



(51) International Patent Classification:

A61M 1/38 (2006.01) A61M 1/02 (2006.01)
A61M 1/36 (2006.01)

(21) International Application Number:

PCT/US2018/028695

(22) International Filing Date:

20 April 2018 (20.04.2018)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/488,404 21 April 2017 (21.04.2017) US
62/539,053 31 July 2017 (31.07.2017) US

(71) Applicant: TERUMO BCT, INC. [US/US]; 10811 West Collins Avenue, Lakewood, Colorado 80215 (US).

(72) Inventors: FELT, Thomas J.; 2745 Juilliard Street, Boulder, Colorado 80305 (US). HLAVINKA, Dennis J.; 7365 North Salvia Court, Arvada, Colorado 80007 (US). HOLMES, Brian M.; 1399 Brighton Court, Evergreen, Colorado 80439 (US). O'BRIEN, Peter; 1510 S. Corona Street, Denver, Colorado 20210 (US). POLODNA, Taylor; 1910 Pinal Road, Golden, Colorado 80401 (US).

(74) Agent: PEREYRA, René A.; Mail Stop 810 1F2, 10811 West Collins Avenue, Lakewood, Colorado 80215 (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, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, 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, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, 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, KM, ML, MR, NE, SN, TD, TG).

(54) Title: SYSTEM FOR HIGH-THROUGHPUT BLOOD COMPONENT COLLECTION

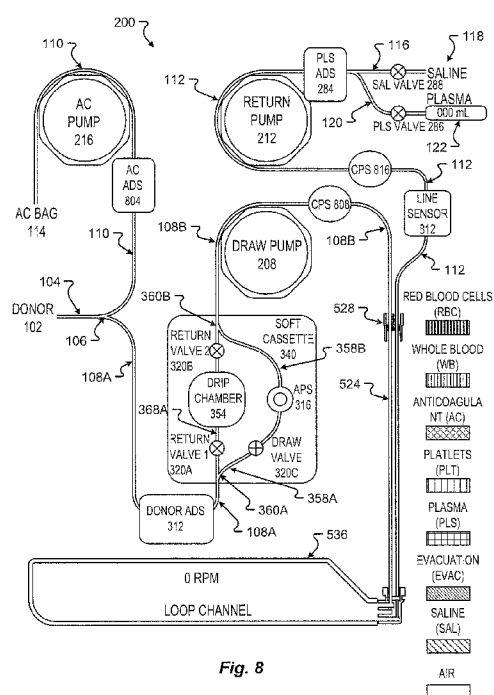


Fig. 8

(57) Abstract: Described are embodiments that include devices for separating components from blood. Embodiments may involve the separation of plasma from whole blood. Also described are embodiments that include methods and devices for positioning portions, e.g., loops, of disposables in medical devices. Embodiments may involve use of surfaces for automatically guiding loops to position them into a predetermined position.



**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))*

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:

06 December 2018 (06.12.2018)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/028695

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/38 A61M1/36 A61M1/02
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 practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/000026 A2 (MISSION MEDICAL INC [US]) 3 January 2003 (2003-01-03) figures 12A, 12B, 23,30A,34,46 page 9, line 16 - page 10, line 12 page 21, line 31 - page 23, line 31; figure 27 page 27, last paragraph - page 28, paragraph top page 30, line 1 - line 28 page 32, line 1 - line 23; figure 37 ----- -/--	12-71



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 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

26 October 2018

Date of mailing of the international search report

06/11/2018

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Mata Vicente, Teresa

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/028695

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 749 546 A1 (GAMBRO INC [US]) 7 February 2007 (2007-02-07) paragraph [0065] paragraph [0072] page 0090 page 0074 paragraph [0090] paragraph [0106] -----	12-20
A	WO 88/05691 A1 (BAXTER TRAVENOL LAB [US]) 11 August 1988 (1988-08-11) figure 1 figure 11 -----	12-20
X	US 2004/058794 A1 (DOLECEK VICTOR D [US] ET AL) 25 March 2004 (2004-03-25) paragraph [0021] paragraph [0049] - paragraph [0053] paragraph [0060] paragraph [0094] - paragraph [0095]; figures 23,24 paragraph [0132] - paragraph [0134]; figure 1 paragraph [0140] paragraph [0146] paragraph [0150] paragraph [0163] - paragraph [0165] paragraph [0173] -----	21-71
X	US 4 113 173 A (LOLACHI HOUSHANG) 12 September 1978 (1978-09-12) figure 11 column 6, line 20 - column 7, line 51 -----	21-24, 27-71
Y	WO 96/29104 A1 (TRAVENOL LAB ISRAEL LTD [IL]; KRAUS MENAHEM [IL]; SHEMESH ELI [IL]; RA) 26 September 1996 (1996-09-26) figure 14 page 14, paragraph 2 - page 15 -----	72-81
A	WO 95/17597 A1 (BAXTER INT [US]) 29 June 1995 (1995-06-29) page 34, line 12 - page 35, line 5; figure 19 -----	72-89
Y	EP 0 134 436 A1 (GAMBRO LUNDIA AB [SE]) 20 March 1985 (1985-03-20) page 5, last paragraph - page 6 figures 3,4 -----	72-81
Y	US 2009/008306 A1 (CICCHELLO GINO [US] ET AL) 8 January 2009 (2009-01-08) paragraph [0152] -----	72-81

