US00RE45315E

(19) **United States**

(12) **Reissued Patent**

Gilcher et al.

(10) **Patent Number: US RE45,315 E**

(45) **Date of Reissued Patent: *Dec. 30, 2014**

(54) **AUTOMATIC BLOOD COLLECTION SYSTEM**

(75) Inventors: **Ronald O. Gilcher**, Fort Myers, FL (US); **Jacques Chammas**, Walpole, MA (US); **Joseph M. Medberry**, Seekonk, MA (US); **Gary R. Stacey**, Marshfield, MA (US)

(73) Assignee: **Haemonetics Corporation**, Braintree, MA (US)

(*) Notice: This patent is subject to a terminal disclaimer.

(21) Appl. No.: **10/865,554**

(22) Filed: **Jun. 10, 2004**

Related U.S. Patent Documents

Reissue of:

(64) Patent No.: **6,402,702**
Issued: **Jun. 11, 2002**
Appl. No.: **09/572,357**
Filed: **May 17, 2000**

U.S. Applications:

(62) Division of application No. 09/174,495, filed on Oct. 16, 1998, now Pat. No. 6,113,554.

(51) **Int. Cl.**
A61M 31/00 (2006.01)
G06Q 10/00 (2012.01)

(Continued)

(52) **U.S. Cl.**
USPC **604/6.01**; 705/2; 702/21; 600/573; 604/31

(58) **Field of Classification Search**
USPC 600/573, 578; 604/4.01, 5.01, 6.01, 604/6.11, 6.15, 6.16, 27, 540, 541, 317, 604/327, 403, 31; 210/782, 767, 781, 210/645–647; 494/12
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,086,924 A 5/1978 Latham, Jr. 128/214
4,385,630 A 5/1983 Gilcher et al. 604/31

(Continued)

FOREIGN PATENT DOCUMENTS

EP WO98/30122 7/1998
GB 2 006 058 A 5/1979
WO WO 95/31266 * 11/1995

OTHER PUBLICATIONS

No Author, Haemonetics' Haemonet Brochure, Oct. 1996, Haemonetics S.A., Switzerland.

(Continued)

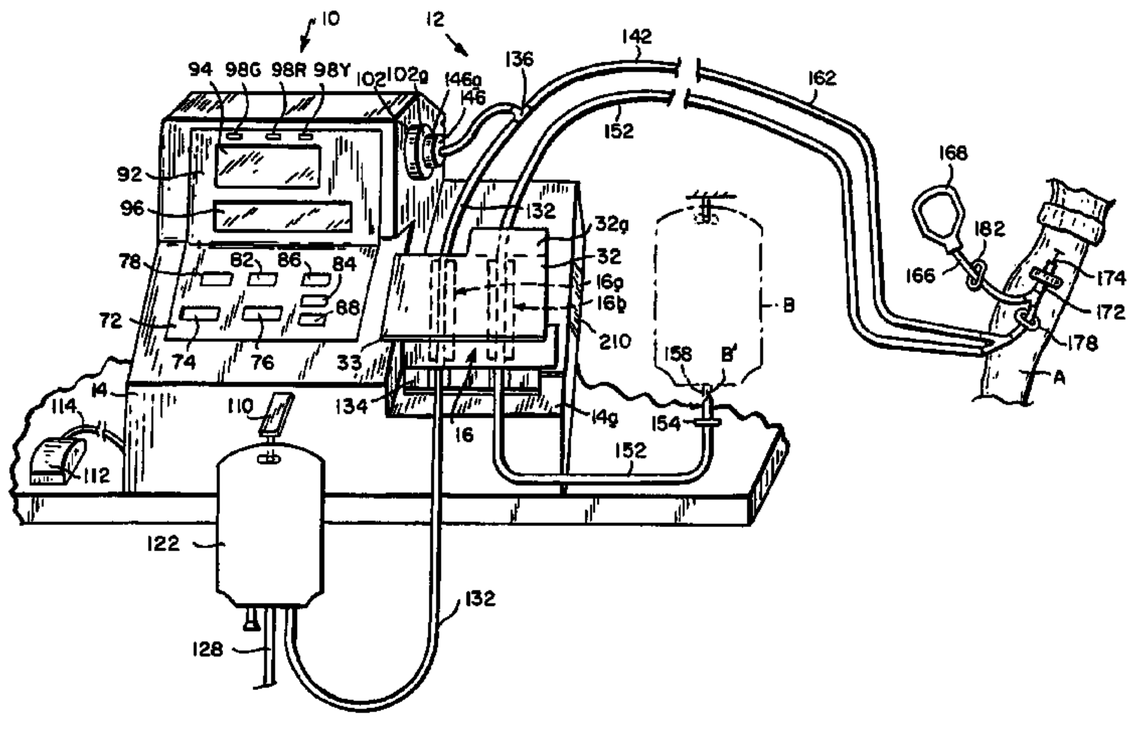
Primary Examiner — Brian Szmal

(74) *Attorney, Agent, or Firm* — Sunstein Kann Murphy & Timbers LLP

(57) **ABSTRACT**

A whole blood collection system includes an automated pump/control unit and an accompanying disposable blood set. When combined and connected to a source of anticoagulant, these elements allow automatic priming of the blood set with anticoagulant and automatic collection of anticoagulated blood product according to three different collection modes. The unit's pump and the blood set are specially designed to cooperate during the collection process to assure that the collected product has a precise blood to anticoagulant ratio. During the collection procedure, the pump/control unit automatically collects data relating to the procedure. Additional data specifically identifying components of the blood set, such as the blood collection bag, along with identification data on the donor's registration form may be scanned into the pump/controller unit by a scanner associated with the unit; this facilitates positive sample identification and tracking. At the end of the procedure, a printer in the pump/controller unit automatically prints out this information so that a detailed record is immediately available about the collected blood product, the procedure for collecting it and the source of the product, i.e., the donor.

34 Claims, 4 Drawing Sheets



(51) **Int. Cl.**

G06Q 50/00	(2012.01)
G01N 33/48	(2006.01)
G01N 33/50	(2006.01)
A61B 5/00	(2006.01)
B65D 81/00	(2006.01)
A61M 1/00	(2006.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,443,333	A	4/1984	Mahurkar	210/87
4,474,568	A	10/1984	Schoendorfer et al.	604/4
4,605,503	A *	8/1986	Bilstad et al.	210/651
4,806,247	A	2/1989	Schoendorfer et al.	210/321.18
5,002,066	A *	3/1991	Simpson et al.	600/573
5,125,920	A *	6/1992	Ishick	604/410
5,387,187	A	2/1995	Fell et al.	604/6
5,460,493	A *	10/1995	Deriega et al.	417/477.2
5,658,240	A	8/1997	Urdahl et al.	
6,113,554	A *	9/2000	Gilcher et al.	604/31
6,256,643	B1	7/2001	Cork et al.	

OTHER PUBLICATIONS

No Author, "Eliminating Health Errors Through Mobile Computering", White Paper from Lattice Inc. Website (c) 1997, 1998.

