



- (51) **International Patent Classification:**
A61M 5/36 (2006.01) A61M 5/38 (2006.01)
- (21) **International Application Number:**
PCT/US201 1/067569
- (22) **International Filing Date:**
28 December 2011 (28.12.2011)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**
12/981,152 29 December 2010 (29.12.2010) US
- (71) **Applicants (for all designated States except US):** BAXTER INTERNATIONAL INC. [US/US]; One Baxter Parkway, Deerfield, IL 60015 (US). BAXTER HEALTHCARE S.A. [CH/CH]; Thurgauerstrasse 130, CH-8152 Glattpark (opfikon) (CH).
- (72) **Inventors; and**
- (75) **Inventors/Applicants (for US only):** DUDAR, Thomas [US/US]; 228 N. Crescent Avenue, Palatine, IL 60067 (US). KROGH, Ross [US/US]; 8091 Breckenridge Road, Long Grove, IL 60047 (US). MARTUCCI, James [US/US]; 816 Fair Way, Libertyville, IL 60048 (US). STERNBERG, Shmuel [US/US]; 709 E. Lenox Lane, Palatine, IL 60074 (US).
- (74) **Agents:** SONI, Viren S. et al; K&L Gates LLP, P.o. Box 1135, Chicago, IL 60690-1135 (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, QA, RO, RS, RU, RW, 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, RW, 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).

Declarations under Rule 4.17:

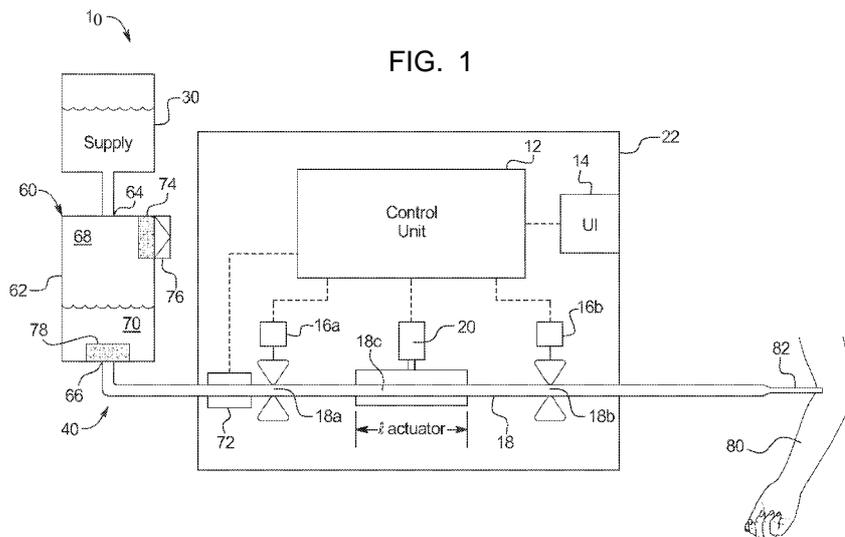
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(H))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(in))

Published:

- with international search report (Art. 21(3))

[Continued on nextpage]

(54) **Title:** INTRAVENOUS PUMPING AIR MANAGEMENT SYSTEMS AND METHODS



(57) **Abstract:** An intravenous ("IV") liquid delivery system includes: an IV pump tubing set; a shuttle pump or membrane pump actuator operable with the IV pump tubing set; upstream and downstream valve actuators operable with the IV pump tubing set; the IV pump tubing set including an air removal device; an air detector configured to sense air in the IV pump tubing set; a control unit configured and arranged to (i) open the upstream valve actuator and close the downstream valve actuator to allow the pump actuator to draw liquid into a pump actuation portion of the IV pump tubing set, and (ii) close the upstream valve actuator and open the downstream valve actuator to allow the pump actuator to push liquid out of the pump actuation portion, the system configured to attempt to remove the air via the air removal device while operating the upstream and downstream valve actuators according to (i) and (ii).



- *with amended claims (Art. 19(1))*

Date of **Publication of the amended claims:** 7 February 2013

(88) Date of publication of the international search report:
27 December 2012

AMENDED CLAIMS

received by the International Bureau on 26 November 2012 (26.1 1.2012)

The invention is claimed as follows:

1. An intravenous ("IV") liquid delivery system (10) comprising:
 - an IV pump tubing set (40) including an upstream valve portion (18a), a downstream valve portion (18b) and a pump portion (18c) located between the upstream and downstream valve portions (18a and 18b, respectively);
 - a pump actuator (20) operable with the pump portion (18c) of the IV pump tubing set (40);
 - an air removal device (60) located upstream of the pump actuator (20), the air removal device (60) including a liquid inlet (64), a liquid outlet (66), an air collection portion (68), and a liquid collection portion (70) located adjacent to the liquid outlet (66), and wherein the air collection portion (68) of the air removal device (60) includes an air passing but liquid retaining filter (74) and a check valve (76) in air flow communication with the air passing but liquid retaining filter (74); and
 - an air detector (72) located downstream from the air removal device (60).
2. The IV liquid delivery system (10) of Claim 1, which further includes upstream and downstream valve actuators (16a and 16b, respectively) operable with the pump actuator (20) to move liquid through the IV pump tubing set (40).
3. The IV liquid delivery system (10) of Claim 1, wherein the air detector (72) is used to integrate the amount of air detected over a period of time.
4. The IV liquid delivery system (10) of Claim 1, wherein the filter (74) is a hydrophobic filter.
5. The IV liquid delivery system (10) of Claim 1, wherein the liquid collection portion (70) includes a liquid passing but air retaining filter (78).
6. The IV liquid delivery system (10) of Claim 1, wherein the IV pump tubing set (40) is configured to be mounted such that the air collection portion (68) is located elevationally above the liquid collection portion (70).

