to connect a ventilator to the control module (gas dispensing device) in order to control the gases dispensed to a patient. The now modified Peters reference does not specifically disclose that the control module comprises a CPU transmitter or a CPU.

Zaitsu teaches a control module 100 (controller) comprising a CPU transmitter 107 (wireless; communication port expansion device) and a CPU 901 (Zaitsu, para. 0056, lines 8-24).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add to the control module of the modified Peters

reference a CPU transmitter and CPU as taught by Zaitsu in order to wirelessly communicate with and send commands to other components of the system.

The now modified Peters reference also discloses the CPU in communication with the CPU transceiver and including a CPU memory 902 (RAM), as shown in Zaitsu's FIG. 9. The modified Peters reference also discloses the transceiver communicates the gas data to the CPU transceiver for storage in the CPU memory (collected data is then downloaded into a main computer) (Peters, col. 7, lines 1-15). The modified Peters reference also discloses the valve comprises a timer 21 (at least two timers) 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 (record time and date of the event; the processor uses the logged open and close times to calculate the amount of time the valve was open and instructs the memory device to record that duration) (Peters, col. 3, lines 45-53). The modified Peters reference also discloses the transceiver communicating the date and time of the opening and closing of the valve to the CPU transceiver for storage in the CPU memory (collected data downloaded to main computer) (Peters, col. 7, lines 1-45).

14. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. (7,114,510) in view of Zaitsu et al. (2002/0013551) as applied to claim 7 above, and in further view of Rice et al. (7,980,245)

Regarding claim 9, the modified Peters reference has everything as claimed including the valve and the control device (see rejection to claim 7 above). The modified

Peters reference also discloses that the control module further comprises an input means 904 (keyboard), and a display 101 (Zaitsu, para. 0056, lines 10-24). The modified Peters reference does not specifically disclose that the patient information is entered into the CPU memory.

Rice teaches data stored in a CPU memory 36 (information tag) including patent information (Rice, col. 5, lines 39-55).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the CPU memory of the modified Peters reference patient information to ensure that the correct configuration is being used for the associated patient.

Regarding claim 10, the now modified Peters reference also discloses that the CPU comprises of an alarm that is triggered when the patient information entered in the CPU and the gas data from the transceiver do not match (improper connection can produce inaccurate data and waste of medical gases, and at worst, a dangerous situation for patients; raising an alarm) (Rice, col. 6, lines 25-40).

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 2-5, 7, 9 and 10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 8,291,904 ('904 reference). Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the claims 2-5, 7, 9 and 10 of the present application and the '904 reference is the inclusion of the

gas container containing the gas comprising NO. However, since nitric oxide is a well-known gas that is delivered to patients. One of ordinary skill in the art would have found it obvious to modify the invention as claimed in claim 2 to include NO.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Toth et al. (5,191,317) and DeVries et al . (7,849,854) both disclose breathing devices with valves that include a transmitter that is able to wirelessly transmit data regarding gas information. Bathe et al. (5,558,083), Epstein (5,100,380), Dickerson, Jr. (5,868,162), Sancoff et al. (5,078,683), and Stewart (7,927,313) all disclose distribution systems with a control module in fluid connection to sources. Wolf et al. (5,505,195), McDermott et al. (6,326,896), Voege et al. (7,298,280), and Pitchford et al. (2011/0284777) all disclose valve devices with transmitters or alarms.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Tsai whose telephone number is (571)270-5246. The examiner can normally be reached on Monday thru Friday, 7:30am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. 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.

/Michael Tsai/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

Notice of References Cited	Application/Control No. 13/509,873	Applicant(s)/Patent Under Reexamination BATHE ET AL.	
	Examiner Michael Tsai	Art Unit 3771	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,078,683	01-1992	Sancoff et al.	604/67
*	B	US-5,100,380	03-1992	Epstein et al.	604/67
*	C	US-5,191,317	03-1993	Toth et al.	340/626
*	D	US-5,505,195	04-1996	Wolf et al.	128/203.15
*	E	US-5,558,083	09-1996	Bathe et al.	128/203.12
*	F	US-5,868,162	02-1999	Dickerson, Jr., William H.	137/557
*	G	US-6,326,896	12-2001	McDermott et al.	340/626
*	H	US-2002/0013551	01-2002	Zaitsu et al.	604/151
*	I	US-7,114,510	10-2006	Peters et al.	137/1
*	J	US-7,298,280	11-2007	Voege et al.	340/606
*	K	US-7,849,854	12-2010	DeVries et al.	128/205.11
*	L	US-7,927,313	04-2011	Stewart et al.	604/189
*	M	US-7,980,245	07-2011	Rice et al.	128/204.21

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.

Notice of References Cited	Application/Control No. 13/509,873	Applicant(s)/Patent Under Reexamination BATHE ET AL.	
	Examiner Michael Tsai	Art Unit 3771	Page 2 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2011/0284777	11-2011	Pitchford et al.	251/65
	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.

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13509873	BATHE ET AL.
	Examiner	Art Unit
	MICHAEL TSAI	3771

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
128	203.12, 203.14, 204.18, 204.21-201.23, 205.24	3/5/2013	MT

SEARCH NOTES		
Search Notes	Date	Examiner
PLUS search requested	2/26/2013	MT
Inventor name and assignee searched	3/5/2013	MT
Consulted Kristin Matter regarding class 128 (suggested subclasses 203.12, 203.14, 204.18, 204.21-201.23, 205.24)	3/5/2013	MT

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner

/M.T./ Examiner.Art Unit 3771	

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	Not yet assigned
Filing Date	Herewith
First Named Inventor	Duncan P. Bathe
Art Unit	Not Yet Assigned
Examiner Name	Unknown

Submitted: May 15, 2012

Attorney Docket No: 3000-US-0026(IKA0011-00US)

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 RelevantFigures 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 RelevantFigures 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 /Michael Tsai/ **DATE CONSIDERED** 03/07/2013

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. /M.T./

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	32	((DUNCAN) near2 (BATHE)).INV.	US-PGPUB; USPAT	OR	ON	2013/03/05 09:27
S2	19	((JOHN) near2 (KLAUS)).INV.	US-PGPUB; USPAT	OR	ON	2013/03/05 09:27
S3	81	((DAVID) near2 (CHRISTENSEN)).INV.	US-PGPUB; USPAT	OR	ON	2013/03/05 09:27
S4	6	("20050172966" | "20090266358" | "6109260" | "6125846" | "6164276" | "6581592").PN.	US-PGPUB; USPAT	OR	ON	2013/03/05 09:33
S5	7039	(128/204.18,204.21-204.23,205.24,203.12,203.14).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/03/05 09:58
S6	174074	(valve regulator (flow near2 control$3)) and (data information info statistic record) with (memory storage retention RAM ROM) and (processor CPU (process$3 near2 (unit element component module)))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 10:14
S8	1473	S6 and "128".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 10:17
S9	16007	(valve regulator (flow near2 control$3)) same (data information info statistic record) with (memory storage retention RAM ROM) same (processor CPU (process$3 near2 (unit element component module)))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 10:18
S11	264	("4493706" | "4551133" | "4553958" | "4559038" | "4559040" | "4565542" | "4573994" | "4650469" | "4653987" | "4671792" | "4681566" | "4762518" | "4798590" | "4853521" | "4925444" | "4966579" | "4976590" | "4978335" | "4997347").PN. OR ("5078683").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 11:37
S12	34066	(valve regulator (flow near2 control$3)) same (programmable (execute with instruction))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 12:43
S13	17862	(valve regulator (flow near2 control$3)) with (programmable (execute with instruction))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 12:44

