

(12) STANDARD PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. **AU 2012242802 B2**

(54) Title
Systems and methods for managing blood donations

(51) International Patent Classification(s)
G06Q 50/24 (2012.01) **A61M 1/38** (2006.01)
A61G 12/00 (2006.01)

(21) Application No: **2012242802** (22) Date of Filing: **2012.04.12**

(87) WIPO No: **WO12/142263**

(30) Priority Data

(31)	Number	(32)	Date	(33)	Country
	61/474,679		2011.04.12		US

(43) Publication Date: **2012.10.18**

(44) Accepted Journal Date: **2017.04.20**

(71) Applicant(s)
Applied Science, Inc.

(72) Inventor(s)
Goodnow, James E.;Bancroft, James A.;Morgan, Jonathan G.

(74) Agent / Attorney
Pizzeys Patent and Trade Mark Attorneys Pty Ltd, PO Box 291, WODEN, ACT, 2606, AU

(56) Related Art
US 2003/0040835 A1
WO 2002/069793 A2



(51) International Patent Classification:

G06Q 50/24 (2012.01) *A61G 12/00* (2006.01)
A61M 1/38 (2006.01)

(21) International Application Number:

PCT/US2012/033289

(22) International Filing Date:

12 April 2012 (12.04.2012)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

61/474,679 12 April 2011 (12.04.2011) US

(71) Applicant (for all designated States except US): **APPLIED SCIENCE, INC.** [US/US]; 983 Golden Gate Terrace, Grass Valley, CA 95945 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **GOODNOW, James, E.** [US/US]; 983 Golden Gate Terrace, Grass Valley, CA 95945 (US). **BANCROFT, James, A.** [GB/US]; 983 Golden Gate Terrace, Grass Valley, CA 95945 (US). **MORGAN, Jonathan, G.** [CA/US]; 983 Golden Gate Terrace, Grass Valley, CA 95945 (US).

(74) Agents: **THOMAS, Justin** et al.; Shay Glenn LLP, 2755 Campus Drive, 210, San Mateo, CA 94403 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report (Art. 21(3))
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(88) Date of publication of the international search report:

10 January 2013

(54) Title: SYSTEMS AND METHODS FOR MANAGING BLOOD DONATIONS

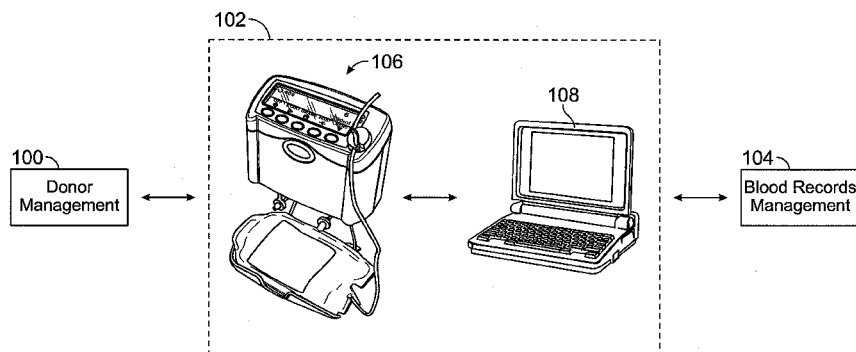


FIG. 1A

(57) Abstract: Methods and apparatus collecting blood from patients and managing blood donations are provided, which may include any number of features. One feature is a blood collection device configured to collect blood from a patient and periodically transmit blood collection data from the device to a control system. Another feature is a system and method for updating firmware on a plurality of blood collection devices. In one embodiment, a software interface with a blood collection control can be used to specify a blood collection protocol, and the blood collection protocol can be then transmitted to one or more blood collection devices.

SYSTEMS AND METHODS FOR MANAGING BLOOD DONATIONS

CROSS REFERENCE TO RELATED APPLICATIONS

- 5 [0001] This application claims the benefit under 35 U.S.C. 119 of U.S. Provisional Patent Application No. 61/474,679, filed April 12, 2011, titled "SYSTEMS AND METHODS FOR MANAGING BLOOD DONATIONS". This application is herein incorporated by reference in its entirety.

INCORPORATION BY REFERENCE

- 10 [0002] All publications, including patents and patent applications, mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication was specifically and individually indicated to be incorporated by reference.

FIELD

- 15 [0003] Described herein are devices and methods for use in blood donation and blood management. In particular, described herein are devices and methods for acquiring blood donations and managing information related to the blood donations.

BRIEF DESCRIPTION OF THE DRAWINGS

- 20 [0004] Fig. 1A is a schematic illustration of a blood donation process.
[0005] Fig. 1B is an illustration of a blood collection device and a control system.
[0006] Figs. 2-5 illustrate various features of a blood data management system.

SUMMARY OF THE DISCLOSURE

- [0007] In one embodiment, a method of monitoring real time blood draw information is provided, comprising collecting blood from a patient with a blood collection device, while collecting blood from the patient, turning on a transmit function of the blood collection device to transmit blood collection data from the blood collection device to a control system, turning off the transmit function of the blood collection device after the blood collection data is received by the control system, and waiting for a time interval before again turning on the transmit function of the blood collection device.
- [0008] In some embodiments, the time interval is up to 30 seconds in length.

