(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
23 October 2008 (23.10.2008)

PCT

(10) International Publication Number
WO 2008/127694 A1

(51) International Patent Classification:
G06F 19/00 (2006.01) *G01N 21/35* (2006.01)

(21) International Application Number:
PCT/US2008/004785

(22) International Filing Date: 11 April 2008 (11.04.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
11/786,537 11 April 2007 (11.04.2007) US

(71) Applicant *(for all designated States except US)*: **CARDINAL HEALTH 303, INC.** [US/US]; 3750 Torrey View Court, San Diego, CA 92130 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **GREENWALD, Roger, J.** [US/US]; 13721 Via Tres Vista, San Diego, CA 92129 (US).

(74) Agents: **HANKINS, John, A.** et al.; McDermott, Will & Emery LLP, 4370 La Jolla Village Drive, Suite 700, San Diego, CA 92122 (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, 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, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: FLUID VERIFICATION SYSTEM AND METHOD FOR INFUSIONS

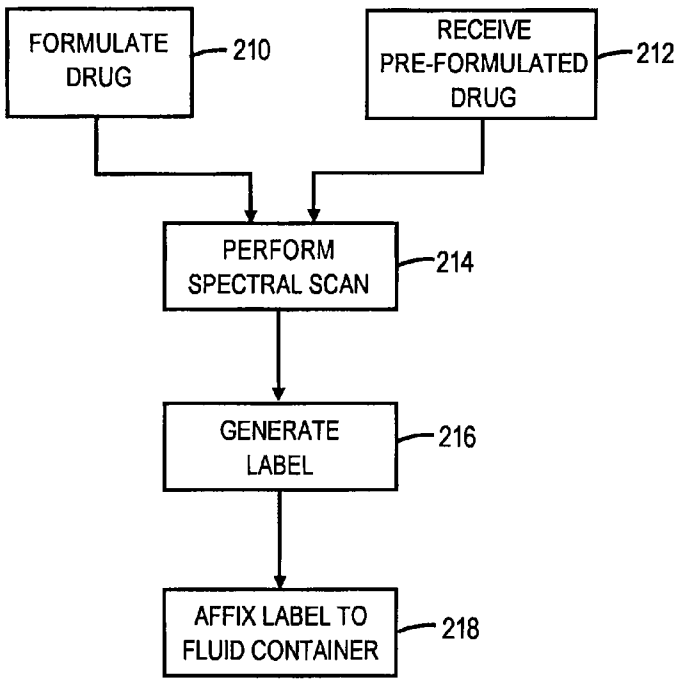

FIG. 7

(57) Abstract: An apparatus and method are provided to verify the composition of a medical fluid in a fluid container. The verification is performed at a centralized location, where light is transmitted through the fluid and detected by a sensor that generates signals representative of the spectral data of the actual composition of the fluid. These signals are compared with the spectral data of an expected composition of the fluid. Based on the comparison, a label is generated that identifies the composition of the fluid and is affixed to the fluid container. The fluid container, with the verified fluid, is distributed to the point of care.

WO 2008/127694 A1

Declaration under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

— *with international search report*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

FLUID VERIFICATION SYSTEM AND METHOD FOR INFUSIONS

Technical Field

The invention is related to the verification of the contents of a fluid, and more particularly, to the analysis of a medical fluid for verifying the existence of a pharmaceutical drug or drugs to be infused into a patient through a fluid infusion channel.

Physicians and other medical personnel apply intravenous ("IV") infusion therapy to treat various medical complications in patients. IV infusion therapy typically involves infusing medical fluids, such as pharmaceutical drugs, from a fluid source through the tubing of a fluid administration set, and to a cannula inserted in a patient's blood vessel.

In a typical facility, a physician enters an order for a medication for a particular patient. This order may be handled either as a simple written prescription slip, or it may be entered into an automated system, such as a physician order entry ("POE") system. The prescription is routed to the pharmacy, where the order is filled. Typically, the prescribed drug is prepared and inserted into a bag at the pharmacy. A pharmacist also identifies the contents of the bag and the patient for whom the bag is intended, with, for example a human-readable label and a bar coded label. The prepared medication is then delivered to a clinician's station for subsequent administration to the patient.

For safety reasons, and in order to achieve optimal results, the pharmaceutical drug is administered in accurate amounts as prescribed by the doctor, and in a controlled fashion such as by using an infusion pump. An infusion pump moves fluid from the medical fluid bag through a fluid infusion channel and into the patient. The infusion pump is programmed by a medical clinician according to the particular pumping or infusion parameters prescribed by the doctor. The pumping parameters programmed into the pump by the clinician are drug and patient specific. That is, the pumping parameters are selected by the doctor based on the particular drug prescribed and the specific patient for whom it is intended. It is the clinician's responsibility to match the prescribed drug with the correct patient and with the properly programmed pump.

Hospitals and other institutions continually strive to provide quality patient care. A medical error, such as when a patient receives the wrong drug, is a significant concern for all health care facilities. In some cases, a single patient may be prescribed simultaneous multiple

infusions, sometimes four or more, of different drugs. Typically, multiple infusions involve different infusion parameters for each drug. Further, such multiple infusions may involve multiple pump channels; e.g., one channel for each infusion; or a secondary to a primary infusion. Some pump systems include four or more pumping modules, each of which comprises an infusion pump operating on a separate fluid tubing to form a separate pumping channel. Regardless of whether a system has multiple channels or multiple systems each having only one channel, it is important that each channel be correctly programmed to infuse the right drug into the patient. Installing the tubing from a pharmaceutical bag into an incorrect pumping module could result in the wrong drug being pumped into the patient, regardless of correct drug labeling.

Prior attempts have been made to assure that the right drug is administered to the right patient through the right channel. In one example, a bar code label identifying the drug and patient is applied to the bag at the pharmacy. After a clinician manually programs the pump, a bar code scanner connected to the pump is used to read the bar code label on the bag to verify that it identifies the same medication as that programmed. In another example, a bar code label is applied to the bag and the label is read with a bar code scanner to automatically program the pump, thus avoiding manual programming entirely. While doctors are more assured that the doses and infusion rates that they prescribe can be delivered to the patients accurately by the pumps available today, such as via the MEDLEY™ patient care system operating the GUARDRAILS® safety system, there remains a concern that the right drug is mounted to the right pump.

Even though the pump systems of today provide significant advances in the art to avoid medication errors, there is a desire to more reliably determine that the correct drug is being infused. For example, the pharmacist may have made a mistake in mixing the component fluids for the bag, or the pharmacist may have applied the wrong bar code label to the bag. The bar code could also contain incorrect information or the clinician could scan the bar code label of the correct bag, but become distracted especially during emergency situations or MEDVAC (helicopter transport for example), and connect the tube from the bag to the wrong pumping channel.

Hence, those skilled in the art recognize that a need exists to more accurately ensure that the correct drug or combination of drugs is properly infused into the correct patient. More particularly, those in the art have recognized a need to more definitely ascertain that the

particular pharmaceutical drug a pump is infusing into the patient is the correct drug in the correct concentration.

The above stated needs and others are met by embodiments of the invention which provide an apparatus for labeling a fluid container, comprising a source of light located and configured so as to direct light through fluid and a light sensor located so as to receive the light that was directed through the fluid after the light has passed through the fluid. The light sensor provides light sensor signals representative of the spectral data of the actual composition of the fluid. A processor is provided that is adapted to compare the spectral data of the actual composition of the fluid with spectral data of an expected composition of the fluid. A label generator is responsive to the processor to generate a label identifying the fluid based on the comparison of the spectral data of the actual composition of the fluid with the spectral data of an expected composition.

The earlier stated needs and others are also met by other embodiments of the invention which provide a method of controlling delivery of a fluid, comprising the steps of directing light through the fluid and sensing the light that was directed through the fluid after the light has passed through the fluid. Light sensor signals representative of the spectral data of the actual composition of the fluid are generated. The spectral data of the actual composition of the fluid is compared with the spectral data of an expected composition of the fluid. A label is generated identifying the fluid based on the comparison of the spectral data of the actual composition of the fluid with the spectral data of the expected composition of the fluid.

The earlier stated needs and others are also met by still further embodiments of the invention which provide a method of verifying a drug prior to delivery of the drug at a point of care, comprising the steps of spectroscopically scanning a fluid, identifying a drug in the scanned fluid based on the scanning, generating a label indicating the drug based on the identifying of the drug, and affixing the label to a fluid container containing the scanned fluid.

Other features, aspects and advantages of the invention will become more apparent from the following detailed description and the accompanying drawings.

FIGURE 1 is a view of a system in accordance with aspects of the invention showing a medical instrument having four medical fluid infusion pumps connected to respective fluid sources and a single patient through respective fluid administration sets. A programming

module is connected to all pumps and is shown as having a connection to a remote processor through a communication link. Further, a portable device is shown to communicate with the medical instrument through a wireless link, although a different connection is possible;

FIG. 2 is an enlarged view of the medical devices of FIG. 1 showing displays and control keys of the fluid infusion pumps attached to the programming module;

FIG. 3 is a view of one of the fluid infusion pumps of FIGS. 1 and 2 with its door in the open position and the fluid infusion channel of its respective administration set in operative engagement with the infusion pump. Also shown at the upstream end of the pump is the optics and light housing for a verification system in accordance with aspects of the invention;

FIG. 4 is a block diagram of a medical fluid verification system and method in accordance with aspects of the invention;

FIG. 5 is a block diagram of aspects of a system and method in accordance with the invention where the comparison is made between spectral data of the contents of a fluid channel and stored spectral data of the expected fluid composition of a channel. Also illustrated are alarm implementations and stored data bases having relevance to aspects of the invention; and

FIG. 6 is an example in perspective block view of an implementation of a fluid channel through which a light beam may be transmitted to verify the contents of the channel, the channel also having a reference portion through which a reference beam of light is transmitted to develop spectral data concerning the composition of the wall of the channel so that accuracy in verifying the channel contents may be improved.

FIG. 7 is a flow chart illustrating certain steps of a method in accordance with certain embodiments of the present invention.

FIG. 8 is a schematic depiction of an apparatus constructed in accordance with embodiments of the present invention.

FIG. 9 is a depiction of a fluid container that can be scanned according to certain embodiments of the present invention.

FIG. 10 is a flow chart illustrating certain steps of the method in accordance with certain embodiments of the present invention.

