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Blomquist

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(54) **INTERFACE FOR MEDICAL INFUSION PUMP**

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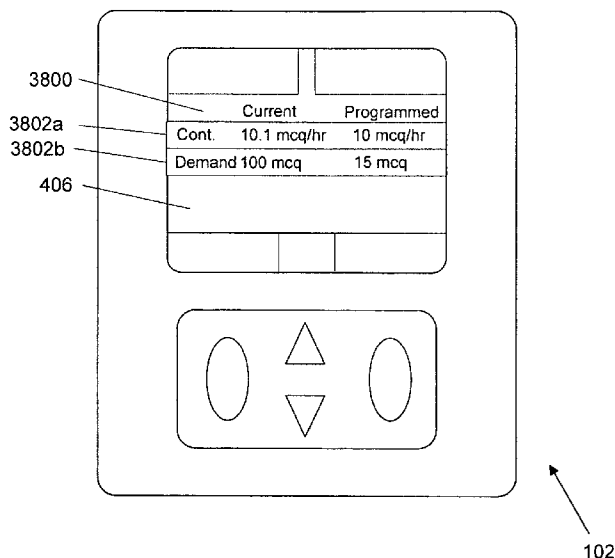
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(57) **ABSTRACT**

An apparatus and method for indicating a change in operation of a medical infusion pump includes a memory configured to store an original pump parameter and a current pump parameter. The apparatus further includes a programmable circuit in electrical communication with the memory, the programmable circuit programmed to display the original pump parameter and the current pump parameter.

25 Claims, 41 Drawing Sheets



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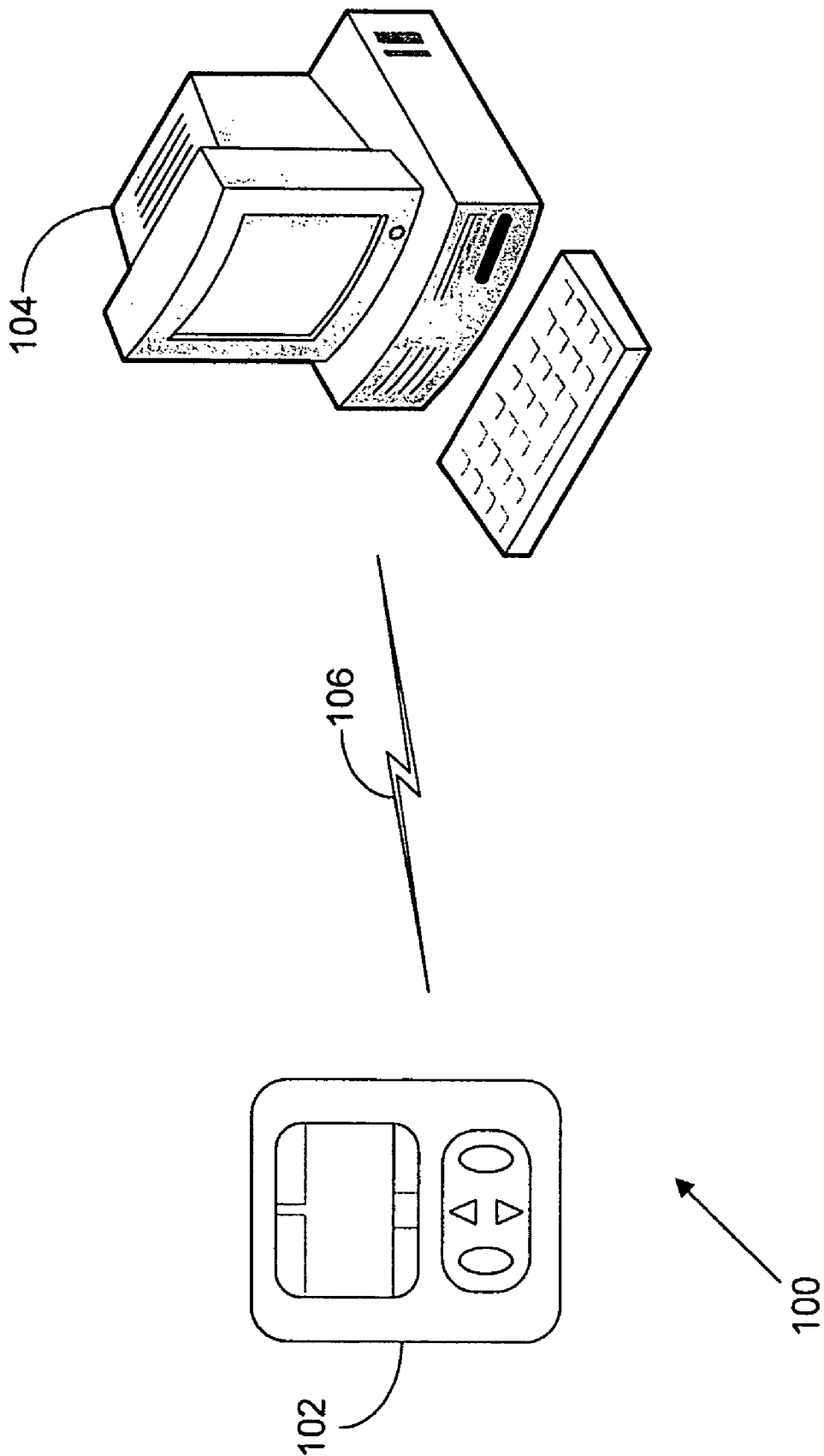


FIG. 1

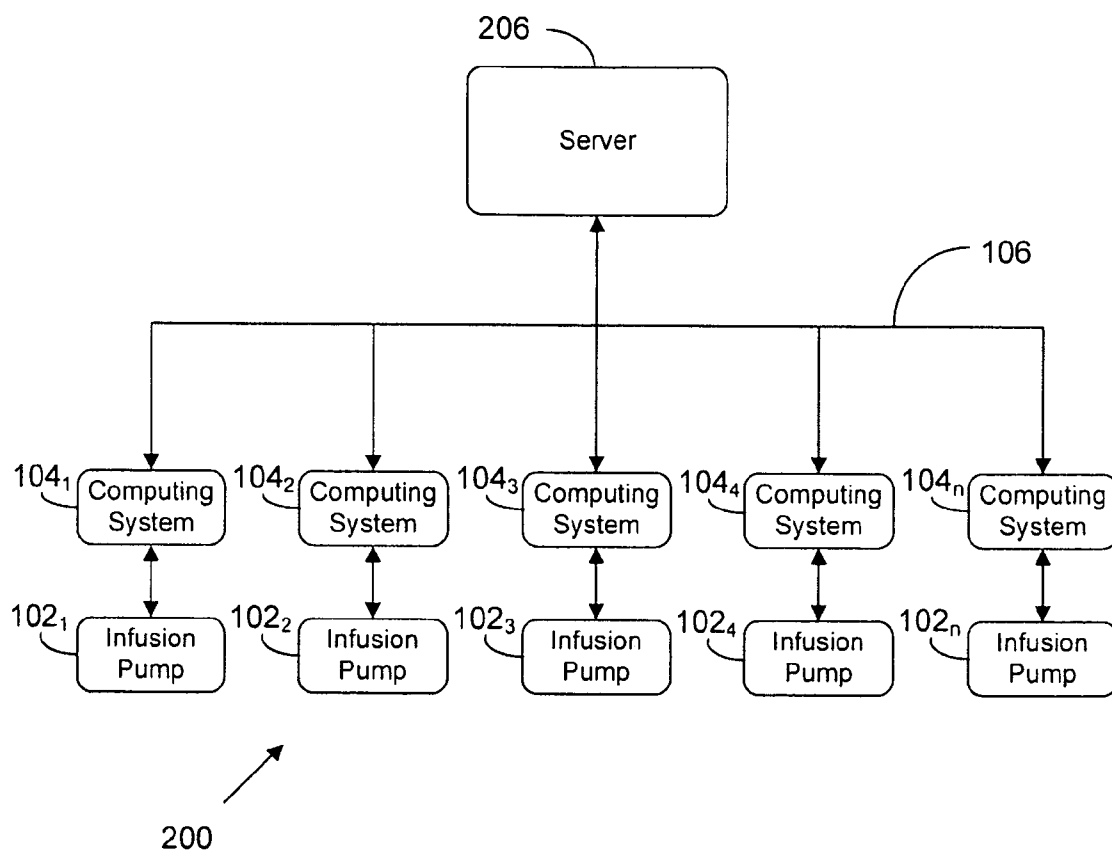


FIG. 2

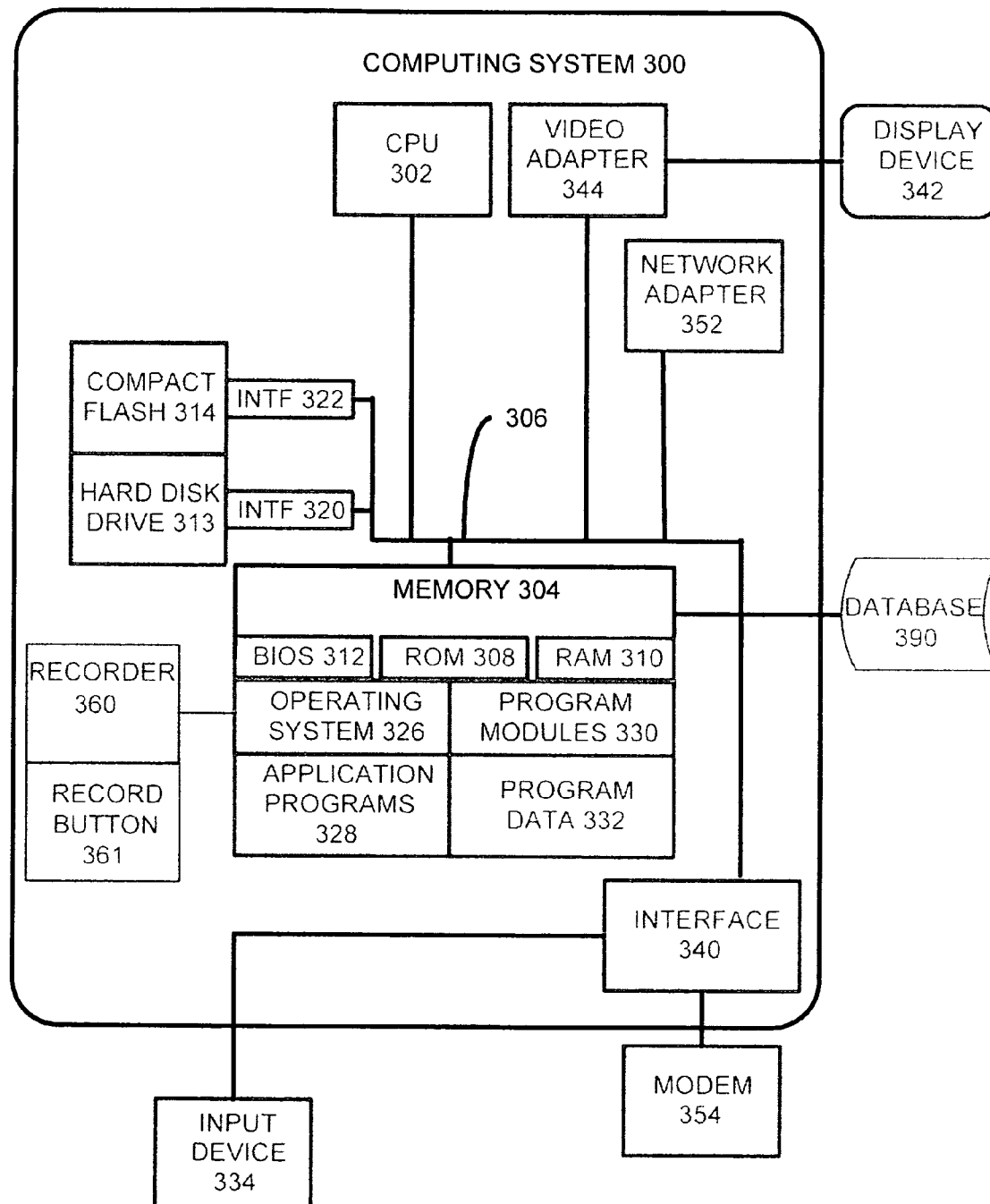


FIG. 3

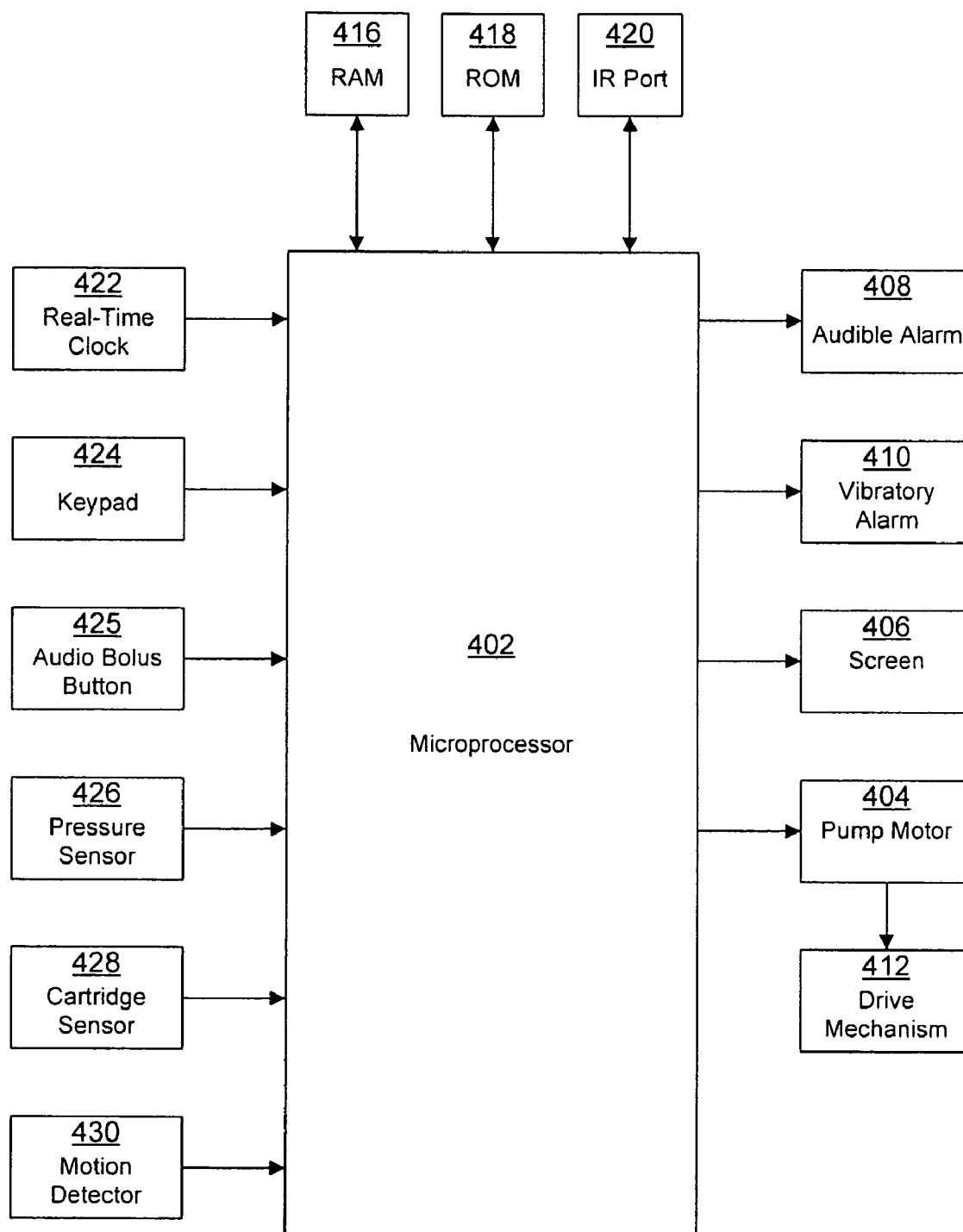
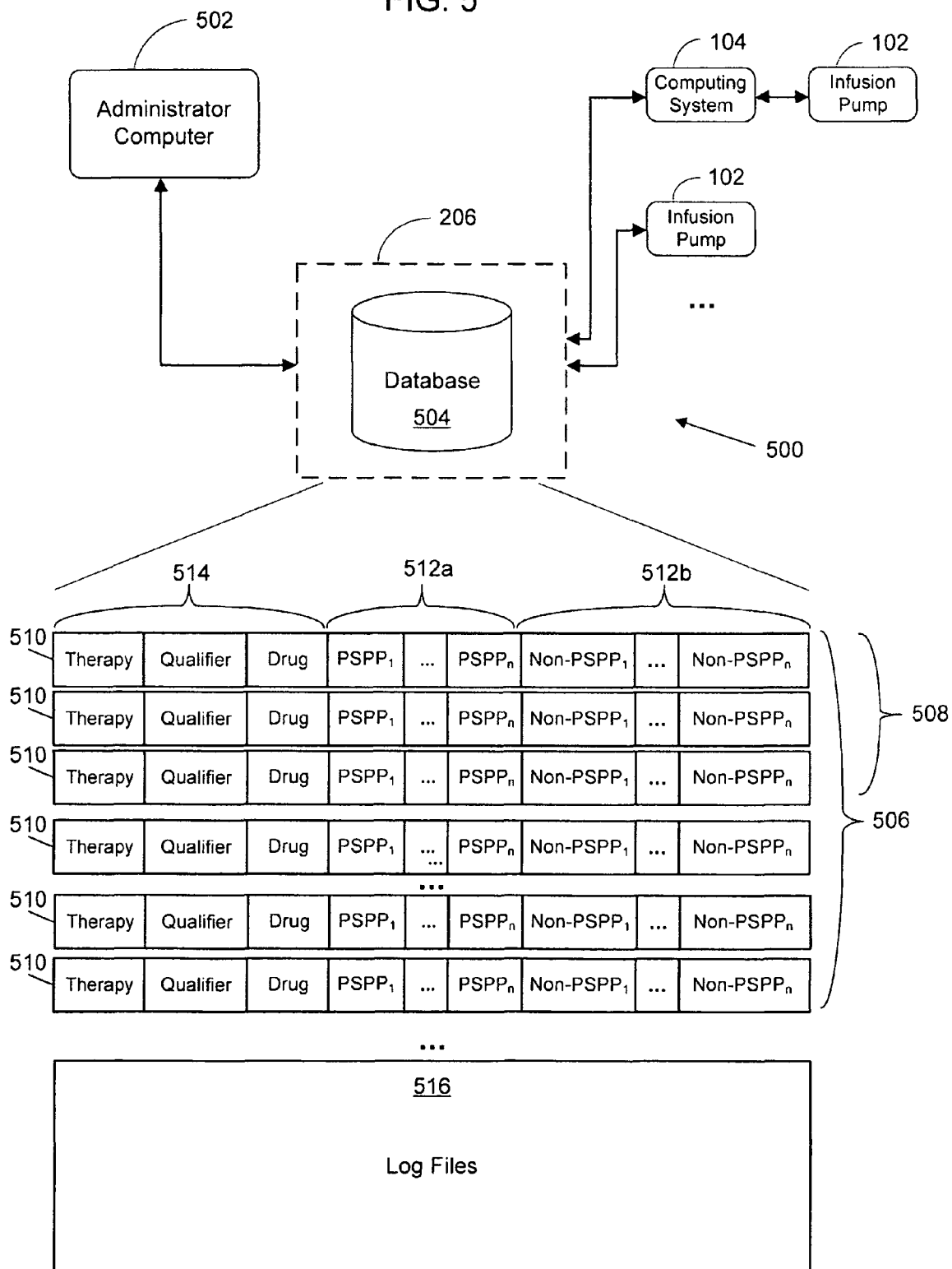


