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(54) **VERIFICATION METHOD AND SYSTEM FOR MEDICAL TREATMENT**

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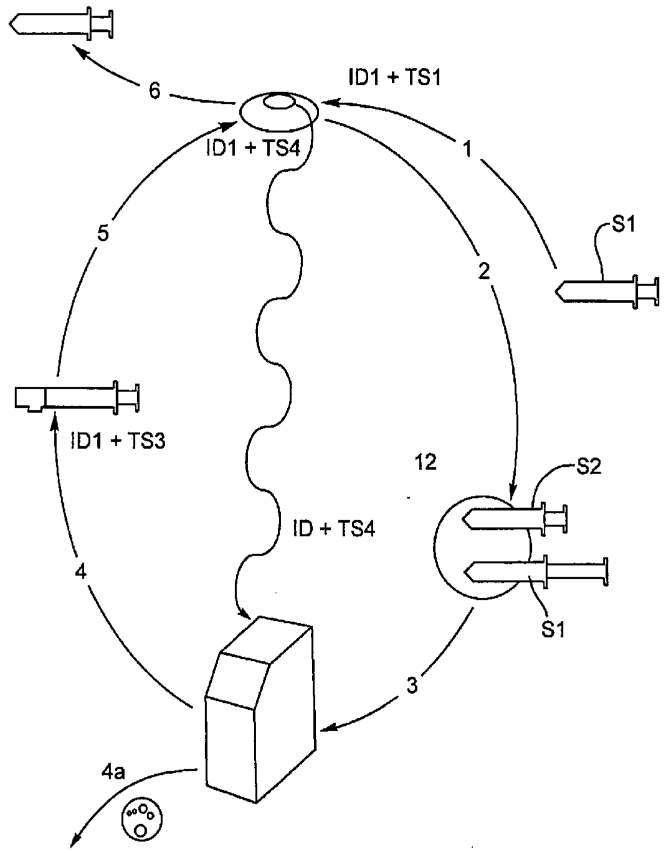
(52) **U.S. Cl.** **600/576**

(57) **ABSTRACT**

A system for the collection, treatment and delivery of an autologous blood sample, comprising a first syringe for drawing an untreated blood sample from a patient, a blood sample treatment chamber having a chamber inlet for receiving untreated blood from the first syringe and chamber outlet for passage of treated blood to a second syringe coupled thereto. The second syringe includes a releasable lock means for allowing discharge of the treated blood to the patient in response to a release signal. The release signal is issued following a positive outcome from a verification process dependent upon temporal data from certain events in the collection, treatment and delivery of the blood sample, and identity data of the patient and the second syringe with the treated blood.



