

US 10,792,416 B2

Page 2

(51)	Int. Cl. <i>A61M 1/38</i> <i>A61M 1/34</i> <i>G01N 15/05</i>	(2006.01) (2006.01) (2006.01)	4,755,300 A	7/1988	Fischel et al.
			4,767,396 A	8/1988	Powers
			4,795,419 A	1/1989	Yawn et al.
			4,795,448 A	1/1989	Stacey et al.
(52)	U.S. Cl. CPC <i>A61M 1/3496</i> (2013.01); <i>A61M 1/3626</i> (2013.01); <i>A61M 1/3672</i> (2013.01); <i>A61M</i> <i>1/3693</i> (2013.01); <i>A61M 2202/0415</i> (2013.01); <i>A61M 2205/3306</i> (2013.01); <i>A61M 2205/3379</i> (2013.01); <i>A61M 2205/3393</i> (2013.01); <i>A61M</i> <i>2230/207</i> (2013.01)		4,806,247 A	2/1989	Schoendorfer et al.
			4,806,252 A	2/1989	Brown et al.
			4,808,307 A	2/1989	Fischel et al.
			4,850,995 A	7/1989	Tie et al.
			4,869,812 A	9/1989	Schoendorfer et al.
			4,871,462 A	10/1989	Fischel et al.
			4,876,013 A	10/1989	Shmidt et al.
			4,889,524 A	12/1989	Fell et al.
			4,911,833 A	3/1990	Schoendorfer et al.
			4,934,995 A	6/1990	Cullis
			4,940,543 A	7/1990	Brown et al.
			4,943,273 A	7/1990	Pages
			4,968,295 A	11/1990	Neumann
			4,983,156 A	1/1991	Knelson
			4,983,158 A	1/1991	Headley
			4,985,153 A	1/1991	Kuroda et al.
			4,994,188 A	2/1991	Prince
			5,039,401 A	8/1991	Columbus et al.
			5,045,048 A	9/1991	Kaleskas et al.
(58)	Field of Classification Search CPC <i>A61M 2202/0415</i> ; <i>A61M 2230/207</i> ; <i>G01N</i> <i>15/05</i> ; <i>G01N 2015/055</i> ; <i>G01N 15/042</i> ; <i>G01N 33/86</i> See application file for complete search history.		5,098,372 A	3/1992	Jonsson
			5,098,373 A	3/1992	Polaschegg
(56)	References Cited U.S. PATENT DOCUMENTS		5,100,372 A	3/1992	Headley
			5,100,564 A	3/1992	Pall et al.
			5,112,298 A	5/1992	Prince et al.
			5,114,396 A	5/1992	Unger et al.
			5,135,667 A	8/1992	Schoendorfer
			5,141,486 A	8/1992	Antwiler
			5,147,290 A	9/1992	Jonsson
			5,154,716 A	10/1992	Bauman et al.
			5,174,894 A	12/1992	Ohsawa et al.
			5,194,145 A	3/1993	Schoendorfer
			5,217,426 A	6/1993	Bacehowski et al.
			5,217,427 A	6/1993	Cullis
			5,234,403 A	8/1993	Yoda et al.
			5,254,248 A	10/1993	Nakamura
			5,273,517 A	12/1993	Barone et al.
			5,277,701 A	1/1994	Christie et al.
			5,298,016 A	3/1994	Gordon
			5,298,171 A	3/1994	Biesel
			5,300,060 A	4/1994	Nelson
			5,316,540 A	5/1994	McMannis et al.
			5,318,511 A	6/1994	Riquier et al.
			5,318,512 A	6/1994	Neumann
			5,348,533 A	9/1994	Papillon et al.
			5,368,542 A	11/1994	McMannis et al.
			5,368,555 A	11/1994	Sussman et al.
			5,386,734 A	2/1995	Pusinelli
			5,387,174 A	2/1995	Rochat
			5,387,187 A	2/1995	Fell et al.
			5,403,272 A	4/1995	Deniega et al.
			5,405,308 A	4/1995	Headley et al.
			5,417,650 A	5/1995	Gordon
			5,431,814 A	7/1995	Jorgensen
			5,437,598 A	8/1995	Antwiler
			5,437,624 A	8/1995	Langley
			5,462,667 A	10/1995	Wollinsky et al.
			5,470,483 A	11/1995	Bene et al.
			5,484,396 A	1/1996	Naficy
			5,494,592 A	2/1996	Latham, Jr. et al.
			5,505,685 A	4/1996	Antwiler
			5,514,070 A	5/1996	Pages
			5,543,062 A	8/1996	Nishimura
			5,551,941 A	9/1996	Howell
			5,585,007 A	12/1996	Antanavich et al.
			5,607,579 A	3/1997	Latham, Jr. et al.
			5,649,903 A	7/1997	Deniega et al.
			5,651,766 A	7/1997	Kingsley et al.
			5,656,163 A	8/1997	Brown
			5,665,061 A	9/1997	Antwiler
			5,712,798 A	1/1998	Langley et al.
			5,728,060 A	3/1998	Kingsley et al.
			5,733,253 A	3/1998	Headley et al.
			5,733,446 A	3/1998	Holm
			5,733,545 A	3/1998	Hood, III
			5,738,792 A	4/1998	Schoendorfer

US 10,792,416 B2

Page 3

(56)

References Cited

U.S. PATENT DOCUMENTS

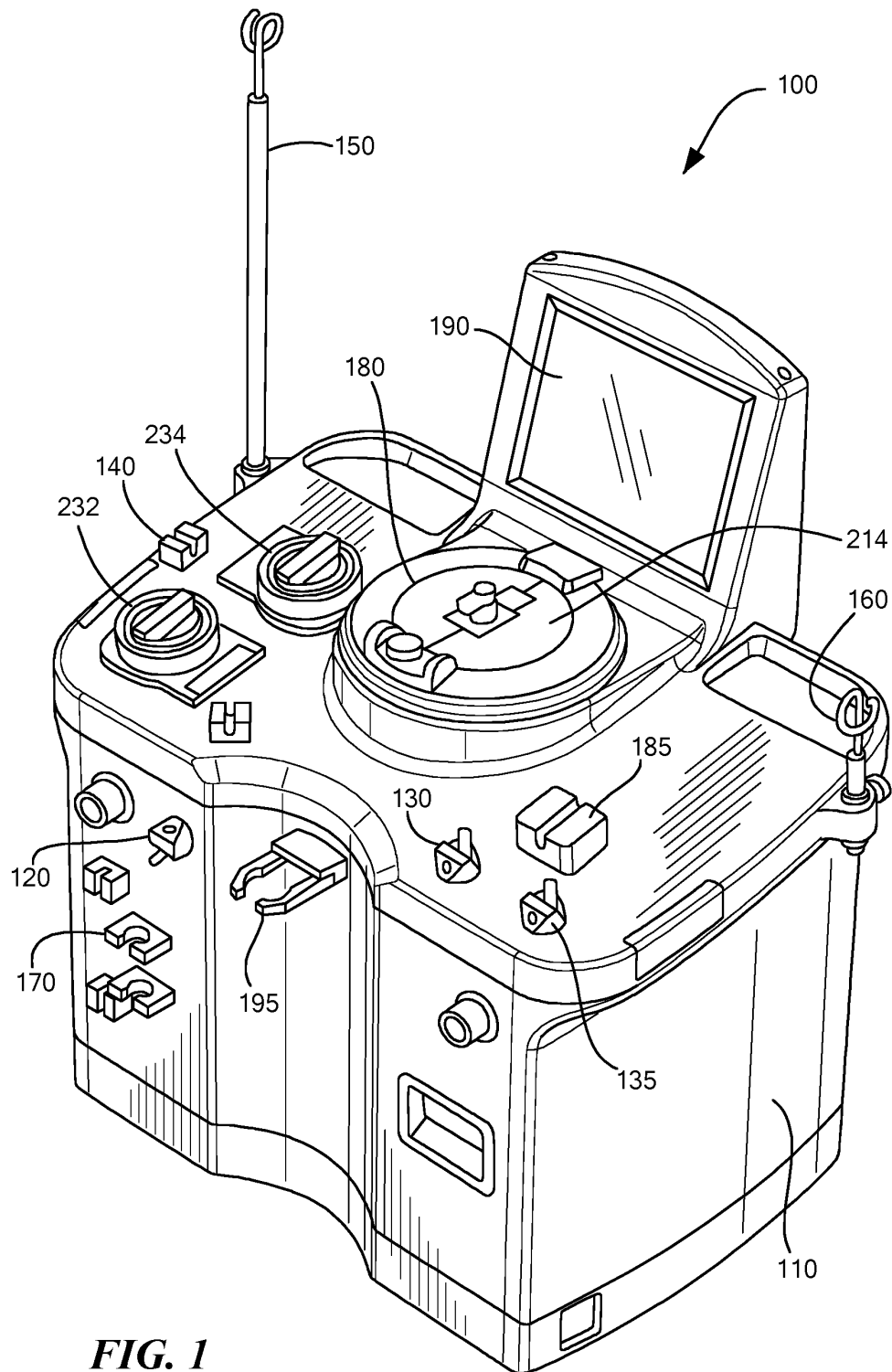
5,762,791 A 6/1998 Deniega et al.
5,779,660 A 7/1998 Kingsley et al.
5,783,085 A 7/1998 Fischel
5,792,351 A 8/1998 Wehrle et al.
5,849,203 A 12/1998 Brown et al.
5,882,289 A 3/1999 Sakota et al.
5,906,589 A 5/1999 Gordon et al.
5,919,125 A 7/1999 Berch
5,964,724 A 10/1999 Rivera et al.
5,970,432 A 10/1999 Ishimoto et al.
5,980,760 A 11/1999 Min et al.
6,007,725 A 12/1999 Brown
6,059,979 A 5/2000 Brown
6,207,063 B1 3/2001 Brown
6,234,989 B1 5/2001 Brierton et al.
6,296,602 B1 10/2001 Headley
6,464,624 B2 10/2002 Pages
6,497,676 B1 12/2002 Childers et al.
6,558,307 B2 5/2003 Headley
6,623,443 B1 9/2003 Polaschegg
6,743,192 B1 6/2004 Sakota et al.
7,115,205 B2 10/2006 Robinson et al.
7,186,231 B2 3/2007 Takagi et al.
7,270,645 B2 9/2007 Langley et al.
7,704,454 B1 4/2010 Langley et al.
8,628,489 B2 1/2014 Pages et al.
8,702,637 B2 4/2014 Pages et al.
8,759,094 B2 6/2014 Ranby
2001/0000185 A1 4/2001 Keller et al.
2001/0027156 A1 10/2001 Egozy et al.
2002/0043492 A1 4/2002 Bischof
2002/0062100 A1 5/2002 Pierce et al.
2002/0120227 A1 8/2002 Childers et al.
2003/0055375 A1 3/2003 Holst et al.
2003/0066807 A1 4/2003 Suzuki
2003/0125881 A1 7/2003 Ryan
2003/0175150 A1 9/2003 Grimm
2004/0186409 A1 9/2004 Cavalcanti et al.
2005/0209522 A1 9/2005 Tadokoro et al.
2005/0235733 A1 10/2005 Holst et al.
2006/0058167 A1 3/2006 Ragusa et al.
2006/0155236 A1 7/2006 Gara et al.
2007/0112289 A1 5/2007 Cavalcanti et al.
2008/0146993 A1 6/2008 Krishna
2012/0175313 A1 7/2012 Barry, Jr. et al.
2014/0039373 A1 2/2014 Ragusa et al.
2014/0356851 A1 12/2014 Pages et al.
2018/0344910 A1 12/2018 Ragusa

