

5 The invention relates to programmable drug
infusion pumps.

 Infusion pumps as used in the field of health care
are electromechanical devices which control the flow rate
of medical fluids. An example of a drug infusion pump is
10 the AS40A® Infusion Pump by Baxter Healthcare Inc. It
operates a medical syringe to deliver a drug to a patient
at a precisely controlled rate. The AS40A employs an
active fluid pumping mechanism, i.e., positive
displacement of the syringe plunger, to expel fluid from
15 the syringe. This type of pump is generally known as a
syringe pump.

 A vital application for infusion pumps in the
human and veterinary medical field is in the delivery of
chemicals, drugs, nutrition, or biological products to
20 patients. Typically, in these applications, one or more
drugs or other substances are mixed into a uniform
solution in a medical fluid and are then delivered
through an infusion pump into the bloodstream of a
recipient via tubing and/or catheters which conduct the
25 fluid from the pump to the recipient's vascular space.

 The fluid flow rate or sequence of rates at which
an infusion pump operates are typically selected based on
a desired pattern of drug delivery appropriate to the
specific circumstance. There are numerous factors that
30 should be considered in the process of specifying a
specific rate of fluid flow from a pump at a particular
moment in time. Those factors may include:

- (i) the nature of the substance being infused,
 including the known pharmacokinetics and
35 pharmacodynamics of a drug;

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- 5 of various organ systems, and ability to tolerate
infusion of various diluent fluid volumes;
- (iv) the occurrence of change in measurable endpoints
related to the actions or effects of the substance
being infused;
- 10 (v) the difference between the estimated concentration
of the drug at the target site of drug action (as
computed based upon actual measurements or based
upon pharmacokinetic models and the prior history
of the infusion and/or other factors), as compared
15 to the desired concentration;
- (vi) local practices, policies, protocols, and
regulations; or
- (vii) other considerations including operator judgement.

The process by which a patient care-giver takes
20 the above considerations into account and chooses fluid
flow rates for drug delivery from a pump is complex and
if done incorrectly can lead to serious problems. The
process is prone to error, especially because of the
requirement for multiple computations and calculations.

25 The complexities are aggravated by several factors. The
staff training cost and the cost of preparing, updating,
and distributing formularies and policy and procedure
protocols within hospitals is large. The difficulty of
establishing safe and uniform practices is compounded by
30 significant local, regional, and nation-to-nation
variations in practice patterns. The complexity of using
such pumps may result in denial of needed therapy to
patients because a care-giver lacks sufficient training,
or does not have ready access or the time to review
35 relevant knowledge or to use other tools (such as

5 in the past to make infusion pumps more suitable for
intravenous drug infusions. For example, companies have
developed calculator-type infusion pumps which allow
users to deliver drug diluted in a fluid by entering data
such as drug concentration, patient weight, and desired
10 doses and dose rates using dose delivery units such as
mcg/kg or mcg/kg/min. Based upon these inputs, the pumps
calculate the volumes and fluid flow rates to be
delivered.

Some pumps include physical templates which can be
15 attached to and which electromagnetically modify (i.e.,
program) the infusion pump. These templates are drug-
drug-concentration-, drug-container-size-, bolus-rate-,
and dose-delivery-unit-specific. The templates contain
knowledge which is useful for end-users in that typical
20 drug delivery doses and dose rates are printed on the
physical templates. For each drug delivery configuration
there must be a separate template. In addition, if a
particular drug delivery configuration will be used
simultaneously on multiple pumps within a facility, there
25 must be available an equal number of identical
templates, one for each pump.

Other approaches to making fluid infusion pumps
more suitable for drug infusion have included the
development of pumps which contain digital communication
30 ports for external control. These permit the infusion
pump to be continuously cabled to a separate remote
personal computing device. The personal computer can
then run a particular program tailored to provide the
desired pattern of drug delivery appropriate to the
35 specific circumstance.

5 information including a series of drug infusion profiles
relating to various drugs to be infused (See PCT
International Publication No. WO 88/10383 entitled
"Infusion Pump and Drive Systems Therefore"). A related
10 approach, which is described by Crankshaw et al. in U.S.
Patent 4,741,732, involves use of EPROM modules which can
be physically plugged into the pump casing. The modules
are drug-specific and thus a separate module is required
for each drug type. The program within a module varies
the infusion rate over time according to a predefined
15 drug delivery profile algorithm.

Summary of the Invention

Applicants have recognized both the limitations of
prior drug infusion technologies and the consequent risk
to patients, and have developed a customizable drug
20 library software capability for infusion pumps which
avoids those limitations and consequent risks. The
electronically customizable drug library, either by
itself or interacting with an automatic drug recognition
capability based upon a machine readable label or data
25 carrier, avoids problems of the prior approaches and both
facilitates and enhances the dissemination, training, and
execution of appropriate and customary drug infusion
practices found in critical care areas of hospitals.

In general, in one aspect, the invention is a
30 system for creating a customized drug library for an
electronically loadable drug infusion pump. The system
includes a drug library containing a plurality of drug
entries, there being associated with each drug entry a
set of associated drug delivery parameters and/or drug

5 sets of drug delivery information associated therewith to
a customized library; and loading means for causing the
system to electronically load the customized library into
the drug infusion pump.

Preferred embodiments include the following
10 features. Each of the associated sets of drug delivery
parameters includes information selected from a group of
parameters including drug concentration, drug delivery
rate, drug dose, and bolus size. The group of parameters
includes minimum, default and maximum drug delivery rate;
15 minimum, default and maximum dose; minimum, default and
maximum bolus size; and maximum bolus rate. The system
also includes means for creating a drug configuration
within the customized library that does not exist in the
drug library. The system further includes means for
20 editing an existing drug configuration in the customized
library. In addition, the system includes a graphical
tool that generates a graph for display on a computer
screen, the graph enabling the user to select an
appropriate drug concentration for a given body weight.
25 The graph is a two-dimensional log-log graph wherein one
axis is body weight and the other axis is fluid flow
rate. There are one or more curves plotted on the graph,
each of the one or more curves being for a given drug
concentration and different doses. The one or more
30 curves are of the form:

$$\text{Body Weight} = \text{Rate} \times \frac{\text{Concentration}}{\text{Dose}} \times K ,$$

Preferred embodiments also include the following
5 features. The system includes a list of available mode
options, means for identifying one or more modes from
that list and means for adding the identified modes to
the customized library. The modes specify the units
available for expressing the drug delivery information
10 and the identified modes are those the modes that will be
available in the infusion pump when the customized
library is loaded into the infusion pump. The available
mode options include milliliter/hour, units/hour,
micrograms/minute, and micrograms/kilogram/minute. The
15 system also includes a list of names of syringe
manufacturers, means for selecting names of syringe
manufacturers from that list and means for adding the
selected names of syringe manufactures to the customized
library. The selected names of syringe manufacturers
20 identify syringes that can be used in the drug infusion
pump when the customized library is loaded into the
infusion pump. The system further includes a list of
syringe sizes, means for one or more syringe sizes from
that list and means for adding the selected syringe sizes
25 to the customized library.