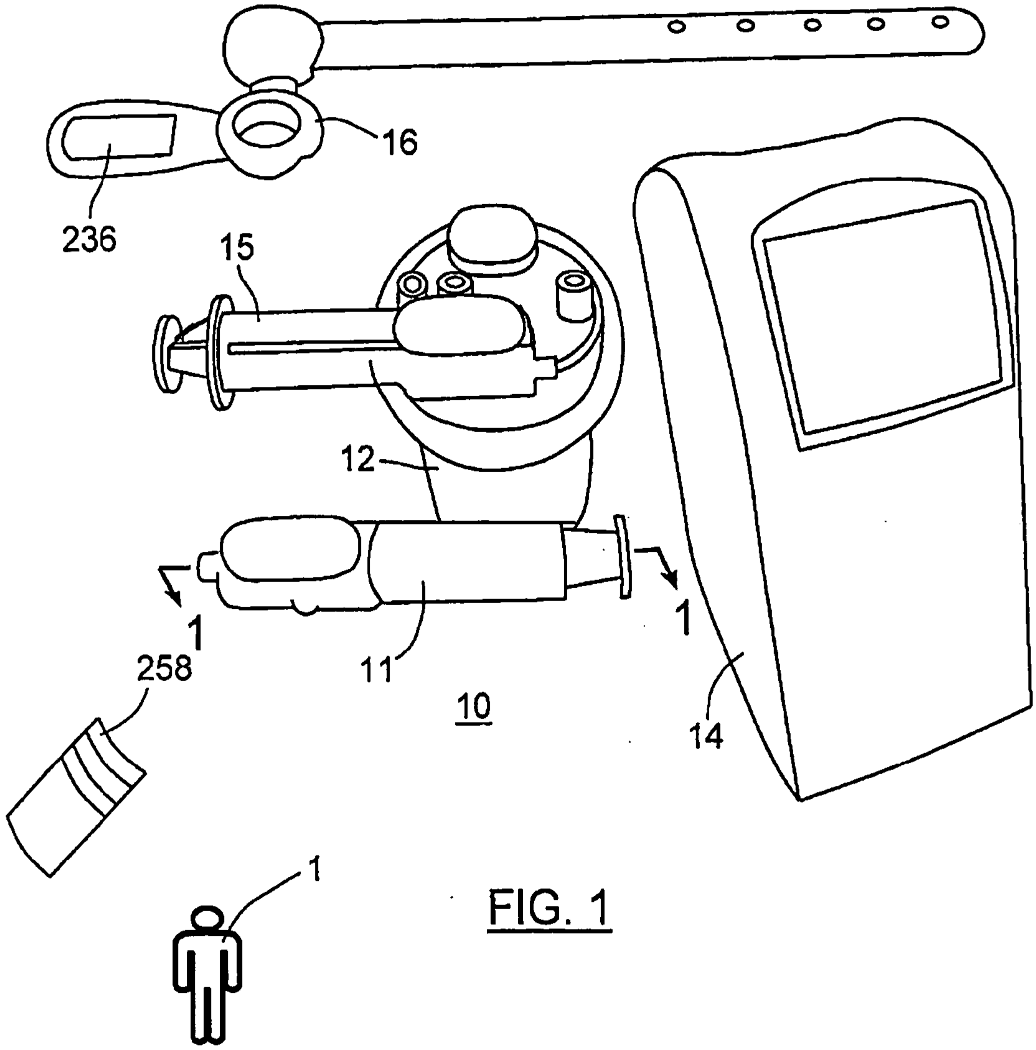


FIG. 1

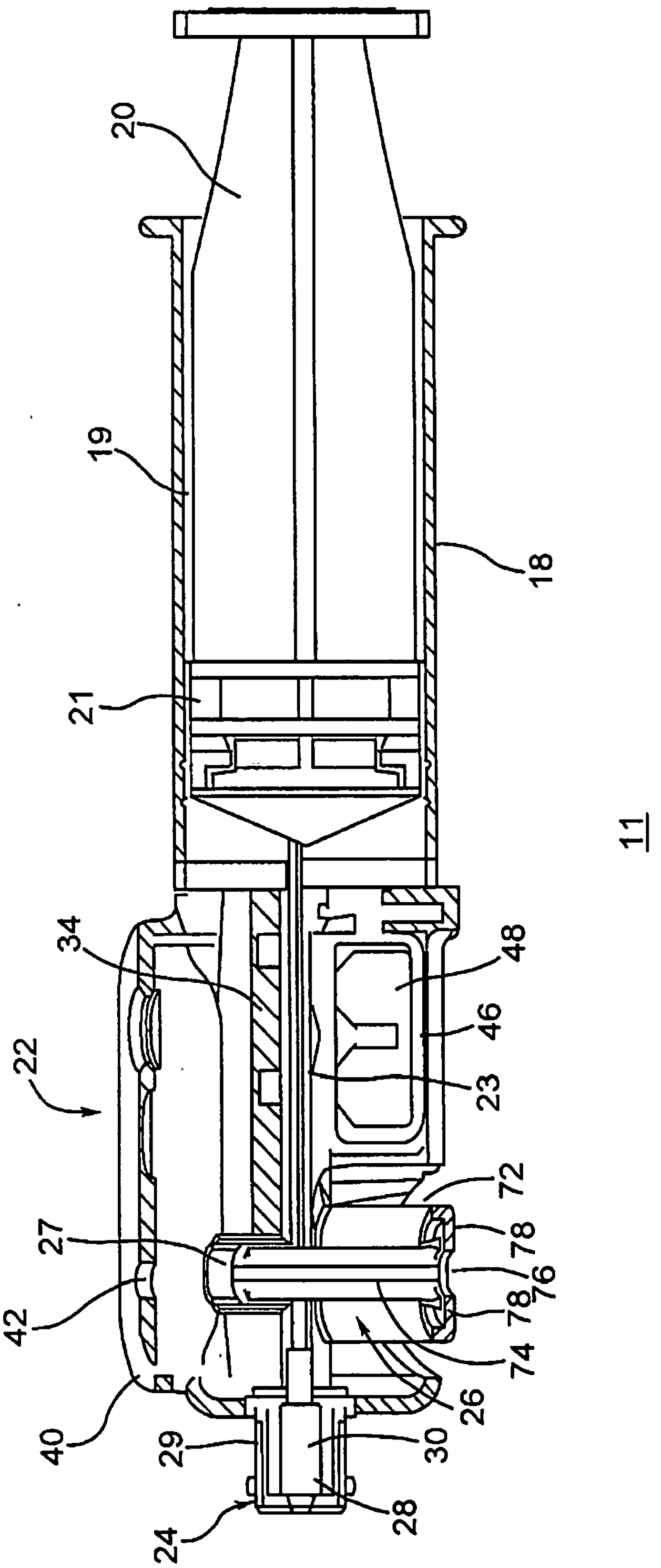


FIG. 2

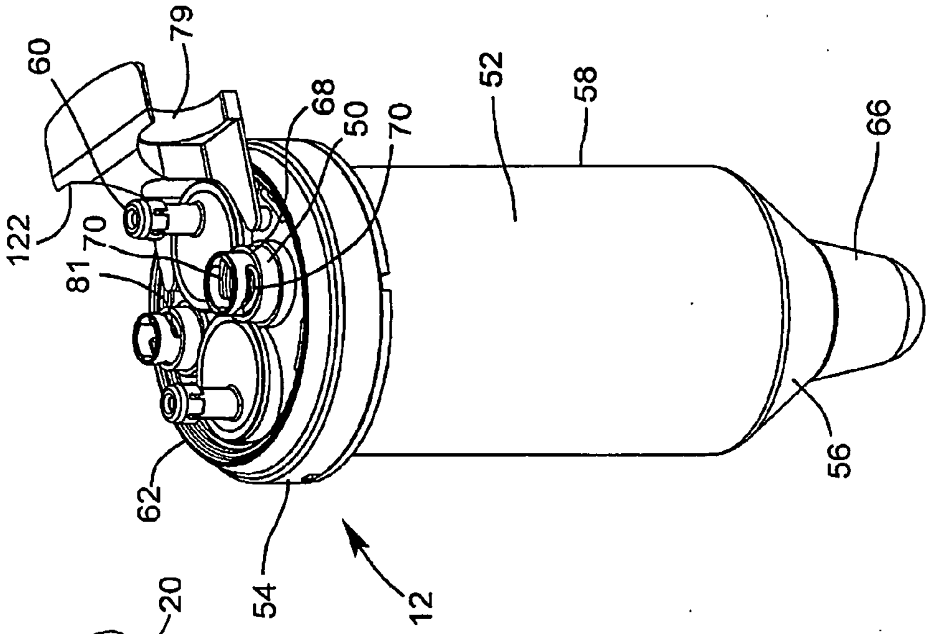


FIG. 4

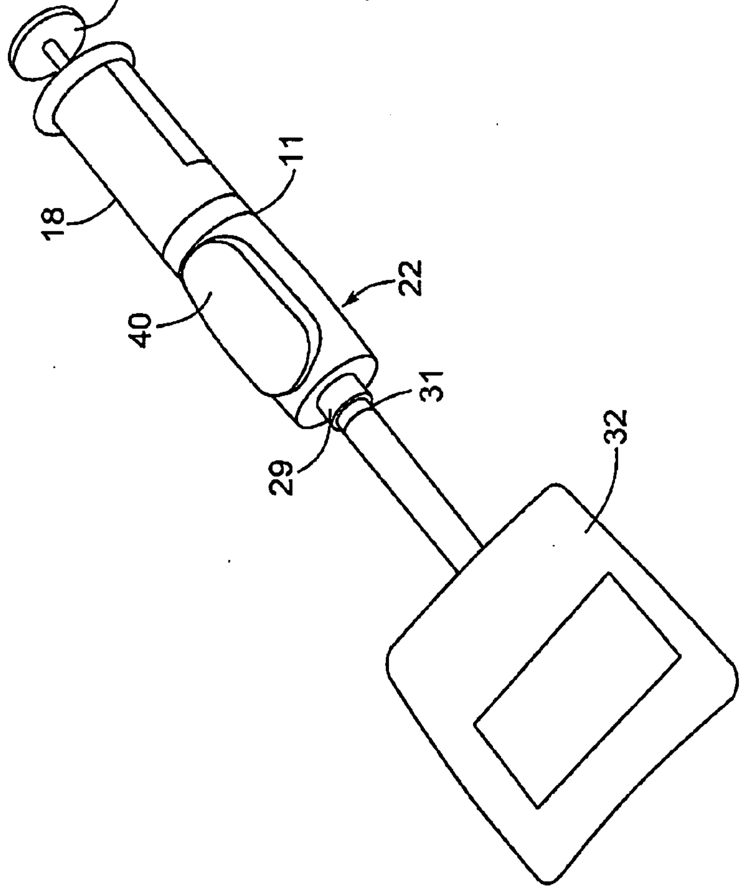


FIG. 3

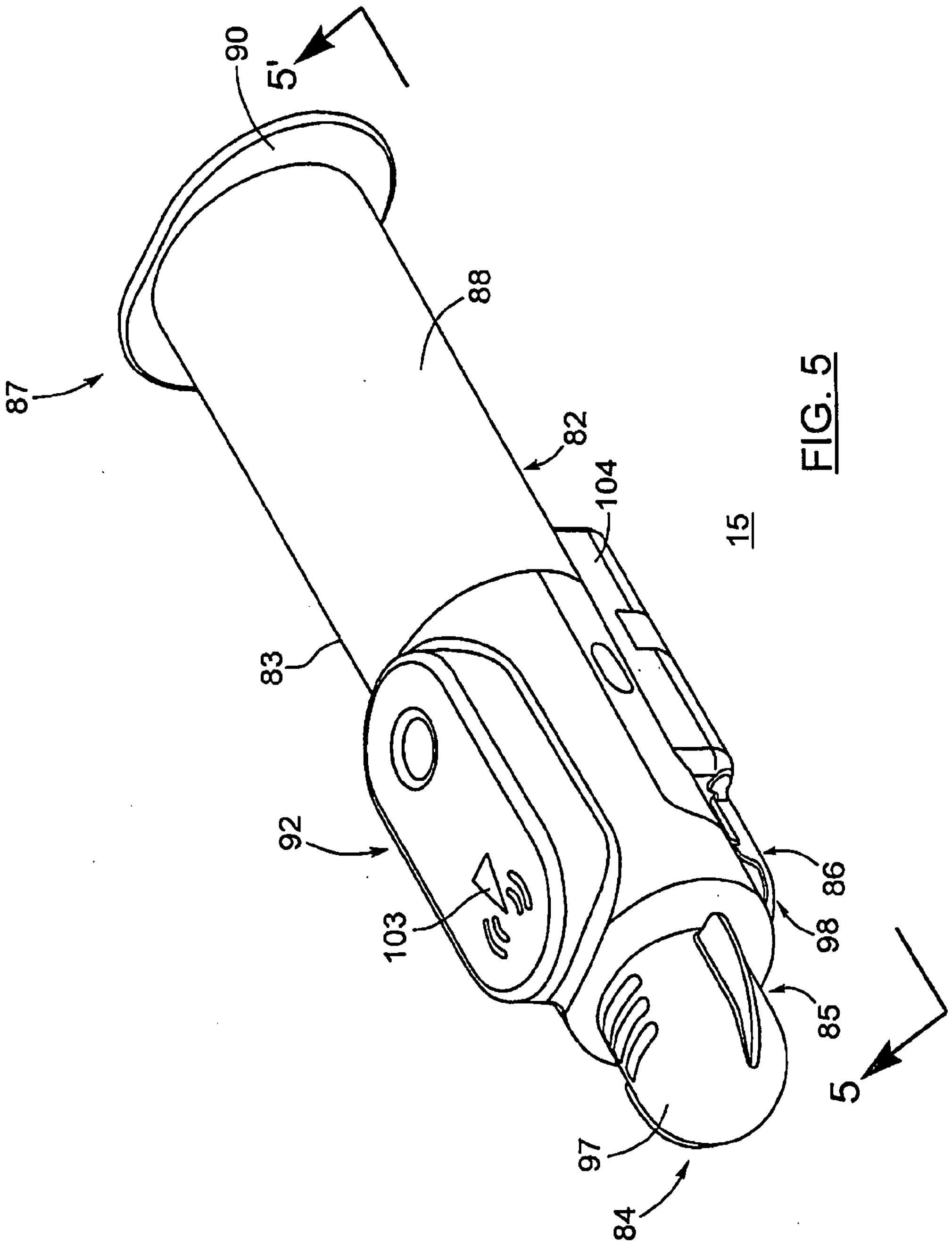


FIG. 5

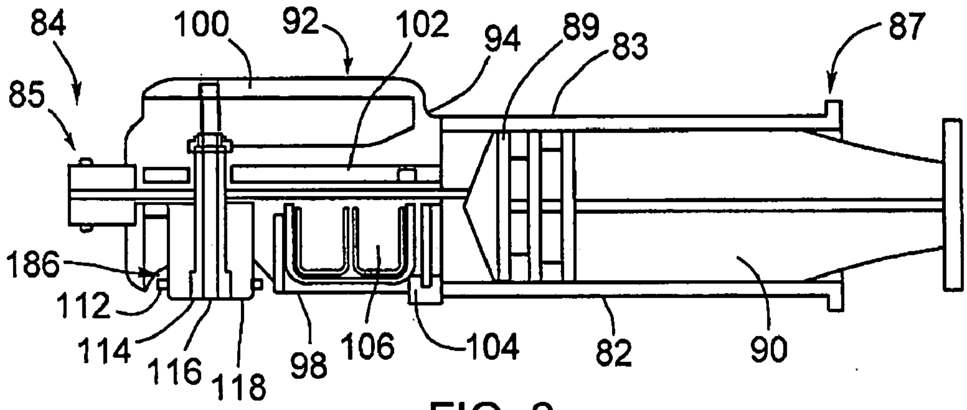


FIG. 6

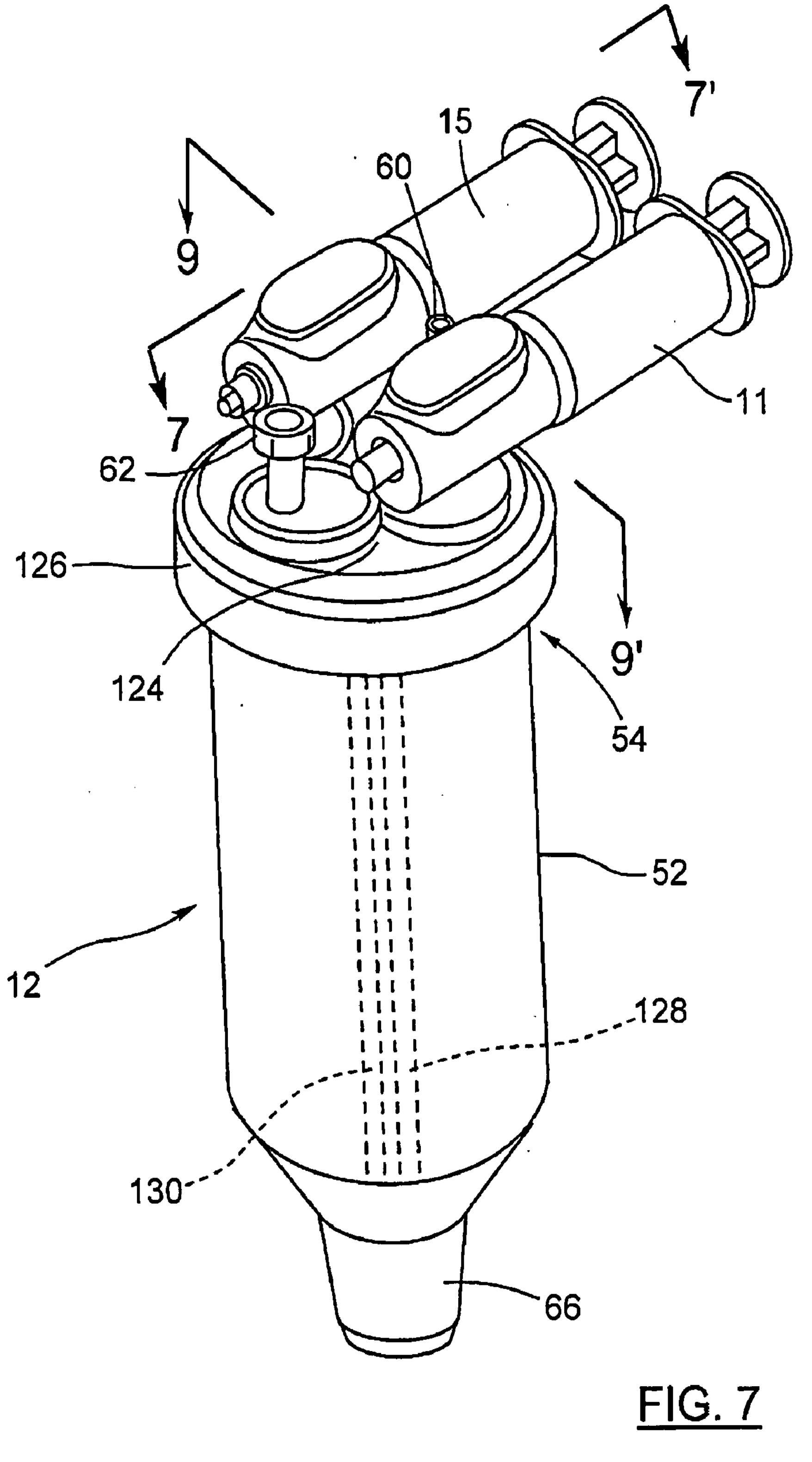


FIG. 7

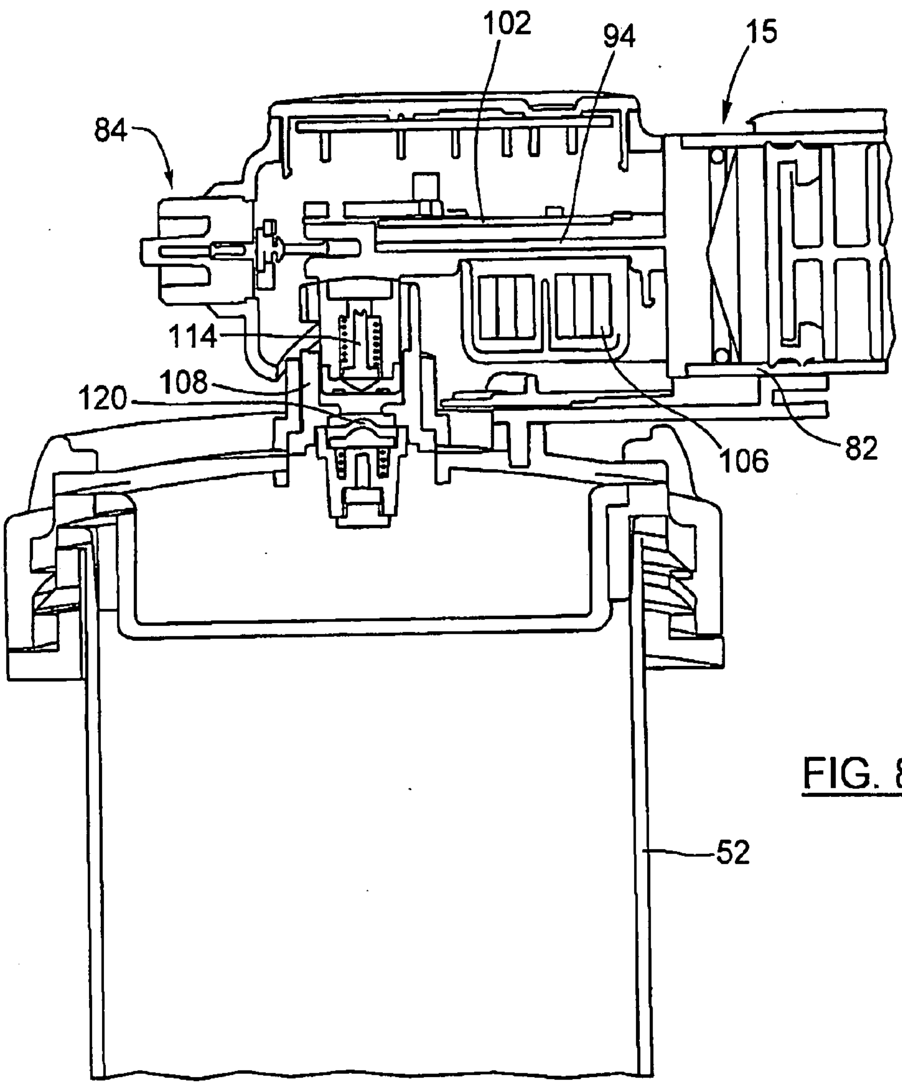


FIG. 8

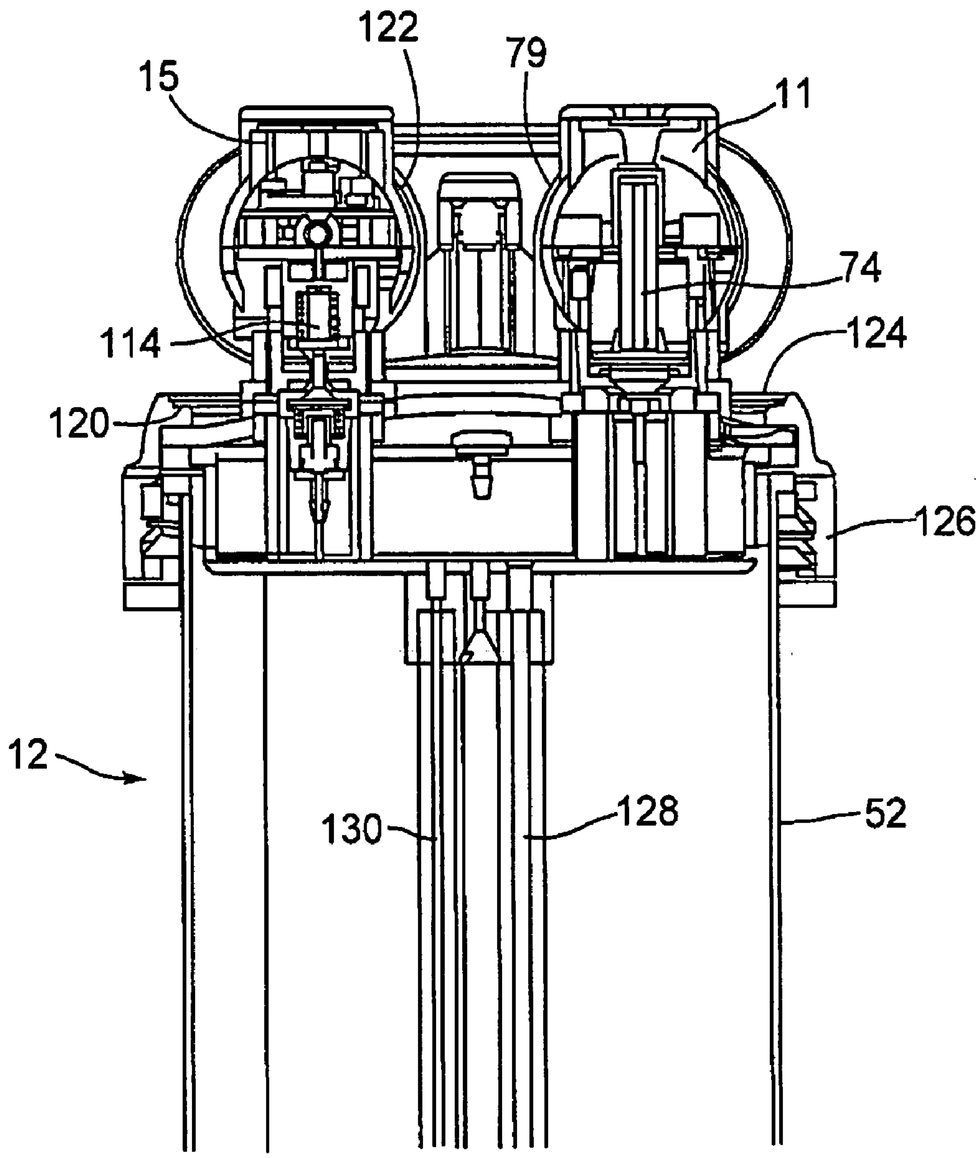


FIG. 9

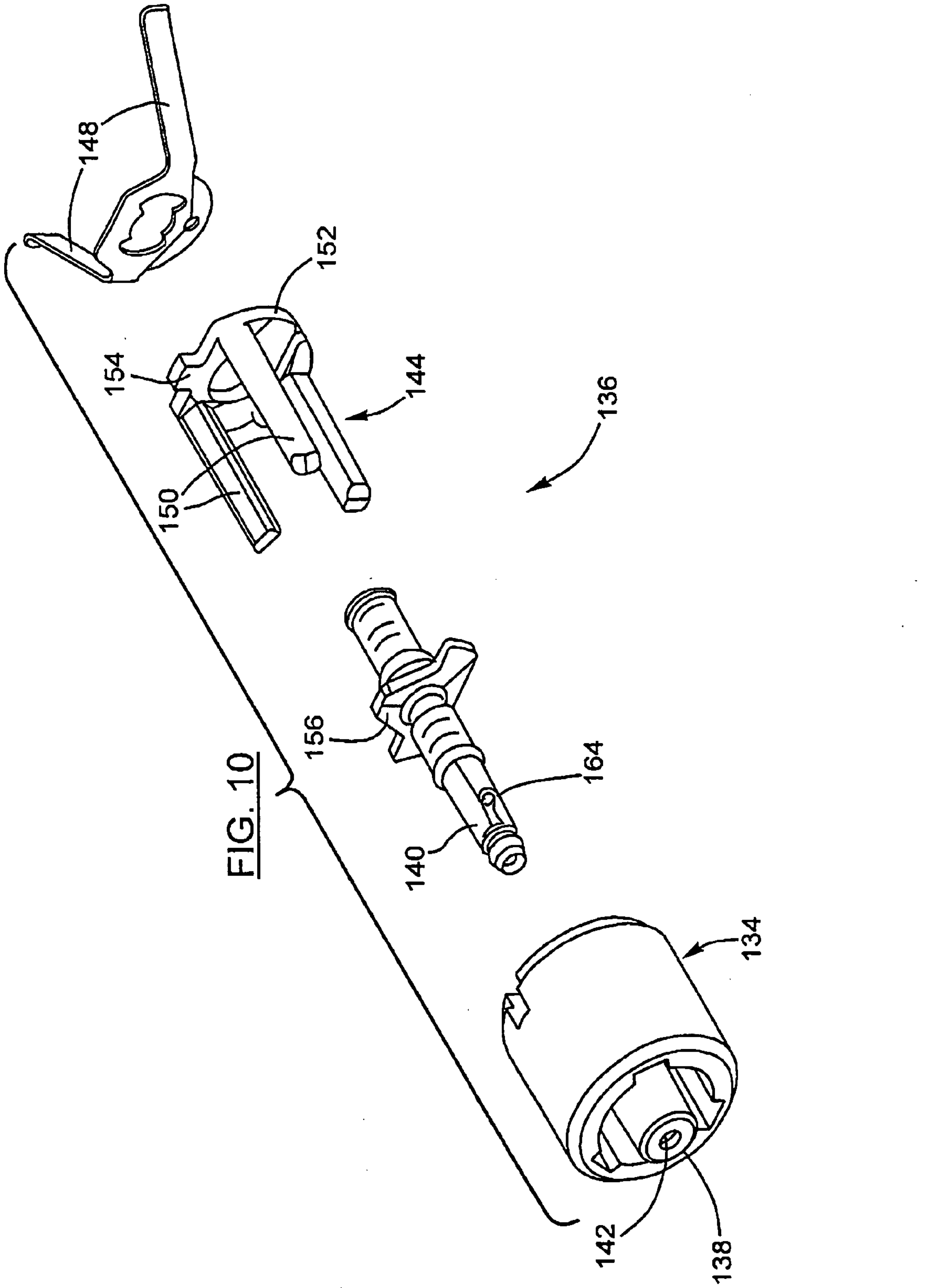


FIG. 10

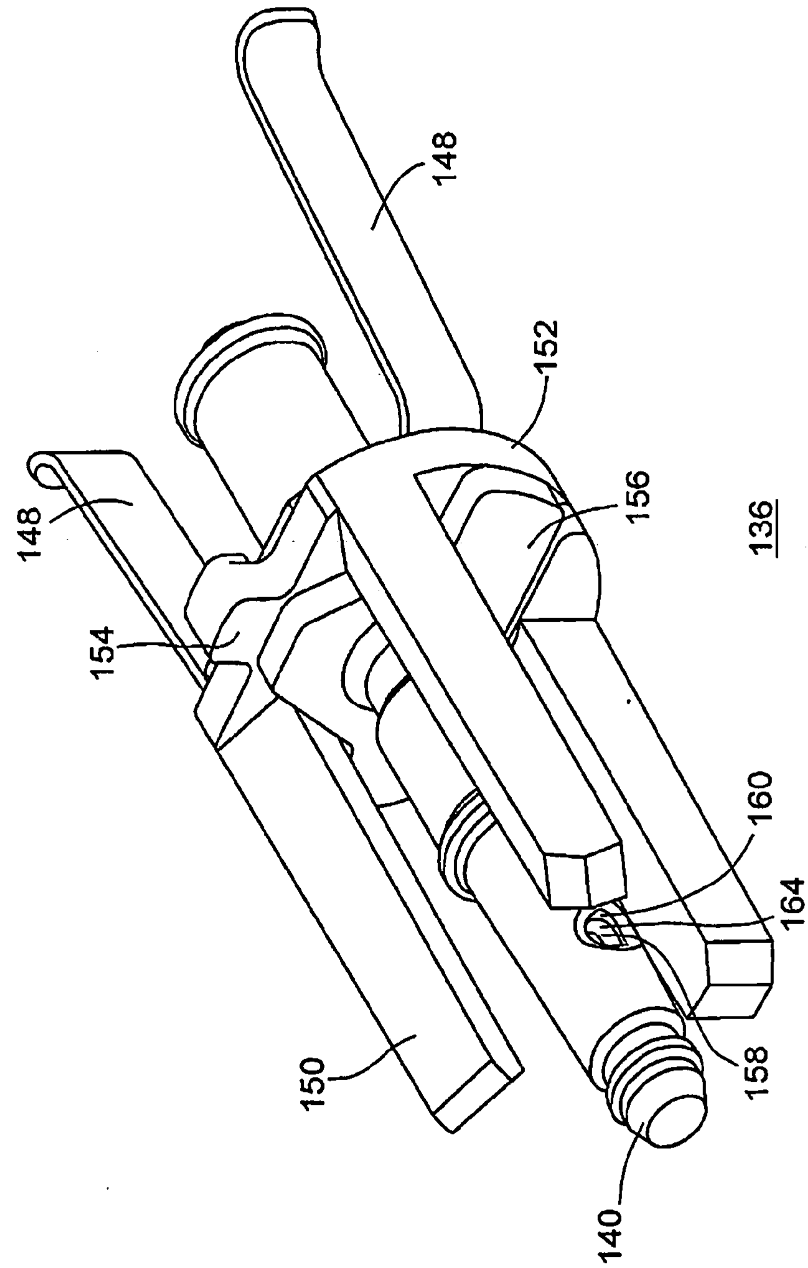


FIG. 11

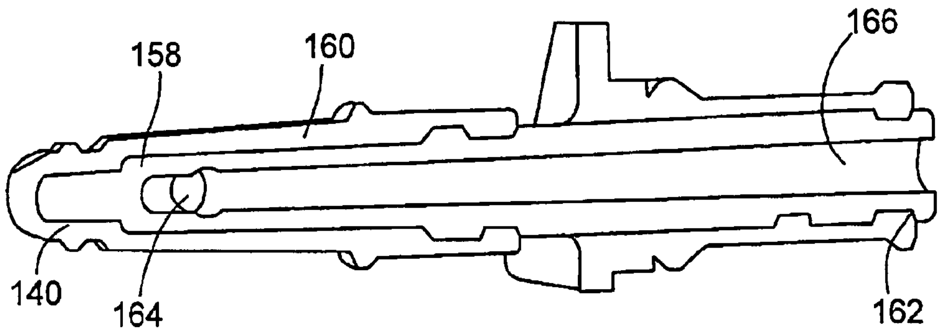


FIG. 12

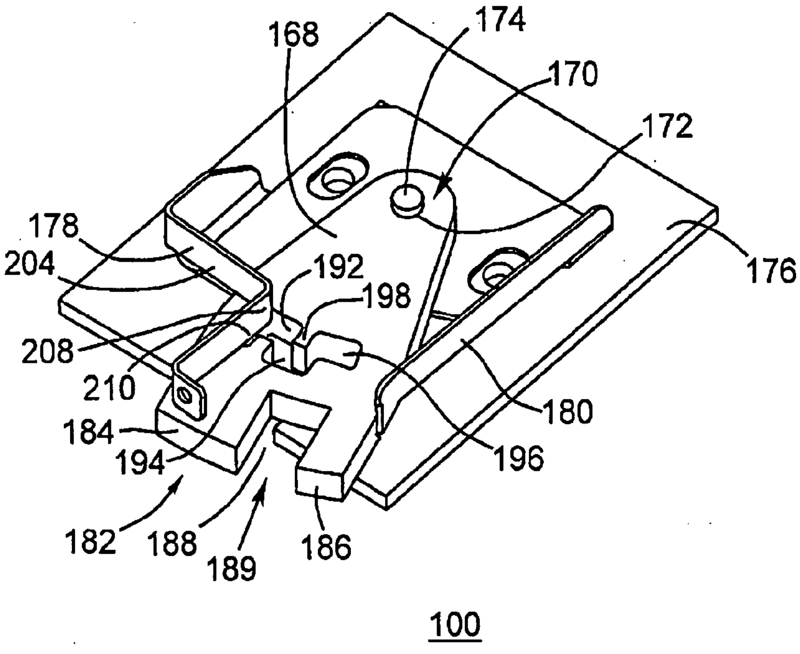


FIG. 13a

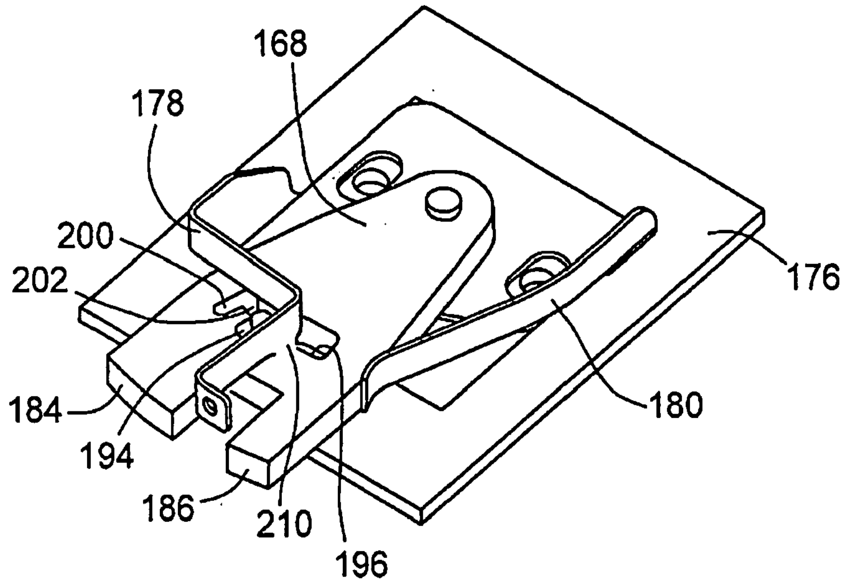


FIG. 13b

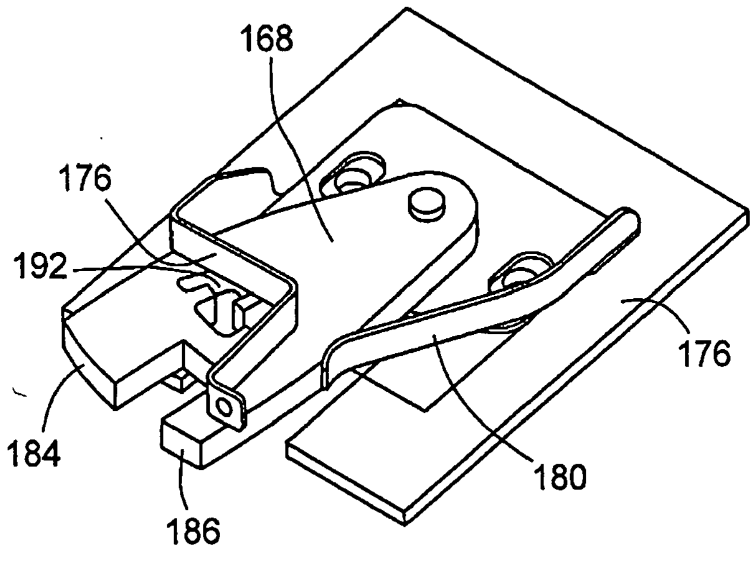


FIG. 13c

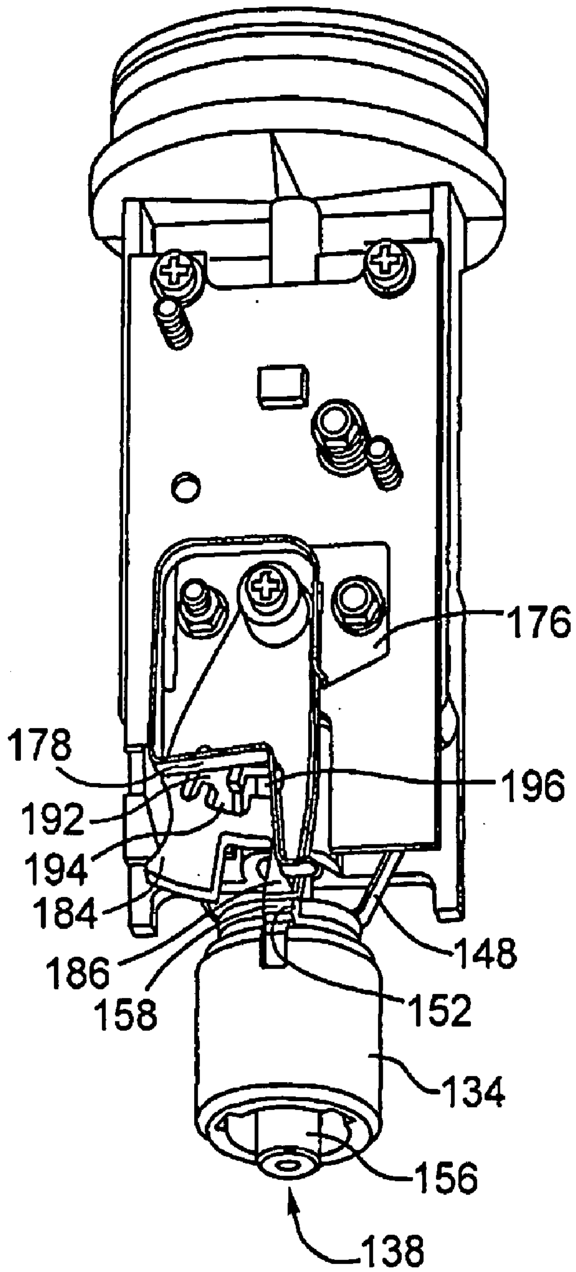


FIG. 13d

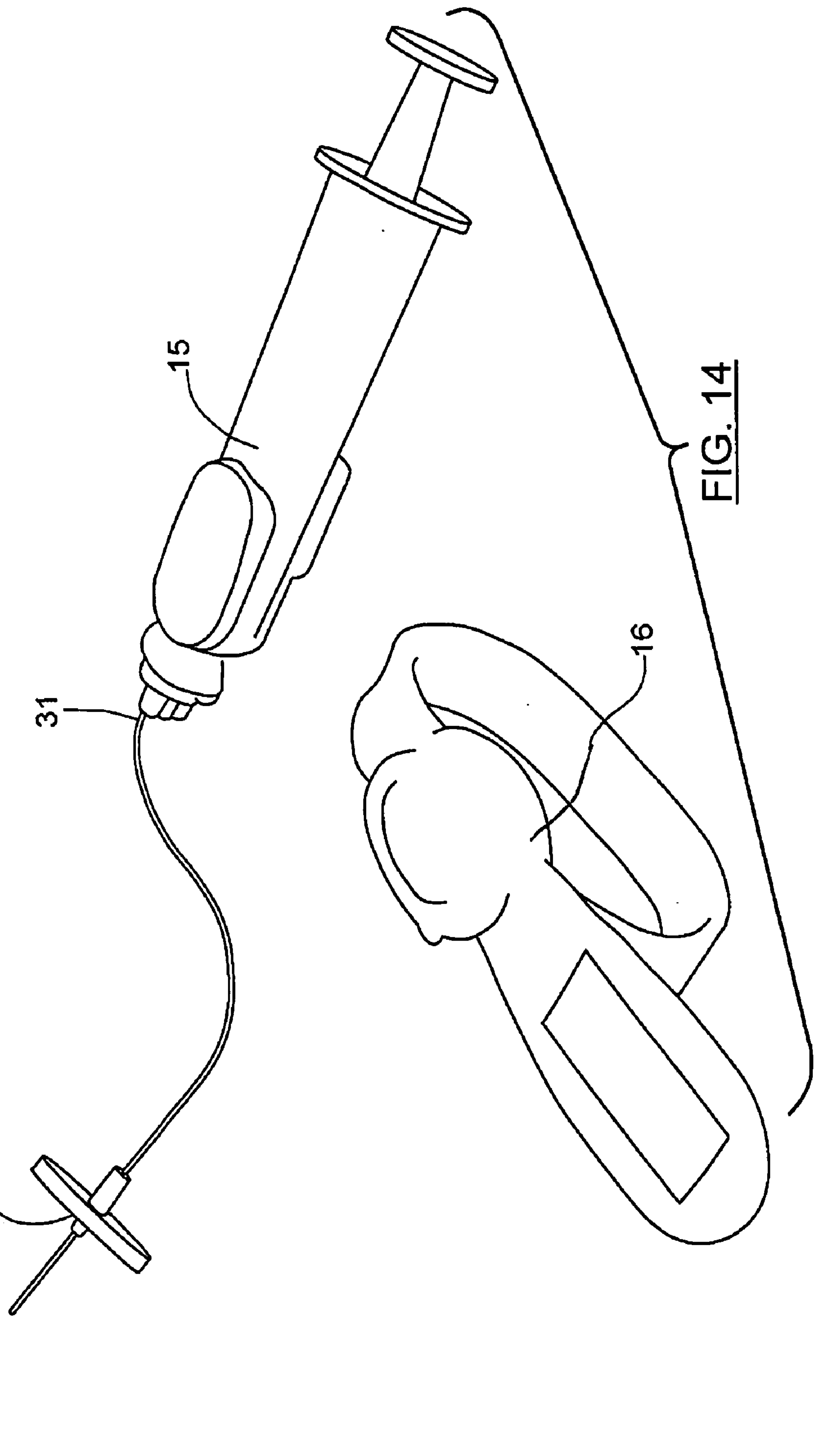


FIG. 14

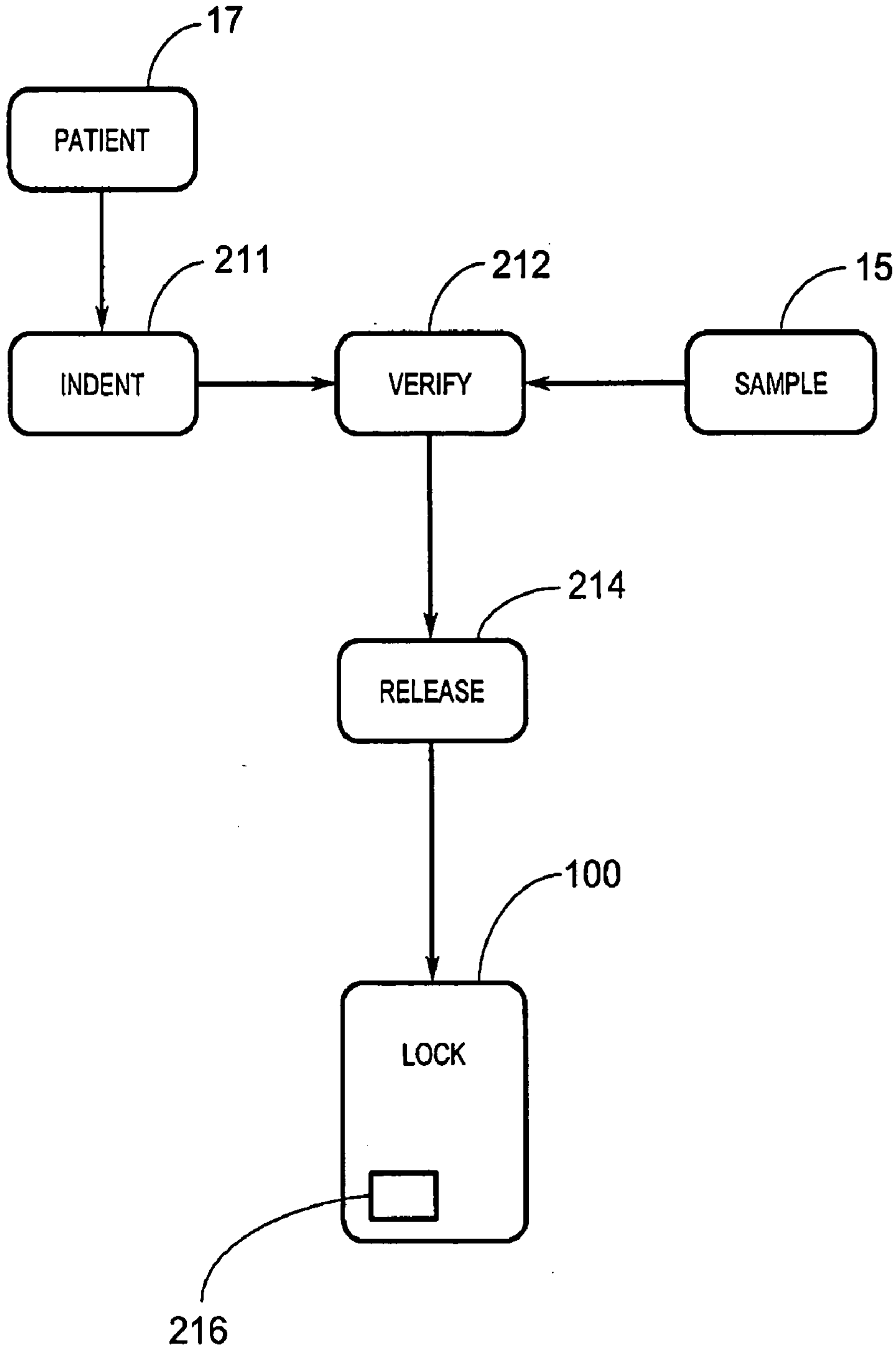

17
PATIENT
211
INDENT
212
VERIFY
15
SAMPLE
214
RELEASE
100
LOCK
216

FIG. 15

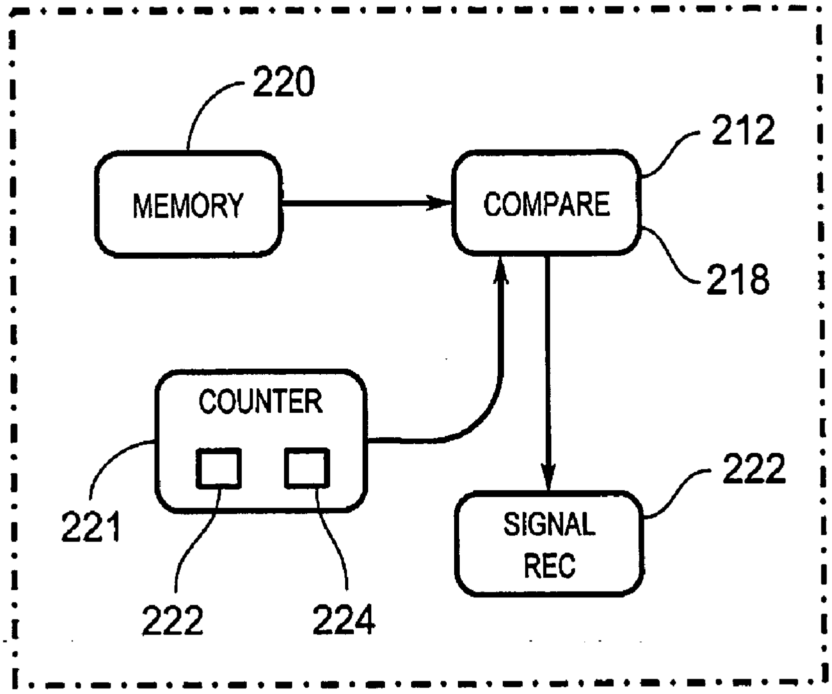

220
MEMORY
COMPARE
212
218
COUNTER
221
222
224
SIGNAL REC
222

FIG. 16

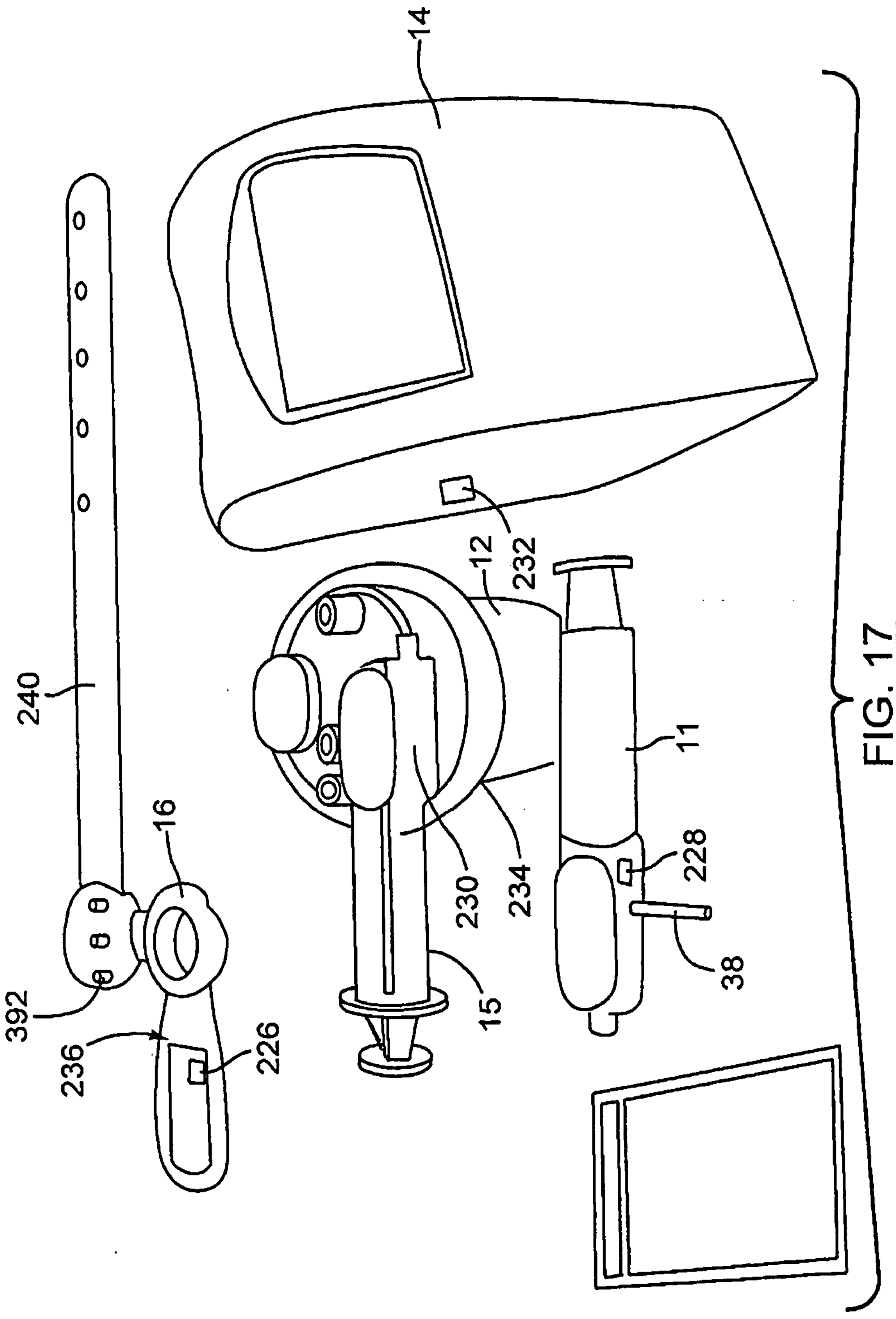


FIG. 17

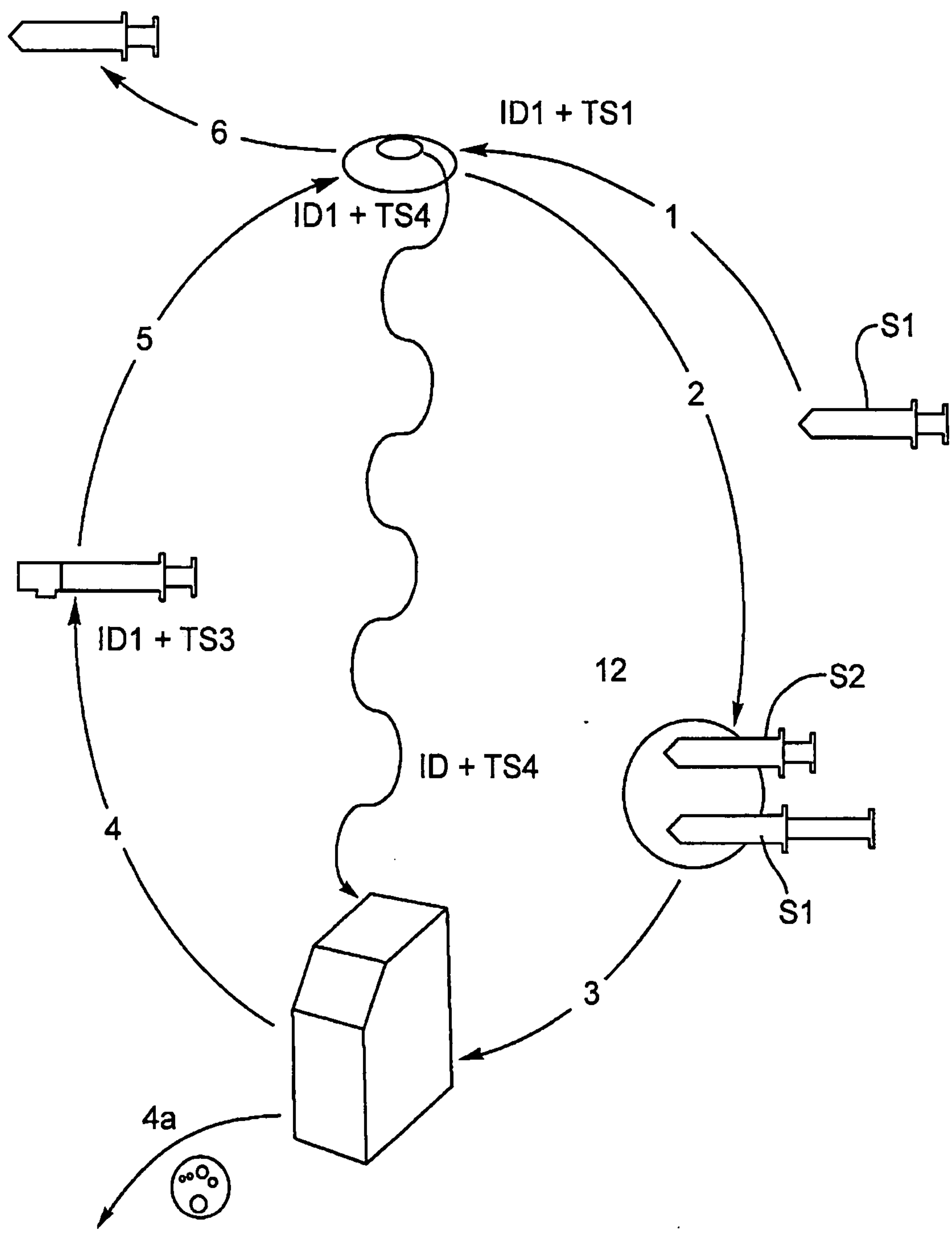


FIG. 18

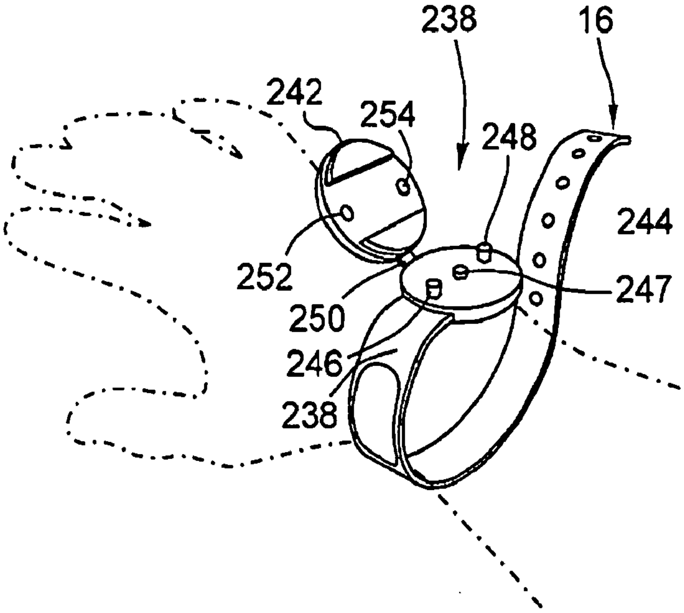


FIG. 19

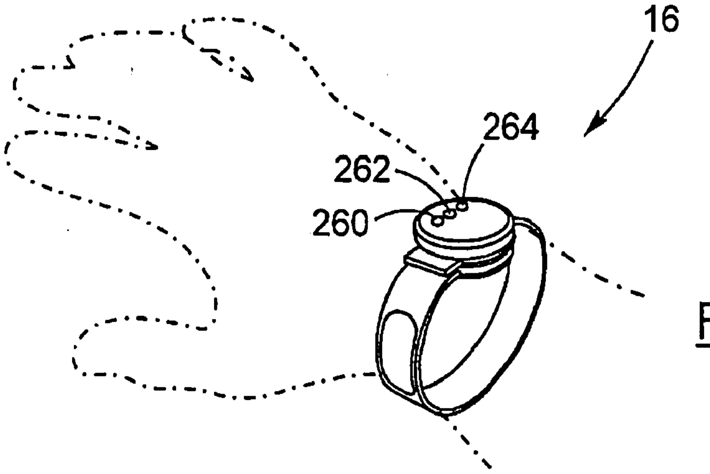


FIG. 20

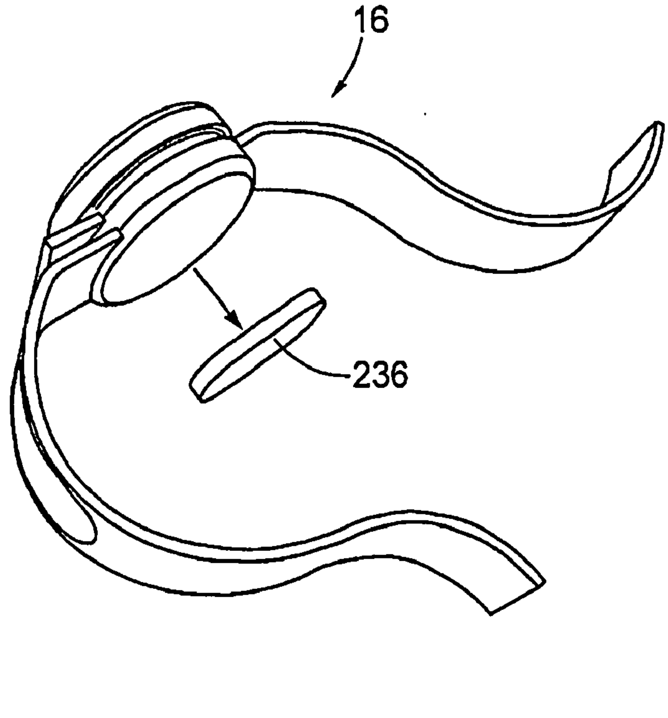


FIG. 21

VERIFICATION METHOD AND SYSTEM FOR MEDICAL TREATMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority to U.S. Provisional Application Ser. No. 60/682,969, filed May 19, 2005, U.S. Provisional Application Ser. No. 60/683,280 filed May 19, 2005, and U.S. Provisional Application Ser. No. 60/683,333, filed May 19, 2005.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention

[0003] The present invention relates to the management of medical treatments. More specifically it relates to a permission-based fluid dispensing device.

[0004] 2. Description of the Prior Art

[0005] Despite remarkable advances in health care technology and delivery, a large number of patients die or are disabled as a result of medical errors. These errors occur in health care settings, such as hospitals, clinics, nursing homes, urgent care centers, physicians' offices, pharmacies, and the care delivered in the home, and they usually result from systems problems rather than one single action or decision.

[0006] For many years, bar code labelling has been the technology of choice in ensuring patient safety. Recently, the Food and Drug Administration (FDA) issued a new rule which requires certain human drug and biological product labels to have bar codes. As such, the bar code for human drug products and biological products (other than blood, blood components, and devices regulated by the Center for Biologics Evaluation and Research) must contain the National Drug Code (NDC) number in a linear barcode. The rule is geared toward reducing the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time. The rule also requires the use of machine-readable information on blood and blood component container labels to help reduce medication errors.

[0007] However, bar codes require line of sight with a reader in order to be read and they cannot store additional information apart from simple identification data, such as a serial no. or SKU. For example, a bar-coded wristband on a patient is not easy to read if the patient gets it wet or is sleeping on top of the arm bearing the wristband, or when the patient is on an emergency room gurney or operating table; these are instances where mistakes in medication or blood transfusion are most prevalent.

[0008] It is an object of the present invention to mitigate or obviate at least one of the above-mentioned disadvantages.

SUMMARY OF THE INVENTION

[0009] In one of its aspects, the present invention provides a system for the collection, treatment and delivery of a blood sample, the system comprising:

[0010] an article for association with a patient having a patient identifier;

[0011] a first syringe having:

[0012] a first syringe inlet for drawing an untreated blood sample from the patient,

[0013] a first fluid chamber for receiving the untreated blood,

[0014] a first syringe outlet for dispensing the untreated blood sample from the first chamber,

[0015] a first incremental counter for recording temporal data corresponding to untreated blood events related to the collection of blood,

[0016] the first syringe being associated with a first unique identifier correlatable to the patient identifier;

[0017] a vessel for processing the blood sample, the vessel having:

[0018] a blood sample processing chamber, the vessel having a chamber inlet; the first syringe outlet being operable to establish a dedicated first fluid coupling with the chamber inlet to dispense the untreated blood sample to the blood sample processing chamber; the vessel having a chamber outlet for dispensing a treated blood sample following treatment to a second syringe,

[0019] the second syringe having:

[0020] a second syringe inlet operable to form a dedicated second fluid coupling with the chamber outlet to receive the blood sample from the blood sample treatment chamber;

[0021] a second chamber for receiving the treated blood;

[0022] a second syringe outlet;

[0023] a passage in communication with the second chamber and the second syringe outlet;

[0024] a second incremental counter for recording temporal data corresponding to blood treatment events, treated blood events and delivery events; the second incremental counter being operable independently of the first incremental counter and being non-synchronized with the first incremental counter;

[0025] the second syringe being associated with a second unique identifier, the second unique identifier operatively associated with the first syringe and correlatable to the first unique identifier;

[0026] a releasable lock formed within the passage for operating the second syringe outlet between a plurality of states;

[0027] a processor having:

[0028] a comparator for comparing the patient identifier to the first unique identifier to determine the correlation between same; and comparing the second unique identifier to the patient identifier to determine the correlation between same, the comparator issuing an output signal;

[0029] logic for receiving the output signal and the temporal data to determine time delays between the events and for determining whether the time delays are within predefined ranges;

[0030] a release signal generator coupled to the logic for issuing a release signal to the releasable lock;

whereby the release signal is issued upon confirmation of the correlation between the patient identifier and the first unique identifier, and the correlation between the patient identifier and the second unique identifier, and provided that the time delays are within predetermined ranges.

[0031] In another of its aspects, the present invention provides identification means for identifying an originating patient of the untreated blood sample, verification means for verifying a match between the originating patient and the treated blood sample, and release signal generating means for generating a release signal in response to a positive verification by the verification means. The identification means and/or the release signal generating means may be located on the second syringe body, or on an external article. The external article may worn, carried, attached or ingested by the patient, such as a pinned or self adhesive label, or a coated object, and the like. Preferably, the external article contains a removable portion containing audit data relating to the patient and/or the treated blood sample. For example, the external article may be conveniently provided as a wristband to be worn by the originating patient.

[0032] In yet another of its aspects, the second syringe body may also include a filtered vent outlet in the passage for expelling one or more gas constituents in the treated blood sample.

[0033] As a further aspect, the present invention provides a method of monitoring a material sample from a patient, comprising the steps of:

[0034] (a) collecting the sample from the patient with a first collection device;

[0035] (b) associating the patient with a first signal carrying data representative of the sample;

[0036] (c) associating the first collection device with a second signal carrying data representative of the sample;

[0037] (d) delivering the sample to a sample treatment chamber;

[0038] (e) processing the sample to form a processed sample;

[0039] (f) collecting the sample in a second collection device;

[0040] (g) associating the second collection device with a third signal carrying data representative of the processed sample;

[0041] (h) comparing the data in the first and third signals to link the processed sample with the patient; and thereafter;

[0042] (i) associating at least one of the steps (a) to (h) with temporal data;

[0043] (j) determining at least one time delay using the temporal data to determine whether the at least one of the steps (a) to (h) occurs within acceptable time limits;

[0044] (k) delivering the processed sample to the patient upon a positive outcome from step (h) and step (j); and