S14	14888	(valve regulator) with (programmable (execute with instruction))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 12:45
S15	169	S14 and "128".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 12:45
S16	218	("1853811" | "2672051" | "2767277" | "2880909" | "2907325" | "3543752" | "3559644" | "3620650" | "3749285" | "3798982" | "3874826" | "3884228" | "3901231" | "3923060" | "3941126" | "3982534" | "4030495" | "4037598" | "4056333" | "4077405" | "4094318" | "4126132" | "4142523" | "4191181" | "4191183" | "4191184" | "4204538" | "4207871" | "4236522" | "4236880" | "4261356" | "4265240" | "4270532" | "4276004" | "4282872" | "4303376" | "4308866" | "4316460" | "4324238" | "4336800" | "4373527" | "4391598" | "4392847" | "4395259" | "4411651" | "4432754" | "4460353" | "4464170" | "4468222" | "4475901" | "4503841" | "4553958" | "4561443" | "4563173" | "4624661" | "4685903" | "4731051" | "4776842").PN. OR ("5100380").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 12:46
S17	5	(("6089229") or ("20090266358") or ("20110240019") or ("20020044059") or ("20110041849")).PN.	US-PGPUB; USPAT	OR	OFF	2013/03/05 12:56
S18	386	(valve regulator) with (programmable (execute with instruction)) same (transmitter transceiver)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 13:26
S19	16	("20030140921" | "20030196666" | "20040173214" | "20050038674" | "20070272240" | "4340045" | "5069220" | "5088332" | "5337738" | "5950621" | "6035851" | "6089105" | "6119686" | "7101341").PN. OR ("7980245").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 14:01
S20	69	("4221219" | "4303376" | "4515588" | "4714462" | "4838887" | "4936758").PN. OR ("5049141").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 14:07
S21	0	(08/122126).APP.	US-PGPUB; USOCR	OR	ON	2013/03/05 14:19
S22	82	("4604847" | "4984158" | "5020527" | "5167506" | "5284133" | "5363842" | "5392768" | "5394866").PN. OR ("5505195").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 14:19
S23	14	("4176617" | "4536756" | "4800373" | "4990894" | "5040477" | "5057822" | "5357242" | "5542287" | "5868162" | "5893944" | "6137417").PN. OR ("6326896").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 14:22

S24	3	("2002/0013551").URPN.	USPAT	OR	ON	2013/03/05 14:22
S25	203	(sensor) same timer same duration with (open close)	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 14:37
S26	20	(ino near2 therapeutic).as.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 15:28
S28	7215	valve with (transmitter Transceiver)	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/05 16:23
S29	83	S28 and "128".clas.	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/05 16:23
S30	90	S28 same gas same data	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/05 16:30
S31	0	S30 not S28	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/05 16:30
S32	86	S30 not S29	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/05 16:31
S33	571	S28 same gas with (data information pressure propert$3 parameter)	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/05 16:35
S34	102	S28 same gas with (data information pressure propert$3 parameter) same ((control$3 near (unit element module device)) computer)	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/05 16:39
S35	3948	(128/204.18,204.21-204.23).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/03/07 12:52
S36	3874	(128/205.24,203.12,203.14).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/03/07 12:52
S37	1	("5558083").PN.	US-PGPUB; USPAT	OR	OFF	2013/03/07 13:17
S38	1214	ventilator and control with (unit module) and "128".clas.	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/07 15:16

EAST Search History (Interference)

<This search history is empty>

3/7/2013 6:19:27 PM
C:\Users\mtsai1\Documents\EAST\Workspaces\13509873.wsp

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. 8620

SERIAL NUMBER	FILING or 371(c) DATE RULE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
13/509,873	06/11/2012	128	3771	3000-US-0026(IKA0011-00US

APPLICANTS

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

**** CONTINUING DATA **************************

This application is a 371 of PCT/US11/20319 01/06/2011 Yes. /MJT/ 3/7/2013

**** FOREIGN APPLICATIONS ************************** None. /MJT/ 3/7/2013

**** IF REQUIRED, FOREIGN FILING LICENSE GRANTED **** ** SMALL ENTITY **

09/20/2012

Foreign Priority claimed ☐ Yes ☑ No 35 USC 119(a-d) conditions met ☐ Yes ☐ No Verified and Acknowledged /MICHAEL J TSAI/ Examiner's Signature	☐ Met after Allowance Initials	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
		WI	12	7	4

ADDRESS

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

TITLE

Gas Delivery Device And System

FILING FEE RECEIVED		
750	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).

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13509873	BATHE ET AL.
	Examiner	**Art Unit**
	MICHAEL TSAI	3771

✓	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	03/07/2013								
	1	-								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	-								
	7	✓								
	8	-								
	9	✓								
	10	✓								
	11	-								
	12	-								
	13	-								
	14	-								
	15	-								
	16	-								
	17	-								
	18	-								

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 NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/509,873	06/11/2012	Duncan P. Bathe	3000-US-0026(IKA0011-00US	8620

48394 7590 05/23/2013

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

EXAMINER	
TSAI, MICHAEL JASPER	
ART UNIT	**PAPER NUMBER**
3771	

NOTIFICATION DATE	DELIVERY MODE
05/23/2013	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

Applicant-Initiated Interview Summary	Application No.	Applicant(s)	
	13/509,873	BATHE ET AL.	
	Examiner	Art Unit	
	Michael Tsai	3771	

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

(1) *Michael Tsai*.

(2) *Justine Yu*.

(3) *Rory Alegria*.

(4) *Erika Senska*.

Date of Interview: *14 May 2013*.

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

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

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: *2,4,5,7 and 9*.

Identification of prior art discussed: *Peters et al. (7,114,510), Zaitsu et al. (2002/0013551), Fine (2011/0240019)*.

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

/Michael Tsai/ Examiner, Art Unit 3771	/Justine R Yu/ Supervisory Patent Examiner, Art Unit 3771

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: Applicant provided an explained that the communication of the valve and the control module is meant to act as a safety mechanism to ensure that the proper gas is being delivered to a patient. Applicant further explained that the device claimed is able to communicate with each other frequently to ensure the proper gas and concentrations are being distributed by the control module. Applicant argued that the Peters reference disclosed a valve that communicated billing information and tracked patient treatment and provided no safety feature. Applicant further argued that the valve of Peters did not communicate with a control module that directly provided gas to a patient. However, Examiner noted that the Peters reference was able to track the treatment and send information to a main computer which in turn allows for the development of treatment protocols and that ventilators are known to have computers. Additionally, Examiner noted that the Peters reference disclosed the gas data stored and transmitted by the memory included gas identification (col.5, lines 45-55). No agreement was reached regarding whether or not Peters disclosed the communication of gas data to a control module. However, Examiner proposed to Applicants to amend the claims to specifically recite the functional language of the control module and the valve to have two way communication for automatically detecting whether or not the correct gas is being distributed to the patient in order to further define the claimed invention over the applied art. Applicant agreed to make amendments to the claims to include the functional language of the two way communication of the valve and the control module. Applicant proposed to amend the second instances of "a control module" in claim 7 and 9 to overcome the 112, second paragraph rejection stated in the office action mailed 3/15/2013. Examiner agreed that such an amendment would overcome the 112, second paragraph rejection. Additionally, Applicant agreed to file a terminal disclaimer for the present application in order to overcome the double patenting rejection as stated in the office action mailed 3/15/2013. Applicant further provided a proposed replacement sheet (see attachement) in order to overcome the drawing objections to FIG. 1. Examiner noted that the labeling of the boxes as shown on the proposed replacement sheet for FIG 1 would overcome the drawing objections, but there was an additional box within the control module that appeared to be unlabeled. Applicant took note of the additional unlabeled box and agreed to further amend FIG. 1.

For Interview only. /MJT/ 5/16/2013

33 Wood Av. South, Suite 210
Iselin, New Jersey 08830
Telephone No. (732) 815-0404
Fax No. (732) 815-1330

SERVILLA WHITNEY LLC

Fax

To:	Examiner Michael Tsai	**From:**	Rory P. Alegria, Esq.
Fax:	571-270-6246	**Pages:**	**3 (including cover)**
Phone:		**Date:**	May 13, 2013
Re:	**Agenda for Interview for App. No. 13/509,873**	**CC:**	

☐ **Urgent** **For Review** ☐ **Please Comment** ☐ **Please Reply** ☐ **Please Recycle**

● Comments:

Please see attached.

PAGE 1/3 * RCVD AT 5/13/2013 2:14:03 PM [Eastern Daylight Time] * SVR:W-PTOFAX-003/15 * DNIS:2706246 * CSID:7328151330 * DURATION (mm-ss):00-49

S/N 13/509,873 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Duncan P. Bathe	Examiner	Tsai, Michael Jasper
Serial No.:	13/509,873	Group Art Unit	3771
Filed:	June 11, 2012	Docket No.:	3000-US-0026 (IKA0011-00US)
		Confirmation No.:	8620

Title: Gas Delivery Device And System

AGENDA FOR INTERVIEW ON MAY 14, 2013 AT 12:30 P.M.