Also in preferred embodiments, the system includes
means for representing a set of features within the
customized library, each of which can be toggled on or
off, and means for toggling on or off each of the
30 features. The set of features includes a drug library
enable flag, wherein the drug library enable flag either
enables or disables, depending upon the condition of the
drug library enable flag, access to the drug entries
within the customized library when the customized library
35 is loaded into said drug infusion pump. The set of

flag, a syringe recognition capability within the drug
5 infusion pump when the customized library is loaded into
the drug infusion pump. The set of features includes a
syringe detection flag, wherein the syringe detection
flag either enables or disables, depending upon the
condition of the syringe detection flag, a syringe
10 detection capability within the drug infusion pump when
the customized library is loaded into the drug infusion
pump. The set of features includes a volume limit
detection flag, wherein the volume limit flag either
enables or disables, depending upon the condition of the
15 volume limit flag, a function within the pump that
enables the user to specify a volume limit for a drug
delivery configuration when the customized library is
loaded into the drug infusion pump.

In addition, preferred embodiments include means
20 for causing the system to read pump configuration
information from the drug infusion pump. In the system,
the means for selecting is normally disabled and the
system further includes password protection logic that
serves to enable the selection means but only if a system
25 user supplies a preselected password to the password
protection logic. There are a plurality of access
levels, each of which corresponds to a different set of
access privileges in the system and the system includes a
table associating each of a plurality of users with a
30 corresponding one of the access levels and the password
protection logic uses that table to assign access
privileges to the system user. The system also includes
an access control means for controlling access to the
loading means, wherein the access control means permits
35 access to the loading means if a system user satisfies a

5 means permits access to the loading means if a valid
approval sign-off exists in the sign-off table and denies
access to the loading means if a valid approval sign-off
does not exist in the sign-off table. The sign-off table
includes an system user name and a system user date and
10 time and an approval name and an approval date and time.
The system user date and time records when a last
modification of the customized file by the user occurred
and the access control means permits access to the
loading means if the approval date and time is later than
15 the system user date and time and denies access to the
loading means if the approval date and time is later than
the system user date and time.

In general, in another aspect, the invention is a
system for use with a computer. The system includes a
20 storage medium containing a drug library, the drug
library containing a plurality of drug entries, there
being associated with each drug entry a set of associated
drug delivery information for configuring a programmable
drug infusion pump, the storage medium being readable by
25 the computer. The system also includes a program that
runs on the computer, the program including means for
enabling a user to select a set of drug entries from
among the plurality of drugs entries in the drug library;
means for enabling the user to add the selected drug
30 entries along with the sets of drug delivery information
associated therewith to a customized library; and means
for enabling the user to cause the computer to
electronically load the customized library into the drug
infusion pump.

5 to a patient from the container; a programmable
controller controlling the drive mechanism; an
electronically loadable memory inside the pump; input
circuitry through which the electronically loadable
memory can be electronically loaded with a drug library,
10 the drug library containing a plurality of drug entries,
there being associated with each drug entry a set of
associated drug delivery parameters and/or drug delivery
protocols for configuring the drug infusion pump; a
user interface enabling a user to program the
15 programmable controller. The user interface includes
means for enabling the user to select a drug entry from
the electronically loaded drug library; and means for
configuring the programmable controller with the set of
drug delivery parameters associated with the selected
20 drug.

Preferred embodiments include the following
features. The container is a syringe and the drive
mechanism operates the syringe. The electronically
loadable memory is non-volatile memory, e.g. EEPROM. The
25 user interface includes a control panel through which the
user can program the programmable controller and a
display screen for displaying drug entries from the drug
library. Each of the associated sets of drug delivery
parameters includes information selected from a group of
30 parameters including drug concentration, drug delivery
rate, drug dose, and bolus size. The electronically
loaded drug library contains a list of available mode
options specifying the units available for expressing
drug delivery information, and the drug infusion pump
35 offers the user the list of available mode options from

5 the drug infusion pump, and the drug infusion pump offers
the user the list of names of syringe manufacturers from
which to make a selection when the electronically loaded
drug library is in the pump. The loaded drug library
contains a list of syringe sizes identifying syringes
10 that can be used in the drug infusion pump, and the drug
infusion pump offers the user the list of syringe sizes
from which to make a selection when the electronically
loaded drug library is in said pump. The loaded drug
library contains a set of features, each of which is
15 either be toggled on or off, and the pump offers the user
only the features from among the set of features that are
toggled on when the electronically loaded drug library is
in said pump.

In general, in still another aspect, the invention
20 is a drug infusion pump for use with a container
containing a given drug, the container including a
machine readable label, the label specifying an
identifier of the given drug and possibly other
information about the given drug. the pump includes a
25 drive mechanism for causing the given drug to be
delivered to a patient from the container; a programmable
controller controlling the drive mechanism; a memory
for storing a drug library containing a plurality of drug
entries, there being associated with each drug entry a
30 set of associated drug delivery parameters for
configuring the drug infusion pump; a label reader for
reading the contents of the label on the container; means
responsive to the label reader for identifying an entry
in the drug library that corresponds to the given drug;
35 means for configuring the programmable controller by

5 identified entry from the drug library.

In preferred embodiments, the machine readable label is a touch memory. In addition, the label includes an expiration date for the given drug and the pump includes an internal clock indicating a current date;
10 means for comparing the expiration date as read by the label reader to the current date as indicated by the internal clock; and means for issuing a warning if the current date is later than the expiration date. The pump further includes means for preventing the controller from
15 running the drive mechanism if the current date is later than the expiration date.

In general, in another aspect, the invention is a drug infusion pump including a drive mechanism for causing the given drug to be delivered to a patient from
20 the container; a programmable controller controlling the drive mechanism; a memory containing an event log; means for configuring the programmable controller to deliver the given drug in accordance with a set of drug delivery parameters; a user interface for operating the pump; and
25 means for creating in the event log a sequence of event records, each event record documenting a different event in the operation and/or programming of the pump.