FIG. 4

FIG. 5



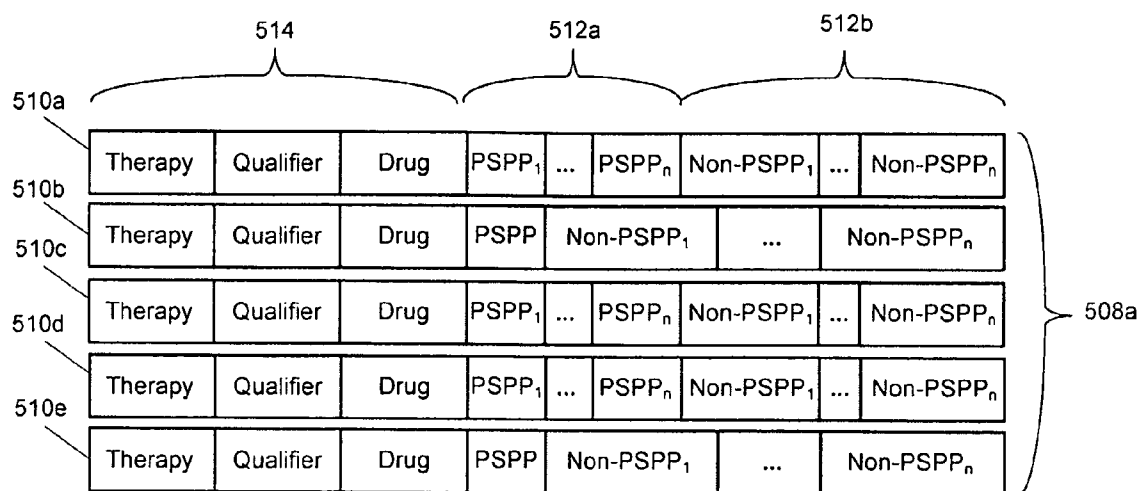


FIG. 6A

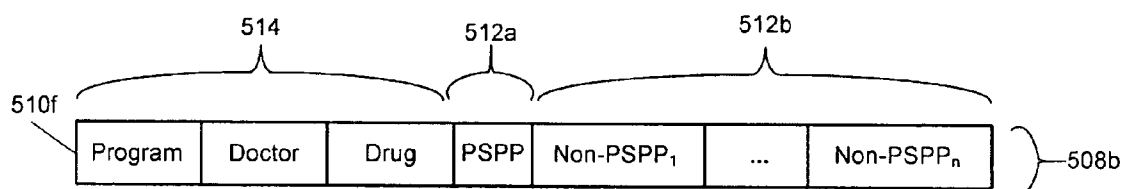


FIG. 6B

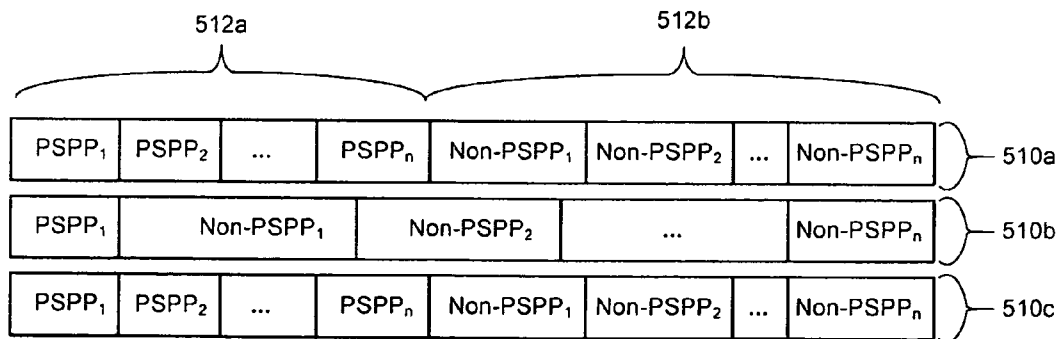


FIG. 6C

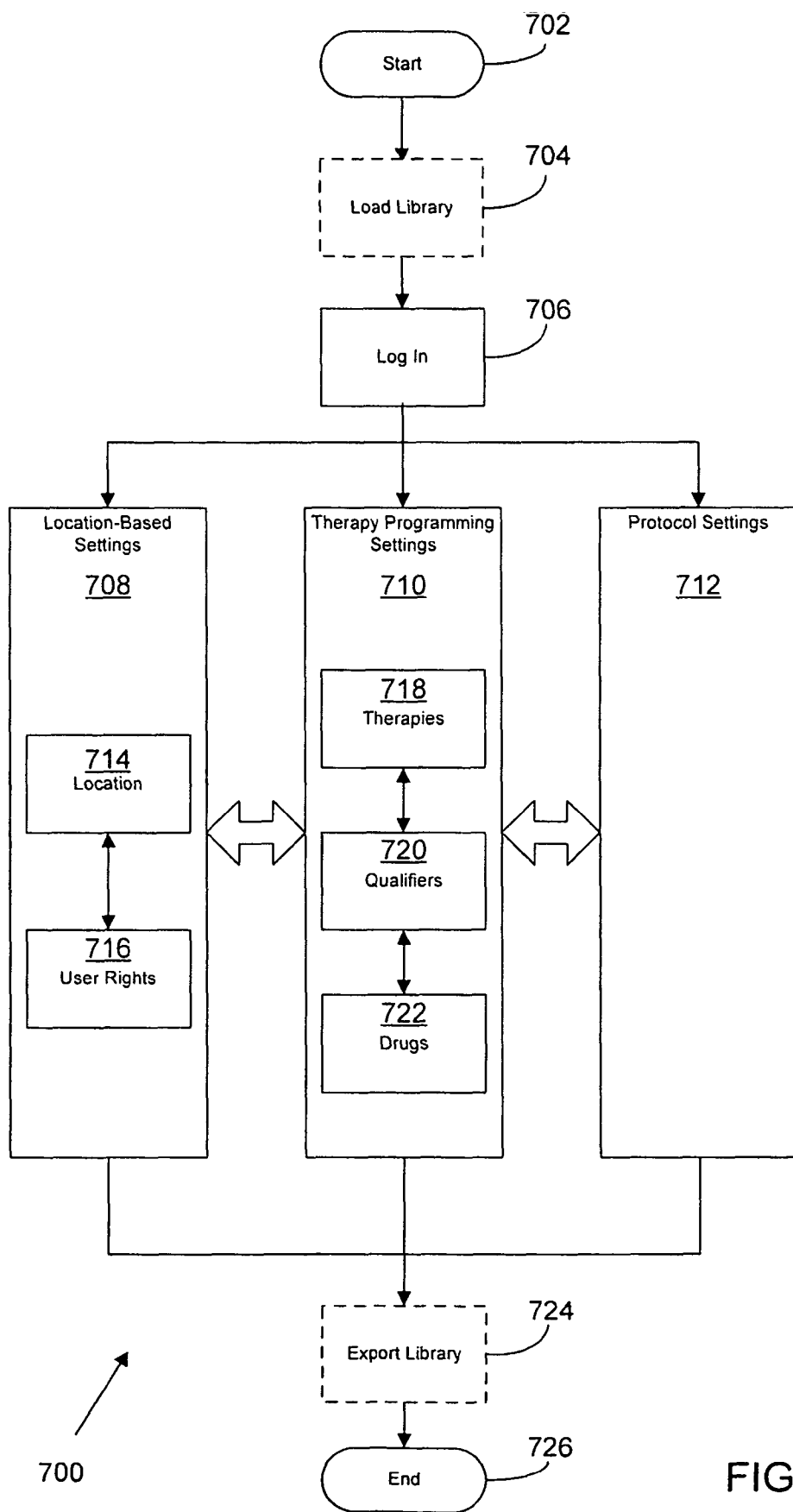


FIG. 7

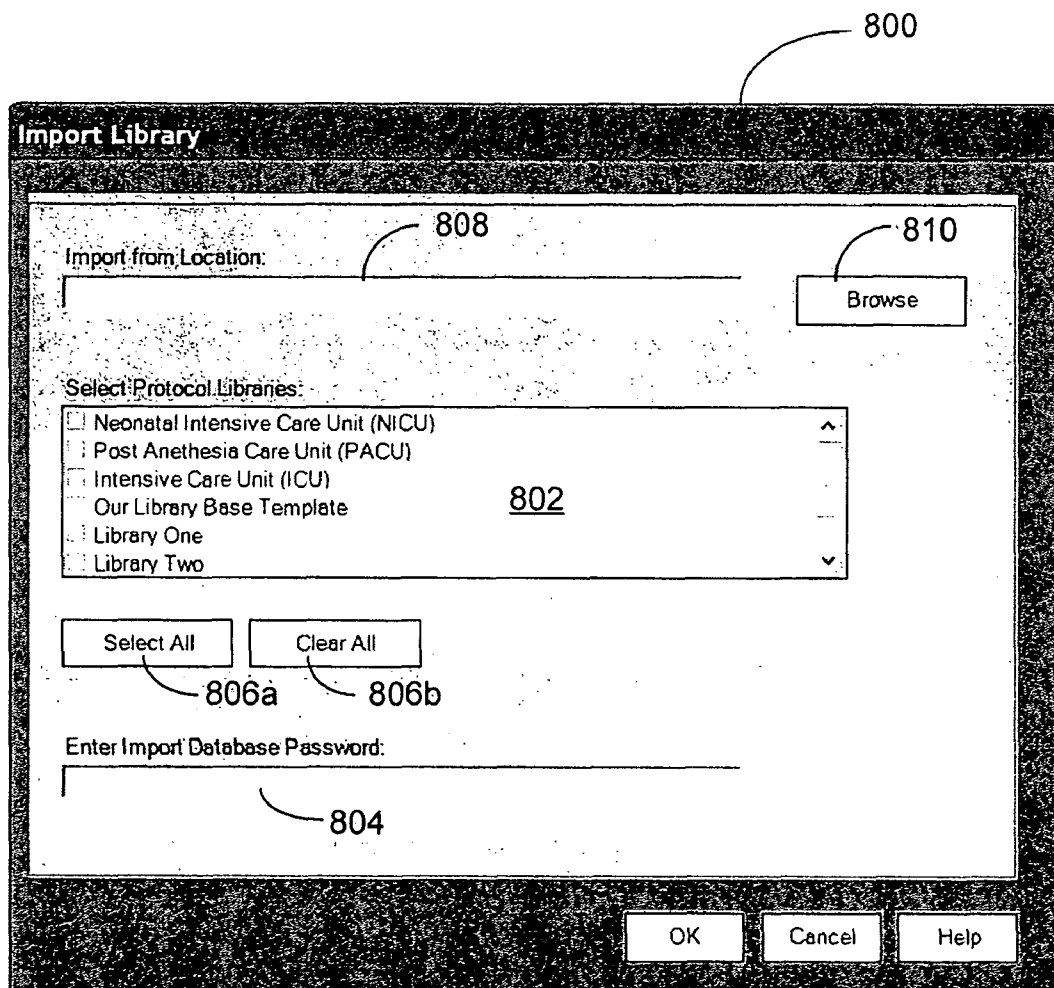
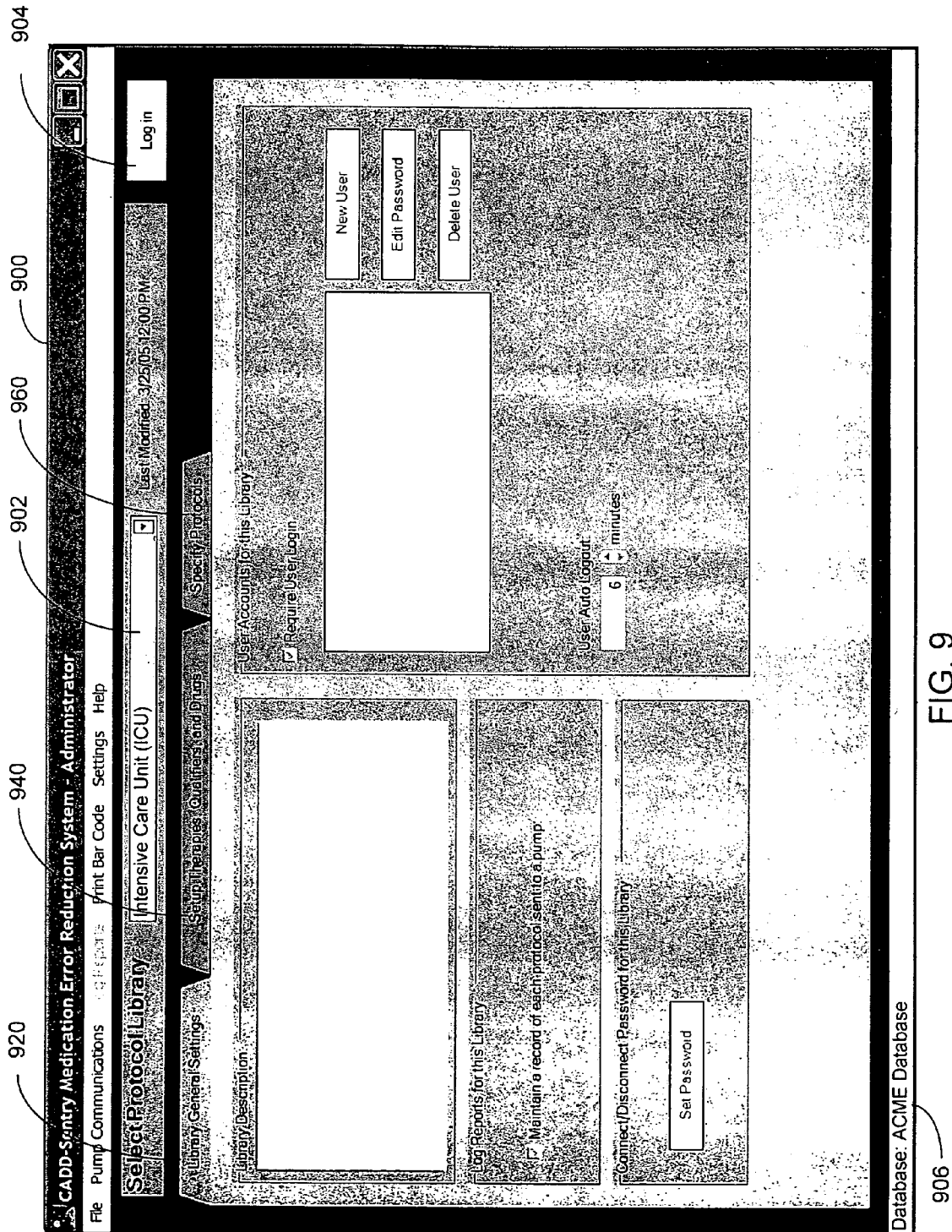


FIG. 8



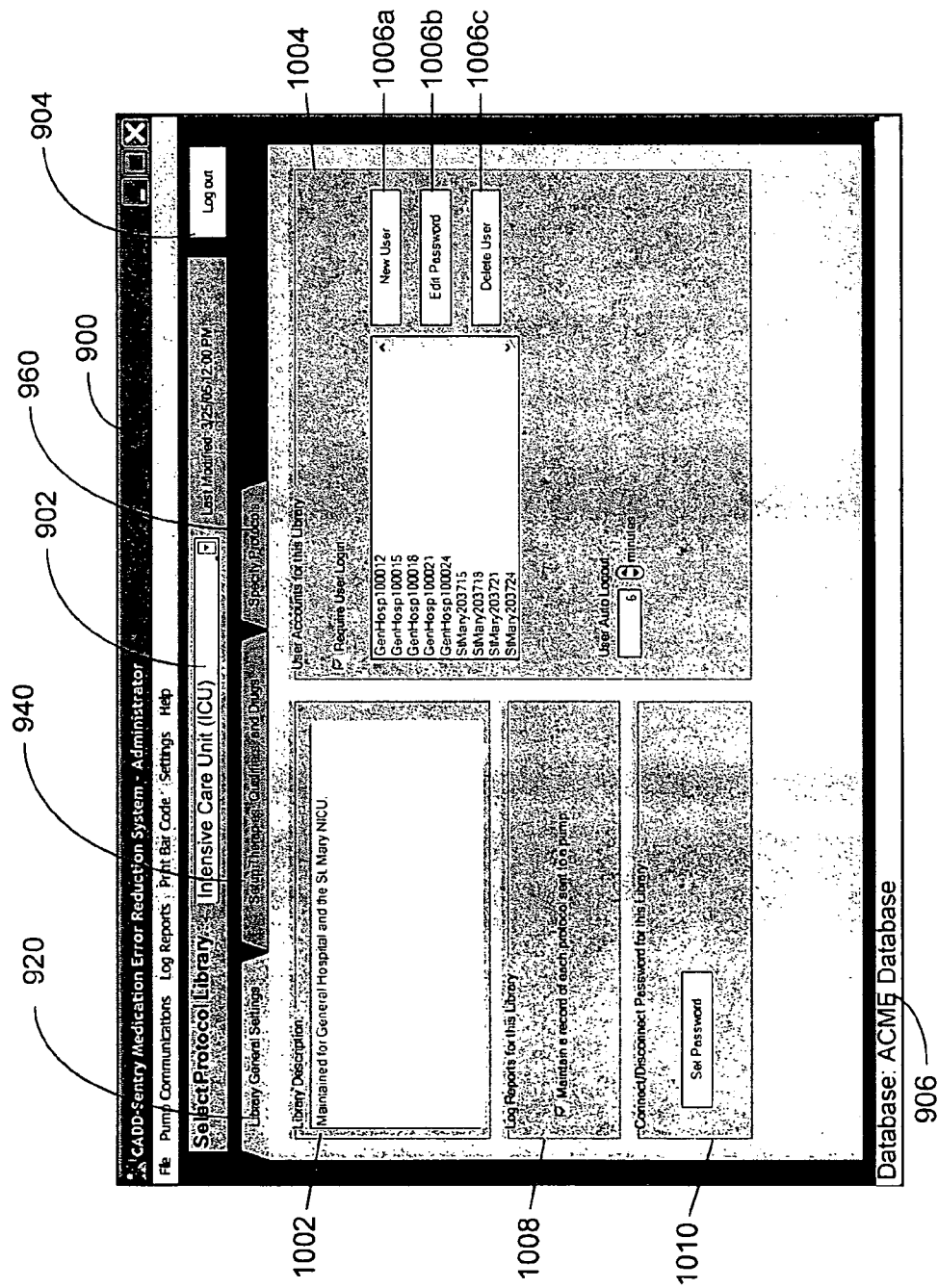


FIG. 10

CADD-Sentry Medication Error Reduction System - Administrator

File Pump Communications Log Reports Print Bar Code Settings Help

Select Protocol Library

Intensive Care Unit (ICU)

User Modified: 3/25/05 12:00 PM Log out

Therapies

Therapy Name	In Use
Patient Controlled Analgesia	Y
Epidural	Y

Notes:

1108

1110

1112a 1112b 1112c

New Edit Delete

Qualifiers

Qualifier Name	In Use
Adults over 65 yrs	N
Adults 40 to 65 yrs	Y
Adolescents 10-14 yrs	Y
Children 5-10 yrs	N

Notes:

1116

1118a 1118b 1118c

New Edit Delete

Drugs in Neonatal Intensive Care (NICU) Library

Name	Units	Concentration	Drug ID	In Use
Fentanyl	Micrograms	10	123456789	Y
Fentanyl	Micrograms	0	asbssa	N
Hydro Morphone	Micrograms	30	9999888	N
Hydro Morphone	Micrograms	80	HydroMorpho	Y
Morphine	Micrograms	0	123456	N

Buttons: New Drug Edit Drug ID Delete Drug Print Bar Code

Database: AQME Database

FIG. 11

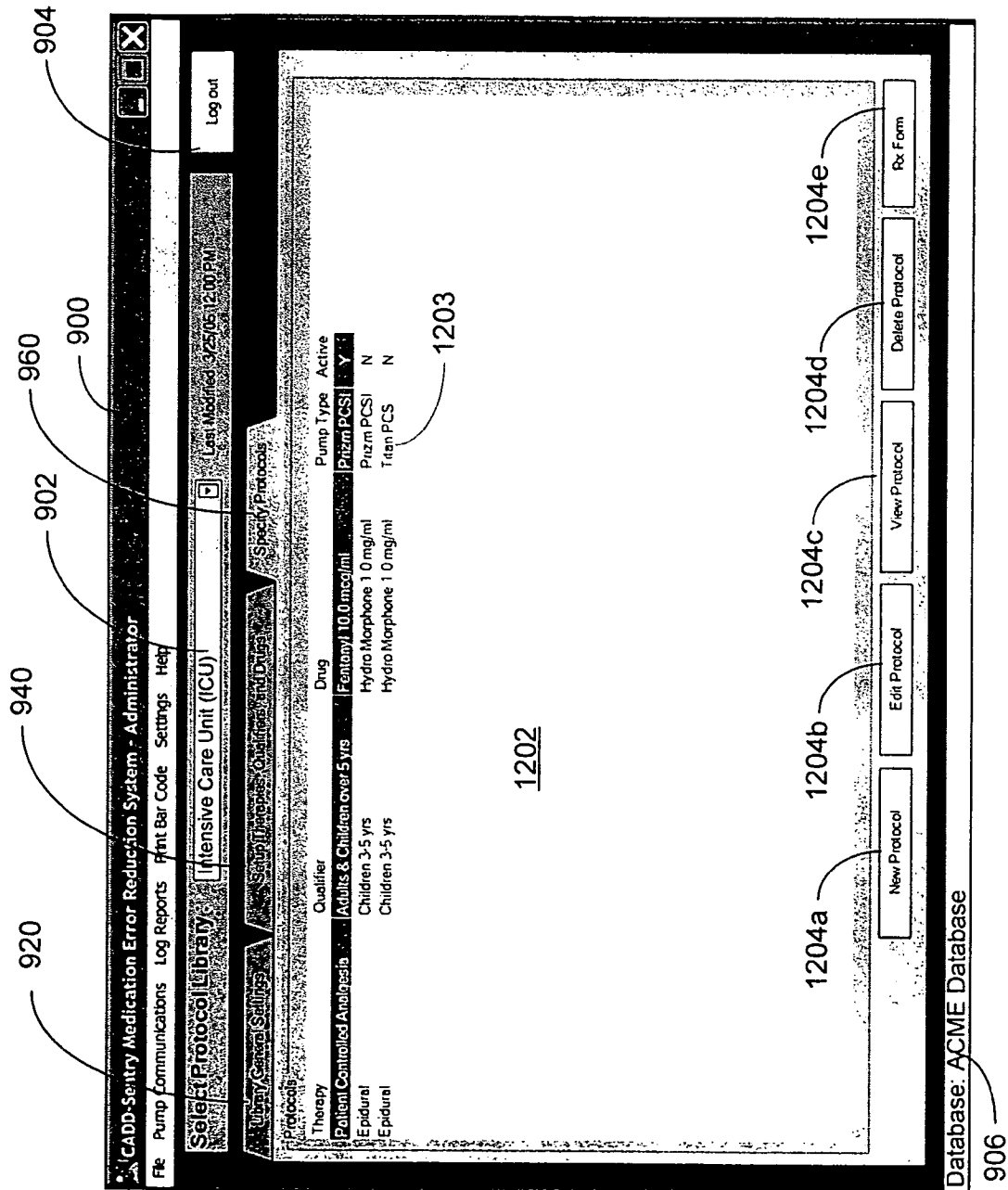


FIG. 12

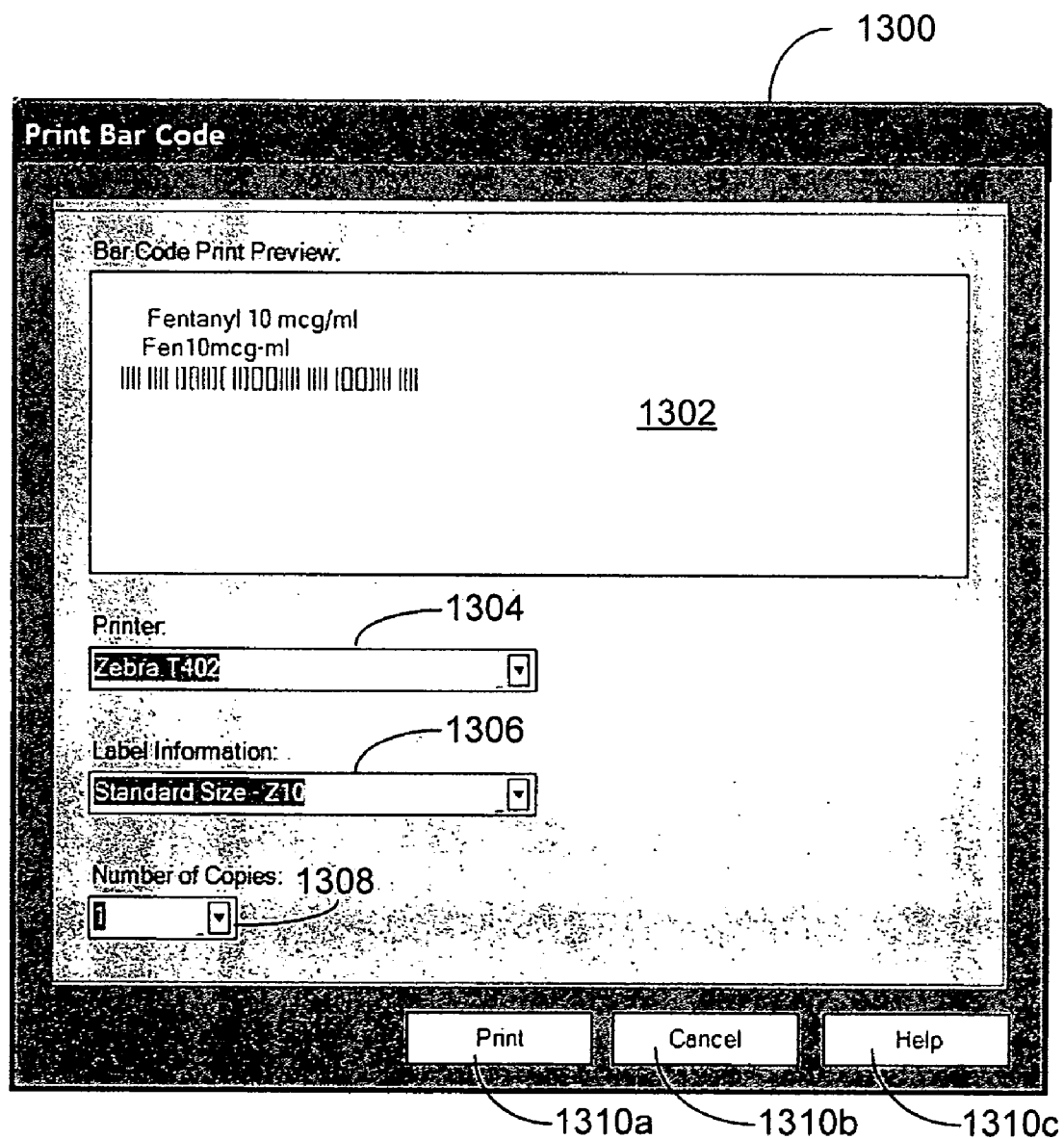


FIG. 13

1400

View Prescription Order Form

77%

Prescription Form:
Patient Controlled Analgesia
Adults & Children over 5 yrs

Date: _____ Time: _____

Therapy: Patient Controlled Analgesia
Notes: Patient controlled analgesia setup with neo-342 and 168pg no 31245
Qualifier: Adults & Children over 5 yrs
Notes: Monitor and record respiratory rate and level of consciousness every two (2) hours times twelve (12) hours upon PCA initiation or dose change, then every four (4) hours.
Record pain location and intensity every four (4) hours.

☐ **Epidural 100.0 mcg/ml**
Continuous Rate mcg/hr (20 to 50 mcg/hr)
Demand Dose mcg (5 to 20 mcg)
Dose Lockout min (100 to 315 hr)
4 Hour Limit mcg (80 to 100 mcg)
Reservoir Volume ml

Precautions: Monitor for side effects such as dizziness, decreased urine output, and vomiting.

☐ **Hydro Morphone 1.0 mcg/ml**
Continuous Rate mcg/hr (20 to 50 mcg/hr)
Demand Dose mcg (5 to 20 mcg)
Dose Lockout min (100 to 315 hr)
4 Hour Limit mcg (80 to 100 mcg)
Reservoir Volume ml

Precautions: Consider reducing dose gradually. Monitor for side effects such as dizziness, anxiety, confusion, decreased urine output, hallucinations, constipation, dry mouth, nausea and vomiting.

☐ **Morphine 1.0 mcg/ml**
Continuous Rate mcg/hr (20 to 50 mcg/hr)
Demand Dose mcg (5 to 20 mcg)
Dose Lockout min (100 to 315 hr)
4 Hour Limit mcg (80 to 100 mcg)
Reservoir Volume ml

FIG. 14

1500

New Protocol

<p>Therapy</p> <p>1502</p> <p>Patient Controlled Analgesia</p> <p>Patient Controlled Analgesia</p> <p>Epidural</p> <p>Therapy Notes:</p> <p>Patient controlled analgesia.</p>	<p>Qualifier</p> <p>1506</p> <p>Qualifier Notes</p>	<p>Drug</p> <p>1510</p> <p>Protocol Notes</p>
1504	1508	1512

Next Cancel Help

FIG. 15

1500

New Protocol

<p>Therapy</p> <p>1502 Patient Controlled Analgesia</p>	<p>Qualifier</p> <p>1506 Adults & Children over 5 yrs Children 3-5 yrs</p>	<p>Drug</p> <p>1510</p>
<p>Therapy Notes</p> <p>Patient controlled analgesia.</p> <p>1504</p>	<p>Qualifier Notes</p> <p>1508</p>	<p>Protocol Notes</p> <p>1512</p>

Next Cancel Help

FIG. 16

1500

New Protocol

<p>Therapy</p> <p>1502</p> <p>Patient Controlled Analgesia</p>	<p>Qualifier</p> <p>1506</p> <p>Adults & Children over 5 yrs</p>	<p>Drug</p> <p>1510</p> <p>Fentanyl 10.0 mcg/ml Hydro Morphine 1.0 mg/ml Morphine 1.0 mg/ml Morphine 10.0 mg/ml</p>
<p>Therapy Notes:</p> <p>1504</p> <p>Patient controlled analgesia.</p>	<p>Qualifier Notes</p> <p>1508</p> <p>Monitor and record respiratory rate and level of consciousness every two (2) hours times twelve (12) hours upon PCA initiation or dose change, then every four (4) hours. Record pain location and intensity every four (4) hours</p>	<p>1512</p>

Next Cancel Help

FIG. 17

Protocol Details

Protocol Name: 1804
 Protocol Version: 1806
 Protocol Type: 1808
 Protocol Status: 1810
 Protocol Author: 1812
 Protocol Date: 1814
 Protocol Location: 1816
 Protocol Description: 1818
 Protocol Category: 1820
 Protocol Subcategory: 1822
 Protocol Subcategory 2: 1824
 Protocol Subcategory 3: 1826
 Protocol Subcategory 4: 1828
 Protocol Subcategory 5: 1830
 Protocol Subcategory 6: 1832
 Protocol Subcategory 7: 1834
 Protocol Subcategory 8: 1836
 Protocol Subcategory 9: 1838
 Protocol Subcategory 10: 1840
 Protocol Subcategory 11: 1842
 Protocol Subcategory 12: 1844
 Protocol Subcategory 13: 1846
 Protocol Subcategory 14: 1848
 Protocol Subcategory 15: 1850
 Protocol Subcategory 16: 1852
 Protocol Subcategory 17: 1854
 Protocol Subcategory 18: 1856
 Protocol Subcategory 19: 1858
 Protocol Subcategory 20: 1860
 Protocol Subcategory 21: 1862
 Protocol Subcategory 22: 1864
 Protocol Subcategory 23: 1866
 Protocol Subcategory 24: 1868
 Protocol Subcategory 25: 1870
 Protocol Subcategory 26: 1872
 Protocol Subcategory 27: 1874
 Protocol Subcategory 28: 1876
 Protocol Subcategory 29: 1878
 Protocol Subcategory 30: 1880
 Protocol Subcategory 31: 1882
 Protocol Subcategory 32: 1884
 Protocol Subcategory 33: 1886
 Protocol Subcategory 34: 1888
 Protocol Subcategory 35: 1890
 Protocol Subcategory 36: 1892
 Protocol Subcategory 37: 1894
 Protocol Subcategory 38: 1896
 Protocol Subcategory 39: 1898
 Protocol Subcategory 40: 1900

General Settings

☐ Require Drug Verification (1812)
☐ Require Second Nurse Verification (1814)
☐ Require Second Nurse Verification (1816)
☐ Require Second Nurse Verification (1818)
☐ Require Second Nurse Verification (1820)
☐ Require Second Nurse Verification (1822)
☐ Require Second Nurse Verification (1824)
☐ Require Second Nurse Verification (1826)
☐ Require Second Nurse Verification (1828)
☐ Require Second Nurse Verification (1830)
☐ Require Second Nurse Verification (1832)
☐ Require Second Nurse Verification (1834)
☐ Require Second Nurse Verification (1836)
☐ Require Second Nurse Verification (1838)
☐ Require Second Nurse Verification (1840)
☐ Require Second Nurse Verification (1842)
☐ Require Second Nurse Verification (1844)
☐ Require Second Nurse Verification (1846)
☐ Require Second Nurse Verification (1848)
☐ Require Second Nurse Verification (1850)
☐ Require Second Nurse Verification (1852)
☐ Require Second Nurse Verification (1854)
☐ Require Second Nurse Verification (1856)
☐ Require Second Nurse Verification (1858)
☐ Require Second Nurse Verification (1860)
☐ Require Second Nurse Verification (1862)
☐ Require Second Nurse Verification (1864)
☐ Require Second Nurse Verification (1866)
☐ Require Second Nurse Verification (1868)
☐ Require Second Nurse Verification (1870)
☐ Require Second Nurse Verification (1872)
☐ Require Second Nurse Verification (1874)
☐ Require Second Nurse Verification (1876)
☐ Require Second Nurse Verification (1878)
☐ Require Second Nurse Verification (1880)
☐ Require Second Nurse Verification (1882)
☐ Require Second Nurse Verification (1884)
☐ Require Second Nurse Verification (1886)
☐ Require Second Nurse Verification (1888)
☐ Require Second Nurse Verification (1890)
☐ Require Second Nurse Verification (1892)
☐ Require Second Nurse Verification (1894)
☐ Require Second Nurse Verification (1896)
☐ Require Second Nurse Verification (1898)
☐ Require Second Nurse Verification (1900)

Limits for Patient Specific Parameters

Continuous Rate (mcg/hr)	Demand Dose (mcg)	Demand Dose Loc (mcg)
Hard Maximum: 1834	Hard Maximum: 1846	Hard Maximum: 1858
Soft Maximum: 1836	Soft Maximum: 1848	Soft Maximum: 1860
Initial Value: 1832	Initial Value: 1844	Initial Value: 1856
Soft Minimum: 1836	Soft Minimum: 1848	Soft Minimum: 1860
Hard Minimum: 1834	Hard Minimum: 1846	Hard Minimum: 1858

Weight-Based

☐ Set as a Weight-Based Protocol (1818)
 Weight Limit: 1818 kg

Buttons: Save (1806a), Cancel (1806b), Help (1806c)

FIG. 18

Protocol Details

☐ Protocol MIBs Active in Patient Care

☐ Therapy: Patient Controlled Analgesia

☐ Qualifier: Adults & Child 10 to 15 years

☐ Drug: Fentanyl 100 mcg/ml

Delivery **Alarms** **Security** **Display/Sound** **Reports**

General Settings

☐ Require Drug Verification

☐ Require Second Nurse Verification

User Login must be enabled to use this feature.