Referring now to the drawings in which like reference numerals refer to like or corresponding elements among the several views, there is shown in FIG. 1, as an example, a

patient care system 20 having four infusion pump modules 22, 24, 26, and 28 each of which is in operative engagement with the tubing of a respective fluid administration set 30, 32, 34, and 36. Four medical fluid sources 38, 40, 42, and 44, which may take various forms but in this case are shown as bottles, are inverted and suspended above the patient care system 20. The patient care system 20 and the bottles 38, 40, 42, and 44 are mounted to a roller stand or IV pole 46. The administration sets 30, 32, 34, and 36 are connected between respective fluid sources and a patient 48 (shown only in block form) so that the patient may receive the fluids in the fluid sources at rates controlled by the respective infusion pump modules. The pumping system shown in FIG. 1 is provided only as an example of a system with which the drug verification system and method of the invention may be used. Other pumping systems and non-pumping systems, such as a gravity feed system, may be usable in accordance with the invention.

It should be noted that the drawing of FIG. 1 is not to scale and that distances have been compressed for the purpose of clarity. In an actual setting, the distance between bottles 38, 40, 42, and 44 and the infusion pump modules 22, 24, 26, and 28 could be much greater. There would be more of an opportunity for the tubings of the administration sets 30, 32, 34, and 36 to become intertwined with each other when all four are dangling from the bottles, which can cause confusion as to which tubing should be in which infusion module. The opportunity for confusion increases as the number of tubings increases.

Referring now to both FIGS. 1 and 2, a programming module ("PM") 50 is connected to the infusion pump modules 22, 24, 26, and 28. Other devices or modules may be attached to the PM. In one embodiment, the PM is used to provide an interface between the infusion pump modules and external devices as well as to provide most of the user interface for the infusion pump modules. The PM includes a display of 52 for visually communicating various information, such as the operating parameters of each of the pump modules as well as displaying alert and alarm messages. The PM may also include a speaker (not shown) to provide audible alarms. The PM also has various input devices in the embodiment including control keys 54. Further details on the PM and on a patient care system such as that shown in FIGS. 1 and 2 may be found in US Patent No. 5,713,856 to Eggers et al., incorporated herein by reference.

The PM 50 may also include a reader 55 receiving information relating to the infusions, such as drug identification, patient identification, nurse identification, and other

information. An identification device 57 is shown on a fluid container 38 which in this case is a bar code. Likewise, the reader 55 in this case is a bar code scanner. However, the identification device may take forms such as an RFID tag, a wireless device, or other, but contains an indication of the expected fluid composition. The indication may also include spectrum data consistent with the expected fluid composition, or merely a drig name. Similarly, the reader may comprise an RFID reader or wireless device compatible with the identification device 57. The PM also has a communications system with which it may communicate with a medical facility server 56 or other computers and with a portable digital assistant ("PDA") 58, such as a palm-based system, that a care giver may have so that information may be transferred between such device and the PM and infusion pump modules. Pump programming information may be uploaded into the PM or verified from the PM. The PM may also be used to store drug libraries for use in conjunction with infusion devices as well as vital signs monitoring devices, and for other uses. The communications system between the PM and other devices may take the form of an RF (radio frequency) system, an infrared system, a Blue Tooth system, or other wired or wireless systems. For illustrative purposes, the communications link between the patient care system 20 and the medical facility server 56 is shown as a solid line indicated by numeral 59. The bar code scanner and communications system may be included integrally with one or more infusion pumps 33, 24, 26, and 28 in cases where a PM 50 is not used.

The patient care system 20 may be interconnected with various medical facility information systems through different means. For example, the hospital may have a main information server 56 containing patient data and drug data. In another example, the medical facility may have various individual servers, such as a pharmacy server, a physician order entry server, a patient administration server, a nurse station server, and others. The patient care system 20 may be connected to one or more of these servers through various means. Hard wiring to local area networks may be in place, but RF, IR, Blue Tooth, and other wired and wireless connections may be used between the patient care system and other information systems of the facility. Information may also be exchanged with the patient care system through the use of the PDA 58. In one embodiment, the PDA may be linked to the main server 56 through wireless or other means and can become the information conduit between the patient and the main server.

A view of the closed front of an infusion pump module 28 is shown in FIG. 2. The pump module includes a front door 60 and a handle 62 that operate to lock the front door in a closed position and unlock and open the door for access to the internal pumping and sensing mechanisms. A display 64, such as an LED display, is located in plain view on the door in this embodiment and may be used to visually communicate various information relevant to the pump module, such as "alerting" and alarm messages. Control keys 66 exist for programming and controlling operations of the infusion pump as desired. The infusion pump module 28 also includes audio alarm equipment in the form of a speaker (not shown).

Turning now to FIG. 3, the infusion pump 22 of FIGS. 1 and 2 is shown in perspective view with the front door 60 open, showing the administration set 30 in operative engagement with the pump 22. A platen 68 is mounted between the door 60 and the pumping mechanism 70. In this case, the pumping mechanism is of the linear peristaltic type. Pressure sensors 72 are included in the pump 22 both upstream and downstream of the pumping mechanism. The pump also includes an air in line sensor 74 at its downstream end. The handle 62 includes a latch arm 76 positioned to engage a yoke 78 located on the housing 80 of the pump. Engagement of the yoke by the latch arm will permit the door to remain locked in the closed position. The handle 62 also includes a sear 82 having at least one hook 84 for use in controlling a flow stop system.

The fluid administration set 30 comprises a fluid infusion conduit extending from the fluid source 38 (FIG. 1) to the patient 48, that includes an upstream tube 86, a pumping segment 88, and a downstream tube 90. Another component of the administration set tubing 30 is an upstream fitment 92 that connects the upstream tube 86 and the pumping segment 88. Similarly, a flow stop 94 connects the pumping segment 88 and the downstream tube 90. The pumping segment 88 is mounted across the pumping mechanism 70 of the infusion pump 22 by the secure engagement of the upstream fitment 92 with an upper housing portion 96 and the engagement of the flow stop 94 with a lower flow stop bracket 98. The distance between the mounted upstream fitment and the flow stop bracket puts tension on the pumping segment 88 that, by design, tends to hold it in position over the pumping mechanism 70. When the administration set 30 is engaged with the pump 22, the pumping segment is positioned against the pumping mechanism 70 and held in place by the platen 68 which swings into operating position as the pump module door 60 is closed.

Referring now to FIG. 4, a block diagram of a drug verification system 100 in accordance with aspects of the invention is shown connected to a patient 48. A fluid source 38, which may take various forms, is connected to the patient 48 through a fluid administration set 30, which is referred to as a fluid delivery "channel" herein. The designation "channel" is particularly appropriate in reference to the pump system shown in FIG. 1 because there are four lines or "channels" of drugs being administered to the same patient simultaneously. In the embodiment of FIG. 4, the fluid delivery channel 30 connecting the fluid source 38 to the patient 48 is implemented by an infusion pump 22 that is used to precisely control the rate of infusion of the drugs of the fluid source into the patient. However, also shown is a secondary fluid supply 102 that is also connected to the fluid channel 30 through a Y-site device 104. It is also typical in the administration of medical fluid to a patient that a secondary infusion be conducted in which a first and second drug may be administered sequentially using the same infusion channel. Such an arrangement is shown in FIG. 4 in which the secondary fluid supply 102 is connected through a secondary fluid line 106 to the channel 30 through the Y-site device 104. As is well known, the secondary fluid source would be elevated above the primary fluid source so that only one fluid flows through the channel at once. A check valve or other device would normally be used to control the fluids in channel 30 although such details well known to those skilled in the art have not been included so that clarity of FIG. 4 may be preserved.

In accordance with the background discussed above, it is desirable to verify the actual composition of the fluid being infused into the patient. Such verification would be desirable regardless of the means used to effect infusion, whether it is an infusion pump, mere gravity, or other means. An example of the use of an infusion pump is provided in the specification and drawings herein; however, it should be recognized that other means may be used. Although, the embodiment described and shown herein positions the sensor of the fluid verification system upstream of the infusion pump, verification may occur at another location or locations. For example, a sensor of fluid verification system may be located downstream of the infusion pump. In the case of gravity feed system, the fluid verification system sensor may be located anywhere along the fluid infusion channel. In the case of a secondary infusion through the same channel, it would be desirable to locate the sensor of the fluid verification system downstream of the point where the secondary fluid is added to the fluid channel, such as is shown in FIG. 4.

The process of verifying pharmaceuticals in an infusion pumping system described above begins with an expected drug selection and drug concentration input to a processor 122 associate with the pumping system 22 by any of the methods described, i.e., key press entry, PDA, RFID, or any other means employed by the technology in the system. The drug selection triggers the processor to access the matching drug spectral data from a drug spectra data base 124. The processor waits for a response of the actual measured drug spectral data, determining if a match or mismatch exists between the expected drug spectral patterns of the drug library selection and the actual drug reading from a fluid infusion channel. Although shown as local to the pump 22 in FIG. 4, the processor and the data base of drug spectral data may be located other than proximate the pump. Further, the data base of drug spectral data may be located remotely from the processor. For example, in the case of the MEDLEY™ Point-Of-Care system, the processor may be located in the programming module 50, FIG. 1, or even elsewhere. The data base of drug spectral data may be located at the hospital server 56 area and the programming module 50 will communicate directly with it. In another case both the processor and the data base of drug spectral data may be located in a PDA 58. Other arrangements are possible.

Detection of fluid in channels "one" through "four" takes place with light energy transmitted through fluids and interacting with the molecules of the fluids. The transmitted light energy at any wavelength may variously be attenuated, frequency shifted, or otherwise influenced by those interactions. Optical analysis means, such as dispersive, Fourier Transform Infrared (FTIR), and Raman spectroscopy, may be used to detect the characteristics of the received optical beams. The spectrum and related data of the fluid so obtained is used to detect the drug or drugs of interest. The light source and other optical and electronic components are selected to produce the required spectral resolution characteristics for differentiating drugs in the infusion channel by comparison to a prerecorded drug library.

In one embodiment, an input beam of monochromatic or heterochromatic light caused to impinge upon the fluid delivery channel such that in traversing the delivery channel the beam passes through the medical fluid contained therein. After having passed through the medical fluid, the light energy, now called an output beam, is then optically analyzed as described above. The input and output beams may be conducted by optical fibers or other suitable optical means such that the light transmitted through the fluid is brought to the spectrometer and detection means contained therein. Both sides of the channel include beam

directing apparatus in this embodiment, although other arrangements are possible. This described optical detection system is indicated generally in FIG. 4 in dashed lines and is given numeral 108. The performance of such a detection system 108 may be improved by means known to those skilled in the art, such as stray light baffling, optical filtering, the use of confocal apertures, and heterodyne detection techniques.