[0009] In other embodiments, the blood collection data is selected from the group consisting of a donation ID, a staff ID, a volume of blood collected, a flow rate of blood collected, a status of the blood collection device, and errors during collection of blood.

[0010] In one embodiment, the collecting blood step further comprises collecting blood from a patient with a plurality of blood collection devices. In an additional embodiment, the method further comprises, at multiple times while collecting blood from the patient, turning on a transmit function of a plurality of blood collection devices to transmit blood collection data from the blood collection devices to a control system, turning off the transmit function of the plurality of blood collection devices after the blood collection data is received by the control system, and waiting for a time interval before again turning on the transmit function of the plurality of blood collection devices.

[0011] In some embodiments, the collecting step comprises automatically collecting blood from the patient with the blood collection device.

[0012] In other embodiments, the method further comprises turning on the transmit function of the blood collection device at least once after blood has been collected from the patient.

[0013] A method of updating firmware on a plurality of blood collection devices is provided, comprising selecting a first blood collection device as a master device and designating one or more additional blood collection devices as slave devices, wherein each blood collection device is configured to collect and measure blood collection, sending a request for a firmware update to a control system from just the master device and not the slave devices, transmitting the firmware update from the control system to the master and slave devices, wherein the master device communicates with the control system while the slave devices passively listen, and replacing a base firmware on the master and slave devices with an upgraded firmware from the control system.

[0014] In some embodiments, the blood collection devices are in wireless communication with the control system.

[0015] In other embodiments, the replacing step comprises simultaneously replacing the base firmware on the blood collection devices with the upgraded firmware from the control system.

[0016] In one embodiment, the replacing step further comprises replacing the base firmware on the master and slave devices with the upgraded firmware from the control system simultaneously.

[0017] Some embodiments further comprise employing measures to insure data integrity of data stored on the blood collection devices.

[0018] In another embodiment, the method further comprises employing measures to insure data integrity of a collection device configuration.

[00019] A method of specifying the collection protocol for a blood collection device is provided, the method comprising specifying in a blood collection control system, a first input, specifying in the blood collection control system, a first time during a blood collection event for the blood collection device to request the first input, specifying in the blood collection control system, a second input, specifying in the blood collection control system, a second time during the blood collection event for the blood collection device to request the second input, compiling in the blood collection control system a blood collection protocol including the first and second inputs and the first and second times, and transmitting the blood collection protocol from the blood collection control system to one or more blood collection devices.

[00020] In one embodiment, the first and second inputs are barcodes.

[00021] In another embodiment, the specifying input steps comprise specifying length and character type requirements for the barcodes.

[00022] In some embodiments, the first time is at the beginning of a blood collection process. In another embodiment, the second time is at the end of a blood collection process.

[00023] In one embodiment, the first input is a donation ID. In another embodiment, the second input is a staff ID.

[00024] In another embodiment, the first time is at the beginning of a blood collection process. In some embodiments, the second time is at the beginning of a blood collection process.

[00025] In one embodiment, the first input is a biometric input. The biometric input can be a fingerprint, for example.

[00026] In another embodiment, the first input is a product code.

[00027] A blood collection and monitoring system is provided, comprising a control system, a blood collection device in communication with the control system, the blood collection device being configured to collect blood from a patient and to collect blood collection data relating to the collected blood, the blood collection device further comprising a transmitter configured to periodically turn on a transmit function to transmit the blood collection data from the blood collection device to the control system.

[00028] In some embodiments, the transmitter of the blood collection device is configured to turn off once the blood collection data has been transmitted to the control system. In another embodiment, the transmitter of the blood collection device automatically turns on again after a preset time. In some embodiments, the preset time is less than 30 seconds in length.

[00029] A blood collection system is also provided, comprising a master blood collection device and a plurality of slave blood collection devices, each blood collection device being configured to collect and measure blood collection, a control system configured to receive a request for a firmware update from only the master blood collection device and not the slave

blood collection devices, the control system further configured to transmit the firmware update to the master and slave blood collection devices, wherein the control system is configured to communicate with the master blood collection while the slave devices passively listen to replace a base firmware on the master and slave blood collection devices with an upgraded firmware from the control system.

[00030] In some embodiments, the control system comprises a wireless transceiver configured to receive the request from the master blood collection device and to transmit the firmware update to the master and slave blood collection devices.

DETAILED DESCRIPTION OF THE DISCLOSURE

[00031] Fig. 1A is a schematic illustration of a blood donation process, starting with a donor registration and management process 100, followed by a blood and data collection process 102, and finally a blood records management process 104. Typically, the donor management process 100 comprises recruiting and locating willing blood donors, determining if blood donors are fit to donate blood, scheduling blood donations, and retaining blood donors for future donations.

