



- (51) **International Patent Classification:**  
G06K 3/02 (2006.01)
- (21) **International Application Number:**  
PCT/US2013/024779
- (22) **International Filing Date:**  
5 February 2013 (05.02.2013)
- (25) **Filing Language:** English
- (26) **Publication Language:** English
- (30) **Priority Data:**  
61/595,144 5 February 2012 (05.02.2012) US
- (71) **Applicant:** CODONICS, INC. [US/US]; 17991 Englewood Dr., Middleburg Heights, OH 44130 (US).
- (72) **Inventors:** KOLBERG, Michael; 2010 Parker Rd., Hinckley, OH 44233 (US). SRNKA, Lawrence; 6949 Schoepf Dr., Northfield Center, OH 44067 (US). BOTTEN, Peter; 870 Beach Rd., Lakewood, OH 44107 (US). KEEFE, Gary; 7567 Deer Path, Brecksville, OH 44141 (US). JABLONSKI, Timothy; 17845 Lake Rd., Lakewood, OH 44107 (US).
- (74) **Agents:** FIRCA, Donald et al.; Pearne & Gordon LLP, 1801 East 9th Street, Suite 1200, Cleveland, OH 44114-3108 (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, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

**Published:**

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

(54) **Title:** DRUG DOCUMENTATION SYSTEM AND METHOD

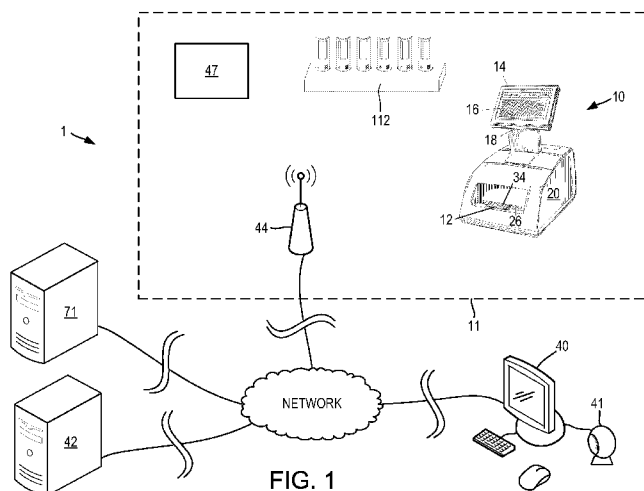


FIG. 1

(57) **Abstract:** Provided is a system for printing a label identifying a medicinal substance and documenting a quantity of the medicinal substance administered to a patient. The system includes a code reader that interrogates a computer-readable code representing the medicinal substance that corresponds to a source container of the medicinal substance at a time when the medicinal substance is to be extracted from the source container. A non-transitory, local computer-readable memory stores a drug formulary that is referenced by a processing component to identify the medicinal substance. A printer prints label content identifying the medicinal substance onto a label to be applied to a delivery container. A quantity detector senses a property indicative of a quantity of the medicinal substance administered to the patient in real time, approximately at a time when the medicinal substance is administered to the patient.

WO 2013/116873 A1

## DRUG DOCUMENTATION SYSTEM AND METHOD

### CROSS-REFERENCE TO RELATED APPLICATIONS

**[0001]** This application claims the benefit of U.S. Provisional Application No. 61/595,144, filed February 5, 2012, which is incorporated in its entirety herein by reference.

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

**[0002]** This application relates generally to a method and apparatus for documenting delivery of a drug and, more specifically, to method and apparatus for encoding information relating to a drug to be administered to a patient in a computer-readable form, and utilizing such encoded information to document delivery of the drug to the patient.

#### 2. Description of Related Art

**[0003]** Traditionally, drugs to be injected to patients in a hospital setting, for example, have been extracted from a vial using a syringe. The vial containing the particular drug to be administered is retrieved and a needle portion of the syringe is inserted into the liquid within the vial through a latex seal. The syringe's plunger is then withdrawn from the syringe, thereby drawing the liquid drug from the vial into the syringe. As the drug is being withdrawn from the vial great care must be taken to extract the proper volume called for by the medical procedure being performed.

**[0004]** In an operating room setting numerous syringes may be prepared ahead of a surgical procedure. To administer each syringe, an anesthesiologist or other authorized individual has traditionally retrieved the syringes and injected the drug into the patient as needed. To document administration of the drug the individual who

performed the injection has traditionally hand written the name of the drug, the quantity injected, and the dosage of the injected drug.

[0005] More recently, computerized systems have been used to gather drug delivery information. Such computerized systems have typically required the anesthesiologist or other individual responsible for administering the drug to enter information indicating themselves as the party responsible for the drugs during the surgical procedure. When the person identified has injected the patient with the drug, that person has traditionally used the computerized system to input the identity of the drug, manually keyed in the quantity of the drug injected and possibly other information such as the dosage of the drug delivered and the flow rate of the drug injected. Both the hand written and traditional drug documentation systems described require an extensive amount of manual human involvement in the entry of data.

#### BRIEF SUMMARY OF THE INVENTION

[0006] According to one aspect, the subject application involves a system for printing a label identifying a medicinal substance and documenting a quantity of the medicinal substance administered to a patient. The system includes a code reader that interrogates a computer-readable code representing the medicinal substance that corresponds to a source container of the medicinal substance at a time when the medicinal substance is to be extracted from the source container. A non-transitory, local computer-readable memory stores a drug formulary that is referenced by a processing component to identify the medicinal substance. A printer prints label content identifying the medicinal substance onto a label to be applied to a delivery container. A quantity detector senses a property indicative of a quantity of the medicinal substance administered to the patient in real time, approximately at a time when the medicinal substance is administered to the patient. This property is utilized by the processing component to determine the quantity of the medicinal substance administered to the patient. A network component transmits the quantity of the medicinal substance administered to the patient over the communication network to be stored by a remotely-located non-transitory computer memory associated with a medical record of the patient.

[0007] The above summary presents a simplified summary in order to provide a basic understanding of some aspects of the systems and/or methods discussed herein. This summary is not an extensive overview of the systems and/or methods discussed herein. It is not intended to identify key/critical elements or to delineate the scope of such systems and/or methods. Its sole purpose is to present some concepts in a simplified form as a prelude to the more detailed description that is presented later.

#### BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWING

[0008] The invention may take physical form in certain parts and arrangement of parts, embodiments of which will be described in detail in this specification and illustrated in the accompanying drawings which form a part hereof and wherein:

[0009] FIG. 1 shows an illustrative embodiment of a network at a medical facility;

[0010] FIG. 2 shows a block diagram of a labeling terminal according to an illustrative embodiment;

[0011] FIG. 3A shows an illustrative embodiment of a labeling terminal in communication with an embodiment of a volume detector;

[0012] FIG. 3B shows an illustrative embodiment of an interface presenting a user with options that are selectable to indicate when a syringe is filled, and indicate when a syringe is at least partially vacated after an injection;

[0013] FIG. 4A shows an illustrative embodiment of a labeling terminal in communication with a code reader that interrogates a label to determine a volume of a drug that has been administered;

[0014] FIG. 4B shows an illustrative embodiment of a labeling substrate supporting a capacitive sensor for sensing a volume of a drug administered to a patient;

[0015] FIG. 5A shows an end view of a syringe on which a clip comprising a capacitive sensor for sensing a volume of a drug that has been administered using the syringe;

[0016] FIG. 5B shows a side view of a syringe on which a clip comprising a capacitive sensor for sensing a volume of a drug that has been administered using the syringe;

[0017] FIG. 5C shows an illustrative embodiment of a clip supporting a capacitive sensor for sensing a volume of a drug administered to a patient;

[0018] FIG. 5D shows an illustrative embodiment of a charging station that charges a battery provided to the clip shown in FIG. 5C;

[0019] FIG. 6A shows an end view of a syringe on which a clip comprising a capacitive sensor for sensing a volume of a drug that has been administered using the syringe;

[0020] FIG. 6B shows a side view of a syringe on which a clip comprising a capacitive sensor for sensing a volume of a drug that has been administered using the syringe;

[0021] FIG. 6C shows an illustrative embodiment of a clip supporting a capacitive sensor for sensing a volume of a drug administered to a patient;

[0022] FIG. 6D shows an illustrative embodiment of a charging station that charges a battery provided to the clip shown in FIG. 5C; and

[0023] FIG. 7 shows an illustrative embodiment of a syringe pump that is programmable according to parameters encoded in a machine-readable code.

#### DETAILED DESCRIPTION OF THE INVENTION

[0024] Certain terminology is used herein for convenience only and is not to be taken as a limitation on the present invention. Relative language used herein is best understood with reference to the drawings, in which like numerals are used to identify like or similar items. Further, in the drawings, certain features may be shown in somewhat schematic form.

[0025] It is also to be noted that the phrase “at least one of”, if used herein, followed by a plurality of members herein means one of the members, or a combination

of more than one of the members. For example, the phrase “at least one of a first widget and a second widget” means in the present application: the first widget, the second widget, or the first widget and the second widget. Likewise, “at least one of a first widget, a second widget and a third widget” means in the present application: the first widget, the second widget, the third widget, the first widget and the second widget, the first widget and the third widget, the second widget and the third widget, or the first widget and the second widget and the third widget.

**[0026]** FIG. 1 shows an illustrative embodiment of a computerized network that transmits information relating to patients and drugs at a healthcare facility such as a hospital. According to the illustrative embodiment shown, the network includes a labeling terminal 10, which can optionally be located in a surgical suite 11 per surgical procedures are performed on patients. The surgical suite 11 can optionally include a sterile field where the actual surgical procedure is performed with minimal risk of infection. The labeling terminal 10 can optionally be located within the sterile field, or adjacent thereto such that labels printed by the labeling terminal 10 to identify a drug in a syringe or other suitable container can be applied to the container for use in the sterile field.

**[0027]** The labeling terminal 10 is operable to scan a computer-readable code and print a label to be applied to a medical container such as a syringe as described in U.S. Patent Application Serial No. 12/901,110, which is hereby incorporated in its entirety by reference. Generally, the labeling terminal 10 includes a touch-screen display 14 that can be pivotally coupled to a cabinet 20 to display a virtual label 16 comprising label content 34 that will be printed onto a label 12 to be applied to a container that stores a drug. The display 14 can display soft keys that, when touched by a technician or any other user, inputs data and commands into the labeling terminal 10. The virtual label 16 is a computer-generated rendering of the label 12 that offers the user visual confirmation of the appearance of the physical label 12 to be printed by a printer 26. A computer-input peripheral such as a non-contact scanner 18 can be provided at a convenient location, such as integrally formed in a bottom portion of the display 14 to read a machine-readable code supported beneath the scanner 18 for example. Integrally forming the scanner 18 as part of the display 14, which itself can integrally form a portion of the

monolithic cabinet 20 provides for space savings over distributed arrangement where the scanner 18 is formed as a separate peripheral, which can be repositioned relative to the display 14. However, other embodiments can allow for a separate and distinct scanner 18 and/or display 14 as the distributed arrangement without departing from the scope of the present invention.

**[0028]** The scanner 18 can be a barcode reader, radio-frequency identification (“RFID”) tag reader, or any other device that reads a machine-readable code such as a barcode or RFID code, respectively, or any other machine-readable code without requiring contact between the computer terminal and the code, and optionally the user during entry of the code. According to alternate embodiments, the display 14 can be utilized by a user as the computer-input peripheral. For such embodiments, the soft keys displayed by the display 14 can be selected to input information such as a medicinal substance being prepared to be administered to a patient or other information to be utilized in generating the label as described herein that is not provided by the computer-readable code.