In preferred embodiments, the events that are recorded in the event log include occurrences of alarms.

30 A significant advantage of the present invention is that it enables clinicians to easily customize their drug infusion pumps by electronically injecting customized drug libraries and configuration data into them. Thus, the clinicians can easily customize their

5 practices and preferences of a community of users
(typically a single hospital, or a subset of users within
that hospital) sharing a group of infusion pumps, thus
essentially incorporating the written practices,
policies, and procedures within the device, at the point
10 of use.

The electronic customizability of drug infusion
pumps allows hospital-based users continually and easily
to update their infusion devices to reflect new drug
introductions, modifications or minor variants of dosing
15 regimens, local practices with respect to the compounding
together of several medications in one fluid container,
and advances in medical knowledge.

The interaction between the internal drug library
and the automated drug recognition capability using
20 machine readable labels provides a seamless link between
drug container-associated information and pump resident
information or knowledge necessary for infusions.

The ability to log pump events and to download
them from the pump to a personal computer enables
25 clinicians to perform automated record-keeping relative
to drug infusion history for a specific patient, and to
collect device utilization information.

The invention offers users the ability (using the
graphical tool) to perform "what-if" prospective analysis
30 of the impact of a particular choice of drug
concentration or mixing upon the fluid flow rates which
would result if certain doses or dose rates were chosen
for patients of various body sizes.

The invention provides the users with a layer of
35 safety in terms of preventing programming errors during

5 embodiments and from the claims.

Brief Description of the Drawings

Fig. 1 shows a drug infusion pump that incorporates an electronically loadable drug library;

Fig. 2 is a block diagram of the circuitry within
10 the infusion pump of Fig. 1;

Fig. 3 shows the keyboard layout on the control panel of the infusion pump;

Fig. 4 is a view of the pump's display screen with all LCD segments activated;

15 Fig. 5 shows a personal computer connected to a drug infusion pump for transferring information from and to the pump;

Fig. 6 is block diagram of the user interface that enables a user to load a customizable drug library and
20 supplementary configuration data into the pump's EEPROM;

Fig. 7 shows a Main Menu screen;

Fig. 8 shows a Drug List screen that is accessible through the "DRUG LIBRARY" menu pick on the Main Menu;

Fig. 9 shows an empty Create/Edit A Custom Drug
25 screen that is accessible by pressing F3/F2 when viewing the Drug List screen;

Fig. 10 shows a Create/Edit A Custom Drug screen that contains information for "New Drug", a user created drug;

30 Fig. 11 shows a Send Configuration to File screen that is accessible through the Main Menu;

Fig. 12 shows a Mode Menu screen that is accessible by selecting the "CONFIGURE MODES" option in the Main Menu;

5 the Main Menu;

Fig. 15 shows a Syringes Menu screen that is accessible by selecting the "CONFIGURE SYRINGES" option in the Main Menu;

Fig. 16 shows a Defaults Menu screen that is
10 accessible by selecting the "CONFIGURE DEFAULTS" option in the Main Menu;

Fig. 17 shows a Miscellaneous Features Menu that is accessible by selecting the "CONFIGURE MISC" option in the Main Menu;

15 Fig. 18 shows a Create/Edit Pump Identifier screen that is accessible by selecting the "CONFIGURE IDENT" option in the Main Menu;

Figs. 19a-c is a flow chart of the program within the pump that enables the user to configure the pump to
20 run a particular drug delivery schedule; and

Fig. 20 shows a display screen generated by the graphical tool;

Fig. 21 is flow chart of the access security that is implemented by the computer interface program to
25 control access to the functionality of the program

Fig. 22 shows an authorization sign-off data structure;

Fig. 23 is a flow chart of the access security that is implemented by the computer interface program to
30 control access to the ability to load a drug library into a pump

Fig. 24 is a table showing the procedures for programming the pump when the drug library is not enabled.

The Drug Infusion Pump

Referring to Fig. 1, a portable infusion pump 10 with an internal memory for storing an electronically loadable drug library includes a user interface consisting of a control panel 12 and a data display 14. Control panel 12 includes a keyboard 16 and a group of status lights 18. Keyboard 16 is a conventional vented-membrane type, using a tactile feedback silicone rubber overlay. Data display 14 is an LCD screen on which drug infusion information can be displayed. Status lights 18 are an array of LEDs that are used to display pump status information. There is also a single audio transducer (not shown).

On the right side of the infusion pump, there is a pair of clamping devices for holding a syringe 20 that has a barrel 28, a flange 30 and a plunger 34. One of the clamping devices is a barrel clamp affixed to the body of pump 10. It includes a barrel clamp cradle 24 and a barrel clamp slider 26 that can be pressed against barrel 28 to grasp syringe 20 and hold it in a fixed position. The barrel clamp operates by simultaneously capturing both barrel 28 and flange 30 of syringe 20. Also on the same side of pump 10 as the barrel clamp is a plunger driver 37 with a plunger clamp 32. It is connected to the internal drive mechanism (not shown). Plunger clamp 32 grasps plunger of the syringe and, when pump 10 is running, plunger driver 37 pushes plunger 34 into syringe barrel 28 at a controlled speed to achieve the desired drug delivery rate. Plunger clamp 32 and the

internal drive mechanism uses a lead screw/split-nut
5 drive and is designed so that the drive is disengaged
when plunger clamp 32 is in the "open" position thereby
allowing the syringe to be removed and plunger driver 37
to be moved manually to any desired starting position.

Mounted on syringe 20 is a touch memory chip 31
10 such as is available from Dallas Semiconductor. This
chip stores information about the syringe including the
date on which its contents were prepared, the identity of
the person who prepared the drug, the name of the drug,
its concentration, the syringe manufacturer and size, and
15 possibly other drug related information, such as
pharmacokinetic model-based drug infusion schedules and
drug delivery profiles. Pump 10 includes a two contacts
33 which are used to read the contents of touch memory
chip 31 into internal memory. Touch memory chip 31 (also
20 referred to as a machine readable label) is in electrical
contact with two conductor strips 35, each of which is
contacted by a different one of the two contacts 33 when
the syringe is mounted in the pump. The electrical
contact with conductor strips 35 enables the touch memory
25 to transfer its contents into internal memory in the
pump.