[00032] The next step of the blood donation process, the blood and data collection process 102, can comprise the collection of a blood donation from a blood donor, as well as collection of information relating to the collection of the blood donation. In some embodiments, the blood and data collection process 102 can comprise a blood collection device 106 and a control system 108, which can be software code stored and executed on a computer system or network. The information relating to the collection of blood donations can comprise, for example, time and location of the blood collection, amount of blood withdrawn, blood type, employee ID of the phlebotomist responsible for collection of the blood, elapsed time of blood collection, interruptions of the blood donation process, etc.

[00033] Finally, once the blood donation is completed, the blood records management process 104 is responsible for managing and storing blood stockpiles, tracking stored volumes of the various blood types, and distributing the blood to places in need of blood donations (e.g., hospitals and other medical centers).

[00034] Fig. 1B is a diagram showing the blood collection device 106 and control system 108 of Fig. 1A. As shown in Fig. 1B, in some embodiments, more than one blood collection device 106 can be networked with and bi-directionally communicate with the control system 108. Blood collection device 106 is configured to provide blood banks and other blood collection centers with an inexpensive yet accurate means of monitoring the collection of blood donations. The device is configured to accurately weigh blood donations during the collection process and to provide blood bag mixing insuring correct disbursement of anticoagulant and alleviating the

need for manual mixing by a phlebotomist. Referring to Fig. 1B, blood collection device 106 can include a graphical user interface (GUI) 110, a scale or bag tray 112, a pinch valve 114, and a barcode scanner 116. The device can be configured to receive a blood donation bag 118 on the scale and pinch valve, as shown. In some embodiments, the blood donation bag comprises a
5 barcode 120 readable via the barcode scanner of the blood collection device.

[00035] The GUI 110 allows a user (e.g., a phlebotomist) to configure, calibrate, and setup the blood collection device for use. In some embodiments, the GUI 110 displays information to the user such as calibration status of the device bag tray 112, weight of the blood donation bag 118, and operation status of the device (e.g., calibration, blood collection underway, blood collection
10 complete, errors during collection, etc). During initial setup of the device, a user may be asked to zero or calibrate the device, with no weight on the bag tray 112 to ensure accurate measurement of collected blood.

[00036] In some embodiments, the device comprises an agitation system suspended on the internal load cell. The agitation system can comprise a motor-driven crank configured to
15 agitate/shake the bag during blood collection. The agitation system has been designed for minimal weight and optimized for the power required to agitate/shake the bag tray 112 and thus, the blood bag.

[00037] When a blood collection bag is placed on the bag tray 112, vertical oscillations of the agitation system can cause blood collected from a donor to flow from one end of the bag to the
20 other, resulting in gentle mixing of the blood and the contained anticoagulant. Since the agitation system can be mounted on the internal load cell, the load cell can then sense the weight of the bag tray 112, the agitation system, the blood bag, and the accumulated blood.

[00038] The blood collection device can further include a pinch valve 114 configured to open and close the blood bag line leading from the patient to the blood donation bag 118. Thus, the
25 blood collection device can be configured to open the pinch valve 114 when the blood collection process begins and close the pinch valve when the blood collection is complete.

[00039] The blood collection device can be configured to automatically measure the weight of accumulated blood during the blood collection process. In some embodiments, the weight of the accumulated blood is measured every time the blood bag and bag tray 112 are in a relatively
30 stable position. In other embodiments, the accumulated blood is measured continuously. By regularly monitoring the weight of collected blood, the blood collection device can calculate blood flow rates from the patient to the blood collection bag. The weight measurements and or flow rates can be used to determine when the blood collection process is complete.

[00040] When a blood collection is started, the blood collection device can first implement a
35 series of weight readings of the empty blood bag, the agitation system, and the bag tray

assembly. This can be recorded in the device's memory as the tare weight. The desired collection volume can be converted mathematically from weight to volume by using the constant specific gravity of blood of 1.058. (1.00 ml of blood weighs 1.058 grams). This converted weight value plus the tare weight results in the target weight and is compared against on-going weight readings as the collection proceeds. The blood collection device can then open the pinch valve to begin the blood collection process.

[00041] The agitation system can be left off until a small increase in weight is seen over the tare weight. As soon as the weight increase is seen by the blood collection device, the agitation system can initiate the shaking/rocking, and various other timing and flow functions can be activated. The blood collection device can continue to read the weight of the blood collection bag. Although these readings are relatively accurate, in some embodiments for greater accuracy, the blood collection system can stop the agitation process when the total weight is slightly less than the target weight. The final readings of collected blood can then be taken with the bag and bag tray in a horizontal position. At this point, it is unnecessary to continue agitating the bag since the anticoagulant is already fully mixed with the blood in the bag. Alternatively, the shaking/rocking could continue throughout the collection provided that accuracy of the weight readings could be assured.

[00042] Since blood bank standards require that blood collections must be completed in a set period of time (20 minutes maximum for current US regulations), smaller volumes of collection can tolerate a slower flow rate. In some embodiments, the blood collection device measures the flow rate and compares it against a computed constant, equal to a minimum flow value for the set period of time described above. As a result, if the required volume is greater, the flow rate must be greater to accomplish the fill in the set period of time (e.g., 20 minutes). If the required volume is less, the flow rate can be slower.