[0045] (l) assembling an audit record having temporal data collected from step (i), the outcome from step (h) and step (j), and data associated with the sample.

[0046] The events related to the collection of untreated blood are tracked by the first incremental counter, while the treatment and post treatment events are tracked by the second incremental counter, such that time delays may be determined from the temporal data Advantageously, these two counters operate independently of one another and do not require to be synchronized with each other, unlike real-time clocks. The counters only operate during the steps (a) to (j) described above, and thus do not require substantial battery power. As such, the battery is sufficient to maintain substantial accuracy of the clock within the time period from steps (a) to (f), and thus the possibility of losing time or decreasing clock accuracy as the battery's power runs down is substantially eliminated.

[0047] In yet another of its aspects, the system includes a releasable lock means operable by a solenoid configured to receive the release signal.

[0048] In yet another of its aspects, the system includes a releasable lock means operable by a motorized means configured to receive the release signal.

[0049] The term "treatment device" used herein below is intended to mean a device used directly or indirectly in the course of a treatment. It may include devices which actually perform a treatment on the patient or a patient-derived sample, or alternatively be an article for performing functions associated with treatments, such as carrying or otherwise transferring the sample to or from a treatment.

BRIEF DESCRIPTION OF THE DRAWINGS

[0050] These and other features of the preferred embodiments of the invention will become more apparent in the following detailed description in which reference is made to the appended drawings wherein:

[0051] **FIG. 1** is a perspective view of a blood treatment system;

[0052] **FIG. 2** is a sectional view of a first syringe shown in **FIG. 1**, taken along line **1-1'**;

[0053] **FIG. 3** is a perspective view of the first syringe of **FIG. 1** coupled to a sodium citrate bag;

[0054] **FIG. 4** is a perspective view of a blood treatment chamber of **FIG. 1**;

[0055] **FIG. 5** is a perspective view of a second syringe of **FIG. 1**;

[0056] **FIG. 6** is a sectional view of the second syringe of **FIG. 5** taken along line **5-5'**;

[0057] **FIG. 7** is another perspective view of the blood treatment chamber carrying the first syringe and the second syringe;

[0058] FIG. 8 is a sectional view of the blood treatment chamber of FIG. 7 taken along line 7-7';

[0059] FIG. 9 is a sectional view of the blood treatment chamber of FIG. 7 taken along line 9-9';

[0060] FIG. 10 is an exploded view of an outlet port of the second syringe of FIG. 5;

[0061] FIG. 11 is a perspective view of a outlet valve;

[0062] FIG. 12 is a sectional view of the outlet valve element of FIG. 10 taken along line 11-11';

[0063] FIG. 13(*a*) is a perspective view of the a portion of locking mechanism in a locked state;

[0064] FIG. 13(*b*) is a perspective view of the a portion of locking mechanism in an open state;

[0065] FIG. 13(*c*) is a perspective view of the portion of locking mechanism in a permanently locked state;

[0066] FIG. 13(*d*) is a perspective view of the portion of locking mechanism adjacent to the outlet port of FIG. 10, in a permanently locked state;

[0067] FIG. 14 is a perspective view of the portion of locking mechanism in a cooperating arrangement with the outlet port;

[0068] FIG. 15 is a flowchart outlining a verification protocol of the system of FIG. 1;

[0069] FIG. 16 is a flowchart outlining a verification portion protocol of FIG. 15;

[0070] FIG. 17 is a detailed perspective view of the blood treatment system;

[0071] FIG. 18 is a schematic view of a verification protocol;

[0072] FIG. 19 is a perspective view of a wristband as shown in FIG. 1, prior to operation;

[0073] FIG. 20 is a perspective view of a wristband as shown in FIG. 1, in operation; and;

[0074] FIG. 21 is a perspective view of a wristband as shown in FIG. 1, prior to operation.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0075] As shown FIG. 1, there is provided a system 10 for the collection, treatment and delivery of an autologous blood sample. The system 10 includes a plurality of entities which are used at different stages during the handling of the blood sample, such as, a first syringe 11 (S1), a sample management unit 12 (SMU), a blood treatment unit 14 (BTU), a second syringe 15 (S2), and a wristband 16 (WB). The first syringe 11 is used to collect an untreated blood sample from an originating patient 17. Following collection of the untreated blood sample, the blood collection syringe 11 is coupled to the sample management unit with the blood delivery syringe 15 already mounted thereon, and the sample management unit is introduced into the blood treatment unit, in which the untreated blood sample is subjected to one or more stressors, such as ozone or ozone/gas mixture, ultra-violet (UV) light and infra-red (IR) energy.