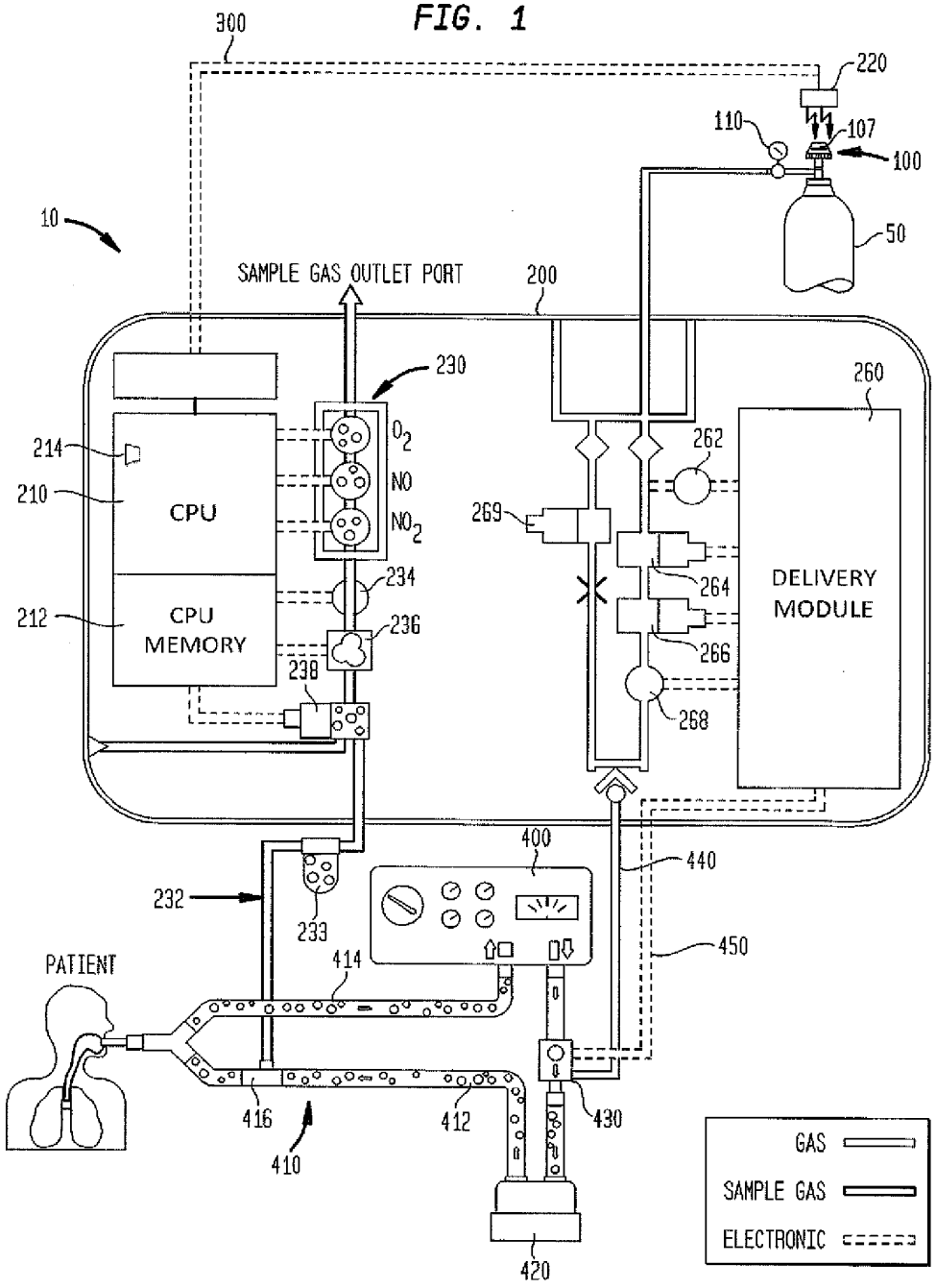
Planned Attendees: Michael Jasper Tsai, Examiner, Art Unit 3771
Justine R. Yu, Supervisory Patent Examiner, Art Unit 3771
Rory Alegria, Reg. No. 66,947, Attorney for Applicant
Erika Senska, Reg. No. 53,312, Attorney for Applicant

I. Discuss the claimed invention of communication between control module of gas delivery device and valve attached to gas source, which provides important safety enhancement
II. Discuss 102 rejection of claims 2 and 4 over Peters (U.S. 7,114,510)
   a. Review rejection
   b. Discuss differences between transmitting billing information from valve to main computer in Peters and communicating gas data from valve to control module that controls gas delivery as recited in claims
III. Discuss 103 rejection of claim 5 over Peters
   a. No need to frequently send billing information of Peters every 10 seconds
IV. Discuss 103 rejection of claims 3 and 7 over Peters in view of Zaitsu (U.S. 2002/0013551)
   a. Zaitsu also fails to disclose communication with a control module that controls gas delivery to a subject
V. Discuss 103 rejection of claims 9 and 10 over Peters in view of Zaitsu and in further view of Rice (U.S. 7,980,245)
   a. Rice also fails to disclose communication with a control module that controls gas delivery to a subject
VI. Discuss 112 rejection of claims 7, 9 and 10
VII. Discuss the obviousness-type double patenting rejection of claims 2-5, 7, 9 and 10 over U.S. 8,291,904
VIII. Discuss objection to FIG. 1 and proposed Replacement Sheet

For Interview only. /MJT/ 5/16/2013

REPLACEMENT SHEET

FIG. 1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Inventor:	Bathe	Examiner	Tsai, Michael Jasper
Serial No.:	13/509,873	Group Art Unit	3771
Filed:	Jan 6, 2011	Docket No.:	3000-US-0026
		Confirmation No.:	8620

Title: Gas Delivery Device And System

AMENDMENT/RESPONSE UNDER 37 C.F.R. § 1.111

This paper is being submitted in response to the Office Action dated March 15, 2013, in the above-identified patent application. The USPTO was closed on Saturday, June 15, 2013 and Sunday, June 16, 2013. Accordingly, the three month period for reply to the Office Action expires on Monday, June 17, 2013 and this paper is being timely filed.

IN THE SPECIFICATION

Please replace paragraph [0005] on pages 1-2 with the following paragraph:

[0005] 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. 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~~ central 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.

IN THE DRAWINGS

Please replace sheets 1 of the drawings with the Replacement Sheet filed herewith.

IN THE CLAIMS

1. (Canceled)

2. (Currently Amended) A gas delivery device to administer therapy gas from a gas source, the gas delivery device comprising:

a valve 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 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 and receive wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject and to verify one or more of the correct gas, the correct gas concentration and that the gas is not expired,

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. (Original) 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. (Currently Amended) A gas delivery device to administer therapy gas from a gas source, the gas delivery device comprising:

a valve 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 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 and receive wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject and to verify one or more of the correct gas, the correct gas concentration and that the gas is not expired,

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

6. (Canceled)

7. (Currently Amended) A gas delivery system comprising:

a gas delivery device to administer therapy gas from a gas source, the gas delivery device comprising:

a valve 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 that controls gas delivery to a subject; 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 and receive wireless optical line-of-sight signals to communicate the gas data to the control module ~~that controls gas delivery to a subject~~ and to verify one or more of the correct gas, the correct gas concentration and that the gas is not expired; and

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

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

a central processing unit (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, and

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. (Canceled)

9. (Currently Amended) A gas delivery system comprising:

a gas delivery device to administer therapy gas from a gas source, the gas delivery device comprising:

a valve 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 that control gas delivery to a subject; 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 and receive wireless optical line-of-sight signals to communicate the gas data to the control module ~~that controls gas delivery to a subject~~ and to verify one or more of the correct gas, the correct gas concentration and that the gas is not expired; and

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

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

a central processing unit (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,

wherein the control module further comprises an input means to enter patient information into the CPU memory; and a display, and

wherein the CPU compares the patient information entered into the CPU memory via the input means and the gas data from the transceiver.

10. (Original) 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. - 18. (Canceled)

REMARKS

Telephone Interview Summary

As a preliminary matter, Applicants would like to thank Examiner Michael Tsai and SPE Justine Yu for the courtesy of their time on May 14, 2013 to discuss the Non-Final Office Action with Applicants' representatives Rory Alegria, the undersigned, and Erika Senska, in-house counsel for the assignee. The §§ 102, 103 and 112 and double patenting rejections were discussed. It was agreed that amending the second instance of "a control module" to "the control module" in claims 7 and 9 would overcome the § 112 rejection. It was also agreed that an amendment to claims 2, 4, 7 and 9 that specified that the processor and transceiver in communication with the memory send and receive wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject and to verify one or more of the correct gas, the correct gas concentration and that the gas is not expired, would overcome the present §§ 102 and 103 rejections based on U.S. 7,114,510 (Peters). Applicants also agreed to file a terminal disclaimer to overcome the double patenting rejection based on U.S. 8,291,904.