The motor which drives plunger clamp 32 is a
conventional DC gear motor driven by a four-transistor
bridge. The drive control system uses pulse-width
30 modulation. In addition, multiple safety systems exist
within the motor drive circuitry. For example, the motor
current is electronically limited; a detected "failsafe"
error cuts off all four legs of the bridge, thus
disabling the motor; and false drive data (e.g. processor

5 drive encoders. The first is a rotary encoder built into the gear motor. The second encoder is a Hall-Effect pair that detects rotation of the lead screw assembly.

Referring to Fig. 2, the internal circuit of infusion pump 10 includes a master microprocessor (Master
10 μ P) 40 and a slave microprocessor (slave μ P) 42 that function as a multitasking system with preemptive scheduling. Master processor 40 is primarily dedicated to operating the pump motor through a motor control module 53. As a background task, Master processor 40
15 performs a continuous check of ROM (read only memory) integrity and periodically checks critical RAM data areas. Slave processor 42 checks Master processor 40 in several areas. It verifies that Master processor is controlling the motor to the intended rate within
20 tolerance limits. It performs "watchdog" checks on system activity, including timekeeping. And it checks the motor armature shaft encoder output against the lead screw's Hall Effect sensor.

(In Fig. 2 note that multiple signal lines are
25 identified by heavy lines and single signal lines are identified by thin lines.)

Three types of memory are employed. A volatile RAM 44 contains program data. A nonvolatile ROM 46 stores the pump operating system (i.e., the firmware).
30 And an EEPROM 48 holds the electronically loadable customized drug library 59 and supplementary configuration data, calibration information 63, as well as an event log 61 recording data gathered about the operation of pump 10.

5 The full collection of sensors 52 includes: a
syringe barrel detector, a syringe barrel diameter
sensor, a syringe barrel flange detector, a plunger
position sensor, a strain gauge, two Hall effect sensors
and a mercury switch.

10 The syringe barrel detector is a series-connected,
pressure-activated switch pair, built into the barrel
clamp cradle. Both switches are closed only when the
barrel is centered in the "V" shaped cradle and the
barrel clamp slider is pressed down over the barrel of
15 the syringe.

 The syringe barrel diameter sensor is a linear-
displacement potentiometer that is built into the barrel
clamp slider. Its output voltage varies in direct
proportion to the syringe barrel diameter and provides an
20 indication of the diameter of the syringe.

 The syringe barrel flange detector is a switch
that is built into the portion of the barrel cradle clamp
that grasps the barrel flange. The syringe barrel flange
is captured when the barrel clamp is closed. This
25 detector determines whether the flange has been captured.

 The plunger position sensor is a linear-
displacement potentiometer, mechanically coupled to the
syringe plunger driver 37. The output varies in direct
proportion to the plunger driver position and is used to
30 determine the distance the plunger has been pushed into
the barrel.

 The strain gauge measures the amount of force
exerted on the lead screw drive mechanism, which is
approximately the same as the force applied to the
35 syringe plunger. This information is used to determine

5 vertical or horizontal orientation. This information is used as a force correction factor, to compensate for the weight of the drive screw assembly.

Pump 10 includes an external RS232 serial port 50. The pump's ROM 46 and EEPROM 48 are loaded through this
10 port. It is also used as a serial data port for various other applications to be described. The data and other signals which come in through serial port 50 from an external source, e.g. a laptop, a personal computer, or another external computer, first pass through a level
15 shifter 47. Level shifter 47 shifts the levels of the signals so that they conform to the internal requirement of the pump's circuitry and then passes the level shifted signals to a buffer 49. Level shifter 47 may either be internal to the pump as is suggested in Fig. 2, or it can
20 be provided in the form of an external adapter.

To load the pump operating system into ROM 46 or the drug library and supplementary configuration data into EEPROM 48, a voltage is asserted on a PRGM program line 51 to indicate to the microprocessor that a memory
25 load is to take place. Executable code is loaded into RAM 44 and run from RAM 44. The executable code sends the incoming data to the appropriate locations in either ROM 46 or EEPROM 48.

Another input for data is a reservoir label line
30 57. This line is used to "read" the contents of the touch memory label that is mounted on the syringe.

Information from the pump is communicated to the pump operator through the previously mentioned display screen and status lights, represented in Fig. 2 by
35 display block 45.

5 that take place in the pump. The details of which events
are records are described below in the section entitled
"Event Log".

As shown in Fig. 3, the keyboard includes ten
digit keys as well as other function keys. There are <up
10 arrow> and <down arrow> keys 60 and 62 which are used to
select, increment or decrement data. A <START> key 64
starts running a selected operation, e.g. infusing a
selected drug. A <STOP> 66 key stops a running task. A
<PURG> key 68 selects a purge operation. A <CLR> key 70
15 resets a field to its default value. A <BOLUS> 72 key
selects a bolus operation. An <EDIT> key 74 enables the
user to alter a previously programmed field. A <LOCK>
key 76 selects and deselects the lock function, i.e., it
locks out all other keys on the keyboard. And a
20 <CONFIRM> key 78 completes a program step or displays
hidden data during a run state (i.e., when pump is
infusing a drug).

As shown in Fig. 4, the display that appears on
the LCD screen is divided into eight fields, each of
25 which is dedicated to a certain category or certain
categories of information. Field 1 displays the syringe
manufacturer code and the nominal syringe size in
milliliters. The single-character text sub-field within
field 1 is also used to display operator responses to
30 configuration prompts.

Field 2 displays the quantity of drug that is to
be infused (mL), infusion rate (mL/hr), or bolus size
(mL). Field 3 displays dose duration (hr:min) or patient
body weight (kg). Field 4 displays the dose interval
35 (hr:min), drug concentration (in mg/mL or Units/mL), or

5 mg, or grams), volume limit (mL), or bolus size (mL).
Field 7 displays the total amount of fluid delivered
(mL). And field 8 is a two line field that displays text
prompts.

The Computer Interface Program:

10 Referring to Fig. 5, a user can electronically
load a customized drug library and supplementary
configuration data into a pump 10 from an external
computer source, which in the described embodiment is a
personal computer 80. PC 80 is connected to pump 10
15 through a connector cable 82 that may include an
externally powered adapter 84, which performs whatever
signal level shifting is required to enable PC 80 and
pump 10 to communicate with each other. For example, in
the described embodiment for safety reasons the 12 volt
20 signals from the RS232 port of the PC are not permitted
into the pump. Thus, adapter 84 shifts the levels of the
RS232 signals prior to passing them to pump 10. In the
reverse direction when information is downloaded from the
pump to the PC, adapter 84 shifts the levels of the pump
25 signals so that they conform to the requirements of the
RS232 port. PC 80 also includes a mouse 83 which can be
used in operating the computer interface program and/or a
graphical tool that is available through the computer
interface program (to be described below).