With continuing reference to FIG. 4, a light source 110 is coupled to input beam-forming optics 112, such as a lens and optical fiber or fibers, to provide a suitable main input beam 114 of light. The main input beam is alternately directed by a chopper 115 to create two separate intermittent beams 111 and 113. One beam, i.e., the channel input beam, is directed at the fluid channel 30 so that the light of the channel input beam may interact with the medical fluid contents of the fluid channel. The other separate intermittent beam, i.e., the reference input beam 113, is directed by means of a mirror 117 through the channel material only, in this case, through its "fin" 119 which is shown in more detail in FIG. 6 and is described below. Proper direction of the main input beam may be accomplished by use of an optical fiber or fibers and a lens (not shown) forming part of the input beam-forming optics 112.

Once the channel input beam 111 has interacted with the contents of the fluid channel 30, a channel output beam 116 results. Likewise, once the reference input beam 113 has interacted with the material of the channel 30, a reference output beam 121 results. In this embodiment, the channel output beam 116 is redirected by the reflection of a second mirror 123. Both the channel output beam and the reference output beam are exposed to a chopper 125 that creates a main output beam 127. Output main beam-forming optics 118, such as lens (not shown) and an optical fiber or fibers, conduct the main output beam 127 to a spectrometer 120. The reference beam output data is subtracted from the fluid spectra data. The channel output of the spectrometer is compared by a processor 122 to a drug spectra data base 124 to verify the composition of the fluid channel. Control over the progress of the infusion may be exerted by the processor as a result of the verification process. In FIG. 4, it is shown that the processor 122 is connected to the infusion pump 22 that is controlling the infusion of the medical fluid 38 to the patient 48. The medical fluid may contain a drug or drugs to be infused to the patient. As an example, if the processor 122 were to determine that the drug detected in the fluid channel 30 is consistent with the drug expected to be there, the

processor initiates a signal to the pump 22 to cease the infusion and provide a signal, such as an alarm.

The light source 110 may comprise an infrared ("IR") energy source or a tungsten energy source or other narrowband or broadband light. Preferably, the light source generates non destructive light that will not alter the chemical composition of the medical fluid undergoing verification. In one embodiment, the light source is selected to generate light that encompasses a wavelength range that interacts with the contents of the fluid in the channel 30. In particular, the light source may be selected so as to produce light in a wavelength range or spectrum with which the possible contents of the fluid channel have distinctive light absorption or reflection properties. In one embodiment, the light source produces appropriate IR energy in wavelength bands suitable to provide distinctive spectral data absorption or transmittance properties in specific wavelength bands in the IR spectrum.

In another embodiment, the light source 110 produces light of a single wavelength that interacts with the contents of the medical fluid undergoing verification by Raman spectroscopy. In one embodiment, the light is a monochromatic beam of visible light suitable to provide distinctive Raman spectral data for the possible fluids within the channel 30. Upon interaction with the fluid contents of the channel, the monochromatic light undergoes excitation with a shift in electrons, known as the Raman Effect. The resulting shifts can then be analyzed to verify the chemical makeup of the fluid.

The output beam-forming optics 118 may also include a light dispersing device, such as a diffraction grating, that separates the output light into its spectrum of individual wavelengths for processing and verification. Alternatively, the light dispersing device may be an interferometer. The distributed light impinges on a sensor that may take the form of a photo detector array such as a CCD matrix or other light sensitive device that generates spectral data signals representative of the wavelength strength of the light impinging on its individual cells. In the case of FIG. 4, the sensor is termed a spectrometer.

The spectrometer 120 communicates with the processor 122 sending the spectral data signals of the actual fluid contents of the channel 30 to the processor for verification. The processor has many functions one of which is to verify that the actual fluid contents of the channel 30, based on the received spectral data signals are the expected fluid contents of the fluid channel 30. The processor may convert analog spectral data signals to digital data for verification. To perform the verification function, the processor matches, or attempts to

match, the spectral data produced by the spectrometer with the drug spectral data retrieved from a drug spectra data base 124. In one embodiment, the clinician has entered the identification of the expected drug contents into the patient case system 20 via an input device, such as the control keys 54 (FIG. 2) or a bar code scanner that reads a bar code label applied to the fluid source 38 by the pharmacist, or by means of a PDA 58 (FIG. 1) or through other means, such as the RFID tag described above, or other device or devices. This may be done at the time the nurse loads the administration set 30 attached to the fluid source 38 into pump 22.

The above identification means are examples only. Other means may be used to identify the expected composition of the fluid source, such as the nurse selecting a drug or drug combination from a scrolling list on the front panel of the PM 50 (FIG. 2). In this embodiment, the PM may first access a drug library 126 through a processor 122 and then display in the scrolling list only those drugs that are present in the drug library. This drug selection made by the nurse or by other means then indicates to the processor what drug is expected to exist in the fluid contents of the channel. In another embodiment, identical drug libraries may exist in the infusion pump 22 and the processor 122. In yet another embodiment, a drug library may exist in the pump and is used by the processor 122. Additionally, the drug library 126 may also be configured to be periodically updated though the communications system 59 using an external device such as a computer 56 running appropriate software or through the PDA 58 (FIG. 1) or by other means. Other means may be used to indicate to the processor 122 what drug or drugs are expected in the fluid contents. For example, a main server may communicate directly with the PM 50 or the processor 122 to indicate the identification of the drug or drugs expected to be in the fluid channel. The above examples are not meant to be exclusive of others and in fact, other arrangements may be used.

As a more general discussion, clinician-generated input prior to the commencement of infusion triggers the initial drug data comparison and verification activities. In one embodiment, detection may continue on a periodic basis for the remainder of the infusion.

The output from the optical detection system 108 comprises data signals that are transmitted to the processor 122 for analysis. The processor's main functions are to gather and interpret:

1. user-entered drug selection spectral data patterns identified from memory's drug library 126, selections matched to unique spectral data from the drug spectra data base 124;

2. diluent ratio in producing expected spectral data;

3. drug spectra as detected by the optical detection system 108 and translate it to a form usable with step 1 above; and

4. spectra data of the material comprising the fluid channel 30 (discussed below)

Further, the processor:

5. wall material spectral data as unique from channel spectral data to isolate the spectral characteristics cause by the drugs alone (discussed below); and

6. attempts to match no. 5 with no. 1 above; i.e., drug spectra as identified by user entry with the drug spectra determined by real-time measurement.

To re-state the above, the processor 122 compares the data obtained by the spectroscopy of a fluid contained in the infusion channel 30 with the stored data 124 for the drug it expects to see in the channel. In this embodiment, the processor may first access the drug spectra data base 124, as directed by customer protocol. When the processor 122 is informed that a drug combination should exist in the channel, an algorithm would be used to determine the appropriate spectrum. The drug spectra data base 124 may contain algorithms to permit the combination of stored spectra for a set of drugs, compounds, and combinations of drugs that represent all possible compositions within the fluid channel. The drug spectra data base would include, for example, the spectra associated with pure or compound drugs, such as sodium chloride or dopamine, and might synthesize the spectra of combinations of these fluids. The expected composition of the fluid channel 30 is identified to the data processor by the user interaction, for example during pump programming. The processor compares expected composition with the sensed drug obtained real-time from the channel's lumen contents. The processor compares the expected and measured spectra and determines the degree of correlation between them. Comparisons may be made on a peak-by-peak basis, by autocorrelation, or by other means known to those skilled in the art. The processor 122 outputs the verification results by providing a signal, indicating that either a match or no match occurred between the expected and real time sensed signals.

In another embodiment, rather than having algorithms to synthesize spectra of combinations of drugs, the data base 124 may simply contain spectra of all possible pure

drugs and combinations of drugs, Since in one case the identification of the drug or drugs in the fluid channel involves a selection from a predetermined list, the choices facing the nurse or medical facility are limited. Therefore, spectra of all of these limited choices may be installed in the data base 124.

In another aspect, the drug spectra data base 124 may also contain light spectrum patterns of additional agents added to a primary infusion. Such situations could occur where a primary infusion of dextrose is occurring and the nurse adds an additional medicine through an injection port of the channel downstream of the primary, but upstream of the pump, such as shown in FIG. 4. The drug spectra data base may contain spectra for each of the possible secondary drugs and for combinations of secondary drugs with primary drugs. The data base 124 would this include spectra that represents all possible compositions of the channel 30 with or without any possible secondary drugs.

An overview of a procedure using the system described in one embodiment comprises:

1. The clinician identifies the expected composition of the fluid source to be infused;

2. The drug source 38 is mounted, the drug channel 30 primed, and the drug channel is properly mounted in the pump 22 in the usual manner;

3. The pump is programmed for the infusion, including the identification of the drug anticipated to be in the fluid container;

4. The pump is activated;

5. Upon activation, but prior to beginning the infusion, the input light beam 114 is transmitted through the fluid delivery channel, and the detection means 108 described in this application are employed;

6. The spectra obtained from the fluid composition in the infusion channel are compared to the stored spectra 124 of the fluid expected to be in the infusion channel;

7. If the analysis confirms that the spectra are sufficiently similar to conclude that the fluid in the infusion channel is in-fact the drug anticipated, the infusion is started. An appropriate message may appear on display to inform the user of the match; and

8. If the comparison indicates the fluid in the infusion channel does not sufficiently match the expected drug, an alarm or warning display and signal may be activated. User intervention is required to begin the infusion in this case.

The infusion pump module 22 shown in FIG. 1 may be used as the infusion pump of FIG. 4, while the PM 50 of FIG. 2 may comprise the processor 122. The drug spectra data base 124 and drug library 126 may be located in the PM 50 as well or in other embodiments, may be located in the infusion pump or even more remotely from the infusion pump and the PM such as in a nurse station or elsewhere. The communications link 59 may be used in conjunction with a drug delivery control system in the PM 50 to allow the clinical institution through a server 56, or other means, to set a drug library into memory 126 of the PM that, as an example, includes drug concentration, dose limits, and systems configuration parameters for drugs, patient weights, and hospital wards. Further details on such a drug library system can be found in US patent No. 5,681,285 to Ford, incorporated herein by reference. Other means may be used to set a drug into memory, such as a wireless connection with a communications device, such as a PDA 58 for example (FIG. 1), or the drug library may be loadable through different type processor, such as a portable computer as shown in U.S. Patent No. 6,269,340 to Ford, incorporated herein by reference. Although two memories 124 and 126 are shown (FIG. 4), they may actually reside in the same physical memory.

The drug library 126 may include limits set by the clinician institution for each drug of the library. Such limits may take the form of maximum and minimum dosages for each drug which may be made dependent on patient factors or other factors associated with delivery of the drug. For example, the dosage limits may vary depending on the weight of the patient or body surface area ("BSA"), depending on the unit or ward of the medical institution in which the drug is being used (for example neonatal care unit (NCU), the intensive care unit (ICU), etc.), and depending on other factors. An alarm may be provided if the nurse sets the pump to operate outside the range between the limits for a particular drug. In some cases, the alarm may be overridden and in other cases it may not. The medical facility may establish "soft" limits for each drug, which may be overridden by the nurse, and "hard" limits which may not. In either case where a limit is exceeded, a pump 22 data log or data log in the PM 50 or other processor in communication with the infusion pump may record each such limit event for later analysis where the attempted setting is higher than the maximum or lower than the minimum dosage.