[0076] Following treatment, the treated blood sample is delivered to a second syringe 15, from which the treated blood sample is administered to the originating patient 17. At one or more critical stages, the system 10 provides for a verification check, aimed at reducing the possibility of error, and thus ensure that the correct blood sample is returned to the correct originating patient 17. The verification check includes the steps of matching the blood sample, either in its treated or untreated form or both, with the originating patient 17. Typically, the wristband 16, the first syringe 11, the sample management unit 12, the second syringe 15, include identification data associated with the originating patient, the data may include indicia, or may be machine-readable via optical or electro/magnetic means.

[0077] As shown in FIG. 2, the first syringe 11 has a first body portion 18 which provides a cylindrical cavity 19 which in cooperation with a syringe plunger 20 forms a sample receiving chamber 21. The first syringe 11 includes a first channel portion 22 with a channel 23 in communication with the first sample receiving chamber 21, and a first syringe inlet port 24 for ingress of the untreated blood sample from the patient 17. The first channel portion 22 also includes a first syringe outlet port 26 for dispensing the untreated blood sample therefrom to the sample management unit 12. The first syringe outlet port 26 includes a channel 27 in communication with the first sample receiving chamber 21 and channel 24.

[0078] The first syringe inlet port 24 is provided with a first syringe inlet valve means 28 in channel 24 for controlling the flow of blood through the first syringe inlet 24. In this case, the first inlet valve means 28 includes a housing 29 containing a valve 30 arranged to be opened by a complementary valve member 31, located on an external device 32, as shown in FIG. 3. The external device 32 may be a blood collection unit, such as a "butterfly" needle or a sodium citrate bag, and so forth. Extending outwardly from the first syringe outlet port 26 is a pair of bayonet pins 72 for coupling the first syringe 11 to the blood treatment chamber 12. Included within the channel 27 of the first syringe 11 is a valve element 74 biased to a closed position against a valve seat 76 on an end cap 78 which forms the outer end of the first syringe outlet port 26.

[0079] Within the first channel portion 22, is a printed circuit board (PCB) 34 having circuitry for transmitting and receiving data related to the syringe and/or its contents, or a patient 17, such as identification data, SKU, serial no., manufacturing date, expiry date, fluid data, health facility data, health practitioner data, medication data, and so forth. The circuitry includes, but is not limited to, a transmitter, a receiver, logic means or processor, a computer readable memory for data storage, a timing circuit, an antenna and a power source. In the preferred embodiment, the circuitry also includes an RFID reader/writer for reading RFID tags associated with other entities within the treatment system. The RFID reader/writer is also coupled to other elements of the circuitry to perform at least one verification check, and other functions. Also coupled to the PCB 34 are input/output devices such as a display, an LED 36, a speaker, and a switch, such as pullout tab 38. The first channel portion 22 also includes a cover 40 with a bore 42 contiguous with an opening 44 of the first outlet port 26. The first syringe 11 also includes a compartment 46 for housing a power supply unit 48 to provide electrical power to the PCB 34 and the input/output devices. The power supply unit **48** typically comprises one or more batteries which may be removed following the single use of the first syringe **11**, in order to enable use in another device or allow for proper recycling in compliance with current environmental regulations. In order to facilitate easy battery installation or removal, the batteries **48** may be placed on a tray which is slidably received by the compartment **46**.