30 Referring to Fig. 6, the PC includes in its memory
or on disk storage a standard drug library 90 containing
drug delivery information for a set of drugs. The
standard drug library is stored as an encrypted file.
The set of drugs within the standard drug library is

5 interface that enables an authorized individual (i.e.,
one with authorized password and access level) to
generate drug configurations specific to that user and
which might include drugs not found within the standard
drug library. Such user-generated drug configurations
10 may then be stored as separate files 92. Computer
interface 94 thus enables the authorized user to easily
construct a customized drug library 96 both by selecting
particular drug entries from the standard drug library 90
and by creating custom drug entries. Once the customized
15 drug library has been constructed, computer interface 94
enables the user to download the customized drug library
and supplementary configuration data into one or more
drug infusion pumps 98 that are to be used in a
particular medical facility for which the customized
20 library was designed.

The media on which the standard drug library is
stored also contains a user file 99 that contains the
full name, password and authorized access level for each
individual that is authorized to access the functionality
25 of the user interface. The way in which the system uses
the information stored in the user file is described
below in the section titled "Security Features".

Referring to Fig. 7, when computer interface
program 94 is executed, it displays a Main Menu 100 on
30 the screen of the PC. The Main Menu identifies as
possible menu selections all of the functions which can
be invoked through the computer interface program. (Note
that the highlighting is illustrated in Fig. 7 by a box
102 enclosing the menu pick.) Users select an option by
35 first highlighting that option and then pressing <ENTER>

5 menu and the down arrow key moves down through the menu.
In each of the menu screens that are be described below,
the selections of the available options are made in a
similar way.

Each of the options that are available through the
10 Main Menu will now be described in the order in which
they are shown in Fig. 7.

Either to select a drug entry from the standard
drug library or to generate a drug entry not available in
the standard drug library, the user first selects the
15 "Drug Library" menu pick. In response, the program
presents the user with the screen shown in Fig. 8. The
top half of the screen presents a window into the current
drug library, which includes all of the drug entries in
the standard drug library as well as drug entries which
20 the user can create. By using the up/down arrow keys,
the user can scroll through the entries in the current
drug library one at a time and in alphabetical order,
each drug entry appearing in the top half of the screen.
As a drug entry is being displayed, the user can then
25 either select/deselect that entry or modify it and
thereby generate a new drug entry.

The template for each drug entry has six fields
identified in Fig. 8 as fields 110-120. Field 110
identifies the name of the drug entry and the
30 concentration. Field 112 identifies whether the drug
entry is a standard drug entry found in the drug library.
If the drug entry was selected from the standard drug
library, this field will contain an "S". On the other
hand, if the drug entry was created by the user, this
35 field will contain a "C". Field 114 specifies the

5 delivered. And field 120 specifies whether the drug will
appear on the drug selection menu within the pump. If
field 120 contains a "Y", it will appear on the list of
active drug entries which are available to the user of
the pump. If field 120 contains a "N", then even though
10 the drug entry is part of the customized library that was
loaded into the pump, it will not be visible to the user
and thus the user will not be able to select it. To
change the status of a drug entry within the customized
drug library in the pump, the user can enter a special
15 editing mode in the pump and activate or deactivate any
of the drug entries in the library.

The particular drug entry shown in Fig. 8 is
alfentan. If the user wishes to select this drug entry
to be included in the customized library that is to be
20 loaded into the pump, the user merely presses the
spacebar. The entry may be deselected by pressing the
spacebar a second time. If the drug entry has been
selected, this is indicated by an asterisk "*" appearing
to the left of the drug entry name (see location 122).

25 To create a custom drug entry, the user presses F3
while the Drug List screen is being displayed. The
program replaces the view of an entry in the drug library
with an empty template, as shown in Fig. 9. The fields
which were previously filled with information now contain
30 dashes indicating locations in which the user can enter
his own data. After entering the name of the drug entry
for which delivery information will be entered, the user
moves to the other fields to supply the desired rate
information. Repeated presses of the TAB key moves the
35 user through the fields one at a time. In all fields,

5 desired mode for representing the drug delivery rate
information. Certain fields may be left empty. For
example, the bolus information can be left blank. When
the pump operator attempts to administer a bolus for this
drug, the pump will declare that as an invalid operation
10 and not permit it.

To edit a custom drug entry, the user presses F2.
The user is then allowed access to the existing custom
drug entry's fields and can edit the contents of those
fields.

15 Fig. 10 shows the "Create/Edit A Custom Drug"
screen after the user has entered drug delivery
information for a fictitious drug called "New Drug". In
this example, notice that the user selected the drug mode
mcg/min.

20 The selection of the "Create/Edit a Custom Drug"
function automatically identifies the new drug as
selected so that will be active when downloaded into the
infusion pump. In other words, it is assumed that the
user is generating a drug that is to appear in the
25 customized drug library. If the user wishes to "hide"
the drug, this is done by simply deselecting the drug
after returning to the "Drug List" screen.

After the user has specified the contents of the
customized drug library, the user can return to the Main
30 Menu from the Drug List screen by pressing <ENTER>. From
the Main Menu, the user can save the drug selections and
supplementary configuration data to a file by selecting
"WRITE TO FILE". In response, the program displays the
screen shown in Fig. 11 and prompts the user to name the
35 file. After entering the file's name, another press of

5 the syringe manufactures that the pump will recognize,
the syringe sizes that it will recognize, the defaults
used by the pump, and other miscellaneous features. This
is done with the aid of the other CONFIGURE functions
that appear on the Main Menu. Each of the configure
10 functions will now be described.

When CONFIGURE MODES is selected, the program
displays the MODE MENU screen shown in Fig. 12. There
are seven modes which can be activated/deactivated from
this screen. The configure modes allow the user to
15 determine which modes will be available in the mode
selection step of pump programming. The choice of mode
typically depends upon the type of drug being
administered as well as the particular convention that
has been adopted by the care facility or medical
20 community using the pumps.

The modes define the way the user is to specify
the drug delivery information. They are: ML/HR,
UNITS/HR, MCG/MIN, MCG/KG/MIN, SINGLE DOSE, MANUAL
SCHEDULE, and AUTO SCHEDULE. Of course, these specific
25 mode options are merely representative of a much larger
range of choices that one might wish to make. The chosen
set of options would likely depend in part on the local
customs of the medical community using the infusion
pumps.