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2018/028695

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.: 1-11, 90, 91
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 1-11, 90 and 91 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv)/Rule 67.1(iv)PCT.
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. ☐ 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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-20

An apheresis system comprising: a first tube having a lumen, fluidly associated with the needle, that moves whole blood from a donor through the lumen; a draw pump engaged with the first tube that draws the whole blood into a centrifuge; the centrifuge that spins to cause centrifugal force to act on the whole blood to separate the whole blood into at least a first blood component and a third blood component; a blood component collection bladder, inserted into the centrifuge and fluidly associated with the first tube, that separates the first blood component from the whole blood; a second tube, fluidly associated with the blood collection bladder, that moves the first blood component from the blood component collection bladder; a collection container, fluidly associated with the second tube, that extracts the first blood component from the apheresis system; a sensor positioned in physical proximity to the second tube to detect when a second blood component is being extracted from the whole blood; and after the second blood component is detected by the sensor and while the centrifuge continues to spin, a return pump, engaged with the second tube, that forces the separated first blood component back towards the blood component collection bladder through the second tube to move at least the third blood component from the blood component collection bladder and back into the donor. A blood component collection set associated with said apheresis system. A method of treatment involving the use of said apheresis system.

2. claims: 21-26

An assembly for separating a component from a multi-component fluid, the assembly comprising: a filler comprising a channel for holding a separation bladder of a disposable, wherein the channel comprises two opposing walls; and a loop rotational position guide comprising a plurality of bearings, the loop rotational position guide holding a flexible loop of a disposable when the separation bladder is loaded in the channel.

3. claims: 27-40

A centrifuge assembly, comprising: a centrifuge housing having an outer surface and an internal cavity, wherein the centrifuge housing rotates about a rotation axis of the centrifuge assembly; a fluid separating body disposed at least partially within the internal cavity of the centrifuge housing and configured to rotate relative to the centrifuge housing about the rotation axis; and a fluid line loop arm

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

attached to a portion of the centrifuge housing and running along a length of the outer surface of the centrifuge housing, the fluid line loop arm including a bearing set disposed at a point along the length of the outer surface, wherein the bearing set is configured to contact a tubing portion of an interconnected fluid line loop and maintain the fluid line loop in an engaged position relative to the centrifuge housing while allowing the fluid line loop to rotate in the engaged position. Method for automatically loading a fluid line loop into said centrifuge assembly.

4. claims: 41-60

A filler for holding a separation bladder in which a component is separated from a composite fluid, the filler comprising: a channel for holding a separation bladder during separation of the component from the composite fluid, the channel comprising: a first wall; and a second wall opposite the first wall; and wherein a first end of the channel is adjacent a central portion of the filler and the channel spirals toward an outside perimeter of the filler. A centrifuge assembly, comprising: a centrifuge housing having an internal cavity, wherein the centrifuge housing rotates about a rotation axis of the centrifuge assembly; and a fluid separating body disposed at least partially within the internal cavity of the centrifuge housing and configured to rotate relative to the centrifuge housing about the rotation axis, wherein the fluid separating body includes a fluid collection insert channel disposed in the fluid separating body following a substantially spiral path running from a first point adjacent to the rotation axis spirally outward to a second point disposed adjacent to a periphery of the fluid separating body, wherein the fluid collection insert channel jogs outwardly toward the periphery of the body near an end of the substantially spiral path defining a third point of the fluid collection insert channel disposed furthest from the rotation axis.

5. claims: 61-71

A blood component collection loop comprising: a flexible loop; a system static loop connector disposed at a first end of the flexible loop, wherein the system static loop connector is connected to the fixed loop connection of a centrifuge to fix the first end of the flexible loop to rotate in unison with the centrifuge; a filler loop connector disposed at a second end, opposite the first end, of the flexible loop, wherein the filler loop connector is connected to a loop connection area of a filler, and wherein torsional forces based on twist in the flexible loop are imparted to the filler through the filler loop connector; and wherein flexible loop is rotationally moved to be captured by a loop rotational position guide positioned on

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

the centrifuge.