The objection to the drawings was also discussed, and Applicants provided a proposed Replacement Sheet. The Examiner requested that in addition to the labeling of boxes 210, 212 and 260 as shown in the original proposed Replacement Sheet, the unlabeled rectangular box in FIG. 1 should be removed. The Replacement Sheet filed herewith reflects the requested labeling and removal of the unlabeled box above the CPU 210.

Applicants respectfully assert that, in view of the following, this case is in condition for allowance. If the Examiner wishes to further discuss this application, he is invited to contact the undersigned.

Status of Claims

Claims 2-5, 7, 9 and 10 are pending in the application. Claims 2-5, 7, 9 and 10 are rejected. No claims are allowed.

Claims 2, 4, 7 and 9 have been amended to more clearly describe and distinctly claim the subject matter the Applicants consider their invention. Specifically, claims 2, 4 7 and 9 have been amended to recite that the processor and transceiver send and receive wireless signals to communicate gas data the control module and to verify one or more of the correct gas, the

correct gas concentration and that the gas is not expired. Claims 7 and 9 have also been amended to specify that the CPU acronym represents a central processing unit and have clarified the language regarding the control module. Support for the amendments can be found at least in paragraphs [0005] and [0056] of the as-filed specification. No new matter has been added by this amendment.

Amendments to the Specification

Applicants request entry of the amendments to the specification to correct a typographical error in paragraph [0005]. Applicants submit that one of ordinary skill in the art would readily understand that the acronym CPU stands for "central processing unit" and not "control processing unit."

Objections to the Drawings

The drawings have been amended to include legends and remove the unlabeled box as requested by the Examiner and Applicants respectfully request withdrawal of this objection.

Claim Rejections – 35 U.S.C. § 112

Claims 7, 9, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants submit that the amendments to claims 7 and 9 correct any alleged deficiencies and request that the rejection be withdrawn.

Double Patenting

Claims 2-5, 7, 9 and 10 are rejected as allegedly unpatentable over claims 1-7 of U.S. Patent No. 8,291,904 (the '904 patent) for obviousness-type double patenting. While Applicants do not necessarily agree with this conclusion, in the interest of furthering prosecution, Applicants submit a terminal disclaimer herewith and request that the rejection be withdrawn.

Claim Rejections – 35 U.S.C. § 102

Claims 2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Peters et al.

(7,114,510). Applicants respectfully traverse this basis for rejection.

Peters is directed to a valve with a smart handle including a memory module to log data relevant to gas usage. See Peters at abstract. Essentially, the device of Peters measures how long the valve is open to determine the treatment time and records other information relevant to gas usage, which hospitals and clinics can use to bill individual patients according to their specific usage. See Peters at col. 1, lines 34-42. Notably, the valve does not comprise a processor and transceiver that communicate gas data to the control module that controls gas delivery to a subject. Instead, the valve memory of Peters only stores information that is relevant to billing, tracking inventory or other record-keeping functions. The Peters device stores the information in the memory device until the information is transferred through the use of a PIR-2 reader, a wand reader 44, or through directly from a port 22' on the handle 16 to a printer. See Peters at col. 6, lines 37-57. Alternatively, a transmitter may be used to transmit the information to a "main computer." See Peters at col. 7, lines 1-15. However, the "main computer" is not the delivery device to which the outlet port 20 connects. See Peters at col. 6, lines 18-21. The main computer "uses the data that has been collected to generate reports, to track treatments, do billings, and to control inventory," (see col. 7, 9-12), whereas the delivery device "is used to adjust the concentration and flow rate or to mix gases administered to the patient" (see col. 6, lines 18-21). Accordingly, Peters does not disclose a gas delivery device in which a valve transceiver sends wireless optical line-of-sight signals to communicate the gas data **to the control module that actually delivers the gas to the patient**.

There is also no indication that the "transmitter" of Peters can **receive** wireless signals from a control module. The Peters device also does not verify one or more of the correct gas, the correct gas concentrations and that the gas is not expired.

Accordingly, as Peters does not disclose all of the limitations of claims 2 and 4, Applicants submit that these claims are novel over Peters.

Claim Rejections – 35 U.S.C. § 103

Claim 5

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. (7,114,510). Applicants respectfully traverse this basis for rejection.

As described above, Peters does not disclose a gas delivery device comprising a valve with a processor and a transceiver in communication with the memory to send and receive wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject and to verify one or more of the correct gas, the correct gas concentration and that the gas is not expired. Indeed, these safety features are not relevant to the billing, inventory tracking or other record-keeping functions of the Peters device. Furthermore, as Peters relates to sending information regarding inventory and billing, there is no need to send a signal as frequently as the device claimed in claim 5. Instead, billing information can be updated on a periodic basis (such as every day, week, or month), but there is simply no reason to update billing information more frequently than one would actually send out bills. In contrast, the claimed frequency of communication helps continue communication between the valve and the gas delivery device without continuously sending out signals and draining the valve power source. See specification at ¶ [0041].

Accordingly, Applicants submit that Peters does not teach or suggest all of the claimed features and that claim 5 is patentable as nonobvious over Peters.

Claims 3 and 7

Claims 3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. (7,114,510) as applied to claim 2 above, and in further view of Zaitsu et al. (2002/0013551). Applicants respectfully traverse this basis for rejection.

Zaitsu is directed to a medical pump monitor system for administering medical fluids using a plurality of medical pumps and managing information of these medical pumps. See Zaitsu abstract and ¶ 1. Zaitsu is not directed to delivery of a medical gas. Accordingly, Zaitsu does not disclose a control module as claimed because the controller of Zaitsu does not deliver a gas to a patient. Zaitsu also fails to disclose sending and receiving wireless signals to communicate gas data comprising one or more of gas identification, gas expiration date and gas concentration to a control module and to verify one or more of the correct gas, the correct gas concentration and that the gas is not expired. As such, Zaitsu does not remedy the deficiencies of Peters described above and claims 3 and 7 are not obvious the combination of Peters and Zaitsu.

Claims 9 and 10

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peters et al. (7,114,510) in view of Zaitsu et al. (2002/0013551) as applied to claim 7 above, and in further view of Rice et al. (7,980,245). Applicants respectfully traverse this basis for rejection.

Rice relates to an optimized system for providing medical support to a patient. See Rice at abstract. Rice does not cure any of the deficiencies of Peters and Zaitsu noted above. Specifically, Rice does not disclose a gas delivery device comprising a valve with a processor and a transceiver in communication with the memory to send and receive wireless optical line-of-sight signals to communicate the gas data to the control module that controls gas delivery to a subject and to verify one or more of the correct gas, the correct gas concentration and that the gas is not expired. Rice also fails to disclose comparing the patient data to the gas data from the transceiver. Accordingly, the combination of Peters, Zaitsu and Rice does not disclose, teach or suggest all of limitations of claims 9 and 10, and these claims are not obvious over the cited references.

CONCLUSION

It is believed that claims 2-5, 7, 9 and 10 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,