30 In the mL/hr mode, illustrated by the screen shown
in Fig. 13a, the user specifies the drug delivery rate
directly. In the units/hr mode, illustrated by the
screen shown in Fig. 13b, the user specifies the
concentration of the drug in units per ml and the desired
35 dose in units per hour. From those two pieces of

5 (in mcg/min). The pump then calculates the rate at which
it must deliver fluid from the syringe. In the
mcg/kg/min mode, illustrated by the screen shown in Fig.
13g, the user specifies the concentration of the drug in
the syringe, the weight of the patient and the desired
10 dose/kg/min for that drug. The processor in the infusion
pump computes the rate at which the pump must deliver
fluid from the syringe.

In SINGLE DOSE mode, illustrated by the screen
shown in Fig. 13c, the user specifies a volume to be
15 delivered and a time in which it is to be delivered. For
example, the user may specify 5 mL of drug to be
delivered over a period of 4 hours. The pump then
computes the rate at which the syringe will deliver the
drug.

20 In MANUAL SCHEDULE and AUTO SCHEDULE modes,
illustrated by the screens shown in Figs 13d and 13e,
respectively, the user specifies a volume to be
delivered, a time over which it is to be delivered, and a
repeat time. Thus, for example, the user might specify 4
25 mL to be delivered over one hour every 8 hours. The
difference between manual schedule and auto schedule is
that in manual schedule mode when it is time for the next
dose, the pump alarms and the user must manually start
the dose. In auto schedule, the next dose starts
30 automatically at the scheduled time.

Mode selection/deselection is done by highlighting
the mode and pressing the spacebar. After all of the
mode selections are specified, pressing the <ENTER> key
causes the program to save that information and return to
35 the Main Menu.

5 pump must know the manufacturer of the syringe in order
to determine the syringe size. It includes tables of
barrel sizes that correspond to specific manufacturers
and to specific syringe sizes used by that manufacturer.
In order to recognize the syringe size, the pump must
10 know the manufacturer of the syringe so it can use the
correct table to convert barrel size to syringe size. In
the described embodiment, there are three manufacturers
that the pump recognizes, namely,

- 1) MONOJECT = Monoject®
- 15 2) B-D = Becton Dickinson Plastipak®
- 3) TERUMO = Terumo®.

As described above, pressing the spacebar
selects/deselects the different choices and pressing the
<ENTER> key saves the results before returning the user
20 to the Main Menu.

Referring again to Fig. 7, from the Main Menu, the
user can also select CONFIGURE SYRINGES. In response,
the program displays the Syringes Menu shown in Fig. 15.
This menu presents a list of all the syringe sizes that
25 the pump can recognize for each manufacturer that it can
recognize. By using the <spacebar>, the user can
select/deselect the desired sizes. If the configuration
information that is downloaded to the pump does not
specify a syringe of a particular size, the pump will not
30 be able to recognize or allow selection of that syringe
size and it cannot be used in the pump.

Many hospitals deal with only one syringe
manufacturer. For example, the hospital may only use B-D
syringes. The person who program the pumps for that
35 facility may wish to select only that manufacturer and

From the Main Menu, the user can select CONFIGURE DEFAULTS. In response, the program displays the Defaults Menu shown in Fig. 16. There are four default categories, namely, drug default, mode default, manufacturer default and syringe default. If the drug default option is selected, when the select drugs step in the pump prompts the user to press an up or down arrow key, the first up or down arrow key cause the pump to display the last drug that was run in the pump. Note that the user has to begin a bolus or infusion to record the default settings for the next time the pump is turned on. The pump records what drug (if any) is being used, what mode is being used, what syringe manufacturer is being used, and what syringe size is being used. Then, if any of the corresponding default options are set, these recorded settings will be the first choices presented to the user when the pump is next turned on.

Another configuration option available through the Main Menu is CONFIGURE MISC. When this option is selected, the program displays the Miscellaneous Feature Menu shown in Fig. 17. Each of the options available through this menu will be described in the order in which it appears.

Drug Library Enable determines whether the customized drug library that is loaded into the pump will be directly accessible when the pump is turned on. If Drug Library Enable is not selected, the customized drug library is present in the EEPROM of the pump but in normal operating mode the pump does not appear to have a drug library stored within it. It operates as if the

5 Drug Library Enable setting.

Syringe Recognition is a convenience feature that simplifies programming by initializing the "SYRINGE size" field to the size of the syringe that is mounted. If Syringe Recognition is enabled, the pump automatically
10 identifies the size of the syringe that is inserted into the pump. If Syringe Recognition is turned off, the pump does not recognize syringe size.

If both syringe recognition and syringe default are turned on, regardless of what the syringe default is,
15 the syringe recognition function takes precedence. Thus, if the user previously ran a 5 ml syringe last and then mounts a 30 ml syringe, the pump will recognize it as a 30 ml syringe.

Syringe Detection is a safety enhancement that
20 enables the pump to issue an alarm if the syringe is improperly mounted in the barrel clamp. This feature is active even while the pump is delivering. Syringe Detection is automatically configured when Syringe Recognition is enabled. A group of three switches is
25 used to perform the detection function. Two of the switches are in the barrel clamp and one switch is in the part that captures the flange of the syringe. When Syringe Detection is enabled, if any of the switches fails to detect the presence of a syringe in the pump
30 when an attempt is made by the user to start motor movement, the pump will display a "Load Syringe" or "Check Syringe" message to the user and will not initiate motor movement.

PSI Range enables the user to select the pump's
35 sensitivity for detecting occlusions. There are three

5 an alarm sounds indicating the presence of a possible occlusion. The alarm will trigger at a lower force for a low setting as compared to a high setting.

Rate Range limits the maximum fluid delivery rate. It too has three possible settings, low, medium, and
10 high. These settings place an upper limit on how fast the pump can deliver the fluid from the syringe. The high setting allows the pump to deliver up to 360 mL/hr. The medium setting has a limit of 120 mL/hr. And the low setting has a limit of 15 mL/hr. This feature prevents
15 the user from accidentally programming the pump to too high a rate. The rate range setting applies severally to bolus, purge, and infusion rate.

Auto Lock is a feature that locks the keyboard automatically after two minutes if there is no activity
20 on the keyboard. This provides protection against inadvertent activation of a key.

The Volume Limit feature is a special feature for the mL/hr mode only. It enables the user to set a limit upon how many milliliters of drug will be delivered.
25 Whenever that limit is reached, the pump stops and alarms.