**[0029]** The cabinet 20 houses or supports components that are operable to produce a label 12 that optionally complies with a medical labeling standard. For instance, the label 12 can be printed in compliance with a standard developed by a trade or professional organization, governing body, government agency, a healthcare provider or facility such as a hospital, or any other standards body setting forth standardized policies for labeling drugs. The components housed within the cabinet 20 are schematically illustrated by the block diagram of FIG. 2, and can be embodied as at least one of: computer hardware such as ASICs, computer processors, programmable logic controllers and other circuitry; a combination of computer hardware and computer-executable instructions; and a non-transitory computer-readable memory storing computer-executable instructions that, when executed, perform portions of the processes described herein. For example, a processing component 22 is provided to execute computer-executable instructions stored in a non-transitory, computer-readable memory 24 such as a hard disk drive, read-only memory (“ROM”), random access memory (“RAM”), optical disc, or any other suitable memory device, or any combination thereof. The computer-executed instructions, when executed by the computer processor 22, result

in the performance of method steps described herein for generating the label 12, transmitting data and information via the network 1, etc... A BIOS 28 is provided to load the operating system and other such administrative instructions 30 stored in the memory 24 and manage hardware interface permissions of the labeling terminal 10. The operating system can be configured to only load authorized updates to prevent unauthorized changes to the formulary 36, configuration data 32 and administration instructions 30. Configuration data 32 controls various features of the labeling terminal 10 that are active and available for use at any given time. The configuration data 32 can optionally be stored, updated and deleted from the memory 24 by the introduction of a so-called smart drive comprising a USB compatible flash memory to the labeling terminal 10. When the smart drive is introduced to the labeling terminal 10, it establishes the configuration data 32 of the labeling terminal 10. The configuration data 32 can optionally be used to deactivate functional features that the labeling terminal 10 would otherwise be able to perform based on the model of the labeling terminal 10 purchased. Accordingly, a common hardware platform of the labeling terminal 10 can be configured in a plurality of different functional configurations based on the configuration data 32.

**[0030]** In addition to the administrative instructions 30, the memory 24 also stores an updatable formulary 36 containing a database of medicinal substances that can be identified by the labeling terminal 10 and select information for each medicinal-substance entry in the database. The formulary 36 can optionally be stored, updated and deleted from the memory 24 by the introduction of a so-called smart drive comprising a USB compatible flash memory to the labeling terminal 10. When the smart drive is introduced to the labeling terminal 10, it establishes the formulary 36 of the labeling terminal 10. Illustrative examples of the select information that can be provided for the medicinal-substance entries includes, but is not limited to, an ID number such as a NDC code, UPC code, EAN code, or any other identifying data that can be used to relate a barcode or other computer-readable code to the medicinal-substance entries; a sound file that, when played, audibly announces the name of the medicinal substance identified in response to scanning a machine readable code; warning data; or any combination thereof.

**[0031]** A network adaptor 38 is operatively connected to communicate with the processing component 22 for translating signals received by the labeling terminal 10



over the network 1 at the medical facility. The network adaptor 38 can be compatible with any type of network communication. For example, the network adaptor 38 can include a hardwired, 10Base-T, 100Base-T, or 1000Base-T Ethernet interface with an RJ-45 socket, a coaxial cable interface, a fiber-optic interface, any format of wireless communication interface such as an antenna compatible with any of the 802.11 standards established by the IEEE, or any combination thereof. Embodiments including wireless network adaptors 38 can employ any desired securing protocol such as WEP, WPA and WPA2, for example, and other suitable security protocol. For embodiments including a network adaptor 38 compatible to communicate over a plurality of different network communication channels, both a hard-wired communication portion of the network adaptor 38 and a wireless communication portion of the network adaptor 38 can optionally be concurrently active. Thus, the labeling terminal 10 can optionally communicate via both the hard-wired and wireless portions of the network adaptor 38 concurrently.

**[0032]** The network 1 also includes a pharmacy computer terminal 40 that is accessible to the pharmacist or other individual authorized to view and edit the formulary 36 to be used by the labeling terminal 10. The pharmacy computer terminal 40 can optionally include a non-transitory, computer-readable memory storing a master drug database (“MDD”) containing drug entries for each of the most commonly used drugs by that medical facility. According to alternate embodiments, the MDD can optionally be stored by a non-transitory, computer-readable memory provided to a storage server 42 (FIG. 1) operatively connected to communicate via the network 1. Regardless of where the MDD is stored, an authorized user of the pharmacy computer terminal 40 can select a subset of drugs from the MDD to be included in the formulary 36 (FIG. 2). Each drug entry included within the formulary 36 can optionally be verified by the authorized user prior to delivering the formulary 36 to the labeling terminal 10. To verify each drug entry, the authorized user can optionally scan a barcode associated with each drug corresponding to a drug entry in the formulary 36 using a barcode scanner 41 in communication with the pharmacy computer terminal 40.

**[0033]** The formulary 36 containing the drug entries to be made available to the labeling terminal 10 is transmitted to the labeling terminal 10 to be stored in the

memory 24. The formulary 36 can be transported to the labeling terminal 10 via the network 1, such as through wireless transmission via the wireless access 44, for example, delivered on a portable USB flash drive, or in any other conventional manner. Although shown connected to the network 1 via the wireless access point 44, the labeling terminal 10 can optionally be connected via a hardwire connection such as an Ethernet connection. Once received by the labeling terminal 10, the formulary 36 received can optionally completely replace, in toto, any existing formularies stored by the memory 24 instead of updating the existing formulary 36.

**[0034]** Use of the labeling terminal 10 will be described briefly according to an embodiment where the scanner 18 is a barcode reader that is operable to scan a two-dimensional barcode provided to a file containing a drug. Generally, the file containing the barcode is held adjacent to the scanner 18 to allow the scanner 18 to interrogate the barcode. In response to interrogation of the barcode, the scanner 18 transmits the signal indicative of the information encoded by the barcode to the processing component 22. In response, a processing component 22 queries formulary 36 for a drug entry that corresponds to the information encoded by the barcode, and retrieves any matches. If a matching drug entry is located, it is retrieved from the formulary 36 and evaluated to determine whether information therein has been validated. If the information included in the retrieved drug entry, such as the drug name and concentration, for example, has previously been validated a step of requesting the operator of the labeling terminal 10 to validate that information can be omitted. On the other hand, if the information corresponding to the retrieved drug entry has not been previously validated, the drug-related information in the matching drug entry retrieved along with a request for validation can be presented via the display 14. The request instructs the operator to confirm that the information such as the drug name concentration displayed accurately represent the drug to be administered to the patient. In response to receiving confirmation that the information displayed in response to scanning the barcode is accurate, the labeling terminal 10 can transmit confirmation received from the operator over the network 1 to a remotely-located recipient, such as the pharmacy terminal computer 40 or another labeling terminal 10 on the network 1.

**[0035]** If the circumstances surrounding the administration of the drug to the patient do not afford the operator with the ability to validate the drug information displayed in response to scanning the barcode, the operator can select a “bypass” soft key presented by the display 14. Printing of the label content 34 can proceed so the label 12 can be generated if the bypass option is selected. However, information indicative of the operator’s identity, the date and time, and the drug entry that was not verified is recorded in a log.

**[0036]** Once validated (or once the validation has been bypassed), the matching drug entry returned by the query allows the processing component 22 to generate the label content 34 to be applied to the label 12 and transmits a signal to the display 14 to present the virtual label 16 to the operator. If the appearance of the virtual label 16 is acceptable to the operator, the operator can select a "print" soft key presented by the display 14. In response to receiving the print command from the operator, the processing component 22 transmit a signal to the printer 26 to initiate printing of the label content 34 onto label stock available to the printer 26, thereby producing the label 12.

**[0037]** The label content 34 printed on the label 12 by the printer includes a barcode 45 (FIG. 4A) or other machine-readable code encoding administration information. The administration information encoded by the barcode 45 can include at least one of: drug-related information, patient information, professional information. The drug-related information can include information specific to the drug being administered that was retrieved from the formulary 3 such as: drug identity, drug type, concentration, National Drug Code (“NDC”) number or other identifier assigned by a governing body, diluting agent (if diluted), maximum allowable volume that can be administered, time at which the syringe was prepared, expiration date and/or time of the drug in the syringe, any other information specific to the drug, or any combination thereof. The patient information can include a patient’s name or other identifying information (e.g., patient ID number), age of the patient, known allergies of the patient, any other known conditions (e.g., diabetic) of the patient, or any combination thereof. The professional information can include the name of the individual who prepared label 12, and the name of the doctor responsible for injecting the patient with the drug, or any combination thereof.

**[0038]** As mentioned above, a portion of the administration information can include information retrieved from the formulary 36, but other portions of the administration information can also be retrieved from other resources available to the labeling terminal 10, either locally or remotely via the network 1. For instance, the operator using the labeling terminal 10 can optionally retrieve at least a portion of the patient information over the network from an electronic medical record stored by the storage server 42, for example. Such information can include information identifying the patient, known allergies, or other conditions. Likewise, at least a portion of the professional information such as the name of the physician responsible for injecting the drug can optionally be retrieved from login data entered into the labeling terminal 10 by the physician when preparing the label 12. Yet additional information to be encoded for inclusion in the barcode 45 can also optionally be received by the labeling terminal 10 upon being manually entered by the operator using the touchscreen display 14 or other suitable computer input peripheral.

**[0039]** The labeling terminal 10 in FIG. 1 is operatively connected to communicate with a volume detector 47 via a wireless communication channel established by wireless access point 44, optionally over the network 1. According to alternate embodiments however, the labeling terminal 10 can communicate with the volume detector 47 via a hard-wired communication channel, optionally over the network 1. Generally, the volume detector senses of at least one of a starting volume of the drug originally within a syringe or other container, as prepared and before the patient is injected with the drug; the end of volume of the drug within the syringe or other container following injection of the drug into the patient using that syringe; and a difference between the starting volume and the end volume (i.e., the volume of the drug injected into the patient).

**[0040]** An illustrative embodiment of the volume detector 47 is shown in FIG. 3A, operatively connected to the labeling terminal 10 via a direct, hard-wired connection. According to the present embodiment, the volume detector 47 includes a scale 50 that detects a weight of a syringe 52 resting thereon. The syringe 52 is labeled with a label 12 produced using the labeling terminal 10 as described herein, and includes the barcode 45. The scale 50 in the present embodiment detects the weight of the syringe 52 with its

starting volume, as prepared and before any of the drug from the syringe 52 is injected into the patient. The scale 50 is also operable to detect the weight of the syringe 52 after the drug from within the syringe 52 is injected into the patient and the syringe is returned to the scale 50. A signal is transmitted to the labeling terminal 10, thereby allowing the labeling terminal 10 to calculate the change in volume of the drug within the syringe based on the difference between the weight of the syringe 52 before and after the drug is injected.