Weight-Based Protocol

Weight Limit: 100 kg

Units for Patient Specific Parameters

Continuous Rate	Demand Dose	Demand Dose Lockout
mcg/kg/hr	mcg/kg	mcg/kg
<input type="checkbox"/> Display	<input type="checkbox"/> Display	<input type="checkbox"/> Display
<input type="checkbox"/> Allow Edit	<input type="checkbox"/> Allow Edit	<input type="checkbox"/> Allow Edit
<input type="checkbox"/> Require Comment	<input type="checkbox"/> Require Comment	<input type="checkbox"/> Require Comment
Hard Maximum	Hard Maximum	Hard Maximum
Soft Maximum	Soft Maximum	Soft Maximum
Initial Value	Initial Value	Initial Value
Soft Minimum	Soft Minimum	Soft Minimum
Hard Minimum	Hard Minimum	Hard Minimum

Save **Cancel** **Help**

FIG. 19

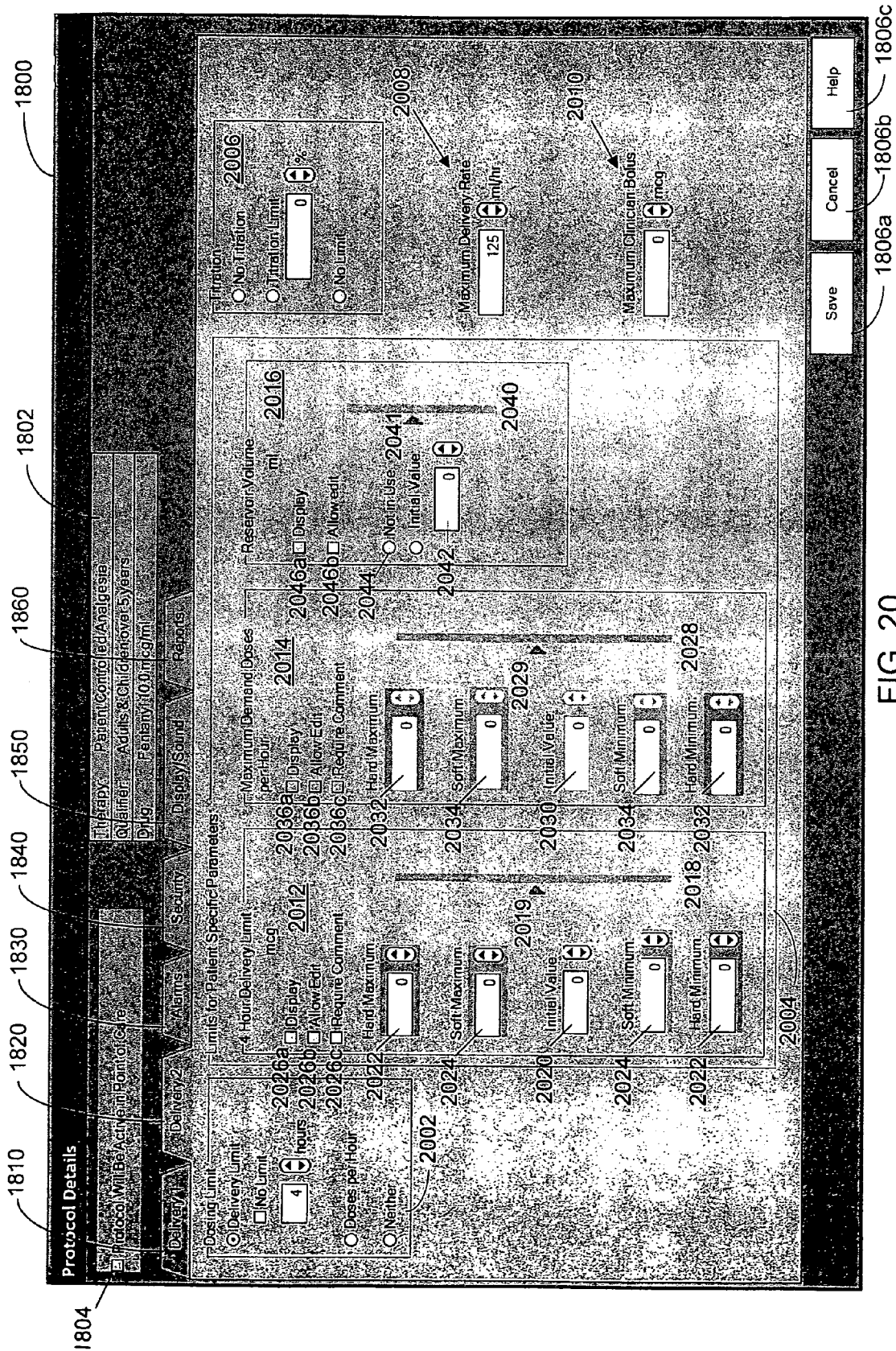


FIG. 20

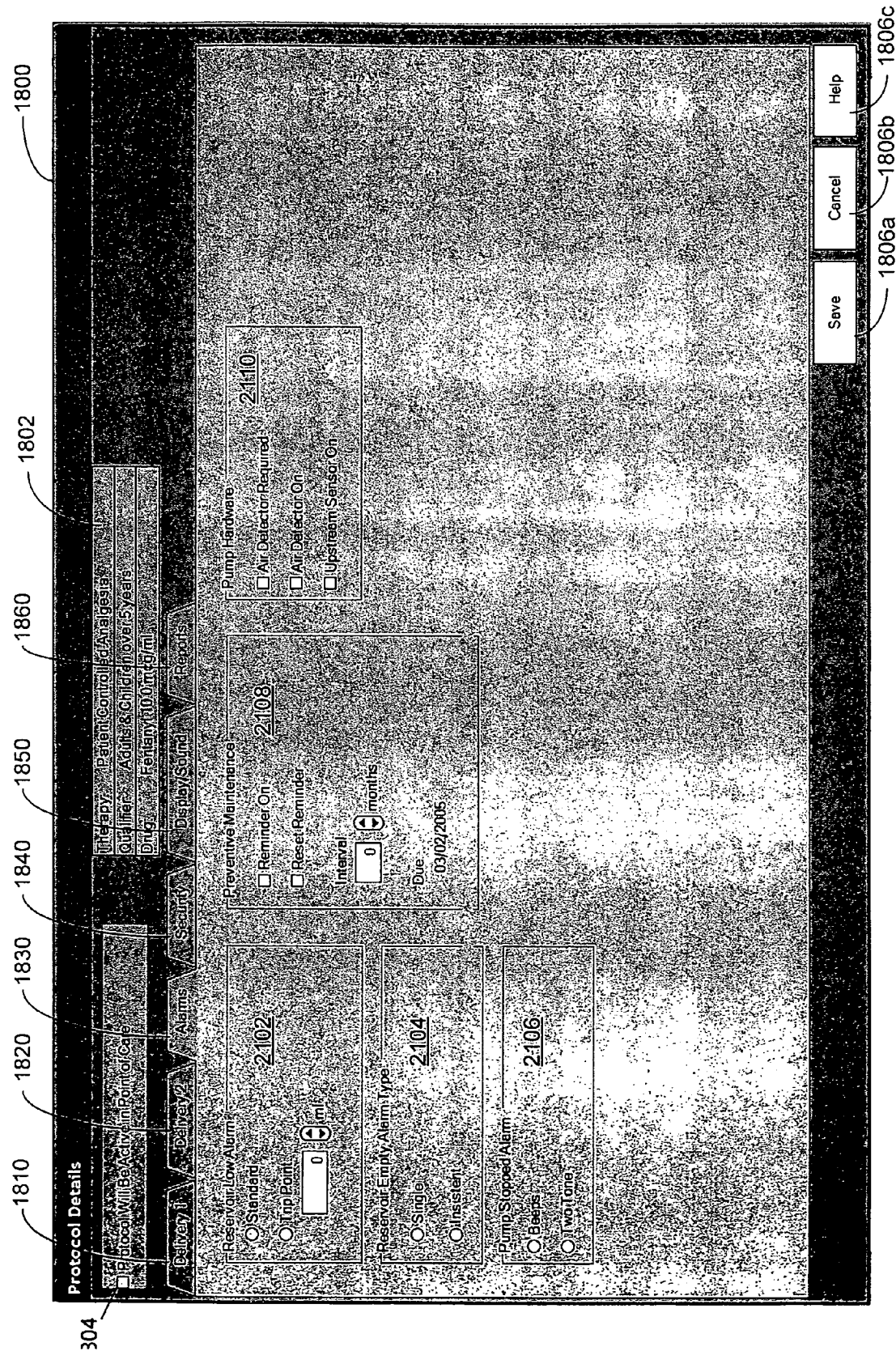


FIG. 21

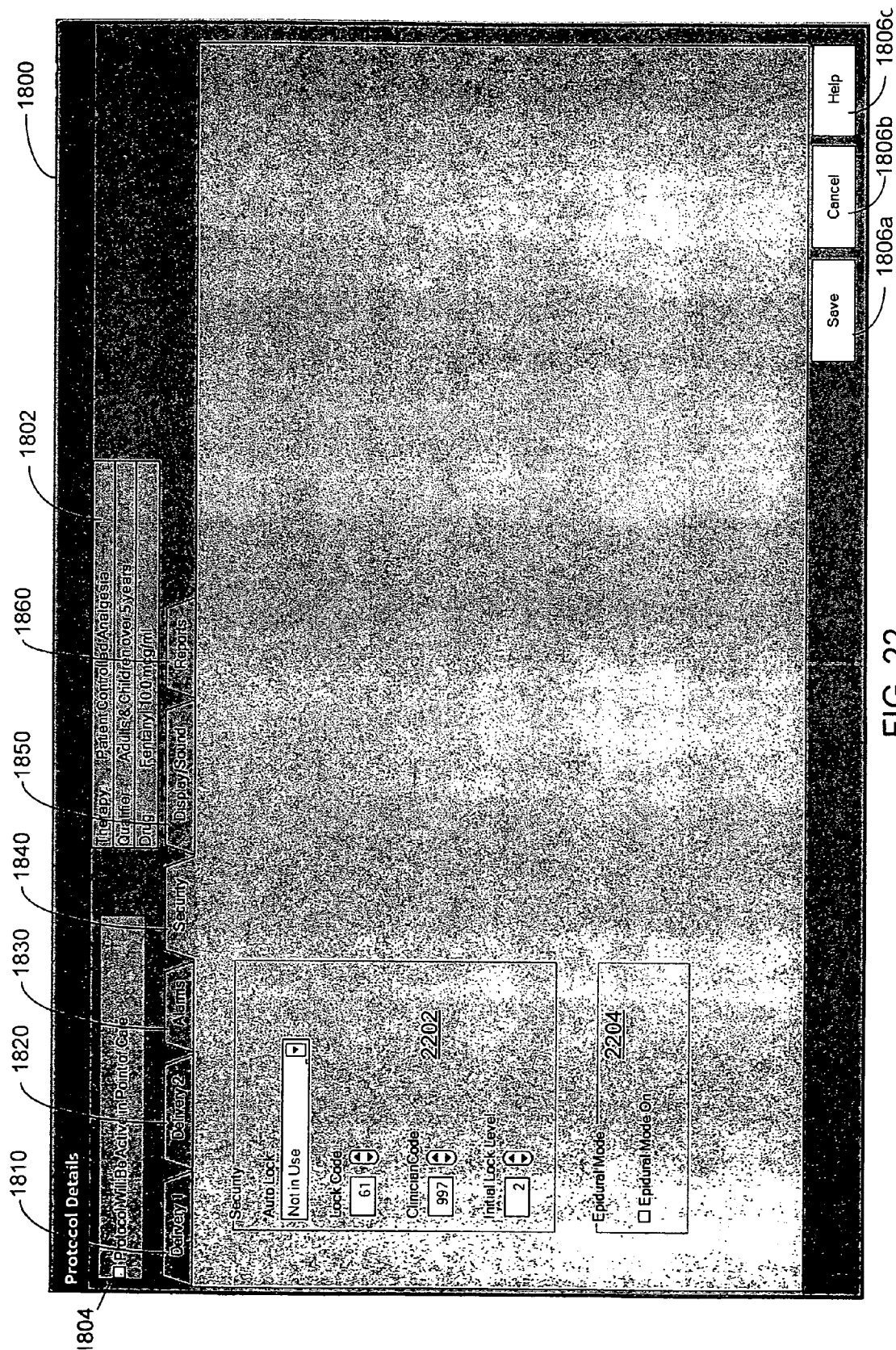


FIG. 22

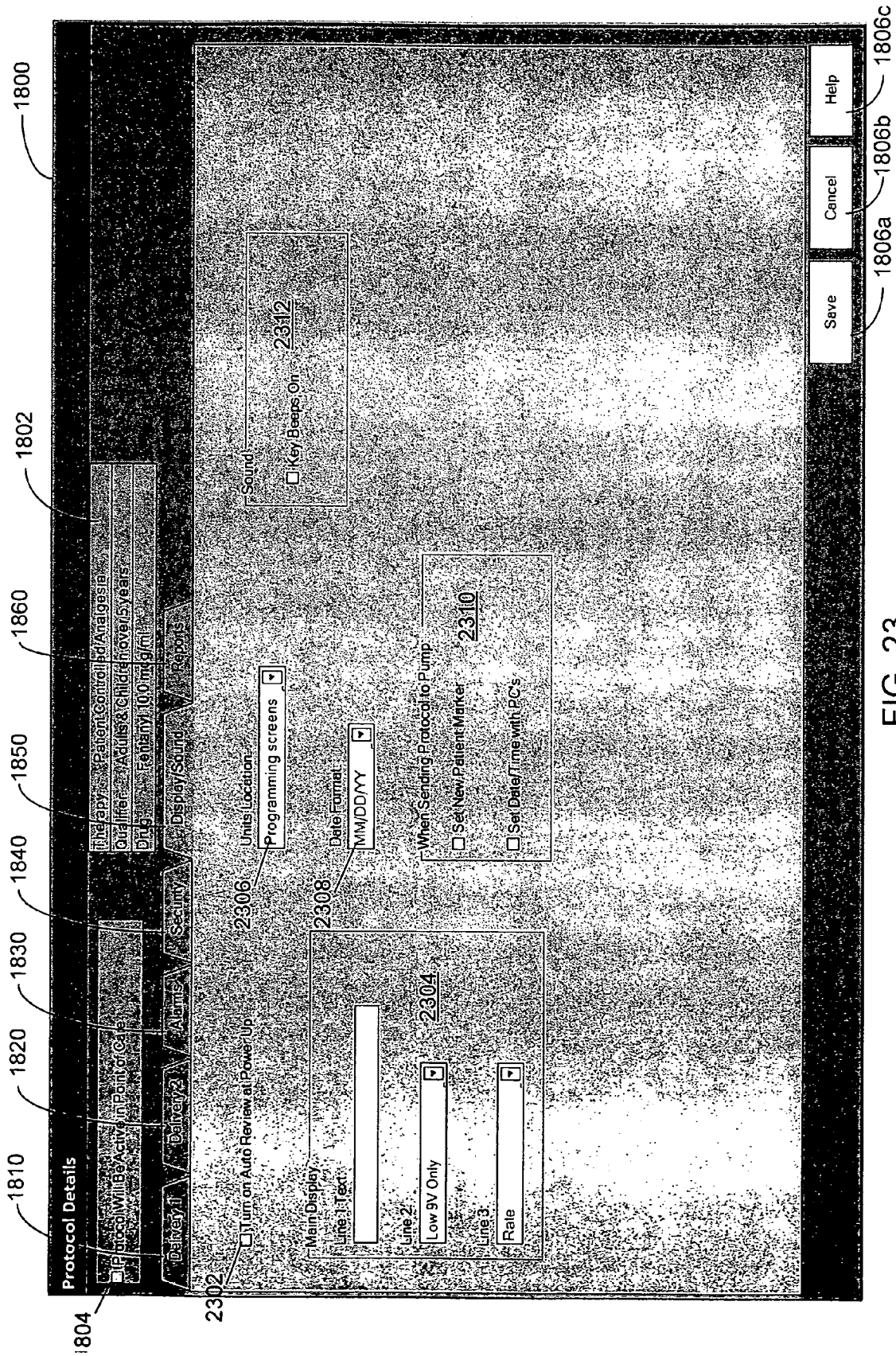
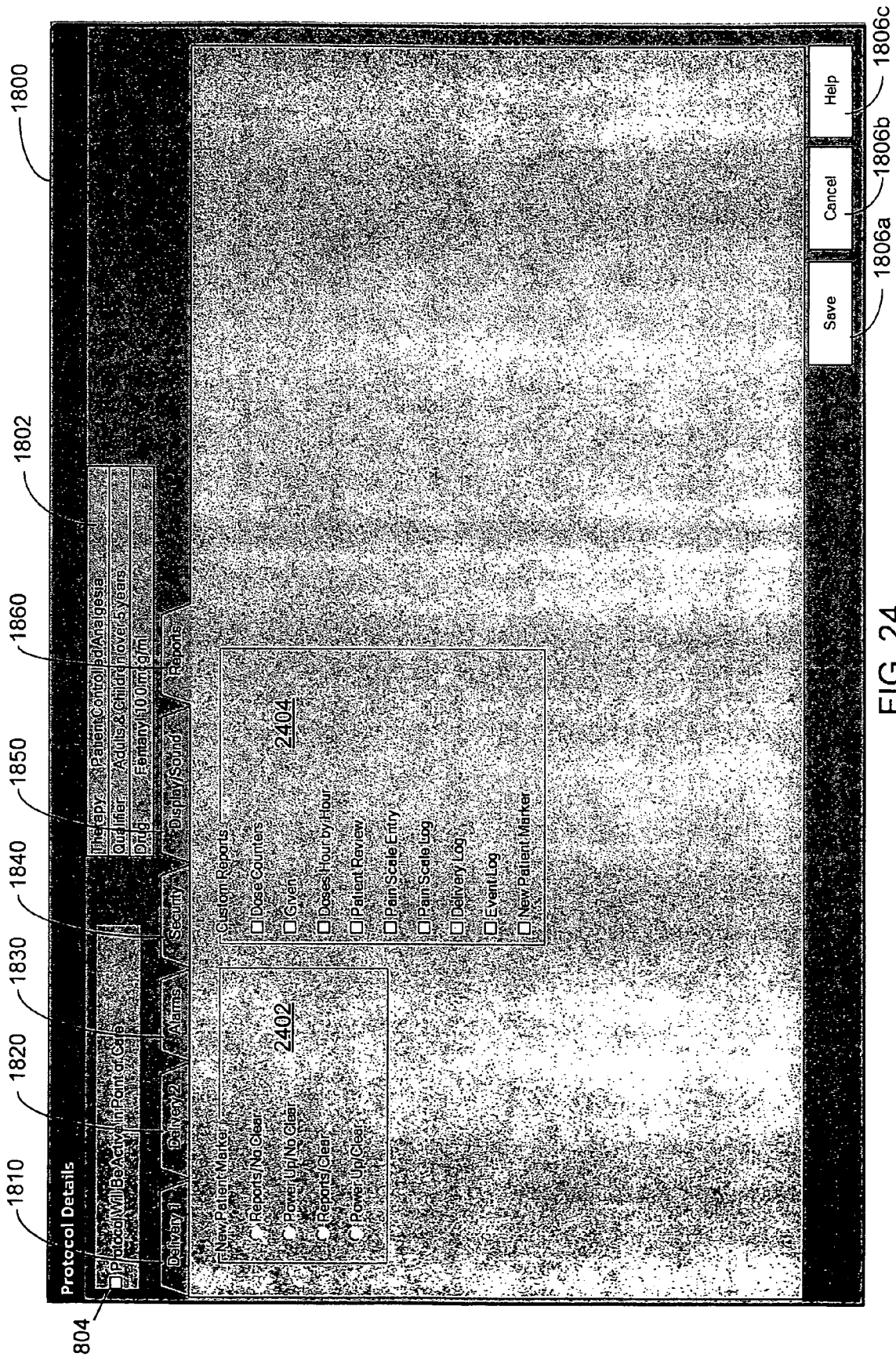


FIG. 23



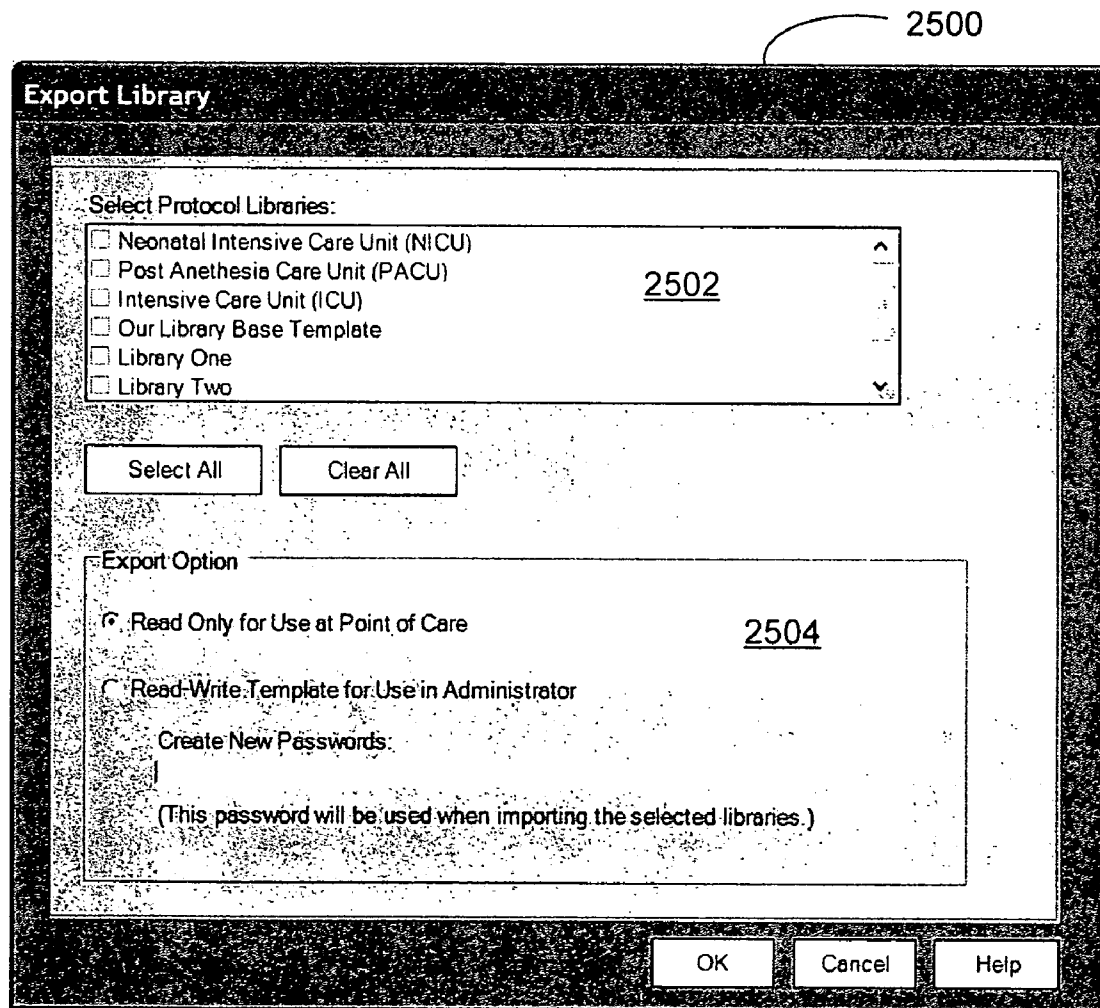


FIG. 25

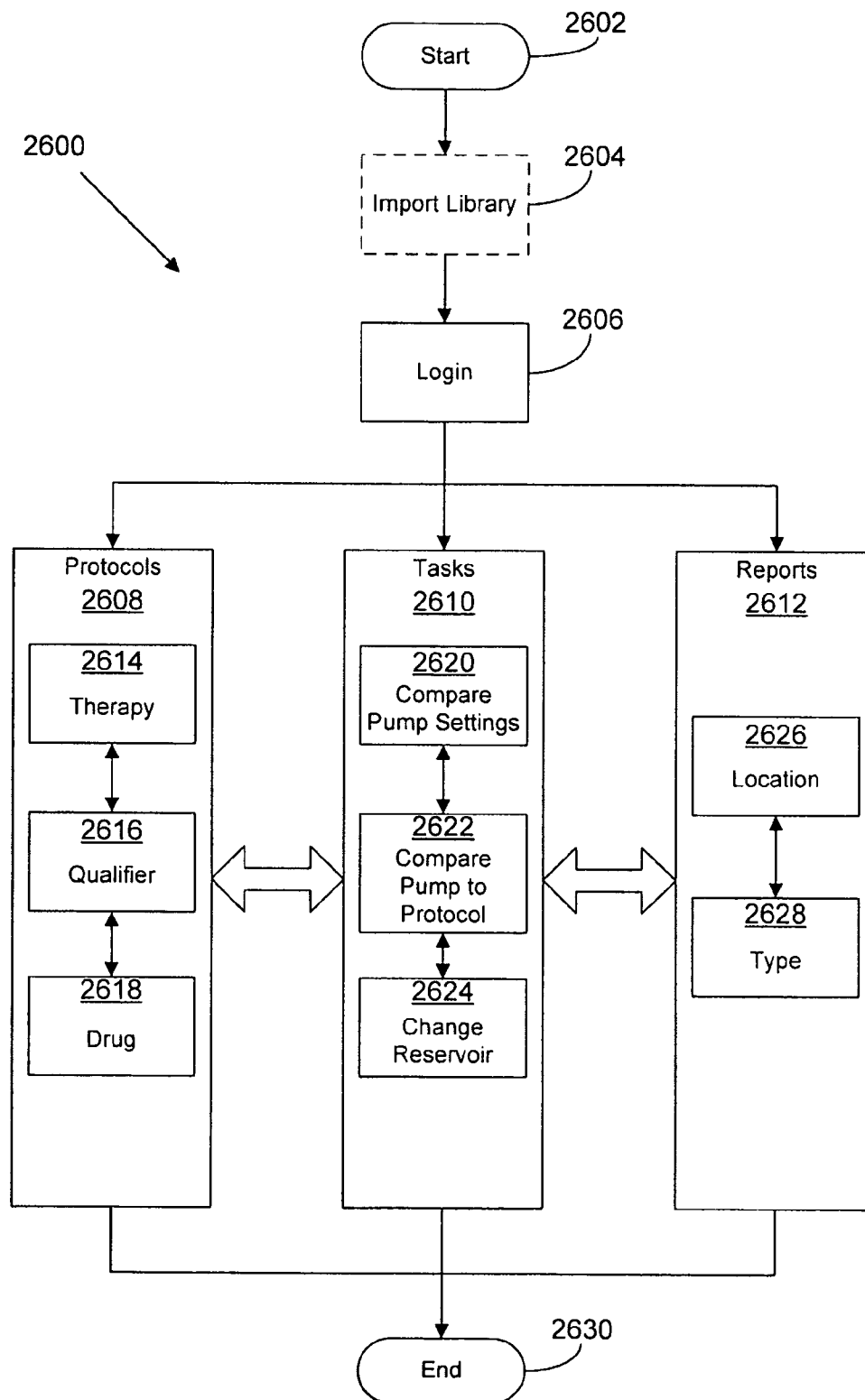


FIG. 26

Import Library to Local Computer

2700

Help

Location

Import From Location: 2702

Browse

C:\ExportFromAdmin.mdb

Library

Name: 2704

Description:

Last Modified On:

Enter Library Password

2706

2708a OK

2708b Cancel

FIG. 27

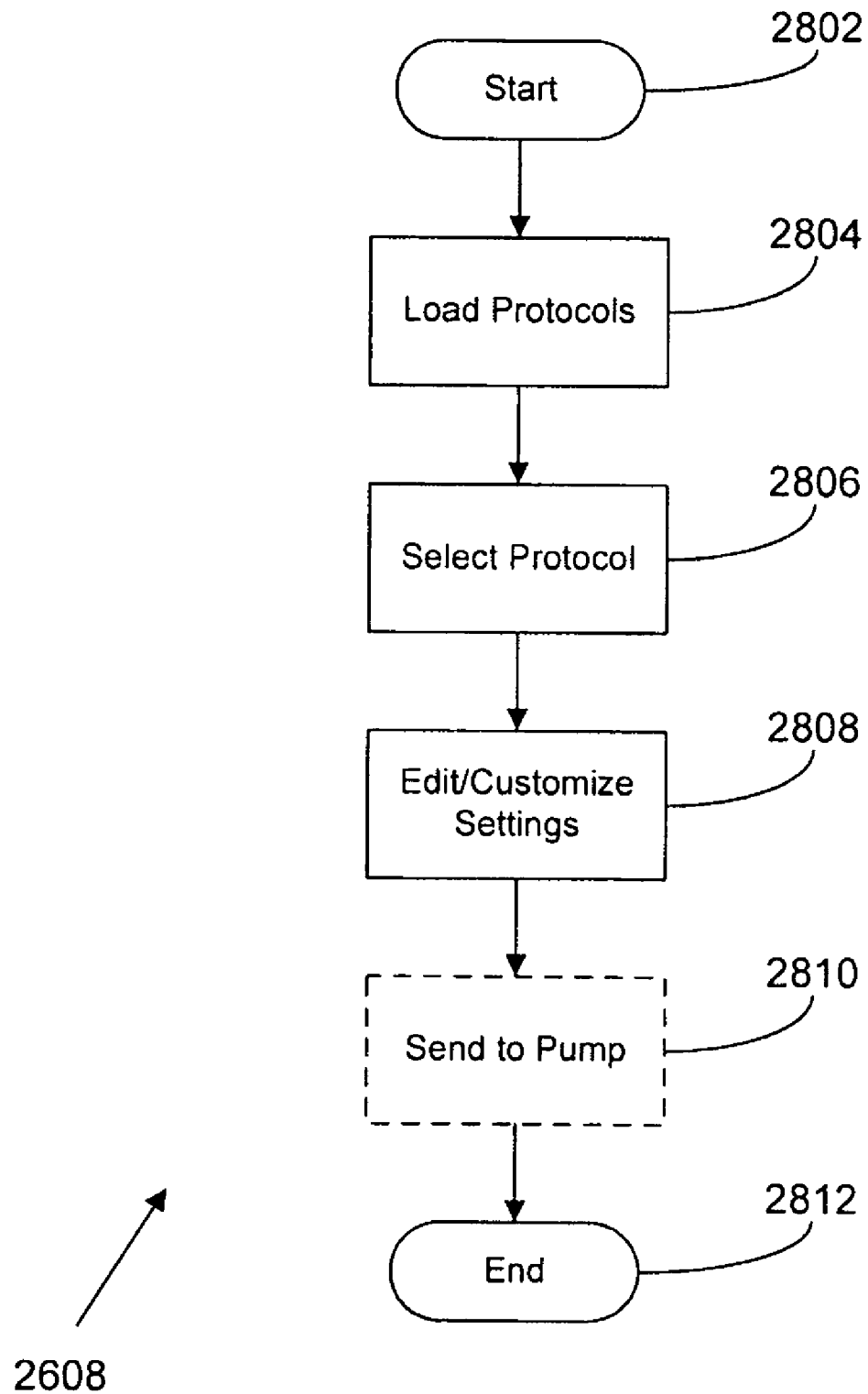
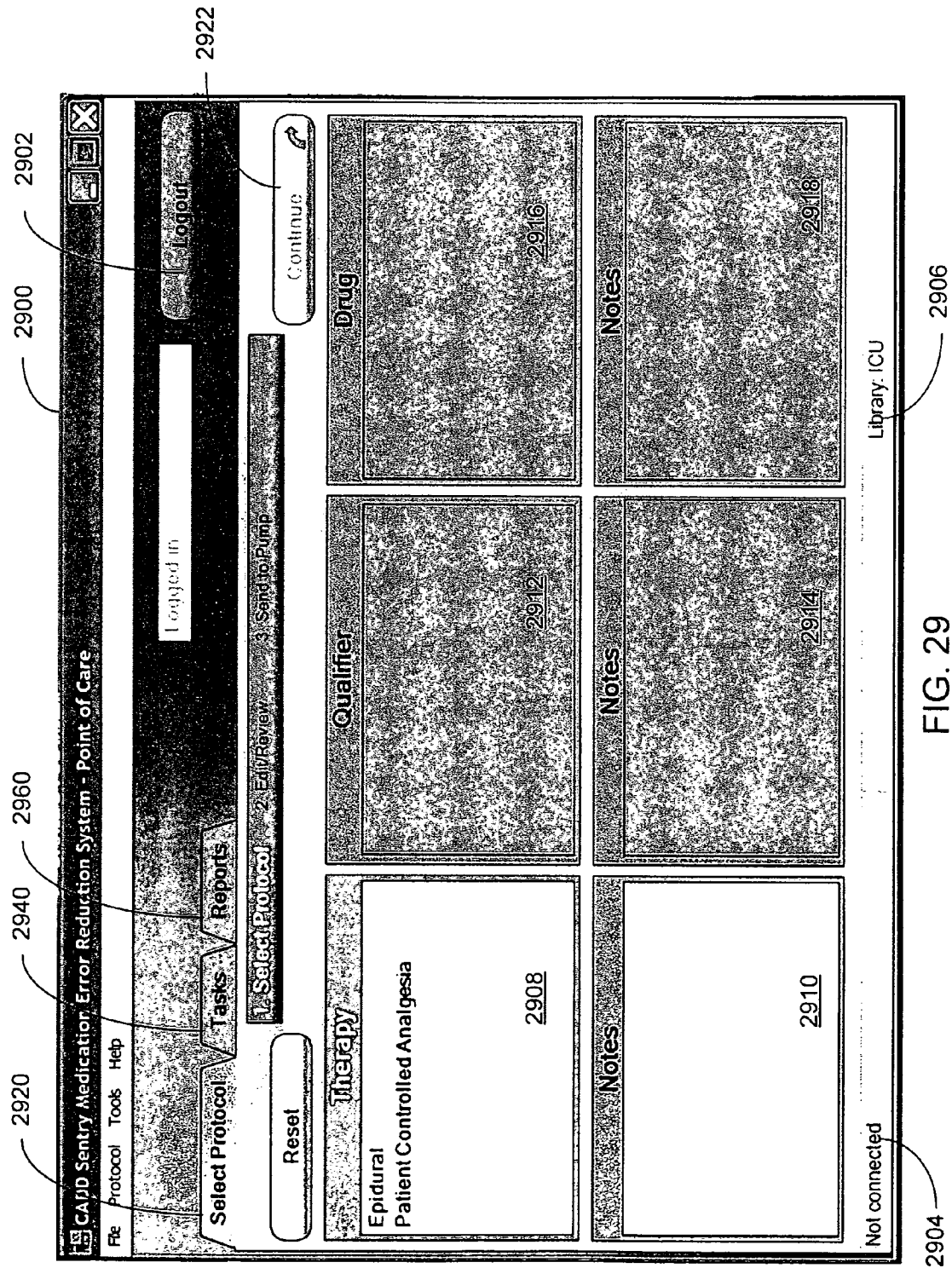
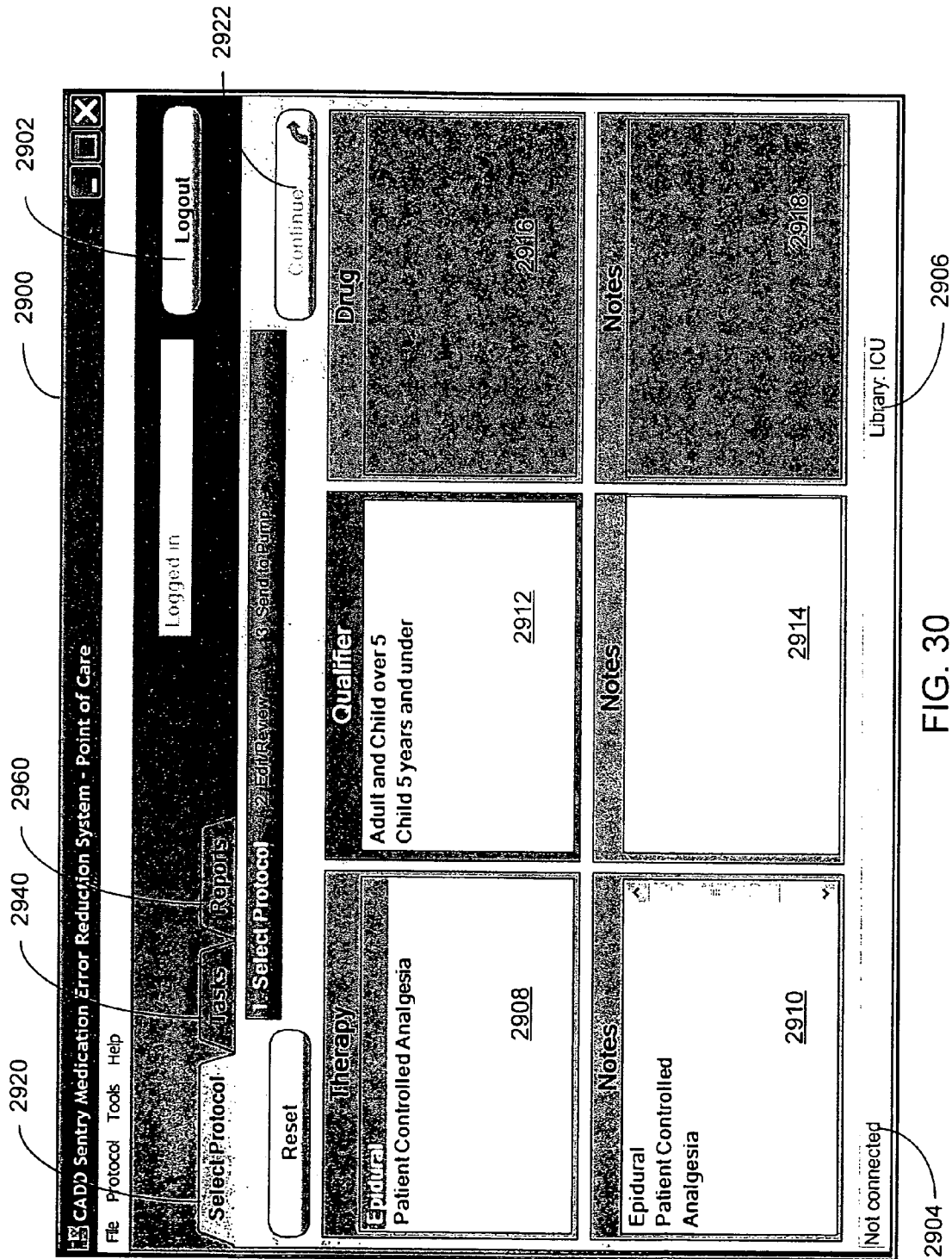


FIG. 28





The screenshot displays the CADD Sentry Medication Error Reduction System interface. The title bar reads "CADD Sentry Medication Error Reduction System - Point of Care". The menu bar includes "File", "Protocol", "Tools", and "Help". The main window is divided into several sections:

- Top Bar (2900):** Contains a "Logged in" field, a "Logout" button, and a "Continue" button.
- Navigation (2920):** Includes tabs for "Select Protocol", "Tasks", and "Reports". Below these is a progress bar with steps: "1. Select Protocol", "2. Edit/Review", and "3. Send to Pump".
- Buttons (2902):** A "Reset" button is located below the progress bar.
- Therapy Section (2908):** A box labeled "Therapy" contains the text "Epidural Patient Controlled Analgesia".
- Qualifier Section (2912):** A box labeled "Qualifier" contains the text "Adult and Child over 5".
- Drug Section (2916):** A box labeled "Drug" contains the text "Fentanyl 10 mcg/ml", "HYDRO Morphine 1 mg/ml", and "Morphine 1 mg/ml".
- Notes Section (2910, 2914, 2918):** Three separate text areas for notes. The first note (2910) contains "Epidural Patient Controlled Analgesia". The second note (2914) contains "Monitor and record respiratory rate and level of consciousness every two(2) hours times twelve(12) hours upon PCA initiation or dose change, then every four(4) hours". The third note (2918) is empty.
- Status (2904):** A label at the bottom left indicates "Not connected".
- Library (2906):** A label at the bottom right indicates "Library: ICU".

FIG. 31

2920 CADD Sentry Medication Error Reduction System - Point of Care

File Protocol Tools Help

2940 2960

2900

2902

Logged in

Logout

2922

Continue

1 Select Protocol

2 Edit Review

3 Send to Pump

Reset

Therapy	Qualifier	Drug	Notes
2908 Epidural Patient Controlled Analgesia	2912 Adult and Child over 5 Adults over 65 years Child 5 years and under	2916 Fentanyl 10 mcg/ml HYDRO Morphine 1 mg/ml Morphine 1 mg/ml	2918 Consider reducing dose gradually. Monitor for side effects such as: dizziness, SOB, anxiety, confusion, decreased urine output, hallucinations, constipation, dry mouth, nausea and vomiting. Monitor for symptoms of overdose: cold clammy
2910 Patient Controlled Analgesia			

Not connected

Library ICU

2904

2906

FIG. 32

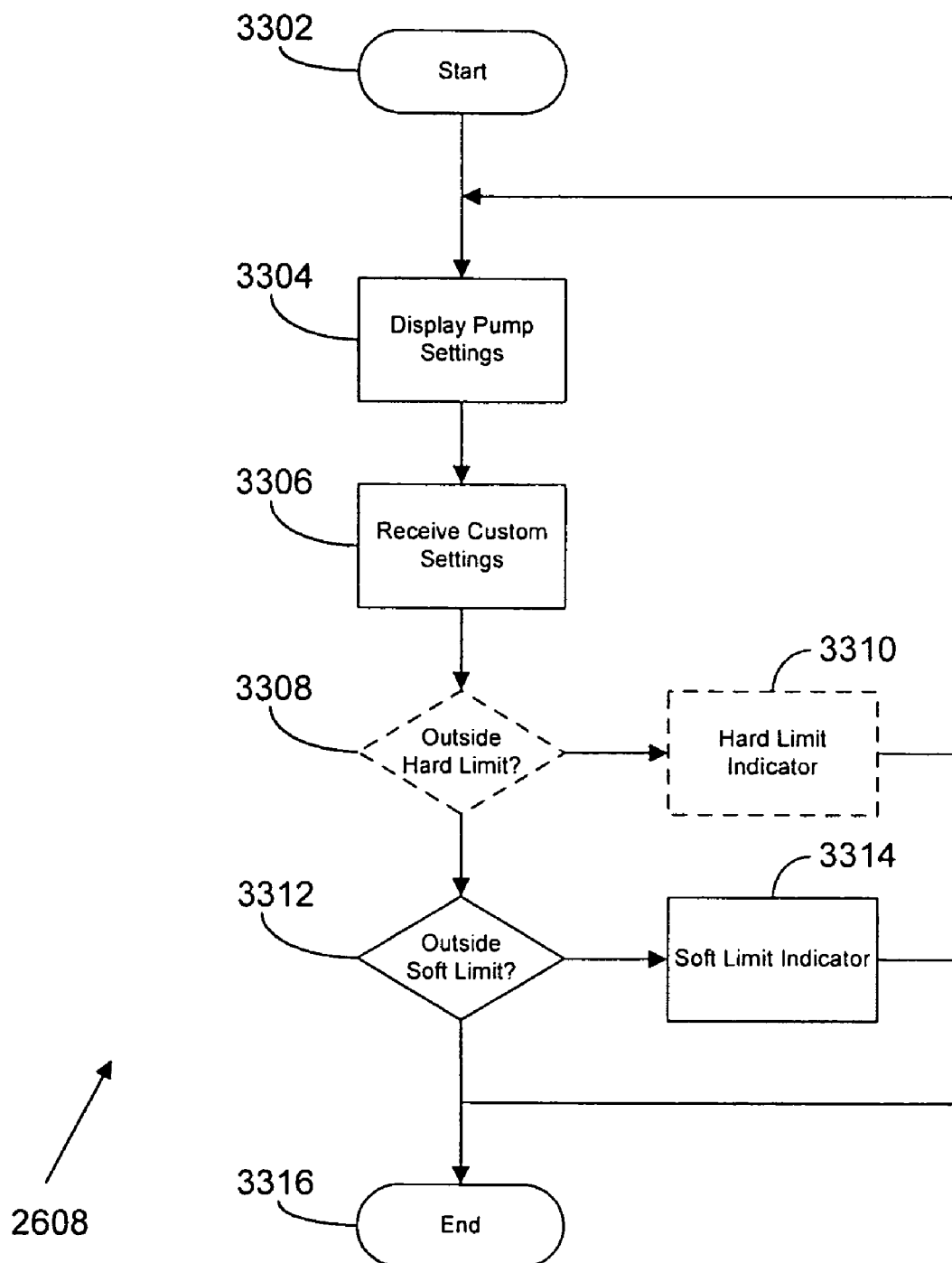


FIG. 33

3414c

3402

3400

3414a

3414b

3414c

Back

2: Edit/Review

3: Send to Pump

Library

Therapy

Qualifier

Drug

ICU

Patient Controlled Analgesia

Adult and Child over 5

Fentanyl 10 mcg/ml

Continuous Rate mcg/hr

3416

150

3404

3419

3420

3420

3418

Demand Dose mcg

10

100

3406

3425

3426

3424

3426

Demand Dose Lockout hrs:min

00:05

24:00

3408

3431

3430

3432

3432

4 hour Limit mcg

50

200

3410

3437

3438

3436

3438

Reservoir Volume ml

50

500

3412

3443

3442

0

0

0

0

FIG. 34

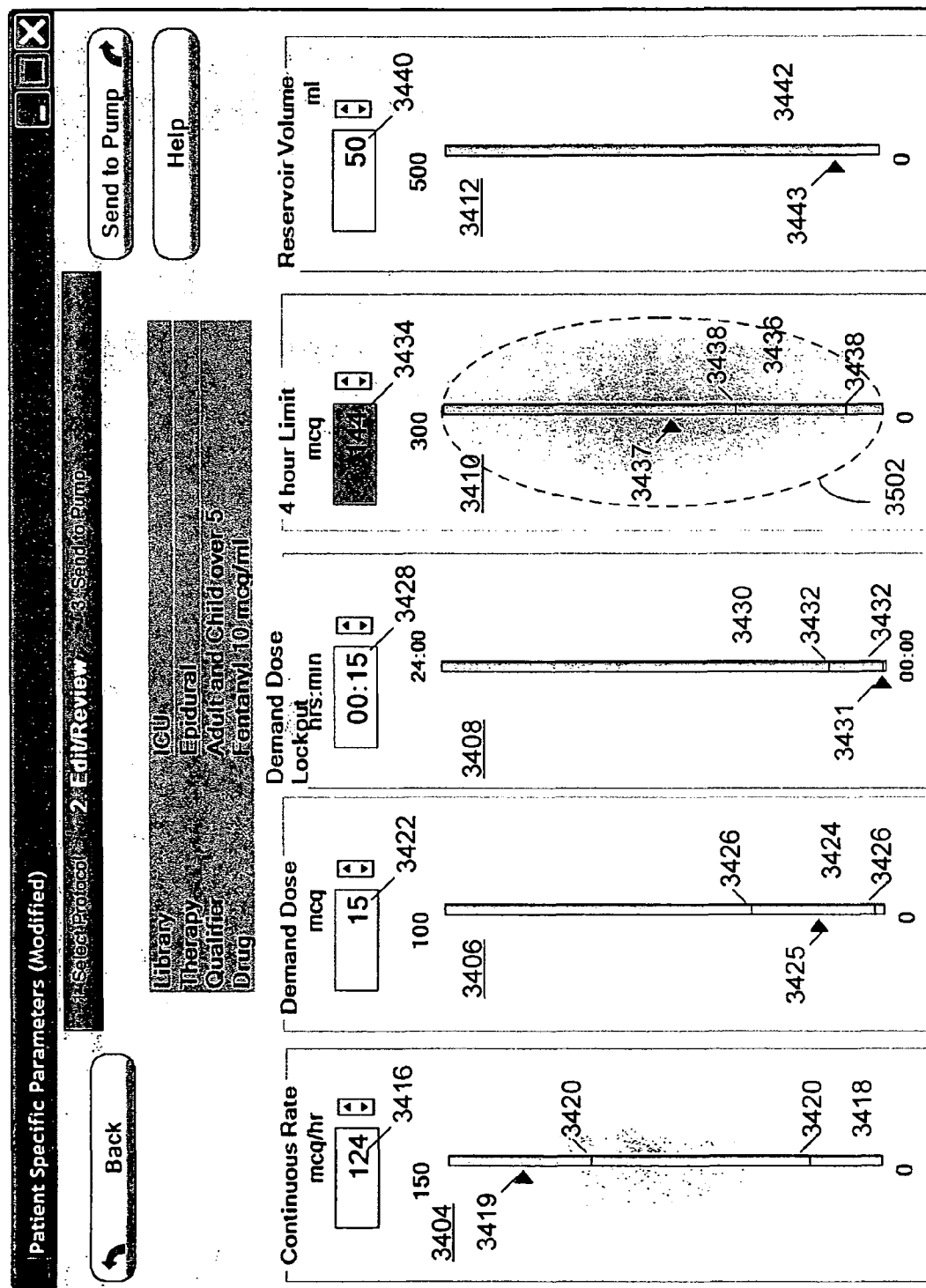


FIG. 35

Send to Pump

Back

3600

Close

Help

1 Select Protocol

2 Edit/Review

3 Send to Pump

Library

ICU

Patient Controlled Analgesia

Adult and Child over 5

Fentanyl 10 mcg/ml

Continuous Rat

45 mcg/hr

3602a

Demand

10 mcg

3602b

Demand Dose Lockout

0.5 hrs:min

3602c

4 hour Limit

50 mc

3602d

Reservoir Volum

50 ml

3602e

Please connect a pump. If a pump is connected you may need to change the COM setting.