The Silent Running features enables the user to eliminate the audio component of certain warnings that are provided by the pump. For example, the pump will
30 issue a warning when there is only 10 minutes left before the syringe will be empty. If silent running is enabled, the audio portion of this alarm will be suppressed. This feature is for use in areas in the hospital where the provider does not want to disturb the patient
35 unnecessarily.

5 that warning every two minutes that the keyboard remains
idle. When the Idle Alarm feature is enabled, the pump
will beep repeatedly until a key is pressed.

Referring again to Fig. 7, if the user selects
"CONFIGURE IDENT", the screen shown in Fig. 18 appears
10 and the user is prompted to enter an identifier that will
be displayed in the pump LCD following the power-on lamp
test. This can be used, for example, to identify the
particular configuration that has been loaded into the
pump or the identity of the intended user of the pump.
15 By selecting "WRITE CONFIGURATION TO FILE", the user can
save the customized drug library and configuration
information to a file on the PC. Later, by selecting
"READ CONFIGURATION FROM FILE", the user can read a
selected configuration file into active memory on the PC
20 for review or further editing.

To load a configuration into the pump, the user
ensures that the pump is properly connected to the PC and
turned on. The user selects the "LOAD PUMP" option, and
the program then downloads the configuration into the
25 pump's EEPROM.

The program also enables a user to read the drug
library and supplementary configuration data from the
EEPROM. To do so the user selects the "GET FROM PUMP"
menu choice. This function reads not only the drug
30 library and supplementary configuration data that had
been previously loaded but also operational information
that has been collected by the pump as well as any
changes to the configuration that have been entered by
the user through the pump's special editing capability.

5 and supplementary configuration data by either displaying it on the screen of the PC or by sending it to a printer.

The "Lock" pick in the Main Menu allows the user to leave the computer interface program running on the PC and prevent unauthorized use of the program's functions while the user is away from the computer. The PC will not allow further access to the computer interface program's functions until the current user's password is reentered.

The Graphical Tool

15 The computer interface program also provides a convenient graphical tool for selecting the appropriate concentration and syringe size for a given drug. Each drug has associated pharmacodynamic (clinical) data having to do with the effects of the specific drug on a particular class of patients. From this data, a minimum, default, and maximum dose and bolus rates can usually be derived. The range from minimum dose to maximum dose defines the therapeutic range of the drug, i.e., the dose range over which the drug should generally be used to effectively achieve the intended therapeutic effects.

It is important to select the appropriate drug concentration for the class of patients to which the drug will be administered. If the drug delivery mode is mcg/kg/min, the rate of fluid delivery is a function of both the weight of the patient and the concentration of the drug in the syringe. If the drug is being delivered to a heavy patient and the concentration is low, the fluid flow rate required to achieve the specified dose can be quite high. This may mean that the syringe that

5 rate required to achieve the specified dose may be so low
that it is outside the range of safe and effective
operation of the pump. For example, the time required to
detect an occlusion (i.e., the time to achieve the
threshold pressure) may become so long that the occlusion
10 detection system is ineffective. In addition, when fluid
flow rate is very low, the transit time required for the
drug to traverse the tubing connecting the pump to the
patient may become unacceptably long. These too are
undesirable outcomes.

15 To select the drug concentration appropriately and
without error can be difficult. The graphical tool that
can be invoked through the Main Menu (see Fig. 6) or from
a Create/Edit A Custom Drug Menu (see Fig. 9) greatly
simplifies the selection of an appropriate drug
20 concentration. When the graphical tool is invoked, the
screen shown in Fig. 20 appears on the display. The
upper region 230 is a log-log graph displaying body
weight along the y-axis (i.e., vertical axis) and fluid
flow rate along the x-axis (i.e., horizontal axis). The
25 lines 231, 232, 233, and 234 are a plot of the following
equation

$$\text{Body Weight} = \frac{\text{Rate} \times \text{Concentration} \times 1000}{\text{Dose} \times 60} ,$$

for different doses (i.e., minimum, default, and maximum
doses and bolus dose rate, respectively) and a given
30 concentration. Since the curves are plotted on a log-log
graph, the equation for those curves becomes:

$$\text{Log}(\text{Body Weight}) = \text{Log}(\text{Rate}) + K ,$$

One can readily see that the displacement of the curves depend upon the concentration and the desired dose (or bolus).

Below the graphical representation are four horizontal axes, each one corresponding to a different syringe size. Each axis indicates the amount of time a syringe of that size will last if it delivers fluid at the rates shown at the corresponding locations on the fluid flow axis of the graph. Shaded regions 238 on the fluid flow axes and shaded regions of the syringe size axes 239a-d represent undesirable operating regions. Operating in shaded region 238 on the fluid flow axes is undesirable because the sensitivity for detecting an occlusion is unacceptable. A flow rate which falls within region 238 would result in undesirably long delays in detecting an occlusion or excessively long catheter transit time. Operating in shaded regions 239a-d on the horizontal axes for the different syringe sizes is undesirable because this would require frequent and multiple syringe loads. These, regions can, of course, be adjusted to reflect the preferences of the user.

The illustrated example is for the drug Amrinone with a concentration of 4 mg/ml and min/def/max doses of 5/7.5/10 mcg/kg/min and a bolus dose rate of 250 mcg/kg/min. The curves are tagged to identify which curve corresponds to which dose and a legend 236 indicates which tag corresponds to which dose. On a color display other possibly more effective ways could be used to identify this mapping of curves to dose. For example, a color coding scheme could be used.

5 are available. An example will help illustrate how the graphical display is used. Assume that the typical body weight is 37 kilograms. This body weight intersects the default dose curve at the point labelled "X", which, in turn, corresponds to a fluid flow rate of about 4.2 ml/hr
10 for a drug having a concentration of 4 mg/ml (see the point labelled "Y"). At this fluid flow rate, a 10 ml syringe will last 2.6 hours (see point labelled "Z"). Also note that the fluid flow rate X falls in none of the shaded regions 238, or 239a-d thereby indicating that the
15 occlusion detection sensitivity would be acceptable and fluid flow rate is not too high.

If, on the other hand, for purposes of illustration, the body weight was 4 kg, the resulting fluid flow rate for the default dose would be about 0.45
20 ml/hr. This level falls well with shaded region 238 and thus would be considered to be too low. To move the rate up to an acceptable level, one must decrease the drug concentration. Note that a decrease in the drug concentration will move the set of curves (i.e., curves
25 231, 232, 233, and 234) to the right in the graph. The program permits the user to change the concentration in two ways. The user can enter a new drug concentration in field 240 and see whether the fluid flow rate resulting from the new concentration falls within the acceptable
30 region. This approach will likely require that the user make several estimates of the drug concentration until arriving at the desired outcome.