**[0041]** In use, the syringe 52 is labeled with a label 12 generated by the labeling terminal 10 as described above. When the drug in the prepared syringe 52 (i.e., storing the starting volume of the drug) is to be administered to the patient, the anesthesiologist logged into the labeling terminal 10 scans the barcode 45 provided to the label 12 using the scanner 18 and then places the prepared syringe 52 on the scale 50. For convenience, a peripheral scanner 18a (FIG. 3A) or other code reader can optionally be located adjacent to the scale 50, and operatively connected to transmit information obtained by scanning the barcode 45 to the labeling terminal 10. Yet other embodiments can include a separate display (not shown) adjacent to the scale 50, or provided to the scale 50, for displaying data obtained by scanning the barcode 45. However, to clearly describe the operation of the present embodiment, the scanner 18 and the display 14 of the labeling terminal 10 are to be utilized. At this time, an interface 49 such as that shown in FIG. 3B can be presented to the anesthesiologist by the display 14. As shown, the interface 49 includes the virtual label 16 having a visual appearance resembling the actual label 12 on the syringe, thereby providing the anesthesiologist with another opportunity to confirm that the drug in the syringe 52 is the proper drug to be injected.

**[0042]** The virtual label 16 in the present embodiment includes the following information that was obtained from the formulary 36 by the processing component 22 in response to the scanner the team interrogating a barcode on the file containing the drug in question: type of drug 51, drug name 54, a dilution indicator 57, concentration 59, and diluent 65. Additionally, the preparation date and time and the expiration date and time, referred to generally at 55, was obtained based on the system clock of the labeling terminal 10 when the label 12 was prepared. Similarly, the initials 61 of the person who prepared the label 12, and optionally the syringe 52, was determined by the labeling

terminal 10 based on the login information entered into the labeling terminal 10 by the anesthesiologist or other person who used the labeling terminal 10 to prepare the label 12. The human-readable (i.e., by eye, and without requiring a translation or other assistance of a computer) label content appearing on the label 12 is the same as that appearing on the virtual label 16. The barcode 45 provided to the label 12 and shown as part of the virtual label 16 uniquely identifies at least a portion, and optionally all of the label content 34 that appears in human-readable form on the label 12 and the virtual label 16.

**[0043]** In response to scanning the barcode 45 provided to the label 12 using the scanner 18, a “FILLED” soft key 67 and a “CONSUMED” soft key 69 are also presented as part of the interface 47 presented by the display 14. Upon receiving input indicating selection of the “FILLED” soft key 67 by the anesthesiologist, the labeling terminal 10 records the weight of the syringe 52 on the scale 50 with the starting volume. Similarly, upon receiving input indicating selection of the “CONSUMED” soft key 69 by the anesthesiologist, the labeling terminal 10 records the weight of the syringe 52 on the scale 50 with the end volume. The processing component 22 of the labeling terminal 10 can, based on the recorded weights of the syringe 52 as determined by the scale 50, calculate the volume of the drug administered to the patient. This can be accomplished by dividing the change in weight of the syringe 52 by the density of the drug in question, which can optionally also be included in the formulary 36 and automatically retrieved by the processing component 22 in response to scanning the barcode on the vial when the syringe 52 is filled with the drug, and optionally included in the barcode 45.

**[0044]** Additionally, the labeling terminal 10 can optionally record the time and/or date at which the weights of the syringe 52 are recorded, and can optionally create a record that includes at least one of: the volume of the drug administered as calculated above, the time and date at which the “CONSUMED” soft key 69 was selected, patient data such as information indicative of an identity of the patient, and information indicative of the anesthesiologists identity or the identity of another party responsible for administration of the drug. If the syringes 52 are not weighed immediately following use, they can be weighed after the procedure has concluded, and the approximate time of use can be manually entered using the touchscreen display 14. Regardless of how it is entered, this data can be transmitted over the network 12 to a remotely-located storage

location, which can be a server 71 (FIG. 1) optionally forming part of an Anesthesia Information Management System (“AIMS”), that records drug delivery information in combination with patient records.

**[0045]** The AIMS, also known as an ARKS (Anesthesia Record Keeping System), includes a server, represented generally at 71 in FIG. 1, that receives and stores drug usage information for each patient during a medical procedure to allow anesthesiologists to electronically record patient vital signs, drugs administered, important events that occurred during the surgery and other relevant information related to anesthesia administration and monitoring during a procedure. Many AIMS systems are programmed with a set of all drugs that could be administered in the operating room. This can be hundreds of drugs. Traditionally, when recording a drug delivery event in the AIMS 71, the user of the AIMS 71 was required to navigate through multiple levels of menus to find the correct drug, which is time consuming and takes attention away from the patient. However, according to the present embodiment, the labeling terminal 10 can optionally transmit to the AIMS 71 any portion, or all of the drug information encoded by the barcode 45, along with other data including at least one of: the weight difference of the syringe 52 when weighed before and after the drug is injected, the calculated volume of the drug injected, the information indicative of the identity of the patient and/or the anesthesiologist, the date and/or time at which the weights of the syringe 52 were taken, and any additional information received by the labeling terminal 10 from the anesthesiologist.

**[0046]** The labeling terminal 10 can also optionally keep a running log of the events that occur involving the labeling terminal 10. For instance, the time, date, anesthesiologist, drug and other related information can optionally be recorded by the labeling terminal 10 each time information is received by, and transmitted from the labeling terminal 10. The running long maintained by the labeling terminal 10 can optionally be transmitted occasionally, such as daily, at the end of the medical procedure, or other predetermined interval terminal storage location via the network one for documentation purposes. Accordingly, the running logs maintained by the labeling terminal 10 can also include entries documenting the weighing of the syringe 52 with a significant amount of the drug remaining. A significant amount of the drug can be

established as any quantity greater than a predetermined threshold minimum volume considered by the medical facility to be worth tracking, and can include syringes 52 for which a label 12 was prepared and filled with the drug but were not used during the medical procedure. The name of the anesthesiologist's possible for such syringe is 52 can also be recorded in the entries stored in the running log.

**[0047]** Recording the weights of the syringe 52 before and after the injection also enables the labeling terminal 10 to issue a warning if the calculated volume of the drug administered falls outside of acceptable limits. Since the acceptable limits can be dependent upon the weight of the patient, the patient's weight can optionally be included in the patient information received by the labeling terminal 10, and can be considered by the labeling terminal 10 in determining whether to issue a warning. For instance, the display 14 can present a warning to the anesthesiologist that the calculated quantity of the drug administered exceeds the quantity generally accepted to be considered safe for a particular patient. Further, if an insufficient amount of sleep agent is calculated to have been administered to an obese patient who is likely to require a greater quantity, the display 14 can also present such a warning. An optional speaker can be provided to the labeling terminal 10 to provide an audible warning to the anesthesiologist in such instances.

**[0048]** Although the volume detector 47 in the embodiment discussed with regard to FIG. 3 is shown in and described as including a scale 50, it is to be understood that the invention is not so limited. For example volume detector 47 can utilize a digital camera or other image capturing device that can optically observe the syringe 52 before and after the injection is made to visually determine the volume administered.

**[0049]** Another embodiment of a volume detector 47 is shown in FIGs. 4A and 4B. According to the present embodiment, the label content 34 printed by the labeling terminal 10 is printed onto a label substrate 81 that includes a differential capacitive sensor 84 adjacent to, or optionally exposed at the underside of the label 12 provided with an adhesive coating that secures the label 12 to the syringe 52. The label content 34 printed for the present embodiment can optionally include the same bits of information, different bits of information, than that shown for the label 12 appearing in FIG. 3B.



However it is to be understood that the label content 34 will include information reflective of the particular drug within the syringe 52. Thus, although the label content 34 shown as part of the virtual label 16 is for the drug succinylcholine, the types of information appearing in the label content 34 printed for other drugs can be similar, but the specifics related to the drug (e.g., drug name, etc...) will vary with the drugs contained in the different syringes 52, the dates and times those syringes 52 are prepared, the name of the person preparing those syringes 52, etc...

**[0050]** The capacitive sensor 84 shown in FIG. 4B includes opposing capacitive elements 86, 88 separated by a dielectric material 87. The opposing capacitive elements 86, 88 are each shaped and arranged relative to the other to have a primary sensing effect at opposite ends of the capacitive sensor 84. As shown, a first capacitive element 86 forms a large capacitive terminal adjacent to a left end 89 of the capacitive sensor 84. The second capacitive element 88 forms a relatively small capacitive (compared to the capacitive terminal formed by the first capacitive element 86 at the left end 89) terminal adjacent to the left end 89. Likewise the second capacitive sensor 88 forms a large capacitive terminal adjacent to a right end 90 of the capacitive sensor 84, while the first capacitive element 86 forms a relatively small (compared to the capacitive terminal formed by the second capacitive element 88 at the right end 90) capacitive terminal at the right end 90 of the capacitive sensor 84. Accordingly, the position of the liquid/air interface of the drug in the syringe 52 along the length (i.e., between the left and right ends 89, 90) of the capacitive sensor 84 can be determined by evaluating the capacitance sensed between the first and second capacitive elements 86, 88.

**[0051]** The label substrate 81 also a low-power, optionally nanowatt processor 92, for example, and a charge-holding capacitor 94 that stores an electric charge for powering the processor 92. Also provided is an antenna 96, such as an RFID coil for example, with which a code reader 98 can communicate to evaluate the capacitance sensed between the first and second capacitive elements 86, 88. The antenna 96 can be a passive device, meaning that the power needed to interrogate the antenna 96 and retrieve the data encoded thereby, can be supplied by an interrogation signal transmitted by the code reader. According to alternate embodiments, antenna 96 can be an active device,

and the power required to retrieve encoded information from the antenna 96 can optionally be supplied by the charge-holding capacitor 94.

**[0052]** For the embodiment shown in FIGs. 4A and 4B, the label content 34 that is to appear on the label 12 can be prepared and printed onto the label substrate 81 as described above. The label 12 is to be applied to the syringe such that a longitudinal axis of the capacitive sensor 84 extends substantially parallel to the longitudinal axis of the syringe 52. Thus, the capacitive sensor 84 is arranged lengthwise on the syringe 52 to measure a depth of the liquid in the syringe 52 when the syringe is held vertically upright with the needle 97 pointed downward.

**[0053]** In use, the barcode 45 printed on the label 12 by the labeling terminal 10 can be scanned by the barcode scanner 18 provided to the labeling terminal or disposed elsewhere in the environment where the drug is to be administered to the patient. Similar to the embodiments described above, the labeling terminal 10 can utilize the information encoded by the barcode 45 to identify the drug within the syringe 52 and present an interface similar to the interface 49 shown in FIG. 3B. Before making an injection with the syringe 52, the anesthesiologist can select the “FILLED” soft key 67 and position the syringe 52 in a substantially vertical orientation adjacent to the code reader 98, which in the present embodiment is a RFID reader. A stand or other support for holding the syringe 52 in a substantially-vertical orientation to promote an accurate reading of the liquid level in the syringe 52 by the capacitive sensor 84 can optionally be provided adjacent to the code reader 98. Interrogating the antenna 96 retrieves therefrom the capacitance measurement by the capacitive sensor 84 under the control of the processor 92.

**[0054]** Following injection of the drug into the patient with the syringe 52, the anesthesiologist can select the “CONSUMED” soft key 69 in the interface 49, and again position the syringe 52 adjacent to the code reader 98 in a substantially vertical orientation. In response to receiving the input of the “CONSUMED” soft key 69, the code reader 98 interrogates the antenna 96 once again to obtain a capacitance sensed by the capacitive sensor 84. The processing component 22 of the labeling terminal 10 can evaluate the capacitance sensed by the capacitive sensor 84 in each instance and relate the

sensed capacitances to different liquid levels within the syringe 52. The change in the liquid level in the syringe 52 is used by the processing component 22 to calculate the volume of the drug administered.