[00043] The blood collection device 106 can also include a barcode scanner 116 configured to read a barcode as an input to the device. For example, donation ID's unique to individual donor can be scanned during the blood collection process to keep track of all collection events related to that unique donation ID. In Fig. 2B, the donation ID can be represented as a barcode 120 located on blood donation bag 118.

[00044] The blood collection device 106 can be in communication with control system 108 during all steps of the blood collection process described above (e.g., calibration, blood collection, and completion of the blood draw). The blood collection device and control system can communicate via any technology known in the art, such as wirelessly through a WiFi or Bluetooth connection, or through a wired Ethernet connection. The control system can comprise

a computer having all the necessary hardware (e.g., CPU, memory, data storage, etc) required to execute a data collection and management software.

[00045] The data collection and management software of control system 108 will now be described. The software creates the interface between one or more blood collection devices and a facility's blood data management system.

[00046] In some embodiments, the software allows viewing and printing of blood collection device(s) data as well as remote configuration and setup of the blood collection devices. In some embodiments, the data collection and management software of the control system 108 can be used to setup the blood collection devices 106 with which it is in communication. The control system can be used to specify which parameters are used during a blood draw by each of the blood collection devices. For example, a standard blood draw may require that 500ml of blood be taken from a patient, and thus all blood collection devices can be pre-configured to automatically draw 500ml of blood from each patient. If, however, a patient is cleared to give only 450ml of blood, then the control system can be used to change the blood draw volume on a particular blood collection device from 500ml to 450ml. To accomplish this, the new blood volume of 450ml can be entered into the control system 108, then the blood collection device that will be used for that particular patient can "pull" the updated configuration from the control system (e.g., by syncing the blood collection device with the control system).

[00047] The software of control system 108 can also be configured to remotely update the firmware of all blood collection devices in communication with the control system. One method of updating the firmware on a plurality of blood collection devices can be described referring to Fig. 1B. A single blood collection device can be set as a "Master" device, and the remaining blood collection devices can be set as "Slave" devices. The "Master" device can then request a firmware upgrade from the control system 108 and then "listen" for a response from the control system, specific to that device. While the "Master" device is requesting the firmware upgrade, the "Slave" devices enter a "listen" mode as well, where they wait for any new firmware instructions from the control system. When the control system receives the firmware upgrade request from the "Master" device, the control system can then transmit the firmware upgrade, if available, to all listening devices, including both the "Master" and "Slave" devices. All devices can then upgrade to the new firmware simultaneously, at the same time, instead of each having to individually request and receive a firmware upgrade from the control system.

[00048] The data collection and management software can employ measures to insure data integrity and prevent unauthorized actions by the user to either the data or the blood collection device configuration. These measures can include individual record checksums, as well as username and password protection to configuration utilities and data file transfer, renaming or

deletion ("release"). The software system can also protect against data loss by retention of up to 150 or more donation records within each blood collection device, for retransmission to the software.

[00049] Figs. 2A-2B illustrate one embodiment of a graphical interface for the data collection and management software. In Fig. 2A, the "Network Status" tab can display the status of all inactive and currently active blood collection devices communicating with the control system. For example, referring to Fig. 2A, each row represents a separate blood collection device (such as blood collection devices 106 in Fig. 1B), represented by a unique device ID, shown in the "ID" column. The "Stat" column displays the status of each device. When a device is not in use, the status can read "Inactive." When the device is in the middle of a blood collection process, the status can read "Mid-Draw." The beginning of a blood collection process can be displayed as a status of "Start-Scan," and the end of a blood collection process can be displayed as a status of "End-Recovery."

[00050] The "Network Status" tab can also display other parameters relevant to the devices being monitored and the blood collection process. For example, the Flow Rates of blood being collected by each device ("Flow" column), the total amount of blood drawn ("ml" column), the target volume of blood to draw ("Target" column), the duration of the blood draw ("Time" column), whether there is an error in the blood draw ("Error" column), the donation ID of the patient ("Donation ID" column), as well as battery, calibration, and wireless communication values of each device ("Batt", "Calibration", and "Radio" columns, respectively) can all be displayed in real time or quasi real time by the software. Other parameters can be monitored and tracked by the software that are not shown in Fig. 2A. For example, the staff ID of the person performing the blood draw can be monitored and recorded. Additionally, secondary donation ID's, Sample Tube ID's, serial numbers of the blood collection devices, and the location and time of the blood draw can be tracked and/or scanned.

[00051] As mentioned above, the "Network Status" tab provides information regarding errors that occur during a blood collection process. In some situations, the error can be related to a malfunction in the blood collection device itself. By tracking the error rates of specific devices, the control system software can be configured to track and identify specific blood collection devices with higher failure/error rates than normal. Similarly, the control system software can be configured to track if a particular staff member (e.g., nurse, phlebotomist) is the supervising staff member on a higher number of blood draw cases that result in errors. This can be used as a tool to identify problems with a particular staff member's performance.