[0080] As shown in **FIG. 4**, the sample management unit **12** is a vessel **49** having an open top portion **51**, a closed bottom portion **56** and a rigid walled portion **58** therebetween, and a cover portion **54** to define a cylindrical treatment cavity **52**, or treatment chamber. The cover portion **54** has a chamber inlet **50** to form a dedicated first fluid coupling with the first syringe outlet port **26**, such that the untreated blood sample may be dispensed into the treatment cavity **52** of the blood sample treatment chamber **12**. The cover portion **54** also has a gas inlet port **60** for delivery of ozone to treat a blood sample, a gas outlet port **62** for the discharge of the ozone, and other gases. The bottom portion **56** has a bowl **66** to receive the blood sample during treatment.

[0081] In the course of the treatment of the blood sample, the treatment cavity **52** is subjected to stressors, such as, UV A, B and C radiation, infrared radiation and ozone is bubbled through the blood sample. As such, the walled portion **58** and the bowl **66** are made from appropriate materials capable of transmitting such radiation, such as low density polyethylene (LDPE) containing a small amount (about 5%) of ethylene vinyl acetate. The chamber inlet **50** has a female collar portion **68** with a pair of helically oriented passages or grooves **70** extending through its wall, or in its wall, to receive the pair of corresponding bayonet pins **72** of the first syringe outlet port **26**. In operation, the first syringe **11** is rotated to urge the bayonet pins **72** along the helical passages **70** and downwardly into the female collar portion **68** until the valve element **74** abuts the valve-actuating element **80**. Subsequently, the valve element **74** is displaced by the valve-actuating element **80** from its closed position against the valve seat **76** to open the fluid coupling. Once fully engaged within the chamber inlet **50**, the first syringe **11** is supported in place by a saddle member **79**, which minimizes motion of the first syringe about the chamber inlet **50**.

[0082] The cover portion **54** has a chamber outlet **81** to form a dedicated second fluid coupling with the second syringe **15**, as shown in **FIG. 8**. The second syringe **15**, shown in more detail in **FIG. 5** and **FIG. 6**, has a second body portion **82** having a barrel **83** with a proximal end **84**, at which is disposed a second inlet port **85**, a second outlet port **86**; and a distal end **87** with a cylindrical wall **88** therebetween to define a second sample receiving chamber **89**. The second inlet port **85** is disposed at an angle to the second outlet port **86**, and intermediate the second sample receiving chamber **89** and the second outlet port **86**. A plunger **90** is slidably disposed at the distal end **87** and is in tight fluid engagement with the cylindrical wall **88**. The plunger **90** serves to draw fluid into the second sample receiving chamber **89** and urge the fluid therefrom. The second syringe **15** also includes a second channel portion **92** with a channel **94** in communication with the second sample receiving chamber **89** and the second outlet port **86**, and a channel **96** in communication with the second inlet port **85** and the second sample receiving chamber **89** via a portion of the channel **94**. In order to prevent large particulate from entering the second outlet port **86**, a second end cap **97** is removably attached thereto, while the second inlet port **85** includes a slidable cap **98** to prevent contamination prior to use with the blood treatment unit **14**. The treated blood sample is dispensed from the second syringe **15** to the originating patient **17** via the second syringe outlet port **86** operable between an open position and a closed position by a releasable lock means **100**, as will be described below.

[0083] Similar to the first syringe **11**, within the second channel portion **92** is a printed circuit board (PCB) **102** having circuitry for transmitting, receiving and storing data related to the syringe and/or its contents or the originating patient **17**, such as identification data, SKU, serial no., manufacturing date, expiry date, fluid data, health facility data, health practitioner data, medication data, and so forth. The circuitry includes RFID reader/writer functionality for reading RFID tags associated with other entities within the treatment system. The RFID reader/writer is also coupled to other elements of the circuitry to perform at least one verification check, and other functions As such, the circuitry includes, but is not limited to, a transmitter, a receiver, logic means or processor, a computer readable medium for data storage, a timing circuit, an antenna and a power source. Also coupled to the PCB **102** are input/output devices such as a display, LED **103**, a speaker or a button. In addition, the PCB **102** also includes circuitry for controlling the operation of the releasable lock means **100**. A compartment **104** houses a power supply unit **106** comprising one or more batteries, and a power circuit resident on the PCB **102** for regulating the power therein and input/output devices. The batteries **106** may be removed after the single use of the second syringe **15**, in order to enable use in another device or allow for proper recycling in compliance with current environmental regulations. In order to facilitate easy battery installation or removal, the batteries **106** may be placed on a tray which is slidably received by the battery compartment **104**.

[0084] The syringe **10** is typically maintained in a low power state, when not in use, to conserve battery energy. However, when the sample management unit **12** is introduced into the blood treatment unit, the syringe **15** is placed into an operating state from the lower power state. Such a transition may be effected via a mechanical switch which is closed before insertion of the sample management unit into the blood treatment unit, or the switch is closed by the blood treatment unit following insertion of the sample management unit into the blood treatment unit. Other ways include an electronic switch actuable by an RF signal or a DC signal from the blood treatment unit, or a DC magnetic reed relay enabled by a magnet in the blood treatment unit.

[0085] As shown in **FIGS. 4 and 7** to **9**, the chamber outlet **81** has a female collar portion **108** with a pair of helically oriented passages or grooves **110** extending through or in its wall to engage a corresponding one or more pins **112** extending outwardly from the second syringe inlet port **85**. Similarly, a valve element **114** is located in the channel **96** and biased to a closed position against a valve seat **116** on an end cap **118** forming the outer end of the second syringe outlet **96**. The valve element **114** is also aligned for abutment with a valve actuating element **120** which is positioned in the chamber outlet **81**. The valve actuating element **120** is thus operable to displace the valve element **114** from its closed position against the valve seat

116 to open the second fluid coupling. The cover portion 54 is also provided with a saddle member 122 for supporting the second syringe 15 when it is in a fully engaged position with chamber outlet 81.

[0086] The cover portion 54 has a top cap 124 and a cap lock 126 bonded, welded or otherwise fixed thereto. The cap lock 126 latches on an upper periphery of the bottom portion 56. The chamber inlet 50 and the chamber outlet 81 are each in fluid communication with the inner treatment cavity 52 by way of conduits 128, 130 extending below the valve actuating elements 80, 120 respectively.

[0087] As shown in **FIGS. 6, 10, 11** and **12**, the second syringe body portion 84 has a cylindrical cavity which in cooperation with the plunger 90 provides a second sample receiving chamber 89. The passage 94 of the blood sample transfer portion 92 has a second access location 132 for fluid communication with the second syringe outlet port 86. The second syringe outlet port 86 and the blood transfer portion 92 are further provided with the releasable lock means shown generally at 100 for forming a locked third fluid coupling between the second access location 132 and the second syringe outlet port 86. As will be described, the releasable lock means 100 is operable in response to a release signal to release the third fluid coupling, as shown in FIGS. 13(*a*) to 13(*d*). With the releasable lock means unlocked, the second syringe outlet port 86 is operable to form a fourth fluid coupling with a fluid fitting on a common blood sample delivery unit with a complementary LUER 31 or similar fitting, such as the needle 32.

[0088] As best shown in **FIG. 10**, the second syringe outlet port 86 includes a male Luer insert 134, an outlet valve means generally shown at 136 for opening and closing the access to the fluid channel 92 to control the flow of the blood sample therethrough. The male Luer insert 134 includes an opening 138 and a thread for the LUER fitting for coupling with female Luer 31 of a needle 32. The outlet valve means 136 includes a valve element portion 140 and a valve seat portion 142 and first actuating means generally shown at 144 for actuating the valve element portion 140 relative to the valve seat portion 142. A pair of resilient members 148, such as a spring, biases the outlet valve means 136 in a closed position. As will be described, the first actuating means 144 is operable to displace the valve element portion 140 in different directions when the second syringe body portion 84 is either engaged or disengaged with a female Luer 31.

[0089] The first actuating means 144 takes the form of a plurality of first actuating elements 150 which extend outwardly from a central web 152, and also second actuating means such as a tab 154 extending therefrom. The central web 152 is fixed to a block 156 positioned in a channel 94 in the body portion 92 of the second syringe 15. The block 156 has a central bore 158 carrying a tubular valve stem 160 having one end carrying the valve element portion 140 and an opposite end carrying a valve stem head 162, which has a peripheral edge region with a sealing element such as an O-ring or the like. The valve stem 160 has a pair of fluid transfer holes as shown at 164 immediately beside the valve element portion 140, thereby forming an inner valve passage which is in fluid communication with the second sample receiving chamber 89, as shown in **FIGS. 11 and 12**. The female Luer 31 includes complementary first actuating elements which displace the first actuating elements 150, when the female Luer 31 member is introduced into the male Luer insert 134. Consequently, the valve stem 160 and the valve element portion 140 are caused to open the central bore 158 within the valve stem 160 to the channel 96 to allow fluid flow through the outlet port 86.

[0090] The outlet port 86 of the second syringe 15 is operable between three states, a locked state, an open state and permanently locked state, by a releasable lock means, such as locking mechanism 100, as shown in FIGS. 13(*a*) to 13(*d*). The locking mechanism 100 includes a pawl 168 coupled to the outlet valve means 136 to control the coupling of the female Luer 31 to the male Luer insert 134 of the second syringe 15. The pawl 168 has one end 170 with an opening 172 for receiving a pivoting pin 174, protruding from a board 176, to allow pivoting thereabout. The pawl 168 is positioned between a first spring plate 178 and a second spring plate 180 which control its swinging motion. Typically, the first spring plate 178 is made from fuse material which temporarily changes consistency under the presence of the predetermined electric current signal, such as nickel titanium naval ordinance laboratory intermetallic material (NITINOL). Nitinol exhibits superelasticity and shape memory, such that nitinol is caused to heat up due to the predetermined electric current signal, as such it is mechanically deformed under stress above a specific temperature, and returns to the pre-stressed position when the stress is removed.

[0091] On the other end 182 of the pawl 168 is a first finger 184 and a second finger 186 defining a recess 188 with an opening 189. Adjacent to the recess 188 is a punched out slot 190 which includes a plurality of interconnected slots 192, 194, 196. These interconnected slots 192, 194, 196 correspond to the above-mentioned locked state, the open state and the permanently locked state, respectively. The slots 192 and 196 are opposite each other and separated by a pawl tooth 198 on one side of slot 190 and linked to one another by slot 194 on the other side of slot 190. The slot 192 is L-shaped and includes one arm 200 and another arm 202 which links to slot 194.

[0092] The first spring plate 178 is secured to the board 176 at one end and includes an arcuate portion 204 positioned above the pawl 168. The arcuate portion 204 is bent at approximately 90 degrees at point 208, and adjacent to the point 208 is an abutment flange 210 which engages the arm 200 of slot 192, in the locked position, as shown in **FIG. 13**(*a*). The subsequent positioning of the abutment flange 210 determines the operating state of the syringe 15.

[0093] The motion of the pawl 168 through the three different positions will now be described. Starting in the rest position, the abutment flange 210 is positioned in the arm 200 of slot 192. Upon receipt of the release signal following the verification process, a predetermined electric signal is caused to flow through the first spring plate 178, and the electric signal is sufficient to cause the first spring plate 178 to relax. The first spring plate 178 is sufficiently relaxed such that the second spring plate 180 forces the abutment flange 210 out of the arm 200 into arm 202, and finally into slot 194 corresponding to the open position, as shown in **FIG. 13**(*b*). A female Luer 31 of a needle 32 can now be attached to the second syringe 15 and the treated blood is expressed from the second sample receiving chamber 89 via the open outlet valve into the patient 17, as shown in **FIG. 14**.

[0094] After a predetermined time, such as **20** minutes, the predetermined electric signal is once again caused to flow through the first spring plate **178**, and causes the first spring plate **178** to relax. The second spring plate **180** forces the abutment flange **210** out of the slot **194** into slot **196** corresponding to the permanently locked position, as shown in FIGS. **13**(*c*) and **13**(*d*). If the female Luer **31** is still attached when the release signal is issued, then the abutment flange **210** is prevented from sliding into the permanently locked position until the female Luer **31** is removed. By permanently locking the second syringe **15**, subsequent use of the second syringe **15** is precluded, thus substantially eliminating contamination risks.

[0095] The operation of the outlet valve means **136** in conjunction with the locking mechanism **100** will now be described with particular reference to **FIGS. 10-14**. In the locked position of the second syringe **15**, the tab **154** rests on the finger **184** and thus restricts the central web **152** from longitudinal displacement away from the opening **138**. Any attempt to couple a female Luer **31** fails, since the complementary first actuating elements cannot displace the first actuating elements **150** and therefore the female Luer **31** and male Luer insert **134** cannot mate. Correspondingly, the outlet valve means **136** is biased closed by the pair of resilient members **148** acting on the central web **152**, and thus the central bore **158** within the valve stem **160** is closed.

[0096] Upon energising the first spring plate **178**, the pawl **168** is caused to rotate in a clockwise direction and the abutment flange **210** is forced out of the arm **200** into arm **202**, and slides into slot **194** corresponding to the unlocked or open position. Concurrently, the finger **184** of the pawl **168** moves away from the tab **154** such that the tab **154** is now aligned with the recess **188**. The female Luer **31** is now be introduced into the male Luer insert **134**, and the complementary first actuating elements abut the first actuating elements **150**. The force applied to mate the female Luer **31** to the male Luer insert **134** displaces the first actuating elements **150** away from the opening **138**, the central web **152** moves in sympathy. The tab **154** enters the recess **188** via the opening **189** and travels the length of the recess **188**. The force applied to couple the Luers **31** and **134** is sufficient to compress the resilient members **148** and thus open the central bore **158** within the valve stem **160**.

[0097] As the treated blood often includes bubbles of gases used during treatment, the second syringe **15** includes a de-bubbling system or bubble removal mechanism to expel gas from syringe, before the treated blood sample is administered to the originating patient **17**. Alternatively, a separate vent cap is attached to the proximal end **84** to interface with the Luer **134**. The vent cap includes a hydrophobic gas permeable membrane to prevent blood from escaping. Generally, more air can be introduced into the second sample receiving chamber **89** to coalesce the existing bubbles, thus facilitating removal of otherwise small bubbles. Thus, the barrel **83** is transparent such that a user can inspect the treated blood sample to verify that gas bubbles have been removed.

[0098] After the treated blood has been administered to the patient **17**, the female Luer **31** is uncoupled from the male Luer insert **134**, as the needle **32** is removed. With the complementary first actuating elements removed from the male Luer insert **134**, the resilient members **148** expand to push the central web **152** towards the opening **138** and the tab **154** travels out of the recess **188** and faces the recess opening **189**. At the predetermined time, a predetermined electric signal is caused to flow through the first spring plate **178**, and the abutment flange **210** is forced out of the slot **194** into slot **196**. The tab **154** now abuts the finger **186**, and thus any longitudinal displacement of the central web **152** from away from the opening **138** is precluded. With the abutment flange **210** unable to be forced to return to slot **194**, the second syringe **15** is now permanently locked, and so a female Luer **31** can not be subsequently coupled to the male Luer insert **134**, as shown in **FIG. 13**(*d*).

[0099] As will be described, the system **10** provides a verification protocol which involves number of verification checks to be sure that the proper treated blood sample is delivered to the proper originating patient **17**, and that certain events in the collection, treatment and delivery of the blood sample to the patient **17** occurs within prescribed time periods. To that end, and as shown in **FIG. 15**, the system has identification means **211** for identifying an originating patient **17**, and the untreated blood sample in the first syringe **11**, verification means **212** for verifying a match between the originating patient **17** and the treated blood sample in second syringe **15**, and release signal generating means **214** for generating a release signal in response to a positive outcome by the verification means. The release signal is transmitted to the releasable lock means **100** to deliver the predetermined current to the first spring plate **178**, thereby to render the second syringe **15** operable to deliver the treated blood sample to the originating patient **17**.