**[0055]** Just as for the embodiments described above, each event involving the labeling terminal 10 can be recorded in a running log, and associated with at least one of: the anesthesiologist logged in to the label terminal 10, patient-specific information and a timestamp. Additionally, the labeling terminal 10 can optionally record the time and/or date at which the capacitances corresponding to the liquid levels are recorded, and can optionally create a record that includes at least one of: the volume of the drug administered as calculated above, the time and date at which the “CONSUMED” soft key 69 was selected, patient data such as information indicative of an identity of the patient, and information indicative of the anesthesiologists identity or the identity of another party responsible for administration of the drug. This data, either as a record or separately, can be transmitted over the network 1 to a remotely-located storage location, which can be a server 71 (FIG. 1) optionally forming part of an Anesthesia Information Management System (“AIMS”), that records drug delivery information in combination with patient records. And again, non real time data (i.e., events that are not entered into the labeling terminal 10 as they occur – e.g., injection administered during the medical procedure but the capacitive sensor 84 is read at the end of the medical procedure) entered manually into the labeling terminal can also be included in the data transmitted.

**[0056]** Although the capacitive sensor 84 and related circuitry are described herein as being provided to the underside of a label substrate 81 on which the label content 34 is printed, it is to be understood that the capacitive sensor 84 and related circuitry can optionally be molded or otherwise formed as part of the syringe 52 itself, can be adhesively applied to the syringe as a placard on which a label 12 printed as described above can be applied, or otherwise applied to the syringe 52 without departing from the scope of the invention. Further, the label substrate 81 can be disposable, or reusable.

**[0057]** Another embodiment of the volume detector 47 is shown in FIGs. 5A-5B. According to the present embodiment, the label 12 bearing label content 34 can be

printed by referencing the formulary 36 with the labeling terminal 10 as described above. Just as before, the label content 34 can include a barcode 45 or other computer-readable code encoding at least a portion of the label content 34. The label 12 is applied to the syringe 52, but unlike the embodiment where the capacitive sensor 84 was provided to the label substrate 81, the label 12 is not necessarily required to be applied to the syringe 52 in any particular orientation. That is because the capacitive sensor 84 is not provided to the label 12 of the present embodiment. Instead, according to the present embodiment, the capacitive sensor 84 comprising the first and second capacitive elements 86, 88 can be provided adjacent to an interior surface 99 of a clip 100 that is to be releasably applied to the syringe 52.

**[0058]** The clip 100 includes a pair of arcuate shell segments 102, 104 that are spring biased to pivot about a hinge 105 by a torsion spring 106 or other suitable biasing device towards their closed positions. A handle 114 including an extension apertures from each shell segment 102, 104 can be squeezed by the anesthesiologist to open, or otherwise separate the shell segments 102, 104 allowing for insertion of the syringe 52. The radius of curvature of the arcuate portions 102, 104 can be approximately the same as the radius of curvature of a reservoir portion of the syringe 52 where the liquid drug is stored, but other embodiments can utilize shell segments 102, 104 of different shapes to accommodate the shape of the syringe 52, or having an arcuate surface with a substantially different radius of curvature than that of the syringe 52. The shell segment 102, 104 can extend a suitable distance along its radius of curvature such that when the shell segments 102, 104 are clamped together, they collectively extend at least halfway about the circumference of the syringe 52 as illustrated in FIG. 5A. However, distal ends 120 of the shell segments 102, 104 are separated from each other by a portion of the syringe 52 including graduation lines 122 that indicate volume increments along the length of the syringe 52. Thus, even with the clip 100 installed on the syringe 52, the graduation lines 122 remain visible.

**[0059]** Similar to the preceding embodiment, a low-power processor 92 can be provided to control a reading of the capacitive sensor 84, but instead of the charge-holding capacitor 94, a rechargeable battery 108 can be provided to supply the power needed by the processor 92 to conduct a measurement of the capacitance using the

passive sensor 84. A pair of charging contacts 110 is electrically connected to the battery 108 to conduct electricity supplied by a charging station 112 (FIG. 5D) for charging the battery 108. As shown, the charging station 112 includes a plurality of receptacles 114 that each receive and portion of a clip 100. Inside the receptacles 114 are charging contacts that cooperate with the charging contacts 110 provided to each clip 100 while the clips 100 are seated on the charging station 112.

**[0060]** In addition to charging the battery 108, the charging terminals 110 can optionally act as an input through which data to be delivered to the processor 92 can be transmitted. For such an embodiment, the charging station 112 can optionally be hard-wired or otherwise coupled to communicate with the labeling terminal 10 as shown in FIG. 1. Accordingly, as the label 12 is being prepared using the labeling terminal 10 as described above, at least one of the drug information, the patient information, any professional information can be transmitted to the processor 92 while the clip 100 is seated on the charging station 112. According to other embodiments, information to be transmitted to the processor 92 can optionally be input from the code reader 98 (FIG. 4A) via the antenna 96.

**[0061]** A multicolor light emitting diode (“LED”) 115 can optionally be embedded in one of the shell segments 102 to provide a visible indication of at least one of: an operational state of the clip 100, a rule established for use of the drug identified by the clip 100, and any other desired information that would be of use to the anesthesiologist administering the drug. For example, the LED 115 can emit a red light if the battery 108 is depleted below an acceptable charge level for use. As another example, the LED 115 can emit a green light to indicate that the clip 100 is sufficiently charged and functioning properly. Yet another example calls for the LED 115 on a clip 100 to be coupled to a syringe 52 containing a paralyzing agent to emit a purple light at a point during the medical procedure the patient is to be revived.

**[0062]** An antenna 96, which can also be a RFID antenna, is also provided to output the sensed capacitance when interrogated by a code reader 98 (FIG. 4A). But due to the added energy supplied by the battery 108 and the added space available to support electronic circuitry, the antenna 96 in the present embodiment can be an infrared (“IR”)

transmitter, an ultrasonic transmitter, and the like. Electric terminals establishing communication between the capacitive sensor 84 and the components on the opposite shell segment 102 can optionally be formed as part of the hinge 105, or metallic wiring can extend between the shell segments 102, 104.

**[0063]** In use, the clip 100 functions much like the embodiment of the label substrate 81 with the capacitive sensor 84 shown in FIG. 4B. The label 12 including the barcode 45 is printed using the label terminal 10 as described above and applied to the syringe 52. Due to the rigid nature of the shell segments 102, 104, however, the clip 100 is self aligning along the length of the syringe 52. In other words, a longitudinal axis of the capacitive sensor 84, will be substantially parallel with a longitudinal axis of the syringe 52 when the clip 100 is fully secured on the syringe 52. Care must be exercised when installing the clip 100, however, to ensure that the starting liquid level of the drug within the syringe 52 and the final liquid level of the drug within the syringe 52 both fall between opposite longitudinal ends of the capacitive sensor 84.

**[0064]** The barcode 45 is printed adjacent to the lateral end of the label 12. The length of the shell segments 102, 104 is long enough to extend along a substantial portion of the syringe 52, but leave the barcode 45 exposed. According to an alternate embodiment, the barcode 45 can be visible and scannable through a transparent portion of one or both of the shell segments 102, 104. At least a portion of the information encoded by the barcode 45 is also programmed into the processor 92 of the clip 100.

**[0065]** Prior to administering the injection, the anesthesiologist scans the barcode 45 using the scanner 18 provided to the labeling terminal 10 or another compatible scanner located adjacent to where the injection is to be administered. As described before with reference to FIG. 3B, the display 14 present the interface 49 to the anesthesiologist. The anesthesiologist orients the syringe 52 with the clip 100 in a substantially-vertical orientation and positions the clip 100 such that the antenna 96 is adjacent to the code reader 98 that is operatively connected to the labeling terminal 10. The anesthesiologist's selection of the "FILLED" soft key 67 initiates reception by the labeling terminal 10 of information indicative of a capacitance sensed by the capacitive sensor 84 with the liquid drug added starting volume. Following the injection, the

anesthesiologist can once again scan the barcode 45 using the scanner 18 or other code reader, select the “CONSUMED” soft key 69 and position the syringe 52 in a substantially-vertical orientation with the antenna 96 adjacent to the code reader 98. Based on the difference between the information received by interrogating the antenna 96 with the code reader 98 before and after the injection, the processing component 22 can obtain the volume of the drug injected.

**[0066]** According to alternate embodiments, the processor 92 can optionally initiate and control sensing of the capacitance using the capacitive sensor 84 occasionally while the clip 100 is in use. For example, the processor 92 provided to the clip 100 can occasionally, or periodically recorded a capacitance as sensed by the capacitive sensor 84. The capacitance can be sensed and recorded by the processor 92 once every 10 minutes, for example, and the sensed values stored in an embedded memory. After the injection has been administered, a significant change in the capacitance will also be recorded in the embedded memory. The capacitance value immediately before and immediately after the change of capacitance, a calculated volume of the drug administered determined by the processor 92, or any other information indicative of the volume of the drug administered, or any combination thereof can be transmitted by the processor 92 to the antenna 96, from where it can be detected by the code reader 98 and transmitted to the processing component 22 of the labeling terminal 10. According to alternate embodiments, rather than transmitting this information to the labeling terminal 10, it can be transmitted to another storage location on the network 1 such as the AIMS server 71 or other desired storage device where it can be stored for documentation purposes and optionally associated with at least one of drug data patient data and professional data.

**[0067]** Just as for the embodiments described above, each event involving the labeling terminal 10 can be recorded in a running log, and associated with at least one of: the anesthesiologist logged in to the label terminal 10, patient-specific information and a timestamp. Additionally, the labeling terminal 10 can optionally record the time and/or date at which the capacitances corresponding to the liquid levels are recorded, and can optionally create a record that includes at least one of: the volume of the drug administered as calculated above, the time and date at which the “CONSUMED” soft key

69 was selected, patient data such as information indicative of an identity of the patient, and information indicative of the anesthesiologists identity or the identity of another party responsible for administration of the drug. This data, either as a record or separately, can be transmitted over the network 1 to a remotely-located storage location, which can be a server 71 (FIG. 1) optionally forming part of the AIMS, that records drug delivery information in combination with patient records. And again, non real time data (i.e., events that are not entered into the labeling terminal 10 as they occur – e.g., injection administered during the medical procedure but the capacitive sensor 84 is read at the end of the medical procedure) entered manually into the labeling terminal 10 can also be included in the data transmitted.

**[0068]** Another embodiment of a clip 140 that can be utilized as a volume detector 47 is illustrated in FIGs. 6A-6D. As shown in FIG. 6A, the clip 140 includes an arcuate sleeve 142 that extends between distal ends 120 that extend about more than half of the circumference of the syringe 52. Similar to the clip 100 described above, the distal ends 120 of the clip 140 are separated by a portion of the syringe 52 bearing graduation lines 122 indicating volumetric increments along a length of the syringe 52. Unlike the previous embodiment of the clip 100, the clip 140 according to the present embodiment is not articulated, but instead forms a substantially rigid, single-piece arcuate sleeve. The radius of curvature of the arcuate sleeve is approximately the same as that of the syringe 52 to which it is coupled, allowing the clip 140 to be snapped in place onto the syringe 52, or slid on axially along a length of the syringe 52 passing over the needle 97. Since the clip 140 is not articulated like the clip 100 described above, the clip 140 can be formed having dimensions specific to certain sizes of syringes 52.