FOREIGN PATENT DOCUMENTS

EP 0171749 A1 2/1986
EP 0208061 A1 1/1987
EP 257755 A1 3/1988
EP 0578086 A1 1/1994
EP 619145 A2 10/1994
EP 0654277 A1 5/1995
EP 664159 A1 7/1995
EP 799645 A1 10/1997
EP 0885619 A1 12/1998
EP 1057534 A1 12/2000
EP 1295619 A2 3/2003
EP 1374927 A1 1/2004
FR 2258898 A1 8/1975
GB 2047110 A 11/1980
JP S59-006952 1/1984
JP S59-069166 4/1984
JP H02-052665 2/1990
JP H03-131268 6/1991
JP H07-075746 3/1995
JP H08-131539 5/1996
JP H09-192215 7/1997
JP 2002-291872 A 10/2002
JP 2008-506424 A 3/2008
SU 660718 A1 5/1979
SU 762982 A1 9/1980
SU 1146098 A1 3/1985
WO 1985/02561 A1 6/1985
WO 1990/00059 A1 1/1990
WO 1990/07383 A1 7/1990
WO 1994/06535 A1 3/1994
WO 1996/11747 A2 4/1996
WO 1996/33023 A1 10/1996
WO 2002/05059 A2 1/2002
WO 2007/041716 A1 4/2007

OTHER PUBLICATIONS

Lemmens et al., Estimating blood volumes in obese and morbidly obese patients. *Obes Surg.* Jun. 2006;16(6):773-6.
Nadler et al., Prediction of blood volume in normal human adults. *Surgery.* Feb. 1962;51(2):224-32.
Winters, Complications of donor apheresis. *J Clin Apher.* Jul. 2006;21(2):132-41.
International Search Report and Written Opinion for Application No. PCT/US2018/57528, dated Jan. 7, 2019 17 pages.

**FIG. 1**

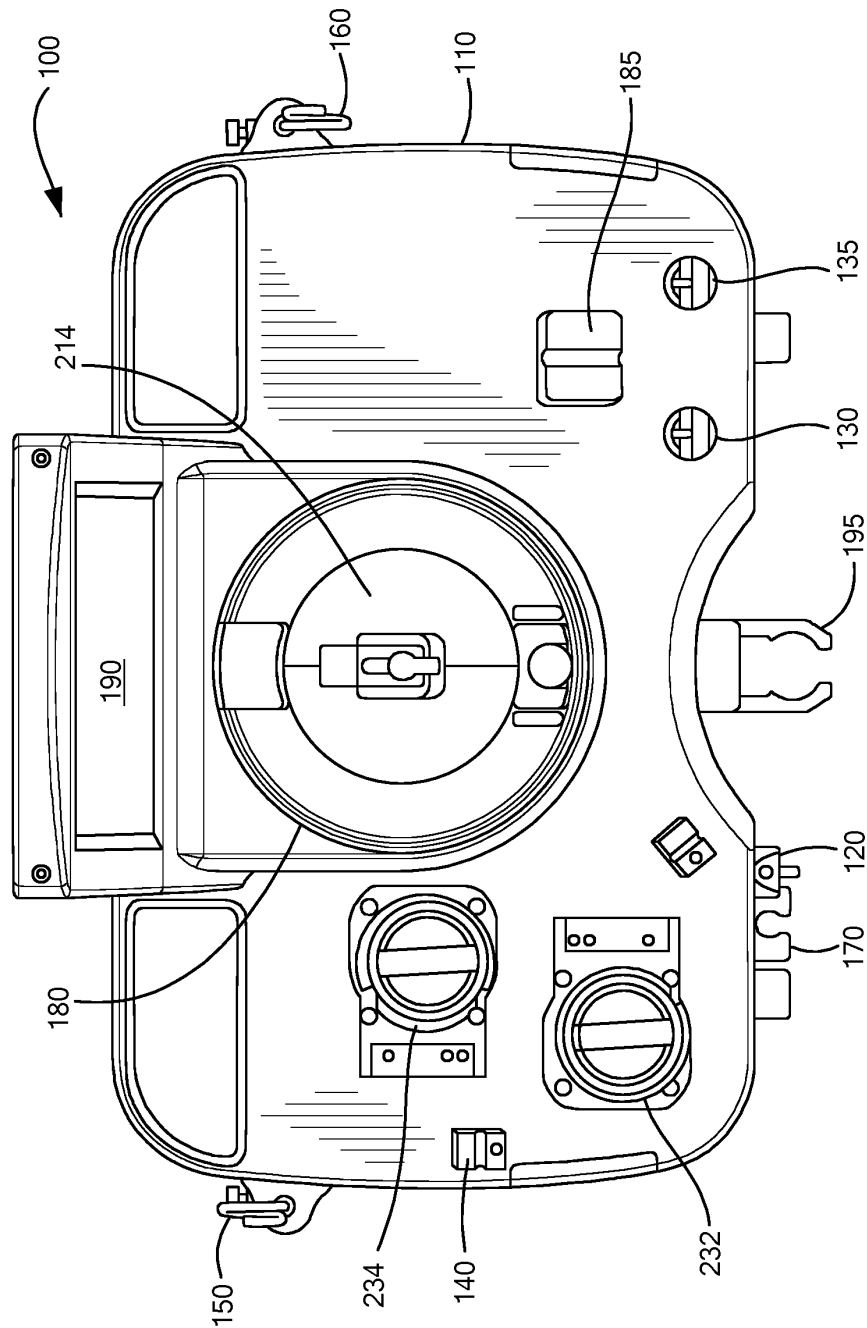
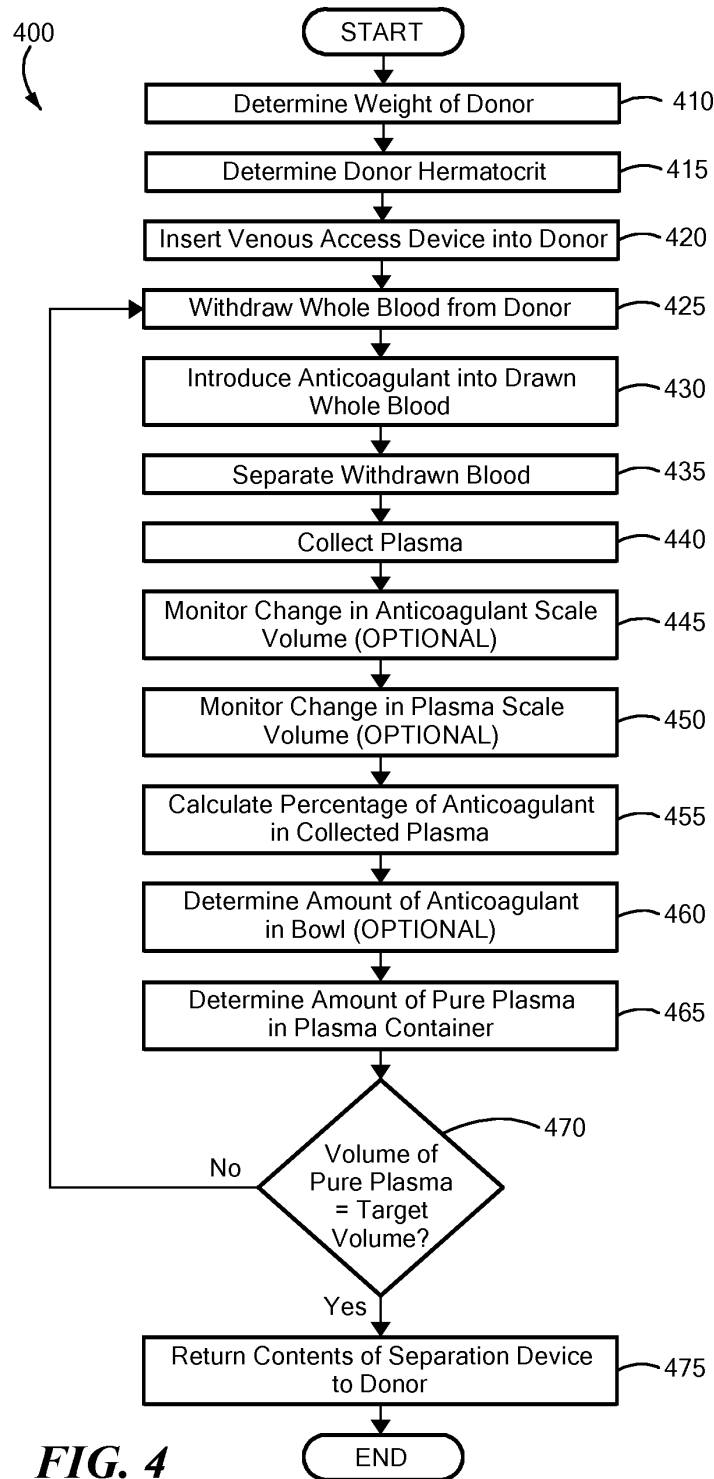
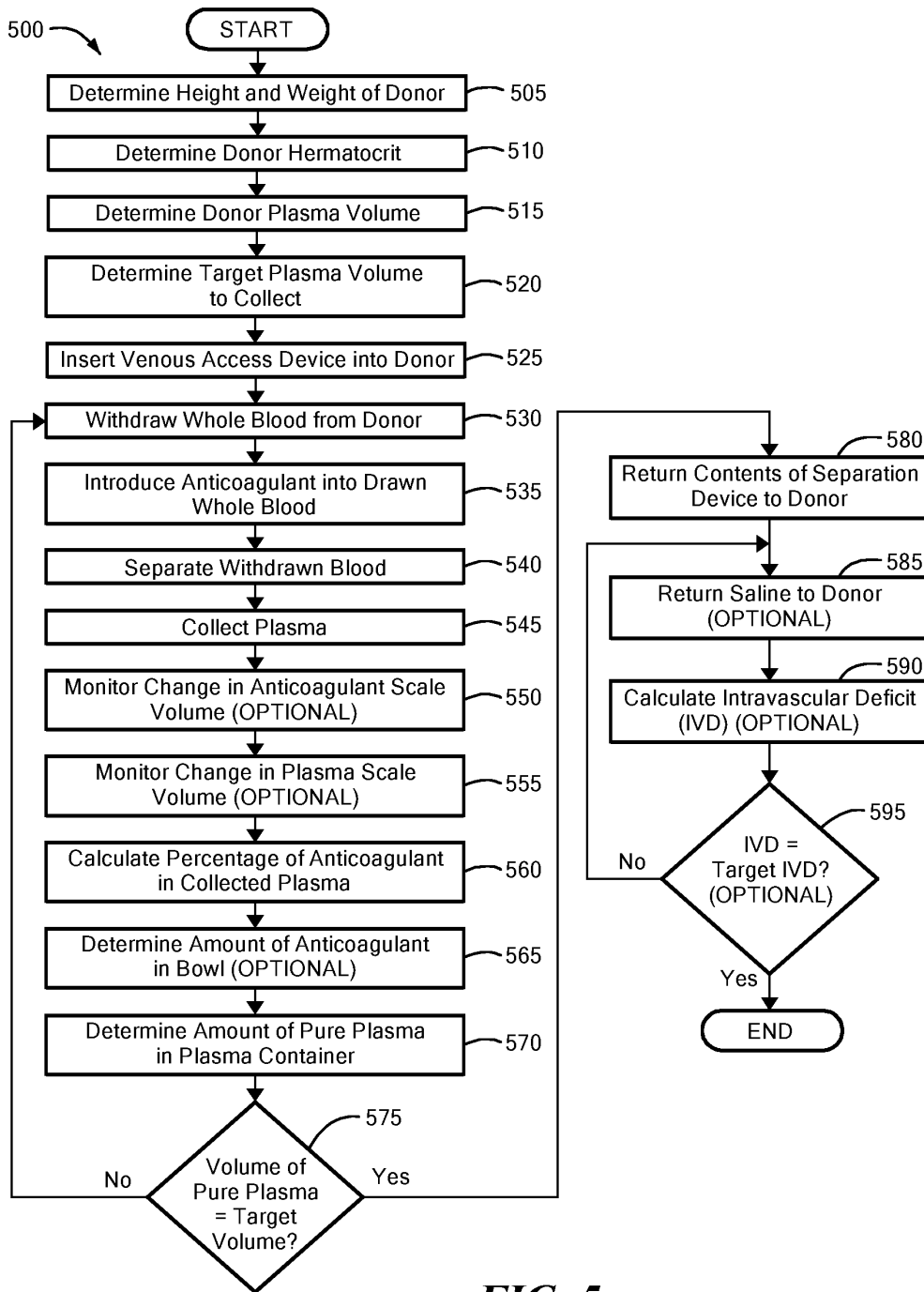