Send

3606

Not Connected

Library: ICU

FIG. 36

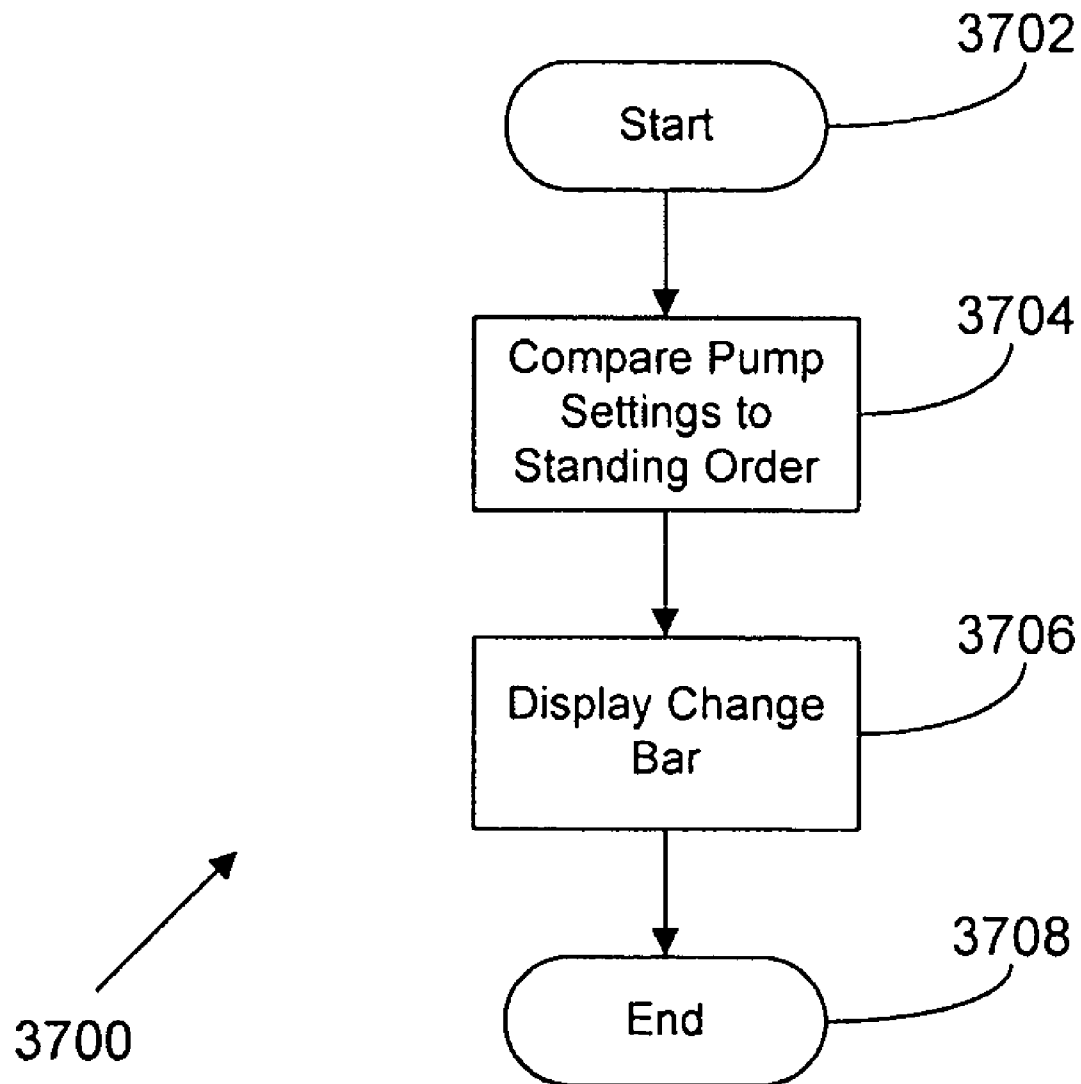
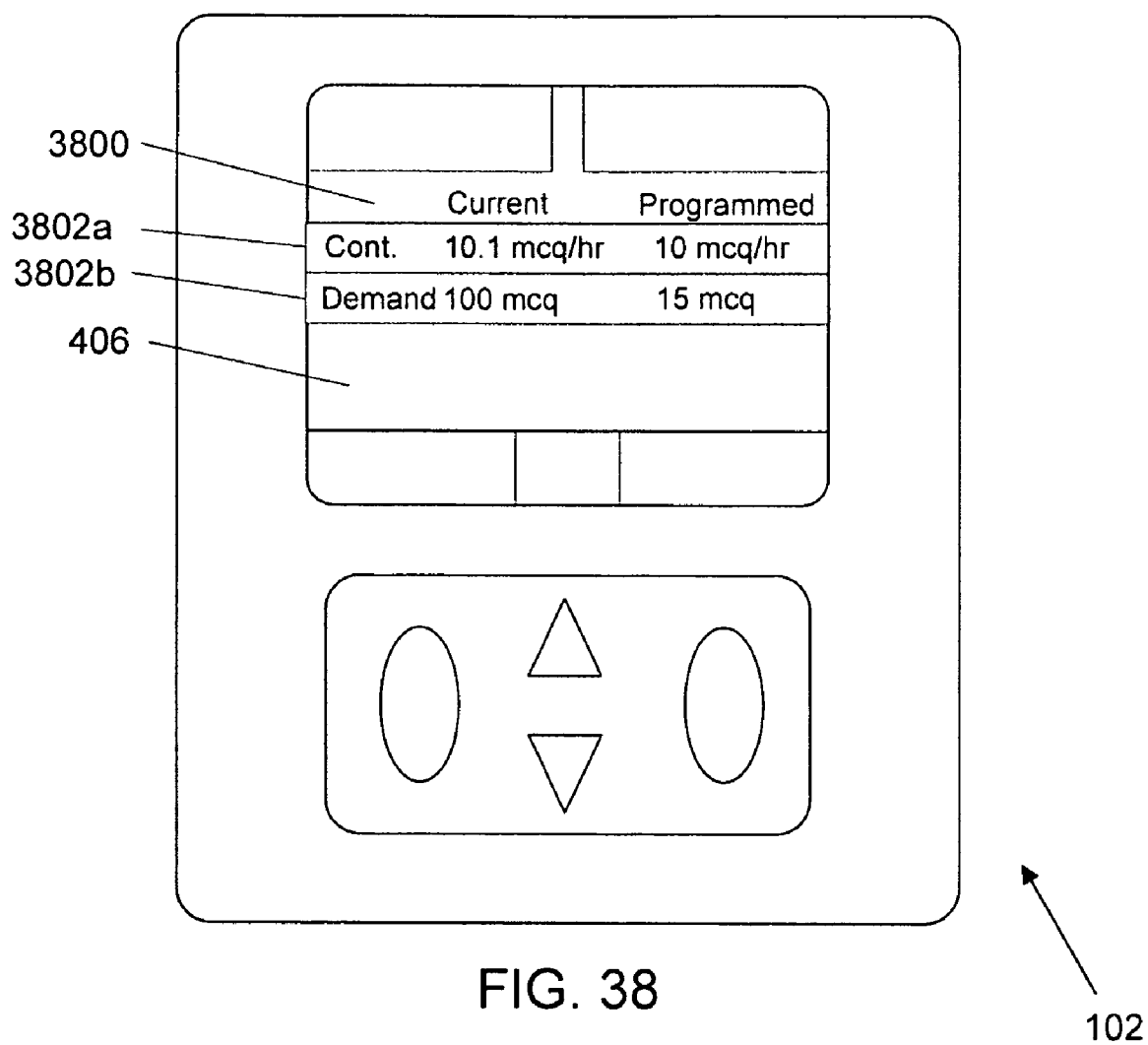
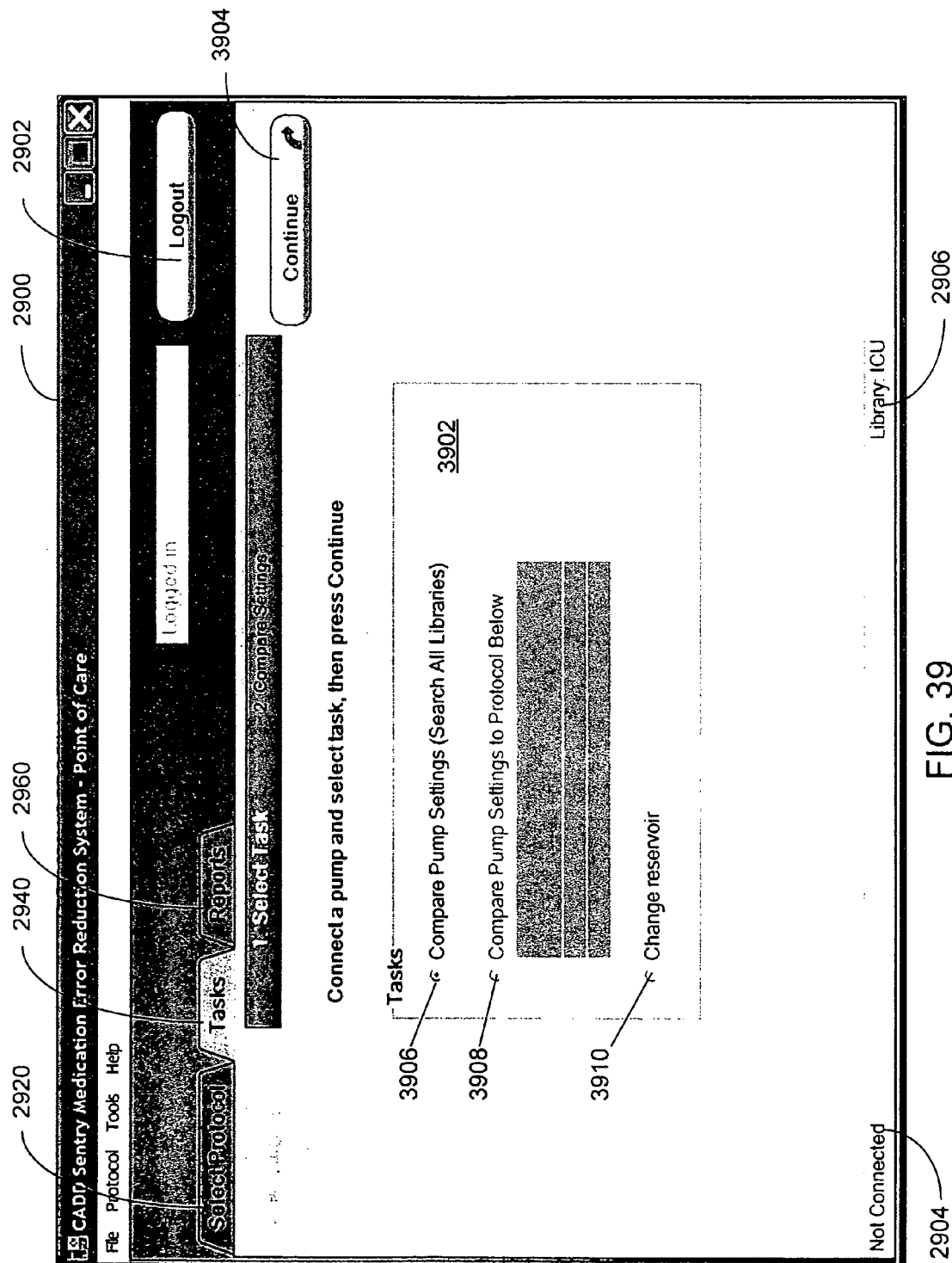
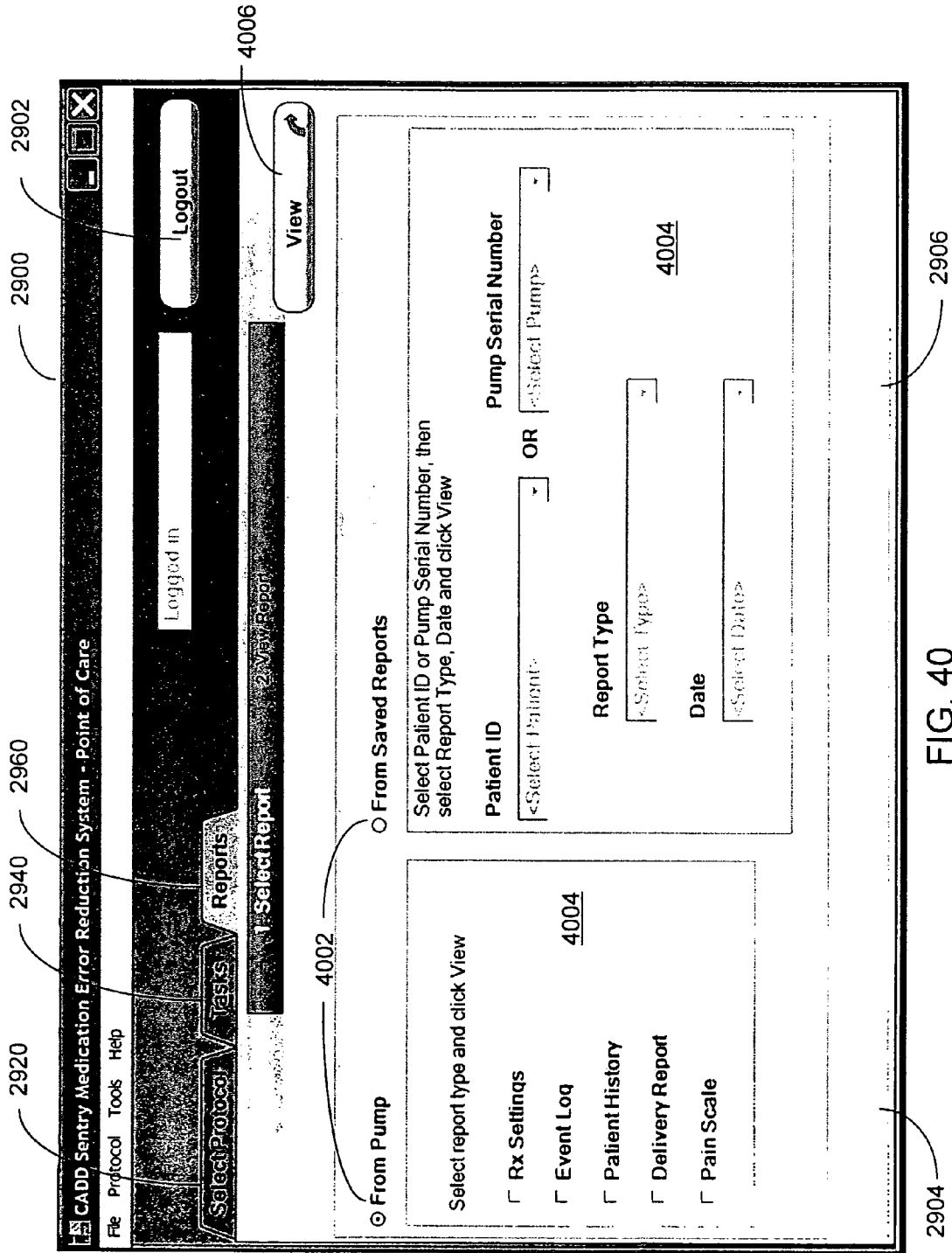


FIG. 37







4100

Report Viewer

1 Select Report 2 View Report

Back

Print

Save

<<<<DELIVERY REPORT>>>>

Patient ID: _____

Patient's Name: _____

CADD-Prizm+ (TM) Model 6101 SN 00611188

Date Printed: 01/12/05 Time: 11:41

Delivery Mode: PCS 6215-

Drug: _____

Current Rx SETTINGS

Units	Milligrams
Concentration	100.0 mg/ml
Continuous Rate	0.00 mg/hr
Demand Dose	0.00 mg
Reservoir Volume	1.0 ml
Milligrams Given	0.00 mg since 01/06/05 at 09:34
Lock Level	LL2
Upstream Sensor Enable	On

DELIVERY SINCE NEW PATIENT

001>
002>
003>
004>
005>
006>
007>
008>
009>
010>
011>
012>
013>
014>
015>
016>
017>
018>
019>
020>
021>
022>
023>
024>
025>
026>

FIG. 41

1

INTERFACE FOR MEDICAL INFUSION PUMP

BACKGROUND

Patients at hospitals and other care centers regularly require controlled drug intake as a part of the patient's prescribed therapy. One form of controlled drug intake is accomplished by infusing fluidic drugs with a medical infusion pump.

Medical infusion pumps, in general, provide regulated drug delivery to a patient. These pumps are used to deliver a selected drug or other therapeutic agent to a patient at a predetermined rate that is programmed into the pump. However, programming and managing such pumps can be difficult and cumbersome. Programming typically includes preloading a pump program into a pump and then entering pump parameters or data into the pump through a keypad that is directly in the pump. Each time the pump is programmed, the data must be reentered by hand.

Managing the status and locations of pumps also can be difficult. A single pump can be used programmed for delivering different fluids in different therapies and in different locations within a hospital. Similarly, the status of a pump and alarms can be difficult to monitor because the pumps are often in locations other than where the caregiver is located and have small displays on which information can be difficult to see.

SUMMARY

According to a first aspect, an apparatus for indicating a change in operation of a medical infusion pump is disclosed. The apparatus includes a memory configured to store an original pump parameter and a non-original pump parameter. The apparatus further includes a monitor. The apparatus also includes a programmable circuit in electrical communication with the memory and the monitor. The programmable circuit is programmed to display on the monitor the original pump parameter and the non-original pump parameter, the non-original pump parameter being displayed juxtaposed to the original pump parameter.

According to a second aspect, an apparatus for indicating a change in operation of a medical infusion pump is disclosed. The apparatus includes a memory configured to store an original pump parameter and a current pump parameter. The apparatus further includes a programmable circuit in electrical communication with the memory, the programmable circuit programmed to display the original pump parameter and the current pump parameter.

According to a third aspect, a method of indicating a change in operation of a medical infusion pump is disclosed. The method includes storing an original pump parameter. The method also includes storing a current pump parameter. The method further includes displaying the original pump parameter and the current pump parameter.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates a pump-computer communication system according to a possible embodiment of the present disclosure;

FIG. 2 illustrates an infusion pump network according to a possible embodiment of the present disclosure;

FIG. 3 illustrates the architecture of a computing system that can be used to implement aspects of the present disclosure;

FIG. 4 illustrates the architecture of a pump that can be used to implement aspects of the present disclosure;

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FIG. 5 is an exemplary infusion pump network according to a possible embodiment of the present disclosure;

FIG. 6A is an exemplary data structure for a pump protocol library according to a possible embodiment of the present disclosure;

FIG. 6B is an exemplary data structure for a pump protocol library according to a possible embodiment of the present disclosure;

FIG. 6C is an exemplary data structure for pump protocols according to a possible embodiment of the present disclosure;

FIG. 7 is an exemplary architecture of administrative software for setting global pump protocols according to a possible embodiment of the present disclosure;

FIG. 8 is one example of a computer user interface library import screen in accordance with the present disclosure;

FIG. 9 is one example of a computer user interface for administrative software in accordance with the present disclosure;

FIG. 10 is one example of a computer user interface location tab in accordance with the present disclosure;

FIG. 11 is one example of a computer user interface therapy tab in accordance with the present disclosure;

FIG. 12 is one example of a computer user interface protocol tab in accordance with the present disclosure;

FIG. 13 is one example of a computer user interface drug bar code display screen in accordance with the present disclosure;

FIG. 14 is one example of a computer user interface prescription order form display screen in accordance with the present disclosure;

FIG. 15 is one example of a computer user interface therapy selection screen in accordance with the present disclosure;

FIG. 16 is one example of a computer user interface qualifier selection screen in accordance with the present disclosure;

FIG. 17 is one example of a computer user interface drug selection screen in accordance with the present disclosure;

FIG. 18 is one example of a computer user interface drug delivery tab in accordance with the present disclosure;

FIG. 19 is one example of a computer user interface weight-based drug delivery tab in accordance with the present disclosure;

FIG. 20 is one example of a computer user interface secondary drug delivery tab in accordance with the present disclosure;

FIG. 21 is one example of a computer user interface alarm tab in accordance with the present disclosure;

FIG. 22 is one example of a computer user interface security tab in accordance with the present disclosure;

FIG. 23 is one example of a computer user interface appearance tab in accordance with the present disclosure;

FIG. 24 is one example of a computer user interface report tab in accordance with the present disclosure;

FIG. 25 is one example of a computer user interface library export screen in accordance with the present disclosure;

FIG. 26 is a flow diagram of methods and systems for custom programming of a medical infusion pump according to a possible embodiment of the present disclosure;

FIG. 27 is one example of a computer user interface library import screen in accordance with the present disclosure;

FIG. 28 is a flow diagram of methods and systems for editing and loading a protocol for a medical infusion pump according to a possible embodiment of the present disclosure;

FIG. 29 is one example of a computer user interface protocol selection screen in accordance with the present disclosure;

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FIG. 30 is one example of a computer user interface therapy selection screen in accordance with the present disclosure;

FIG. 31 is one example of a computer user interface qualifier selection screen in accordance with the present disclosure;

FIG. 32 is one example of a computer user interface drug selection screen in accordance with the present disclosure;

FIG. 33 is a flow diagram of methods and systems for custom programming of a medical infusion pump according to a possible embodiment of the present disclosure;

FIG. 34 is one example of a computer user interface drug delivery customization screen in accordance with the present disclosure;

FIG. 35 is one example of a computer user interface drug delivery customization screen in accordance with the present disclosure;

FIG. 36 is one example of a computer user interface medical infusion pump programming screen in accordance with the present disclosure;

FIG. 37 is a flow diagram of methods and systems for displaying medical infusion pump customizations according to a possible embodiment of the present disclosure;

FIG. 38 is one example of a computer user interface pump comparison screen in accordance with the present disclosure;

FIG. 39 is a schematic front view of a medical infusion pump displaying a change bar according to a possible embodiment of the present disclosure;

FIG. 40 is one example of a computer user interface report generation screen in accordance with the present disclosure; and

FIG. 41 is one example of a computer user interface report screen in accordance with the present disclosure.

DETAILED DESCRIPTION

Various embodiments will be described in detail with reference to the drawings, wherein like reference numerals represent like parts and assemblies throughout the several views. Reference to various embodiments does not limit the scope of the claims attached hereto. Additionally, any examples set forth in this specification are not intended to be limiting and merely set forth some of the many possible embodiments for the appended claims.

The following discussion is intended to provide a brief, general description of a suitable computing environment in which the invention may be implemented. Although not required, the invention will be described in the general context of computer-executable instructions being executed by a computer, for example, a hand held computer, a personal computing system, or a medical infusion pump. The structure, creation, and use of a message store hierarchical folder structure are described after the discussion of an exemplary operating environment.

Additionally, the logical operations of the various embodiments of the invention described herein are implemented as: (1) a sequence of computer implemented operations running on a computing system; and/or (2) interconnected machine modules within the computing system. Modules represent functions executed by program code such as commonly available programming languages or as the code found in a dynamic-link library (DLL). The implementation used is a matter of choice dependent on the performance requirements of the pump and the computing systems with which it interfaces. Accordingly, the logical operations making up the embodiments of the invention described herein can be referred to alternatively as operations, modules, and the like.

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FIG. 1 illustrates an exemplary embodiment of an infusion pump network 100 having a medical infusion pump 102, a computing system 104, and a communications link 106. The medical infusion pump 102 is configured to deliver therapeutic fluids, such as drugs, saline, or nutrition to a patient. Examples, of medical infusion pumps 102 include ambulatory pumps, stationary pumps, and pole mounted pumps.

The computing system 104 is configured to execute computer-readable instructions, such as computer software. The computing system 104 can be located in a variety of locations such as the point of care (POC) where a patient is being treated, in a healthcare facility at a location remote from the POC, or even at an off-site location remote from the healthcare facility itself. In further embodiments, the medical infusion pump 102 acts as the computing system 104.

In the exemplary embodiment, the computing system 104 is programmed to generate and store pump protocols for execution in the context of a pump application program. Each pump protocol includes a series of pump parameters. Pump parameters refer to settings that define an operational aspect of a medical infusion pump. The pump parameters dictate the control of the pump.

Pump protocols are collections of these pump parameters defining the variable operational characteristics of a medical infusion pump during application of a specific therapy, qualifier, and drug. The pump protocol includes a listing of operational parameters to be included in the pump, and correlates to an index for referring to a specific protocol containing a specific set of pump parameters. The index can be associated with a therapy, qualifier, and drug, and is either contained within the protocol or associated with a specific protocol. The pump protocol includes patient specific pump parameters and non-patient specific pump parameters. Patient specific pump parameters refer to those parameters which are set on a patient-by-patient basis, and for example include the basal delivery rate or bolus amount. Non-patient specific pump parameters refer to those parameters which are set for the pump to perform specific tasks, and do not account for the specific patient to which they are applied. These parameters are generally related to the pump, the infusion pump network, or the medical care to be provided by the pump and/or pump network. Non-patient specific pump parameters can include, for example, a range of permissible values for basal delivery, a range of values and patterns for basal delivery, a range of permissible values for boluses, a range of values and patterns for extended boluses, a starting value within a particular range of values, alarm values, protocols for data communication, and various flag settings.

A pump application program is a program having instructions (e.g., executable code, rules, and/or data) that control operation of the pump for a specific therapy or type of delivery (e.g., continuous delivery, intermittent delivery, pain control, chemotherapy, total parenteral nutrition, etc.). For example, a pump application program might contain instructions that define operation of a pump to accomplish various of the pump parameters. Pump application programs include, for example, pump protocols including both patient specific and non-patient specific pump parameters, and instructions for allocating memory, user interfaces, or algorithms for monitoring various sensors and driving a motor for the pump mechanism.

The communications link 106 connects the pump 102 and computing system 104. In various embodiments, the communications link 106 can include serial or parallel connections, wired or wireless connections, and a direct or networked connection to a computer. Additionally, the pump 102 and the computing system 104 can communicate using any protocol

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appropriate for data communication. Examples of network connections to a computer include Intranet, Internet, and LAN (e.g., Ethernet). Examples of wired connections to a computer include USB, RS-232, Firewire, and power-line modem connection. Examples of wireless connections include Bluetooth, 802.11a/b/g, infrared (IR), and radio frequency (RF).

FIG. 2 illustrates an exemplary embodiment of an infusion pump network 200 having a server 206 networked with a plurality of computing systems 104₁-104_n. The network 200 can be any wired or wireless network that enables data communication between the server, computing systems, and medical infusion pumps. Examples of networks include the Internet, Intranets, and LANs. Each computing system 104 can communicate with a medical infusion pump 102₁-102_n through a communication link 106.

In the exemplary embodiment, the individual computing systems 104_n execute software for generating and managing pump application programs and sets of pump operating parameters. The pump application programs and sets of pump operating parameters are stored on the server 206 so they can be accessed by other individual computing systems 104_n. The individual computing systems 104_n are also programmed to retrieve previously created pump application programs and sets of pump operating parameters that are stored on the server 206 for viewing, editing, and downloading to medical infusion pumps 102_n.

In alternative embodiments, the medical infusion pumps 102_n can directly access the server to retrieve pump application programs and sets of pump operating parameters. For example, the medical infusion pumps 102_n can be loaded with client software such as a web browser and communicate directly with the network 200, either through a wired or wireless connection as described herein.

In other alternative embodiments, one or more of the computing systems is not configured to communicate directly with a medical infusion pump 102_n, but rather provides administrative access to the server 206 for generating, viewing, and editing pump application programs and sets of pump operating parameters. Additionally, servers, workstations, and other computing systems unaffiliated with the medical infusion pumps 102_n can be included in the network 200.

In yet other alternative embodiments, the software is executed in the server 206. For example, the server functions as an application service provider that communicates user interface and other data entries in mark-up language such as HTML or some other language or protocol that allows a user to execute software from a remote location. In these embodiments, the server 206 can function as an application service provider in which the server provides access to the software for generating and storing pump application programs and pump protocols that a user can create and download to a medical infusion pump. For example, the server 206 could be located at a pump manufacture, pharmaceutical manufacture, pharmacist, or some other third party separate from the user. The server 206 in such an embodiment can be accessed either from an individual computing system 104 or by a medical infusion pump 102 that has networking capabilities and client software.

Example embodiments of a server 206 and a medical infusion pump 102 having a web browser are disclosed in U.S. patent application Ser. No. 11/066,425, which was filed on Feb. 22, 2005 and is entitled Server for Medical Device, the entire disclosure of which is hereby incorporated by reference.

FIG. 3 illustrates an exemplary architecture that can be used to implement aspects of the present disclosure, including

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the computing systems 104 and the server 206. The computing system architecture includes a general purpose computing device in the form of a computing system 300. The computing system 300 can be used, for example, as the computing system or server of FIG. 2, and can execute program modules included in the administrative software or user software disclosed below.

The computing system 300 including at least one processing system 302. A variety of processing units are available from a variety of manufacturers, for example, Intel or Advanced Micro Devices. The computing system 300 also includes a system memory 304, and a system bus 306 that couples various system components including the system memory 304 to the processing unit 302. The system bus 306 may be any of a number of types of bus structures including a memory bus, or memory controller; a peripheral bus; and a local bus using any of a variety of bus architectures.

The system memory 304 can include read only memory (ROM) 308 and random access memory (RAM) 310. A basic input/output system 312 (BIOS), containing the basic routines that help transfer information between elements within the computing system 300, such as during start up, is typically stored in the ROM 308.

The computing system 300 can also include a secondary storage device 313, such as a hard disk drive, for reading from and writing to a hard disk (not shown), and/or a compact flash card 314.

The hard disk drive 313 and compact flash card 314 are connected to the system bus 306 by a hard disk drive interface 320 and a compact flash card interface 322, respectively. The drives and cards and their associated computer readable media provide nonvolatile storage of computer readable instructions, data structures, program modules and other data for the computing system 300.

Although the exemplary environment described herein employs a hard disk drive 313 and a compact flash card 314, other types of computer-readable media, capable of storing data, can be used in the exemplary system. Examples of these other types of computer-readable mediums include magnetic cassettes, flash memory cards, digital video disks, Bernoulli cartridges, CD ROMs, DVD ROMs, random access memories (RAMs), or read only memories (ROMs).

A number of program modules may be stored on the hard disk 313, compact flash card 314, ROM 308, or RAM 310, including an operating system 326, one or more application programs 328, other program modules 330, and program data 332. A user may enter commands and information into the computing system 300 through an input device 334. Examples of input devices might include a keyboard, mouse, microphone, joystick, game pad, satellite dish, scanner, digital camera, touch screen, and a telephone. These and other input devices are often connected to the processing unit 302 through an interface 340 that is coupled to the system bus 306. These input devices also might be connected by any number of interfaces, such as a parallel port, serial port, game port, or a universal serial bus (USB). Wireless communication between input devices and interfaces 340 is possible as well, and can include infrared, Bluetooth, 802.11a/b/g, cellular, or other radio frequency communication systems. A display device 342, such as a monitor or touch screen LCD panel, is also connected to the system bus 306 via an interface, such as a video adapter 344. The display device 342 might be internal or external. In addition to the display device 342, computing systems, in general, typically include other peripheral devices (not shown), such as speakers, printers, and palm devices.

When used in a LAN networking environment, the computing system 300 is connected to the local network through

a network interface or adapter **352**. When used in a WAN networking environment, such as the Internet, the computing system **300** typically includes a modem **354** or other communications type, such as a direct connection, for establishing communications over the wide area network. The modem **354**, which can be internal or external, is connected to the system bus **306** via the interface **340**. In a networked environment, program modules depicted relative to the computing system **300**, or portions thereof, may be stored in a remote memory storage device. It will be appreciated that the network connections shown are exemplary and other methods of establishing a communications link between the computing systems may be used.

The computing system **300** might also include a recorder **360** connected to the memory **304**. The recorder **360** includes a microphone for receiving sound input and is in communication with the memory **304** for buffering and storing the sound input. The recorder **360** also can include a record button **361** for activating the microphone and communicating the sound input to the memory **304**.

A computing device, such as computing system **300**, typically includes at least some form of computer-readable media. Computer readable media can be any available media that can be accessed by the computing system **300**. By way of example, and not limitation, computer-readable media might comprise computer storage media and communication media.

Computer storage media includes volatile and nonvolatile, removable and non-removable media implemented in any method or technology for storage of information such as computer readable instructions, data structures, program modules or other data. Computer storage media includes, but is not limited to, RAM, ROM, EEPROM, flash memory or other memory technology, CD-ROM, digital versatile disks (DVD) or other optical storage, magnetic cassettes, magnetic tape, magnetic disk storage or other magnetic storage devices, or any other medium that can be used to store the desired information and that can be accessed by the computing system **300**.

Communication media typically embodies computer-readable instructions, data structures, program modules or other data in a modulated data signal such as a carrier wave or other transport mechanism and includes any information delivery media. The term "modulated data signal" refers to a signal that has one or more of its characteristics set or changed in such a manner as to encode information in the signal. By way of example, and not limitation, communication media includes wired media such as a wired network or direct-wired connection, and wireless media such as acoustic, RF, infrared, and other wireless media. Combinations of any of the above should also be included within the scope of computer-readable media. Computer-readable media may also be referred to as computer program product.

FIG. 4 illustrates the architecture of a medical infusion pump **400** that can be used to implement aspects of the present disclosure. A microprocessor **402** is in electrical communication with and controls a pump motor **404**, a screen **406**, an audible alarm **408**, and a vibratory alarm **410**. Other embodiments can use a microcomputer, or any other type of programmable circuit, in place of the microprocessor.