**[0069]** The clip also includes a flexible display region 145 such as an organic light emitting diode (“OLED”) screen, for example, or other suitable display that can substantially conform to the curvature of the clip 140. A charging station 112 can be operatively connected to the labeling terminal 10 (FIG. 1) to receive a plurality of the clips 140, thereby charging a battery 108 and optionally programming a processor 92 provided to the clip 140 via charging terminals 110 that cooperate with mating terminals provided to the charging station 112. Communications between the processor 92 in the labeling terminal 10 or other computer terminal provided with the code reader 98 is



facilitated by the antenna 96, or such communications can be facilitated via a hard-wired communication channel, such as the tether connecting the charging station 112 to the labeling terminal 10.

**[0070]** Unlike the embodiments discussed above, the clip 140 according to the present embodiment eliminates the need to print a label 12 to be applied to the syringe 52 using the labeling terminal 10. Instead, an onboard barcode scanner 18b, similar to the scanner 18 provided to the labeling terminal 10, is supported by the clip 140. The scanner 18 and/or the scanner 18b can interrogate a barcode provided to the vial containing the drug to be extracted into the syringe 52 and reference a limited formulary stored in an embedded memory provided to the processor 92. Alternatively, the clip 140 can communicate via the antenna 96 with the labeling terminal 10 or other network-connected computer terminal storing a formulary. The labeling terminal 10 or other computer terminal can then reference the formulary 36 stored in the memory 24 or other formulary, respectively, using the information received from the clip 140 to identify a matching drug entry in the formulary referenced and identify the drug being withdrawn into the syringe 52.

**[0071]** For embodiments where the clip 140 communicates with an external computer terminal, at least a portion of the matching drug entry including a name of the drug, the concentration, and optionally any other information included in the virtual label 16 in FIG. 3B, for example, can be transmitted back to the clip 140 and stored in the embedded memory. For embodiments where a limited, locally-stored formulary is referenced, the processor 92 can retrieve the matching without communicating with a remotely-located computer terminal. Regardless of how the drug corresponding to the barcode scanned using the scanner 18b is identified, the types of label content 34 appearing on the virtual label 16, or a portion thereof, shown in figure 3B can be displayed by the display region 145 on the clip 140. Communications from the labeling terminal 10 and/or from the clip 140 resulting from scanning the barcode, can be presented via the display 14 provided to the labeling terminal 10, via the display region 145 provided to the clip 140, or both. For instance, if it is determined, in response to scanning the barcode using the scanner 18b, then the matching entry in the formulary

cannot be found, the display 14 and the display region 145 can indicate the absence of the matching entry to the anesthesiologist.

**[0072]** The display region 145 can optionally be made touch-sensitive, allowing the anesthesiologist to input commands by contacting certain portions of the display region 145. The commands being input to the labeling terminal 10 via the touch screen display 14 can also optionally be input to the clip 140 via the display region 145. For example, the display region 145 can optionally display the “FILLED” and “CONSUMED” soft keys 67, 69 shown in FIG. 3B to indicate the status of the drug within the syringe 52 (i.e., before or after the injection). The display region 145 can optionally be made nonresponsive during times when the syringe 52 is in use to avoid inadvertent input being entered via the display region 145.

**[0073]** In use, the anesthesiologist can optionally couple the clip 142 the syringe 52 as part of the process of preparing the syringe 52 and extracting the drug from a vial. With the clip 140 in place on the syringe 52, the onboard scanner 18b and/or the scanner 18 provided to the labeling terminal 10 can be used to scan a barcode provided to, or accompanying the vial containing the drug to be extracted. If the onboard scanner 18b is utilized to scan the barcode, the processor 92 can optionally reference a limited, locally-stored formulary stored on an embedded memory or other flash memory supported by the clip 140 to locate any matching entries and identify the drug in question. Alternately, information indicative of the barcode scanned using the onboard scanner 18b can be transmitted by the processor 92 via the antenna 96 to a remotely located computer terminal, such as the labeling terminal 10 or the pharmacy computer 40 for example. The recipient computer terminal can reference a more complete formulary for any matching entries corresponding to the barcode that was scanned. Information corresponding to any matching entries uncovered by the recipient computer terminal can be transmitted back to the clip 140 and received via the antenna 96 and then transmitted to the processor 92.

**[0074]** Regardless of whether the matching drug entry was found locally or remotely, the virtual label 16 containing the label content 34 similar to that shown in FIG. 3B can be presented by the display region 145 on the clip 140. In the syringe 52 is filled with the drug, the user can input selection of the “FILLED” soft key 67 included in the

interface 49 presented by the display region 145 to indicate a pre-injection amount of the drug in the syringe 52. Similarly the anesthesiologist can input selection of the “CONSUMED” soft key 69 presented by the display region 145 after the injection has occurred to indicate the final volume of drug within the syringe 52.

**[0075]** The processor 92 can occasionally determine the capacitance sensed by the capacitive sensor 84 and the clip 140 and stored the sensed values of capacitance in the embedded memory or other local memory provided to the clip 140. The processor 92 can optionally also initiate a determination of the capacitance using the capacitive sensor 84 in response to selection of the “FILLED” soft key 67 in the “CONSUMED” soft key 69. Based on the sensed values of capacitance the processor 92 can consider the known dimensions of the syringe 52 to calculate the change in volume of the liquid drug therein. This change in volume corresponds to the amount of the drug injected, and can be displayed by the display region 145, and transmitted by the processor 92 from the antenna 96 to be received and stored by a remotely-located storage device on the network 1.

**[0076]** Just as for the embodiments described above, each event involving the labeling terminal 10, the clip 140, or other remotely-located terminal can be recorded in a running log, and associated with at least one of: the anesthesiologist logged in to the label terminal 10, patient-specific information and a timestamp. Additionally, the labeling terminal 10 can optionally record the time and/or date at which the capacitances corresponding to the liquid levels are recorded, and can optionally create a record that includes at least one of: the volume of the drug administered as calculated above, the time and date at which the “CONSUMED” soft key 69 was selected, patient data such as information indicative of an identity of the patient, and information indicative of the anesthesiologists identity or the identity of another party responsible for administration of the drug. This data, either as a record or separately, can be transmitted over the network 1 to a remotely-located storage location, which can be a server 71 (FIG. 1) optionally forming part of the AIMS, that records drug delivery information in combination with patient records. And again, non real time data (i.e., events that are not entered into the labeling terminal 10 as they occur – e.g., injection administered during the medical procedure but the capacitive sensor 84 is read at the end of the medical procedure)

entered manually into the labeling terminal can also be included in the data transmitted. Further, the data transmission can occur substantially in real-time as events occur, or occasionally such as when a medical procedure has concluded, at the end of each day, or at another predetermined time.

**[0077]** The above embodiments utilizing the capacitive sensor 84 to sense a liquid level at different times within the syringe 52 have relied on changes in capacitance sensed when air is present between the capacitive elements 86, 88 versus when a liquid drug is present. However it is to be understood that other embodiments of sensor that do not rely on capacitance, or do not rely on capacitance alone are also within the scope of the present invention. For example, a magnetically-sensitive sensor can be utilized to monitor the travel of a magnet embedded in a plunger of the syringe 52 yet other embodiments can utilize optical sensing by comparing an appearance of the drug within the syringe 52 before and after the injection is performed. For embodiments can utilize alter sonic monitoring of the liquid level within the syringe 52. According to such embodiments, the code reader 98 in FIG. 4A can optionally emit ultrasonic waves that reflect differently depending upon the liquid level within the syringe 52. All such embodiments, including those that are not specifically described above fall within the scope of the claims him are considered to be within the scope of the present disclosure.

**[0078]** A multicolor light emitting diode (“LED”) 115 can optionally be embedded in one of the shell segments 102 to provide a visible indication of at least one of: an operational state of the clip 100, a rule established for use of the drug identified by the clip 100, and any other desired information that would be of use to the anesthesiologist administering the drug. For example, the LED 115 can emit a red light if the battery 108 is depleted below an acceptable charge level for use. As another example, the LED 115 can emit a green light to indicate that the clip 100 is sufficiently charged and functioning properly. Yet another example calls for the LED 115 on a clip 100 to be coupled to a syringe 52 containing a paralyzing agent to emit a purple light at a point during the medical procedure the patient is to be revived.

**[0079]** Any of the embodiments utilizing the capacitive or other suitable sensor 84 to sense a change in the volume of the drug in the syringe 52 can optionally

transmit data to react to a situation where warning should be issued, such as when the calculated volume of the drug administered falls outside of acceptable limits. Since the acceptable limits can be dependent upon the weight of the patient, the patient's weight can optionally be included in the patient information received by the labeling terminal 10, and can be considered by the labeling terminal 10 in determining whether to issue a warning. For instance, the display 14 and/or the display region 145 can present a warning to the anesthesiologist that the calculated quantity of the drug administered exceeds the quantity generally accepted to be considered safe for a particular patient. Further, if an insufficient amount of sleep agent is calculated to have been administered to an obese patient who is likely to require a greater quantity, the display 14 can also present such a warning.

**[0080]** Further, non real time data (i.e., events that are not entered into, or transmitted to the labeling terminal 10 as they occur – e.g., injection administered during the medical procedure but the capacitive sensor 84 is read at the end of the medical procedure) entered manually into the labeling terminal can also be included in the data transmitted.

**[0081]** In addition to labeling the syringe 52 is described above the label 12 can be prepared with the computer readable code, described herein as a barcode 45, to label other objects used in the medical field to administer a drug to a patient. For example, the labeling terminal 10 can be used to generate a label 12 including a barcode 45, or other machine-readable code, for programming an automated drug delivery device, referred to herein as a syringe pump 200 shown in FIG. 7. A physician can prescribe a drug at a specific dose for a particular patient, to be administered over time via the syringe pump 200. The prescription can: be electronically transmitted to the labeling terminal 10 via the network 1, include a sheet of paper bearing a barcode to be scanned using the scanner 18 provided to the labeling terminal 10, and/or manually keyed into the labeling terminal 10 using the touchscreen display 14 or a connected to the computer keyboard or similar peripheral

**[0082]** To prepare the syringe 52, the barcode label on the drug vial is scanned using the scanner 18, the encoded information obtained from scanning the barcode is

used to conduct a query of the formulary 36 stored in the memory 24 in an attempt to identify a matching entries. The virtual label 16 is presented via the display 14 for visual confirmation that the label content 34 is accurate, the label content 34 including the barcode 45 is printed on the label 12, and the label 12 is applied to a syringe 52. The drug identified by the label 12 is drawn into the syringe 52 and the syringe 52 is transported to a site such as the intensive care unit of the medical facility where it is to be administered to a patient via an automated drug delivery device such as a syringe pump.

**[0083]** The barcode 45 included in the label content 34 of the label 12 includes at least the following information: drug name, information indicating an identity of the person who prepared the syringe 52, the date and/or time that the syringe 52 was prepared, the concentration and/or dose of the drug, the expiration date and/or time of the syringe 52, prescribed delivery date, at least one, and optionally a plurality or all of the syringe pump programming parameters required to be entered to the syringe pump 200 to deliver the drug as prescribed, and the patient name and/or patient ID number.