[00052] In some embodiments, the information is displayed in real time, and each blood collection device continuously updates the software of the control system with the current values

of data or status of each device being monitored. However, in other embodiments, the blood collection device can update these parameters in quasi real time, that is, the device can update the parameters to the software periodically after a preset period of time (e.g., every 30 seconds, every minute, every 5 minutes, etc).

5 [00053] In one embodiment of a quasi real time configuration, the blood collection device can be configured to automatically “turn on” a transmit signal after the preset period of time to transmit the collected parameters to the control system software. Upon completion of the data transmission, the blood collection device can then be configured to automatically “turn off” the transmit signal after the blood collection data is received by the control system. Although the
10 blood collection device continues to collect data relating to the blood draw when the transmit signal is off, transmitting or uploading the data to the control system only periodically, saves power and can allow a blood collection device to operate on battery power for weeks at a time instead of only days. In some embodiments, the blood collection device can be configured to wait a time interval (e.g., the preset time above) before again turning on the transmit function of
15 the blood collection device. The collected parameters that can be transmitted can include, among others, a donation ID, a staff ID, a volume of blood collected, a flow rate of blood collected, a status of the blood collection device, or errors during collection of blood.

[00054] Fig. 2B illustrates a “Recent Draws” tab in the software that can display all of the information described above (e.g., device ID, Status, amount of blood drawn, target volume of
20 blood, duration of blood draw, error messages, donation ID, battery, calibration, and radio values) for blood collection events that have occurred in the past. In some embodiments, the “Recent Draws” tab displays this information for past blood collection events that have not yet been uploaded or “released” from the software system to another computer system or network device. The “Release Data” tab can release all of the past blood collection events and data from
25 the “Recent Draws” tab to a location specified by the user. For example, the data can be released as a data file onto the local computer system, or alternatively, can be uploaded and released to a remote system.

[00055] The “Options” tab in the software can allow individual configuration of several options within the software. For example, referring to Fig. 3, a user can configure how and when
30 to release the “Recent Draws” data. As shown in Fig. 3, the data can be configured to be automatically released after a set period of time (e.g., every 720 minutes in Fig. 3), and the location and name of the data file to be created can be specified (e.g., “Hemoflow Release Data File” to be stored on the computer “desktop”).

[00056] The “Options” tab also allows vast customization of various inputs into the blood
35 collection device. For example, in many embodiments, the blood collection device can be

configured to scan a unique identifier as an input (e.g., scan a barcode with barcode scanner incorporated in the blood collection device, or scan a biological feature, such as a fingerprint, with a biometric scanner incorporated in the blood collection device). When a barcode is used as an input into the blood collection device, various features of the barcode itself can be customized in the software.

[00057] Fig. 4 illustrates how to customize various barcode components in the software to be used within a blood collection process. The length of a barcode, the type of barcode, and the order in which each particular barcode is to be scanned during a blood collection process can be customized in the software. Referring to the "Field 1" box in Fig. 4, a user can specify through the software a specific "Exact String" of characters for the barcode scanner of the blood collection device to look for to accept a barcode as an input. In this example, the "Exact String" can be the characters "=G1234" with a Field Size of 6 characters. When the barcode scanner of the blood collection device is used to scan a barcode as an input, only barcodes beginning with this "Exact String" of characters will be recognized. The remaining characters of the barcode can be customized in the other fields of the software. Referring still to Fig. 4, "Field 2" can specify that the next 5 characters (from the Field Size column) be "Numeric" characters, "Field 3" can specify that the 3 characters following "Field 2" are "Alpha" characters, and "Field 4" can specify that the final 2 characters be "Numeric" characters.

[00058] Still referring to Fig. 4, a user of the software can specify when in the blood collection process the blood collection device prompts a phlebotomist for the barcode. In this example, "Barcode No. 1" is requested at the "Start of Donation" (referring to the "When" box in Fig. 4). Furthermore, a user of the software can even customize what is displayed on the blood collection device when the specific barcode is requested for input, as shown in the "Display" box of Fig. 4. In this example, a 16 character barcode, starting with the characters "=G1234", followed by 5 numbers, followed by 3 letters, followed by 2 numbers, will be requested by the blood collection device at the start of a blood collection procedure. The blood collection device will display the words "Nurse ID" at that time in the procedure, to indicate to the nurse or phlebotomist to scan his or her employee barcode at that point in the procedure.

[00059] This gives the software the ability to configure many types of barcodes as inputs to the blood collection device, and also to specify what point of the procedure to scan that barcode. Fig. 5 illustrates one sequence of different types of barcodes that can be scanned at different times in a blood collection procedure. As described above, each of the barcode types, names, and times can be customized in the software system. Referring to Fig. 5, at the start of a blood collection procedure, the blood collection device can request the Donation ID barcode on a main blood bag to be scanned, followed by scanning the Donor ID barcode on a donor card, followed

by scanning a Technician ID barcode of a nurse/phlebotomist, followed by scanning a Product Code of a product, such as blood. Once sequence steps 1-4 have been completed, the blood collection device will be allowed to begin the blood collection process. Next, sequence steps 5-6, of scanning the barcodes of Sample Tubes 1 and 2, will be requested during the blood collection process, prior to the end of drawing blood. Finally, after the blood draw is complete, a second Technician ID will be scanned (either the original nurse/phlebotomist or the nurse/phlebotomist monitoring the procedure at the time of completion).