[0100] As will be described, the identification means **211** and the release signal generating means **214** are located on the second syringe **15**, but may be located in the aforementioned entities. The releasable lock means **100** has a signal receiving means **216** for receiving the release signal.

[0101] As shown in **FIG. 16**, the verification means **212** includes comparison means **218** for comparing patient identity data with treated blood sample identity data, both stored in memory means **220**, and signal receiving means **216** to receive one or more signals associated with the originating patient identity data and/or the blood sample identity data (either untreated, treated or both). In this case, the one or more signals contain the originating patient identity data and/or the blood sample identity data. However, as an alternative, the one or more signals may contain data which is associated with or related to the patient **17** or blood sample identity data. For example, the data in the signals may include one or more codes which allow the patient identity data or the blood sample identify data to be obtained from a data structure in the memory means **220** or some other location, for example in the form of a look up table, for instance

[0102] The verification means **212** also includes a counter means **221** which provides temporal data related to a predetermined event including and/or between an untreated blood sample collection event and a treated blood sample delivery event. The temporal data may also include at least one elapsed time value between two predetermined events including or between the untreated blood sample collection event and the treated blood sample delivery event. The counter means **221** may be implemented as a first incremental counter **222** on first syringe **11** and a second incremental counter **224** on the second syringe **15** are used to track time delay. The first incremental counter **222** tracks the events related to the collection of untreated blood, while the treatment and post treatment events are tracked by the second incremental counter **224**. These two incremental counters **222** and **224** operate independently of one another and do not require to be synchronized with each other. The battery power is sufficient to maintain substantial accuracy of their internal clock within the time period from collection of the untreated blood sample to the delivery of the treated blood sample to the patient **17**. Therefore, the possibility of losing time or decreasing clock accuracy as the battery's power runs down is substantially eliminated.

[0103] In this case, the verification means **212** may be operable to prevent release of the locked third fluid coupling when the elapsed time value has exceeded a predetermined value. Before treatment of the untreated blood sample, the verification means **212** is also operable to prevent treatment of the blood sample when the elapsed time value has exceeded a predetermined value. Similarly, following treatment, the verification means **212** is operable to verify a match between the untreated blood sample in the first syringe **11** and the originating patient **17**.

[0104] The verification protocol may be implemented in a number of forms, although the most preferred at present is by the use of one or more radio frequency signal transmitters and receivers and RFID tags. As shown in **FIG. 17**, the wristband **16** is provided with a passive RFID tag, such as WB RFID tag **226**, while the first syringe **11** and the second syringe **15** include the aforementioned printed circuit board (PCB) **102** having circuitry for transmitting, receiving and storing data related to the syringe and/or its contents or the originating patient **17**, including a S1 RFID reader/writer **228** and a S2 RFID reader/writer **230**, respectively. The passive WB RFID tag **226** comprises an antenna coil and a silicon chip that includes modulation circuitry and non-volatile memory. The passive WB RFID tag **226** is energized by an external time-varying electromagnetic radio frequency (RF) wave that is transmitted by a RFID reader/writer, such as the S1 RFID reader/writer **228** or the S2 RFID reader/writer **230**. Therefore, S1 RFID reader/writer **228** or the S2 RFID reader/writer **230** is capable of writing data onto the WB RFID tag **226**, and reading data back from WB RFID tag **226** by detecting the backscatter modulation.

[0105] The blood treatment unit **14** is also equipped with a BTU RFID reader/writer **232** to receive a pre-treatment identity data from the S1 RFID reader/writer **228** and to receive post treatment data from the S2 RFID reader/writer **230**. Similarly, the blood treatment chamber **12** is equipped with a passive SMU RFID tag **234** to provide an identification code. The BTU RFID reader/writer **232** issues query signals to the SMU RFID tag **234** to determine whether the blood treatment chamber **12** is valid for use in the treatment process, that is, whether the blood treatment chamber **12** is an authentic product or whether it has been previously used.

[0106] As shown in FIGS. **19** to **21**, the wristband **16** (WB) contains a removable portion **236** containing the WB RFID tag **226** and audit data written onto it relating to the patient **17** and/or the treated blood sample. The wristband **16** may also include a buckle assembly **238** having a base portion **240** and cover portion **241**. The base portion **240** is integrally formed with a band **242** of resilient material which a number of perforations forming passages **244** to receive the buckle assembly **238**. The base portion **240** has pins **246**, **247**, **248** that are dimensioned to fit through the passages **244**. The cover portion **242** is hinged to the base portion **240** by way of a hinge shown at **250**. The cover portion **242** also has a pair of cavities **252**, each for receiving one of the pins **246** or **248**. The pin **247** may press against a switch (not shown) in the base portion **240** to activate portions of the circuitry of the wristband **16**, upon securement of the band **242** around the patient's **17** arm.

[0107] The method of monitoring a material sample will now be described with reference to the FIGS. **1** to **21**. The verification protocol makes use of a number of identification codes, such as a first syringe identity code representative of the untreated blood sample therein, and the a wristband identity code representative of the originating patient **17**. To simplify the data transfer, the first syringe identity code and the wristband identity code may include common identity data, though the data between them may be different or related as the case may be. The first syringe identity code may, if desired, include a first time value representative of the time of untreated sample collection from the originating patient **17** (or a designated event either before or after the sample collection step) and/or verification thereof. Thus, the S1 RFID reader/writer **228** functions as a first signal emitter for emitting a first signal carrying the first syringe identification code data, and/or common identity data, while the WB RFID tag **226** on the wristband **16** functions as a first signal receiver to receive the first signal. The second syringe **15** is assigned a second syringe identity code, which is representative of the treated blood sample therein. The second syringe identity code includes a second time value representative of the time of the treated sample delivery thereto from the treatment cavity **52** (or a designated event either before or after the treated sample delivery step) and/or verification thereof.

[0108] Thus, the S2 RFID reader/writer **230** functions as a second signal emitter for emitting a second signal carrying the treated blood sample identity data and the WB RFID tag **226** functions as a second signal receiver means to receive the second signal, wherein the verification means **212** is operable to compare the first signal data with data representative of the treated blood sample.

[0109] Referring to **FIG. 18**, the verification protocol will now be discussed along with a typical blood treatment procedure. As shown in **FIG. 1**, a kit for a blood treatment procedure is assembled including, among other things, the wristband **16**, the first syringe **11**, the second syringe **15**, the sample management unit **12** and a number of prepared labels **258** with patient identification printed thereon. The procedure starts with the activation of the first syringe **11** via an actuating means such as the pullout tab button **38**. Once activated, the circuitry on PCB **34** is powered on by the batteries **48** and conducts a power-on-self-test (POST) procedure and subsequently the first syringe **11** is ready for use, barring any detected faults during the POST procedure. The S1 RFID reader/writer **228** is then activated and starts transmitting query signals and waits for an acknowledgement response from the passive WB RFID tag **226**. The first incremental counter **222** is also initiated and outputs temporal data, and keeps track of the untreated blood events and log time stamps associated with predefined untreated blood events, in association with the logic means. To that end, a timestamp TS0 indicative of the event of power-on is recorded by the second incremental counter **224** and stored in memory. The S1 RFID reader/writer **228** and the WB RFID tag **226** each contain common patient identity data or sample treatment data, coded as ID **1**.

[0110] Before the first syringe **11** is used to draw blood from the patient **17**, a blood anti-coagulant, such as sodium citrate solution, is also drawn into the first sample receiving chamber **21** to prevent clotting of the blood, as shown in **FIG. 3**. A sample of blood is then withdrawn from the patient **17**, and once primed, the first syringe **11** is brought to within RF range of the wristband **16**. The S1 RFID reader/writer **228** queries the WB RFID tag **226** to verify that the data read from or emitted by the WB RFID tag **226** corresponds to the common patient identity data ID**1** on S1 RFID reader/writer **228**. The process is terminated if there is no correlation between the data on the wristband **16** and the first syringe **11**. However, if a positive correlation has been made, the S1 RFID reader/writer **228** records a "time data stamp" TS**1** stamp on the S1 RFID reader/writer **228**, and writes the same time-stamp to the WB RFID tag **226**, Therefore the S1 RFID reader/writer **228** and the WB RFID tag **226** now carry TS**0**, TS**1** and ID**1**. As an example, the data now on the S1 RFID reader/writer **228** and the WB RFID tag **226**, the may be represented as: S**1** ID**1** TS**0** TS**1** meaning that the untreated blood sample drawn into the first syringe **11** is from a patient with the identification ID**1**, the first syringe **11** was powered on at time TS**0**, and the common patient identity data ID**1** on the first syringe **11** and the wristband **16** was matched at time TS**1**.

[0111] The first syringe **11** logic means receives temporal data from the first incremental counter **222** and determines the elapsed time from the start of the procedure (TS**0**) and the instant that the common patient identity data ID**1** on the first syringe **11** and the wristband **16** is matched. The process advances as long as the time unit difference between TS**0** and TS**1** is within an acceptable predefined range.

[0112] In the next step, the first syringe **11** is installed on the blood treatment chamber **12** (with the second syringe **15** already positioned thereon), which is then delivered to the blood treatment unit **14**. As such, the S1 RFID reader/writer **228** emits the data TS**0**, TS**1**, ID**1** to the BTU RFID reader/writer **232**. The data also include a time value TS**2** denoting a treatment start time. The blood treatment unit **14** then calculates the time delay between TS**1** and TS**2** of the first syringe **11**. In addition, the blood treatment unit **14** issues a query signal to the SMU RFID tag **234** on the sample management unit **12** and, in response thereto, the SMU RFID tag **234** issues a signal containing its identification code to the blood treatment unit **14**. A determination as to whether the SMU RFID tag **234** is valid, and also whether the delay is acceptable. If the SMU RFID tag **234** is invalid, and/or the delay is unacceptable then the process ends, otherwise the process continues. This identification code, in this case, includes an "enable" code indicating that the blood treatment chamber **12** has not been previously used for a blood treatment, thus reducing the risk of contamination the current untreated blood sample SI. Alternatively, the SMU RFID tag **234** need not issue an enable code, but rather merely emit a signal containing identity data such as a SKU or the like.

[0113] If the time delay between TS**1** and TS**2** is acceptable, the blood treatment unit **14** the procedure continues with the untreated blood sample in the first syringe **11** being delivered to the treatment cavity **52**, via the chamber inlet **50** and conduit **128**. The S1 RFID reader/writer **228** is subsequently disabled to prevent further use by including a disable code thereon. In addition, a SMU RFID tag **234** on the blood treatment chamber **12** receives a disable code from the BTU **14** after the blood sample is delivered to it, thereby preventing the reuse of the blood treatment chamber **12**. Alternatively, the SMU RFID tag **234** may be disabled in other ways without writing a disable code thereon. For example, the SMU RFID tag **234** may be rendered inoperable by issuing the SMU RFID tag **234** a signal causing a fuse to be blown therein.

[0114] In the course of the treatment, the second syringe **15** is powered on and starts querying the BTU RFID reader/writer **232** for data. A new time stamp signifying the end of the blood sample treatment "TS3" is written to the BTU RFID reader/writer **232**, and subsequently TS**3** is read by the S2 RFID reader/writer **230**, and stored thereon. The treated blood is then delivered from the treatment cavity **52** via the conduit **130** and to the second syringe **15**, and. If desired, the blood treatment unit **14** may also include the TS**1** stamp, meaning that the data written to the S2 RFID reader/writer **230** would include ID**1**, TS**0**, TS**1**, TS**2**, and TS**3**. In this case, the second syringe **15** includes the treatment start time TS**2** and the treatment end time TS**3**. Alternatively, or in addition, TS**2** or TS**3** may include a treatment duration time, or some other code indicating that all previous verification steps have been successfully carried out.

[0115] For example, the blood treatment unit **14** may record the following data:

[0116] S**1** ID**1** TS**0** TS**1**

[0117] PATIENT ID

[0118] TREATMENT START TS**2**

[0119] TREATMENT END TS**3**

[0120] S**1** ID**1** TS**0** TS**1** TS**3**

[0121] In this case, the PATIENT ID code may include other patient-related data that is manually or automatically entered into the blood treatment unit **14**. Alternatively, the patient-related data is transferred to the blood treatment unit **14** from a central data storage centre, a server computer, a memory bank or the like.

[0122] The second syringe **15** is then transported back to the originating patient **17** wearing the wristband **16** and the S2 RFID reader/writer **230** continually polls the WB RFID tag **226** until the latter is within range of the query signals. In response to the query signals, the WB RFID tag **226** then emits ID**1** data, at time "TS4". The S2 RFID reader/writer **230** then calculates the time delay between TS**3** data and the time of arrival, TS**4**, of the second syringe **15** back to the wristband **16**. If the expected time delay is exceeded, then the second syringe **15** remains locked by the locking mechanism **100**, otherwise the process continues.

[0123] The second syringe **15** records ID**1**, and the time stamp "TS4". In addition, the second syringe **15** may include the PATIENT ID data as well as the ID**1**, TS**1**, TS**2**, TS**3**. This data is subsequently written onto the WB RFID **226**. At this stage, the S2 RFID reader/writer **230** issues a release signal to the locking mechanism **100** to unlock the second syringe **15**, by issuing a predetermined current to the spring plate **178** to force the abutment flange into slot **194**, thereby rendering the second syringe **15** operable for injection.

[0124] As an example, the WB RFID tag **226** therefore records:

[0125] S1 ID1 TS0 TS1

[0126] S215 ID1 TS0 TS1 TS2

[0127] SAMPLE MATCH TS3

[0128] S2 UNLOCK TS4

[0129] The verification protocol is then completed when the TS4 is recorded in the WB RFID tag **226** after it performs a sample match between the ID1 data on the S2 RFID reader/writer **230** and the WB RFID tag **226**. As shown in **FIG. 21**, the removable portion **236** of the wristband **16** is then separated therefrom and matched with the originating patient's record and the patient record is returned to the blood treatment unit **14** for a data exchange between the WB RFID tag **226** and the blood treatment unit **14**, to complete the audit trail.

[0130] Alternatively, an RF reading audit record capture station may be provided which is local to the patient **17** or to a patient record area in a medical facility, thereby eliminating the need for the patient record to be returned to the blood treatment unit **14**. In this case, the audit record capture station may be capable of downloading the patient record to complete the audit trail. The RF reading audit record capture station may be part of the internal network of the medical facility, either through a wired or wireless data port, or may be part of a network localized to one or more blood treatment unit systems in the medical facility. It may collect data and allow for later batch recording to a computer readable medium, such as an optical disc, hard drive or other storage device. It may be attached to or integrally formed with a computing device, personal digital assistant, a mobile phone or the like. It may also be embodied as software configured to run on a computing device, together with an RFID reading attachment thereon.

[0131] The data ID1 and TS4 is delivered to blood treatment unit **14** or other system to complete the audit trail. The time stamp may also include an "event" code, which may comprise five major events:

[0132] 1) S1 start time

[0133] 2) WB acknowledges with S1

[0134] 3) Start of Treatment

[0135] 4) End of Treatment

[0136] 5) Match between the Treated Sample and the Originating Patient.

[0137] The time stamp may also include any one or more of a number of Error events

[0138] 1) No match

[0139] 2) S1 does not match with WB at before/after collection

[0140] 3) S2 does not match with WB on return after Treatment.

[0141] 4) Time Delay-exceed time to collect of blood

[0142] 5) Time Delay-exceed time to deliver sample to BTU

[0143] 6) Time Delay-exceeds time to return to patient.

[0144] The TS3 time stamp may also include a "match" code as follows:

[0145] 01 Match

[0146] 02 No match

[0147] In another embodiment, the wristband includes electronic circuitry coupled to the passive WB RFID tag **226**, and a battery for providing power to the electronic circuitry. As shown in **FIG. 20**, the wristband **16** includes outputs means, such as LEDs **260**, **262**, **264**, or a speaker (not shown), which are operated in different combinations of one or more thereof. For example, the LEDs **260**, **262** may be operable to illuminate in accordance to a predetermined cycle indicative of the communication associated with verification process with the first syringe **11** and the second syringe **15**. The third LED **264** may be provided for alarm situations.