**[0084]** The syringe pump 200 of FIG. 7 includes a delivery site scanner 202 that can be a portable device for scanning a patient's wristband 206 or other identifying information including a patient barcode 208, and optionally a built-in scanner 204 that is integrally included as part of the syringe pump 200. In response to scanning the patient's barcode 208 and the barcode 45 on the label 12 provided to the syringe 52 a processing component of the scanner(s) 202 and/or 204 compares the patient information included in the label content 34 and optionally encoded by the barcode 45 to the patient information (e.g., patient ID) extracted from the patient barcode 208 to make sure the dates match. Further, the processing component of the delivery site scanner 202 also compares the expiration date indicated by the barcode 45 extends beyond the date and/or time at which the delivery of the drug in the syringe 52 is to be completed, and that the prescribed delivery date matches the current date.

**[0085]** If the above checks are successful, the delivery site scanner 202 transmits a signal to the processing component of the syringe pump 200, requesting the pump 200 to activate, deactivate or both activate and deactivate a feature of the syringe pump 200. For example, the request transmitted by the delivery site scanner 202 can

cause the processing component of the syringe pump 200 to turn a light 215 provided to the syringe pump 200 on, off or flashing on and off thereby identifying the syringe pump 200 that is operatively connected to, and communicating with the delivery site scanner 202 while being programmed. Such a feature is useful when there are a plurality of syringe pumps 200 supported by a single stand, commonly referred to as a tree. There may be several IV lines suspended from the syringe pumps on the tree, causing confusion as to which of the IV lines the actual syringe pump 200 that is to receive the syringe 52 is connected. Activation of the feature helps to distinguish the syringe pump 200 that is to receive the syringe 52 from those that are not.

**[0086]** The processing component of the delivery site scanner 202 communicates with the syringe pump 200 through a receiver 220. The receiver 220 can be a wireless pump receiver (e.g. Dongle) that can be attached to the pump's digital interface (e.g. RS-232 port). The Dongle can communicate with the pump 200 using the pump's digital interface. The Dongle can also communicate wirelessly with the delivery site scanner 202. The Dongle can contain unique primary identification information that is an integral part of the device. This identification information allows wireless communications received by the Dongle or transmitted to the Dongle to be recognized as being associated with that particular Dongle.

**[0087]** A barcode 225 containing unique secondary identification information can also be attached to the Dongle. The barcode on the Dongle can be scanned by the delivery site scanner 202, thereby creating a temporary communication association between the delivery site scanner 202 and the Dongle attached to the pump 200. This association will ensure the appropriate syringe pump 200 is the only device exchanging information with the delivery site scanner 202 for the duration of the association. When an association is made between the delivery site scanner 202 and the Dongle attached to the syringe pump 200, at least one of a visual or audio indication of the association can be displayed by the delivery site scanner 202 to provide an indication to the user that the association is currently active.

**[0088]** An existing association can be terminated by one or more of the following methods; creating a new association between the delivery site scanner 202 and

another Dongle attached to a different pump; or manually by the user; or by completing the programming or desired interaction with the syringe pump 200; or by a timeout that is triggered when the syringe pump 200 is not programmed after a configurable period of time.

**[0089]** The information exchanged between the delivery site scanner 202 and the receiver 220 can be bi-directional. It can include status information transmitted from the pump 200 to the delivery site scanner 202 including any programming information already in use by the pump 200. It can also include status information transmitted from the pump 200 to the delivery site scanner 202 indicating the pump 200 is ready for new programming. The delivery site scanner 202 can transmit information to the pump 200 that includes programming information for the pump 200 extracted from the barcode 45 scanned by the delivery site scanner 202.

**[0090]** Also, a Line Identifier 217 can optionally be included to further ensure that the proper pump 200 is selected. For example, a color coded plastic clip can be provided to match the color of a sticker on the pump 200.

**[0091]** If the light 215 serving as the Device Identification Lamp is not available on the device, the delivery site barcode scanner 202 requires the clinician to scan a Device Identification Barcode 222 attached to the syringe pump 20 for verification that it is the correct device.

**[0092]** As mentioned above, barcode scanner 202 can also optionally be built into the syringe pump 200. This would eliminate the need for identifying the correct pump 200 with which the user wishes to communicate wirelessly. For example, a scanner module can be plugged into the pump's RS-232 port and mounts to the side of the pump 200 via an adhesive or mechanical fastener. Such a built-in scanner can optionally be trained on a location where the barcode 45 would be located when the syringe 52 is received by the pump 200.

**[0093]** The delivery site scanner 202, via the Pump Receiver, electronically transmits the programming parameters for operation of the pump 10, including rate and total volume, for example. An optional display 230 on the delivery site scanner 202 can display instructions guiding the clinician through the procedure and displays confirmation



that each step was correct. It could display, drug name, patient name, rate, volume, warnings, etc., and may also be accompanied by an audio output from a speaker or output port provided to the delivery site scanner 202. The display 230 can present to the clinician what will be programmed into the pump 20, for example, "For patient 1234, Propofol, 50ml total volume at 1ml per minute, please confirm" can be displayed along with a soft key or tactile button that requires the user's input before programming begins.

**[0094]** The display 230 and/or audio output can also optionally issue warnings are issued if the parameters to be programmed are outside of acceptable parameters. For example, a warning can be issued if the volume exceeds guardrails set (limits), which may be a function of patient weight, that can be determined by the delivery site scanner 202 in response to scanning the patient's barcode 208.

**[0095]** The wireless, network connected delivery site scanner 202 could also optionally communicate with a networked storage server to record events, such as: time, date, dose, drug, patient, etc. for every patient on every IV pump in the medical facility. And similar to the discussion above regarding the use of the barcode to label syringes 52, filled, but unused syringes can be documented and entered into a running log.

**[0096]** This invention is not limited to barcodes, and other computer-readable codes such as RFID, etc. could be utilized. Further, not only syringe pumps can be programmed in this manner, but also smart pumps, etc. could be programmed.

**[0097]** Illustrative embodiments have been described, hereinabove. It will be apparent to those skilled in the art that the above devices and methods may incorporate changes and modifications without departing from the general scope of this invention. It is intended to include all such modifications and alterations within the scope of the present invention. Furthermore, to the extent that the term "includes" is used in either the detailed description or the claims, such term is intended to be inclusive in a manner similar to the term "comprising" as "comprising" is interpreted when employed as a transitional word in a claim.

## CLAIM(S)

What is claimed is:

1. A system for printing a label identifying a medicinal substance, the system comprising:

a code reader that interrogates a computer-readable code corresponding to a source container of the medicinal substance at a time when the medicinal substance is to be extracted from the source container and inserted into a delivery container used to administer the medicinal substance to a patient;

a non-transitory, local computer-readable memory that stores a drug formulary comprising a plurality of entries, including an entry for the medicinal substance;

a processing component that identifies, from the formulary, the medicinal substance that corresponds to the computer-readable code read by the code reader;

a printer for printing label content identifying the medicinal substance identified by the processing component onto a label that is to be applied to the delivery container, the label content including a barcode encoding the identity of the medicinal substance;

a quantity detector that senses a property indicative of a quantity of the medicinal substance administered to the patient in real time, approximately at a time when the medicinal substance is administered to the patient, and transmits a signal indicative of the property sensed, wherein the property sensed is utilized by the processing component to determine the quantity of the medicinal substance administered to the patient; and

a network component that transmits the quantity of the medicinal substance administered to the patient over the communication network to be stored by a remotely-located non-transitory computer memory associated with a medical record of the patient.

2. The system of claim 1, wherein the label content printed by the printer includes patient information encoded in a machine-readable format indicative of an identity of the patient to which the medicinal substance is to be delivered.

3. The system of claim 1, wherein the quantity detector comprises a scale that senses a weight of the medicinal substance in the delivery container before and after the medicinal substance is administered to the patient.

4. The system of claim 1, wherein the quantity detector comprises an optical imaging sensor that captures an image of the delivery container storing the medicinal substance and transmits the signal indicative of the image to be utilized by the processing component to determine the quantity of the medicinal substance administered to the patient.

5. The system of claim 1, wherein the quantity detector comprises a capacitive sensor that senses a change of capacitance adjacent to the delivery container storing the medicinal substance and transmits the signal indicative of the change of capacitance to be utilized by the processing component to determine the quantity of the medicinal substance administered to the patient.

6. The system of claim 1 further comprising a warning component that issues a warning indicating that the quantity of the medicinal substance administered to the patient is different than a predetermined quantity of the medicinal substance desired to be administered to the patient.

7. The system of claim 1, wherein the quantity of the medicinal substance comprises at least one of a volume and a weight of the medicinal substance.