FIG. 2

**FIG. 4**

**FIG. 5**

1

SYSTEM AND METHOD FOR COLLECTING PLASMA

This application is a continuation-in-part of co-pending U.S. patent application Ser. No. 15/608,183, entitled "System and Method for Collecting Plasma," filed May 30, 2017, and naming Michael Ragusa as inventor, the disclosure of which is incorporated herein, in its entirety, by reference.

TECHNICAL FIELD

The present invention relates to systems and methods for blood apheresis, and more particularly system and methods for collecting a plasma product.

BACKGROUND ART

Apheresis is a procedure in which individual blood components can be separated and collected from whole blood temporarily withdrawn from a subject. Typically, whole blood is withdrawn through a needle inserted into a vein of the subject's arm and into a cell separator, such as a centrifugal bowl. Once the whole blood is separated into its various components, one or more of the components (e.g., plasma) can be removed from the centrifugal bowl. The remaining components can be returned to the subject along with optional compensation fluid to make up for the volume of the removed component. The process of drawing and returning continues until the quantity of the desired component has been collected, at which point the process is stopped. A central feature of apheresis systems is that the processed but unwanted components are returned to the donor. Separated blood components may include, for example, a high density component such as red blood cells, an intermediate density component such as platelets or white blood cells, and a lower density component such as plasma.

Many jurisdictions have regulations regarding the amount of whole blood and/or blood components that can be removed from a donor. For example, the U.S. Food and Drug Administration ("the FDA") sets both an upper limit on the volume of plasma that may be collected (e.g., 800 ml for an adult weighing more than 175 pounds) as well as an upper limit on the total collection volume (e.g., 880 ml for an adult weighing more than 175 pounds). Prior art plasma collection systems are unable to determine the total volume of plasma that has been collected (e.g., because the product collected is a mixture of plasma and anticoagulant) and, therefore collect based on the total collection volume, even if the total volume of plasma that has been collected is below the limit prescribed by the FDA. Additionally, prior art collection systems do not tailor the amount of plasma collected to the individual (e.g., other than what weight group they fall into) and, therefore, the percentage of the patient's plasma that is collected varies widely from patient to patient (e.g., only 23% percent of the plasma is collected for some patients and 29%—or greater—of the plasma is collected for others).

SUMMARY OF THE INVENTION

In accordance with some embodiments of the present invention, a method for collecting plasma includes determining the weight and hematocrit of a donor, and inserting a venous-access device into the donor. Once the venous access device is inserted, the method may withdraw whole blood from the donor through the venous-access device and a draw line that is connected to a blood component separation device. The method may then introduce anticoagulant

2

into the withdrawn whole blood through an anticoagulant line and separate, using the blood component separation device, the withdrawn whole blood into a plasma component and at least a second blood component. Once separated, the plasma component may be collected from the blood component separation device and into a plasma collection container. During processing, the method may calculate (1) a percentage of anticoagulant in the collected plasma component, and (2) a volume of pure plasma collected within the plasma collection container. The volume of pure plasma may be based, at least in part, on the calculated percentage of anticoagulant in the collected plasma component. The method may continue the process (e.g., withdrawing whole blood, introducing anticoagulant into the whole blood, separating the blood, collecting the plasma, and calculating the percentage of anticoagulant and volume of pure plasma) until a target volume of pure plasma is collected within the plasma collection container.

In some embodiments, the method may determine a change in volume within an anticoagulant container, and the calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on the change in volume within the anticoagulant container. Additionally or alternatively, the method may determine a volume of anticoagulant introduced into the whole blood based on a number of rotations of an anticoagulant pump. In such embodiments, the calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on the number of rotations of the anticoagulant pump. The method may also determine a volume of anticoagulant within the blood component separation device, and the calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on the volume of anticoagulant within the blood component separation device.

In further embodiments, the method may monitor the volume and/or weight of the plasma component collected within the plasma collection container (e.g., using a weight sensor), and the calculated volume of pure plasma collected within the plasma collection device may be based, at least in part, on the monitored volume and/or weight of the collected plasma component. Additionally or alternatively, determining the hematocrit of the donor may include monitoring a volume of red blood cells collection within the blood separation device. In such embodiments, the determined hematocrit of the donor may be based, at least in part, on the monitored volume of red blood cells collected within the blood separation device and the volume of whole blood withdrawn from the donor.

The target volume of pure plasma may be based, at least in part, on the weight of the donor. The percentage of anticoagulant in the collected plasma component may include at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant that is added to the system during a priming step. After collecting at least a portion of the target volume of pure plasma, the method may return the second blood component to the donor through a return line.