[00060] As for additional details pertinent to the present invention, materials and manufacturing techniques may be employed as within the level of those with skill in the relevant art. The same may hold true with respect to method-based aspects of the invention in terms of additional acts commonly or logically employed. Also, it is contemplated that any optional feature of the inventive variations described may be set forth and claimed independently, or in combination with any one or more of the features described herein. Likewise, reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "and," "said," and "the" include plural referents unless the context clearly dictates otherwise. It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation. Unless defined otherwise herein, all technical and scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which this invention belongs. The breadth of the present invention is not to be limited by the subject specification, but rather only by the plain meaning of the claim terms employed.

[00061] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising", will be understood to imply the inclusion of a stated integer or step or group of integers or steps but not the exclusion of any other integer or step or group of integers or steps.

[00062] The reference to any prior art in this specification is not, and should not be taken as, an acknowledgement or any form of suggestion that the referenced prior art forms part of the common general knowledge in Australia.

CLAIMS

What is claimed is:

1. A method of specifying the collection protocol for a blood collection device, the method comprising:

specifying in a blood collection control system, a first input to be scanned, the first input being selected from the group consisting of a donation ID barcode on a blood collection bag, a donor ID, a technician ID that identifies the user at a start of the blood collection event, a blood product code, a first sample tube, a second sample tube, a biometric input, and a technician ID that identifies the user at an end of the blood collection event;

specifying in the blood collection control system, a first time during a blood collection event for the blood collection device to prompt a user to scan the first input;

specifying in the blood collection control system, a second input to be scanned, the second input being selected from the group consisting of a donation ID barcode on a blood collection bag, a donor ID, a technician ID that identifies the user at a start of the blood collection event, a blood product code, a first sample tube, a second sample tube, a biometric input, and a technician ID that identifies the user at an end of the blood collection event;

specifying in the blood collection control system, a second time during the blood collection event for the blood collection device to prompt the user to scan the second input;

compiling in the blood collection control system a customized blood collection protocol operable on a blood collection device and configured to prompt the user for the first input at the first time and the second input at the second time;

transmitting the blood collection protocol from the blood collection control system to one or more blood collection devices;

initiating a blood draw from a patient with one of the blood collection devices running the customized blood collection protocol;

prompting the user for the first input at the first time during the blood draw;

prompting the user for the second input at the second time during the blood draw; and

completing the blood draw from the patient.

2. The method of claim 1 wherein the specifying input steps comprise specifying length and character type requirements for the first and second inputs.