* cited by examiner

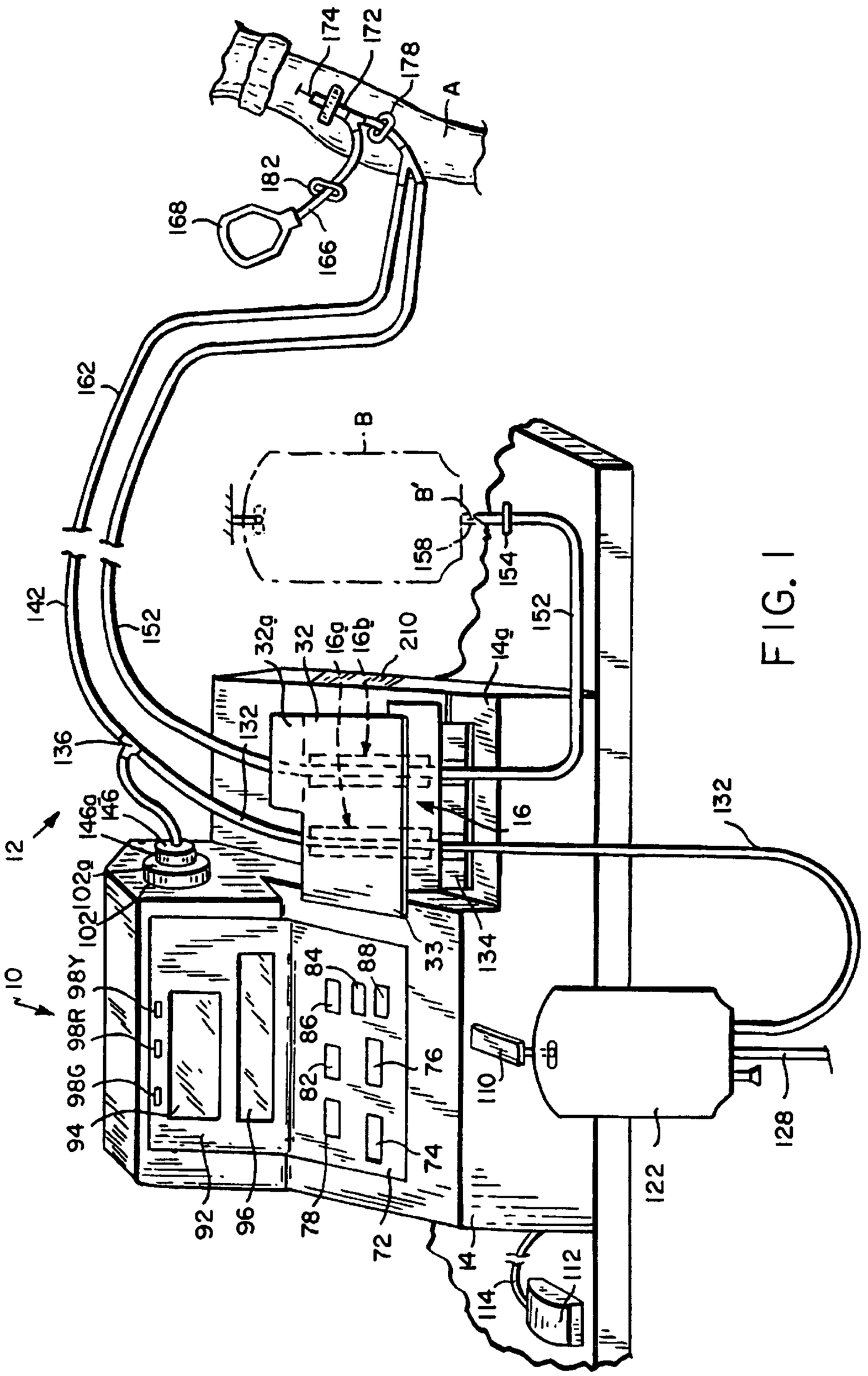

174
172
178
A
182
168
166
162
B
B'
158
154
142
152
32a
32
16a
16b
210
14a
152
136
132
146a
146
16
132
12
102a
102
98Y
98R
98G
94
10
84
88
86
82
76
74
92
96
78
72
33
34
134
110
122
128
14
114
112

FIG. 1

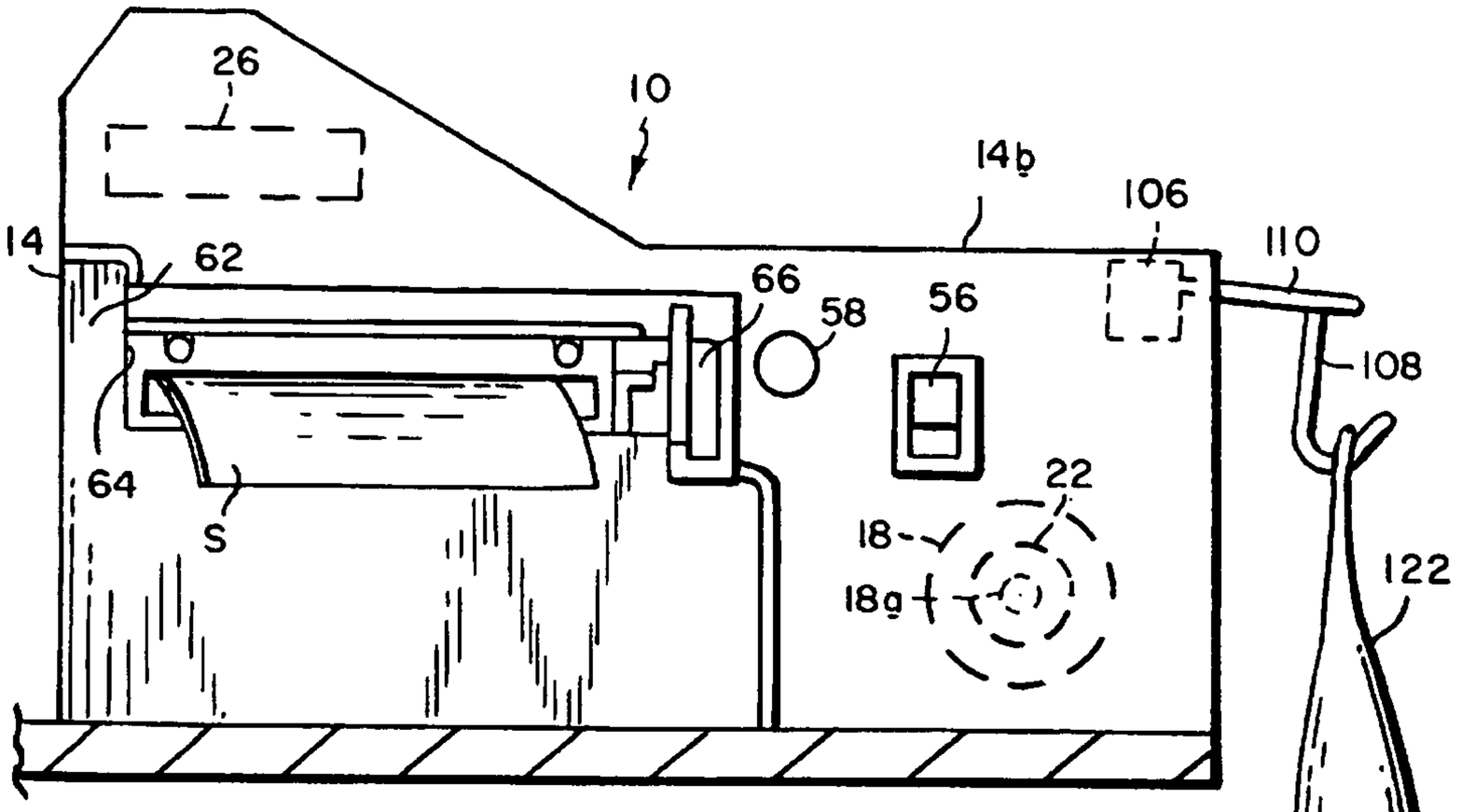

26
10
14b
106
110
14
62
66
58
56
108
64
S
22
18
18g
122

FIG. 2

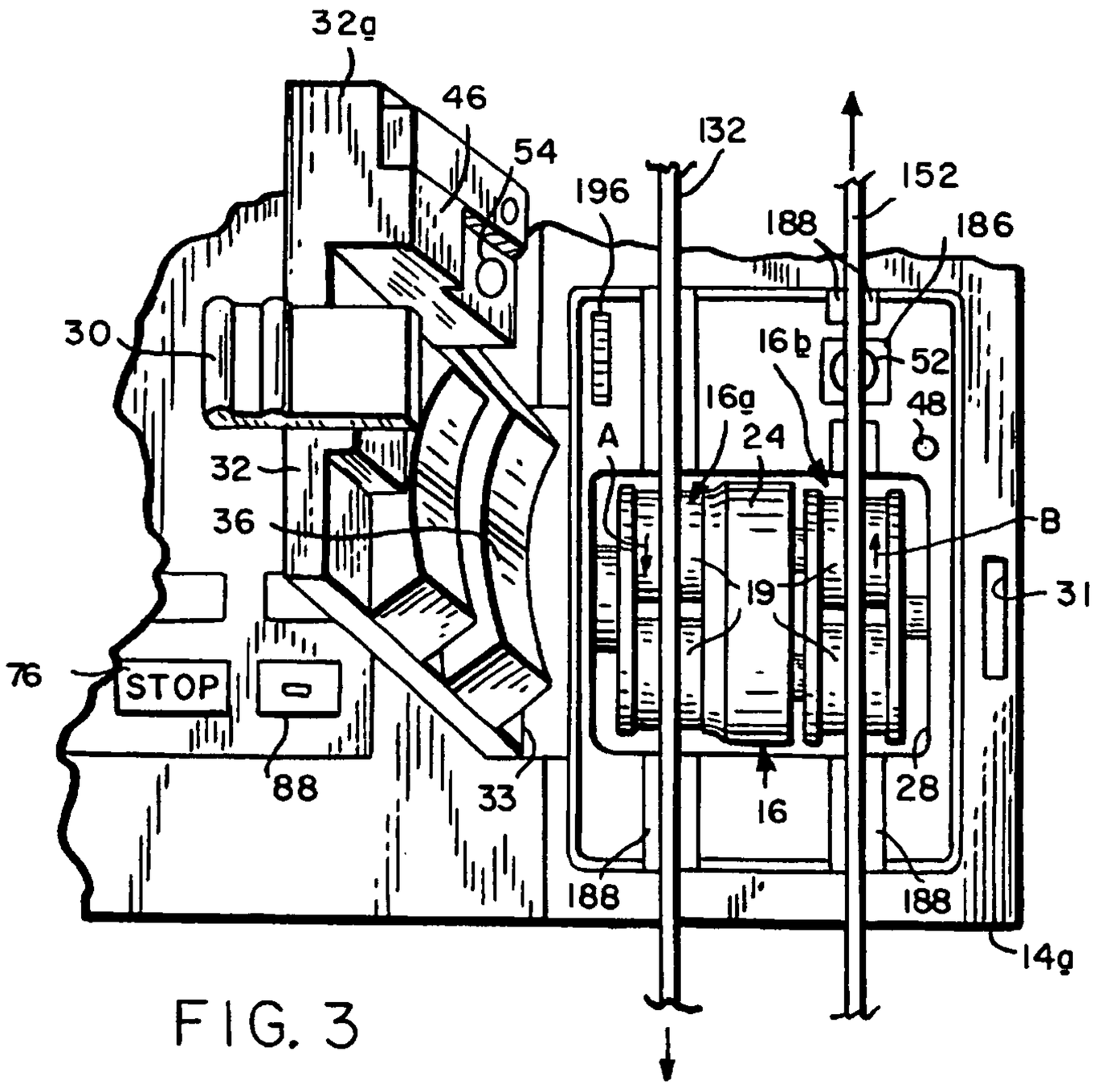

32g
46
54
132
152
196
188
186
30
16b
52
16g
24
48
A
32
36
8
19
31
76
STOP
88
33
16
28
188
188
14g