In accordance with additional embodiments, a system for collecting plasma includes a venous-access device for drawing whole blood from a subject and returning blood components to the subject, and a blood component separation device for separating the drawn blood into a plasma component and a second blood component. The blood component separation device has an outlet and is configured to send the plasma component to a plasma container. The system may also include a blood draw line fluidly connected to the venous-access device and an anticoagulant line connected to

3

an anticoagulant source. The blood draw line transports drawn whole blood to the blood component separation device, and the flow through the blood draw line may be controlled by a blood draw pump. The anticoagulant line may introduce anticoagulant into the drawn whole blood.

Additionally, the system may include a controller that controls the operation of the centrifuge bowl. The controller may also calculate (1) a percentage of anticoagulant in the collected plasma component, and (2) a volume of pure plasma collected within the plasma container. The volume of pure plasma may be based, at least in part, upon the percentage of anticoagulant in the collected plasma component. The controller may stop the blood draw pump when a target volume of pure plasma (e.g., based, at least in part, on the weight of the donor) is collected within the plasma container. In some embodiments, the percentage of anticoagulant in the collected plasma component may be based, at least in part, on the volume of anticoagulant added to the drawn whole blood and the subject's hematocrit.

The system may also include an anticoagulant source weight sensor that measures the weight of the anticoagulant source. The controller may monitor the change in volume within the anticoagulant container based on the measured weight of the anticoagulant source, and the calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on the change in volume within the anticoagulant source. Additionally or alternatively, the controller may monitor the number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood. In such embodiments, the calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on the number of rotations of the anticoagulant pump.

In some embodiments, the system may include an optical sensor located on the blood component separation device. The optical sensor may monitor the contents of the blood component separation device and determine if a volume of anticoagulant remains within the blood component separation device. The calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on the volume of anticoagulant within the blood component separation device.

In additional embodiments, the system may also include a plasma container weight sensor that monitors a volume and/or weight of the plasma component collected within the plasma collection container. The calculated volume of pure plasma collected within the plasma collection container may be based, at least in part, on the monitored volume and/or weight of collected plasma component. The system may also have an optical sensor located on the blood component separation device. The optical sensor may monitor the volume of red blood cells collected within the blood separation device. The controller may then determine the subject's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood separation device and the volume of whole blood withdrawn from the donor. The percentage of anticoagulant in the collected plasma component may include at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant added to the system during a priming step.

In accordance with additional embodiments, a method for collecting plasma determines the weight, height, and hematocrit of a donor, and calculates a donor plasma volume based, at least in part, on the weight, height and hematocrit of the donor. The method then calculates a target plasma collection volume based, at least in part, on the calculated

4

donor plasma volume and a target percentage of plasma (e.g., between 26.5 and 29.5 percent of the donor's plasma volume), and withdraws whole blood from the donor through the venous-access device and a first line that is connected to a blood component separation device. As the whole blood is withdrawn, the method may introduce anticoagulant into the withdrawn whole blood through an anticoagulant line.

The blood component separation device separates the withdrawn whole blood into a plasma component and at least a second blood component, and the method may collect the plasma component from the blood component separation device and into a plasma collection container. During processing, the method may calculate a volume of pure plasma collected within the plasma collection container. The method continues the withdrawing, introduction of anticoagulant, separating, collecting, and calculating steps until the volume of pure plasma collected within the plasma collection container equals the target plasma collection volume.

In some embodiments, after collecting at least a portion of the target plasma collection volume, the method may return the contents of the blood component separation device to the donor through the first line. Additionally or alternatively, the method may calculate an intravascular deficit based, at least in part on, the volume of pure plasma collected and the volume of the contents of the blood component separation device that are returned to the donor. The method may also return a volume of saline to the donor to obtain a target intravascular deficit. The target intravascular deficit may be between -250 and 500 milliliters (e.g., it may be 0 milliliters or 250 milliliters). The donor plasma volume may be calculated based, at least in part, on the donor's body mass index that, in turn, is calculated based on the donor's weight and height.

In further embodiments, the method may include calculating a percentage of anticoagulant in the collected plasma component. In such embodiments, the volume of pure plasma may be based, at least in part, on the calculated percentage of anticoagulant in the collected plasma component. The calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on a change in volume within the anticoagulant container, the number of rotations of the anticoagulant pump, and/or the volume of anticoagulant within the blood component separation device. The method may determine the change in volume within the anticoagulant container, the volume of anticoagulant introduced into the whole blood, and/or the volume of anticoagulant within the blood component separation device. The percentage of anticoagulant in the collected plasma component may include at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant added during a priming step.

In some embodiments, the method may include monitoring a volume or and/or weight of the plasma component collected within the plasma collection container. In such embodiments, the calculated volume of pure plasma collected within the plasma collection device may be based, at least in part, on the monitored volume and/or weight of collected plasma component. To determine the donor's hematocrit, the method may monitor the volume of red blood cells collected within the blood separation device. The hematocrit of the donor may be based, at least in part, on the monitored volume of red blood cells collected within the blood separation device and the volume of whole blood withdrawn from the donor.

5

In accordance with still further embodiments, a system for collecting plasma includes a venous-access device for drawing whole blood from a subject and returning blood components to the subject, and a blood component separation device for separating the drawn blood into a plasma component and a second blood component. The blood component separation device may have an outlet and may send the plasma component to a plasma container. The system may also have a first line and an anticoagulant line. The first line may be fluidly connected to the venous-access device and may (1) transport drawn whole blood to the blood component separation device and (2) return fluid within the blood component separation device to the subject. The flow through the first line may be controlled by a first pump. The anticoagulant line may be connected to an anticoagulant source and may introduce anticoagulant into the drawn whole blood.

The system may also include a controller that controls the operation of the centrifuge bowl and the first pump. The controller may calculate (1) a donor plasma volume, (2) a target plasma collection volume, and (3) a volume of pure plasma collected within the plasma container. The donor plasma volume may be based, at least in part, on a weight and height of the donor and a hematocrit of the donor. The target plasma collection volume may be based, at least in part, on the calculated donor plasma volume and a target percentage of plasma. The volume of pure plasma collected within the plasma container may be based, at least in part, upon a percentage of anticoagulant in the collected plasma component. The controller may stop the first pump when the calculated volume of pure plasma collected within the plasma collection container equals the target plasma collection volume.

In further embodiments, the controller may return, after collecting at least a portion of the target plasma collection volume, fluid remaining within the blood component separation device via the first line. Additionally or alternatively, the controller may calculate an intravascular deficit based, at least in part, on the volume of pure plasma collected and the volume of the contents of the blood component separation device returned to the donor. The system may also include a saline line that fluidly connects to a saline source and the blood component separation device. The controller may return a volume of saline to the donor to obtain a target intravascular deficit (e.g., between -250 and 500 milliliters).

The controller may calculate the donor's body mass index based, at least in part, on the weight and height of the donor. The donor plasma volume may, in turn, be calculated based, at least in part, on the donor's body mass index. The target percentage of plasma may be between 26.5 and 29.5 percent (e.g., 28.5 percent) of the donor's plasma volume.

In additional embodiments, the controller may calculate the percentage of anticoagulant in the collected plasma component, for example, based on the volume of anticoagulant added to the drawn whole blood, and the subject's hematocrit. The system may also include an anticoagulant source weight sensor that measures the weight of the anticoagulant source. The controller may then monitor a change in volume within the anticoagulant container based on the measured weight of the anticoagulant source. The calculated percentage of anticoagulant in the collected plasma may be based, at least in part, on the change in volume within the anticoagulant source. Additionally or alternatively the controller may monitor a number of rotations of the anticoagulant pump to determine the volume of anticoagulant introduced into the whole blood. In such embodiments, the calculated percentage of anticoagulant in the collected

6

plasma may be based, at least in part, on the number of rotations of the anticoagulant pump.

The system may also include an optical sensor and/or a plasma container weight sensor. The optical sensor may be located on the blood component separation device and may monitor the contents of the blood component separation device to determine if a volume of anticoagulant remains within the blood component separation device. The calculated percentage of anticoagulant in the collected plasma may then be based, at least in part, on the volume of anticoagulant within the blood component separation device. The plasma container weight sensor may monitor a volume and/or weight of the plasma component collected within the plasma container. The calculated volume of pure plasma collected within the plasma collection device may then be based, at least in part, on the monitored volume and/or weight of collected plasma component. The optical sensor may also monitor the volume of red blood cells collected within the blood separation device, and the controller may determine the subject's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood separation device and the volume of whole blood withdrawn from the donor. The percentage of anticoagulant in the collected plasma component may include at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant added during a priming step.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing features of the invention will be more readily understood by reference to the following detailed description, taken with reference to the accompanying drawings, in which:

FIG. 1 schematically shows a perspective view of a blood processing system in accordance with some embodiments of the present invention.

FIG. 2 schematically shows a top view of the blood processing system of FIG. 1, in accordance with some embodiments of the present invention;

FIG. 3 schematically shows a disposable set installed within the blood processing system of FIG. 1, in accordance with some embodiments of the present invention.

FIG. 4 is a flowchart depicting a method of collecting plasma, in accordance with embodiments of the present invention.

FIG. 5 is a flowchart depicting an alternative method of collecting plasma, in accordance with further embodiments of the present invention.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

Illustrative embodiments of the present invention provide blood processing systems and methods for collecting a target volume of pure plasma. The system and method calculate a percentage of anticoagulant collected within a plasma collection container (e.g., in addition to the plasma that is collected within the container) based on the amount of anticoagulant added to the system and the hematocrit of the donor. The system/method may then calculate the volume of pure plasma (e.g., plasma without anticoagulant) that has been collected within the container. Further embodiments may tailor the volume of plasma collected based on the donor's plasma volume and a target percentage of plasma to collect. Details of the illustrative embodiments are discussed below.