6. claims: 72-91

A soft cassette comprising: a first port; a second port; a direct flow lumen fluidly connected to the first port and the second port; a drip chamber inter-disposed in the direct flow lumen such that the fluid passing through the direct flow lumen passes through the drip chamber; and a fluid flow bypass path both fluidly connected to the direct flow lumen adjacent the first port and between the first port and the drip chamber and fluidly connected to the direct flow lumen adjacent the second port and between the second port and the drip chamber, such that fluid flowing through the fluid flow bypass path bypasses the drip chamber. A blood component collection set, the blood component collection set comprising said cassette. A method for moving fluids through said cassette.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2018/028695

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 03000026	A2	03-01-2003	AT 340652 T 15-10-2006
		AU 2002327241 B2 16-03-2006	
		CA 2452055 A1 03-01-2003	
		DE 60215014 T2 16-05-2007	
		EP 1412091 A2 28-04-2004	
		ES 2271324 T3 16-04-2007	
		JP 4070716 B2 02-04-2008	
		JP 2004531321 A 14-10-2004	
		US 2003199803 A1 23-10-2003	
		US 2004245189 A1 09-12-2004	
		US 2007012623 A1 18-01-2007	
		WO 03000026 A2 03-01-2003	
EP 1749546	A1	07-02-2007	NONE
WO 8805691	A1	11-08-1988	CA 1317917 C 18-05-1993
		DE 3855891 D1 28-05-1997	
		DE 3855891 T2 20-11-1997	
		DE 3856327 D1 27-05-1999	
		DE 3856327 T2 26-08-1999	
		DE 3884871 D1 18-11-1993	
		DE 3884871 T2 19-05-1994	
		EP 0299054 A1 18-01-1989	
		EP 0486480 A2 20-05-1992	
		EP 0765687 A1 02-04-1997	
		JP 2556741 B2 20-11-1996	
		JP H01502029 A 13-07-1989	
		US 4834890 A 30-05-1989	
		US 5316666 A 31-05-1994	
		WO 8805691 A1 11-08-1988	
US 2004058794	A1	25-03-2004	US 2003013590 A1 16-01-2003
		US 2004058794 A1 25-03-2004	
		US 2005098507 A1 12-05-2005	
		US 2008171646 A1 17-07-2008	
		US 2009294383 A1 03-12-2009	
		US 2009298665 A1 03-12-2009	
US 4113173	A	12-09-1978	AU 507774 B2 28-02-1980
		BE 840101 A 16-07-1976	
		BR 7601896 A 28-09-1976	
		CA 1055454 A 29-05-1979	
		DE 2612988 A1 07-10-1976	
		DK 124876 A 28-09-1976	
		ES 446449 A1 01-11-1977	
		FI 760823 A 28-09-1976	
		FR 2305238 A1 22-10-1976	
		GB 1537095 A 29-12-1978	
		IT 1203007 B 15-02-1989	
		JP H0160307 B2 21-12-1989	
		JP S5837022 B2 13-08-1983	
		JP S51120470 A 21-10-1976	
		JP S57147462 A 11-09-1982	
		NL 7603039 A 29-09-1976	
		NO 761022 A 28-09-1976	
		SE 442088 B 02-12-1985	
		US 4113173 A 12-09-1978	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2018/028695

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9629104	A1	26-09-1996	AU 5526096 A 08-10-1996
		EP 0900095 A1 10-03-1999	
		US 5902281 A 11-05-1999	
		WO 9629104 A1 26-09-1996	
WO 9517597	A1	29-06-1995	CA 2155733 A1 29-06-1995
		DE 69411546 D1 13-08-1998	
		DE 69411546 T2 15-04-1999	
		EP 0685037 A1 06-12-1995	
		JP H08507583 A 13-08-1996	
		US 5484239 A 16-01-1996	
		WO 9517597 A1 29-06-1995	
EP 0134436	A1	20-03-1985	DE 3468326 D1 11-02-1988
		EP 0134436 A1 20-03-1985	
		JP H0665346 B2 24-08-1994	
		JP S6034456 A 22-02-1985	
		SE 451541 B 19-10-1987	
		US 4838865 A 13-06-1989	
US 2009008306	A1	08-01-2009	EP 2167159 A2 31-03-2010
		EP 3011984 A1 27-04-2016	
		US 2009008306 A1 08-01-2009	
		US 2013334138 A1 19-12-2013	
		US 2013345621 A1 26-12-2013	
		US 2016106904 A1 21-04-2016	
		US 2017065759 A1 09-03-2017	
		US 2017189601 A1 06-07-2017	
		US 2018078692 A1 22-03-2018	
		WO 2009006489 A2 08-01-2009	