FIG. 3

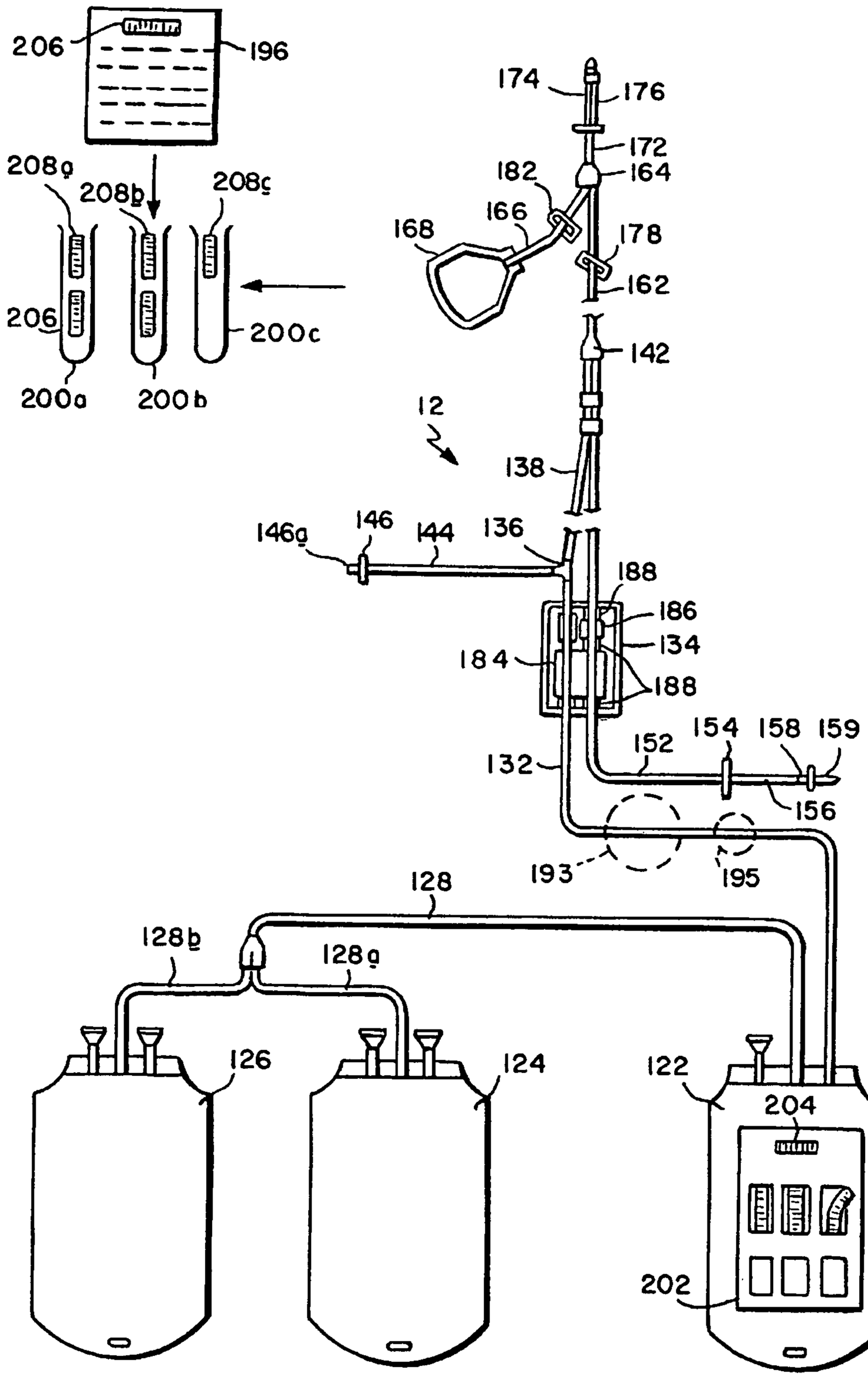

206
196
208a
208b
208c
206
200c
200a
200b
174
176
172
182
164
166
168
178
162
142
12
138
146a
146
144
136
188
186
134
184
188
154
158
159
152
132
156
193
195
128
128b
128a
126
124
122
204
202

FIG. 4

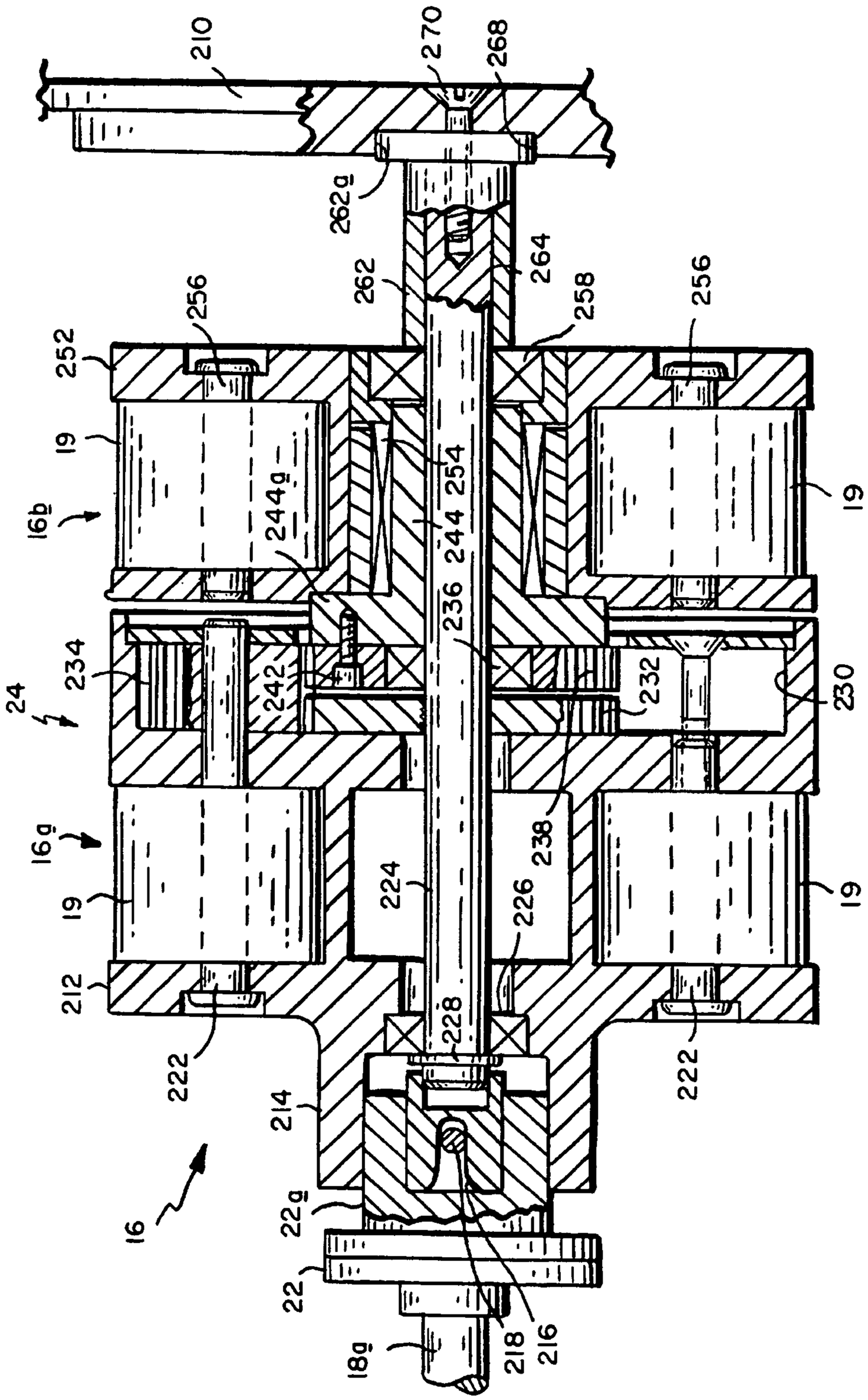

210
270
268
262a
264
262
256
258
256
252
19
16b
244a
244 254
19
236
234
242
232
230
24
238
16a
224
226
19
212
228
222
222
214
16
22a
22
18a
218
216

FIG. 5

AUTOMATIC BLOOD COLLECTION SYSTEM

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.

RELATED APPLICATION

More than one reissue application has been filed for the reissue of U.S. Pat. No. 6,402,702. The reissue applications are application Ser. Nos. 10/865,554 (the present application), and 14/151,641, which is a continuation reissue application of U.S. Pat. No. 6,402,702.

This application is a division of Ser. No. 09/174,495, filed Oct. 16, 1998, now U.S. Pat. No. 6,113,554.

This invention relates to an automatic whole blood collection system. It relates more particularly to a method and apparatus for standardizing volumetric whole blood collection and red blood cell mass collection so that the collection process can be accomplished efficiently with minimum damage to the blood and with minimum discomfort to the donor.