[0148] In another embodiment, the wristband includes electronics circuitry coupled to the passive WB RFID tag **226**, and a battery for providing power to the electronic circuitry. As shown in **FIG. 20**, the wristband **16** includes outputs means, such as LEDs **260**, **262**, **264**, or a speaker (not shown), which are operated in different combinations of one or more thereof. For example, the LEDs **260**, **262** may be operable to illuminate in accordance to a predetermined cycle indicative of the communication associated with verification process with the first syringe **11** and the second syringe **15**. The third LED **264** may be provided for alarm situations.

[0149] The wristband **16** may be replaced by some other article to be worn, carried, attached or ingested by the patient **17**, such as a pinned or self adhesive label **258** and the like.

[0150] The second syringe **15** may also include a second sample receiving chamber **89** volume detector to determine whether the received treated blood from the treatment cavity **52** is within a predefined range suitable for injection into the patient **17** to provide the desired medical treatment.

[0151] In another embodiment, the system **10** includes a blood sample treatment chamber, similar to the sample blood treatment chamber **12** of **FIG. 4**, with an expandable treatment cavity **52** formed by a cover portion **54**, a bottom portion **56** and a flexible walled portion **58** therebetween.

[0152] In yet another embodiment, the system includes a locking mechanism **100** operable by a solenoid or motorized means configured to receive the release signal.

[0153] In another embodiment, the system includes a wristband **16** with electronic circuitry for transmitting, receiving and storing data related the originating patient **17**, such as identification data or an identifier, SKU, serial no., manufacturing date, expiry date, health facility data, health practitioner data, medication data, and so forth. The circuitry includes, but is not limited to, a transmitter, a receiver, logic means or processor, a computer readable memory for data storage, a timing circuit, an antenna and a power source. The circuitry also includes an RFID reader/writer for reading

RFID tags associated with other entities within the treatment system, such as the first syringe **11**, the second syringe **15**, or the sample management unit **12**. A wristband tag. This wristband **16** acts as the archive data storage for the entire treatment and therefore provides the audit trail once the treatment has been completed. The data may be stored in the computer readable medium, such as RAM, ROM, flash memory, and so forth. or the wristband may include an RFID tag to which the data is written.

[0154] The first syringe **11** and the second syringe **15** include a printed circuit board (PCB) having circuitry for transmitting, receiving and storing data related to the syringe and/or its contents or the originating patient **17**, such as identification data or identifiers, SKU, serial no., manufacturing date, expiry date, fluid data, health facility data, health practitioner data, medication data, and so forth. The circuitry is implemented as an active RFID tag having a transmitter, a receiver, logic means or processor, a computer readable medium for data storage, a timing circuit, an antenna and a power source such as a batteries. Also coupled to the PCB are input/output devices such as a display, LED, a speaker or a button. The second syringe **15** also includes circuitry for controlling the operation of a releasable lock means or electromechanical interlock to prevent re-injection of treated blood in the event that the wristband **16** identifier and second syringe identifiers do not match.

[0155] Similar to the preferred embodiment, the system includes a BTU reader/writer which can communicate (read and write) to RFID tags of the first syringe **11** and the second syringe **15** and to a tag on the sample management unit **12**. The first syringe **11** RFID tag stores and record data relating to the patient for example, the time blood was removed for treatment. It will also ensure that the syringe **11** cannot be re-used. The first syringe **11** RFID tag will also include an elapsed time counter and a matching identifier to that contained in the wristband written at the time of manufacture or packaging. The second syringe **15** RFID tag includes similar functions and includes logic and circuitry to drive an electromechanical interlock.

[0156] The flow of treatment events are similar to the one described above. Prior to removal of blood, a check is performed to verify that the unique treatment set ID numbers contained in the wristband **16** and in the first syringe **11** match, by having the syringe **11** active tag emit the data to the wristband **16** reader/writer. If there is a match, this event is recorded by the wristband and blood is withdrawn from the patient. At the same time the elapsed time counters in the syringe **11** tag and wristband **16** will start.

[0157] The first syringe **11** is then be fitted onto the sample management unit (SMU) **12**, which is already fitted with a single-use second syringe **15**. The SMU **12** with both syringes **11**,**15** is then taken to the blood treatment unit (BTU) **14** with a BTU reader/writer. The patient details are entered into the BTU reader at this stage. The blood treatment unit **12** reader/writer will read the first syringe **11** tag and write the details (including the unique ID) to the second syringe **11** tag. The BTU reader/writer will also write a message to the SMU tag to indicate it has been used. The BTU reader/writer will read the elapsed time from the first syringe **11** tag and calculate treatment time details. These are then written to the second syringe **11** tag along with patient ID.

[0158] Following the blood treatment, the BTU reader/writer writes the completed treatment time to the second syringe **15** tag. The SMU **12** is removed from BTU. S**2** syringe is removed from the SMU **12**, and the SMU **12** and S**1** syringe are discarded. The second syringe **15** is then presented to the wristband **12** on the patient and, provided the unique IDs match and elapsed time is within set parameters, the second syringe **15** locking mechanism is released and the second syringe **15** can be used to inject the treated blood into the patient. The wristband **12** reader/writer writes the patient data and procedure details to the wristband **12** tag or computer readable medium, for subsequent removal for storage with patient records. The wristband **12** reader/writer is then deactivated and its strap is cut to allow removal from the patient and disposal. A network RFID reader is used to read the encrypted data in the wristband tag memory unit or computer readable medium for transfer to the health facility database on a computer or network.

[0159] In another embodiment, the BTU reader/writer or an external reader/writer provides all the verification checks

[0160] Even though the description above is in large part focused on the use of system **10** in the treatment of autologous blood samples, it will be understood that the system **10**, its components and alternatives thereof, may be used for samples other than blood samples, such as bone marrow or, lymphatic fluids, semen, ova-fluid mixtures, other bodily fluids or other medical fluids which may or may not be "autologous", for example fluid mixtures perhaps containing a patient's desired solid sample such as from organs, body cells and cell tissue, skin cells and skin samples, spinal cords. The system **10** may also be used for medical testing where it is important to ensure that test results of a particular test can be delivered to the originating patient **17**.

[0161] While the system **10** makes use of syringes **11** and **15**, it will be understood that other devices may be used such as, alone or in combination, one or more syringes, IV bottles, powder and/or atomized fluids and/or gas inhalant dispensers, implant delivery dispensers, ventilators, syringe pumps, intubation tubes, gastrointestinal feeding tubes, or a plurality and/or a combination thereof. One of the treatment devices may also comprise a blood treatment device such as that disclosed in International Publication No. WO0119318A1 entitled "APPARATUS AND PROCESS FOR CONDITIONING MAMMALIAN BLOOD" (the entire contents of which are incorporated herein by reference). Alternatively, one treatment device may be equipped to perform a range of invasive and non-invasive treatments such as surgeries, treatments for diseases such as cancer, as well as exploratory or diagnostic investigations such as X-rays, CAT Scans, MRI's and the like.

[0162] Although the invention has been described with reference to certain specific embodiments, various modifications thereof will be apparent to those skilled in the art without departing from the spirit and scope of the invention as outlined in the claims appended hereto.

1. A system for the collection, treatment and delivery of a blood sample, the system comprising:

an article for association with a patient having a patient identifier;

a first syringe having:

a first syringe inlet for drawing an untreated blood sample from the patient,

a first fluid chamber for receiving the untreated blood,

a first syringe outlet for dispensing the untreated blood sample from the first chamber,

a first incremental counter for recording temporal data corresponding to untreated blood events related to the collection of blood,

the first syringe being associated with a first unique identifier correlatable to the patient identifier;

a vessel for processing the blood sample, the vessel having:

a blood sample processing chamber, the vessel having a chamber inlet; the first syringe outlet being operable to establish a dedicated first fluid coupling with the chamber inlet to dispense the untreated blood sample to the blood sample processing chamber; the vessel having a chamber outlet for dispensing a treated blood sample following treatment to a second syringe,

the second syringe having:

a second syringe inlet operable to form a dedicated second fluid coupling with the chamber outlet to receive the blood sample from the blood sample treatment chamber;

a second chamber for receiving the treated blood;

a second syringe outlet;

a passage in communication with the second chamber and the second syringe outlet;

a second incremental counter for recording temporal data corresponding to blood treatment events, treated blood events and delivery events; the second incremental counter being operable independently of the first incremental counter and being non-synchronized with the first incremental counter;

the second syringe being associated with a second unique identifier, the second unique identifier operatively associated with the first syringe and correlatable to the first unique identifier;

a releasable lock formed within the passage for operating the second syringe outlet between a plurality of states;

a processor having:

a comparator for comparing the patient identifier to the first unique identifier to determine the correlation between same; and comparing the second unique identifier to the patient identifier to determine the correlation between same, the comparator issuing an output signal;

logic for receiving the output signal and the temporal data to determine time delays between the events and for determining whether the time delays are within predefined ranges;

a release signal generator coupled to the logic for issuing a release signal to the releasable lock;

whereby the release signal is issued upon confirmation of the correlation between the patient identifier and the first unique identifier, and the correlation between the patient identifier and the second unique identifier, and provided that the time delays are within predetermined ranges.

2. The system of claim 1 wherein the first syringe further comprises:

an inlet valve assembly in communication with the first fluid chamber; and

an outlet valve assembly disposed intermediate the first fluid chamber and the inlet valve assembly;

the inlet valve assembly including:

an inlet valve member operable in an open position and a closed position;

a resilient member biasing the inlet valve member to its closed position;

the outlet valve assembly including:

an outlet valve member operable between a closed position and an open position; and

a sealing member; and

an anchoring member engaging the outlet valve assembly to maintain the outlet valve member in a closed position;

whereby with the outlet valve member in the closed position, the inlet valve member is placed into the open position upon compression of the resilient member to allow fluid flow into the chamber;

and the outlet valve member is operable by disengaging the anchoring member and defeating the sealing member when the fluid chamber is primed, while the inlet valve member is in a closed position;

thereby to allow discharge from the fluid chamber.

3. The system of claim 1 wherein the releasable lock being operable in response to a release signal to operate the syringe outlet valve between an open state and a closed state.

4. The system of claim 3 wherein the releasable lock includes:

a pivoted pawl member;

interconnected slots corresponding to the closed state, the open state and the permanently closed state;

a first resilient member having a flange restricted to travel within the interconnected slots, wherein the first resilient member is spring made from a fuse material which temporarily changes consistency under the presence of the release signal, the position of the flange within the interconnected slots dictating the state of the outlet valve.

5. The system of claim 4 wherein the fuse material is nickel titanium naval ordinance laboratory intermetallic material (NITINOL).

6. The system of claim 5 wherein the releasable lock includes a second resilient member to force the flange into a slot corresponding to a permanently closed state.

7. The system of claim 6 including the article, first syringe, the second syringe, the vessel, electronic circuitry for transmitting, receiving and storing data related to the collection, treatment and delivery of the autologous blood.

8. The system of claim 7 wherein the circuitry includes any of the following: a transmitter, a receiver, an antenna, processor, computer readable medium, a timing circuit for maintaining temporal data related to the collection, treatment and delivery of the autologous blood sample, a power source and input/output devices.

9. The system of claim 8 wherein the circuitry of the first syringe and the second syringe includes an active RFID tag deriving power from the power source.

10. The system of claim 9 wherein the article includes an RFID reader/writer in communication with the active RFID tags on the first syringe and the second syringe.

11. The system of claim 10 wherein the article includes the processor, the comparator, the logic and the release signal generator to issue a release signal to the releasable lock upon confirmation of the correlation between the patient identifier and the first unique identifier, and the correlation between the patient identifier and the second unique identifier, and provided that the time delays are within predetermined ranges.

12. The system of claim 8 wherein the circuitry of the article and the vessel include a passive RFID tag.

13. The system of claim 12 wherein the first syringe and the second syringe include an RFID reader/writer in communication with the passive RFID tags on the article and the vessel.

14. The system of claim 13 wherein the second syringe includes the processor, the comparator, the logic and the release signal generator to issue a release signal to the releasable lock upon confirmation of the correlation between the patient identifier and the first unique identifier, and the correlation between the patient identifier and the second unique identifier, and provided that the time delays are within predetermined ranges.

15. The system of claim 14 wherein the vessel further comprising:

a body having:

a top portion, a bottom portion, and a walled portion therebetween;

a cover portion sealing received by a body opening adjacent to the top portion to define the blood sample processing chamber;

the cover portion having a gas inlet port coupled for carrying at least one gas into the blood sample processing chamber to interface with the untreated sample, a gas outlet port coupled for carrying at least one gas from the blood sample processing chamber; a chamber inlet port for releasably coupling the first syringe to supply the untreated sample, and a chamber outlet for releasably coupling the second syringe being for receiving a treated sample; and

a temperature sensor for determining the temperature of the at least one fluid in the treatment cavity.

16. The system of claim 15 wherein the walled portion is rigid.

17. The system of claim 15 wherein the walled portion is flexible.

18. The system of claim 15 wherein at least one of said ports includes a Luer connector for coupling to a complementary Luer connector.

19. The cover of claim 15 wherein at least one of said ports includes a bayonet coupling part for coupling to a complementary bayonet coupling part.

20. The system of claim 11 wherein the vessel further comprising:

a body having:

a top portion, a bottom portion, and a walled portion therebetween;

a cover portion sealing received by a body opening adjacent to the top portion to define the blood sample processing chamber;

the cover portion having a gas inlet port coupled for carrying at least one gas into the blood sample processing chamber to interface with the untreated sample, a gas outlet port coupled for carrying at least one gas from the blood sample processing chamber; a chamber inlet port for releasably coupling the first syringe to supply the untreated sample, and a chamber outlet for releasably coupling the second syringe being for receiving a treated sample; and

a temperature sensor for determining the temperature of the at least one fluid in the treatment cavity.

21. The system of claim 20 wherein the walled portion is rigid.

22. The system of claim 20 wherein the walled portion is flexible.

23. The system of claim 20 wherein at least one of said ports includes a Luer connector for coupling to a complementary Luer connector.

24. The cover of claim 20 wherein at least one of said ports includes a bayonet coupling part for coupling to a complementary bayonet coupling part.

25. A method of monitoring a material sample from a patient, comprising the steps of:

(a) collecting the sample from the patient with a first collection device;

(b) associating the patient with a first signal carrying data representative of the sample;

(c) associating the first collection device with a second signal carrying data representative of the sample;

(d) delivering the sample to a sample treatment chamber;

(e) processing the sample to form a processed sample;

(f) collecting the sample in a second collection device;

(g) associating the second collection device with a third signal carrying data representative of the processed sample;

(h) comparing the data in the first and third signals to link the processed sample with the patient; and thereafter

(i) associating at least one of the steps (a) to (h) with temporal data;

(j) determining at least one time delay using said temporal data to determine whether said at least one of the steps (a) to (h) occurs within an acceptable time limit;

(k) delivering the processed sample to the patient upon a positive outcome from step (h) and step (j); and

(l) assembling an audit record having temporal data collected from step (i), the outcome from step (h) and step (j), and data associated with the sample.

* * * * *

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摘要(译)

一种用于收集，治疗和递送自体血液样品的系统，包括用于从患者抽取未处理的血液样品的第一注射器，血液样品处理室，其具有用于从第一注射器接收未处理的血液的腔室入口和用于接收来自第一注射器的腔室出口。经处理的血液通过与其连接的第二个注射器。第二注射器包括可释放的锁定装置，用于允许响应于释放信号将处理过的血液排出到患者体内。根据来自血液样本的收集，治疗和递送中的某些事件的时间数据以及患者和第二注射器与治疗的血液的身份数据的验证过程的积极结果发布释放信号。