As shown in FIGS. 1 and 2, the blood processing system 100 includes a cabinet 110 that houses the main components of the system 100 (e.g., the non-disposable components). Within the cabinet 110, the system 100 may include a first/blood pump 232 that draws whole blood from a subject, and a second/anticoagulant pump 234 that pumps anticoagulant through the system 100 and into the drawn whole blood. Additionally, the system 100 may include a number of valves that may be opened and/or closed to control the fluid flow through the system 100. For example, the system 100 may include a donor valve 120 that may open and close to selectively prevent and allow fluid flow through a donor line 218 (e.g., an inlet line; FIG. 3), and a plasma valve 130 that selectively prevents and allows fluid flow through an outlet/plasma line 222 (FIG. 3). Some embodiments may also include a saline valve 135 that selectively prevents and allows saline to flow through a saline line 223.

To facilitate the connection and installation of a disposable set and to support the corresponding fluid containers, the system 100 may include an anticoagulant pole 150 on which the anticoagulant solution container 210 (FIG. 3) may be hung, and a saline pole 160 on which a saline solution container 217 (FIG. 3) may be hung (e.g., if the procedure being performed requires the use of saline). Additionally, in some applications, it may be necessary and/or desirable to filter the whole blood drawn from the subject for processing. To that end, the system 100 may include blood filter holder 170 in which the blood filter (located on the disposable set) may be placed.

As discussed in greater detail below, apheresis systems 100 in accordance with embodiments of the present invention withdraw whole blood from a subject through a venous access device 206 (FIG. 3) using the blood pump 232. As the system 100 withdraws the whole blood from the subject, the whole blood enters a blood component separation device 214, such as a Latham type centrifuge (other type of separation chambers and devices may be used, such as, without limitation, an integral blow-molded centrifuge bowl, as described in U.S. Pat. Nos. 4,983,158 and 4,943,273, which are hereby incorporated by reference). The blood component separation device 214 separates the whole blood into its constituent components (e.g., red blood cells, white blood cell, plasma, and platelets). Accordingly, to facilitate operation of the separation device 214, the system 100 may also include a well 180 in which the separation device 214 may be placed and in which the separation device 214 rotates (e.g., to generate the centrifugal forces required to separate the whole blood).

To allow the user/technician to monitor the system operation and control/set the various parameters of the procedure, the system 100 may include a user interface 190 (e.g., a touch screen device) that displays the operation parameters, any alarm messages, and buttons which the user/technician may depress to control the various parameters. Additional components of the blood processing system 100 are discussed in greater detail below (e.g., in relation to the system operation).

FIG. 3 is a schematic block diagram of the blood processing system 100 and a disposable collection set 200 (with an inlet disposable set 200A and an outlet disposable set 200B) that may be loaded onto/into the blood processing system 100, in accordance with the present invention. The collection set 200 includes a venous access device 206 (e.g., a phlebotomy needle) for withdrawing blood from a donor's arm 208, a container of anti-coagulant 210, a centrifugation bowl 214 (e.g., a blood component separation device), a saline container 217, and a final plasma collection bag 216.

The blood/inlet line 218 couples the venous access device 206 to an inlet port 220 of the bowl 214, the plasma/outlet line 222 couples an outlet port 224 of the bowl 214 to the plasma collection bag 216, and a saline line 223 connects the outlet port 224 of the bowl 214 to the saline container 217. An anticoagulant line 225 connects the anti-coagulant container 210 to the inlet line 218. In addition to the components mentioned above and as shown in FIG. 3, the blood processing system 100 includes a controller 226, a motor 228, and a centrifuge chuck 230. The controller 226 is operably coupled to the two pumps 232 and 234, and to the motor 228, which, in turn, drives the chuck 230. The controller 226 may be operably coupled to and in communication with the user interface 190.

In operation, the disposable collection set 200 (e.g., the inlet disposable set 200A and the outlet disposable set 200B) may be loaded onto/into the blood processing system 100 prior to blood processing. In particular, the blood/inlet line 218 is routed through the blood/first pump 232 and the anticoagulant line 225 from the anti-coagulant container 210 is routed through the anticoagulant/second pump 234. The centrifugation bowl 214 may then be securely loaded into the chuck 230. Once the bowl 214 is secured in place, the technician may install the outlet disposable set 200B. For example the technician may connect a bowl connector 300 to the outlet 224 of the bowl 214, install the plasma container 216 into the weight sensor 195, run the saline line 223 through valve 135, and run the plasma/outlet line 222 through valve 130 and the line sensor 185. Once the disposable set 200 is installed and the anticoagulant and saline containers 210/217 are connected, the system 100 is ready to begin blood processing.

FIG. 4 is a flowchart depicting an exemplary method of collecting plasma in accordance with various embodiments of the present invention. Prior to connecting the donor to the blood processing device 100, it is beneficial (and perhaps necessary in some instances) to obtain/determine some information regarding the donor, namely, the donor's weight (Step 410) and hematocrit (Step 415). Not only does this information help determine if the individual is a viable donor and the volumes of blood components that may be withdrawn/collected (e.g., per the FDA guidelines), the hematocrit may be used during processing to help collect a target volume of plasma. The technician may obtain/determine the donor's weight by weighing the donor (e.g., on a scale). To obtain/determine the donor's hematocrit, the technician may draw a blood sample from the donor and test the sample of blood. Additionally or alternatively, as discussed in greater detail below, the system may determine the hematocrit during blood processing. For example, the blood processing device 100 may include a hematocrit sensor (not shown) that determines the hematocrit of the blood flowing into the blood processing device 100 and/or the system 100 may determine the hematocrit based on a volume of red blood cells collected within the bowl 214.

Once the lines 222/223 are in place and the technician has determined the donor's weight and/or hematocrit (if needed), the user/technician may insert the venous access device 206 into the donor's arm 208 (Step 420). Next, the controller 226 activates the two pumps 232, 234 and the motor 228. Operation of the two pumps 232, 234 causes whole blood to be drawn from the donor (step 425), anticoagulant from container 210 to be introduced into the drawn whole blood (step 430), and the now anticoagulated whole blood to be delivered to the inlet port 220 of the bowl 214.

It should be noted that the anticoagulant line 225 may also include a bacteria filter (not shown) that prevents any bacteria in the anticoagulant source 210, the anticoagulant, or the anticoagulant line 225 from entering the system 100 and/or the subject. Additionally, the anticoagulant line 225 may include an air detector 140 that detects the presence of air within the anticoagulant. The presence of air bubbles within any of the system 100 lines can be problematic for the operation the system 100 and may also be harmful to the subject if the air bubbles enter the blood stream. Therefore, the air detector may be connected to an interlock that stops the flow within the anticoagulant line 225 in the event that an air bubble is detected (e.g., by stopping the anticoagulant pump 234), thereby preventing the air bubbles from entering the subject.

As the anti-coagulated whole blood is withdrawn from the subject and contained within the blood component separation device 214, the blood component separation device 214 separates the whole blood into several blood components (Step 435). For example, the blood component separation device 214 may separate the whole blood into a first, second, third, and, perhaps, fourth blood component. More specifically, the blood component separation device 214 (and the centrifugal forces created by rotation of the separation device 214) can separate the whole blood into plasma, platelets, red blood cells ("RBC"), and, perhaps, white blood cells ("WBC"). The higher density component, i.e., RBC, is forced to the outer wall of the bowl 214 while the lower density plasma lies nearer the core. A buffy coat is formed between the plasma and the RBC. The buffy coat is made up of an inner layer of platelets, a transitional layer of platelets and WBC and an outer layer of WBC. The plasma is the component closest to the outlet port and is the first fluid component displaced from the bowl 214 via the outlet port 224 as additional anticoagulated whole blood enters the bowl 214 through the inlet port 220.

As shown in FIG. 3, the system 100 may also include an optical sensor 213 that may be applied to a shoulder portion of the bowl 214. The optical sensor monitors each layer of the blood components as they gradually and coaxially advance toward the core from the outer wall of the bowl 214. The optical sensor 213 may be mounted in a position (e.g., within the well 180) at which it can detect the buffy coat and/or the red blood cells reaching a particular radius, and the steps of drawing the whole blood from the subject/donor and introducing the whole blood into the bowl 12 may be altered and/or terminated in response to the detection.

Additionally, in some embodiments, the optical sensor 213 may be used to determine the hematocrit of the donor during processing. For example, as the bowl 214 fills with red blood cells and the optical sensor 213 detects the layer of red blood cells, the system 100 (e.g., the controller) can determine the volume of red blood cells within bowl 214 based on the location of the red blood cell layer and the fixed/known bowl volume. The system 100 may then calculate the donor hematocrit based on the volume of red blood cells within the bowl and the volume of whole blood that has been processed to that point.

Once the blood component separation device 214 has separated the blood into the various components, one or more of the components can be removed from the blood component separation device 214. For instance, the plasma may be removed to a plasma container 216 (e.g., a plasma bottle) through line 222 (Step 440). As noted above, some embodiments of the system 100 may include a weight sensor 195 (FIG. 1) that measures the amount of plasma collected. The plasma collection process may continue until a target

volume of pure plasma (discussed in greater detail below) is collected within the plasma collection container 216. Although not shown, if the blood processing system 100 and/or the disposable set 200 include platelet, red blood cell, and/or white blood cell bags, each of the bags/containers may include similar weight sensors (e.g., load cells).