BACKGROUND OF THE INVENTION

Prior systems for collecting blood rely on venous pressure and hydrostatic pressure to cause blood to flow from a donor's arm. A phlebotomy needle that is connected by tubing to a blood collection bag containing anticoagulant is inserted into a donor's arm. Hydrostatic pressure is achieved by positioning the collection bag about 18 inches below the level of the donor's arm and venous pressure is controllable to some extent by varying the pressure in a cuff attached to the donor's arm above the venipuncture site and, by directing the donor to alternately flex and relax his/her hand. Older collection apparatus used a relatively large needle (e.g., 16 gauge) which, when inserted, caused appreciable patient discomfort. Also, during the collection process, the non-anticoagulated whole blood drawn from the donor had to pass through the phlebotomy needle and along a length of tubing before it reached the anticoagulant in the blood collection bag. If the rate of flow of blood through the tubing was not maintained high enough, clotting could occur, reducing the usefulness of the collected blood.

To avoid the aforementioned problems, there has been developed relatively recently blood donation apparatus which utilizes a peristaltic or roller pump to withdraw whole blood from a donor through a much smaller (e.g., 19 gauge) phlebotomy needle, and to pump the blood through a tube leading to the collection bag. Anticoagulant flowing through a second tube leading from an anticoagulant source is mixed with the whole blood right at the outlet of the phlebotomy needle. The anticoagulant tube passes through the same pump head that draws the whole blood from the donor, so that the ratio of blood to anticoagulant is determined by the ratio of the diameter and elastic properties of the drawn blood tube with respect to those of the anticoagulant tube. Such a blood donation apparatus is disclosed in U.S. Pat. No. 4,385,630.

While that patented apparatus is a considerable improvement over the prior blood collection apparatus, it still has certain drawbacks. For example, it must be primed manually so that anticoagulant fills the anticoagulant tube down to the phlebotomy needle. Also, it employs a peristaltic pump with a single roller pump head acting on both the blood tube and anticoagulant tube. Therefore, the blood-to-anticoagulant ratio depends upon the tubing characteristics, making it difficult to change that ratio. Still further, the disposable blood collection set used in that prior blood donation apparatus is relatively difficult to install in the pump unit such that the drawn blood and anticoagulant tubes are properly positioned on the unit's pump head.

That patented blood donation apparatus is further disadvantaged because it is only able to collect a set volume of whole blood. Often, it is desirable to have the option of collecting different blood volumes. For example, in some cases, it may be necessary to collect a specific mass of red blood cells (RBC) based on the donor's known hematocrit, i.e., the percentage by volume of RBC in drawn whole blood. Even if the target volume of RBC is always the same in such cases, the volume of whole blood to be drawn will vary from donor to donor.

Finally, that known apparatus does not provide a record of the collection procedure and does not positively correlate the drawn blood with the donor of that blood. Therefore, there is always the possibility of the collected blood being misidentified and misused.

SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a fully automatic whole blood collection system.

Another object of the invention is to provide a collection system of this type which is self-priming.

A further object of the invention is to provide a system such this which is relatively easy to use.

Yet another object of the invention is to provide such a system which is programmable to allow the collection of different blood volumes.

Still another object of the invention is to provide a whole blood collection system which facilitates positive identification of the donor's blood and simplifies the keeping of records relating to the blood donations.

A further object of the invention is to provide a blood collection system which allows phlebotomists to draw blood safely and reliably from several donors in rapid succession.

Yet another object of the invention is to provide a disposable blood collection set for use in the above system.

A further object of the invention is to provide a method of tracking a donor's blood collected by the above whole blood collection system.

Other objects will, in part, be obvious and will, in part, appear hereinafter.

The invention accordingly comprises the several steps and the relation of one or more of such steps with respect to each of the others, and the apparatus embodying the features of construction, combination of elements and arrangement of parts which are adapted to effect such steps, all as exemplified in the following detailed description, and the scope of the invention will be indicated in the claims.

Briefly, the whole blood collection system of the present invention comprises an automated pump/control unit and an accompanying disposable blood set. When combined and connected to a source of anticoagulant, these elements allow automatic priming of the blood set with anticoagulant and automatic collection of anticoagulated blood product according to three different collection modes to be described. As will be seen, the unit's pump and the blood set are specially designed to cooperate during the collection process to assure that the collected product has a precise blood to anticoagulant ratio, typically in excess of 5:1, e.g., 8:1.

During the collection procedure, the pump/control unit automatically collects data relating to the procedure. Addi-

tional data specifically identifying components of the blood set, such as the blood collection bag, along with identification data on the donor's registration form and on various blood samples may be scanned into the pump/controller unit by a scanner associated with the unit; this facilitates positive sample identification and tracking. At the end of the procedure, a printer in the pump/controller unit automatically prints out this information so that a detailed record is immediately available about the collected blood product, the procedure for collecting it and the source of the product, i.e., the donor. Thus, there is minimum likelihood of the product being mislabeled.

As will be seen, the system is easy to use and quite efficient so that the collection time is kept to a minimum, allowing a phlebotomist to draw blood safely and reliably from several donors in rapid succession with minimum discomfort to the donors.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature and objects of the invention, reference should be had to the following detailed description taken in connection with the accompanying drawings, in which:

FIG. **1** is an isometric view of an automatic whole blood collection system according to the invention;

FIG. **2** is a right side elevational view of the FIG. **1** system's pump/control unit;

FIG. **3** is a fragmentary top plan view of the FIG. **2** unit showing the unit's pump platen in its open position;

FIG. **4** is a plan view of the FIG. **1** system's disposable blood collection set, and

FIG. **5** is a longitudinal sectional view with parts broken away on a larger scale showing the peristaltic pump in the FIG. **2** unit in greater detail.

DETAILED DESCRIPTION OF AN ILLUSTRATIVE EMBODIMENT

Referring to FIGS. **1** to **3** of the drawings, the whole blood collection system comprises a pump/control unit shown generally at **10** and a disposable blood collection set indicated generally at **12**. As shown in those figures, unit **10** includes a housing **14** which houses a special peristaltic pump shown generally at **16** and driven by the shaft **18**a of an electric motor **18** by way of a one-way clutch **22** (FIGS. **2** and **5**).

As best seen in FIG. **3**, pump **16** has two rotary heads **16**a and **16**b, each head being constituted by four rollers **19**.

The two pump heads **16**a and **16**b are mechanically coupled together by means of a speed reducer and rotation reverser **24** so that when head **16**a is rotated by motor **18** in the direction of arrow A, the pump head **16**b will rotate in the opposite direction, i.e., in the direction of the arrow B, at a slower rate. In accordance with the invention, the gear ratio of speed reducer **24** is selected so that the ratio of the speeds of heads **16**a and **16**b is the same as the desired ratio of blood to anticoagulant in the blood being drawn from a donor by this system, a typical ratio being in excess of 5:1, e.g., 8:1. Thus, the ratio of blood to anticoagulant can be changed simply by substituting a different speed reducer **24** having the desired gear reduction ratio.

The motor **18** that drives pump **16** is preferably a 28 volt DC motor energized by voltage from a standard AC/DC converter (not shown) which may be plugged into a suitable electrical outlet. Motor **18** is controlled by a controller **26** located in housing **14** as shown in FIG. **2**.

Pump **16** is positioned in housing **14** so that one or two rollers of each head **16**a and **16**b are exposed through an opening **28** in a top wall **14**a of housing **14**. As shown at FIGS. **1** and **3**, a platen **32** is connected by a hinge **33** to the housing top wall **14**a so that the platen can swing between a closed position shown in FIG. **1** wherein the platen overlies pump **16** and closes the opening **28**, and an open position illustrated in FIG. **3** wherein the platen is swung away from opening **28** (thereby exposing the pump heads **16**a and **16**b). The platen may be releasably retained in its closed position by the engagement of a latch **30** pivotally mounted to the platen in a keeper **31** present in housing top wall **14**a adjacent opening **28** therein.

As best seen in FIG. **3**, the underside of platen **32** has protruding undersurface areas **34**a and **34**b which are curved to accommodate the rotational movements of the pump heads **16**a and **16**b, respectively. When the platen **32** is in its closed position shown in FIG. **1**, the undersurface areas **34**a and **34**b extend through opening **28** and are spaced opposite the uppermost roller(s) **19** of the pump heads **16**a and **16**b, respectively, a distance less than the diameter of the tubing comprising the blood collection set **12**. Resultantly, when tubing segments are positioned on the pump heads **16**a and **16**b as shown in FIG. **3**, and the platen **32** is closed, energizing motor **18** causes each pump head to produce a rolling pinch in those tubing segments which pumps fluid through the associated tubing in the direction of the corresponding arrow A or B. The one-way clutch **22** assures that the pump heads can only rotate in the directions of those arrows.

As shown on FIG. **3**, the platen **32** has a side extension **32**a which extends to the rear of housing **14** and overlies the housing top wall **14**a. The undersurface of the side extension **32**a has a pad **46** which, when the platen is closed as in FIG. **1**, engages and closes a proximity switch **48** projecting through the housing top wall **14**a adjacent to opening **28** therein. Switch **48** provides an interlock. Unless the controller **26** detects that switch **48** is closed (indicating that platen **32** is closed and latched), the controller will not activate motor **18**.

Also mounted in the housing top wall **14**a just behind pump head **16**b is a sonic emitter/detector **52**. A second similar emitter/detector **54** is mounted in the underside of platen side extension **32**a adjacent pad **46**. When tubes are positioned on the pump heads **16**a and **16**b as shown in FIG. **3** and platen **32** is closed, the two emitter/detectors **52**, **54** are located respectively above and below a segment of the tube on pump head **16**b. Thus, each device **52**, **54** is positioned to receive the acoustic signals produced by the other after they have passed through that tube. The received signals from the two devices **52**, **54** are compared by controller **26** to detect the presence and absence of fluid, i.e., blood, in that tube. In fact, the emitter/detectors **52**, **54** are accurate enough to detect microbubbles, but are calibrated for bubbles as small as 0.3 inch at a pump **16** speed of 100 RPM. The controller **26** is programmed to deactivate pump motor **18** in the absence of fluid in the tube on pump head **16**b.