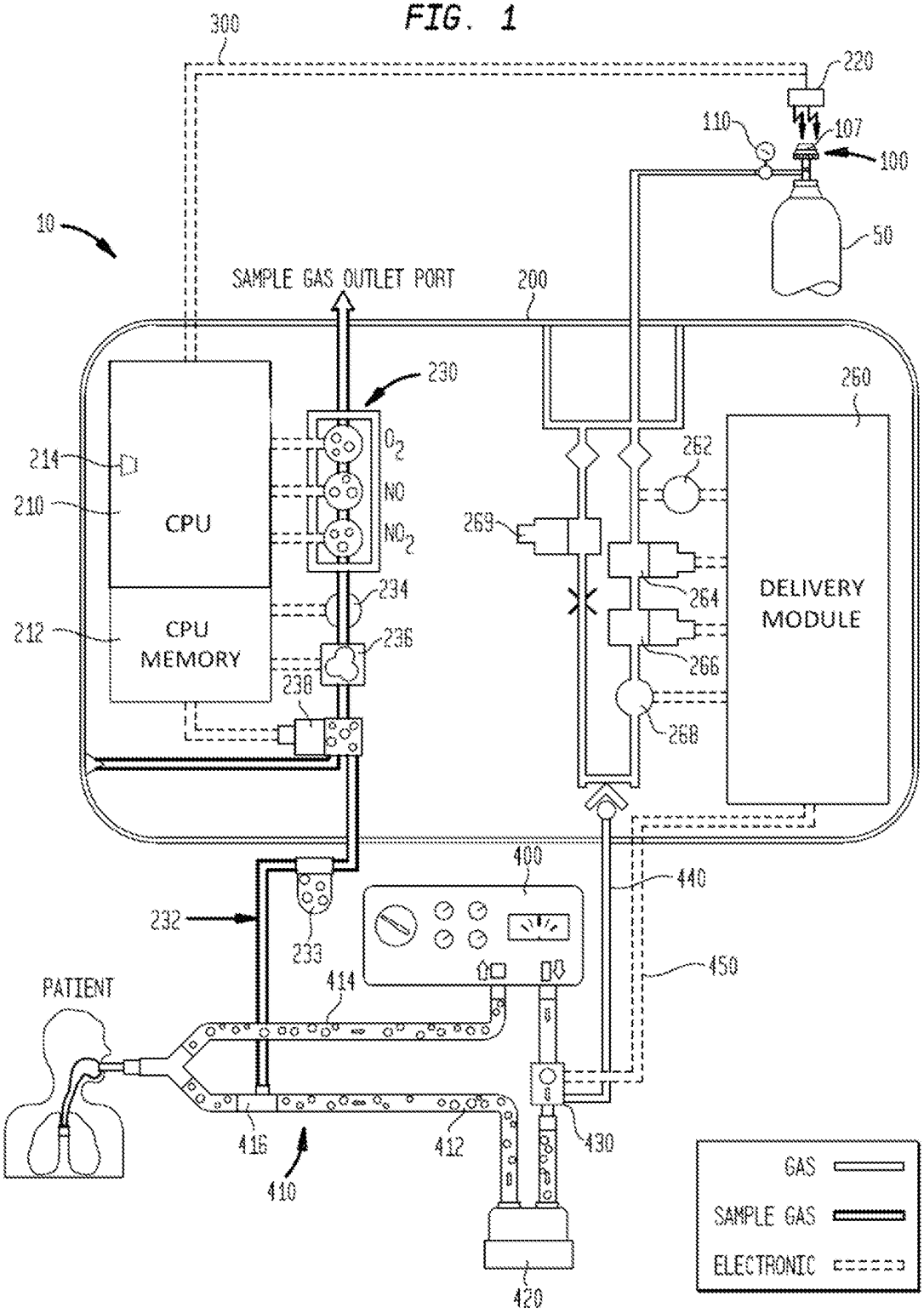
Dated: June 17, 2013

By: /Rory P. Alegria, Reg. #66,947/

Rory P. Alegria
Reg. No. 66,947
Servilla Whitney LLC
33 Wood Ave S
Second Floor, Suite 210
Iselin, NJ 08830

Telephone: (732) 815-0404
Attorney for Applicant

FIG. 1


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

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	13/509,873
Filing Date	Jan 6, 2011
First Named Inventor	Duncan P. Bathe
Art Unit	3771
Examiner Name	Tsai, Michael Jasper

Submitted: June 17, 2013

Sheet	1	of	1

Attorney Docket No: 3000-US-0026

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 RelevantFigures Appear
		20020044059	Apr 18, 2002	Reeder, Ryan A., et al.	
		20110041849	Feb 24, 2011	Chen, Bo et al.	
		20110240019	Oct 6, 2011	Fine, David H., et al.	
		6089229	Jul 18, 2000	Bathe, Duncan P., et al.	
		8291904	Oct 23, 2012	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 RelevantFigures 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]
		First Action Interview Pilot Program Pre-Interview Communication, dated March 20, 2013, 6 pgs.	

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

Electronic Patent Application Fee Transmittal	
Application Number:	13509873
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-0026(IKA0011-00US
Filed as Small Entity	

U.S. National Stage under 35 USC 371 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($)
Miscellaneous:				
Submission- Information Disclosure Stmt	2806	1	90	90
Statutory or Terminal Disclaimer	1814	1	160	160
		Total in USD ($)		**250**

Electronic Acknowledgement Receipt	
EFS ID:	16054775
Application Number:	13509873
International Application Number:	
Confirmation Number:	8620
Title of Invention:	Gas Delivery Device And System
First Named Inventor/Applicant Name:	Duncan P. Bathe
Customer Number:	48394
Filer:	Rory P. Alegria
Filer Authorized By:	
Attorney Docket Number:	3000-US-0026(IKA0011-00US
Receipt Date:	17-JUN-2013
Filing Date:	11-JUN-2012
Time Stamp:	12:17:27
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$250
RAM confirmation Number	10856
Deposit Account	
Authorized User	

File Listing:

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

1		00366973.PDF	68298 0e65d9528d8f6b54e1aeebcc2d83a5255ac3ec4d	yes	12

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Amendment/Req. Reconsideration-After Non-Final Reject	1	1
	Specification	2	2
	Miscellaneous Incoming Letter	3	3
	Claims	4	7
	Applicant Arguments/Remarks Made in an Amendment	8	12

Warnings:					
Information:					
2	Drawings-only black and white line drawings	00366710.PDF	1219504 013bec96464d2bdeaa7e9028a08713e1a30a39f9	no	1
Warnings:					
Information:					
3	Power of Attorney	00366950.PDF	582610 08d0b6c3cc2dba46d9681e858afb18e07f8fb13a	no	1
Warnings:					
Information:					
4	Terminal Disclaimer Filed	00366967.PDF	53497 d90d80033ea26c52c0f4a8bab2effbaab1fe0416	no	1
Warnings:					
Information:					
5	Transmittal Letter	00366968.PDF	17930 e14a978380b63e33338e17112a44ee5b517bc483	no	1
Warnings:					
Information:					
6	Information Disclosure Statement (IDS) Form (SB08)	00366972.PDF	28881 0abfaed96efc5d804a69572b2203ff8c98af9a16	no	1
Warnings:					
Information:					
This is not an USPTO supplied IDS fillable form					

7	Non Patent Literature	00347663.PDF	176822 08c730174749647588a5186666f765936db33ac3	no	6
Warnings:					
Information:					
8	Fee Worksheet (SB06)	fee-info.pdf	31899 8004813a4bc32cda2ea435e6294f2d9ee9a051ff	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	2179441		

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/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.

PTO/SB/26 (07-09)
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.

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 3000-US-0026

In re Application of: Duncan P. Bathe, et al

Application No.: 13/509,873

Filed: January 6, 2011

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 **prior patent** No. 8,291,904 B2 as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patent** is presently shortened by any terminal disclaimer. 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 the **prior patent** 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 the term 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 the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

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 presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

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
June 17, 2013 — Date

Rory P. Alegria — Typed or printed name

732 815-0404 — Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Duncan P. Bathe et al.	Examiner:	Tsai, Michael Jasper
Serial No.:	13/509,873	Group Art Unit:	3771
Filed:	January 6, 2011	Docket:	3000-US-0026
Title:	Gas Delivery Device And System	Confirmation No.:	8620

SUPPLEMENTAL 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 Supplemental 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.

Pursuant to 37 C.F.R. §1.97(c)(2), Applicants have included the fee of $90.00 as set forth in 37 C.F.R. §1.17(p). Please charge any additional fees or credit any overpayment to Deposit Account No. 50-3329. 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,

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

Date June 17, 2013

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

PTO/SB/06 (09-11)
Approved for use through 1/31/2014. 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 13/509,873	Filing Date 06/11/2012	☐ To be Mailed

ENTITY: ☐ LARGE ☒ SMALL ☐ MICRO

APPLICATION AS FILED – PART I

	(Column 1)	(Column 2)		
FOR	NUMBER FILED	NUMBER EXTRA	RATE ($)	FEE ($)
☐ BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	
☐ SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	
☐ EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X $ =	
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	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 $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).			
☐ 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	

APPLICATION AS AMENDED – PART II

AMENDMENT	06/17/2013	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE ($)	ADDITIONAL FEE ($)
	Total (37 CFR 1.16(i))	* 7	Minus	** 20	= 0	X $40 =	0
	Independent (37 CFR 1.16(h))	* 4	Minus	***4	= 0	X $210 =	0
	☐ Application Size Fee (37 CFR 1.16(s))						
	☐ FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))						
						TOTAL ADD'L FEE	0

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

LIE
/DENISE LILES/

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	13/509,873	BATHE ET AL.	

Document Code - DISQ	**Internal Document – DO NOT MAIL**

TERMINAL DISCLAIMER	☐ APPROVED	☒ DISAPPROVED
Date Filed : 06/17/2013	**This patent is subject to a Terminal Disclaimer**	

Approved/Disapproved by:

Dorethea Lawrence

A copy of this form P/A, 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 fhis form is used. A new TD. No FEE is required.