The pump motor **404** drives a drive mechanism **412**. The drive mechanism **412** delivers the therapeutic fluid to a patient. The drive mechanism can be connected to a plunger system, a peristaltic drive mechanism, or another type of fluid delivery system.

The screen **406** can have many different configurations such as an LCD screen. The screen **406** displays a user inter-

face that presents various items of information useful to a patient or caregiver. The audible alarm **408** is a beeper, and an alarm provides actual alarms, warnings, and reminders. Similar to other portable electronic devices such as a cellular telephone, the vibratory alarm **410** provides an alarm to either supplement the audio alarms or replace the audio alarm when an audible beep would be disruptive or not heard. A user can selectively enable or disable the audible **408** and vibratory **410** alarms. In one possible embodiment, however, both the audible **408** and vibratory **410** alarms cannot be disabled at the same time.

The microprocessor **402** is in electrical communication with both a random access memory (RAM) **416** and a read only memory (ROM) **418**, which are onboard the pump **400** but external to the microprocessor **402** itself. In one possible embodiment, the microprocessor **402** includes internal memory as well. The RAM **416** is a static RAM stores that data that can change over time such as pump settings and a historical log of events experienced by the medical infusion pump **400**. The ROM **418** stores code for the operating system and the application programs. The ROM **418** can be any type of programmable ROM such as an EPROM. In one possible embodiment, the RAM **416** has 500 kilobytes of memory capacity and the ROM **418** has 2 megabytes of memory capacity.

An infrared (IR) port **420** is in electrical communication with the microprocessor. As explained in more detail below, the IR port **420** provides data communication with an external device such as a computer for programming an application program, programming pump settings, and downloading historical data logs. The medical infusion pump **400** can include other types of communication ports in place of or in addition to the IR port **420**. Examples of other possible communication ports include a radio frequency (RF) port or a port that provides a hard-wired data communication link such as an RS-232 port, a USB port, or the like.

A real-time clock **422** provides a clock signal to the microprocessor **402**. An advantage of having a real-time clock **422** is that it provides the program with the actual time in real-time so that the programs executed by the medical infusion pump can track and control the actual time of day that drug delivery and other events occur. Various durations described here are used for alerts, alarms, reminders, and other functions. In one possible embodiment, the timers are formed by the real-time clock **422** and software executed by the microprocessor **402**.

A keypad **424** also provides input to the microprocessor **402**. Although other possible types of keypads are possible, one type of keypad has four buttons and is a membrane-type of keypad, which provides resistance to water and other environmental conditions. The keypad **424** contains soft keys for which the function of the keys can change as a user executes different menu selections and commands.

An audio bolus button **425** optionally provides input to the microprocessor **402**. The audio bolus button **425** can program the pump **400** to audibly administer a bolus of drugs or other therapeutic fluids without requiring visual confirmation using the pump. In an example embodiment, the audio bolus button **425** can be pressed a series of times to trigger bolus delivery of a selected volume, based on a preprogrammed trigger granularity. A single button press can represent a bolus of 5 grams, as selected by a user, and subsequent presses of the audio bolus button can represent multiples thereof.

Other inputs into the microprocessor **402** can include an occlusion sensor **426**, which is sensitive to occlusions in the therapeutic fluid delivery line; a cartridge sensor **428**, which is sensitive to the presence of a therapeutic fluid cartridge; and a motion detector **430**, which detects motion of a gear (not

shown) in the drive mechanism **412**. In an exemplary embodiment, the cartridge sensor **428** includes one or more sensors configured to detect insertion of a therapeutic fluid cartridge. The pump **400** can detect the type of cartridge present via a mechanical interface, and can include in the pump software instructions regarding operation in conjunction with the cartridge. Examples of cassette sensing features are described, for example, in U.S. Pat. No. 5,531,697, filed on Apr. 15, 1994, issued on Jul. 2, 1996, and entitled Systems and Methods for Cassette Identification for Drug Pumps.

FIG. 5 illustrates a schematic architecture of a medical infusion pump network **500** according to an exemplary embodiment. The medical infusion pump network **500** includes an administrator computer **502** communicatively connected to the server **206** of FIG. 2, which includes a database **504**. The medical infusion pump network **500** also includes one or more medical infusion pumps **102** and computing systems **104**.

The administrator computer **502** and computing systems **104** are systems such as those described above in conjunction with FIG. 3. The administrator computer **502** includes administrative software installed on or accessible to the computer for generating one or more libraries **508** of pump protocols **510**. An exemplary embodiment of the administrative software is described below in FIGS. 7-25.

In the present disclosure, libraries refer to collections of pump protocols generated using the administrative software described herein. Libraries can be stored in files, databases, or other data structures. Libraries contain pump protocols as well as indices pointing to the protocols, and are loaded in user software to select a specific pump protocol for operation of a medical infusion pump.

The computing systems **104** include user software for accessing one or more libraries **508** of protocols **510** and programming a medical infusion pump **102** with a protocol **510** or a library **508**. In one possible embodiment, the computing systems **104** are optional in that the user software resides directly on the medical infusion pumps **102**. An exemplary embodiment of the user software is described below in FIGS. 26-41.

The medical infusion pumps **102** connect either to a computing system **104** or directly to the server **206**, and are described above in conjunction with FIG. 4. In a first embodiment, the medical infusion pumps **102** are configured to accept a pump protocol from the server **206** or the computing system **104**. In a second embodiment, the medical infusion pumps **102** are configured to accept a library **508** of pump protocols **510** directly from the server **206** or from the computing system **104**.

The database **504** contains pump protocol data **506** and log files **516**. The pump protocol data **506** forms a plurality of libraries **508** which in turn each include a number of protocols **510**. Each protocol **510** is stored as a data record, and includes a set of parameters, including patient specific pump parameters **512a** and non-patient specific pump parameters **512b**, as described above. Each library **508** can contain one or more pump protocols **510**.

The log files **516** include log data regarding access and usage of the libraries **508**, and can include information related to the administrator computer **502**, the medical infusion pumps **102**, or the computing systems **104** authorized to connect to the server **206**. In one possible embodiment, the log files include access records, which record instances in which medical infusion pumps access a library **508** on the server **206**.

FIGS. 6A-6C illustrate exemplary data sets accepted by medical infusion pumps **102**. The specific data set accepted

by a medical infusion pump **102** is dependent upon that pump, but in various embodiments, the pumps accept data sets representing pump libraries, pump protocols, or pump programs. FIG. 6A shows a library **508** in greater detail. The library **508** can be loaded into the memory of a medical infusion pump **102**, allowing a user of the pump to select a protocol for operation. The library **508** includes a number of protocols **510**, which include patient specific pump parameters **512a**, non-patient specific pump parameters **512b**, and an index **514**. The number of protocols **510** within a given library can vary, and depends upon the number defined using the administrative software.

The total number of pump parameters **512a-512b** remains constant for each particular model of pump, but can vary between types of pumps. Additionally, the pump parameters **512a-512b** can be configured in a number of formats within each protocol **510** for the same type of pump. For example, the number of patient specific pump parameters **512a** can vary between protocols due to the specific type of drug and therapy applied. For example, a protocol defining a continuous drug delivery may only require a single patient specific protocol, namely, the drug delivery rate. In another example, a protocol defining intermittent drug delivery may require additional patient specific pump parameters, such as the time between drug delivery phases, a bolus amount, patient bolus amounts, and other parameters. The number of non-patient specific pump parameters **512b** represents the difference between the total number of parameters programmable into a pump and the number of patient specific pump parameters **512a** as dictated by the therapy and drug applied.

The index **514** can be any generic index referencing a specific location within the library. Each index is unique within the library, although another library may contain the same index and relate that index to a different set of pump parameters contained within that library. In the exemplary embodiment shown, the index **514** includes therapy, qualifier, and drug regions. By selecting a combination of a therapy, a qualifier, and a drug, a user of the system can select one of the protocols **510** from the library **508**. Therapies, as referred to herein, are the methods of patient treatment for diseases or generalized rehabilitation. For example, a therapy can be an epidural treatment or patient-controlled analgesia. Qualifiers include factors affecting the administration of a therapy, such as weight, age, or sensitivity of a patient to a specific therapy. Drugs refer to any therapeutic fluids deliverable by a medical infusion pump.

Each of the protocol entries on the server can be assigned an identification code in order to ensure that the medical infusion pumps access a correct library and/or protocol, and that the protocols on the medical infusion pumps and computing systems associated with the server **206** of FIG. 5 are up to date. These identification codes are generated by the server and stored in conjunction with the protocol in the server **206**, as well as in the medical infusion pump **102** and/or its associated computing system **104**. The identification codes can be generated using globally unique identifiers (GUID), and are used to track the specific protocol and/or library accessed by each pump **102** or computing system **104** in the database **504**. A GUID is a 128-bit pseudo random number used to provide a statistically unique identifier for corresponding the protocol on the pump **102** to the protocol as stored in the server **206**. The GUID can be generated by the server **206** and transmitted alongside the protocol and/or library when transmitted to the computing system **104** or infusion pump **102**. The server copy of the GUID can be stored alongside the protocol in the database **504**, and the pump copy can be stored in RAM in the medical infusion pump **102** or computing system **104**. Each

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time the medical infusion pump **102** or computing system **104** accesses the protocol on the server **206**, the GUID assigned to that protocol as stored in the pump **102** or computing system **104** can be matched to the protocol as stored in the database **504** to ensure that the correct protocol is accessed. Different protocols in different libraries can use the same index of therapy, qualifier, and drug, and can be stored in the same database, but have a unique GUID and are therefore uniquely identifiable. In a possible embodiment, the GUID system can be used in conjunction with user access control systems, such as are disclosed in conjunction with both the user software and administrative software, below. In a further embodiment, a new GUID can be generated and associated with each protocol when first created, or optionally each time the protocol is edited using administrative software, such as is described below.

FIG. 6B illustrates a second possible embodiment of a library **508**. The library **508** contains a number of protocols **510**, which, as in FIG. 6A, include patient specific pump parameters **512a**, non-patient specific pump parameters **512b**, and an index **514**. The number of protocols **510** included in each library **508** may vary, so the number of protocols **510** in the library **508** of FIG. 6B may be different from the number of protocols in the library shown in 6A. In the embodiment shown, the library **508** contains one protocol **510**. Additionally, one or more of the therapy, qualifier, and drug regions in the index **514** can be replaced by other index criteria, such as locations, pump programs, doctor identification, or other indexable criteria capable of referring to a unique pump protocol within the library. In the example shown, the "therapy" region is used to select a pump program, such as a continuous delivery program, an intermittent delivery program, or a specific type of program such as a pain management program. The "qualifier" region is used to select a doctor, and may be the name of a doctor using the infusion pump network of FIG. 5.

FIG. 6C illustrates a series of possible pump protocols **510a-510c**. The pump protocols **510a-510c** incorporate patient specific pump parameters **512a** and non-patient specific pump parameters **512b**. Protocols **510** are specific to a pump **102**, in that the pump has a specific number and type of parameters that are programmable. Therefore, the total number of pump parameters remains constant. However, the number of patient specific pump parameters **512a** can vary depending upon the protocol selected for programming into the pump, which in turn dictates that the number of non-patient specific pump parameters **512b** varies as well. In a possible embodiment, one of the protocols **510** is selected using a computing system **104** or infusion pump **102**. If selected using the computing system, the protocol is then programmed into the medical infusion pump **102**.

In another possible embodiment, the pump protocol **510** is selected using the infusion pump **102** or the computing system **104**. The pump protocol **510** is then incorporated into a pump program to provide a set of instructions dictating the operation of a medical infusion pump **102** according to the protocol **510**. The complete pump program is then downloaded into the pump **102**. In yet another possible embodiment, the pump program is downloaded to the pump **102** at a different time from the pump protocol **510**. In still a further embodiment, multiple pump programs reside within the pump **102**, and the pump protocol **510** contains a parameter which dictates which pump program is to be used. In a further embodiment, the pump program within the pump is altered based on one or more of the pump parameters included in the pump protocol **510**.

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FIG. 7 illustrates exemplary architecture of administrative software **700** for generating one or more libraries of pump protocols. The software **700** can operate within the server **206**, pump **102**, computing system **104**, or a combination thereof.

The administrative software **700** allows a user, for example a doctor, nurse, pharmacist, or other caregiver, to create, define, and edit pump application programs and protocols for execution in and control of medical infusion pumps **102**. For example, the administrative software **700** can generate protocols and programs that can be loaded using the user software described in FIGS. 26-41, below.

The administrative software **700** provides protocol-based programming of medical infusion pumps in which the user creates a pump application program by designating a particular therapy and other criteria such as a location and qualifiers (e.g., patient age, weight, skin surface area). Once criteria are selected, the administrative software **700** applies rules and other logic that assembles sets of pump parameters into a pump protocol. For example, the administrative software **700** might be used to select one delivery pattern and enable bolus delivery if the selected therapy is for delivering pain medication and another delivery pattern and not enable bolus delivery if the selected therapy is for parenteral nutrition. In another example, the administrative software **700** might be used to select one range of permissible delivery rates if one of the criteria indicates the patient is an adolescent and different range of permissible delivery rates if the patient is an adult. Other embodiments permit programming a medical infusion pump **102** without using therapy-based programming. Additional embodiments of protocol- or therapy-based programming is discussed in more detail in U.S. patent application Ser. No. 11/003,147, filed on Dec. 3, 2004 and entitled Programming Medical Pumps with Electronic Standing Order Template, the entire disclosure of which is hereby incorporated by reference.

Operation of the software **700** begins at a start module **702**. The start module **702** corresponds to initial execution of the administrative software by clicking on an icon on the computer or by some other mechanism for executing software. Upon startup, the software **700** connects to a library loaded in the database **504** of FIG. 5.

Following the start module, operational flow optionally proceeds to a load library module **704**, which allows a user to access a listing of library files available to the administrative software **700**. The library files contain one or more libraries, which in turn contain a collection of pump protocols as described above. The collection of library files can be stored in the server **206** or in one or more individual computing systems **102**. The load library module **704** allows the user to select a library file containing one or more libraries for viewing, editing, and downloading to a medical infusion pump **102**. If a user does not want to download or otherwise access an existing library, it can selectively bypass the load library module **704**. An example of when a user bypasses the load library module **704** is if the user plans to only create a new library or edit one or more protocols within the currently loaded library. In an alternative embodiment, the software always executes the load library module **704** and the user then selectively chooses whether to load any previously created libraries via a stored library file.

Following the start module **702** and optional load library module **704**, operational flow proceeds to a login module **706**. The login module **706** regulates user rights in the software **700**. User rights define access levels to the currently connected library in user software, and are configurable for users such as doctors, nurses, or other caregivers. Based on the user

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rights assigned to a caregiver, that user will have a set access level allowing the user to view, add, or edit pump libraries within the user software, described in detail below. Access levels can be set according to a variety of criteria. Examples include the type of caregiver (e.g., physician, nurse, pharmacist), location (e.g., hospital, clinic, pharmacy, manufacturer), or a particular department within a location.

In possible embodiments, different access levels also provide different rights with respect to a particular pump protocol or pump operational parameters. For example, one access level might give a user a right to edit, create, and download pump protocols and/or pump application programs. One access level might permit a user the right to edit, create, and download only specified pump parameters, such as the patient specific pump parameters described in conjunction with FIGS. 5-6. One access level might permit a user the right to only edit or download pump parameters. One access level might permit a user the right to only view and download pump parameters. Different embodiments can include the ability to provide an access level for a user any combination of rights to create, edit, view, and/or download pump application programs and/or pump operational parameters. An example of lock levels are disclosed in U.S. Pat. No. 6,475,180, issued on Nov. 5, 2002 and entitled Drug Pump Systems and Methods, the entire disclosure of which is hereby incorporated by reference.

Once the user is logged in and the library is optionally loaded, the user selectively executes three different modules, a library module 708, a therapy module 710, and a protocol module 712.

The library module 708 assigns a label that identifies an entity and user attributes for the selected entity. Entity attributes can be properties specific to the library, such as a name of a doctor, a name of a healthcare regimen, or a location of the medical infusion pump or pump network, for example the hospital or department at which the pump is located. User attributes define the users allowed to access and modify pump parameters for protocols associated with a particular library by using the medical infusion pump, and can also define users allowed to modify pump protocols using user software, as described below. The library module 708 contains a library definition module 714 and a user rights module 716, which are configured to perform these tasks, respectively.

The therapy module 710 adds and modifies therapies, qualifiers associated with the therapies, and drugs. The therapy module includes a therapy definition module 718, a qualifier definition module 720, and a drug definition module 722. The therapy definition module 718 controls addition and editing of therapies, which are the methods of patient treatment for diseases or generalized rehabilitation as previously described. The qualifier module 720 defines qualifiers and associates the qualifiers with one or more therapies. The drug definition module 722 defines one or more drugs that can be used in the medical infusion pump.

The protocol module 712 adds, edits, and defines protocols by associating therapies, qualifiers, and drugs with pump parameters to form libraries of pump protocols for a medical infusion pump. The protocol module 712 allows a user to select a therapy defined in the therapy definition module 718. The protocol module further allows the user to associate a qualifier defined in the qualifier definition module 720 with the selected therapy. For example, one or both of "adults" and "children 5-10 years" qualifiers can be associated with an epidural therapy. The protocol module 712 also associates one or more drugs with each therapy and qualifier combination, indicating that use of the drug is appropriate for that

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therapy and qualifier. The protocol module 712 guides the user in defining a protocol by assigning default pump parameters to be associated with the selected therapy, qualifier, and drug.

The protocol module 712 allows a user to associate more than one qualifier to each therapy, and also allows a user to associate more than one drug to each therapy and qualifier combination. For example, a protocol used in an epidural therapy for an adult can include a higher basal delivery rate parameter than a protocol used with a child for the same therapy. Likewise, usage of one drug can require a higher or lower dosage than another drug for the same therapy and qualifier because of concentration, reaction, or other factors.

Operational flow proceeds from the modules 708, 710, 712 to an optional export library module 724. The export library module 724 saves the defined or edited pump application programs and parameters in a file or other data structure that can be loaded by the administrative software 700 at another time or location, or can be loaded by user software such as described below in FIGS. 26-41. If the export library module 724 does not execute, the library remains within the normally connected database 504 of FIG. 5, but is not extracted into a file for portability to a pump not connected to the network or to another medical infusion pump network. One or more libraries can be exported into a single library file.

Operation of the software 700 terminates at an end module 726. The end module 726 corresponds to termination of the administrative software 700 by clicking on a close window button on the computer or by some other mechanism for terminating execution of software.

In one embodiment of the administrative software 700, a user of the software 700 defines each protocol included in a library. In defining each protocol, the user assigns the index to the protocol, such as the therapy, qualifier, and drug defined in the modules 708, 710, 712 above. In a second possible embodiment, the administrative software includes a number of default settings or pump parameter modifications used when specific therapies, qualifiers, or drugs are selected. The user selects a therapy, qualifier, and drug to associate with a pump protocol. The administrative software 700 can include instructions dictating that selection of one or more of the therapies, qualifiers, and drugs sets or modifies one or more of the patient specific pump parameters or non-patient specific pump parameters. In one example of this second embodiment, a user setting a drug having a maximum safe consumption rate will trigger the administrative software 700 to preset an acceptable range of programmable delivery rates and a default delivery rate in the protocol, as well as alarms or other non-patient specific pump parameters. In another possible example of this second embodiment, a user setting a qualifier indicating a low age, such as "Children 5-10 years old", will set or adjust the protocol to result in a low delivery rate and demand dose being incorporated into the protocol, and will set one or more parameters related to alarms for use in a medical infusion pump.

Referring now to FIG. 8, a library import screen 800 is shown. The library import screen corresponds to the load library module 704, and is optionally used to load a library file containing one or more libraries of pump programs in the administrative software 700 of FIG. 7, above. The library import screen 800 includes a file selection field 802 and a password field 804. The term field as used herein can include the window, or screen, generally, and can also include menus, selectable lists, or buttons within the window.

The file selection field 802 displays one or more library files that are available to be selected. The file selection field 802 allows a user to select one or more of the protocol library

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files, in conjunction with selection control buttons **806a**, **806b**. The password field **804** controls access to the selected library file by requiring a user to input a correct password associated with the selected file, or library within the file.

A location field **808** presents the directory path of the selected library file and a browse button **810** provides browsing capabilities to allow a user to find a library file other than those displayed in the library selection field **802**.

In use, the library import screen **800** initially presents a listing of library files in the file selection field **802** available to the administrative software. The user selects one of the displayed library files, or presses the browse button **810** to search for additional library files. The user selects a library file by clicking on the displayed library file, or by other selection method. The directory path of the selected library file appears in the location field **808**, and the user then enters a password in the password field **804** corresponding to the selected library file. The user confirms the choice using the selection control buttons **806a**, **806b**. The administrative software confirms that the user-entered password is correct, and accesses the library file.

Referring now to FIG. 9, a user interface **900** for the administrative software **700** of FIG. 7 is shown. The user interface **900** includes features associated with the modules incorporated in the administrative software **700**, and corresponds to the screen displayed following the start operation **702** of FIG. 7. The user interface **900** includes a number of features providing global control and status information to a user.

Global control features included in the user interface **900** relate to library and pump access settings. A library field **902** provides a listing of libraries currently loaded by the software. The library field **902** contains the libraries which have been loaded using the load library module **704** of FIG. 7. A login button **904** generates a login screen that checks whether a user has the right to modify pump parameters and protocols.

The user interface **900** can display information related to the status of the network of medical infusion pumps. A database identification field **906** identifies the database **504** currently connected to the administrator computer **502**, as shown in FIG. 5. In additional exemplary embodiments, additional information can be displayed, such as the location of the server and/or medical infusion pumps connected to the infusion pump network or a serial number or other identification number of the pumps or libraries.

The user interface **900** also includes a location tab **920**, a therapy tab **940**, and a protocol tab **960**. Referring back to FIG. 5, the location tab **920** corresponds to the location module **708**, the therapy tab **940** corresponds to the therapy module **710**, and the protocol tab **960** corresponds to the protocol module **712**. By clicking on or otherwise selecting a tab, a user transfers operation to the module corresponding to that tab.

Referring now to FIGS. 10-12, the user interface **900** is shown, and location tab **920**, therapy tab **940**, and protocol tab **960** are described in greater detail. FIG. 10 shows the user interface **900** after selection of the location tab **920**, or after initial execution of the login module **706** and optional load library module **704**.

A region of the location tab **920** supersedes the therapy tab **940** and protocol tab **960**. Within the region exposed by the location tab **920**, a library selected in the library field **902** populates a library description field **1002** and a user accounts field **1004**. The library description field **1002** describes the library that is currently loaded, and includes attributes of the location in which the library is used, or other information about the library. The location attributes can include the name of the hospital or the department in the hospital associated

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with the library. The additional information can include information related to the users of the library, the contents of the library, or other information. The library description field **1002** corresponds to the location attributes module **714** of FIG. 7. The user accounts field **1004** displays a listing of user accounts associated with the library. Each of the user accounts generally correspond to a user, but can also correspond to a location of a computing system **104** or medical infusion pump **102**. The user accounts define the persons allowed to access and modify pump protocols, and/or parameters associated with the library at the point of care, such as a medical infusion pump **102** or computing system **104** executing user software. The user accounts field **1004** enables a user to add, edit, or delete users from the listing using the buttons **1006a-1006c** provided. The user accounts field corresponds to the user rights module **716** of FIG. 7.

In a possible embodiment, a log report field **1008** can optionally direct the server **206** to generate a record for various events occurring in the database **504**. For example, a log report can be created each time a protocol is sent to a medical infusion pump **102**. Alternately, a log report is created each time a library is sent to a medical infusion pump **102**. In further embodiments, a log report is created each time a library is edited or accessed. In still further embodiments, globally unique identifiers are entered into the log report related to instances where computing systems **104** and/or infusion pumps **102** access a library in the database **504**. In the embodiment shown, the log report field **1008** is a selectable check box, but can be implemented as any other type of selectable field.

A password field **1010** sets a password for the currently selected library file. The password protects access to the library from the perspective of user software residing on either a computing system **104** or an infusion pump **102** such that only users with knowledge of the password associated with the library file can load the library using the load library module **704** of FIG. 7 and user interface **800**.

Referring now to FIG. 11, the user interface **900** is shown with the therapy tab **940** selected. A region of the therapy tab **940** supersedes the location tab **920** and the protocol tab **960**. The therapy tab **940** corresponds to the therapies module **710**, which defines therapies, qualifiers, and drugs used by medical infusion pumps associated with the administrative software **700** of FIG. 7. The therapy tab **940** includes a therapy definition field **1102**, a qualifier definition field **1104**, and a drug definition field **1106**.

The therapy definition field **1102** corresponds to the therapy definition module **718** of FIG. 7, and includes a therapy listing **1108**, a therapy notes field **1110**, and control buttons **1112a-1112c**. The therapy listing **1108** displays the therapies currently defined in the library displayed in the library listing **802**. Two example therapies, "Patient Controlled Analgesia" and "Epidural", are shown in the therapy listing **1108**, and are associated with a library named "Neonatal Intensive Care Unit". The therapy notes field **1110** contains administrative user-defined notes related to the therapy selected in the therapy listing **1108**. The notes relate to a therapy, and include information related to administration of the therapy, such as messages related to dosage, bolus amount, or administration. The therapy notes field **1110** presents administrative user-created notes to convey therapy-specific information to caregivers using or programming the pump. Control buttons **1112a-1112c** allow a user to add, edit, and delete therapies from the therapy listing **1108** and therapy notes field **1110**.

The qualifier definition field **1104** corresponds to the qualifier definition module **720** of FIG. 7, and includes a qualifier

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listing **1114**, a qualifier notes field **1116**, and control buttons **1118a-1118c**. The qualifier definition field **1104** lists the qualifiers associated with the therapy selected from the list shown in the therapy listing **1108**. For example, an administrative user might add a "Children 5-10 yrs" entry to the qualifier listing **1114**. Each therapy relates to one or more qualifiers, such as a general qualifier, a weight based qualifier, or an age based qualifier. The qualifier notes field **1116** contains notes describing the difference in application of the therapy based on the qualifier selected. In the case of the "Children 5-10 years" qualifier, the qualifier notes field **1116** can indicate a lower than normal dosage to be administered. Notes associated with the qualifier display in the qualifier notes field **1116** only when the qualifier is selected.

The drug definition field **1106** corresponds to the drug definition module **722** of FIG. 7, and includes a drug listing **1120** and control buttons **1122a-1122d**. The drug listing **1120** includes information related to the therapeutic fluid used in the medical infusion pump. This information can include the drug name, identification code, units, concentration, and usage. The control buttons **1122a-1122c** allow a user to add, edit, or delete drugs in the drug listing **1120**. A bar code control button **1122d** generates a bar code screen including information related to a drug.

Referring now to FIG. 12, the user interface **900** is shown with protocol tab **960** selected. The protocol tab **960** supersedes the location tab **920** and the therapy tab **940**. The protocol tab **960** corresponds to the protocol module **712** of FIG. 7, and associates therapies, qualifiers, and drugs to allow a user to define protocols by setting pump parameters for inclusion within pump programs. The protocol tab **960** includes a protocol field **1202** and control buttons **1204a-1204e**. The protocol field **1202** lists the combinations of therapies, qualifiers, and drugs for which a protocol is defined. The protocol field **1202** also lists a pump type **1203** for which each protocol is defined. By specifying a pump type for which each protocol is defined, it is possible to enable pump-specific protocol programming, while still using the administrative software **700** and user software, described below, for all pump types configurable using the protocol-based programming scheme described herein.

The control buttons **1204a-1204e** operate to add, edit, view, and/or delete the protocol for the combinations of therapies, qualifiers, and drugs. The control buttons **1204a-1204d** allow a user to set pump parameters so as to define the protocol. Control button **1204e** generates a prescription form screen representing the protocol for the selected therapy, qualifier, and drug.