As shown in FIGS. **1** and **2**, various controls are mounted in housing **14** to control the operation of the pump/control unit **10**. More particularly, there is an ON/OFF power switch **56** mounted in the right side wall **14**b of housing **14**. Next to switch **56** is a PAPER LOAD button **58** which, when actuated, allows the removal of a digital thermal printer **62** from the side of housing **14** in order to load paper into the printer. Printer **62** prints blood collection data as alphanumeric characters and bar codes on a paper strip S which issues from a slot

64 in the printer. The printer also has a paper feed knob **66** which may be turned to advance the paper strip S, e.g., when loading paper into the printer.

The pump/control unit **10** also includes a control panel **72** located at the front of the housing and containing several control buttons. A START button **74** starts unit **10** at the beginning of the blood collection process, and a STOP button **76** can be depressed to stop the collection process at any point in the collection cycle. At the end of the cycle, controller **26** causes printer **62** to automatically print out data relating to that procedure. Also, a PRINT button **78** may be used to activate printer **62** to print more copies of the data, and a MUTE button **82** quiets the audible alarms (not shown) built into unit **10**. Panel **72** also has a set of three related buttons, namely, a MODE button **84**, a "+" button **86** and a "−" button **88**. These buttons are used to enter a donor's hematocrit or the targeted blood collection volume before the start of a collection procedure, as will be described in detail later. The closing of each of the aforementioned switches and control buttons is detected by controller **26**, which is programmed to control the operation of the various elements of unit **10** in the manner to be described.

Referring now to FIG. **1**, the pump/control unit **10** has, in addition, several displays mounted in a display panel **92**, which projects up behind control panel **72**. The display panel includes a numeric display **94** which displays the blood volume collected by unit **10**. A second display **96** displays two lines of alphanumeric characters and is used to deliver user messages. There are also three LEDs located above display **94**, i.e., a green LED **98**G, a red LED **98**R and a yellow LED **98**Y. These lights are used as indicators of the operating conditions of unit **10** as will be described. All of the displays are controlled by controller **26**.

Unit **10** also includes a pressure detector **102** which has an inlet nipple **102**a and which is mounted to housing **14** adjacent to display panel **92** as shown in FIG. **1**. As will be described in more detail later, when unit **10** is in operation, detector **102** monitors the donor's blood pressure in the blood line from the donor to the collection system. The controller **26** monitors feedback signals from the transducer and controls the speed of the pump motor **18** in order to maximize the blood flow while keeping the pressure level at a value that ensures the donor's comfort. Controller **26** may be programmed to limit pump head **16**a to a maximum speed of, say, 100 RPM, so that in a typical collection procedure, about 75-80 ml of anticoagulated blood will be drawn through the tubing on that pump head.

The pump/control unit **10** has, in addition, an electronic weigher **106**. The weigher may comprise a transducer (e.g., piezoelectric bender, strain gauge, etc.) which produces an electrical output or value sampled by controller **26** and which represents the weight of a blood bag hanging on a hook **108** at the end of a lever arm **110** projecting from the front of housing **14** (see FIGS. **1** and **2**). As will be described later, the output of the weigher **106** is used to determine the volume of the collected blood product.

Preferably, also, the pump/control unit **10** is provided with a hand-held bar code scanner **112** connected by a cable **114** to controller **26** as shown in FIG. **1**. The scanner **112** is used to scan bar codes printed on the donor's registration form and on components of the blood collection set **12** and on blood samples for entry into the controller's memory in order to track the donor, the collected blood product and any test samples taken during the collection procedure.

Turn now to FIG. **4** which shows in detail the various elements of the disposable blood collection set **12**. The set **12** includes a main collection bag **122** and two satellite bags **124** and **126**. Bag **122** may have a volume of 600 ml, for example, and be used to collect whole blood or RBC, while the two satellite bags **124** and **126** may each have a volume of 400 ml and be used to collect platelets and plasma, respectively. The bags are interconnected by a tube **128** leading from bag **122** and splitting into branches **128**a and **128**b leading to bags **124** and **126**, respectively. Preferably, there is a breakable seal (not shown) in tube **128** to prevent transfer of fluid between bag **122** and bags **124** and **126** during storage and shipment.

The disposable set **12** also has a tube **132** extending from bag **122** over a tubing tray **134** to one arm of a T-connection **136**. Tube **132** communicates at connection **136** with a tube **138** which leads to a Y-connection **142**. The leg of the T-connection **136** connects to one end of a length of tubing **144** which extends to the outlet side of an antibacterial filter **146** (e.g., 0.22 μ) which prevents infiltration of contaminants into set **12**. Filter **146** has an inlet luer **146**a adapted to be coupled to the nipple **102**a of the pressure sensor **102** on unit **10** as illustrated in FIG. **1**.

Tray **134** also supports an anticoagulant tube **152** which extends from the Y-connection **142** to the outlet of an antibacterial filter **154** (e.g., 0.22 μ). The filter inlet is connected via tubing **156** to a tubular spike **158** which is adapted to be coupled to the spike port B' of a bag B containing anticoagulant as shown in phantom in FIG. **1**. Prior to using set **12**, the spike **158** may be protectively enclosed in a sheath **159**. The leg of Y-connection **142** is connected to a tube **162** which leads to one branch of a second Y-connection **164**, the other branch of which is connected via a tube **166** to a small presample pouch **168**. This pouch allows the collection of a sample of a donor's blood without a separate venipuncture. The leg of connector **164** is connected by a short length of tubing **172** to a small (i.e., 18 or 19 gauge) phlebotomy needle **174** with a back-eye. Preferably, needle **174** is protected by a cap **176** prior to use. Preferably also, the tubes **162** and **166** are provided with clamps **178** and **182**, respectively, for reasons that will become apparent.

Still referring to FIG. **4**, the tubing tray **134** of the blood set **12** is a generally rectangular card-like element preferably made of plastic. It is provided with a relatively large rectangular opening **184** and a smaller simiarly shaped window **186** adjacent to opening **184**. The tray is formed with sets of closely spaced parallel ribs **188** which are adapted to capture the blood tube **132** and the anticoagulant tube **152** so that the segments of those tubes overlying tray **134** are straight and parallel to one another and such that a tube **132** segment **132**a bridges opening **184** and different **152**a and **152**b of the tube **152** segment bridge opening **184** and window **186**, respectively. The tubes may be retained between their respective sets of ribs **188** by friction and compression forces. Alternatively, the tubes may be bonded or heat sealed in place.

If desired, set **12** may be provided with components to facilitate initial filtration or processing of drawn blood. For example, as shown in phantom in FIG. **4**, a blood centrifuge bowl **193** may be interposed along tubing **132**, allowing the anticoagulated blood to be separated into its components; see e.g., U.S. Pat. No. 5,387,187, the contents of which is hereby incorporated herein by reference. Also, an in-line filter **195** for white blood cells or platlets may be disposed before or after the bowl **193** as shown in that same figure.

Prior to use, the disposable blood set **12** may be packaged in a suitable sterile pouch or bag (not shown).

In order to operate the system, unit **10** is turned on via switch **56** and the desired collection mode is selected by depressing MODE button **84**. Thereupon, the unit performs various diagnostic tests to ensure that the unit's displays and systems are operating properly according to a routine pro-

grammed into controller **26**. If any of the tests fails, an action message will be displayed by display **96**, thereby prompting appropriate corrective action. When the self testing is completed, unit **10** will indicate its readiness to accept disposable set **12** by displaying in display **96**, "PLEASE INSTALL DISPOSABLE."

The controller **26** in the pump/control unit **10** is programmed for three collection modes selected by successively depressing the MODE button **84** after unit **10** is powered up as aforesaid. A STANDARD mode represents the default mode at power up; in accordance therewith, display **96** will indicate "STANDARD MODE," a target volume of 450 ml and its equivalent of 513 ml of anticoagulated blood. When operating in this mode, the system will collect a set volume (i.e., 450 ml) of whole blood, mix it with anticoagulant at an 8:1 ratio (i.e., a volume of 63 ml), and then stop automatically.

If button **84** is depressed once, unit **10** switches to a VOLUME mode operation whereby the system collects a predetermined volume of fresh blood over a range of 50 to 500 ml, mixes it with anticoagulant at an 8:**1** ratio and then stops automatically. During VOLUME mode operation, display **96** may initially show a default target volume of 450 ml for the fresh blood and its equivalent of 513 ml of anticoagulated blood. The target volume (as displayed) may be increased or decreased in 10 ml increments by depressing the "+" button **86** or the "–" button **88**, and the displayed volume of the anticoagulated blood will increase or decrease accordingly.

When button **84** is depressed twice at power up, unit **10** operates in a RED CELL mode during which the system collects whole blood equivalent to a selected volume, e.g., 180 ml, of concentrated RBC, mixes the whole blood with anticoagulant at an 8:1 ratio and then stops automatically. In this mode, display **96** will show "RED CELL MODE" and display initially "40% HEMATOCRIT." In this mode, the default 40% hematocrit value may be increased by 1% each time the "+" button **86** is depressed and decreased 1% each time the "–" button **88** is depressed. When the displayed hematocrit matches the already known donor's hematocrit, depression of the STOP button **74** will enter that value into the controller **26** memory. Based thereon, display **96** will display the calculated target volume of anticoagulated blood based on the donor's hematocrit and 180 ml of RBC.