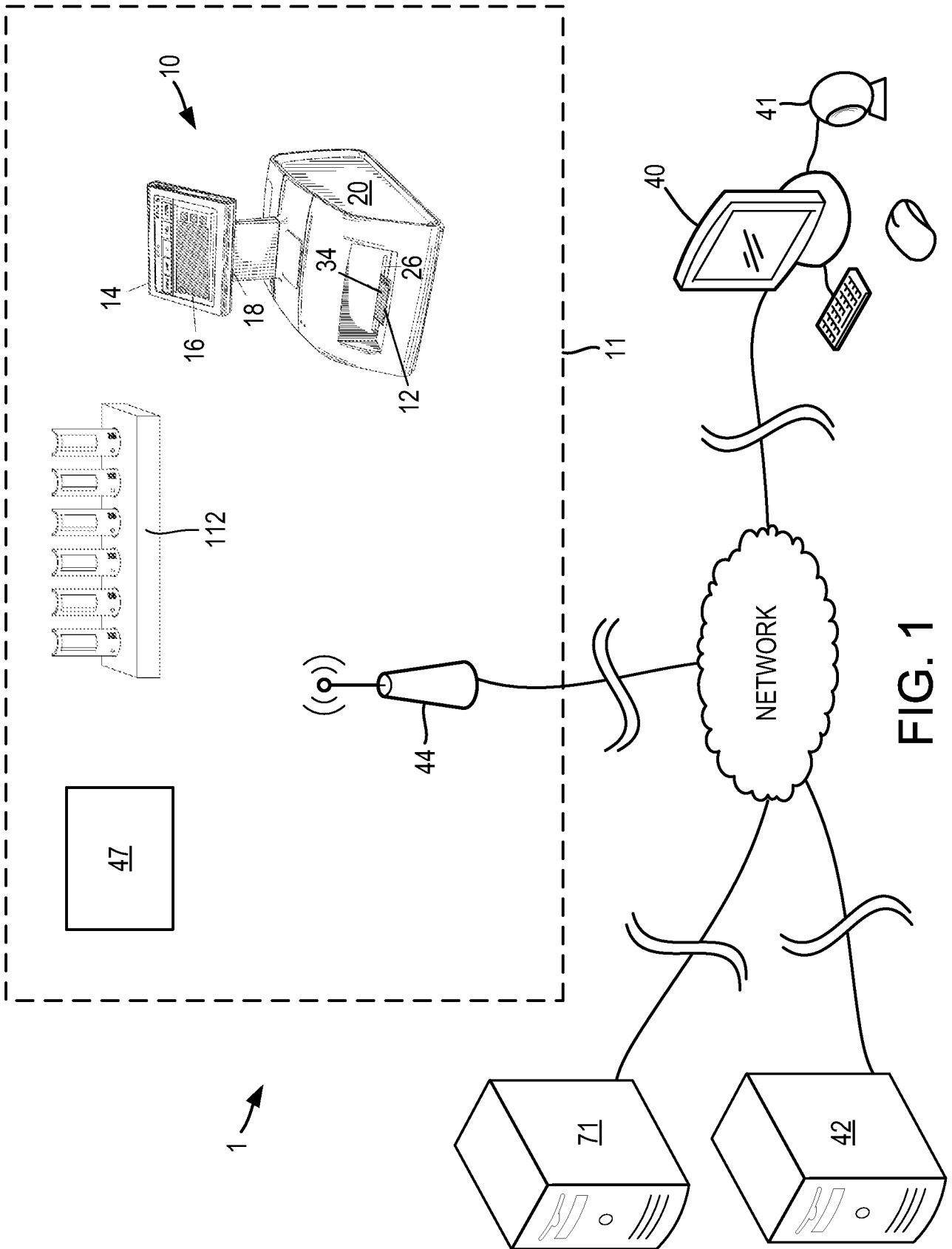


FIG. 1

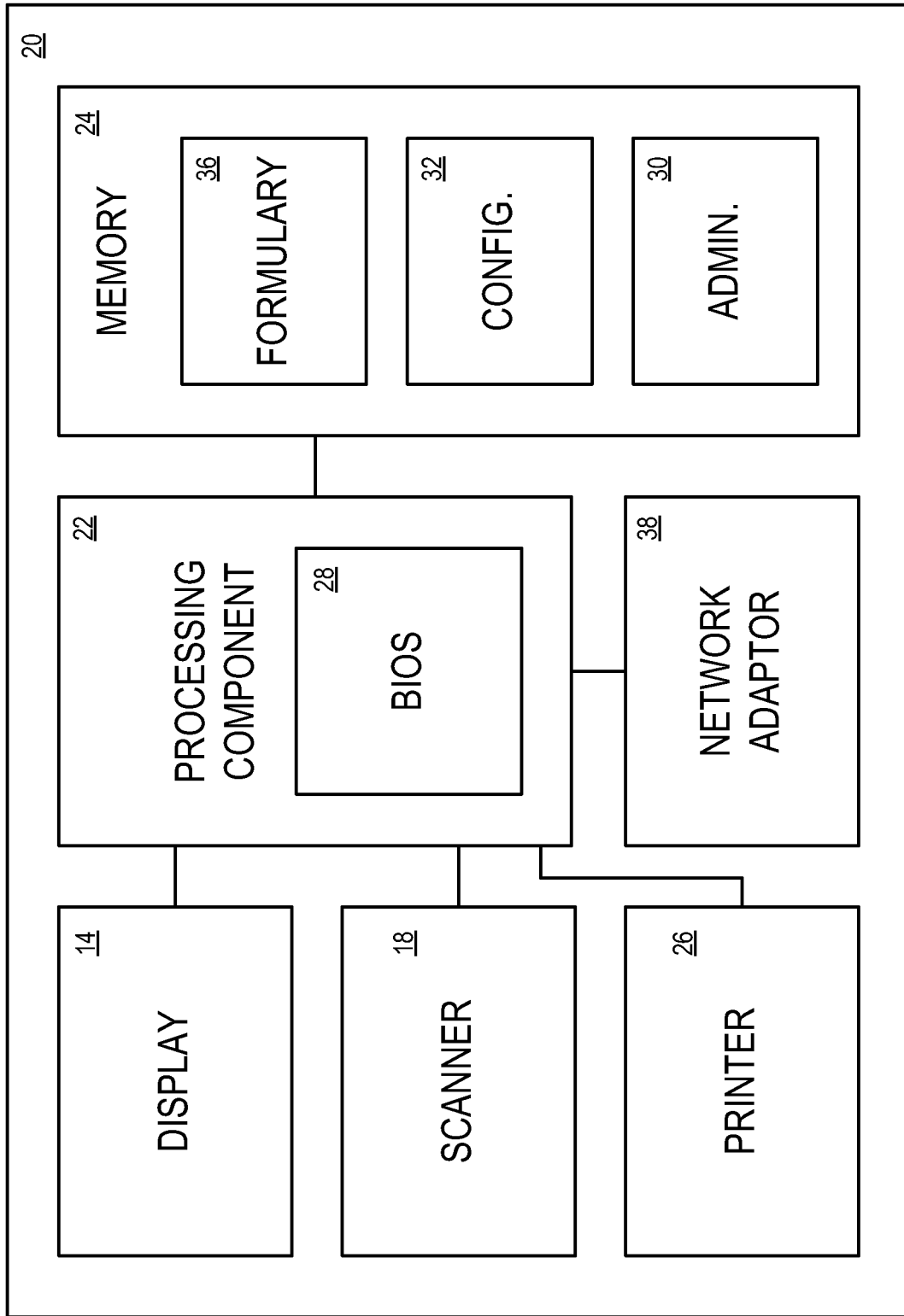
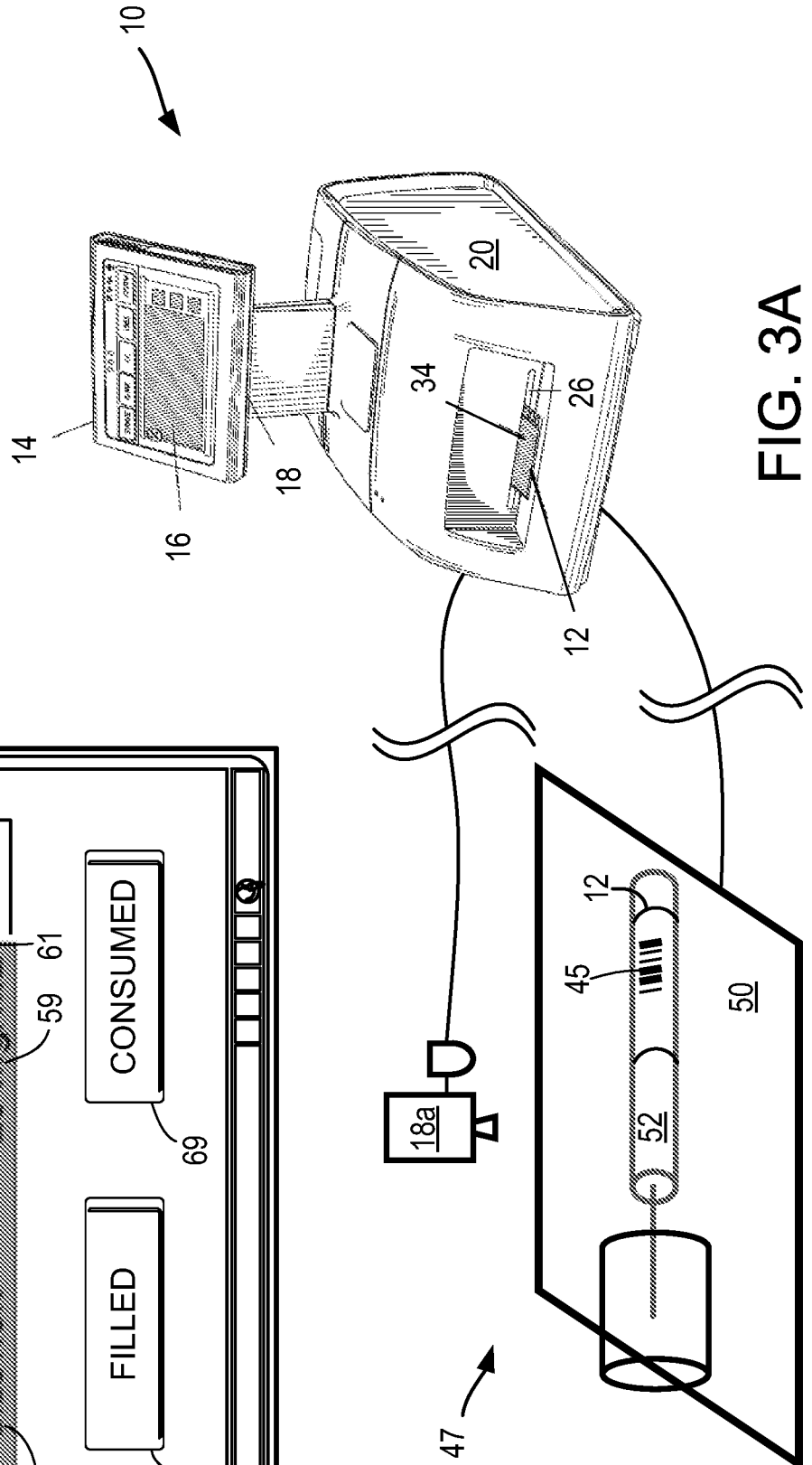
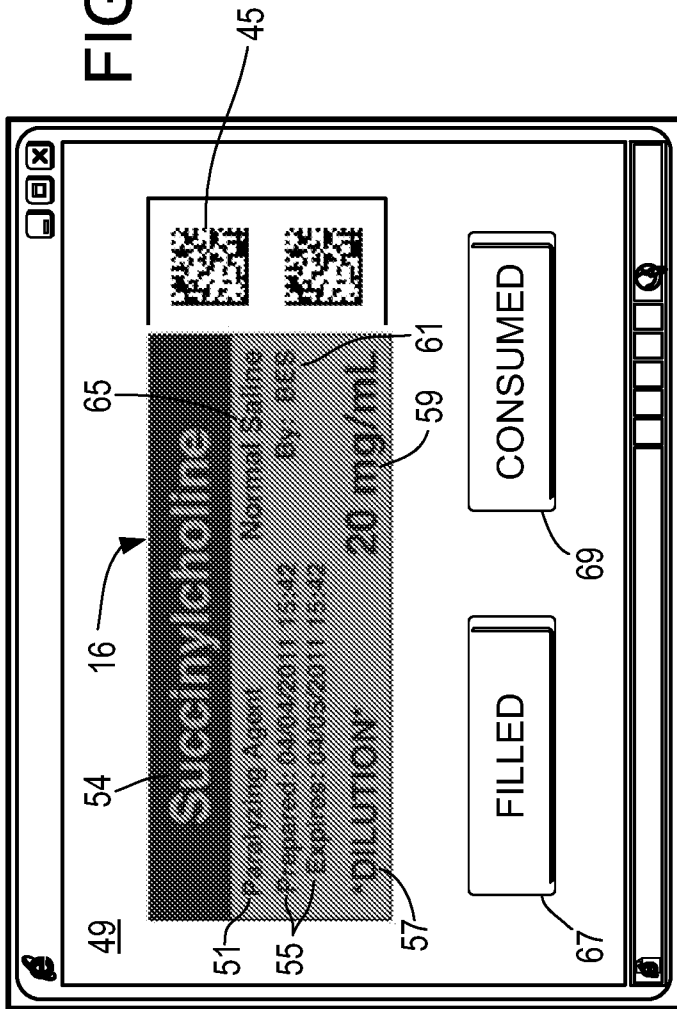
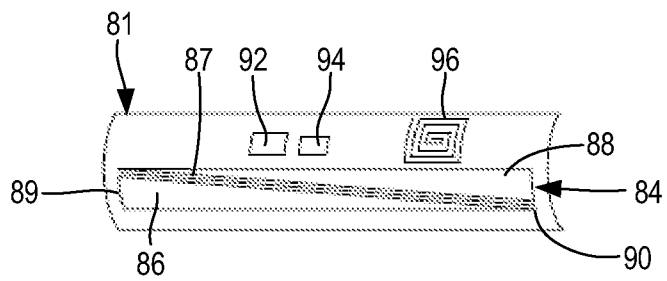
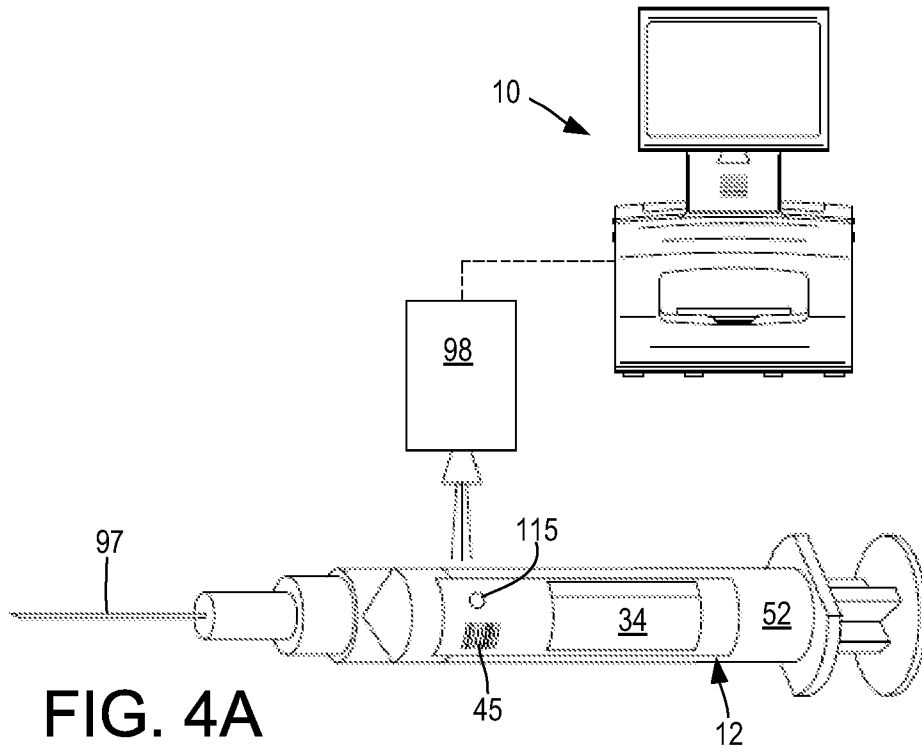