U.S. Patent and Trademark Office

PTO/SB/26 (07-09)
Approved for use through 07/31/2012. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) 3000-US-0026

In re Application of: Duncan P. Bathe, et al

Application No.: 13/509,873

Filed: January 6, 2011

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 **prior patent** No. 8,291,904 B2 as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patent** is presently shortened by any terminal disclaimer. 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 the **prior patent** 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 the term 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 the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

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 presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

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
June 20, 2013 — Date

Rory P. Alegria — Typed or printed name

732 815-0404 — Telephone Number

☐ Terminal disclaimer fee under 37 CFR 1.20(d) included. was submitted on 6-17-13

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner).
Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

PTO/SB/96 (01-09)
Approved for use through 02/28/2009. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: Bathe

Application No./Patent No.: 13/509,873 Filed/Issue Date: January 6, 2011

Titled: Gas Delivery Device and System

INO Therapeutics LLC , a Corporation

(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:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

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

2. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

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

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at

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/ — Signature

June 20, 2013 — Date

Rory P. Alegria — Printed or Typed Name

Attorney — Title

Electronic Acknowledgement Receipt	
EFS ID:	16103847
Application Number:	13509873
International Application Number:	
Confirmation Number:	8620
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-0026(IKA0011-00US
Receipt Date:	20-JUN-2013
Filing Date:	11-JUN-2012
Time Stamp:	15:59:55
Application Type:	U.S. National Stage under 35 USC 371

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	Terminal Disclaimer Filed	00368041.PDF	56079 b7d0d18a2776ce9782e8dca4b19f152820a8891a	no	1
Warnings:					
Information:					

2	Assignee showing of ownership per 37 CFR 3.73.	00368040.PDF	31894 cf3573a82cdc7e8ab11e89fda8dd1240eec83df7	no	1

Warnings:	
Information:	
Total Files Size (in bytes):	87973

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.

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	13/509,873	BATHE ET AL.	

Document Code - DISQ	Internal Document – DO NOT MAIL

TERMINAL DISCLAIMER	☒ APPROVED	☐ DISAPPROVED
Date Filed : 20 JUN 2013	This patent is subject to a Terminal Disclaimer	

Approved/Disapproved by:
JAB

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

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/509,873	06/11/2012	Duncan P. Bathe	3000-US-0026(IKA0011-00US

CONFIRMATION NO. 8620

IMPROPER CPOA LETTER

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

OC000000062118102

Date Mailed: 06/28/2013

NOTICE REGARDING POWER OF ATTORNEY

This is in response to the power of attorney filed 06/17/2013. The power of attorney in this application is not accepted for the reason(s) listed below:

- The power of attorney is from an assignee and the statement required by 37 CFR 3.73(c) has not been received.

/ddinh/

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

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	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
13/509,873	06/11/2012	Duncan P. Bathe	3000-US-0026(IKA0011-00US

CONFIRMATION NO. 8620

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

POA ACCEPTANCE LETTER

OC000000062280334

Date Mailed: 07/01/2013

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 06/20/2013.

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.

/tnnguyen/

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

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 08/19/2013

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

EXAMINER
TSAI, MICHAEL JASPER

ART UNIT	PAPER NUMBER
3771	

DATE MAILED: 08/19/2013

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/509,873	06/11/2012	Duncan P. Bathe	3000-US-0026(IKA0011-00US	8620

TITLE OF INVENTION: GAS DELIVERY DEVICE AND SYSTEM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$890	$300	$0	$1190	11/19/2013

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 ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

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 08/19/2013
SERVILLA WHITNEY 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.
13/509,873	06/11/2012	Duncan P. Bathe	3000-US-0026(IKA0011-00US	8620

TITLE OF INVENTION: GAS DELIVERY DEVICE AND SYSTEM

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$890	$300	$0	$1190	11/19/2013

EXAMINER	ART UNIT	CLASS-SUBCLASS
TSAI, MICHAEL JASPER	3771	128-205240

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)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see form PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

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
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/509,873	06/11/2012	Duncan P. Bathe	3000-US-0026(IKA0011-00US	8620

48394 7590 08/19/2013

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

EXAMINER	
TSAI, MICHAEL JASPER	

ART UNIT	PAPER NUMBER
3771	

DATE MAILED: 08/19/2013

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. 13/509,873	Applicant(s) BATHE ET AL.	
	Examiner Michael Tsai	Art Unit 3771	AIA (First Inventor to File) Status No

-- 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 *6/17/2013*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
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 *2-5,7,9 and 10*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   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. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ 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).
6. ☐ 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. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 6/17/2013
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
5. ☐ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/Michael Tsai/ Examiner, Art Unit 3771	/Justine R Yu/ Supervisory Patent Examiner, Art Unit 3771

Reasons for Allowance

1. The following is an examiner's statement of reasons for allowance: Examiner found the arguments to claims 2-5, 7, 9, and 10 presented in the remarks filed on 6/17/2013 on pages 10-12 to be convincing.

2. The closest prior art of record Peters (7,114,510) discloses a valve with a smart handle including a memory module, a processor, and a transceiver. Peters also discloses that the memory is able to store gas data comprising gas identification. Peters also discloses that the processor and transceiver for communicating gas data to a control module. However, Peters fails to disclose, teach, or fairly suggest a circuit including a processor and transceiver that is able to communicate with the memory to send and receive wireless signals to communicate the gas data to the control module that controls gas delivery to a subject and to verify one or more of the correct gas, the correct gas concentration and that the gas is not expired. Therefore, claims 2-5, 7, 9, and 10 have been found allowable since any conclusion of obviousness would be based upon improper hindsight reasoning using knowledge gleaned only from the applicant's disclosure.

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."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Tsai whose telephone number is (571)270-5246. The examiner can normally be reached on Monday thru Friday, 7:30am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. 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.

/Michael Tsai/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771

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	13/509,873
Filing Date	Jan 6, 2011
First Named Inventor	Duncan P. Bathe
Art Unit	3771
Examiner Name	Tsai, Michael Jasper

Submitted: June 17, 2013

Sheet	1	of	1

Attorney Docket No: 3000-US-0026

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 RelevantFigures Appear
		20020044059	Apr 18, 2002	Reeder, Ryan A., et al.	
		20110041849	Feb 24, 2011	Chen, Bo et al.	
		20110240019	Oct 6, 2011	Fine, David H., et al.	
		6089229	Jul 18, 2000	Bathe, Duncan P., et al.	
		8291904	Oct 23, 2012	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 RelevantFigures 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]
		First Action Interview Pilot Program Pre-Interview Communication, dated March 20, 2013, 6 pgs.	

EXAMINER /Michael Tsai/ **DATE CONSIDERED** 08/07/2013

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. [2] Applicant's unique citation designation number (optional) [3] Applicant is to place a check mark here if English language Translation is attached

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

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13509873	BATHE ET AL.
	Examiner	**Art Unit**
	MICHAEL TSAI	3771

✓	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	03/07/2013	08/07/2013							
	1	-	-							
	2	✓	=							
	3	✓	=							
	4	✓	=							
	5	✓	=							
	6	-	-							
	7	✓	=							
	8	-	-							
	9	✓	=							
	10	✓	=							
	11	-	-							
	12	-	-							
	13	-	-							
	14	-	-							
	15	-	-							
	16	-	-							
	17	-	-							
	18	-	-							

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13509873	BATHE ET AL.
	Examiner	**Art Unit**
	MICHAEL TSAI	3771

CPC		
Symbol	**Type**	**Version**

CPC Combination Sets				
Symbol	**Type**	**Set**	**Ranking**	**Version**

/MICHAEL TSAI/ Examiner.Art Unit 3771	8/7/2013	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	7	
/JUSTINE YU/ Supervisory Patent Examiner.Art Unit 3771	08/11/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13509873	BATHE ET AL.
	Examiner	**Art Unit**
	MICHAEL TSAI	3771

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
128	205.24

CROSS REFERENCE(S)

CLASS	SUBCLASS (ONE SUBCLASS PER BLOCK)				
128	203.14	204.21			

INTERNATIONAL CLASSIFICATION					
CLAIMED					**NON-CLAIMED**
A	6	2	B	9 / 02 (2006.01.01)	
F	1	6	K	31 / 02 (2006.01.01)	

/MICHAEL TSAI/ Examiner.Art Unit 3771	8/7/2013	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	7	
/JUSTINE YU/ Supervisory Patent Examiner.Art Unit 3771	08/11/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13509873	BATHE ET AL.
	Examiner	**Art Unit**
	MICHAEL TSAI	3771