After mode selection and testing and when signaled to do so by display **96** as described above, the collection set **12** may be installed in unit **10** as shown in FIG. **3**. More particularly, set **12** is removed from its sterile pouch and with clamps **178** and **182** closed, the bag **122** component of the set is hung from scale hook **108**. Then, the platen **32** of unit **10** is opened and the tubing tray **134** positioned on the housing top wall **14**a as shown in FIG. **3** such that the segments of tubes **132** and **152** on tray **134** are centered, and lay flat, on the pump heads **16**a and **16**b, respectively, and so that the segment **152**b of tube **152** bridging window **186** on the tray is centered on the acoustic detector **52**.

The platen **32** is then closed and latched so as to clamp the respective tubing segments **132**a and **152**a bridging the tray opening **128** between the pump heads **16**a and **16**b and the platen surfaces **36**a and **36**b. When the platen is latched, the platen pad **46** presses down on the tray, thereby depressing the proximity switch **48** which signals the controller **26** that pump **16** is properly loaded and latched.

Next, the inlet luer **146**a of filter **146** is coupled to the inlet nipple **102**a of the pressure sensor **102**.

When set **12** is installed in unit **10** as aforesaid, unit **10** will indicate its readiness to start an autoprime sequence to prime set **12** by displaying on display **94** the message "000 ml" and displaying on display **96** the words "CLAMP NEEDLE—PRESS START TO PRIME." At this point, the operator may insert the spike **158** of set **12** into the port B' of the anticoagulant bag B as shown in FIG. **1**, close clamp **178** and press the START button **74**. Display **196** will now indicate the priming mode by displaying the word "PRIMING." During priming, the green LED **98**G will be illuminated and controller **26** will activate the pump motor **18** causing the pump heads **16**a and **16**b to rotate respectively in the direction of the arrows A and B in FIG. **3**. The pump head **16**b will draw anticoagulant from bag B through filter **154** and along the anticoagulant tube **152** so that the fluid passes over emitter detector **52**. Once that detector detects the anticoagulant in tube **152**, controller **26** will cause motor **18** to rotate the pump **16** a predetermined number of revolutions and then stop. This number of pump revolutions is enough to prime the set **12** with anticoagulant fluid up to the Y-connection **142** where the blood tube **132** and anticoagulant tube **152** merge.

During this priming sequence, the display **94** will indicate "000 ml" collected volume, although the pump **16** is rotating. If the sonic emitter/detectors **52**, **54** do not detect anticoagulant in the tube **152**, controller **26** will stop pump **16** automatically after the pump has completed a further predetermined number of revolutions. A message will there-upon appear on display **96** to indicate that anticoagulant has not been detected in tube **152**.

On other hand, when the blood collection set **12** is properly primed, the display **96** will indicate that the system is ready to collect a donor's blood by displaying the message "READY" and the estimated collection time (e.g., "EST. TIME 8:00") on display **96** while display **94** will show "000 ml."

At this point, the cap **176** may be removed from the phlebotomy needle **174** and the needle inserted into the donor's arm A as shown in FIG. **1**. Then, the clamp **178** may be released from tube **162**, allowing blood to flow from the donor's arm along tube **162** whereupon it mixes with anticoagulant at the Y-connection **142**. If it is desired to collect a sample of the donor's blood before the release of clamp **178**, the clamp **182** may be released from the tube **166** leading to the sample pouch **168**, allowing fresh blood to flow into that pouch until it is full, following which clamp **182** is closed on tube **166**. As noted above, the pouch **168** allows a sample of the donor's blood to be taken without a separate venipuncture. Pouch **168** should remain clamped off during the entire blood collection process.

The system is now ready to collect the donor's blood. For purposes of the following description, we will assume that unit **10** is operating in its STANDARD mode. Collection is initiated by pressing the START button **74** on unit **10**. At start, the controller **26** is programmed to cause motor **18** to rotate pump **16** and accelerate it until the pump reaches a steady state that causes blood to flow along tubes **162**, **138** and **132** to collection bag **122**. This steady state is defined as the pump velocity when the pressure detected by the pressure sensor **102** falls within the limits that provide for maximum flow with maximum donor comfort. During acceleration, the yellow LED **98**Y will flash. When the pump **16** reaches a steady state, LED **98**Y will turn off and the green LED **98**G will flash once per revolution of pump head **16**a to indicate that the pump is working. If the pressure level remains normal, the pump will continue to draw blood and stop automatically when the collected volume of anti-coagulated blood in bag **122** reaches the selected volume, e.g., 513 ml. The operator can manually stop the collection procedure at any time by pressing the STOP button **76** on control panel **72**.

During collection, the display **94** provides a real time display of the instantaneous volume of the collected anti-coagulated blood. This information is obtained from the weigher

106, which is constantly weighing bag 122 as it is being filled. The signals from the wiegher are processed by controller 26 to produce equivalent volume data used to control the pumping time of pump 16 and the information displayed by display 94. Also, the display 96 indicates the elapsed time since the pump 16 started to draw anticoagulated blood as well as the estimated time remaining to end the procedure. For example, that display may show the words "ELAPSED 4:12—REMAINING 3 MIN."

If unit 10 should be stopped manually by the operator depressing the STOP button during the collection procedure before the system has collected 513 ml of the blood product, the display 96 will indicate that the system is ready to continue collection of blood by displaying "<START >TO CONT." The volume count displayed by display 94 will remain at its present level and cannot be reset to zero. Also, the green LED 98G will stop flashing and the yellow LED 98Y will be turned on and the digits in the display 94 will flash to indicate that the pump 16 has stopped.

If the pump 16 should stop automatically for any safety reason (before collecting the set volume of product, i.e., 513 ml), the red LED 98R will be turned on and a message will appear on display 96 to guide the operator.

When the collection procedure is completed, display 94 will flash the collected volume number and display 96 will indicate the elapsed time for the procedure. If the procedure ends in 6 minutes and 35 seconds, for example, display 94 will flash 513 ml (representing 450 ml of the donor's blood plus 63 ml of anticoagulant fluid) and the display 96 will display the message "PROC. TIME 06:35—SCAN DATA," which message remains on the display until the operator scans all the data using scanner 112.

At this point, the tube 162 from needle 174 may be clamped using clamp 178, the needle 174 may be removed from the donor's arm A and a dressing applied to the puncture site. Also, the anticoagulant tube 152 may be clamped downstream from filter 154 using a hemostat (not shown).

When blood is drawn from a donor, the donor is required to fill out a registration form indicated at 196 at FIG. 4. The requested information for the form includes biographical information, prior medical history, allergic reactions and other conditions that could affect the quality of the donor's blood. Also, during or following the collection procedure, blood collected in the sample pouch 168 is often transferred to a plurality of sample tubes such as tubes 200a, 200b and 200c in FIG. 4 so that the blood sample can be subjected to various tests. That being the case, it is essential that the various disposable components of the blood collection system such as in blood bag 122 and the sample tubes 200a to 200c be correlated with the particular donor via his/her registration form 196 so that the drawn blood can be properly identified. To this end, the present system incorporates a labeling procedure which facilitates tracking the blood bags and sample tubes to avoid mis-identification of the drawn blood.

More particularly, when a donor fills out the registration form 196 and the blood collection set 12 is selected for that donor, a large label 202 may be adhered to the blood collection bag 122 of that set as shown in FIG. 4. That label carries a fixed bar code 204 as well as a plurality of removable bar code strips 206, each bearing the same code as strip 204. The strips 206 can be peeled away from label 202 and adhered to the donor's registration form 196 as well as to the pouch 160, tray 134 (FIG. 3) and sample tubes 200a to 200c as shown in FIG. 4.

Preferably also, the sample tubes 200a to 200c carry fixed bar codes 208a, 208b and 208c which classify the tubes and/or identify the particular test that is to be performed on the blood sample in that tube.

Using scanner 112 of our system, an operator may scan the bar codes on blood bag 122, the donor registration form 206 and the sample tubes 200a to 200c into the memory of controller 26 so that the bar code numbers are stored in the memory. Thus, the memory contains the necessary data to correlate the blood bag and sample tubes with the particular donor registration form. Furthermore, scanning of the sample tube bar codes or identifiers 208a to 208c allows the system to store information about the count and type of tubes to ensure that all necessary tests are performed on the drawn sample of that particular donor's blood and to signal if there is no match. For example, controller 26 may contain a database relating different types of tests with the tubes (or other disposable items) associated with that test. Upon completion of the procedure, scanning of the fixed and donor bar codes on the tubes ensures that all necessary samples have been taken, and that the tubes all contain samples from the proper donor.

Following scanning, the controller 26 automatically activates printer 62 (FIG. 2) which thereupon prints a hard copy of all of the information stored in the controller 26 memory associated with the collection of that particular donor's blood, i.e., blood value, volume collected and process time. The data will also include the aforesaid identification numbers scanned into the memory by scanner 112. Inclusion of the identifiers in the stored data assures that when the blood collection bag 122 and sample tubes 200a to 200c are separated, they can still be correlated with the particular donor via his/her registration form 196 to provide positive collected product and sample identification. Of course, ensuring proper identification of collected blood requires recourse to the stored data, and also assumes that scanning has been accomplished properly.