3. The method of claim 1 wherein the first time is at the beginning of a blood collection process.

4. The method of claim 1 wherein the second time is at the end of a blood collection process.

5. The method of claim 1 wherein the biometric input comprises a fingerprint.

1/7

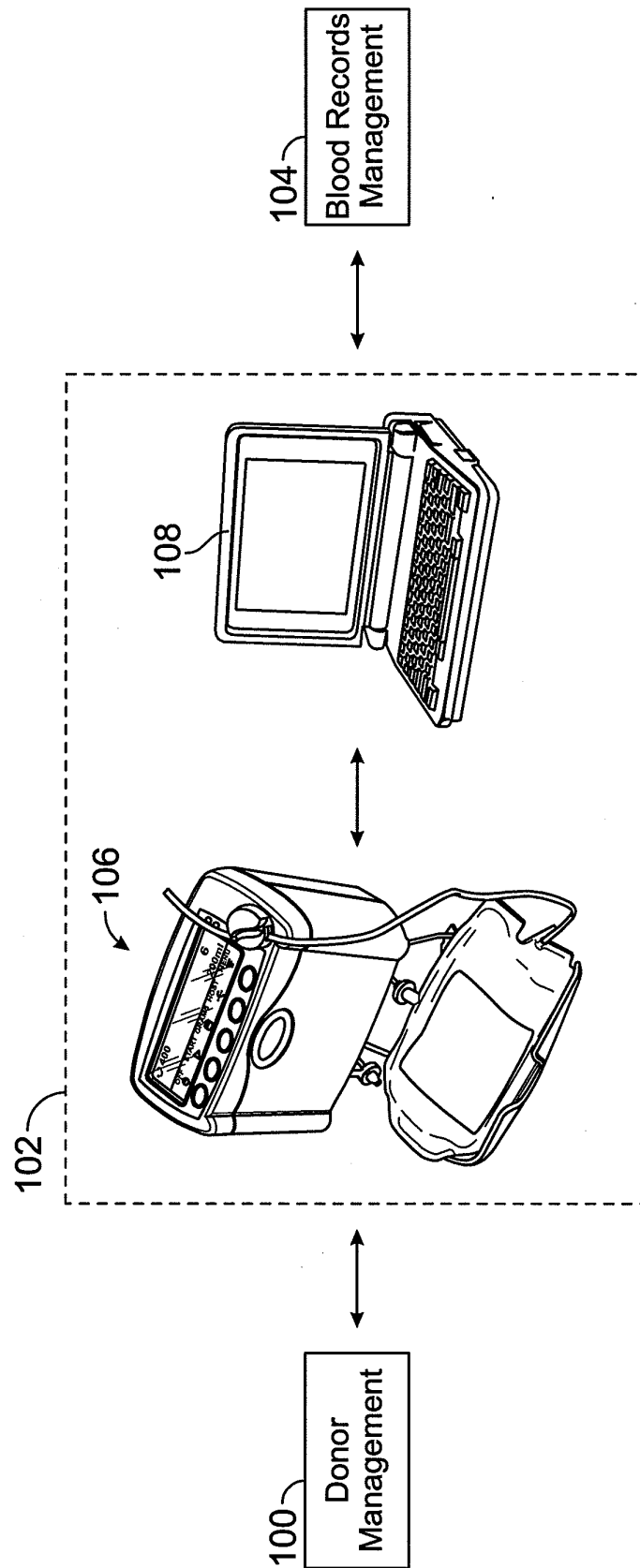
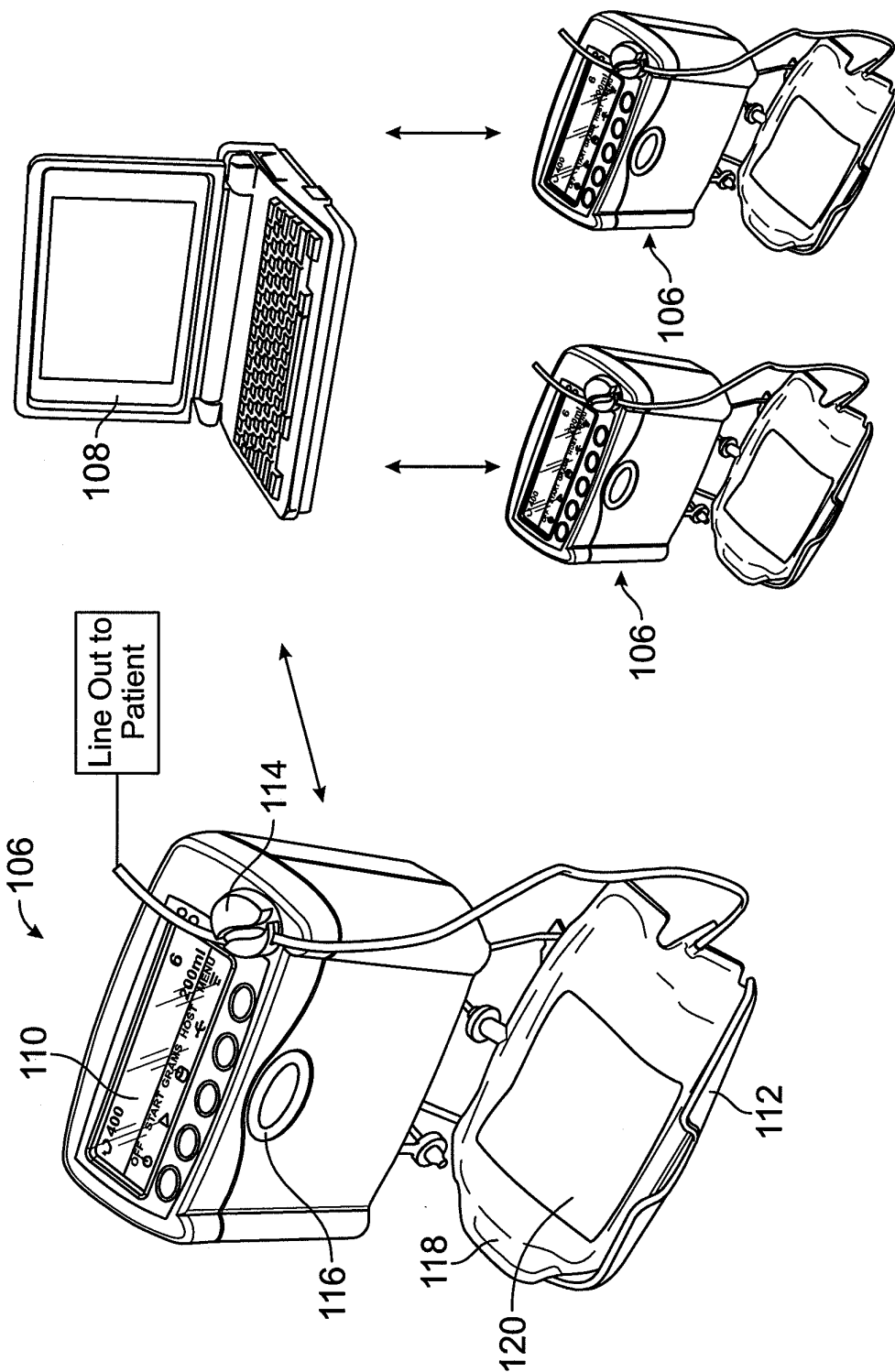