FIG. 2





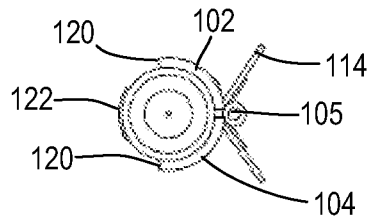


FIG. 5A

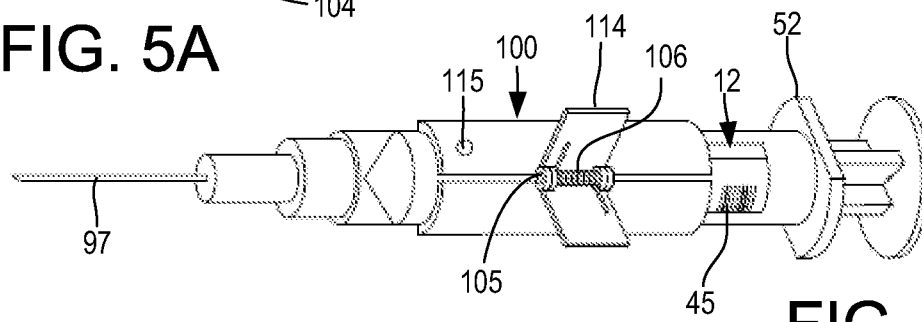


FIG. 5B

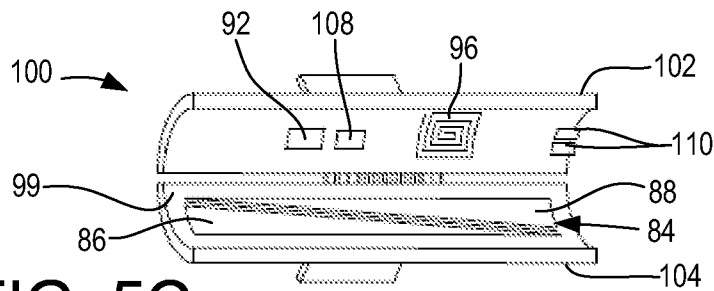


FIG. 5C

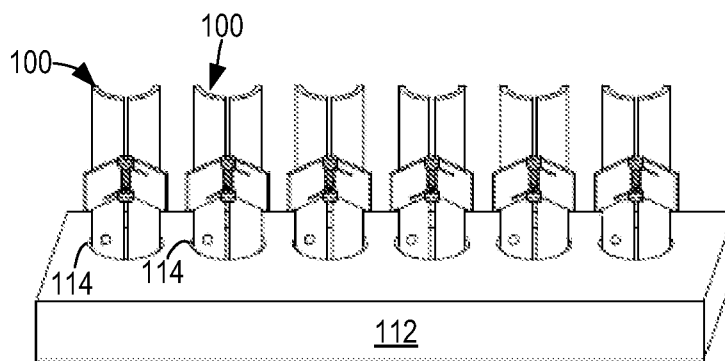
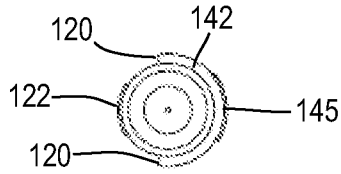
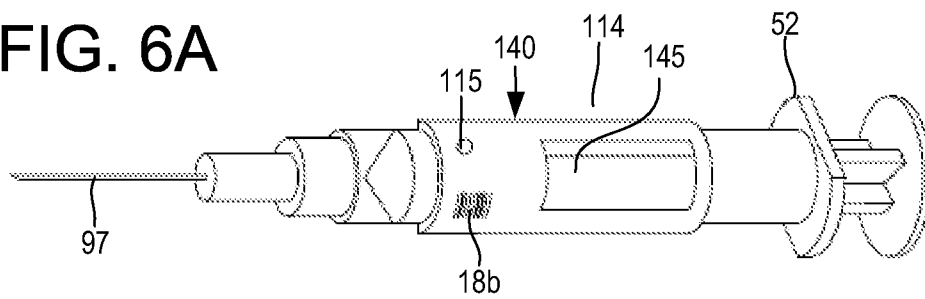


FIG. 5D

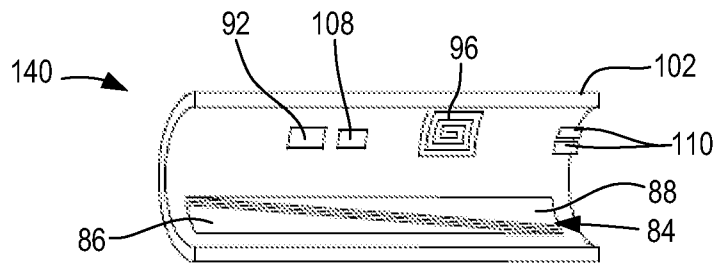




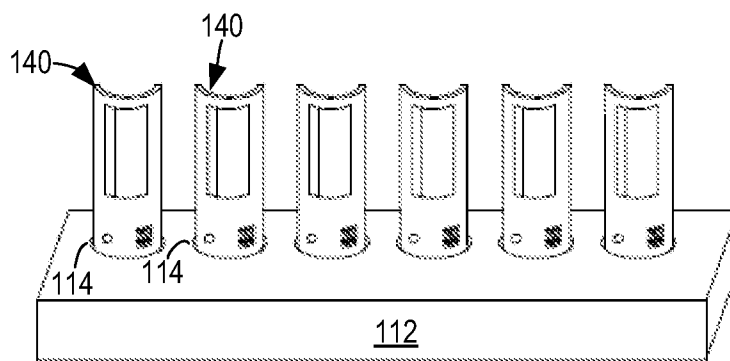
**FIG. 6A**



**FIG. 6B**



**FIG. 6C**



**FIG. 6D**

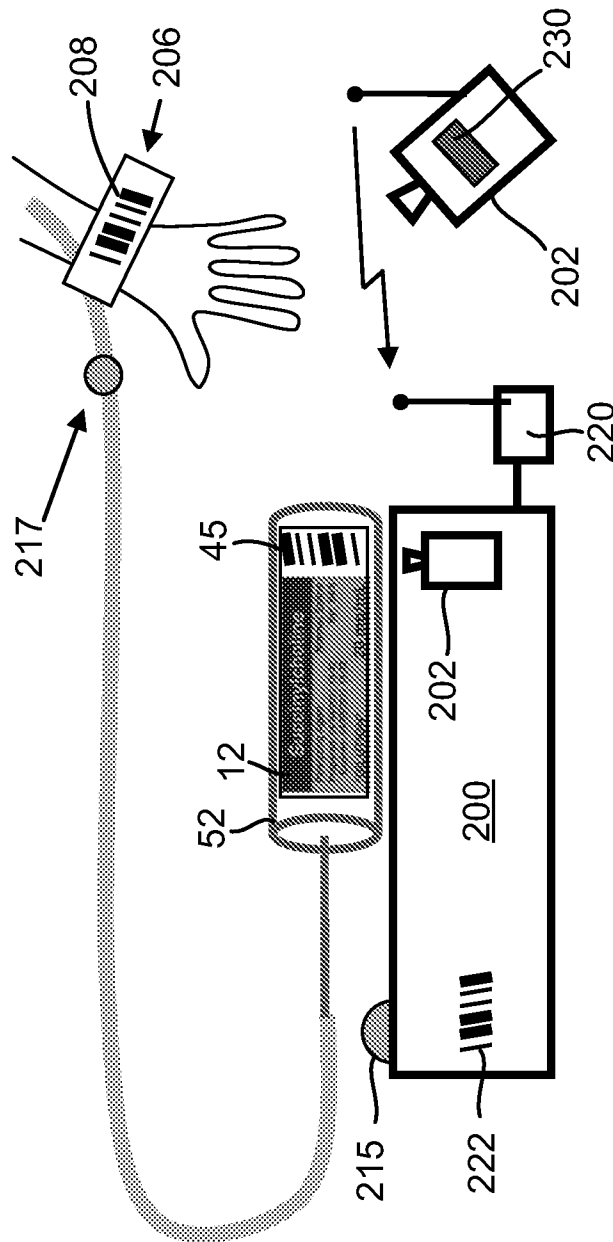


FIG. 7

**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/US 2013/024779

A. CLASSIFICATION OF SUBJECT MATTER **G06K 3/02 (2006.01)**

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)

G06Q 50/00, 50/10, 50/22, G09F 3/00, G06F 17/00, G06K 1/00-1/22, 3/00-3/02

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 practicable, search terms used)

Esp@cenet, DWPI, PAJ, USPTO, RUPTO

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2011/0093279 A1 (WILTON C. LEVINE et al.) 21.04.2011	1-7
A	US 2008/0314978 A1 (UNIVERSITY HEALTH NETWORK et al.) 25.12.2008	1-7
A	WO 2009/012371 A2 (INRANGE SYSTEMS INC et al.) 22.01.2009	1-7
A	US 2004133305 A1 (STRATAMED LABS INC) 08.07.2004	1-7

Further documents are listed in the continuation of Box C.

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

23 May 2013 (23.05.2013)

Date of mailing of the international search report

14 June 2013 (14.06.2013)

Name and mailing address of the ISA/ FIPS  
Russia, 123995, Moscow, G-59, GSP-5,  
Berezhkovskaya nab., 30-1

Facsimile No. +7 (499) 243-33-37

Authorized officer

T. Zelenova

Telephone No. 8(495)531-64-81