FIG. 13 shows a bar code screen **1300** displaying a bar code for a drug defined in the administrative software **700** of FIG. 7. A drug identification code is associated with each drug in the drug listing **1120** of FIG. 11. A drug is selected from among those in the drug listing **1120** of FIG. 11, and the bar code screen **1300** displays upon clicking on the control button **1122d**.

The bar code screen **1300** includes a print preview field **1302**, a printer drop down menu **1304**, a label information menu **1306**, a copies drop down menu **1308**, and control buttons **1310a-1310c**. The print preview field **1302** displays a bar code associated with the selected drug. The printer drop down menu **1304** lists available printers configured to print the bar code. The label information drop down menu **1306** defines the label configuration to which the bar code is directed. The label configuration includes, for example, the size and layout of the label paper. The copies drop down menu **1308** dictates the number of copies of the bar code that are

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printed. Control buttons **1310a-1310c** provide printing, cancellation, and help procedures to a user.

In use, the bar code corresponds to a drug identification code associated with the drug. In a possible embodiment, a pharmacist can print the barcode associated with the drug using the administrative software **700** via the bar code screen **1300** and affix the printed bar code label to the drug container. The labels indicate the drug and dosage being delivered by the pump. This provides an easily accessible and visually prominent indication of the drug being delivered by a medical infusion pump.

A caregiver connecting a drug to a medical infusion pump **102** will scan the bar code on the drug container, which will correspond to the drug identification code associated with the drug in the administrative software **700**. This ensures that the caregiver affixes the drug to the pump which corresponds to the protocol selected using administrative software **700**.

FIG. 14 shows a prescription form screen **1400** displaying prescription information related to a specific therapy, qualifier, and drug. The prescription form screen displays upon selection of control button **1204e** on protocol tab **960**. The prescription form screen **1400** corresponds to the currently selected protocol, and therefore incorporates information specific to the selected protocol. Prescription information includes, for example, directions for application of the drug according to the defined protocol, and parameters such as drug delivery rates or bolus amounts. The prescription form also includes usage notes describing operation or application of the selected therapy, qualifier, and drug.

A doctor using the prescription form dictates the protocol used in the pump by using a prescription form analogous to the prescription form screen. The prescription form **1400** generated by the administrative software will correspond to the prescription form completed by the doctor. In the embodiment shown, the prescription form screen **1400** that is generated includes information specific to the drug and therapy administered, which may be notes related to administration of the drug and therapy as dictated by the doctor. For example, the prescription form will include drug information, such as the name, type, concentration, and notes regarding the drug, and will also include information related to patient specific pump parameters associated with a selected therapy, qualifier, and drug selected from a library.

Referring now to FIG. 15-17, a protocol definition user interface **1500** defines the relationships between the therapies, qualifiers, and drugs added to the library by the therapy module **710** and using the therapy tab **960**. A user defines a protocol by setting an index by sequentially selecting a therapy, a qualifier, and a drug, and then by associating pump parameters with that index. In setting the index using the user interface **1500**, a therapy drop down menu **1502** connects to a therapy notes field **1504**, a qualifier drop down menu **1506** connects to a qualifier notes field **1508**, and a drug drop down menu **1510** connects to a drug notes field **1512**.

FIG. 15 shows the initial state of the protocol definition user interface **1500**. A list of therapies appears in the therapy drop down menu **1502**, while the remaining menus **1506**, **1510** and fields **1504**, **1508**, **1512** remain blank.

FIG. 16 shows the state of the protocol definition user interface **1500** after a therapy is selected in the therapy drop down menu **1502**. Notes related to the selected therapy appear in the therapy notes field **1504**, and a list of qualifiers associated with the selected therapy appears in the qualifier drop down menu **1506**. The notes correspond to the therapy notes entered in the therapy notes field **1110**. The list of qualifiers corresponds to the qualifiers associated to the therapy by listing in the qualifier listing **1114**. For example, two quali-

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ers, "Adults & Children over 5 yrs" and "Children 3-5 yrs" can be associated with the "Patient Controlled Analgesia" therapy. When that therapy is selected in the therapy drop down menu **1502**, the two associated qualifiers populate the qualifier drop down menu **1506**.

FIG. **17** shows the state of the protocol definition interface **1500** after a qualifier is selected in the qualifier drop down menu **1506**. Notes related to the qualifier appear in the qualifier notes field **1508**, and a list of drugs available within the library or database appears in the drug drop down menu **1510**. The notes correspond to changes in the therapy due to the qualifier selected. Continuing the example from FIG. **14**, the "Adults & Children over 5 yrs" qualifier is selected. Notes related to customization of the "Patient Controlled Analgesia" therapy based on the selected qualifier are displayed in the qualifier notes field **1508**. Furthermore, a list of four drugs/drug concentrations appear in the drug drop down menu **1510**, which are the drugs defined and available within the library or database.

Analogously, upon selection of a drug from the drug drop down menu **1510**, drug notes (not shown) appear in the drug notes field **1512**.

Referring now to FIGS. **18-24**, a parameter user interface **1800** provides additional tabbed screens allowing a user to define pump parameters. The pump parameters complete the protocol definition associated with the therapy, qualifier, and drug combination selected in FIGS. **15-17**. As described in conjunction with FIG. **7**, selection of the index defined by a therapy, qualifier, and drug using the protocol definition interface **1500** may trigger the administrative software **700** to set or modify one or more of the pump parameters. Alternately, none of the pump parameters are set during the definition and selection of the index formed by the therapy, qualifier, and drug using the protocol definition interface **1500**. In such an embodiment, the parameter user interface **1800** is used to define the pump parameters that are programmable into a medical infusion pump.

The parameter user interface **1800** includes a status region **1802**, a protocol activation field **1804**, and control buttons **1806a-1806c**. The status region **1802** displays the therapy, qualifier, and drug associated with the assignable pump parameters. The protocol activation field **1804** publishes the protocol within the library such that the protocol is visible to user software accessing the library when it resides within the database **504** of FIG. **5**. The protocol activation field **1804** allows a user of the administrative software **700** to control when protocols become available for use by user software. In some circumstances, it can be advantageous to prevent user software from accessing data, particularly while that data is being edited in the administrative software **700**. One example of user software used to access pump protocols is illustrated below in conjunction with FIGS. **26-41**. The control buttons **1806a-1806c** provide save, cancel, and help options to a user of the administrative software.

The parameter user interface **1800** further includes a number of tabs, including a drug delivery tab **1810**, a secondary drug delivery tab **1820**, an alarm tab **1830**, a security tab **1840**, a display/sound tab **1850**, and a report tab **1860**. Parameters set within each of the tabs are discussed in FIGS. **18-24**.

FIG. **18** shows the parameter user interface **1800** with the drug delivery tab **1810** selected. The drug delivery tab **1810** allows a user to set drug delivery rate parameters, and includes a general settings region **1812** and a patient specific parameters region **1814**.

The general settings region **1812** includes verification settings **1816** and weight based settings **1818**. The verification settings **1816** includes drug verification and caregiver verifi-

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cation settings. Specifically, the verification settings require that a caregiver verifies that the correct drug is provided to the medical infusion pump. The verification settings also require a second caregiver to verify the settings of the medical infusion pump. The weight based settings **1818** set a weight based protocol at a programmable, variable weight limit. By weight based protocol, it is intended that dosage delivery rates, boluses, thresholds, and other delivery parameters change from a "dosage per hour" basis to a "dosage per weight factor" rate, where the weight factor can be on a per unit measure weight basis for the user of the medical infusion pump **102** (i.e. "per kilogram" or other), or based on the user's body surface area, a weight based therapy, or other options.

The patient specific parameters region **1814** includes a continuous rate region **1822**, a demand dose region **1824**, and a demand dose lockout region **1826**. Continuous rate refers to the constant drug delivery rate of the medical infusion pump, also referred to as the basal rate. Demand dose refers to an added drug delivery bolus amount delivered by the pump upon a demand by a patient. Demand dose lockout refers to the time interval after a demand dose is delivered, during which another demand dose will not be delivered by the pump.

The continuous rate region **1822** includes a meter, shown as a slider bar **1828** and an indicator **1829**. The meter generally has two or more locations, each corresponding to a parameter value that can be programmed in the medical infusion pump. Generally, the positional relationship of the meter indicates the setting of the meter. In a possible embodiment of the slider bar **1828** shown, the indicator **1829** is movable relative to the slider bar **1828** to set a default value, or "initial value" continuous drug delivery rate parameter. In a second possible embodiment, the default value is set using an initial value gauge **1832**.

The continuous rate region also includes hard limit gauges **1834**, soft limit gauges **1836**, and user interface options **1838a-1838c**. The initial value gauge **1832**, hard limit gauges **1834**, and soft limit gauges **1836** include values, which may include numerical ranges. The hard limit gauges **1834** set a hard maximum and hard minimum which form an acceptable pump programming range. The range of acceptable pump activity represents the absolute maximum and minimum values programmable into the pump by user software, as described below. This configuration allows for control of the range of values visible to a user of the medical infusion pump or associated computing system.

The limits set by the soft limit gauges **1836** represent a manually exceedable threshold value. The soft limit can be overridden by a user of a medical infusion pump on a pump-by-pump basis. Pump activity outside the range defined by soft limits can trigger an alarm or otherwise alert a caregiver that a pump is functioning outside of the usual operational range of the pump. A variety of alarm levels or alerts can be set by the soft limit gauges **1836**. For example, the alert can be a flag set in the software. The alert could additionally be an audible alarm, or a visual indicator displayed on at least a portion of the medical infusion pump. The visual indicator could be a flashing indicator or changed/changing color on the display of the medical infusion pump.

In a second possible embodiment, the hard limit gauges set a non-limiting range, and the user software described below can be programmed within its full operational range. In such an embodiment, pump activity outside the range set by the hard limit gauges **1834** can trigger an alarm or otherwise alert a caregiver that a pump is functioning outside of the usual operational range of the pump. In this embodiment, the soft limit gauges **1836** set a narrower range, operation outside of

which can trigger a warning or second alarm indicating pump activity outside of an expected range of pump operation. This warning or second alarm indicates a pump condition less serious than the alarm triggered by the hard limits.

The user interface options **1838a-1838c** enable the user software to display and edit the delivery rate, editing of the delivery rate, and requiring comments by users of a pump who wish to exceed the soft limits when setting the drug delivery rate. Selection of the display option **1838a** publishes the pump parameter so that the value is visible to a user of the pump or computing system.

The demand dose region **1824** includes a slider bar **1842** and an indicator **1843**. The slider bar and indicator operate in a similar manner to the slider bar **1828** and indicator **1829** in the continuous rate region **1822**, but control demand dose settings. Likewise, the demand dose region **1824** includes an initial value gauge **1844**, as well as hard limit gauges **1846** and soft limit gauges **1848** setting visible thresholds and triggering alarms as in the continuous rate region **1822**. Demand dose options **1852a-1852c** provide analogous display, editing, and comment options to the user interface options **1838a-1838c**.

The demand dose lockout region **1826** includes a slider bar **1854** and an indicator **1855**, and also includes an initial value gauge **1856**, hard limit gauges **1858**, and soft limit gauges **1862**. Each of these features functions analogously to those discussed above in conjunction with the continuous rate region **1822**. The demand dose lockout region also includes lockout options **1864a-1864c** analogous to the user interface options **1838a-1838c**.

FIG. **19** shows the parameter user interface **1800** with the drug delivery tab **1810** modified to provide a weight based drug delivery protocol. The modification of the user interface **1800** occurs in the drug delivery tab **1810** upon user selection of the weight based settings **1818** discussed in FIG. **18**. The continuous rate region **1822** and demand dose region **1824** are modified to reflect dosage rates on a “per kilogram” or other weight measure basis.

FIG. **20** shows the parameter user interface **1800** with the secondary drug delivery tab **1820** selected. The secondary drug delivery tab **1820** provides additional medical infusion pump programming options for assigning pump parameters in a specific protocol. The secondary drug delivery tab **1820** includes a dosing limit region **2002**, a patient specific parameter region **2004**, a titration region **2006**, a maximum delivery rate gauge **2008**, and a maximum clinician bolus gauge **2010**.

The dosing limit region **2002** displays limits for total drug delivery within a specified amount of time. The dosing limit region **2002** includes options for setting a limit on doses per hour, a timed medication delivery limit, or other limits. A user selects one of the options for setting the dosage limit.

The patient specific parameter region **2004** sets parameters related to the dosage limits coordinated to the options in the dosing limit region **2002**. The patient specific parameter region **1804** includes a timed delivery limit region **2012**, an hourly demand doses region **2014**, and a reservoir region **2016**.

The timed delivery limit region **2012** sets the delivery limit on a per assigned time period when the option for setting a limit on doses per hour is selected in the dosing limit region **2002**. The timed delivery limit region **2012** includes a meter, shown as a slider bar **2018** and indicator **2019**. The timed delivery limit region **2012** also includes an initial value gauge **2020**, hard limit gauges **2022**, soft limit gauges **2024**, and control options **2026a-2026c**. Operation of the slider bar **2018**, indicator **2019**, gauges **2020-2024**, and control options

2026a-2026c is analogous to operation of the slider bar features as discussed in conjunction with FIG. **18**, above.

The hourly demand doses region **2014** sets the delivery limit on a per hour basis when the doses per hour limit is selected in the dosing limit region **2002**. The maximum demand doses region **2014** includes a slider bar **2028**, indicator **2029**, gauges **2030-2034**, and control options **2036a-2036c**, operation of which is likewise analogous to operation of the slider bar features discussed in FIG. **18**.

The timed delivery limit region **2012** and hourly demand doses region **2014** are operated in the alternative, in that only one of the two regions is active at one time. The region that is active depends upon the option selected in the dosing limit region **2002**. Selection of a timed delivery limit in the dosing limit region **2002** activates the timed delivery limit region **2012** and deactivates the hourly demand doses region **2014**. Selection of an hourly delivery limit activates the hourly demand doses region **2014** and deactivates the timed delivery limit region **2012**.

The reservoir region **2016** sets the initial volume settings and display settings for tracking the volume of fluid in the reservoir attached to the medical infusion pump. The reservoir region **2016** includes a meter, shown as a slider bar **2040** and indicator **2041**, operation of which is analogous to the slider bar and indicator discussed in conjunction with FIG. **18**. The reservoir region further includes an initial value gauge **2042**, a disable option **2044**, and control options **2046a-2046b**. The initial value gauge **2042** provides an alternate method for setting the initial value of the reservoir volume to the slider bar **2040** and indicator **2041**. The disable option **2044** disables the reservoir volume monitor. The control options **2046a-2046b** provide display and edit capabilities to a user of the pump.

The remaining regions, i.e. the titration region **2006**, the maximum deliver rate gauge **2008**, and the maximum clinician bolus gauge **2010**, set pump specific settings related to drug delivery limits. The titration region **2006** enables or disables titration in the medical infusion pump, and sets an optional titration limit in the pump. The maximum delivery rate gauge **2008** sets a maximum delivery rate for the infusion pump. The maximum delivery rate is measured in milliliters per hour, and includes both the basal delivery rate and bolus delivery. The maximum clinician bolus gauge **2010** sets the maximum bolus which can be delivered by a caregiver. The maximum clinician bolus may be a larger bolus than the standard patient-controlled bolus, but must be administered under the supervision of a caregiver. Other regions can be included in the tab **1820** as well.

FIG. **21** shows the parameter user interface **1800** with the alarm tab **1830** selected. The alarm tab includes a number of regions used for maintenance and hardware-related alarms, as opposed to the drug delivery threshold alarms discussed above in conjunction with the slider bars. The alarm tab **1830** allows the user to enable and disable alarms in the medical infusion pump. The alarm tab **1830** includes a reservoir low alarm region **2102**, a reservoir empty alarm region **2104**, a pump stop alarm **2106**, a maintenance alarm **2108**, and a hardware alarm **2110**. The reservoir low alarm region **2102** provides an alarm indicator when a drug supply volume falls below a threshold level. The threshold level can be a standard level or an administrative user-set volume level. The reservoir empty alarm region **2104** sets a single occurrence or repeating alarm when a drug supply volume falls below a threshold level. The pump stop alarm **2106** sets an alarm which occurs when the medical infusion pump stops operating. The maintenance alarm **2108** enables a maintenance alarm, which alerts a user when maintenance is needed. The hardware

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alarm **2110** provides options for detection of optional components used with the infusion pump. For example, the hardware alarm **2110** can trigger upon detection of an air detector or other component. The pump hardware detector region **2110** can provide the option of enabling an alarm sent to a caregiver.

FIG. **22** shows the parameter user interface **1800** with the security tab **1840** selected. The security tab **1840** includes options related to security of the medical infusion pumps. The security tab **1840** includes a security region **2202** and an epidural region **2204**. The security region **2202** presents a number of security options for controlling access to each medical infusion pump. Security options can include an automatic lock, a lock code, clinician code, and an initial lock level. The epidural region **2204** selectably places the pump into a mode configured for epidural therapy.

FIG. **23** shows the parameter user interface **1800** with the display/sound tab **1850** selected. The display/sound tab **1850** includes options related to the display and sound settings for each medical infusion pump. The display/sound tab **1850** includes an auto-review option **2302**, a main display region **2304**, a units option **2306**, a date format option **2308**, a send protocol region **2310**, and a sound region **2312**. The auto-review option **2302** enables a power-up display of options in the medical infusion pump. The main display region **2304** presents a number of programmable fields that will, by default, be displayed on the medical infusion pump. For example, the main display region **2304** includes programmable text display entry, power source information, and drug delivery rate. Other display options related to properties of the medical infusion pump are available as well. The units option **2306** selectably assigns a units location for display on the medical infusion pump. The date format option **2308** assigns date formats for displaying on the medical infusion pump. The send protocol region **2310** sets one or more patient markers or date/time stamps in the infusion pump network upon distribution of programming instructions to the medical infusion pump. The sound region **2312** enables sound in the medical infusion pump, such as beeping sounds when one or more keys/key sequences are depressed.

FIG. **24** shows the parameter user interface **1800** with the report tab **1860** selected. The report tab **1860** presents options for displaying reports by a medical infusion pump related to events occurring in the pump. The report tab **1860** includes a new patient marker region **2402** and a custom report region **2404**. The new patient marker region **2402** includes a list of options to perform related to report generation upon association of a medical infusion pump with a new patient. For example, the new patient marker region **2402** includes a number of report-clearing options and power-on options to be performed when a medical infusion pump is assigned to a new patient. The custom report region **2404** provides a number of selectable options for display in a custom report regarding events tracked in the medical infusion pump network. The custom report region **2404** provides all of the options tracked in the infusion pump network **500**, which can be stored in the log files **516**. A user selects one or more of the options to generate a report. For example, the custom report region **2404** can include dose counters, doses per hour, pain scale information, drug delivery information, an event log, and a patient marker. The report generated by the custom report region **2404** options displays on the screen of the medical infusion pump **102** or computing system, **104**. Both the new patient marker region **2402** and the custom report region **2404** can include additional options as well.

Referring now to FIG. **25**, a library export screen **2500** is optionally used to save the pump parameters and protocols for

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exporting from the database **504** of FIG. **5**. One or more libraries are exported using the library export screen **2500**, including all of the pump protocols, and containing all of the defined therapies, qualifiers, drugs, and combinations thereof. The library export screen **2500** corresponds to the export library module **724** of FIG. **7**, and provides file extraction, in that one or more protocol libraries built using the administrative software **700** are exported to a data file or database. The export library screen **2500** includes a library field **2502** and an export option region **2504**. The library field **2502** displays a number of libraries available to the system that can be exported to a portable file. The export option region **2504** provides export options to the administrative user seeking to export the library data to a file. For example, export options can include creating a read-only file, or a read-write template for use in another instantiation of the software system disclosed herein. The read-only file might be selected in the case that the library is to be loaded onto a medical infusion pump that is disconnected from the database **504** of FIG. **5**. The read-write file might be selected if the library is to be transferred to a separate infusion pump network **500** altogether, in which administrative software on that subsequent infusion pump network may be used to subsequently edit that library. Additionally, the export option region **2504** includes an assignable password to add security to the library file exported such that a user attempting to access the protocols contained in the library file must know and enter the correct password.

The above description and figures corresponding to the administrative software **700** provides a therapy-centric programming schema for a medical infusion pump. For example, a certain drug used in conjunction with a medical infusion pump may be appropriate for use with a specific therapy for an adult, but may not be appropriate for the same therapy for a child. Certain drugs may only be appropriate in certain therapies, and under certain qualifying conditions. Pump parameters are initially set according to the protocols defined in the administrative software **700**, but are customizable on a pump-by-pump basis using user software associated with a specific pump and/or patient.

FIG. **26** illustrates exemplary architecture of user software **2600** for accessing a pump application program and programming a medical infusion pump. The software **2600** can operate within the pump **102**, computing system **104**, or a combination thereof. The user software **2600** allows a user, for example a doctor, nurse, pharmacist, or other caregiver, to select and customize pump application protocols, and parameters for execution in and control of a medical infusion pump **102**. Depending upon the pump configuration, the user may select a protocol or a library for loading into a medical infusion pump. Additional data structures could be loaded into the medical infusion pump as well. Although the user software **2600** is discussed in conjunction with the administrative software **700** previously described in FIGS. **7-25**, it is understood that the user software systems described herein are operable in conjunction with additional hardware/software embodiments.

The medical infusion pumps as described store pump data in memory, such as the memory shown above in FIG. **3**. The pump data can include pump parameters, parameter values, programs, and other functional and data systems configured to operate the medical infusion pump. As referred to herein, a set of pump parameters can include the entire memory contents of the pump, or can include a subset of the memory contents, such as selected data values, that can be altered to change operation of the pump.

The user software **2600** is instantiated by a start module **2602**. The start module **2602** corresponds to initial execution of the user software **2600** by clicking on an icon on the computer or by some other mechanism for executing software. Upon execution of the start module **2602**, the user software **2600** connects to a library on a server **206** containing one or more pump protocols.

Following the start module **2602**, operational flow optionally proceeds to a library import module **2604**. The library import module **2606** provides the ability to import one or more libraries into the software **2600**. This feature can be used by a computing system **104** or medical infusion pump **102** that is not connected to the same medical infusion pump network **500** as the database storing the library **504**. If the computing system **104** or medical infusion pump **102** is connected to the medical infusion pump network **500**, each component is by default connected to the server **206** and database **504**.

The libraries available to be imported include pump protocols and parameters, and may have been created using the administrative software of FIGS. 7-25. The collection of pump protocols can be accessed from the server **206** or in one or more individual computing systems **102**. The library import module **2604** allows the user to select one or more pump application programs for downloading to a medical infusion pump **102**.

Once connected to the desired library either by default or via the library import module **2604**, operational flow proceeds to a login module **2606**. The login module **2606** regulates user rights in the software **2600** by controlling access to the libraries **508** in the database **504** of FIG. 5. User rights define access levels in the software for users such as doctors, nurses, other caregivers, or patients. A user will have a set access level allowing the user to view or edit pump application protocols and parameters within the user software **2600**. Access levels are set using the user rights module **716** of the administrative software **700**, described above in conjunction with FIG. 7. Access levels can be set by a user of the administrative software **700** according to a variety of criteria, such as the type of caregiver (e.g., physician, nurse, or pharmacist).

Different access levels also can provide different rights with respect to pump operational parameters. For example, one access level might give a user a right to edit patient specific pump parameters. One access level might permit a user the right to only view and download the patient specific pump operational parameters. Different embodiments can include the ability to provide an access level for a user any combination of rights to edit, view, and/or download pump operational parameters, protocols, or libraries.

Once the user is logged in, the user selectively executes three different modules, a protocol selection module **2608**, a task module **2610**, and a report module **2612**.

The protocol selection module **2608** selects a protocol for use with a medical infusion pump from the protocols loaded in the user software **2600**. The protocol selection module **2608** guides the user through selection of a therapy, qualifier, and drug combination defined to be a protocol by the administrative software. The protocol selection module **2608** includes a therapy selection module **2614**, a qualifier selection module **2616**, and a drug selection module **2618** for this purpose. The therapy selection module **2416** selects a therapy to be administered by the drug infusion pump **102**. The therapy is one of the therapies included in the library selected in the library import module **2606**. The qualifier selection module **2616** selects a qualifier from those associated with the therapy in the library. The drug selection module **2618** selects a drug associated with the therapy and drug. The protocol

selection module **2608** further allows customization of the protocol by allowing a user to modify pump parameters, such as the drug delivery rate, the demand dose, the demand dose lockout, drug delivery limits, and reservoir volume.

The task module **2610** guides a user through maintenance and monitoring tasks that are required for each medical infusion pump **102**. These maintenance and monitoring tasks can include pump settings comparison and testing, as well as changing the reservoir holding the drug delivered by the medical infusion pump **102**. The task module **2610** includes a pump settings module **2620**, a comparison module **2622**, and a reservoir module **2624**. The pump settings module **2620** compares the local pump settings to a standing order set for the pump, for example by a caregiver who programmed or customized the medical infusion pump. During operation of the pump settings module **2620**, the user software **2600** receives a GUID specific to a protocol and generated by the server **206**, and stores the GUID on the pump or computing system. The GUID generated by the server and stored on the pump or computing system is made available to the server when the pump or computing system accesses the library to look up and verify the future access of the correct protocol and/or library. This ensures that the pump settings are compared to the correct protocol stored on the server. The comparison module **2622** compares the local pump settings to a protocol, such as the protocols defined using the administrative software **700**. The reservoir module **2624** determines if a drug reservoir is nearly empty and guides a patient or caregiver through the drug cartridge changing process occasionally required during use of a medical infusion pump.

The report module **2612** generates a report from preexisting logged information for a selected medical infusion pump **102**. The report module includes a location module **2626** and a type module **2628**. The location module **2626** requests the location of the pump from which a report is generated, such as a specific pump or a previously saved report stored on the pump or computing system. The type module **2628** presents a number of types of reports which can be generated from the logged information, such as a drug delivery report or event log, and can display the report responsive to a user request.

Operation of the software terminates at an end module **2630**. The end module **2630** corresponds to termination of the administrative software **2600** by clicking on a close window button on the computer or by some other mechanism for terminating execution of software.

FIG. 27 shows a library import screen **2700** used to optionally load a library of pump protocols into the user software **2600**. The library import screen **2700** corresponds to the login module **2604**, and presents a location field **2702** and a library field **2704** used to browse to and select a library from a library database or file. An optional password field **2706** accepts user input to allow the user to enter a password for accessing a password protected library file, such as one created using the export library screen shown in FIG. 25. Control buttons **2708a-2708b** provide confirmation and cancellation options to the user, allowing the user to complete the library access process.

FIGS. 28-32 illustrate an exemplary process and user interface through which the protocol selection module **2608** leads a user to select a protocol for use with a medical infusion pump. The methods, systems and user interfaces described in conjunction with FIGS. 28-32 can be performed either on a computing system, such as a computing system **104** associated with a medical infusion pump **102**, or on a medical fusion pump **102** configured to accept a library of pump protocols directly. Medical infusion pumps **102** accepting a single pump protocol use a corresponding computing system **104**.

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Referring to FIG. 28, operation of the protocol selection module 2608 is instantiated by a start module 2802. The start module 2802 corresponds to initial execution of the user software 2600, or initial selection of the protocol selection module 2608 by clicking on an icon or tab on the computer or by some other mechanism for executing software.

Following the start module 2802, operational flow proceeds to a load protocols module 2804. The load protocols module 2804 populates the user software 2600 with the protocols from the loaded library. For example, the load protocols module 2804 can populate a listing of protocols for selection using the user software 2600.

Following the load protocols module 2804, operational flow proceeds to a select protocol module 2806. The select protocol module 2806 selects a protocol from among the protocols loaded into the user software 2600 by guiding a user through selection of a therapy, qualifier, and drug defining one of the protocols loaded in the software 2600. The select protocol module 2806 corresponds to the therapy selection module 2614, qualifier selection module 2616, and drug selection module 2618 shown in FIG. 26.