The analysis of the spectral data is shown in further detail in the block diagram of FIG. 5. The expected composition of the fluid source is identified to the processor 122 through an input device, such as the keys 54 of the PM or from a remote location through a

communications link 59 and as otherwise described above. Data of the expected composition is accessed from the drug spectra data base 124 of the memory 130. The processor 122 then compares the data base drug spectrum to the drug spectrum received from the spectrometer 120 representing the fluid composition of a channel under analysis. Comparison techniques that may be used in matching the data have been described above and algorithms used for comparison and matching are stored in the algorithm portion 132 of the memory 130, or elsewhere. In the event that the comparison by the processor indicates that the spectrum of the actual fluid composition of the channel does not match the spectrum of the expected fluid composition of the channel, the processor may provide an audio alarm signal by means of the speaker 134, and/or a visual alarm by means of the screen 52 and the PM or other screen, and/or remote alarms through a communication link such as 59 or other link. The memory may store all alarm and alarm-related data 136 including any overrides 138 of alarms occurring with this medical instrument. Such stored alarm and override data may be processed by the processor 122 or downloaded to another system for analysis and reporting to medical care personnel. Uses of such data include determining if the drug limits in the library are suitable or if medical practices at the medical facility need adjustment. Other uses of the data can be made. Results of verification may also be stored in memory 128.

Disclosure is now provided of an example of a mechanical implementation of a channel for use with an optical detection system 108, the channel usable with the fluid verification system and method described above. Referring now to FIG. 6, an upstream fitment 158, similar to that fitment 92 shown in FIG. 3, interconnects an upstream tube 86 and a pumping segment 88 that form parts of a fluid channel 30. The fitment 158 is shown having two fins 119, one of which is used with the reference input beam 113. The channel input beam 111 is shown as being positioned such that it extends through the approximate center of the fitment 158. After both input beams of light 111 and 113 have penetrated the fitment and exited on the far side, in this embodiment, a channel output beam 116 and a reference output beam 121 result.

As shown in FIG. 3, the fitment 92 may be used to secure the fluid channel 30 in the proper location in regard to the pump so that successful fluid verification, air-in-line sensing 74, pressure sensing 72, and mechanical pumping 70 may occur. In the embodiment of FIG. 6, the fitment 158 would replace the fitment 92 in FIG. 3. FIG. 3 also shows a housing 160 within which may be mounted various components of the fluid verification system 100. In

particular, although not shown in FIG. 3, components of the optical detection system 108 may be located in the fluid verification housing 160. For example, the beam forming optics 112, the first chopper 115, first mirror 117, second mirror 123, second chopper 125 and the output beam forming optics 118 may be located in the housing 160. Additional, or fewer, of these components may be located in the housing depending on their implementation.

In another embodiment, the fluid verification system 100 could be configured to automatically compensate for the absorption and Raman spectrum of the material of the fitting 158 without an input reference beam 113 because the light absorption and Raman properties of the typical plastic materials used for fluid infusion conduits are generally well known. In this embodiment, the fluid verification system may store the data on the conduit spectrum and automatically subtract the conduit spectrum from the fluid composition spectrum during fluid analysis.

In the case where a care giver must infuse a drug that is not in the drug library 126, the verification system 100 may be placed in override and no spectral comparisons will be made, although the pump may still be operated.

In yet another embodiment where further processing capability is available, the verification system 100 may first perform the above-disclosed matching function between expected fluid composition and actual detected fluid composition. If a match does not exist, the system will indicate this fact to the care giver through the means discussed above. The care giver may then have the option of requesting the system to attempt to match the spectrum of the actual detected fluid composition to a spectrum or spectra in the drug spectra data base 124 to identify the fluid composition. If identification is successful, the identity of the drug may be indicated on display 52, communicated verbally 134, or otherwise communicated to the care giver, or to others. In another aspect, the system may also be configured to permit the care giver to directly request the system 100 to compare the spectra of selected drugs from the drug library 126 against the spectrum of the actual detected fluid conduit composition. Through this latter means, if identification is successful, the care giver may then be able to determine that the fluid administration set from one drug was mistakenly installed in the infusion pump under verification and can then more quickly move the administration set to the correct pump.

In another embodiment where a system such as that shown in FIGS. 1 and 2 is used in which a PM 50 controls multiple infusion pump modules 22, 24, 26, and 28, and an

identification of the actual drug in the administration set is successful, the PM may simply reprogram that infusion module for the correct drug either automatically or at the option of the care giver. With a system such as this, the necessary pumping program may be entered into the PM when the bag of medicament is first received, and the PM will properly program the specific infusion pump module with that program once the module detects the presence of the administration set with that particular medicament in it. Other variations on this procedure are possible.

In the case of a secondary infusion followed or preceded by a primary infusion as shown in FIG. 1, it would be desirable to check the composition of the fluid channel downstream of the Y-site 104 multiple times to verify both the contents of the primary fluid and the secondary fluid being infused to the patient. In such cases the infusion channel may contain only one or the other drug at a particular time. Thus, in addition to verifying the contents of the infusion channel prior to the start of the infusion, it would be a desirable feature to have the detection means periodically monitor the contents of the fluid channel 30 on an ongoing basis. Such continuous monitoring would also permit the system to determine when the secondary infusion is complete because the spectrum of the fluid contents of the fluid channel will change. Automating the drug verification system 100 would permit the process 122 of the system to switch the pumping parameters of the infusion pump 22 to those required for the primary infusion or the secondary infusion at precisely the correct time.

In addition to the embodiments described above, certain embodiments of the invention provide drug identification and verification at a central site that may be remote from the point of care, where the drugs are delivered to a patient. Such an embodiment provides an additional layer of protection against incorrect delivery of drugs to a patient. There is a potential that pre-formulated drugs that are purchased by a distributor, such as a pharmacy, are incorrectly marked, including the type of drug or other parameter, such as concentration. Also, there exists the possibility that a drug formulation at the distributor (e.g., pharmacy) is incorrectly formulated, and not as intended. For example, a mistake may have been made in the formulation that produced a concentration of the drug that is different than intended. Or incorrect starting materials for the drug formulation may have been mistakenly used.

The verification system in the embodiments described with respect to Figures 7-10 produce a level of verification of correct drug that eliminates or mitigates the need for

individual spectroscopic analysis of fluid at individual points of care. Hence, the centralized verification system of the embodiments of Figures 7-10 may represent a more economical solution to a caregiver, such as a hospital, since the spectroscopic analysis is centralized and not repeated throughout the facility. At the same time, provision is made at the point of care for verifying that the fluid in the fluid container is that fluid intended to be delivered to the patient at the point of care. This helps to prevent a fluid that was correctly labeled at the distributor from being delivered (e.g., infused) to a patient that is not supposed to be receiving that fluid.

Figure 8 schematically depicts an apparatus for labeling a fluid container, constructed in accordance with disclosed embodiments. The apparatus includes a spectroscopic analysis system 180 and a label generator 182. The spectroscopic analysis system 180 may be of generally the same construction as that described above with respect to Figure 1-6, or may be of another design. However, rather than performing the analysis as fluid is pumped through a tube between a fluid source and infusion pump at the point of care, the spectroscopic scanning and analysis is performed at a central location, and can be done in-situ through a fluid container. Alternatively, small samples of fluid can be removed from their containers for scanning.

The apparatus of Figure 8 may be in a centralized location or locations, such as a pharmacy, for example, though not limited to such example. In operation, the centralized location, which will be termed a "distributor" for descriptive purposes, verifies both purchased fluids and formulated fluids.

As in the earlier-described embodiments, the embodiment of Figure 8 may be configured to have increased sensitivity in fluid identification. The enhanced sensitivity can be achieved by subtracting the spectral signature of the fluid container in the manner described with respect to the embodiment of Figures 1-6. An exemplary fluid container 184 is depicted in Figure 9. For purposes of scanning, the fluid container 184 must have a wall 190 that allows at least some light transmission. The spectral characteristics of the fluid container 184 may be optically or electronically removed from the spectral analysis of the fluid 186 contained in the fluid container 184 in the manner discussed earlier. The spectral characteristics of the fluid container 184 may be stored from previously scanned empty fluid containers. Or, a non-fluid containing section 188 of the fluid container 184 may be scanned

to obtain the spectral characteristics of the fluid container 184. This allows for contemporaneous scanning of the fluid and the fluid container.

The distributor may receive drug/fluid spectra compiled by the manufacturer of the product for use in the verification of the fluids purchased from the manufacturer, or from a library compiled by the manufacturer of the spectroscopic analysis system 180. Besides verifying purchased fluids, the spectroscopic analysis system 180 can be used in the formulation of fluids. When a distributor, or other user, formulates new mixtures, the spectra can be added to the drug library by scanning initial batches of these mixtures using the spectroscopic analysis system 180 itself. Thus, the new mixtures of the formulations are compared to initial mixtures of the formulations. In this way, subsequent mixtures can be checked against a created standard.

After the spectroscopic analysis, and based on this analysis, a label is generated by a label generator 182 coupled to the spectroscopic analysis system 180. The label can be a machine-readable label, and include a bar code or RFID, or other indicia that can be read by a machine. The label can include information identifying the fluid, based on the comparison of the spectral data of the actual composition of the fluid with the spectral data of the expected composition of the fluid. The label can include other types of information, including the concentration of the fluid, and other information useful in the drug delivery process.

Figure 7 depicts a method for controlling delivery of a fluid in accordance with disclosed embodiments. Only certain steps are shown in Figure 7, for illustrative purposes, with other steps being omitted or included within the illustrated steps. In step 210, a drug is formulated by the distributor. Alternatively, a pre-formulated drug is received at step 212 by the distributor. The distributor performs a spectral scan of the fluid in step 214, whether the drug is formulated by the distributor in step 210 or is a pre-formulated drug received in step 212. The scan can be in-situ in the fluid container, or of a sample removed from the fluid container. The spectral data of the actual composition of the fluid is compared with the expected composition of the fluid. If the compositions are inconsistent, an indication is made to the operator for appropriate action, such as discarding the scanned fluid, re-formulating the fluid, notifying the drug manufacturer, etc. When the compositions are consistent, the label generator 182 generates a label in step 216 with the appropriate information, such as identifying information, and other useful information. The label is then affixed to the fluid container in step 218.