It is possible to add a second level of validation directly to the bag 122 itself by affixing thereto an additional bar code label that unambiguously identifies both the bag and the donor. For example, following scanning of the donor bar code 206 and bar code 204, printer 62 may be caused to print a master bar code label containing both bar code numbers; this label may be affixed to bag 122 and/or to the donor's registration form. In this way, the donor's identifier appears directly on bag 122, and mislabeling can be detected by scanning both bar codes now appearing on the bag (since the master bar code must contain the bar code originally appearing on bag 122).

Printer 62 may also print other information entered into or generated by the system such as time, date, procedure time, any procedural problems encountered, collected blood product volume, anticoagulant volume used for the particular collection, expiration date code for the anticoagulant and similar relevant information. Once again, this same information may be stored for each procedure in the controller 26 database, facilitating later retrieval and analysis. Thus, unit 10 constitutes both a data collector and a data tracker.

After the data has been printed out, display 96 will show the message "PROCEDURE COMPLETE," signaling that set 12 may be separated from the pump/control unit 10 by opening platen 32 and disconnecting the filter luer 146a from nipple 102a on unit 10 and removing bag 122 from hook 108. After the tubes 132 and 166 leading from bag 122 and pouch 168, respectively, have been sealed closed at the outlets from those bags, those tubes may be cut up from the seals to separate the bag and pouch from the remainder of set 12, which remainder may then be disposed of in accordance with accepted OSHA standards.

The procedure is more or less the same for the VOLUME and RED CELL modes of operation. In the former case, the collected product is a selected volume of anticoagulated whole blood. In the latter case, the collected product is a selected volume of anticoagulated blood based on the donor's hematocrit and a selected volume (e.g., 180 ml) of RBC. In both cases, the ratio of blood to anticoagulant is 8:1 as occurs when unit **10** is operating in its STANDARD mode and similar information is collected, displayed and printed out by printer **62**.

Refer now to FIG. **5** which shows the pump **16** in greater detail. The pump may be accessed by removing a door **210** (FIGS. **1** and **5**) in the sidewall of the pump housing **14**. When door **210** is removed, the pump, which is attached to the door, disengages from the output shaft **22**a of clutch **22** and slides out of the housing **14**.

Pump **16** includes a housing **212** having a cylindrical neck **214** which slides over the output shaft **22**a of clutch **22**. Neck **214** has diametrically opposite slots **216** for receiving diametrically opposite pins **218** projecting out from the clutch shaft **22**a. Therefore, when the collar is engaged to that shaft as shown in FIG. **5**, it is rotatably fixed to the shaft.

The housing **212** rotatably supports the pump rollers **19** of pump head **16**a by way of a circular array of axles **222**. Housing **222** also has an axial opening for receiving a shaft **224**. One end of the shaft extends through a bearing unit **226** at the base of neck **214** and is fixed axially by a C-clip **228**. The shaft **224** extends all the way through housing **212** and out the opposite end of the housing which end is recessed at **230** for accommodating a relatively large gear **232** which is fixed to rotate with shaft **224**. Also located in recess **230** is at least one relatively small diameter spur gear **234** which is rotatably mounted to one of the axles **222** so that it meshes with gear **232**. A bearing unit **236** in recess **230** supports shaft **224** at its midpoint. Disposed radially outboard bearing **236** is a second relatively large gear **238** connected by fasteners **242** to the head **244**a of a bushing **244** which is free to rotate on the shaft. The gear **238** also meshes with spur gear **234**. In other words, that gear **234** meshes with both of the large gears **232** and **238**. All of those gears comprise the speed reducer **24**.

The pump head **16**b comprises a spool **252** which encircles bushing **244**. Preferably, a bearing element **254** is present between the spool and the bushing so that the spool can rotate freely. Preferably also, the bearing element **254** is a unidirectional bearing element so that the spool can only rotate in one direction on the bushing. As with housing **212**, the spool **252** carries a circular array of axles **256** which rotatably support the rollers **19** of the pump head **16**b.

Another bearing element **258** is recessed into the outer end of spool **252** so that the spool can rotate readily on shaft **224**. The free end of the shaft projects beyond spool **252** in order to receive a sleeve **262** engaged onto the end of the shaft. That end of the shaft **224** is provided with flats **264** which interfit with sleeve **262** so that those two members are rotatably locked together. The end of sleeve **262** carries a key **262**a which fits in a keyway **268** in the inside surface of door **210**. The end of shaft **224** and sleeve **262** are positively connected to door **210** by means of a threaded fastener **270** which extends through axial holes in the door and sleeve and is turned down into a threaded hole in the end of shaft **224**.

When pump **16** is in operation, shaft **224** is held stationary by door **210**. Housing **212** is rotated by clutch **22** thereby rotating the pump head **16**a. The gears **232**, **234** and **238** in the speed reducer **24** effect a gear reduction as well as a motion reversal so that the spool **252** comprising the pump head **16**b rotates in the opposite direction from the housing **212** in head **16**a at a reduced speed, e.g., with a speed reduction ratio of 8:1. Because of the one-way clutching action incorporated into bearing element **254**, the spool **252** will only be rotated in a direction which pumps anticoagulant from bag B (FIG. **1**).

If it is desired to change the ratio of blood to anticoagulant in the blood being drawn by the present system, it is only necessary to substitute for the pump **16**, a similar pump having a different gear reduction in the gear reducer **24**.

While the illustrated pump **16** is designed so that the pump head **16**a rotates in one direction and the pump head **16**b rotates in the opposite direction, it should be understood that the gear reducer **24** can be designed with additional gears so that the two heads rotate in the same direction. In addition, the pump may incorporate more than two pump heads to pump fluids through several lines simultaneously at different rates. Furthermore, in some applications, it may be desirable to drive the pump with a bi-directional motor so that the pump head **16**a which pumps blood product, can pump in both directions while the pump head **16**b, due to the presence of the one-way clutch therein, can only rotate in one direction. Such an arrangement may be used for apheresis as described in the above U.S. Pat. No. 5,387,187.

Although the foregoing operations are representative of a typical blood-collection procedure, the invention may be employed for other types of procedures, or implemented to serve different functions. For example, the invention may be configured for surgical wound drainage rather than blood collection. In this application, controller **26** operates pump **16** to apply a constant negative pressure to a wound via a length of tubing. Blood is withdrawn and filtered in accordance with known autotransfusion procedures, and is typically returned to the patient.

It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in the above sequence of steps and in the above construction without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention described herein.

What is claimed is:

[1. Blood collection apparatus comprising

a phlebotomy needle;

a blood collection bag having an inlet;

a first tube having one end in fluid communication with the needle and a second end connected to said inlet;

a second tube composed of in-line first and second segments, and having one end in fluid communication with said needle and an other end adapted for connection to an anticoagulant source;

a tubing tray, said tray having an opening therethrough and a window in line with said opening;

means for securing said first tube to the tray so that a segment thereof is maintained opposite said opening, and

means for securing said second tube to the tray so that in-line first and second segments thereof are maintained opposite said opening and said window, respectively, said first segment being spaced from said segment of the first tube.**]**

[2. The apparatus defined in claim **1** wherein said tray and said openings and window are generally rectangular in shape.**]**

[3. The apparatus defined in claim 1 and further including connection means at the other end of the second tube for connecting said other end to an anticoagulant bag.]

[4. The apparatus defined in claim 3 and further including an antibacterial filter connected in the second tube between said segment of the second tube and said connection means.]

[5. The apparatus defined in claim 3 and further including means for coupling a pressure sensor to the first tube at a location therealong between said segment of the first tube and said needle.]

[6. The apparatus defined in claim 5 wherein the coupling means include a length of tubing containing an antibacterial filter.]

[7. The apparatus defined in claim 1 wherein said apparatus also includes

at least one satellite collection bag, and

tubing connecting the interiors of said at least one satellite bag and said blood collection bag.]

[8. The apparatus defined in claim 1 and further including fluid conduit means for connecting said needle to said one ends of said first and second tubes, and

a blood sample pouch in fluid communication with said conduit means.]

[9. The apparatus defined in claim 8 and further including a first clamp for interrupting fluid flow from said needle to said pouch, and

a second clamp for interrupting fluid flow from said needle to said first and second tubes.]

[10. The apparatus defined in claim 8 and further including scannable codes affixed to said blood collection bag and/or said sample pouch and/or sample tubes associated with the apparatus for being correlated with a scannable code affixed to a donor registration form to track the contents of said bag and/or pouch and/or tubes.]

[11. The apparatus defined in claim 1 and further including scannable codes affixed to said blood collection bag and/or a said sample pouch and/or sample tubes associated with the apparatus for being correlated with a scannable code affixed to a donor registration form to track the contents of said bag and/or pouch and/or tubes.]

[12. The apparatus defined in claim 1 and further including an adhesive label affixed to said blood collection bag, said label having a scannable identifier code thereon, said label also containing a plurality of peel-away stickers, each sticker bearing a scannable code corresponding to said identifier code.]

13. A blood collection system comprising:

a blood collection machine,

a computer connected in communication with the blood collection machine,

an operator interface with operator input controls in communication with the computer, including a data input device in communication with the computer and configured to read and input information into the computer,

a display in communication with the computer and configured to display information about a blood collection procedure to an operator,

a disposable tubing set connectable to the blood collection machine defining at least a portion of a blood collection pathway and having identification information that is readable by the data input device,

wherein the computer is configured to control the operation of the blood collection machine and collect procedure information during a blood collection procedure and the computer is further configured to receive commands from the operator interface and to receive donor information.