7. The rV liquid delivery system (10) of Claim 1, wherein the air removal device (60) includes a housing (62) having a larger cross-sectional area than that of a tube (18) of the IV pump tubing set (40).

8. The IV liquid delivery system (10) of Claim 1, wherein the air removal device (60) is provided as part of the IV pump tubing set (40).

9. The IV liquid delivery system (10) of Claim 1, wherein the air detector (72) is a first air detector (72), and which includes a second air detector (72b) located downstream of the air removal device (60) and downstream of the upstream valve portion (18a).

10. An intravenous ("IV") liquid delivery system (110) comprising:
an IV pump tubing set (140);
a pump actuator (20) operable with the IV pump tubing set (140);
an air removal device (160) located downstream of the pump actuator (20), the air removal device (160) including an air passing but liquid retaining filter (74) and a liquid passing but air retaining filter (78);
a device that indicates that the air removal device (160) is present;
an air detector (72a) located upstream from the air removal device (160); and
a control unit (12) operable with the indicating device, the control unit (12) configured so that when the air removal device (160) is indicated as being present, the pump actuator (20) is allowed to operate the IV pump tubing set (140) even if air is detected upstream of the air removal device (160) by the upstream air detector (72a).

11. The rV liquid delivery system (110) of Claim 10, which includes an air detector (72b) located downstream of the pump actuator (20), and wherein the control unit (12) is further configured to stop the pump actuator (20) if air is detected at the downstream air detector (72b).

12. The IV liquid delivery system (110) of Claim 10, wherein the control unit (12) is further configured so that when the air removal device (160) is indicated as not being present, the pump actuator (20) is stopped if air is detected upstream of the air removal device (160) by the upstream air detector (72a).

13. The IV liquid delivery system (110) of Claim 10, wherein the indicating device includes a sensor (120) positioned to sense the presence of the air removal device (160).

14. The IV liquid delivery system (110) of Claim 10, wherein the indicating device includes a code (118) provided with one of the IV pump tubing set (40) and the air removal device (160).

15. An intravenous ("IV") liquid delivery system (210) comprising:
an IV pump tubing set (240);
a pump actuator (20) operable with the IV pump tubing set (240);
an upstream valve actuator (16a) operable with the IV pump tubing set (240) upstream of the pump actuator (20);
a downstream valve actuator (16b) operable with the IV pump tubing set (240) downstream of the pump actuator (20);
an air purge valve actuator (16ap) operable with the IV pump tubing set (240) downstream of the downstream valve actuator (16b);
an air removal device (260) located between the downstream valve actuator (16b) and the air purge valve actuator (16ap), the system (210) configured to close the air purge valve actuator (16ap) to force air in the IV pump tubing set (240) to be purged through the air removal device (260); and
an air detector (72b) located downstream from the air removal device (260).

16. The IV liquid delivery system (210) of Claim 15, wherein the pump actuator (20) is a shuttle pump or membrane pump actuator, the shuttle pump or membrane pump actuator operable with the upstream and downstream valve actuators (16a and 16b, respectively) to move liquid through the IV pump tubing set (240).

17. The IV liquid delivery system (210) of Claim 15, wherein the air removal device (260) includes an air passing but liquid retaining filter (74).

18. The IV liquid delivery system (210) of Claim 15, which is configured and arranged to close the air purge valve actuator (16ap) for a time or a number of pump-out strokes sufficient to force air in the IV pump tubing set (240) to be purged through the air removal device (260).

19. The IV liquid delivery system (210) of Claim 15, wherein the IV pump tubing set (240) includes the air removal device (260) positioned between a downstream valve actuator portion (18b) of the IV pump tubing set (240) and an air purge valve actuator portion (18ap) of the IV pump tubing set (240).

20. The IV liquid delivery system (210) of Claim 15, which is configured and arranged to maintain open the air purge valve actuator (16ap) and sequence the pump, upstream and downstream valve actuators (20, 16a and 16b, respectively) for pumping.

21. The IV liquid delivery system (210) of Claim 15, wherein the air detector (72b) is a second air detector (72b), and which includes a first air detector (72a) located upstream of the pump actuator (20).

22. The IV liquid delivery system (210) of Claim 15, wherein the air removal device (260) extends off of a primary liquid delivery line (18) of the IV pump tubing set (240).

