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Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

— *as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))*

— *of inventorship (Rule 4.17(iv))*

[Continued on next page]

(54) Title: PNEUMATICALLY COUPLED FLUID CONTROL SYSTEM AND PROCESS WITH AIR DETECTION AND ELIMINATION

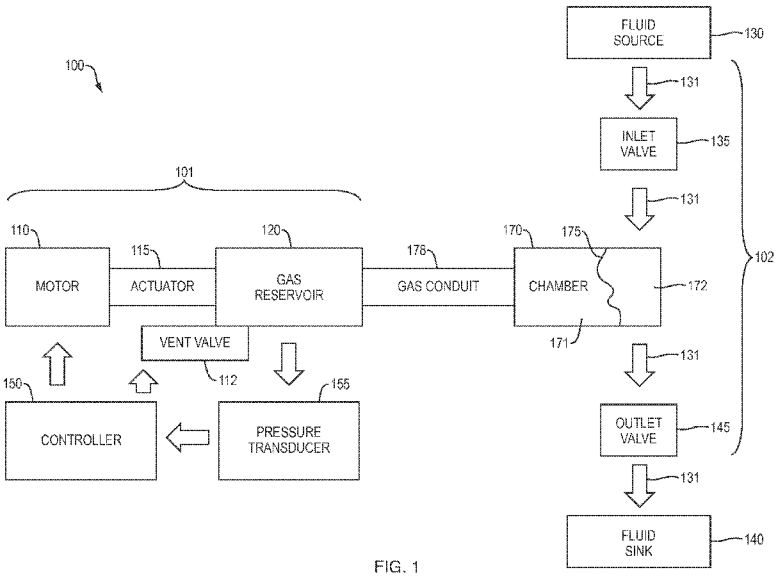

FIG. 1

(57) Abstract: A fluid control system for delivery of a liquid includes a pneumatic drive that incorporates a linear actuator to effect known volume changes in a gas reservoir. The gas reservoir is in fluid communication with a gas-side reservoir that is separated from a fluid-side reservoir by a flexible membrane. Movement of the linear actuator effects positive or negative volume differences on the gas in the gas-side reservoir, resulting in a decrease or increase in pressure of the gas that is transmitted to the fluid-side reservoir to draw fluid, primarily liquid, in from a source or deliver liquid out to a sink. In another aspect, a mechanism is provided for the detection and elimination of air bubbles in the fluid path.

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Published:

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

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(88) Date of publication of the international search report:
29 January 2015

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US14/39211

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/50; A61M 1/14; B01D 61/32, (2014.01)
CPC - A61M 1/0058, 5/36; B01D 15/08
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8): A61B 17/50; A61M 1/14; B01D 61/32 (2014.01)
CPC: A61M 1/0058, 5/36; B01D 15/08; USPC: 210/636, 645, 646, 650; 604/30, 67, 123

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); Proquest; Espacenet; Google/Google Scholar; Medline/PubMed; Search terms used: captured, entrapped, contained, residual, remaining, fluid, liquid, solvent, hydrophobic, filter, membrane, negative, reduced, pressure, sensor, air-side, liquid-side, controller, volume, chang*, inlet, outlet, valve, pneumatic, etc.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 8409441 B2 (WILT, MJ) April 2, 2013; figures 2B, 3A, 11A; column 19, lines 25-35; column 21, lines 60-67; column 22, lines 1-11; column 26, lines 26-42; column 29, lines 26-50; column 52, line 5 to column 53, line 42	1-4, 6, 8-11
Y	US 2006/0149211 A1 (SIMPSON, PJ et al.) July 6, 2006; figure 7; paragraph [0043]	1-4, 6
Y	US 2011/0028937 A1 (POWERS, BG et al.) February 3, 2011; paragraph [0034]	8-11
Y	US 7654982 B2 (CARLISLE, JA et al.) February 2, 2010; figure 3-4; column 4, lines 3-7; column 4, lines 53-60; column 5, lines 1-22, 32-67; column 6, lines 1-15; column 9, lines 7-61	4
A	US 8382771 B2 (DUDAR, T et al.) February 26, 2013; column 9, lines 1-15; column 15, lines 1-26	5, 7

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

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

Date of the actual completion of the international search	Date of mailing of the international search report
18 November 2014 (18.11.2014)	09 DEC 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US14/39211

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

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

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

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

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

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-7 are directed toward a fluid control system for delivery of a fluid.

Group II: Claims 8-11 are directed toward a process for determining presence of air in an infusion of fluid from a fluid source to a liquid sink.

-***-Continued Within the Next Supplemental Box-***-

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

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

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

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

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US14/39211

-***-Continued from Box No. III - Observations where unity of invention is lacking-***-

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I include a pneumatic drive in communication with the gas-side chamber to provide known incremental positive or negative volume changes that cause positive or negative pressure changes in the gas-side chamber, and wherein said pressure changes in the gas-side chamber are communicated to the fluid-side chamber via the flexible membrane; and an air elimination mechanism comprising hydrophobic filter comprising a first side disposed in communication with the fluid-side chamber, and a second side disposed in communication with a one-way valve, the hydrophobic filter blocking flow of liquid therethrough and allowing passage of air therethrough, which are not present in Group II; the special technical features of Group II include determining volumes of fluid in the fluid-side chamber from incremental changes in volume of the gas reservoir and the gas-side chamber and any connecting dead space by an ideal gas law relationship, wherein P1V1=P2V2 , wherein P1 and P2 are pressures measured at two times before and after volume changes and V1 and V2 are volumes at the two times, which are not present in Group I.

The common technical features of Groups I and II are a fluid source; a fluid/liquid sink; and a chamber comprising a fluid-side chamber and a gas-side chamber, the fluid- side chamber and the gas-side chamber separated by a flexible membrane.

These common technical features are disclosed by US 2011/0028937 A1 to Powers, et al. (hereinafter Powers). Powers discloses a fluid source (fluid from fluid source flows through inlets 5 or 6 and enters the chamber 19; figure 1b; paragraphs [0028], [0041]); a fluid/liquid sink (fluid travels to the patient (fluid sink) connection through the outlet 8; figure 1b; paragraph [0028]); and a chamber comprising a fluid-side chamber (26; figure 5a; paragraph [0043]) and a gas-side chamber (27; figure 5a; paragraph [0042]), the fluid- side chamber and the gas-side chamber separated by a flexible membrane (25; figure 5a; paragraph [0042]).

Since the common technical features are previously disclosed by the Powers reference, the common features are not special and so Groups I and II lack unity.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I include a pneumatic drive in communication with the gas-side chamber to provide known incremental positive or negative volume changes that cause positive or negative pressure changes in the gas-side chamber, and wherein said pressure changes in the gas-side chamber are communicated to the fluid-side chamber via the flexible membrane; and an air elimination mechanism comprising hydrophobic filter comprising a first side disposed in communication with the fluid-side chamber, and a second side disposed in communication with a one-way valve, the hydrophobic filter blocking flow of liquid therethrough and allowing passage of air therethrough, which are not present in Group II; the special technical features of Group II include determining volumes of fluid in the fluid-side chamber from incremental changes in volume of the gas reservoir and the gas-side chamber and any connecting dead space by an ideal gas law relationship, wherein P1V1=P2V2 , wherein P1 and P2 are pressures measured at two times before and after volume changes and V1 and V2 are volumes at the two times, which are not present in Group I.

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