☐ 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
	1		17												
1	2		18												
2	3														
3	4														
4	5														
	6														
5	7														
	8														
6	9														
7	10														
	11														
	12														
	13														
	14														
	15														
	16														

/MICHAEL TSAI/ Examiner.Art Unit 3771	8/7/2013	**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	7	
/JUSTINE YU/ Supervisory Patent Examiner.Art Unit 3771	08/11/2013	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	1

U.S. Patent and Trademark Office Part of Paper No. 20130807

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	13509873	BATHE ET AL.
	Examiner	Art Unit
	MICHAEL TSAI	3771

CPC- SEARCHED		
Symbol	Date	Examiner

CPC COMBINATION SETS - SEARCHED		
Symbol	Date	Examiner

US CLASSIFICATION SEARCHED			
Class	Subclass	Date	Examiner
128	203.12, 203.14, 204.18, 204.21-201.23, 205.24	3/5/2013	MT
	updated search	7/29/2013	MT

SEARCH NOTES		
Search Notes	Date	Examiner
PLUS search requested	2/26/2013	MT
Inventor name and assignee searched	3/5/2013	MT
Consulted Kristin Matter regarding class 128 (suggested subclasses 203.12, 203.14, 204.18, 204.21-201.23, 205.24)	3/5/2013	MT

INTERFERENCE SEARCH			
US Class/ CPC Symbol	US Subclass / CPC Group	Date	Examiner
	PGPubs database searched. See: East printout.	8/7/2013	MT

/M.T./ Examiner.Art Unit 3771	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
S1	32	((DUNCAN) near2 (BATHE)).INV.	US-PGPUB; USPAT	OR	ON	2013/03/05 09:27
S2	19	((JOHN) near2 (KLAUS)).INV.	US-PGPUB; USPAT	OR	ON	2013/03/05 09:27
S3	81	((DAVID) near2 (CHRISTENSEN)).INV.	US-PGPUB; USPAT	OR	ON	2013/03/05 09:27
S4	6	("20050172966" | "20090266358" | "6109260" | "6125846" | "6164276" | "6581592").PN.	US-PGPUB; USPAT	OR	ON	2013/03/05 09:33
S5	7039	(128/204.18,204.21-204.23,205.24,203.12,203.14).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/03/05 09:58
S6	174074	(valve regulator (flow near2 control$3)) and (data information info statistic record) with (memory storage retention RAM ROM) and (processor CPU (process$3 near2 (unit element component module)))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 10:14
S8	1473	S6 and "128".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 10:17
S9	16007	(valve regulator (flow near2 control$3)) same (data information info statistic record) with (memory storage retention RAM ROM) same (processor CPU (process$3 near2 (unit element component module)))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 10:18
S11	264	("4493706" | "4551133" | "4553958" | "4559038" | "4559040" | "4565542" | "4573994" | "4650469" | "4653987" | "4671792" | "4681566" | "4762518" | "4798590" | "4853521" | "4925444" | "4966579" | "4976590" | "4978335" | "4997347").PN. OR ("5078683").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 11:37
S12	34066	(valve regulator (flow near2 control$3)) same (programmable (execute with instruction))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 12:43
S13	17862	(valve regulator (flow near2 control$3)) with (programmable (execute with instruction))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 12:44

S14	14888	(valve regulator) with (programmable (execute with instruction))	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 12:45
S15	169	S14 and "128".clas.	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 12:45
S16	218	("1853811" | "2672051" | "2767277" | "2880909" | "2907325" | "3543752" | "3559644" | "3620650" | "3749285" | "3798982" | "3874826" | "3884228" | "3901231" | "3923060" | "3941126" | "3982534" | "4030495" | "4037598" | "4056333" | "4077405" | "4094318" | "4126132" | "4142523" | "4191181" | "4191183" | "4191184" | "4204538" | "4207871" | "4236522" | "4236880" | "4261356" | "4265240" | "4270532" | "4276004" | "4282872" | "4303376" | "4308866" | "4316460" | "4324238" | "4336800" | "4373527" | "4391598" | "4392847" | "4395259" | "4411651" | "4432754" | "4460353" | "4464170" | "4468222" | "4475901" | "4503841" | "4553958" | "4561443" | "4563173" | "4624661" | "4685903" | "4731051" | "4776842").PN. OR ("5100380").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 12:46
S17	5	(("6089229") or ("20090266358") or ("20110240019") or ("20020044059") or ("20110041849")).PN.	US-PGPUB; USPAT	OR	OFF	2013/03/05 12:56
S18	386	(valve regulator) with (programmable (execute with instruction)) same (transmitter transceiver)	US-PGPUB; USPAT; EPO; JPO; DERWENT	OR	ON	2013/03/05 13:26
S19	16	("20030140921" | "20030196666" | "20040173214" | "20050038674" | "20070272240" | "4340045" | "5069220" | "5088332" | "5337738" | "5950621" | "6035851" | "6089105" | "6119686" | "7101341").PN. OR ("7980245").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 14:01
S20	69	("4221219" | "4303376" | "4515588" | "4714462" | "4838887" | "4936758").PN. OR ("5049141").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 14:07
S21	0	(08/122126).APP.	US-PGPUB; USOCR	OR	ON	2013/03/05 14:19
S22	82	("4604847" | "4984158" | "5020527" | "5167506" | "5284133" | "5363842" | "5392768" | "5394866").PN. OR ("5505195").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 14:19
S23	14	("4176617" | "4536756" | "4800373" | "4990894" | "5040477" | "5057822" | "5357242" | "5542287" | "5868162" | "5893944" | "6137417").PN. OR ("6326896").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 14:22

S24	3	("2002/0013551").URPN.	USPAT	OR	ON	2013/03/05 14:22
S25	203	(sensor) same timer same duration with (open close)	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 14:37
S26	20	(ino near2 therapeutic).as.	US-PGPUB; USPAT; USOCR	OR	ON	2013/03/05 15:28
S28	7215	valve with (transmitter Transceiver)	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/05 16:23
S29	83	S28 and "128".clas.	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/05 16:23
S30	90	S28 same gas same data	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/05 16:30
S31	0	S30 not S28	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/05 16:30
S32	86	S30 not S29	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/05 16:31
S33	571	S28 same gas with (data information pressure propert$3 parameter)	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/05 16:35
S34	102	S28 same gas with (data information pressure propert$3 parameter) same ((control$3 near (unit element module device)) computer)	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/05 16:39
S35	3948	(128/204.18,204.21-204.23).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/03/07 12:52
S36	3874	(128/205.24,203.12,203.14).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/03/07 12:52
S37	1	("5558083").PN.	US-PGPUB; USPAT	OR	OFF	2013/03/07 13:17
S38	1214	ventilator and control with (unit module) and "128".clas.	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/03/07 15:16
S40	10125	"128".clas. and gas with (data information pressure propert$3 parameter)	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/07/29 14:06
S41	2	"128".clas. and gas with (data information pressure propert$3 parameter) same (verify confirm	US-PGPUB; USPAT;	OR	ON	2013/07/29 14:17

		authenticate validate) same valve and (transmitter transceiver)	EPO; JPO			
S42	77	gas with (data information pressure propert$3 parameter) same (verify confirm authenticate validate) same valve and (transmitter transceiver)	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/07/29 14:17
S43	1331	gas with (data information pressure propert$3 parameter) same (verify confirm authenticate validate identify) and (transmitter transceiver)	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/07/29 14:50
S44	155	gas with (data information pressure propert$3 parameter) same (verify confirm authenticate validate identify) same(transmitter transceiver)	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/07/29 14:50
S45	209	(data information pressure propert$3 parameter) same (verify confirm authenticate validate identify) same(transmitter transceiver) same valve	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/07/29 15:25
S46	110	"128".clas. and gas with (data information pressure propert$3 parameter) same (verify confirm authenticate validate)	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/07/29 15:35
S49	7295	(128/204.18,204.21-204.23,205.24,203.12,203.14).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/07/29 15:50
S50	5021	S49 and valve	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/07/29 15:51
S51	311	S49 and valve and gas with (verif$3 verification confirm$3 confirmation authenticat$3 validat$3 validification identif$3 identification)	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/07/29 15:54
S52	5	US-20020044059-$.DID. OR US-20110041849-$.DID. OR US-20110240019-$.DID. OR US-6089229-$.DID. OR US-8291904-$.DID.	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/07/29 15:59
S53	1035	(251/129.04).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/07/30 11:00
S54	1697	(700/282).CCLS.	US-PGPUB; USPAT	OR	OFF	2013/07/30 11:00
S55	268	(S53 S54) and valve with (memory (data near2 storage))	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/07/30 13:47
S56	15	("5202666" | "5409037" | "5441070" | "5680329" | "5945910" | "6003170" | "6236317").PN. OR ("7114510").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2013/07/30 13:51
S57	28	(S53 S54) and valve with (memory (data near2 storage)) and (gas fluid liquid solution) with (identif$3 identification)	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/07/30 14:05
S58	31	"128".clas. and valve with (memory (data near2 storage)) and (gas fluid	US-PGPUB;	OR	ON	2013/07/30 14:07

		liquid solution medicine medication medicament drug) with (identif$3 identification)	USPAT; EPO; JPO			
S59	28	(S53 S54) and valve with (memory (data near2 storage)) and (gas fluid liquid solution medicine medication medicament drug) with (identif$3 identification)	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/07/30 14:08
S60	42	(S53 S54) and valve same (memory (data near2 storage)) and (gas fluid liquid solution medicine medication medicament drug) with (identif$3 identification)	US-PGPUB; USPAT; EPO; JPO	OR	ON	2013/07/30 14:08