Following the select protocol module 2806, operational flow proceeds to a settings module 2808. The settings module 2808 provides editing and customization of the pump parameters assigned to a medical infusion pump as dictated by the protocol selected by the user. The parameters include, for example, the drug delivery rate, demand dose rate, or demand dose lockout.

Following the settings module 2808, operational flow proceeds to an optional pump programming module 2810. The pump programming module 2810 programs a medical infusion pump with the settings both as defined by the protocol and selected by the select protocol module 2806, and as customized by the settings module 2808. The pump programming module 2810 executes if the user software 2600 resides on a computing system 104 connected to a medical infusion pump 102. The pump programming module may not execute if the software 2600 resides on the medical infusion pump 102 itself, because the protocols are already loaded into the pump alongside the library accessed by the user software 2600.

After the pump programming module 2810 completes, operation of the protocol selection module 2608 terminates at an end module 2812. The end module 2812 corresponds to successful programming of the medical infusion pump.

FIGS. 29-32 illustrate a user interface 2900 used to guide a caregiver through the pump programming process. The user interface 2900 operates on a computing system associated to a medical infusion pump. The user interface 2900 includes a login button 2902, a connection status indicator 2904, a library indicator 2906, and a protocol tab 2920, a tasks tab 2940, and a reports tab 2960.

The login button 2902, when selected, generates a login screen that checks whether a user has the right to access pump programs, protocols, or parameters. The connection status indicator 2904 displays the connection status of the user software. Connection status can include a connection to a medical infusion pump or connection to a networked server. The library indicator 2906 displays the current library loaded using the library import screen 2700 of FIG. 27.

Referring now to FIG. 29, the user interface 2900 is shown with the protocol tab 2920 selected. FIG. 29 corresponds to an initial state of the protocol selection module 2608 following the load protocols module 2804 of FIG. 28. The protocol tab 2920 guides a user through the process of selecting a protocol, customizing one or more parameters in the protocol, and programming a medical infusion pump with the customized pump program. The protocol tab includes a therapy selection

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field 2908, a therapy notes field 2910, a qualifier selection field 2912, a qualifier notes field 2914, a drug selection field, 2916, a drug notes field 2918, and a continue button 2922.

The therapy selection field 2908 lists the therapies included in the currently loaded library. For example, the two therapies shown are "Epidural" and "Patient Controlled Analgesia". The therapy notes field displays the notes associated with the selected therapy. In the initial state, the therapy selection field 2908 and therapy notes field 2910 are active, and the qualifier fields 2912, 2914, drug fields 2916, 2918, and continue button 2922 are inactive. No therapy is initially selected in the therapy listing field 2908, so the therapy notes field 2910 remains empty.

FIG. 30 shows the user interface 2900 with the protocol tab 2920 selected and a therapy selected from the therapy selection field 2908. Notes related to the selected therapy appear in the therapy notes field 2910, and the qualifier selection field 2912 and qualifier notes field 2914 activate. A listing of qualifiers associated with the selected therapy appears in the qualifier selection field 2912. The therapy notes shown recite "Epidural Patient Controlled Analgesia" corresponding to the selected therapy, but could contain particular information related to the therapy, such as warnings, descriptions, or other information about application of the therapy. The qualifiers, which appear once the therapy is selected, are shown to include "Adult and Child over 5" and "Child 5 years and under". No qualifier is initially selected, so the qualifier notes field 2914 remains empty. The drug selection field 2916, drug notes field 2918, and the continue button 2922 remain inactive.

FIG. 31 shows the user interface 2900 with the protocol tab 2920 selected and both a therapy selected from the therapy selection field 2908 and a qualifier selected in the qualifier selection field 2912. Notes related to the qualifier appear in the qualifier notes field 2914, and the drug selection field 2916 and drug notes field 2918 are active. For example, "Adult and Child over 5" is shown to be, and the qualifier notes field 2914 displays specific notes applicable to those patients. A listing of drugs associated with the therapy and qualifier appears in the drug selection field 2916. Three exemplary drug menu listings including "Fentanyl 10 mcg/ml", "HYDRO Morphine 1 mg/ml" and "Morphine 1 mg/ml" are shown. No drug is initially selected, so the drug notes field 2918 remains empty. The continue button 2922 remains inactive.

FIG. 32 shows the user interface 2900 with the protocol tab 2920 selected and a therapy, qualifier, and drug selected in each of the respective selection fields 2908, 2912, and 2916. Once a therapy, qualifier, and drug are selected a specific protocol is designated from among the protocols defined in the administrative software 700. Each notes field 2910, 2914, and 2918 displays information related to the selected therapy, qualifier, and drug, respectively. The continue button 2922 activates, allowing the user to continue with customization of the selected protocol by changing one or more pump parameters related to the therapy, qualifier, and drug.

FIG. 33 illustrates an exemplary process by which the administrative software 2600 customizes one or more parameters of a selected pump protocol, and corresponds to the settings module 2608 of FIG. 26. The settings module 2608 allows customization of one or more pump parameters while monitoring whether the customized value is within an acceptably safe dosage or drug delivery range.

The settings module 2608 is instantiated by a start module 3302. The start module 3302 corresponds to selection of the confirmation button 2922 of FIGS. 29-32.

Following the start module **3302**, operational flow proceeds to a display module **3304**. The display module **3304** displays the default protocol settings of the protocol loaded onto a medical infusion pump screen or a computing system associated with the pump. The display module **3304** presents a number of meters to a user related to the drug delivery rates and other parameters controlled by the pump. The meters provide user controls for modifying one or more pump parameters.

In various embodiments, the display module **3304** can be configured to display a variety of coloring and image features. In one possible embodiment, the meters are slider bars that can include graphical thresholds set by the administrative software. A cautionary color change of the user interface (i.e. green or gray to yellow or red) can represent a warning to the user that the current setting is outside of the administratively set thresholds.

In another possible embodiment, the overall background color of the user interface is color-coded to correspond to hospital coding procedures, and can represent one or more location-specific warning or status conditions. Additionally, the color coding can be located behind an image displayed on the pump screen, and can be keyed to a location of the medical infusion pump, the drug administered, or a warning condition within the pump.

Following the display module **3304**, operational flow proceeds to a custom settings module **3306**. The custom settings module **3306** receives the current customized pump settings based on user-customization of one or more pump parameters. The custom settings module **3306** can provide a user customization interface for setting pump parameters to values other than the initial or default values set in the administrative software **700**.

Following the custom settings module **3306**, operational flow depends upon the implementation of the hard limits and soft limits in the administrative software **700**. If the hard limit gauges in FIGS. **18-20** provide a warning but do not dictate an absolute maximum/minimum for the range of programmable values within the user software **2600**, operational flow proceeds to a hard limit determination operation **3308**. If the hard limit gauges dictate an absolute maximum/minimum for the range of programmable values within the user software **2600**, the hard limit will likely not be exceeded, so operational flow proceeds directly to the soft limit determination operation **3312**.

The optional hard limit determination operation **3308** determines if the pump settings are outside the "hard limits" set in the administrative software **700**. If the pump settings exceed the hard limit (i.e. above the maximum or below the minimum value), operational flow branches "yes" to a hard limit indicator module **3310**. If the pump settings do not exceed the hard limit, operational flow branches "no" to a soft limit determination operation **3312**.

The optional hard limit indicator module **3310** executes in conjunction with the hard limit determination operation **3308**, and generates an indicator to a user that the hard limit set in the administrative software is exceeded by the current settings of the medical infusion pump. If the hard limit determination operation **3308** is bypassed or otherwise absent from the user software **2600**, the hard limit indicator module **3310** can be absent/bypassed as well. The hard limit indicator module **3310** creates an alert indicator on the display of the pump or associated computing system, or sends an alert to the server or other computing system to alert a caregiver that an alert condition has been reached by the pump due to exceeding the hard limit. Operational flow proceeds to the display

module **3704** to update the display and to allow additional user modification of the pump settings.

The soft limit determination operation **3312** determines if the pump settings are outside the "soft limits" set in the administrative software **700**. If the pump settings exceed the soft limit, operational flow branches "yes" to a soft limit indicator module **3314**. If the pump settings do not exceed the soft limit, operational flow branches "no" to return to the display module **3304**.

The soft limit indicator module **3314** generates an indicator to a user that the soft limit set in the administrative software is exceeded by the current parameter settings. The soft limit indicator module **3314** creates an alert indicator different from the hard limit indicator module **3310** if the hard limit indicator module **3310** exists or executes within the software **2600**. For example, the soft limit alert indicator can be a different color, display a different message, or send a different alert to a remote medical care provider.

Following the soft limit indicator module **3314**, operational flow proceeds to the display module **3304** to update the display and allow additional user modifications of the pump settings. Upon termination of operation of the medical infusion pump, operational flow terminates at the end module **3316**.

Referring now to FIGS. **34-35**, an exemplary user interface **3400** for customizing pump parameters is shown. The user interface **3400** corresponds to the settings module **2808** of FIG. **28**, and operates generally as described in FIG. **33**. The user interface **3400** includes a status indicator **3402**, a continuous rate region, **3404**, a demand dose region **3406**, a demand dose lockout region **3408**, a timed limit region **3410**, and a reservoir region **3412**. The user interface **3400** further includes control buttons **3414a-3414c**.

The regions **3404-3412** correspond to the patient specific pump parameters **512a** of FIG. **5**, and can include one or more of continuous rate, demand dose, demand dose lockout, timed limits, reservoir volume, and other patient-specific parameters. Only those patient specific pump parameters that are associated with the selected index of therapy, qualifier, and drug appear in the user interface **3400**, and can be as few as one parameter and can incorporate as many parameters as are programmable within a medical infusion pump.

The user interface **3400** presents a standardized interface to a patient or caregiver using the user software **2600**, such as at the point of care of a patient or other location on the infusion pump network. The user interface **2600** corresponds to any of a number of types of user software **2600** and administrative software **700**. The user interface **3400** also can be configured to be used with various types of medical infusion pumps **102**. Most pumps require programming with both patient specific pump parameters and non-patient specific pump parameters, but vary as to the data structure in which this data is passed to the pump. The user interface **3400** reflects from the user software **2600** the number of regions to create corresponding to the number of patient specific pump parameters, which are generic to various types of pumps. Therefore, the user interface **3400** can be used with any of a number of pumps having various brands, interfaces, data structures, or other variances.

The status indicator **3402** displays the library, therapy, qualifier, and drug which define the protocol loaded by the user software **2600**. In the exemplary user interface, the library is an "ICU" library, the therapy selected is "Patient Controlled Analgesia", the qualifier is "Adult and Child over 5", and the drug is "Fentanyl 10 mcg/ml".

The continuous rate region **3404** defines the continuous, or basal, rate of drug delivery in the specific medical infusion pump. The continuous rate region **3404** includes a numerical

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reading **3416** and a meter, shown as a slider bar **3418** and an indicator **3419**. The meter generally has two or more locations, each corresponding to a parameter value that can be programmed in the medical infusion pump. Generally, the positional relationship of the meter indicates the setting of the meter. The numerical reading **3416** reflects the current value for the continuous drug delivery rate.

In the embodiment of the meter shown as the slider bar **3418**, the indicator **3419** slides along the slider bar **3418**, and the positional relationship between the slider bar **3418** and indicator **3419** dictates the continuous drug delivery rate. Threshold indicators **3420** determine the safe limits within which the continuous rate can be set, and can represent either the hard limits or the soft limits set for the parameter by the administrative software **700**. In the embodiment of the user software **2600** whose absolute threshold levels are limited by the hard limits set in the administrative software **700**, the ends of each bar **3418** represent the hard limits and the threshold indicators **3420** represent the soft limits for the continuous rate. The thresholds are tested using the method described in FIG. **33**.

The demand dose region **3406** customizes the demand dose, or bolus, delivered by the medical infusion pump. The demand dose region includes a numerical reading **3422** and a meter, shown as a slider bar **3424** and indicator **3425**. The slider bar **3424** includes threshold indicators **3426** displaying either the hard or soft limit defined in the administrative software. The numerical reading **3422**, slider bar **3424**, indicator **3425**, and threshold indicators **3426** operate analogously to those in the continuous rate region **3404**, but set the bolus level parameter rather than the continuous rate parameter.

The demand dose lockout region **3408** customizes the time period after a bolus is delivered in which no additional bolus can be provided. The demand dose lockout region **3408** includes a numerical reading **3428** and a meter, shown as a slider bar **3430** and indicator **3431**. The slider bar **3430** includes threshold indicators **3432** displaying either the hard or soft limit defined in the administrative software. The numerical reading **3428**, slider bar **3430**, indicator **3431**, and threshold indicators **3432** operate analogously to those in the continuous rate region **3404**, but set the demand dose lockout period parameter rather than the continuous rate parameter.

The timed limit region **3410** customizes the amount of the selected drug deliverable by a medical infusion pump within a specified timeframe. The timed limit region **3410** also includes a numerical reading **3434** and a meter, shown as a slider bar **3436** and indicator **3437**. The slider bar **3436** includes threshold indicators **3438** displaying either the hard or soft limit defined in the administrative software. The numerical reading **3434**, slider bar **3436**, indicator **3437**, and threshold indicators **3438** operate analogously to those in the continuous rate region **3404**, but set the timed drug delivery threshold parameter rather than the continuous rate parameter.

The reservoir region **3412** defines the size of the reservoir used in conjunction with the medical infusion pump. The size of the reservoir is relevant to computing drug delivery volumes for the purpose of setting alarms and other indicators for replacing or refilling the reservoir. The reservoir region **3412**, like the other regions, includes a numerical reading **3440** and a meter, shown as a slider bar **3442** and indicator **3443**. The slider bar **3442** includes threshold indicators **3444** displaying either the hard or soft limit defined in the administrative software. The numerical reading **3440**, slider bar **3442**, and indicator **3443** operate analogously to those in the continuous rate region **3404**, but set the reservoir volume parameter

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rather than the continuous rate parameter. In the embodiment shown, no threshold indicators are included in the reservoir region. This is because the reservoir region **3412** is allowed to use the entire operational range of the reservoir, since no hard limits are set in the reservoir volume region **2016** of FIG. **20** in the administrative software. However, in additional embodiments, one or more threshold indicators can be incorporated into the reservoir region to trigger a warning when the drug reservoir associated with the medical infusion pump contains less than the volume of drugs set by the threshold volume.

The meters in each region **3404-3412** may be adjustable in that each of the patient specific pump parameters are adjustable using a meter. The administrative software **700** enables the adjustment of one or more of the meters by allowing adjustment of those patient specific pump parameters using the options displayed on the user interface **1800** of FIGS. **18-20**.

The control buttons **3414a-3414c** allow a user to send the currently set parameters to the associated medical infusion pump, cancel the parameter customization, or receive help in the process.

FIG. **35** shows the user interface **3400** wherein the indicator **3437** in the timed limit region **3410** resides along the slider bar **3436** at a location outside the range defined by the threshold indicators **3438**. A colored region **3502** appears around the slider bar and indicator, providing a visual warning to the user of the user software **2600** that abnormal or unadvisable pump settings exist. The colored region **3502** can change color (i.e. green or gray to yellow or red) indicating that the value is outside a threshold level.

It is noted that additional screen coloration or textual messages can be used to graphically send messages to a user or programmer of the medical infusion pump or associated computing system. For example, a color code system can be used to reflect a variety of conditions of the medical infusion pump. For example, a color could represent the current coding of the hospital or other health care facility at which the pump may be located. Additionally, the color code can represent a warning condition, a location at which the pump is used, a drug being administered by the pump, or an alert condition. Of course, the color code could represent additional characteristics of the medical infusion pump as well.

The color code can display on the computing system associated with the medical infusion pump, or can be reflected on a monitor associated to the medical infusion pump itself. Text messages can be sent from the server to be displayed on the monitor of the pump or computing system, such as warnings regarding medication, usage tips for the medical infusion pump, or other medical advice. Additionally, the color code can be placed behind images displayed on the pump which can also represent a region of the hospital, an image of the drug being administered, or other background images. Additionally, the screen coloration described can be represented as a flashing screen, a color changing (cross-fading or otherwise) screen, or various other color patterns.

FIG. **36** shows a pump programming user interface **3600** for guiding a user through the process of sending a pump program to a medical infusion pump. The programming screen can display properties of a pump to be programmed, and can include the settings **3602a-3602e** that are to be sent to the pump, a protocol indicator field **3604**, and a confirmation button **3606**.

The settings **3602a-3602e** reflect the customized pump parameters set using the user interface **3600** of FIGS. **34-35**. The customized pump parameters correspond to the patient specific pump parameters **512a** of FIG. **5**, and can include one

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or more of continuous rate, demand dose, demand dose lock-out, timed limits, reservoir volume, and other patient-specific parameters.

The protocol indicator field **3604** displays the current protocol selected, in this case shown as "Patient Controlled Analgesia", "Adult and Child over 5", and "Fentanyl 10 mcg/ml". The confirmation button **3606** sends the pump program, including the settings **3602a-3602e** for the pump parameters, to the pump.

Once the pump is programmed, the pump program executes according to the protocol selected in conjunction with the customized parameters. Referring now to FIG. 37, an exemplary software process **3700** for displaying medical infusion pump customizations is shown. The process occurs within the pump **102**, computing system **104**, or a combination thereof, and can be part of a pump program sent to a medical infusion pump.

Customizations in protocol programming refer to differences between the actual pump operation and a standing order (i.e. settings programmed by an administrative user). The standing order can be an original pump parameter or initial value, and the pump operation for comparison can be either a current pump parameter or simply a non-original pump parameter.

A start module **3702** initiates the process **3700**. Operational flow proceeds to a comparison module, shown as a compare pump settings to standing order module **3704**. The pump settings stored on the pump or computing system as shown above in FIG. 5 can be compared against a standing order stored on a server as a pump protocol. To ensure that the correct standing order is accessed for comparison, a GUID assigned to the loaded pump settings corresponds to the protocol stored on the server. A display change bar module **3706** presents an indicator on either the medical infusion pump or associated computing system. In the display change bar module, the original pump parameter, or portion of a standing order, can be juxtaposed against the non-original pump parameter, such as in a table format. One or both of the original and non-original pump parameters can be a standard or customized pump parameter. Pump parameters that are displayed in the display change bar module **3706** include drug delivery rate, drug capacity, remaining capacity of the medical infusion pump, bolus levels or occurrences, alarm occurrences, threshold, and/or frequency, drug delivery periods, or other parameters.

In one possible embodiment, a legend can indicate the meaning of the pump parameters being displayed, and a time/date stamp can display the time at which the original and/or non-original pump parameter was measured. In additional embodiments, differences between the original and non-original pump parameters can be highlighted when displayed, such as by using a color change or other indicator.

Operational flow terminates at an end module **3708**.

FIG. 38 is an exemplary schematic illustration of a change bar **3800** displayed on a medical infusion pump **102**. The change bar **3800** as shown is displayed on the screen **406** of the pump described above in FIG. 4. Alternately, the change bar **3800** can be displayed on a computing system **104** associated with the medical infusion pump **102**.

The change bar **3800** includes a plurality of change bar entries **3802**. The change bar entries correspond to pump parameters, and in the figure shown the entries **3802a-3802b** correspond to patient specific pump parameters. The change bar can display non patient specific pump parameters as well.

The change bar **3800** can compare any of a number of original and non-original pump parameters. In one embodiment, the change bar **3800** compares the current operation of

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the pump to the originally programmed operation of the pump. In another embodiment, the change bar **3800** compares the operation of the pump as initially programmed to the suggested programming of the pump based on the original pump protocol. In a further embodiment, the change bar **3800** compares historical activity of the pump to the current pump protocol.

In one embodiment of the change bar **3800**, the change bar entries **3802a-3802b** change color when the difference between the original and the non-original pump parameters exceeds a threshold amount. The threshold amount can be, for example, the soft limits set in the administrative software **700**. In a further embodiment, the text can change color when a difference greater than the threshold is detected. The change bar can incorporate additional graphics and images on the display.

Referring now to FIG. 39, user software **2600** is again described in which the user interface **2900** of FIGS. 29-32 is shown with the tasks tab **2940** selected. The tasks tab **2940** includes a tasks region **3902** for selection of one or more task options, of which a comparison is displayed when the user selects the "continue" option **3904** shown. Tasks include operations related to maintenance of the pump once in operation. The tasks region **3902** includes a number of pump comparison options, such as a compare pump settings option **3906**, a compare pump settings to protocol option **3908**, and a change reservoir option **3910**. The compare pump settings option **3906** compares the pump settings to the original protocol from which the pump parameters were based. The compare pump settings to protocol option **3908** compares all pump settings for the protocol selected.

The user software **2600** accesses the protocol loaded on the server **206** to compare the current pump settings to the original or current protocol using the options **3904**, **3906**. To accomplish this, it is necessary for the user software **2600** to clarify to the server **206** which protocol is being compared within the database **504** of FIG. 5. The user software **2600**, in conjunction with the server **206** uses the globally unique identifier (GUID) described above in FIG. 5 to provide the identifier for corresponding the protocol on the pump **102** to the protocol as stored in the server **206**. The GUID can be generated by the server **206** and transmitted alongside the protocol and/or library when transmitted to the computing system **104** or infusion pump **102**, as described above.

The change reservoir option **3910** guides a user of the software **2600** through changing a drug reservoir used in conjunction with the medical infusion pump.

FIG. 40 shows the user interface **2900** with the reports tab **2960** selected. During or after pump operation, reports including drug delivery or event logs are used to detect the condition of a patient or of the medical infusion pump. The events which can be tracked using reports tab **2960** are those which are available due to being automatically tracked by the medical infusion pump. The reports tab **2960** presents a number of selectable options for generating reports of pump activity, including time/date information, drug delivery information, and other event information. The reports tab **2960** includes source fields **4002** and option regions **4004**. The source fields **4002** present a variety of sources from which reports can be drawn. The source fields **4002** can include the medical infusion pump and stored reports saved within the network. The option regions **4004** present a number of options related to the selected source. For example, a report generated directly from a medical infusion pump can be produced based on prescription settings, and event log, a patient history, drug delivery, or a reported pain scale. A report generated from a saved report can be produced by indicating the

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patient identification, the pump identification, or the report type and date. A view field **4006**, upon selection by a user, generates the report based on the source and options selected.

FIG. **41** shows a report user interface **4100** for displaying operation of a medical infusion pump. The report user interface **4100** shows the report generated using the options selected in the report tab **2960**. The report shown in the report screen is a drug delivery report, and can be printed, saved, or discarded by the user. The drug delivery report can include the volume of the drug delivered, as well as the timing of delivery of the drug. Additional attributes of the medical infusion pump can be reported in the drug delivery report as well.

Aspects of the invention described as being carried out by a computing system or otherwise described as a method of control or manipulation of data may be implemented in one or a combination of hardware, firmware, and software. Embodiments of the invention may also be implemented as instructions stored on a machine-readable medium, which may be read and executed by at least one processor to perform the operations described herein. A machine-readable medium may include any mechanism for storing or transmitting information in a form readable by a machine (e.g., a computer). For example, a machine-readable medium may include read-only memory (ROM), random-access memory (RAM), magnetic disc storage media, optical storage media, flash-memory devices, electrical, optical, acoustical or other form of propagated signals (e.g., carrier waves, infrared signals, digital signals, etc.), and others.

In the foregoing detailed description, various features are occasionally grouped together in a single embodiment for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting an intention that the claimed embodiments of the subject matter require more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive subject matter lies in less than all features of a single disclosed embodiment. Thus, the following claims are hereby incorporated into the detailed description, with each claim standing on its own as a separate preferred embodiment. Therefore, the spirit and scope of the appended claims should not be limited to the description of the preferred versions contained herein.

The claimed invention is:

1. An apparatus for indicating a change in operation of a medical infusion pump, the apparatus comprising:

a memory configured to store an original pump parameter and a non-original pump parameter;

a monitor;

a programmable circuit in electrical communication with the memory and the monitor, the programmable circuit programmed to display on the monitor the original pump parameter and the non-original pump parameter, the non-original pump parameter being displayed juxtaposed to the original pump parameter, the non-original pump parameter further being a current pump parameter.

2. The apparatus of claim 1, wherein the original pump parameter and the non-original pump parameter are parameters selected from the group consisting of:

drug delivery rate;
drug capacity;
remaining capacity;
bolus level;
bolus occurrence;
alarm occurrences;
alarm frequency;
alarm threshold; and
delivery period.

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3. The apparatus of claim 1, wherein the programmable circuit is further programmed to display a table juxtaposing the non-original pump parameter and the original pump parameter.

4. The apparatus of claim 1, wherein the programmable circuit is further programmed to display a legend associated with the non-original pump parameter and the original pump parameter.

5. The apparatus of claim 1, wherein the programmable circuit is further programmed to display a time/date stamp associated with the non-original pump parameter.

6. The apparatus of claim 1, wherein the original pump parameter includes a customized pump parameter value.

7. The apparatus of claim 1, wherein the non-original pump parameter includes a customized pump parameter value.

8. The apparatus of claim 1, wherein the programmable circuit is further programmed to highlight differences between the non-original pump parameter and the original pump parameter.

9. An apparatus for indicating a change in operation of a medical infusion pump, the apparatus comprising:

a memory configured to store an original pump parameter and a current pump parameter;

a programmable circuit in electrical communication with the memory, the programmable circuit programmed to display the original pump parameter juxtaposed to the current pump parameter.

10. The apparatus of claim 9, further comprising a monitor in electrical communication with the programmable circuit and wherein the programmable circuit is programmed to display on the monitor the original pump parameter and the current pump parameter.

11. The apparatus of claim 10, wherein the current pump parameter is displayed on the monitor juxtaposed to the original pump parameter.

12. The apparatus of claim 9, wherein the original pump parameter and the current pump parameter are parameters selected from the group consisting of:

drug delivery rate;
drug capacity;
demand dose;
demand dose lockout;
remaining capacity;
bolus level;
bolus occurrence;
alarm occurrences;
alarm frequency;
alarm threshold; and
delivery period.

13. The apparatus of claim 9, wherein the programmable circuit is further programmed to display a table juxtaposing the current pump parameter and the original pump parameter.

14. The apparatus of claim 9, wherein the programmable circuit is further programmed to display a legend associated with the current pump parameter and the original pump parameter.

15. The apparatus of claim 9, wherein the programmable circuit is further programmed to display a time/date stamp associated with the current pump parameter.

16. The apparatus of claim 9, wherein the original pump parameter includes a customized pump parameter value.

17. The apparatus of claim 9, wherein the non-original pump parameter includes a customized pump parameter value.

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18. The apparatus of claim 9, wherein the programmable circuit is further programmed to highlight differences between the current pump parameter and the original pump parameter.

19. A method of indicating a change in operation of a 5 medical infusion pump, the method comprising:

storing an original pump parameter;
storing a current pump parameter;
displaying the original pump parameter juxtaposed to the 10 current pump parameter.

20. The method of claim 19, wherein displaying comprises juxtaposing the current pump parameter to the original pump parameter.

21. The method of claim 19, wherein the original pump 15 parameter and the current pump parameter are parameters selected from the group consisting of:

drug delivery rate;
drug capacity;
demand dose;
demand dose lockout;

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remaining capacity;
bolus level;
bolus occurrence;
alarm occurrences;
alarm frequency;
alarm threshold; and
delivery period.

22. The method of claim 19, wherein displaying comprises displaying a table including the current pump parameter and the original pump parameter.

23. The method of claim 19, further comprising displaying a legend associated with the current pump parameter and the original pump parameter.

24. The method of claim 19, further comprising displaying 15 a time/date stamp associated with the current pump parameter.

25. The method of claim 19, wherein displaying comprises juxtaposing the current pump parameter and the original pump parameter.

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