After a fluid has been identified, a label generated and affixed to the fluid container, the fluid can be provided to the point of care through delivery channels, whether that is entirely internal within a hospital, for instance, or with external distribution. Figure 10 depicts an exemplary process that occurs at the point of care employing the verification apparatus and procedure discussed above. The fluid container 184, with the affixed label that verifies the contents of the container 184, is received at the point of care in step 220. The label of the fluid container is scanned in step 222 at the point of care by an appropriate label reading device. For example, if the information on the label is encoded in a bar code, the label reading device includes a bar code reader. This helps to eliminate human error in reading a label.

In step 224, an infusion device, or other drug delivery device, is programmed using a drug library or other means. A comparison of the scanned data from the label and of the programmed data is made in step 226 by an appropriate processing device, such as a processor. A determination is made in step 228, based on this comparison, whether the drug (fluid) in the container is consistent with the expected drug programmed into the drug delivery device. If consistent, infusion of the drug is allowed to proceed in step 230. An infusion pumping device may be used to perform the infusion of the drug (fluid) into the patient.

If the results of the comparison indicate that the scanned data from the label is inconsistent with the input identification of the expected fluid, the fluid pumping device, such as the infusion pump, is controlled to prevent delivery of the fluid to the patient in step 232. An indication is made in step 232 that the label is inconsistent with the input identification of the expected fluid. The indication may be an alarm, for example. Hence, by using the verification apparatus of the present invention, in which the fluid is verified at a central location, delivery of an incorrect drug at the point of care is prevented. The prevention initially occurs at the centralized location, where a label is generated after the drug is verified so that a care giver can be confident that the labeled fluid container will contain the correct drug. Further prevention occurs at the point of care where the verified drug, as identified by the affixed label, is compared to an expected drug, with infusion occurring only if the verified drug is consistent with the expected drug.

The disclosed embodiments provide a cost-effective verification system that employs a centralized fluid verification and fluid container labeling apparatus that aids in the

prevention of incorrect drug delivery at the point of care. The use of a centralized verification and labeling apparatus mitigates certain concerns regarding incorrect drugs being infused into a patient, while not requiring a separate spectral analysis system at each point of care.

Although specific embodiments of the invention have been described and illustrated it is clear that the invention is susceptible to modifications and embodiments within the ability of those skilled in the art, and without the exercise of the inventive faculty. Thus, it should be understood that various changes in form, detail, and application of the present invention may be made without departing from the spirit and scope of the invention.

CLAIMS

1. An apparatus for labeling a fluid container, comprising:

a source of light located and configured so as to direct light through fluid;

a light sensor located so as to receive the light that was directed through the fluid after the light has passed through the fluid, the light sensor providing light sensor signals representative of the spectral data of the actual composition of the fluid;

a processor that is adapted to compare the spectral data of the actual composition of the fluid with spectral data of an expected composition of the fluid; and

a label generator responsive to the processor to generate a label identifying the fluid based on the comparison of the spectral data of the actual composition of the fluid with the spectral data of an expected composition.

2. The apparatus of claim 1, wherein the processor is adapted to determine the concentration of the fluid, and the label generator is adapted to generate the label with an indication of the fluid concentration.

3. The apparatus of claim 1, wherein the label is a machine readable label.

4. The apparatus of claim 3, wherein the machine readable label is an optically readable label.

5. The apparatus of claim 3, wherein the machine readable label includes an RFID component.

6. The apparatus of claim 1, wherein the fluid is contained within a container having at least one wall through which the light is directed, the processor adjusting the spectral data of the actual composition of the fluid with spectral data representative of the wall prior to comparing of the spectral data of the actual composition of the fluid with the spectral data of an expected composition of the fluid.

7. The apparatus of claim 6, wherein the spectral data representative of the wall is stored data determined by measuring spectral data of an empty container.

8. The apparatus of claim 6, wherein the spectral data representative of the wall is determined by measuring spectral data of a wall of a fluid containing container in a non-fluid containing section of the container.

9. The apparatus of claim 7, further comprising a data storage device, and wherein the data storage device is configured to store the expected spectral data of the composition of a pre-formulated fluid.

10. A method of controlling delivery of a fluid, comprising:

directing light through the fluid;

sensing the light that was directed through the fluid after the light has passed through the fluid, and providing light sensor signals representative of the spectral data of the actual composition of the fluid;

comparing the spectral data of the actual composition of the fluid with spectral data of an expected composition of the fluid; and

generating a label identifying the fluid based on the comparison of the spectral data of the actual composition of the fluid with the spectral data of the expected composition of the fluid.

11. The method of claim 10, further comprising determining concentration of the fluid based on the comparison of the spectral data of the actual composition of the fluid with the spectral data of the expected composition of the fluid.

12. The method of claim 10, wherein the label is a machine readable label.

13. The method of claim 12, wherein the machine-readable label is an optically readable label.

14. The method of claim 12, wherein the machine-readable label includes an RFID component.

15. The method of claim 10, wherein the fluid is contained within a container having at least one wall through which the light is directed, and further comprising adjusting the spectral data of the actual composition of the fluid with spectral data representative of the wall prior to comparing of the spectral data of the actual composition of the fluid with the spectral data of an expected composition of the fluid.

16. The method of claim 15, wherein the spectral data representative of the wall is stored data determined by measuring spectral data of an empty container.

17. The method of claim 15, wherein the spectral data representative of the wall is determined by measuring spectral data of a wall of a fluid containing container in a non-fluid containing section of the container.

18. The method of claim 10, further comprising:

affixing the generated label to a fluid container;

reading the label at a delivery point;

comparing the fluid identification on the label to an expected fluid at the delivery point;

preventing delivery of the fluid if the fluid identification on the label and the expected fluid at the delivery point are inconsistent.

19. The method of claim 18, wherein the delivery point includes a fluid pumping device, and a control device that controls the fluid pumping device, and further comprising inputting an identification of the expected fluid to the control device, the control device comparing the fluid identification on the label to the input identification of the expected fluid and controlling the fluid pumping device as a function of the comparing.

20. The method of claim 19, wherein the control device controls the fluid pumping device to prevent delivery of the fluid if the fluid identification on the label and the expected

fluid at the delivery point are inconsistent, and to allow delivery of the fluid if the fluid identification on the label and the expected fluid at the delivery point are consistent.

21. The method of claim 20, wherein the fluid pumping device is an infusion pump.

22. A method of verifying a drug prior to delivery of the drug at a point of care, comprising the steps of:

spectroscopically scanning a fluid;

identifying a drug in the scanned fluid based on the scanning;

generating a label indicating the drug based on the identifying of the drug; and

affixing the label to a fluid container containing the scanned fluid.

23. The method of claim 22, further comprising:

machine reading the label of the fluid container at the point of care;

comparing at the point of care the identified drug in the fluid container and indicated on the label to an expected drug; and

preventing delivery of the drug to a patient when the identified drug in the fluid container and indicated on the label is inconsistent with the expected drug, and allowing delivery of the drug to the patient when the identified drug in the fluid container and indicated on the label is consistent with the expected drug.

24. The method of claim 23, wherein the steps of preventing and allowing delivery includes controlling operation of a pumping device.

25. The method of claim 24, further comprising inputting an identification of the expected drug into a control device.

26. The method of claim 23, wherein the step of scanning the fluid includes:

directing light through the fluid; and

sensing the light that was directed through the fluid after the light has passed through the fluid, and providing light sensor signals representative of the spectral data of the actual composition of the fluid.

27. The method of claim 26, wherein the step of identifying a drug includes comparing the spectral data of the actual composition of the fluid with spectral data of an expected composition of the fluid.

28. The method of claim 27, wherein the step of generating a label includes identifying the fluid based on the comparison of the spectral data of the actual composition of the fluid with the spectral data of the expected composition of the fluid.

29. The method of claim 27, further comprising determining concentration of the fluid based on the comparison of the spectral data of the actual composition of the fluid with the spectral data of the expected composition of the fluid.

30. The method of claim 27, wherein the fluid is contained within a container having at least one wall through which the light is directed, and further comprising adjusting the spectral data of the actual composition of the fluid with spectral data representative of the wall prior to comparing of the spectral data of the actual composition of the fluid with the spectral data of an expected composition of the fluid.

31. The method of claim 30, wherein the spectral data representative of the wall is stored data determined by measuring spectral data of an empty container.

32. The method of claim 30, wherein the spectral data representative of the wall is determined by measuring spectral data of a wall of a fluid containing container in a non-fluid containing section of the container.

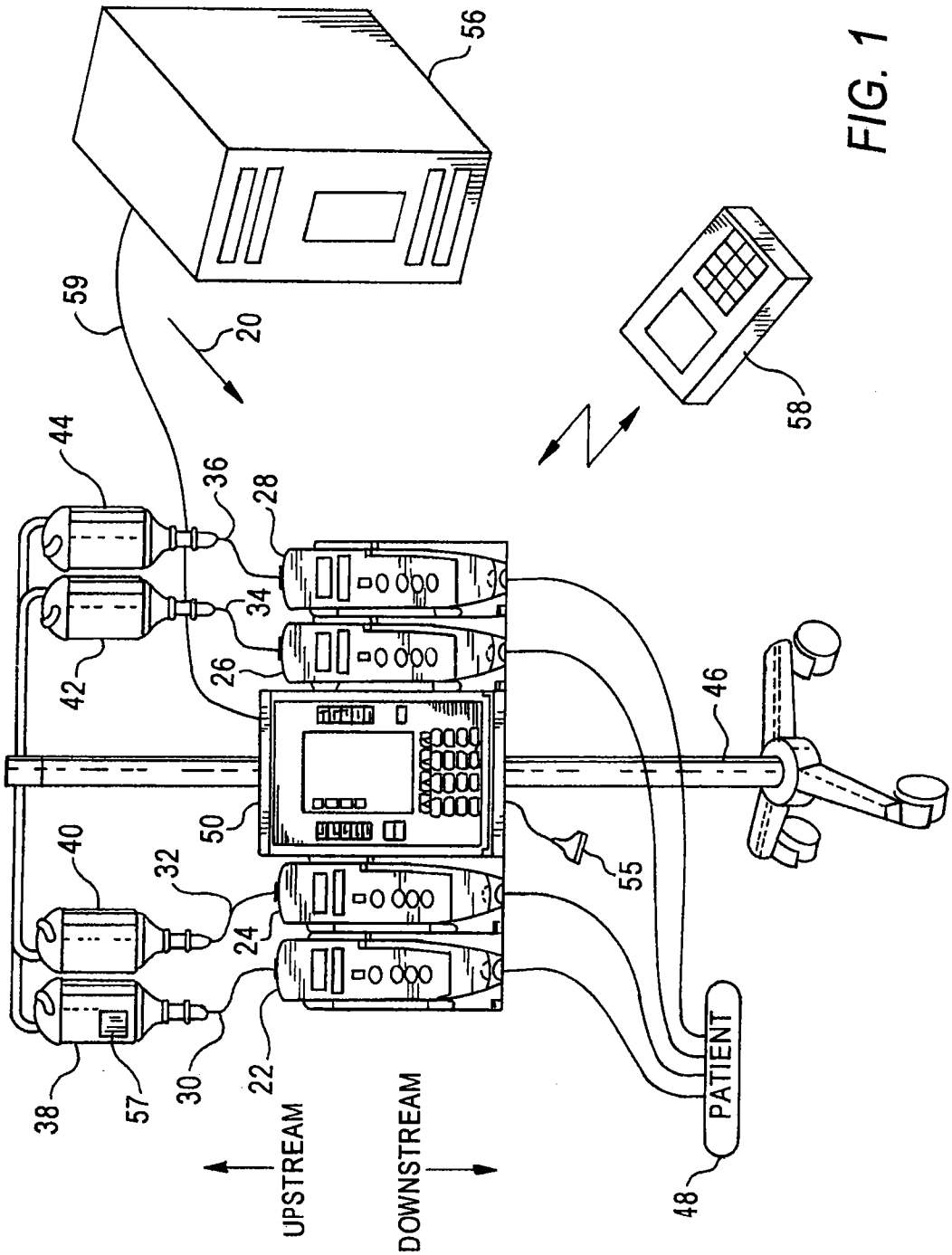
56
59
20
58
44
36
28
34
42
26
46
50
40
32
55
24
22
30
38
57
UPSTREAM
DOWNSTREAM
PATIENT
48