23. An intravenous ("IV") liquid delivery system (310) comprising:
an IV pump tubing set (340);
a pump actuator (20) operable with the IV pump tubing set (340);
an upstream valve actuator (16a) operable with the IV pump tubing set (340) upstream of the pump actuator (20);
an air detector (72a) located upstream of the upstream valve actuator (16a);
a downstream valve actuator (16b) operable with the IV pump tubing set (340) downstream of the pump actuator (20); and
an air purge valve actuator (16ap) operable with the IV pump tubing set (340) downstream of the downstream valve actuator (16b),

wherein the IV pump tubing set (340) further includes a bypass recirculation line (18by) extending from a point located between the downstream valve actuator (16b) and the air purge valve actuator (16ap) to a point in the IV pump tubing set (340) upstream of the air detector (72a), and wherein upon a detection of air in a medical fluid by the air detector (72a), the air purge valve actuator (16ap) is closed and the pump actuator (20), the upstream valve actuator (16a) and the downstream valve actuator (16b) are operated to recirculate the medical fluid using the bypass recirculation line (18by) to purge air from the medical fluid.

24. The IV liquid delivery system (310) of Claim 23, wherein the bypass recirculation line (18by) extends to a supply (30) of the medical fluid for the IV pump tubing set (340).

25. The IV liquid delivery system (310) of Claim 23, wherein the bypass recirculation line (18by) is in fluid communication with an air removal device (60) to purge air from the medical fluid.

26. An intravenous ("IV") liquid delivery system (510) comprising:
an IV pump tubing set (540);
a pump actuator (20) operable with the IV pump tubing set (540);
an air removal device (560) located downstream of the pump actuator (20), the air removal device (560) including

a housing (562) having an inlet end (564) and an outlet end (566),

a first potted member (572a) located adjacent the inlet end (564),

a second potted member (572b) located adjacent the outlet end (566), and

a plurality of air passing but liquid retaining hollow fibers (574) extending from the first potted member (572a) to the second potted member (572b), wherein medical fluid potentially entraining air is passed through the hollow fibers (574) so as to provide a path of least resistance radially out of the hollow fibers (574);
and

an air detector (72b) located downstream of the air removal device (560).

27. The IV liquid delivery system (510) of Claim 26, wherein the air detector (72b) is a second air detector (72b), and which includes a first air detector (72a) located upstream of the pump actuator (20), the first air detector (72a) used for at least one of (i) providing an air sense alert and (ii) providing a signal used to integrate air volume through the IV pump tubing set (540).

28. The IV liquid delivery system (510) of Claim 26, wherein the air detector (72b) is used to shut down the system (510) in case air in the IV pump tubing set (540) escapes the air removal device (560).

29. An intravenous ("IV") liquid delivery system (10, 110, 210, 310, 410, 510) comprising:

an IV pump tubing set (40, 140, 240, 340, 440, 540);

a shuttle pump or membrane pump actuator (20) operable with the IV pump tubing set (40, 140, 240, 340, 440, 540);

an upstream valve actuator (16a) operable with the IV pump tubing set (40, 140, 240, 340, 440, 540);

a downstream valve actuator (16b) operable with the IV pump tubing set (40, 140, 240, 340, 440, 540);

the IV pump tubing set (40, 140, 240, 340, 440, 540) including an air removal device (60, 160, 260, 460, 560);

an air detector (72, 72a, 72b) configured to sense air in the IV pump tubing set (40, 140, 240, 340, 440, 540);

a control unit (12) configured and arranged to (i) open the upstream valve actuator (16a) and close the downstream valve actuator (16b) to allow the pump actuator (20) to draw liquid into a pump actuation portion (18c) of the IV pump tubing set (40, 140, 240, 340, 440, 540), and (ii) close the upstream valve actuator (16a) and open the downstream valve actuator (16b) to allow the pump actuator (20) to push liquid out of the pump actuation portion (18c); and

wherein the system (10, 110, 210, 310, 410, 510) is configured to attempt to remove the air via the air removal device (60, 160, 260, 460, 560) while operating the upstream and downstream valve actuators (16a and 16b, respectively) according to (i) and (ii).

30. The IV liquid delivery system (10, 110, 210, 310, 410, 510) of Claim 29, wherein the air removal device (60, 160, 260, 460, 560) is located (a) upstream of the upstream valve actuator (16a) or (b) downstream of the pump actuator (20).

31. The IV liquid delivery system (210, 310, 410) of Claim 29, wherein the air detector (72, 72a) is a first air detector (72, 72a) and which includes (a) a second air detector (72b) and (b) an air purge valve actuator (16ap) located downstream of the downstream valve actuator (16b), the control unit (12) further configured to receive a signal from the second air detector (72b) indicative of air in the IV pump tubing set (240, 340, 440) and close the air purge valve actuator (16ap) to attempt to remove the air via the air removal device (60, 160, 260, 460, 560) while operating the upstream and downstream valve actuators (16a and 16b, respectively) according to (i) and (ii).