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- (71) Applicant (for all designated States except US):  
NXSTAGE MEDICAL, INC. [US/US]; 439 South Union Street, Fifth Floor, Lawrence, MA 01843 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): BURBANK, Jeffrey, H. [US/US]; 18 Sunrise Road, Boxford, MA 01920 (US). BRUGGER, James, M. [US/US]; 4 Savory Street, Newburyport, MA 01950 (US). TREU, Dennis, M. [US/US]; 8 Twin Brook Lane, Bedford, NH 03110 (US). WYETH, Mark, T. [US/US]; 10492 Allante Court, Gibsonia, PA 15044 (US).
- (74) Agents: CATAN, Mark, A. et al.; Miles & Stockbridge P.C., 1751 Pinnacle Drive, Suite 500, McLean, VA 22102-3833 (US).

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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:  
15 November 2012

(54) Title: PERITONEAL DIALYSIS SYSTEMS, DEVICES, AND METHODS

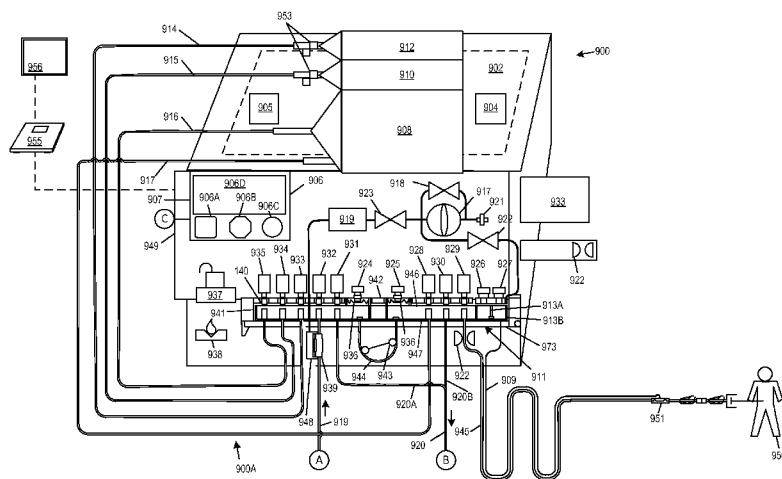


Fig. 8A

(57) Abstract: An automated peritoneal dialysis system provides various features including prescription-driven dialysis fluid preparation, an integrated disposable fluid circuit, and sensor capabilities that allow accurate filling and draining control with high safety margins. Features include a peritoneal fluid circuit with a pressure sensor at either end and methods and devices for using the pressure signals. Other features and embodiments are disclosed.

WO 2012/129501 A3

**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/US2012/030350

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(8) - A61M 1/28 (2012.01)

USPC - 604/29

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 19/00; A61M 1/00, 1/14, 1/28 (2012.01)

USPC - 210/321.71, 646; 604/5.01, 5.04, 27, 28, 29, 30, 31, 65, 66, 67

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)

PatBase, Google Patent, Google, ProQuest

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/0004590 A1 (HEDMANN et al) 07 January 2010 (07.01.2010) entire document	1-3, 122-123
Y		8-10, 14-16, 19-20, 22-24, 26-30, 37, 124
X	US 2010/0204765 A1 (HALL et al) 12 August 2010 (12.08.2010) entire document	31-36
Y	US 2002/0120227 A1 (CHILDERS et al) 29 August 2002 (29.08.2002) entire document	8-10, 124
Y	US 2004/0221643 A1 (EHWALD et al) 11 November 2004 (11.11.2004) entire document	14-16
Y	US 2007/0179422 A1 (SCHNELL et al) 02 August 2007 (02.08.2007) entire document	19-20
Y	US 7,842,002 B2 (MANTLE) 30 November 2010 (30.11.2010) entire document	22-24, 29-30, 37
Y	US 5,141,493 A (JACOBSEN et al) 25 August 1992 (25.08.1992) entire document	26-28
Y	US 3,786,810 A (PANNIER JR et al) 22 January 1974 (22.01.1974) entire document	26-28

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

27 August 2012

Date of mailing of the international search report

**13 SEP 2012**

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:

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300  
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2012/030350

**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.: 4-7,11-13,17-18,21,25,41-54,58,59,63-66,68-71,77,81,85-86,90-92,96-100,104-106,110-113,125-131,135-137  
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 Continuation Sheet Attached

- 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  
Information on patent family members

International application No.