FIG. 1

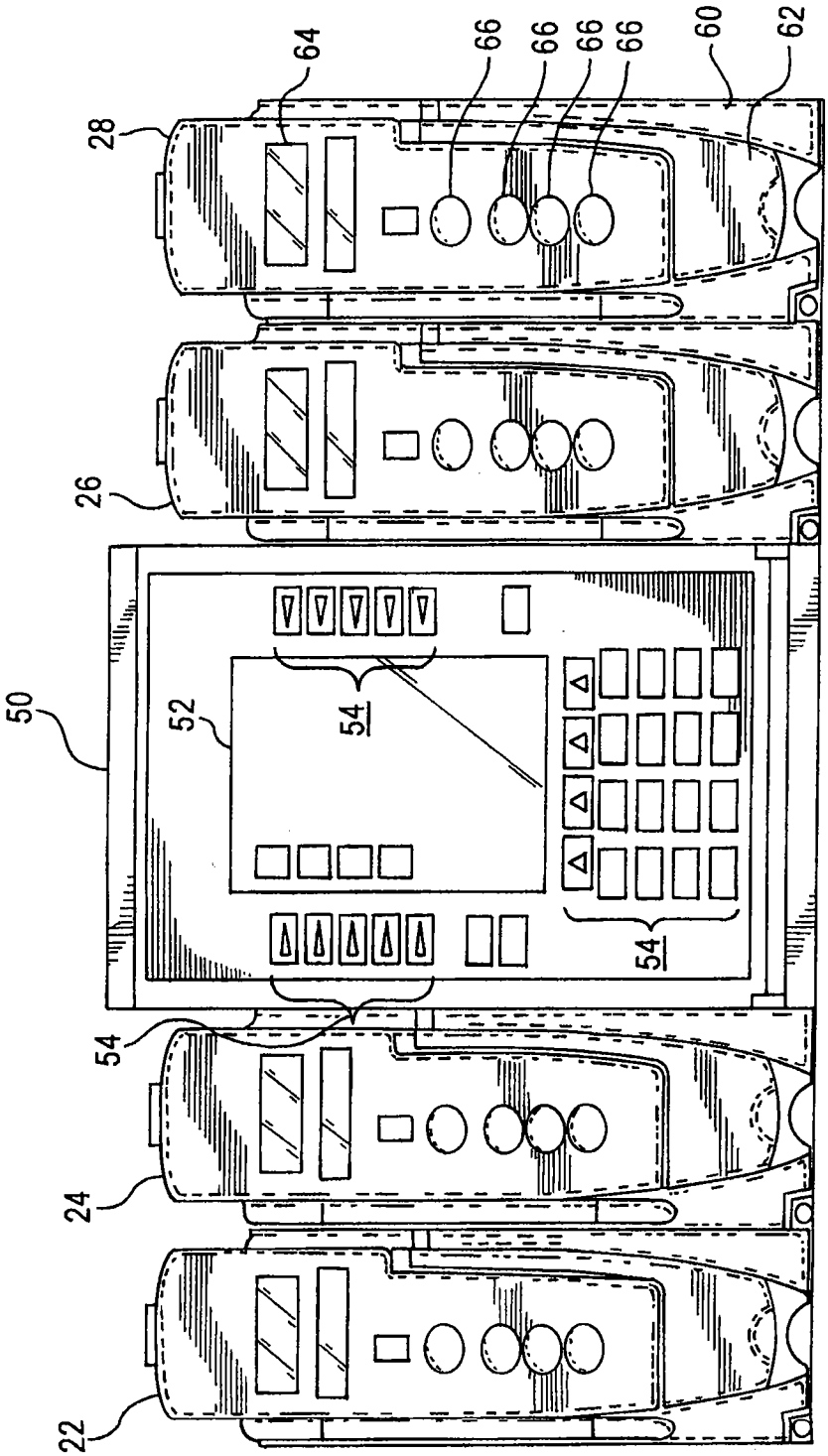

FIG.2

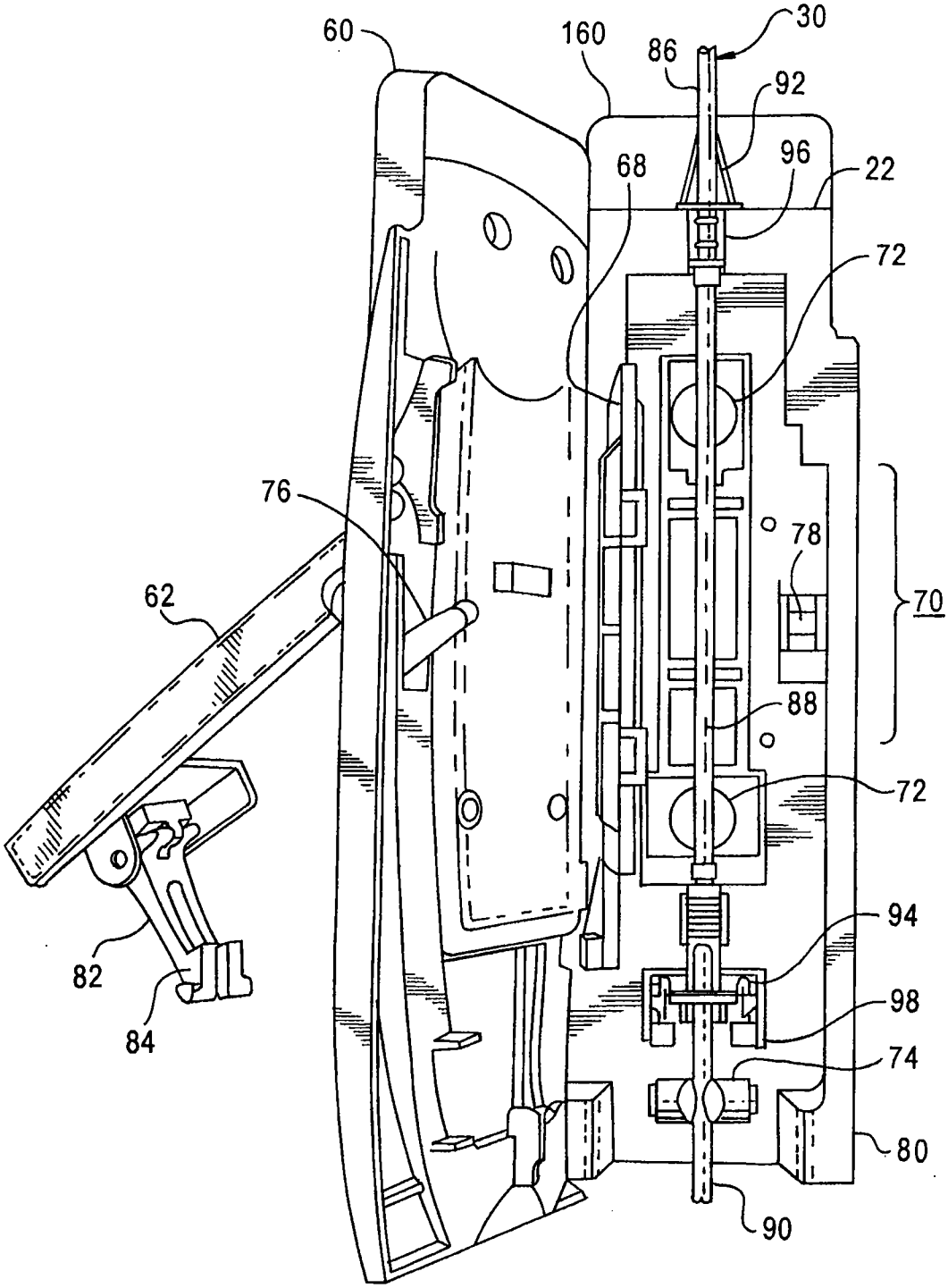

FIG. 3

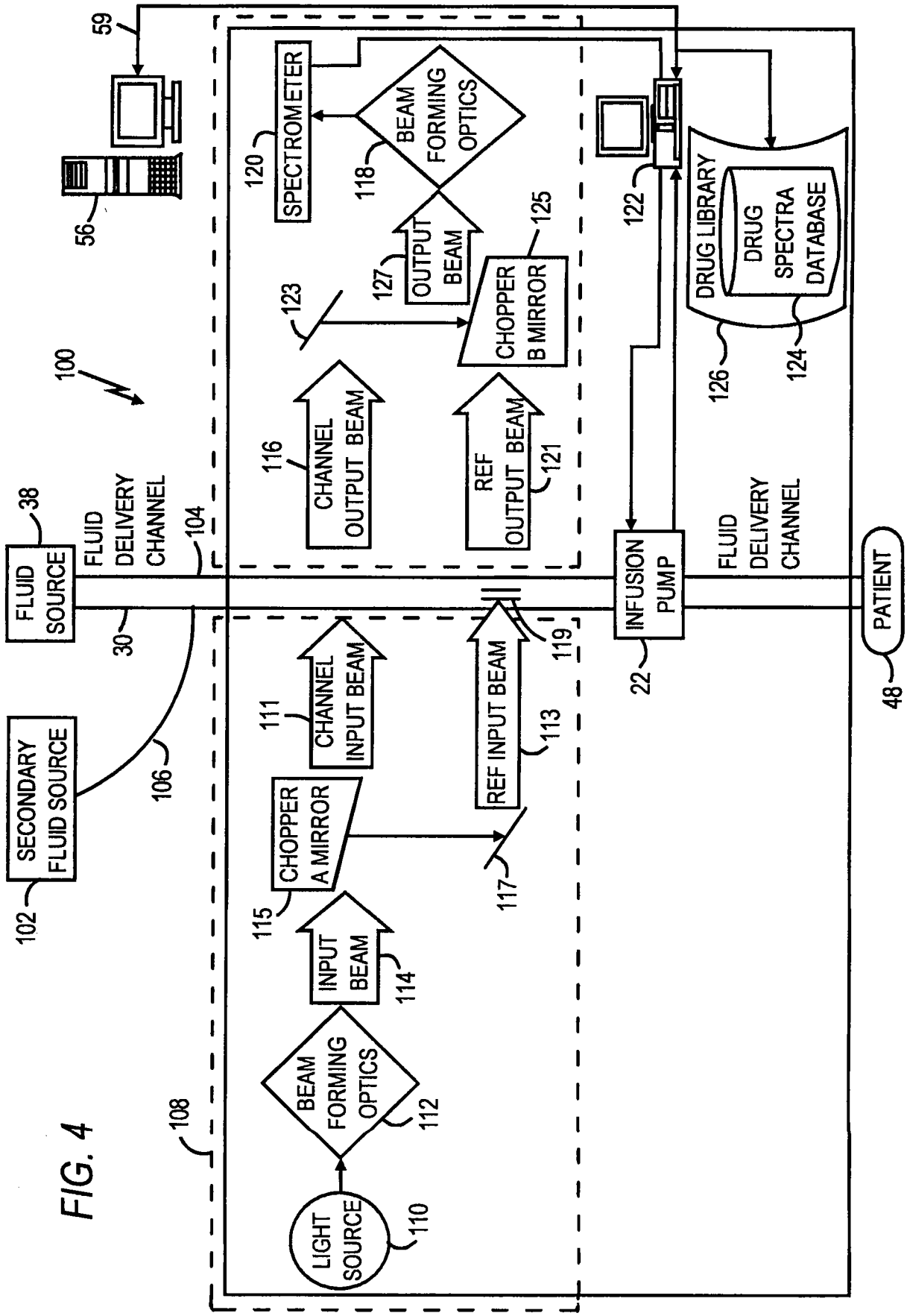
59
56
100
120
SPECTROMETER
118
BEAM FORMING OPTICS
122
DRUG LIBRARY
DRUG SPECTRA DATABASE
126
124
127
OUTPUT BEAM
123
125
CHOPPER B MIRROR
116
CHANNEL OUTPUT BEAM
REF OUTPUT BEAM
121
38
FLUID SOURCE
FLUID DELIVERY CHANNEL
104
30
INFUSION PUMP
FLUID DELIVERY CHANNEL
PATIENT
22
48
119
111
CHANNEL INPUT BEAM
REF INPUT BEAM