In some embodiments, the system 100 may also include a line sensor 185 (mentioned above) that can determine the type of fluid (e.g., plasma, platelets, red blood cells etc.) exiting the blood component separation device 214. In particular, the line sensor 185 consists of an LED which emits light through the blood components leaving the bowl 214 and a photo detector which receives the light after it passes through the components. The amount of light received by the photo detector is correlated to the density of the fluid passing through the line. For example, if plasma is exiting the bowl 214, the line sensor 185 will be able to detect when the plasma exiting the bowl 214 becomes cloudy with platelets (e.g., the fluid exiting the bowl 214 is changing from plasma to platelets). The system 100 may then use this information to either stop the removal of blood components from the bowl 214, stop drawing whole blood from the subject, or redirect the flow by, for example, closing one valve and opening another.

It is important to note that during processing, the osmolarity of the red blood cells prevents the anticoagulant introduced into the whole blood from entering/remaining with the red blood cells (e.g., within the bowl 214). Rather, the anticoagulant mixes with the plasma component. Therefore, the anticoagulant exits the bowl 214 with the plasma and is collected within collection container 216 along with the plasma. In other words, the weight of the product measured by the weight sensor 195 is the weight of the plasma, as well as any anticoagulant that is mixed with the plasma—the weight provided by the weight sensor 195 is not the weight of pure plasma.

Additionally, whole blood contains a variable amount of plasma, as determined by the donor's hematocrit. The hematocrit for typical donors can vary from 38% to 54%, which means that for 100 ml of whole blood, the volume of plasma can vary from 36 to 62 ml. Furthermore, the amount of anticoagulant added to the withdrawn whole blood is fixed (e.g., it does not depend on the hematocrit of the donor), meaning that the percentage of anticoagulant in the collected plasma may vary from 9.7% to 12.7% for donor hematocrits between 38% to 54%, respectively. Therefore, not only does the volume measured by the weight sensor 195 include the volume of anticoagulant, that volume of anticoagulant may vary from donor to donor based on the hematocrit.

As mentioned above, some embodiments of the present invention continue the blood processing/separation procedure until a target volume of pure plasma (e.g., plasma only—without the volume of any anticoagulant mixed with the plasma included in the target volume) is collected within the plasma collection container 216. To that end, some embodiments of the present invention may calculate the volume of pure plasma within the plasma collection container 216. For example, the technician or the system 100 (e.g., the controller) may calculate the percentage of anticoagulant within the collected plasma (Step 455) (e.g., the plasma contained within the plasma collection container 216) based on the amount of anticoagulant added/metered into the whole blood and the hematocrit of the donor. The technician and/or system can calculate the percentage of anticoagulant according to the following equation, where AC is the amount of anticoagulant added to the system 100. As noted above, because the osmolarity of the red blood

11

cells prevents the anticoagulant from mixing with it, essentially all of the anticoagulant exits the bowl **214** and is collected within the plasma collection container **216** along with the plasma.

$$\% AC = \frac{1}{1 + (AC - 1)(1 - Hct_p)}$$

The amount of anticoagulant that is added to the system **100** can be determined in a number of ways. For example, the system **100** can base the amount of anticoagulant (e.g., the value of “AC” in the above equation) on the predetermined ratio of anticoagulant per unit of anticoagulated whole blood. In some embodiments, the value of “AC” may be the inverse of the predetermined ratio (e.g., “AC” would be 16 if the ratio of anticoagulant to anticoagulated whole blood was 1:16). Additionally or alternatively, the technician/system **100** can monitor the volume of anticoagulant added to the system. In such embodiments, the technician/system can monitor the volume of anticoagulant added to the system **100** based on the number of rotations of the anticoagulant pump (e.g., each rotation of the anticoagulant pump introduces a set volume of anticoagulant into the system **100**) and/or based on the change in weight of the anticoagulant container **210** as measured by a weight sensor (discussed in greater detail below).

Once the technician/system **100** has calculated the percentage of anticoagulant within the plasma collection container **216**, the technician/system **100** may then use this information to calculate the volume of pure plasma within the plasma collection container **216** (Step **465**). For example, the technician/system **100** may determine the volume of anticoagulant within the container (based on the percentage of anticoagulant within the container **216**) and subtract this volume from the total volume of fluid within the container **216** as measured by the weight sensor **195**. The system **100** may continue to monitor the volume of pure plasma collected within the container **216** and continue processing whole blood (e.g., continue performing Steps **425**, **430**, **435**, **440**, **455**, **460** and **465**) until a target volume of pure plasma is collected within the plasma collection container **216** (Step **470**) (e.g., 800 mL for an adult donor weighing more than 175 pounds or other limit prescribed by the FDA or similar governing body).

Once the system **100** has collected the target volume of pure plasma within the plasma collection container **216**, the system **100** can return the remaining components (e.g., the components remaining within the bowl **214**) to the subject (Step **475**). For example, when all the plasma has been removed and the bowl **214** is full of RBCs (and any other blood component not collected), the controller **226** stops the draw of whole blood from the subject and reverses the direction of the blood/first pump **232** to draw the RBCs (and other components) from the bowl **214** directly back to the subject. Alternatively, if the system **100** is so equipped, the system may return the components to the subject via a dedicated return line.

In addition to the non-collected blood components (e.g., the components remaining in the bowl **214**), the system **100** may also return saline to the patient/subject. The saline may be used as a compensation fluid to make up for the volume of the blood component (e.g., plasma) that was removed and collected, and is not being returned to the patient. To that end, during the return step (e.g., Step **475**), the saline valve **135** may be opened to allow saline from the saline container

12

217 to flow through the saline line **223** and into the bowl **214** (via outlet **224**) where it can be returned to the patient/donor with or after the remaining blood components.

It should be noted that some embodiments may perform some additional and optional steps to help determine the volume of pure plasma within the plasma collection container **216**. For example, as mentioned above, some embodiments may monitor the change in weight of the anticoagulant container **210** (e.g., as measured by a weight sensor/load cell on the anticoagulant container **210**) (step **445**). This measurement provides an indication of the volume of anticoagulant that has been added to the system **100**, and may be used help determine the percentage of anticoagulant within the plasma collection container **216**. Additionally or alternatively, some embodiments may similarly, monitor the change in weight and/or volume of the plasma and anticoagulant collected within the plasma collection container **216** (e.g., via weight sensor **195**) (step **450**). This measurement may be used to calculate of the total volume of pure plasma collected within the plasma collection container **216** (e.g., to obtain the total weight from which to subtract the calculated volume of anticoagulant).

Some embodiments may also (optionally) monitor the volume of anticoagulant remaining in the bowl **214** (step **460**) (e.g., anticoagulant that did not mix with the plasma and/or otherwise remained in the bowl). For example, the system **100** may utilize the optical sensor on the bowl **214** to determine whether any anticoagulant remains within the bowl **214**. If it does, the method **400** system **100** may modify the calculation of the amount of pure plasma collected within the plasma collection container (e.g., either increase the calculated amount or decreased the calculated amount), based on the volume of anticoagulant remaining within the bowl **214**.

The various embodiment of the present invention described above provide numerous benefits over prior art plasma collection systems. In particular, as noted above, prior art plasmapheresis devices end plasma collection based on a total volume of anticoagulated plasma (e.g., pure plasma plus the added anticoagulant). Although this is the easiest method because it requires only that the product collection container be weighed, the amount of true product—the pure plasma—is dependent on the donor’s hematocrit. In other words, prior art systems will collect more plasma from low hematocrit donors than from high hematocrit donors because of the variation of the percentage of anticoagulant in the product. Various embodiments of the present invention address the issues of prior art systems by collecting a standard volume (e.g., a target volume) of pure plasma from each donor. As noted above, embodiments of the present invention accomplish this by using knowledge of the donor’s hematocrit and the amount of anticoagulant collected within the plasma collection container **216** (e.g., by counting pump rotations and/or using scale/weight sensors, etc.) to determine the percentage of anticoagulant in the product. Additionally, by stopping the plasma collection process based on a volume of pure plasma collected, embodiments of the present invention are able to collect a greater volume of plasma as compared to prior art systems that stop based on a plasma/anticoagulant mixture.

FIG. **5** shows an alternative method for collecting plasma, using the system (or similar system) shown within FIGS. **1-3**, that bases the total volume of plasma to collect on the individual donor (e.g., based on their height, weight, hematocrit, blood volume and/or plasma volume). In a manner similar to that described above for the method shown in FIG. **4**, prior to connecting the donor to the blood processing

device **100**, the system/method may obtain/determine some information regarding the donor, namely, the donor's weight and height (Step **505**) and hematocrit (Step **510**). For example, the technician may obtain/determine the donor's weight by weighing the donor (e.g., on a scale) and the donor's height by measuring the donor. To obtain/determine the donor's hematocrit (e.g., in a manner similar to that described above), the technician may test a blood sample or the system may determine the hematocrit during blood processing using a hematocrit sensor and/or based on the volume of red blood cells collected within the bowl **214**.

Using the donor height and weight, and the hematocrit, the system **100** method **500** may calculate the donor's plasma volume (e.g., the volume of plasma within the donor's blood) (Step **515**). For example, the system **100** method **500** may calculate the donor/subject's body mass index ("BMI") using the donor's height and weight (e.g., BMI=weight/height), and then the total blood volume within the donor/subject using the calculated BMI (e.g., see Lemmens et al., *Estimating Blood Volume in Obese and Morbidly Obese Patients*, Obesity Surgery, 2006:16, 773-776, the subject matter incorporated herein by reference). The total blood volume may be calculated using the following equation:

$$\ln BV = \frac{70}{\sqrt{BMI}p/22}$$

In the above equation, $\ln BV$ is the indexed blood volume (e.g., the donor's total blood volume), BMI_p is the patient's BMI (e.g., kg/m²), 22 is the BMI value (e.g., also in kg/m²) for an ideal body weight (IBW), and 70 is the total blood volume (in mL/kg) for a donor at their ideal weight (BMI=22 kg/m²). Once the system **100** has calculated the total blood volume within the donor/subject, the system **100** (e.g., the controller) may then determine/calculate the volume of plasma within the donor's blood (Step **515**) based, for example, on the donor's hematocrit.