PCT/US2012/030350

(CONTINUATION OF BOX III)

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 1-3, 8-10, 14-16, 19, 20, 22-24, 26-37 and 122-124 are drawn to a method of performing a dialysis treatment.

Group II, claims 38-40 and 55-57 are drawn to a method of performing a peritoneal dialysis treatment.

Group III, claims 60-62 and 67 are drawn to a peritoneal dialysis disposable unit.

Group IV, claims 72-76 are drawn to a peritoneal dialysis device.

Group V, claims 78-80 are drawn to a method of performing peritoneal dialysis treatment.

Group VI, claims 82-84, 87-89, 93-95 and 114-116 are drawn to a method of performing a dialysis treatment.

Group VII, claims 101-103 and 107-109 are drawn to a disposable fluid circuit.

Group VIII, claims 132-134 are drawn to a fluid flow system for peritoneal dialysis.

The inventions listed as Groups I - VIII 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, using a dialysate supply line, generating proximal and distal pressure signals using pressure detectors; supplying peritoneal dialysis fluid at a rate that is responsive to the distal pressure signal, are not present in Groups II-VIII; the special technical features of Group II, connecting a disposable unit to a source of water, said disposable unit including at least a first container holding a sterile concentrate containing an osmotic agent; using the controller, pumping a quantity of the concentrated osmotic agent that is at least sufficient to achieve the desired final concentration into the mixing container, are not present in Groups I or III-VIII; the special technical features of Group III, a manifold unit containing a mechanism for selectively interconnecting a first array of fluid paths, respectively, with a second array of fluid paths, the interconnecting being completed through a pumping portion, are not present in Groups I, II or IV-VIII; the special technical features of Group IV, a disposable tubing set including a fill line with a patient access connector at one end and a dialysis fluid receiving end opposite the patient access connector end, are not present in Groups I-III or V-VIII; the special technical features of Group V, conveying dialysis fluid to a peritoneal cavity through a catheter during a patient fill phase; allowing the dialysis fluid to dwell within the peritoneal cavity during a patient dwell phase; conveying dialysis fluid away from the peritoneal cavity through the catheter during a patient drain phase, are not present in Groups I-IV or VI-VIII; the special technical features of Group VI, storing a therapeutic program in a memory of a controller, the program including pressure data characteristic of a target pressure profile having at least two pressure magnitudes; using a pump and a dialysis fluid supply line, are not present in Groups I-V, VII or VIII; the special technical features of Group VII, a peritoneal dialysis tubing set including connection tube with a connector for a peritoneal catheter at a distal end and a connector configured to connect to a peritoneal cyclor; a pressure pod at the distal end, the pressure pod being of the type that has a flow chamber for carrying a liquid and an air chamber separated from the flow chamber by a diaphragm and an air port in fluid communication with the air chamber, are not present in Groups I-VI or VIII; and the special technical features of Group VIII, a cyclor unit configured with a pump actuator, a controller, and valve actuators; a first disposable fluid circuit that includes valve portions configured to engage with the valve actuators, pump portions configured to engage with the pump actuator; a second disposable fluid circuit that includes valve portions configured to engage with the valve actuators, pump portions configured to engage with the pump actuator, and respective connections for at least one source of dialysis fluid and a peritoneal fill line, are not present in Groups I-VII.

Since none of the special technical features of the Groups I - VIII inventions is found in more than one of the inventions, unity is lacking.