113
SECONDARY FLUID SOURCE
106
102
CHOPPER A MIRROR
117
115
INPUT BEAM
114
BEAM FORMING OPTICS
112
108
LIGHT SOURCE
110

FIG. 4

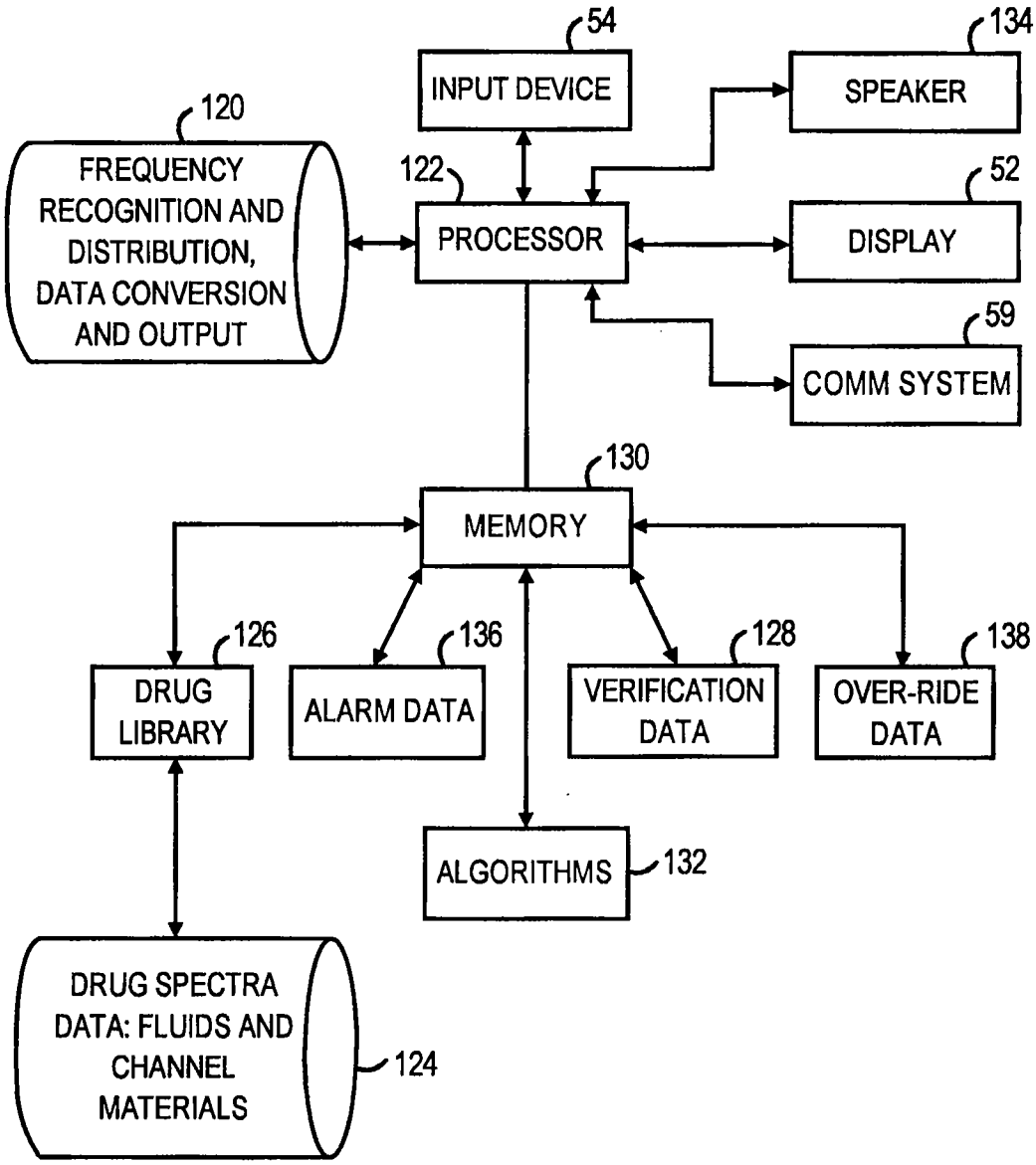
54
INPUT DEVICE
134
SPEAKER
120
FREQUENCY RECOGNITION AND DISTRIBUTION, DATA CONVERSION AND OUTPUT
122
PROCESSOR
52
DISPLAY
59
COMM SYSTEM
130
MEMORY
126
DRUG LIBRARY
136
ALARM DATA
128
VERIFICATION DATA
138
OVER-RIDE DATA
ALGORITHMS
132
DRUG SPECTRA DATA: FLUIDS AND CHANNEL MATERIALS
124