FIG. 1A

2/7



3/7

<div>Network Status</div> <div>Recent Draws</div> <div>System Utility</div> <div>Release Data</div> <div>Options</div> <div>Hide Display</div>											
ID	Stat	Flow	ml	Target	Time	Error	Donation ID	Batt	Calibration	Radio	
Scale 10	Mid-Draw	6	325	470	06:25	---	G1234983546	66%	28-Feb, 08:34	70%	
Scale 24	Inactive	0	0	470	0:00	---		100%	28-Feb, 08:35	65%	
Scale 52	End-Recovery	0	474	470	08:45	Low Flow	G1234996745	66%	28-Feb, 08:36	75%	
Scale 07	Inactive	0	0	470	0:00	---		33%	28-Feb, 08:37	65%	
Scale 63	Inactive	0	0	470	0:00	---		33%	28-Feb, 08:39	65%	
Scale 53	Inactive	0	0	470	0:00	---		100%	28-Feb, 08:42	65%	
Scale 15	Inactive	0	0	470	0:00	---		100%	28-Feb, 08:45	65%	
Scale 22	Start-Scan	0	0	470	0:00	---	G1234678594	66%	28-Feb, 08:50	65%	
Scale 33	Inactive	0	0	470	0:00	---		66%	28-Feb, 08:51	65%	
Scale 65	Inactive	0	0	470	0:00	---		100%	28-Feb, 08:52	65%	

FIG. 2A

4/7

<div>Network Status</div> <div>Recent Draws</div> <div>System Utility</div> <div>Release Data</div> <div>Options</div> <div>Hide Display</div>									
ID	Stat	ml	Target	Time	Error	Donation ID	Batt	Calibration	Radio
Scale 65	Complete	470	470	08:00	---	G1234983546	66%	28-Feb, 08:34	70%
Scale 33	Complete	470	470	08:00	---	G1234983477	100%	28-Feb, 08:35	65%
Scale 07	Timeout	380	470	15:00	Timeout	G1234996745	66%	28-Feb, 08:36	75%
Scale 63	Complete	470	470	08:00	---	G1234983542	33%	28-Feb, 08:37	65%
Scale 10	Complete	470	470	08:00	---	G1234983470	33%	28-Feb, 08:39	65%
Scale 52	Complete	495	470	08:00	---	G1234996788	100%	28-Feb, 08:42	65%
Scale 33	Complete	470	470	08:00	---	G1234983503	100%	28-Feb, 08:45	65%
Scale 10	Complete	470	470	08:00	---	G1234983447	66%	28-Feb, 08:50	65%
Scale 07	Complete	470	470	08:00	---	G1234996711	66%	28-Feb, 08:51	65%
Scale 15	Complete	470	470	08:00	---	G1234996780	100%	28-Feb, 08:52	65%

FIG. 2B

5/7

Network Status	Recent Draws	System Utility	Release Data	Options	Hide Display
<div>Wireless Channel</div> <div>10 <input checked="" type="checkbox"/> ?</div> <div>Auto-release (Min)</div> <div>720 <input checked="" type="checkbox"/> ?</div> <div>Release Filename</div> <div>E:\desktop\Hemoflow Release Data File <input type="button" value="Browse"/> ?</div> <div>Start Minimized (Hide)</div> <div><input checked="" type="checkbox"/> <input type="checkbox"/> File Auto-number <input checked="" type="checkbox"/> ?</div> <div>Auto-run at Start</div> <div><input checked="" type="checkbox"/></div>					

FIG. 3

Network Status

Recent Draws

System Utility

Release Data

Options

Hide Display

Staff ID Barcode No. 1

	Type	Exact String	Field Size
Field 1	Exact String	=G1234	6
Field 2	Numeric/Match ID		5
Field 3	Alpha/Match ID		3
Field 4	Numeric/No Match		2
Field 5	{not used}		0
Field 6	{not used}		0
Field 7	{not used}		0
Field 7	{not used}		0

Example

=G12345555ABC99

When

Start of Donation

Display 20 Char Max

Nurse ID

Total Length=

16

Sequence Order No.

2

FIG. 4

7/7

Network Status	Recent Draws	System Utility	Release Data	Options	Hide Display
----------------	--------------	----------------	--------------	---------	--------------

Barcode Summary Table

Seq Order	Name	Display Name	Example	Length	Match ID	When
1	Donation ID	Main Bag ID	=ABCD12345098756	16	No	Start
2	Donor ID	Donor Card	=%55559999	12	No	Start
3	Technician ID- 1	Nurse at Start	=&123455555ABC00	16	Yes	Start
4	Product Code	Product Code	=(45674	7	No	Start
5	Sample Tube 1	Tube 1	=ABCD12345098756	16	Yes	Flex
6	Sample Tube 2	Tube 2	=ABCD12345098756	16	Yes	Flex
7	Technician ID- 2	Nurse at End	=&123455555ABC00	16	Yes	End

FIG. 5