As mentioned above, the embodiment shown in FIG. 5 bases the volume of plasma to collect on the individual donor. To that end, once the system **100** method **500** has determined the donor's plasma volume, the system **100** method **500** may then calculate the target volume of plasma to collect (Step **520**). For example, the system **100** method **500** may multiply the total plasma volume within the patient by a target percentage of plasma to collect to obtain the target plasma volume to collect (e.g., if the total plasma volume is 2700 ml and the target percentage to collect is 28.5%, then the target plasma volume to collect is 769.5 ml). The target percentage of plasma to collect may depend on the application and/or the donor, and may be input directly into the system **100** (e.g., using the user interface **190**) or may be preset from the factory. In some embodiments, the target percentage may be between 26.5 and 30%, and preferably may be 28.5%. However, in other embodiments, the target percentage may be below 26.5% or above 30%.

Once the lines **222/223** are in place and the system **100** method **500** has calculated the target plasma volume, the user/technician may insert the venous access device **206** into the donor's arm **208** (Step **525**). Next, in a manner similar to that described above for the method shown in FIG. 4, the controller **226** activates the two pumps **232, 234** and the motor **228**. Operation of the two pumps **232, 234** causes whole blood to be drawn from the donor (step **530**), anticoagulant from container **210** to be introduced into the

drawn whole blood (step **535**), and the now anticoagulated whole blood to be delivered to the inlet port **220** of the bowl **214**.

As the anti-coagulated whole blood is withdrawn from the subject and introduced into the blood component separation device **214**, the blood component separation device **214** separates the whole blood into the respective blood components (e.g., into plasma, platelets, RBC, and, perhaps, WBC) (Step **540**). As discussed above, the higher density component, i.e., RBC, is forced to the outer wall of the bowl **214** and the plasma is the component closest to the outlet port and, therefore, is the first fluid component displaced from the bowl **214** via the outlet port **224** as additional anticoagulated whole blood enters the bowl **214** through the inlet port **220**. During separation and processing, the optical sensor **213** monitors each layer of the blood components as they gradually and coaxially advance toward the core from the outer wall of the bowl **214**, and the steps of drawing the whole blood from the subject/donor and introducing the whole blood into the bowl **12** may be altered and/or terminated in response to the detection. Additionally, as discussed above, the optical sensor **213** may be used to determine the hematocrit of the donor during processing (e.g., if it is not known and/or determined prior to the start of processing).

Once the blood component separation device **214** has separated the blood into the various components, the plasma may be removed to a plasma container **216** (e.g., a plasma bottle) through line **222** (Step **545**). As noted above, some embodiments of the system **100** may include a weight sensor **195** (FIG. 1) that measures the amount of plasma collected. The plasma collection process may continue until the target plasma collection volume (discussed in greater detail below) is collected within the plasma collection container **216**. If equipped with the line sensor **185**, the system **100** may then use the information from the sensor **185** to either stop the removal of blood components from the bowl **214**, stop drawing whole blood from the subject, or redirect the flow by, for example, closing one valve an opening another.

As mentioned above, some embodiments of the present invention continue the blood processing/separation procedure until a target plasma collection volume is collected. In order to ensure that this volume does not include the volume of any anticoagulant collected within the container **216**, the target plasma collection volume should only include the volume of pure plasma (e.g., plasma only—without the volume of any anticoagulant mixed with the plasma included in the target volume). To that end and in a manner similar to that described above, some embodiments of the present invention may calculate the volume of pure plasma within the plasma collection container **216**. To determine the volume of pure plasma, the technician or the system **100** (e.g., the controller) may calculate the percentage of anticoagulant within the collected plasma (Step **560**) (e.g., the plasma contained within the plasma collection container **216**) based on the amount of anticoagulant added/metered into the whole blood and the hematocrit of the donor (see equation provided above). The amount of anticoagulant that is added to the system **100** can be determined in any of the ways mentioned above (e.g., based on the predetermined ratio of anticoagulant per unit of anticoagulated whole blood, by monitoring the volume of anticoagulant added to the system, etc.).

Once the technician/system **100** has calculated the percentage of anticoagulant within the plasma collection container **216**, the technician/system **100** may then use this information to calculate the volume of pure plasma within the plasma collection container **216** (Step **570**). For

15

example, as discussed above, the technician/system **100** may determine the volume of anticoagulant within the container (based on the percentage of anticoagulant within the container **216**) and subtract this volume from the total volume of fluid within the container **216** as measured by the weight sensor **195**. The system **100** may continue to monitor the volume of pure plasma collected within the container **216** and continue processing whole blood (e.g., continue performing Steps **530**, **535**, **540**, **545**, **560**, **570** and, possibly, steps **550**, **555** and **565**) until the volume of pure plasma collected within the plasma collection container **216** reaches the target plasma volume (Step **575**) (e.g., as calculated based on the individual plasma volume of the donor and the target percentage of plasma to collect).

Once the system **100** has collected the target plasma volume within the plasma collection container **216**, the system **100** can return the remaining components (e.g., the components remaining within the bowl **214**) to the subject (Step **580**) by stopping the draw of whole blood from the subject and reversing the direction of the blood/first pump **232** to draw the RBCS (and other components) from the bowl **214** and back to the subject (e.g., directly via the blood/inlet line **218** or, if so equipped, via a dedicated return line).

It is important to note that, because the system **100** method **500** collect and do not return some of the blood components (e.g., the plasma), the volume of fluid that is returned to the donor/subject is less than the volume that was removed. This, in turn, creates an intravascular deficit that is equal to the amount of plasma collected (e.g., the volume of whole blood removed from the donor minus the volume of plasma collected/not returned). In instances in which the intravascular deficit is too large, the donor is at risk of fainting when the procedure is complete and they get up to leave the facility. To reduce the intravascular deficit (and the risk of donor injury), as noted above, some embodiments of the present invention return saline to the patient/subject (Step **585**). The saline may be used as a compensation fluid to make up for the volume of the blood component (e.g., plasma) removed. To that end, during the return step (e.g., Step **580**), the controller **226** (or the technician) may open the saline valve to allow saline from the saline container **217** to flow through the saline line **223** and into the bowl **214** (via outlet **224**), where it can be returned to the patient/donor with or after the remaining blood components.

As mentioned above, the volume of plasma that is collected from the donor varies from donor to donor (e.g., because it is based on the donor's height, weight, hematocrit, and blood volume). Therefore, the volume of saline that is returned to the donor to reduce the intravascular deficit may similarly be dependent on the donor. To that end, when returning the contents of the separation device and the saline (Steps **580** and **585**) to the donor, the system **100** method/**500** may calculate the intravascular deficit (Step **590**) based on the total volume of whole blood removed from the donor and the volume of blood components and saline that has been returned (or based on the volume of plasma collected and the volume of blood components and saline that have been returned). The system **100** method/**500** may continue returning saline until the donor's intravascular deficit reaches a target intravascular deficit (Step **595**).

The target intravascular deficit may be any intravascular deficit that reduces the donor's risk for fainting and may be the same for each donor. For example, the target intravascular deficit may be set to 0 mL or 250 mL for each donor. Alternatively, like the target plasma volume to collect, the target intravascular deficit may be different for each donor.

16

In other words, the target intravascular deficit may be set to 0 mL for some donors and 250 mL for others. It should be noted that 0 and 250 mL are provided as examples only and other embodiments may have target intravascular deficits between 0 and 250, or greater than 250 mL. Additionally, in some instances, it may be beneficial to return more fluid to the donor than was removed/collected. In such instances, the target intravascular deficit may be set less than zero (e.g., -1 to -250 mL) so that the donor has more fluid/volume after the procedure than they did before the procedure.

Like the method **400** shown in FIG. 4, the method **500** may similarly perform some additional and optional steps to help determine the volume of pure plasma within the plasma collection container **216**. For example, some embodiments may monitor the change in weight of the anticoagulant container **210** (e.g., as measured by a weight sensor/load cell on the anticoagulant container **210**) (step **550**). This measurement provides an indication of the volume of anticoagulant that has been added to the system **100**, and may be used help determine the percentage of anticoagulant within the plasma collection container **216**. Additionally or alternatively, some embodiments may similarly, monitor the change in weight and/or volume of the plasma and anticoagulant collected within the plasma collection container **216** (e.g., via weight sensor **195**) (step **555**). This measurement may be used to calculate of the total volume of pure plasma collected within the plasma collection container **216** (e.g., to obtain the total weight from which to subtract the calculated volume of anticoagulant). Also, some embodiments may also monitor the volume of anticoagulant remaining in the bowl **214** (step **565**) (e.g., anticoagulant that did not mix with the plasma and/or otherwise remained in the bowl) using the optical sensor on the bowl **214** to determine whether any anticoagulant remains within the bowl **214** and modify the calculation of the amount of pure plasma collected within the plasma collection container (e.g., either increase the calculated amount or decreased the calculated amount), based on the volume of anticoagulant remaining within the bowl **214**.