14. The blood collection system as defined in claim 13 wherein the data input device comprises a bar code scanner configured to read donor information into the computer.

15. The blood collection system as defined in claim 14 wherein the scanner is a portable hand held device.

16. The blood collection system as defined in claim 15 wherein the barcode scanner is configured to read donor information for a procedure and communicate the information to the computer.

17. The blood collection system as defined in claim 16 wherein the donor information includes a donor identifier.

18. The blood collection system as defined in claim 16 wherein the system further comprises a database in communication with the computer and the donor information is stored in the database for later retrieval and analysis.

19. The blood collection system as defined in claim 13 wherein the blood collection system is configured to perform a blood component collection.

20. The blood collection system as defined in claim 13 wherein the blood collection system is configured to perform apheresis.

21. The blood collection system as defined in claim 13 wherein the operator interface further comprises a control panel with a plurality of operator input controls.

22. The blood collection system as defined in claim 13 wherein the operator interface is configured to receive input from the operator to select a mode of operation in which the blood collection system will operate.

23. The blood collection system as defined in claim 13 wherein parameters of system operation controlled by the computer include pump motor speed and volume collected.

24. The blood collection system as defined in claim 13 further comprising: a sensor positioned in a fluid pathway to monitor the performance of a collection procedure and being in communication with the computer, the sensor configured to communicate status information about the procedure to the computer, the computer configured to automatically make adjustments to the system operation based on that information to change collection performance.

25. The blood collection system as defined in claim 13 further wherein the collection system is configured to signal the computer when the disposable tubing set is completely loaded onto the machine.

26. The blood collection system as defined in claim 25 wherein the computer is configured to operate the blood collection system to prime a tubing set loaded onto the machine and indicate to the operator through the display when the system is ready to begin a procedure.

27. The blood collection system as defined in claim 13 wherein the computer is configured to start the blood collection system and accelerate the blood collection system until a steady state operating condition is achieved.

28. The blood collection system as defined in claim 13 wherein the system further comprises a database in communication with the computer and procedure information for each procedure is stored in the database.

29. The blood collection system as defined in claim 28 wherein the procedure information includes, time and date of the procedure, procedure time, any procedural problems encountered and blood volume collected.

30. The blood collection system as defined in claim 13 wherein the system further comprises a printer in communication with the computer and configured to print out donor information and procedure information for a given procedure.

31. The blood collection system as defined in claim 13 wherein the blood collection machine is configured for surgical wound drainage.

32. The blood collection system as defined in claim 13 wherein the computer is programmed to define at least a portion of a blood collection procedure.

33. The blood collection system as defined in claim 32 wherein the computer is programmed to define a plurality of blood collection modes.

34. A blood collection system comprising:

a blood collection machine,

a computer connected in communication with the blood collection system and in communication with a database and being programmed to define at least a portion of a blood collection procedure,

an operator interface with operator input controls in communication with the computer,

a data input device barcode scanner is configured to read donor information for a procedure and communicate the information to the computer,

a disposable tubing set with identification information that is readable by the data input device connected to the computer to input the information into the computer,

a printer in communication with the computer,

a display in communication with the computer and configured to display information about a blood collection procedure to an operator,

wherein the computer is configured to control the operation of the blood collection machine and collect procedure information during a blood collection procedure and the computer is further configured to receive commands from the operator interface and to receive donor information.

35. A blood collection system comprising:

a blood collection machine,

a disposable tubing set,

means for electronically controlling the operation of the system and for collecting and storing information regarding a blood collection procedure performed including information obtained from the machine,

means for interfacing with an operator in communication with the means for controlling the system,

means for displaying information about a blood collection procedure to an operator in communication with the means for controlling the system,

means for reading information electronically in communication with the means for controlling the system.

36. A method of collecting blood comprising:

providing a blood collection system in communication with a computer that communicates with a database,

providing an operator interface, a visual display and a barcode reader each in communication with the computer,

reading donor information into the computer for a given procedure,

installing a tubing set on the blood collection system and connecting the tubing set to a donor,

providing commands to the computer though the interface to operate the system to perform blood collection procedure with information relating to performance of the procedure being communicated to the computer.

37. The method defined in claim 36 wherein the method of providing commands to the computer further includes selecting the type of blood collection procedure to be performed.

38. The method of claim 36 further comprising: forwarding the donor information and procedure information from the computer to the database for later retrieval and analysis.

39. A system for managing at least one procedure in a blood collection facility and remotely monitoring the status of the blood collection procedure performed upon a donor and facilitated by an operator, the system comprising:

a blood component collection machine for collecting a blood component from a blood donor;

a tubing set having an identifier, the tubing set being operatively connectable to the blood donor and the blood component collection machine;

a system computer being operatively responsive to the blood component collection instrument, the system computer configured to define a blood component collection process and being capable of monitoring a status of the tubing set identifier;

an operator interface being operatively connected to the system server, the operator interface comprising a reader for entering information to be transmitted to the system computer, the operator interface configured to transmit the tubing set identifier to the system computer; and

a display unit being operatively connected to the system computer, the system computer configured to monitor the tubing set status.

40. A system for collecting blood and interfacing with an operator administering one or more procedures in a blood component collection facility for collecting at least one blood component from a donor, the blood component collection facility comprising a blood component collection machine capable of being adapted to the donor, the system comprising:

a blood component collection system configured to perform a procedure for removing a blood component from a blood component donor, the procedure including data associated with the removing the blood component from the blood component donor;

a system computer operatively connected to the blood component collection system, the system computer configured to define at least a portion of the blood component collection process;

an operator interface operatively connected to the system computer, the operator interface comprising a reader for entering one of a plurality of identifiers, each identifier associated with the blood component collection facility;

a transmitter operatively connected to the operator interface, the transmitter configured to transmit information associated with the blood component collection facility to the system computer; and

a donor identifier assigned to the donor wherein the operator interface is configured to transmit the donor identifier to the system server, the donor identifier is being associated with the data associated with the removing the blood component from the blood component donor.

41. A system for managing a database of blood component collection procedures, the system comprising:

a blood component collection system for collecting a blood component from a blood component donor;

a system computer being operatively connected to the blood component collection system, the system computer defining at least a portion of a blood component collection process, wherein the system computer is in data communication with a system database having stored blood component collection procedures; and

an interface being operatively connected to the system computer.

42. A system for managing a procedure in a blood component collection facility, the system comprising:

a blood component donor identifier corresponding to a blood component donor; a blood component collection system for collecting a blood component from the blood component donor;

a system computer being operatively connected to the blood component collection system, the system computer defining at least one step of a blood component collection process; and

an interface having a reader and being operatively connected to the system computer for receiving the blood component donor identifier and transmitting the donor identifier to the system computer.

43. A system for monitoring and tracking at least a portion of a blood component collection procedure in a blood component collection facility, the system comprising:

a blood component collection machine for collecting a blood component from a donor, the donor having a donor identifier;

a tubing set having a tubing set identifier, the tubing set for collecting the blood component from the donor;

a system computer being operatively connected to the blood component collection machine, the system computer configured to monitor monitoring operation of the blood component collection instrument and receive information about the operation of the blood component collection instrument;

a non-transitory memory operably connected to the system computer, the memory for storing the information received by the system computer; and

an interface operably connected to the system computer, the interface further having a display for monitoring at least one portion of the blood component collection procedure.

44. A method of configuring a blood component collection machine comprising the steps of:

collecting a biological characteristic of a donor;

calculating a nomogram by utilizing the biological characteristic of the donor;

transmitting the nomogram to a blood component collection instrument;

selecting a blood component collection application in response to the nomogram, the blood component collection application defining at least a portion of a blood component collection process; and

loading the selected blood component collection application wherein the blood component collection instrument is configured for the blood component collection process involving the donor.

45. A blood processing information management system comprising:

a database;

a data input device connected in data communication relationship with the database;

a computer connected in data communication relationship with at least one of the database and the data input device; and

a communication conduit connected in data communication relationship with at least one of the database, the data input device and the computer; and

at least one blood processing machine;

whereby the communication conduit is connected in data communication relationship with the at least one blood processing machine to provide for data communication to and from the at least one blood processing machine;

whereby the communication conduit is configured to communicate data to the at least one blood processing machine, the data being preparation data generated by the computer, the at least one blood processing machine configured to use the preparation data in preparation of the at least one machine for a blood processing procedure; and

whereby the communication conduit is configured to communicate data from the at least one blood processing machine, whereby the data is procedure data, which represents information about a blood processing procedure run on the at least one blood processing machine.

46. A processing information management system comprising:

a database;

a barcode data input device connected in data communication relationship with the database and configured to input barcode data;

a computer connected in data communication relationship with at least one of the central database and the data input device;

a communication conduit connected in data communication relationship with at least one of the central database, the data input device and the computer;

and at least one blood processing machine;

whereby the communication conduit is connected in data communication relationship with the at least one blood processing machine to provide for data communication to and from the at least one blood processing machine;

whereby the communication conduit is configured to communicate data including barcode data and run data;

whereby the communication conduit is configured to communicate barcode data to the at least one blood processing machine, and whereby the communication subsystem is configured to communicate barcode and run data from the at least one extracorporeal blood processing machine, whereby the run data represents information about an blood processing procedure run on the at least one blood processing machine.

* * * * *