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	0	(valve and (circuit$4) and (processor CPU (process$3 near2 (unit module element device) computer)) and (memory storage) and (transceiver (transmitter and receiver)) and (verif$3 identif$3 confirm$3 validate$3) with gas).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2013/08/07 21:40
L2	100	(valve and (circuit$4) and (processor CPU (process$3 near2 (unit module element device) computer)) and (memory storage) and (transceiver (transmitter and receiver))).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2013/08/07 21:40
L3	25	(valve and (circuit$4) and (processor CPU (process$3 near2 (unit module element device) computer)) and (memory storage) and (transceiver (transmitter and receiver)) and gas).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2013/08/07 21:42

8/7/2013 9:52:06 PM
C:\Users\mtsai1\Documents\EAST\Workspaces\13509873.wsp

UNITED STATES PATENT AND TRADEMARK OFFICE
COMMISSIONER FOR PATENTS
P.O.BOX 1450
ALEXANDRIA VA 22313-1451

PRESORTED
FIRST-CLASS MAIL
U.S. POSTAGE PAID
POSTEDIGITAL
NNNNN

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

Courtesy Reminder for
Application Serial No: 13/509,873

Attorney Docket No:
3000-US-0026(IKA0011-00US
Customer Number: 48394
Date of Electronic Notification: 08/19/2013

This is a courtesy reminder that new correspondence is available for this application. If you have not done so already, please review the correspondence. The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

An email notification regarding the correspondence was sent to the following email address(es) associated with your customer number:

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

To view your correspondence online or update your email addresses, please visit us anytime at **https://sportal.uspto.gov/secure/myportal/privatepair.** If you have any questions, please email the Electronic Business Center (EBC) at EBC@uspto.gov or call 1-866-217-9197.

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)

Servilla Whitney 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.
13/509,873	06/11/2012	Duncan P. Bath	3000-US-00026	8620

TITLE OF INVENTION:

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$890	$300	$0	$1190	11/19/2013

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 Servilla Whitney 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 October 1, 2013

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
	13/509.873

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_____

October 1, 2013
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:	13509873
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-0026(IKA0011-00US

Filed as Small Entity

U.S. National Stage under 35 USC 371 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	890	890
Publ. Fee- Early, Voluntary, or Normal	1504	1	300	300

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**1190**

Electronic Acknowledgement Receipt	
EFS ID:	17003459
Application Number:	13509873
International Application Number:	
Confirmation Number:	8620
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-0026(IKA0011-00US
Receipt Date:	01-OCT-2013
Filing Date:	11-JUN-2012
Time Stamp:	11:07:58
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$1190
RAM confirmation Number	16270
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)	00388186.PDF	39695 ce64e0c1f53d9a8952e1b981c20855884803bba1	no	1
Warnings:					
Information:					
2	Miscellaneous Incoming Letter	00388185.PDF	34650 30d71b0e6d5223284e995107435141e47c8a46ea	no	1
Warnings:					
Information:					
3	Fee Worksheet (SB06)	fee-info.pdf	32123 fe7b5dc8c96b4248908f87cea476b1a4aecee05f	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	106468		

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
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
13/509,873	11/05/2013	8573209	3000-US-0026(IKA0011-00US	8620

48394 7590 10/16/2013

SERVILLA WHITNEY 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;

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Duncan P. Bathe, et al.	Examiner:	Tsai, Michael Jasper
Serial No.:	13/509,873	Group Art Unit:	3771
Filed:	Jan. 6, 2011	Docket:	3000-US-0026
		Conf. No.:	8620
Title:	Gas Delivery Device And System		

PETITION FOR REPLACEMENT LETTERS PATENT UNDER 37 C.F.R. § 1.182

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

Dear Sir:

I, Karen M. Whitney, attorney for the patent holder INO Therapeutics LLC, respectfully request a replacement Letters Patent for U.S. Patent No. 8,573,209, issued on Nov. 5, 2013. The reason for this request is that the original Letters Patent was irreparably damaged in an office fire on or about Jan. 22, 2014.

The fee for this Petition in the amount of $200.00 (small entity), as set forth in 37 C.F.R. § 1.17(f), is submitted with the filing of this Petition. Please charge any additional fees or credit any overpayment to Deposit Account No. 50-3329.

INO Therapeutics LLC has previously filed a completed Power of Attorney and Correspondence Address Indication Form. Accordingly, please address all correspondence relating to this Petition, including the replacement Letters Patent if this Petition is granted, to the address listed below.

Respectfully submitted,

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

Date Mar. 28, 2014 By /Karen M. Whitney, Reg. No. 52,355/
Karen M. Whitney
Reg. No. 52,355

Electronic Patent Application Fee Transmittal

Application Number:	13509873
Filing Date:	11-Jun-2012
Title of Invention:	GAS DELIVERY DEVICE AND SYSTEM
First Named Inventor/Applicant Name:	Duncan P. Bathe
Filer:	Karen M. Whitney/Rachel Lackert
Attorney Docket Number:	3000-US-0026(IKA0011-00US

Filed as Small Entity

U.S. National Stage under 35 USC 371 Filing Fees

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Petition Fee - 37 CFR 1.17(F)(Group I)	2462	1	200	200
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
			Total in USD ($)	**200**

Electronic Acknowledgement Receipt	
EFS ID:	18610029
Application Number:	13509873
International Application Number:	
Confirmation Number:	8620
Title of Invention:	GAS DELIVERY DEVICE AND SYSTEM
First Named Inventor/Applicant Name:	Duncan P. Bathe
Customer Number:	48394
Filer:	Karen M. Whitney/Linda Murphy
Filer Authorized By:	Karen M. Whitney
Attorney Docket Number:	3000-US-0026(IKA0011-00US
Receipt Date:	28-MAR-2014
Filing Date:	11-JUN-2012
Time Stamp:	16:29:50
Application Type:	U.S. National Stage under 35 USC 371

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	$200
RAM confirmation Number	2984
Deposit Account	
Authorized User	

File Listing:

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

1	Petition for review by the Office of Petitions.	00430060.PDF	18586 45962cdadf39aa61d814e5d127f5e176cb4445a5	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	30565 8b12616da0ce63a439959e3fb542e93414ab0cdc	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	49151		

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.

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

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

MAILED
APR 08 2014
OFFICE OF PETITIONS

In re Patent No. 8,573,209
Issue Date: November 5, 2013
Application No. 13/509,873
Inventor: Bathe et al.
Filed: June 11, 2012
Attorney Docket No. 3000-US-0026(IKA0011-00US
Title: GAS DELIVERY DEVICE AND SYSTEM

DECISION ON PETITION
PURSUANT TO
37 C.F.R. § 1.182

This is a decision on the petition filed on March 28, 2014, pursuant to 37 C.F.R. § 1.182, requesting issuance of a duplicate Letters Patent for the above-identified patent.

The file record discloses that application No. 13/509,873 matured into U.S. Patent No. 8,573,209 on November 5, 2013. The electronic records further reveal that on that same date, the Patent Grant was mailed to the address of record. However, Petitioner requests a duplicate, asserting that the Letters Patent "was irreparably damaged in an office fire." Receipt of the $200 petition fee is acknowledged.

The petition is **GRANTED.**

The Publishing Division is directed to issue a duplicate Letters Patent.

The Publishing Division (which may be reached at 571-272-4200) will be made aware of this decision in due course. Telephone inquiries regarding this decision should be directed to the undersigned at (571) 272-3225.

/Paul Shanoski/
Paul Shanoski
Attorney Advisor
Office of Petitions