As noted above, prior art systems that follow the current FDA nomogram for plasma collection collect a volume of plasma product (e.g., anticoagulant and plasma mixed together) based solely on the weight of the donor—the same volume is collected from every donor at the same weight. However, the total blood volume and plasma volume for two donors may vary greatly. For example, when comparing two donors in the same weight grouping according to the FDA nomogram—one obese and one not obese—the obese donor will effectively have a lower blood volume than the non-obese donor. Furthermore, with respect to the total plasma volume, donors with high hematocrit will have lower plasma volumes. In other words, because the total blood volume and total plasma volume vary from donor to donor (even among donors that weight the same), the percentage of the donor's plasma that is ultimately collected may vary widely from donor to donor. By tailoring the plasma collection to the donor (e.g., based on the donor's height, weight, BMI, hematocrit, total blood volume, and/or total plasma volume) and collecting a predetermined percent of plasma from each donor, embodiments of the preset invention are able to collect a greater volume of plasma (e.g., pure plasma) from some donors but less plasma from more vulnerable donors (e.g., smaller donors with high hematocrit, donors with lower plasma volume, etc.), as compared to systems that do not base the collection volume on the individual donor.

Similarly, current systems do not tailor the saline return volume to the patient (e.g., each donor at a given level

17

receives the same volume of saline, for example, if the target plasma product volume is 800 mL, the donor will receive 500 mL of saline). However, because prior art systems collect based on the volume of the plasma product (which includes both plasma and anticoagulant) and the volume of pure plasma that is actually collected (and therefore, the volume removed from the donor) varies based on the donor hematocrit, the intravascular deficit for each donor will vary. In other words, the volume of saline returned to the donor may be sufficient for some, but insufficient for others. By tailoring the saline return to the individual donor, embodiments of the present invention are able to ensure that each donor has the same intravascular deficit (if any) once the procedure is complete. This, in turn, allows embodiments of the present invention to achieve isovolemia for each donor and greatly reduce any adverse reactions that the donor may experience (e.g., falling, fainting, light-headedness, vasovagal reactions, etc.).

It is also important to note that, although the various embodiments discussed above are in relation to a blood processing system that collects plasma, the features discussed herein may be applied to any type of blood processing system. For example, the features described herein may be implemented on blood processing systems that collect and/or process red blood cells, platelets and/or white blood cells.

The embodiments of the invention described above are intended to be merely exemplary; numerous variations and modifications will be apparent to those skilled in the art. All such variations and modifications are intended to be within the scope of the present invention as defined in any appended claims.

What is claimed is:

1. A method for collecting plasma comprising:

- (a) determining a weight and height of a donor;
- (b) determining a hematocrit of the donor;
- (c) calculating a donor plasma volume based, at least in part, on the weight and height of the donor and the hematocrit of the donor;
- (d) calculating a target plasma collection volume based, at least in part, on the calculated donor plasma volume and a target percentage of plasma;
- (e) withdrawing whole blood from the donor through the venous-access device and a first line, the first line connected to a blood component separation device;
- (f) introducing anticoagulant into the withdrawn whole blood through an anticoagulant line;
- (g) separating the withdrawn whole blood into a plasma component and at least a second blood component using the blood component separation device;
- (h) collecting the plasma component from the blood component separation device and into a plasma collection container;
- (i) calculating a volume of anticoagulant in the collected plasma component as the plasma component is being collected in the plasma collection container;
- (j) calculating a volume of pure plasma collected within the plasma collection container based, at least in part, on the calculated volume of anticoagulant in the collected plasma component; and
- (k) continuing steps (e) through (j) until the calculated volume of pure plasma collected within the plasma collection container equals the target plasma collection volume.

18

2. A method according to claim 1, further comprising: returning, after collecting at least a portion of the target plasma collection volume, the contents of the blood component separation device to the donor through the first line.
3. A method according to claim 2, further comprising: calculating an intravascular deficit based, at least in part on, the volume of pure plasma collected and a volume of the contents of the blood component separation device returned to the donor.
4. A method according to claim 3, further comprising: returning a volume of saline to the donor to obtain a target intravascular deficit.
5. A method according to claim 4, wherein the target intravascular deficit is 0 milliliters.
6. A method according to claim 4, wherein the target intravascular deficit is between -250 and 500 milliliters.
7. A method according to claim 1, further comprising: calculating the donor's body mass index based, at least in part on the weight and height of the donor, the donor plasma volume calculated based, at least in part, on the donor's body mass index.
8. A method according to claim 1, wherein the target percentage of plasma is between 26.5 and 29.5 percent of the donor's plasma volume.
9. A method according to claim 1, further comprising: inserting a venous-access device into the donor prior to step (e).
10. A method according to claim 1, further comprising: determining a change in volume within an anticoagulant container, the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the change in volume within the anticoagulant container.
11. A method according claim 1, further comprising: determining a volume of anticoagulant introduced into the whole blood based on a number of rotations of an anticoagulant pump, the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the number of rotations of the anticoagulant pump.
12. A method according to claim 1, further comprising: determining a volume of anticoagulant within the blood component separation device, the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the volume of anticoagulant within the blood component separation device.
13. A method according to claim 1, wherein the volume of anticoagulant in the collected plasma component includes at least a portion of the anticoagulant introduced into the withdrawn blood and at least a portion of a volume of anticoagulant added during a priming step.
14. A method according to claim 1, further comprising: monitoring a volume of plasma component collected within the plasma collection container, the calculated volume of pure plasma collected within the plasma collection container based, at least in part, on the monitored volume of collected plasma component.
15. A method according to claim 1, further comprising: monitoring a weight of plasma component collected within the plasma collection container, the calculated volume of pure plasma collected within the plasma collection container based, at least in part, on the monitored weight of collected plasma component.
16. A method according to claim 1, wherein step (b) includes monitoring a volume of red blood cells collected within the blood component separation device, the determined hematocrit of the donor based, at least in part, on the

19

monitored volume of red blood cells collected within the blood component separation device and a volume of whole blood withdrawn from the donor.

17. A system for collecting plasma comprising:
- a venous-access device for drawing whole blood from a donor and returning blood components to the donor;
 - a blood component separation device for separating the drawn blood into a plasma component and a second blood component, the blood component separation device having an outlet and being configured to send the plasma component to a plasma container;
 - a first line fluidly connected to the venous-access device and configured to transport drawn whole blood to the blood component separation device and return fluid within the blood component separation device to the donor, the flow through the first line being controlled by a first pump;
 - an anticoagulant line connected to an anticoagulant source, the anticoagulant line configured to introduce anticoagulant into the drawn whole blood; and
 - a controller configured to control the operation of the blood component separation device and the first pump, the controller configured to calculate (1) a donor plasma volume based, at least in part, on a weight and height of the donor and a hematocrit of the donor, (2) a target plasma collection volume based, at least in part, on the calculated donor plasma volume and a target percentage of plasma, (3) a volume of anticoagulant in the collected plasma component as the plasma component is being collected in the plasma container, and (4) a volume of pure plasma collected within the plasma container based, at least in part, upon the volume of anticoagulant in the collected plasma component, the controller configured to stop the first pump when the calculated volume of pure plasma collected within the plasma container equals the target plasma collection volume.
18. A system according to claim 17, wherein the controller is further configured to:
- return, after collecting at least a portion of the target plasma collection volume, fluid remaining within the blood component separation device via the first line.
19. A system according to claim 18, wherein the controller is further configured to:
- calculate an intravascular deficit based, at least in part on, the volume of pure plasma collected and a volume of the contents of the blood component separation device returned to the donor.
20. A system according to claim 19, further comprising:
- a saline line configured to fluidly connect to a saline source and the blood component separation device, the controller configured to return a volume of saline to the donor to obtain a target intravascular deficit.
21. A system according to claim 20, wherein the target intravascular deficit is between -250 and 500 milliliters.
22. A system according to claim 17, wherein the controller is further configured to:

20

calculate the donor's body mass index based, at least in part, on the weight and height of the donor, the donor plasma volume calculated based, at least in part, on the donor's body mass index.

23. A system according to claim 17, wherein the target percentage of plasma is between 26.5 and 29.5 percent of the donor's plasma volume.

24. A system according to claim 17, wherein the volume of anticoagulant in the collected plasma component is based, at least in part, on a volume of anticoagulant added to the drawn whole blood and the donor's hematocrit.

25. A system according to claim 17, further comprising: an anticoagulant source weight sensor configured to measure the weight of the anticoagulant source, the controller further configured to monitor a change in volume within the anticoagulant source based on the measured weight of the anticoagulant source, the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the change in volume within the anticoagulant source.

26. A system according to claim 17, wherein the controller is configured to monitor a number of rotations of an anticoagulant pump to determine a volume of anticoagulant introduced into the whole blood, the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the number of rotations of the anticoagulant pump.

27. A system according to claim 17, further comprising: an optical sensor located on the blood component separation device and configured to monitor the contents of the blood component separation device and determine if a volume of anticoagulant remains within the blood component separation device, the calculated volume of anticoagulant in the collected plasma component being based, at least in part, on the volume of anticoagulant within the blood component separation device.

28. A system according to claim 17, further comprising: a plasma container weight sensor configured to monitor a volume of plasma component collected within the plasma container, the calculated volume of pure plasma collected within the plasma container based, at least in part, on the monitored volume of collected plasma component.

29. A system according to claim 17, further comprising: a plasma container weight sensor configured to monitor a weight of plasma component collected within the plasma container, the calculated volume of pure plasma collected within the plasma container based, at least in part, on the monitored weight of collected plasma component.

30. A system according to claim 17, further comprising: an optical sensor located on the blood component separation device and configured to monitor a volume of red blood cells collected within the blood component separation device, the controller configured to determine the donor's hematocrit based, at least in part, upon on the monitored volume of red blood cells collected within the blood component separation device and a volume of whole blood withdrawn from the donor.

* * * * *