FIG. 5

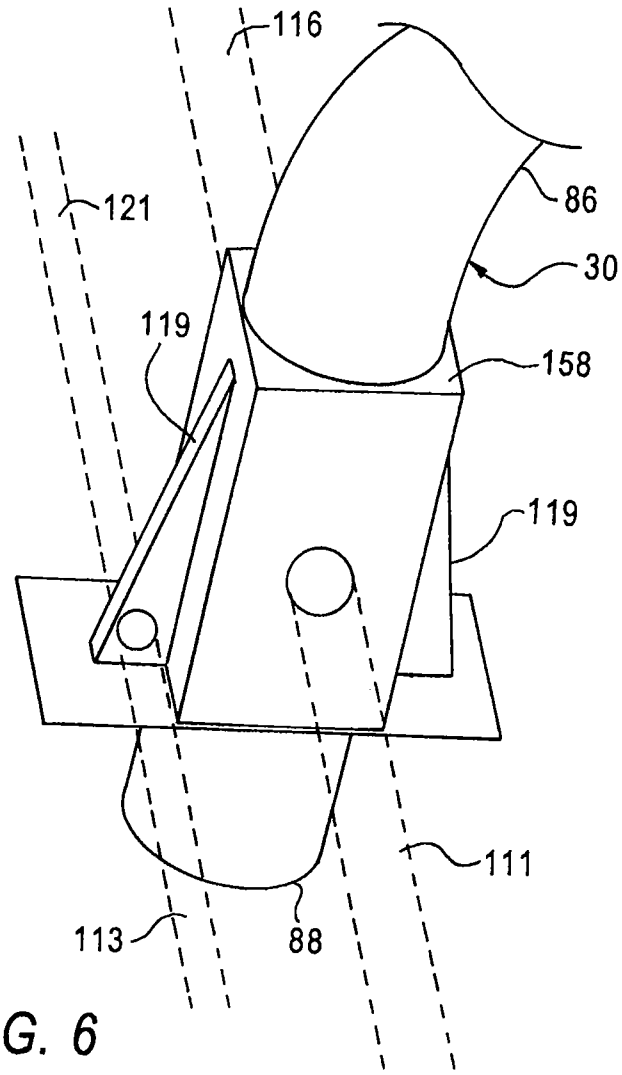

FIG. 6

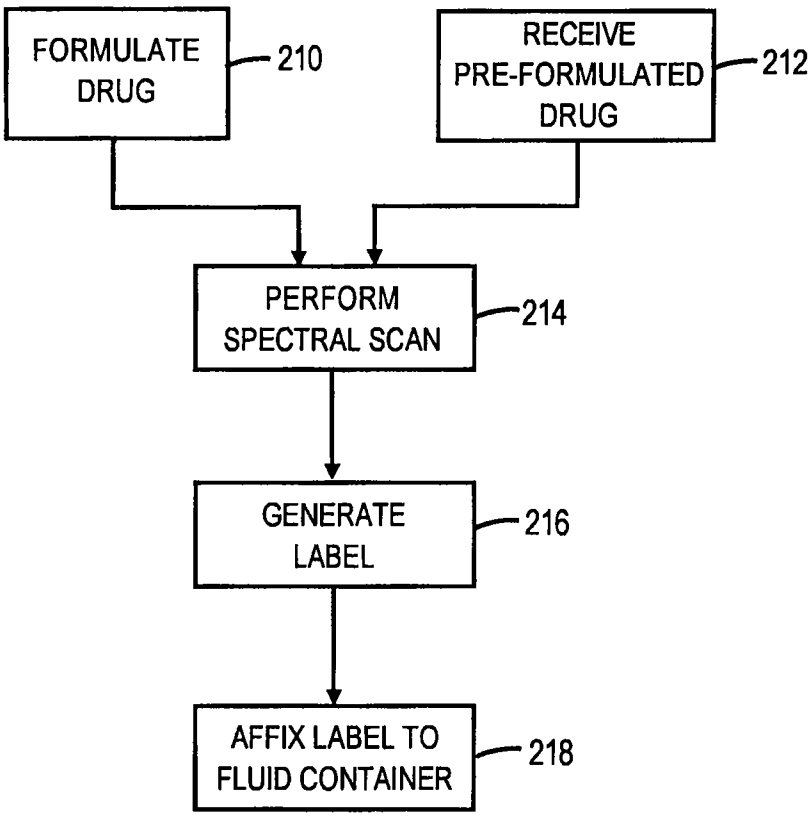
FORMULATE DRUG
210
RECEIVE PRE-FORMULATED DRUG
212
PERFORM SPECTRAL SCAN
214
GENERATE LABEL
216
AFFIX LABEL TO FLUID CONTAINER
218

FIG. 7

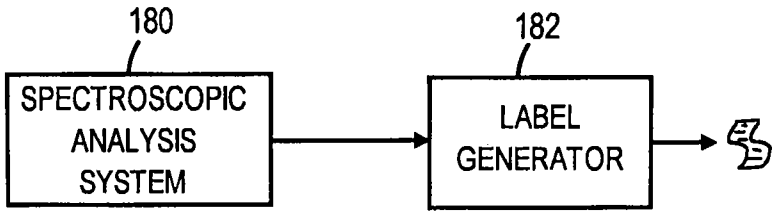
180
SPECTROSCOPIC ANALYSIS SYSTEM
182
LABEL GENERATOR

FIG. 8

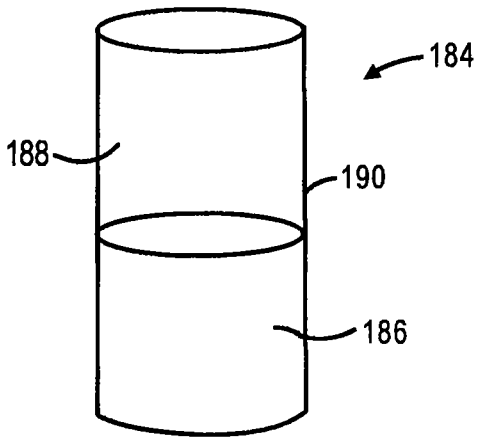
184
188
190
186

FIG. 9

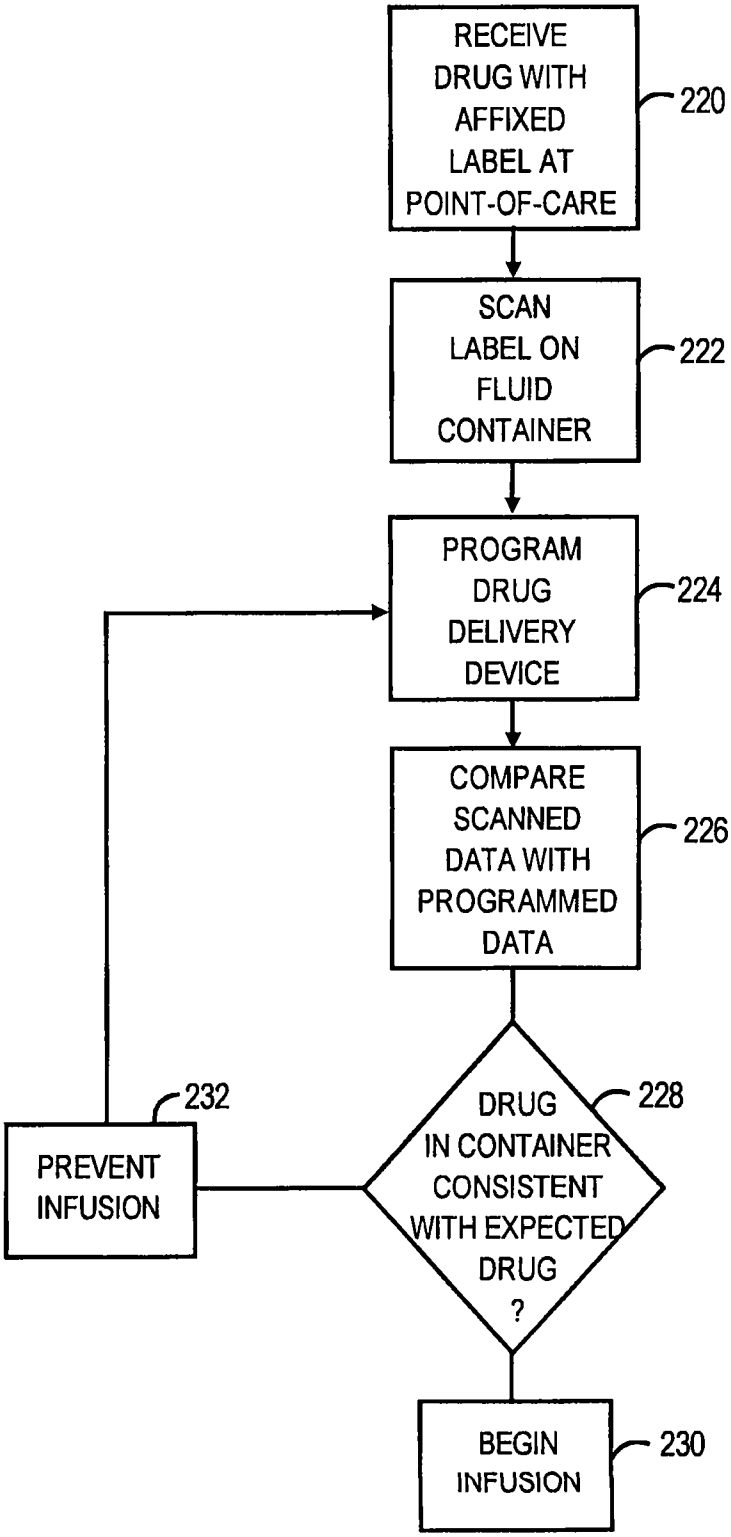
RECEIVE DRUG WITH AFFIXED LABEL AT POINT-OF-CARE
220
SCAN LABEL ON FLUID CONTAINER
222
PROGRAM DRUG DELIVERY DEVICE
224
COMPARE SCANNED DATA WITH PROGRAMMED DATA
226
DRUG IN CONTAINER CONSISTENT WITH EXPECTED DRUG ?
228
PREVENT INFUSION
232
BEGIN INFUSION
230

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/004785

A. CLASSIFICATION OF SUBJECT MATTER
INV. G06F19/00 G01N21/35

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
G06F G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 111 639 A (REDUTO LAWRENCE A [US]) 29 August 2000 (2000-08-29) the whole document -----	1,2,10, 11,18-29
X	WO 2004/033003 A (ALLGEYER DEAN O [US]) 22 April 2004 (2004-04-22) abstract, summary, page 20,21,24,25 -----	1-5, 10-14, 18-29
X	US 2005/099624 A1 (STAEHR LINDA B [US] ET AL) 12 May 2005 (2005-05-12) the whole document ----- -/--	1,3-10, 15-17, 22,23, 26,27, 30-32

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 August 2008	20/08/2008

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Huber, Alexander

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2008/004785

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2005/277890 A1 (STEWART JANICE [US] ET AL) 15 December 2005 (2005-12-15) abstract, summary, paragraphs 34 and 51, claims 90-92	18-29
A	US 2006/287884 A1 (SANDY NEAL J [US] ET AL) 21 December 2006 (2006-12-21) the whole document	18-29
A	US 2004/243434 A1 (PETERKA MICHAEL ANTHONY [US] ET AL) 2 December 2004 (2004-12-02) the whole document	18-29
A	US 5 153 827 A (COUTRE JAMES E [US] ET AL) 6 October 1992 (1992-10-06) the whole document	1-32

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2008/004785

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers allsearchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search reportcovers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-2,3-5, 10-11,12-14,18-21,22-29

   Labeling a fluid container by spectral analysis of the fluid and comparison to expected spectral data, characterized in that it also determines the fluid's concentration, and in that the labels are machine-readable. This relates in particular to the determination of the fluid's details and the automatic reading of the container's contents.

   ---

2. claims: 1,6-9,10,15-17,22-23,26-27,30-32

   Labeling a fluid container by spectral analysis of the fluid and comparison to expected spectral data, characterized in that the spectral data is adjusted by the spectral data of the walls of the container which contains the fluid. This relates in particular to the faultless determination of the fluid.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2008/004785

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 6111639	A	29-08-2000	NONE		
WO 2004033003	A	22-04-2004	AT	400312 T	15-07-2008
			AU	2003239122 A1	04-05-2004
			EP	1545659 A1	29-06-2005
US 2005099624	A1	12-05-2005	AU	2004288704 A1	26-05-2005
			CA	2544523 A1	26-05-2005
			EP	1696980 A1	06-09-2006
			JP	2007512041 T	17-05-2007
			NZ	546980 A	30-05-2008
			US	2007201025 A1	30-08-2007
			WO	2005046766 A1	26-05-2005
US 2005277890	A1	15-12-2005	AU	2005249904 A1	15-12-2005
			BR	PI0511611 A	02-01-2008
			CA	2560996 A1	15-12-2005
			CN	1950125 A	18-04-2007
			EP	1755729 A1	28-02-2007
			WO	2005118054 A1	15-12-2005
US 2006287884	A1	21-12-2006	CN	1971271 A	30-05-2007
			EP	1739585 A2	03-01-2007
US 2004243434	A1	02-12-2004	CA	2526681 A1	09-12-2004
			EP	1642190 A2	05-04-2006
			JP	2007502485 T	08-02-2007
			KR	20060038936 A	04-05-2006
			US	2008035659 A1	14-02-2008
			WO	2004107122 A2	09-12-2004
US 5153827	A	06-10-1992	CA	2008715 A1	30-07-1990
			US	5317506 A	31-05-1994