The program also permits the user to determine the appropriate drug concentration by "dragging" the set of
35 curves to the location on the graphical display that will

5 the program computes the concentration that would be
required to achieve that location of the curves. The
program does this simply by computing a new value for K,
the offset coefficient for the curves.

10 Dragging can be performed either by a mouse which
is attached to the PC or by the cursor keys on the
keyboard of the PC. In addition, since it is desirable
to have concentrations of integer amounts (or of discrete
amounts selected from a set of available concentrations),
the program only permits curves to be drawn at the
15 permitted discrete concentration values. Thus, when the
user drags the curves to a new location and releases the
curves, the curves "snap" to a location representing the
closest permitted discrete value for the concentration.
For example, in this way, concentrations of 3.567 mg/ml
20 are not permitted.

Security Features

The computer interface program includes several
security features which are designed to prevent its
unauthorized use and to prevent loading of unapproved
25 drug library/configuration data files into the infusion
pump. These features will now be described.

Access to the computer interface program itself is
permitted only to persons who are identified in the user
file 99 (see Fig. 6) and who provide the private password
30 assigned to them. The user file is an encrypted disk
file on the PC 80, which includes the full name of each
person authorized to use the program, the password
associated with each name, and the access level
associated with each name.

5 it. Picks for functions not allowed by the access level
of the current user are omitted from their respective
menus.

Supervisory access level allows access to the user
file 99. Addition and deletion of user access records
10 are allowed, as is alteration of any person's name,
password and/or access level specification within the
user file 99. Supervisory access level also allows the
use of the "Write to File with Approval" pick from the
Main Menu, which enables supervisory approval of a drug
15 library/configuration data file. Without supervisory
approval, a drug library/configuration data file cannot
be loaded into a pump.

Access levels 1 and higher allow authorship of
drug library changes through the "Drug Library" pick from
20 the Main Menu, including the creation, deletion and
editing of custom drug entries.

Access levels 2 and higher allow authorship of
drug library changes through the "Drug Library" pick from
the Main Menu, excluding the creation, deletion and
25 editing of custom drug entries.

Access levels 3 and higher allow authorship of
configuration data changes via the "Configure <group>"
pick from the Main Menu, and allow the "Write to File"
pick from the Main Menu.

30 Access levels 4 and higher allow the "Read From
File", "Get From Pump" and "Load Pump" picks from the
Main Menu. Also allowed at this access level and higher
is the "View/Print Drug Library/Configuration Data" and
"Locks" pick from the Main Menu.

5 file 99 (see Fig. 6) and, assuming it is listed, whether
the user has entered the proper password (step 252). If
the name does not appear in the user file or the password
is incorrect, the program denies the user any access to
the computer interface program. If the user name and
10 password are listed in the user file, the program allows
the user access to the rest of its functionality
consistent with the user's access level (step 256).

Referring to Fig. 22, each drug library and
supplementary configuration data file that any user
15 creates, whether stored on disk or within the infusion
pump, includes a data structure 260 with three name, date
and time fields in it. The computer interface program
uses data structure 260 to determine whether the
particular drug library and supplementary configuration
20 data file with which it is associated can be loaded into
a pump. The first field (field 262) contains the
identity of the author of the file. In this case, the
author is defined as the last person to edit or modify
the file. Author field 262 also includes the date and
25 time of the last modification to the file. The second
field (field 264) includes the name of the person who
approved the file for loading into a pump. This field
will only contain a name of a person who has supervisory
level access as specified in the user file. Approval
30 field 264 also contains the date and time of when the
approval was given. Finally, the last field (field 266)
is reserved for the identity of the person who loads the
file into a pump. Like the other fields, it will also
contain a date and time but in this case the event being
35 recorded is instruction to load the file to a pump. When

5 possible at a later date by reading the contents of the pump to determine who authored the pumps drug library/configuration data file, who approved it, and who loaded it into the pump.

Whenever a user creates or modifies a file, the
10 program erases the entries in approval field 264 and updates the information in author field 262. Thus, the act of modifying a file after it has been approved for loading into a pump cancels the approval. Before that file can be loaded into a pump it must again be
15 authorized by an appropriate person.

Referring to Fig. 7, the Main Menu includes a "Write to File with Approval" menu pick which enables a user to authorize a configuration file. This functionality can be invoked only by a person having a
20 supervisory access level.

Referring to Fig. 23, when a user attempts to load a file into a pump by selecting "LOAD CONFIGURATION TO PUMP" in the Main Menu, the program performs the necessary checks before permitting the user to perform
25 the loading operation. First, the program determines whether there is a valid user identified in author field 262 (step 280). If that field contains a valid user, the program checks whether a valid user having supervisory access level is identified in approval field 264 (step
30 282). The approval must come from a user different from the author. If the contents of the data structure fails either of the tests in steps 280 or 282, the program dose not permit the user to load the drug library/configuration data file into the pump. On the
35 other hand, if the contents of the data structure passes

5 If the approval date is earlier than the date in author
field 262, it fails the test. If the dates are the same,
the program checks the time stamps in the two fields for
which was earlier. If the file was changed after the
time at which approval was given, the program returns to
10 the Main Menu and does not allow the user to load that
file. If the file received its approval after the last
change to the file, the program allows the user to
proceed with loading the file.

Before loading the file, however, the program
15 updates the information in field 266 of data structure
260 with the current user's name and the current date and
time (step 286). After the contents of data structure
260 have been updated to identify the person who is
loading the drug library into a pump, the program loads
20 the pump as requested (step 288).

Infusion Pump Operation

The procedure for operating the pump and using the
customized drug library stored in its EEPROM to program
the drug infusion pump will now be described, with the
25 aid of Figs. 19a-c.

The infusion pump is turned on by moving a power
on switch on the side of the pump (not shown in the
figures) to its "ON" position. Upon being turned on, the
pump performs a power-up initialization including a self-
30 test. The user interface portion of the self-test
includes lamp and audio tests. Portions of the self-test
are also performed as background tests during normal
operation.

5 displays the initial group selection.

First the pump checks whether the drug library feature is enabled (step 300). If the Drug Library option is not enabled, the pump proceeds as though no drug library is present (step 302). That is, the user
10 programs the pump by entering all of the drug delivery details through the keyboard on the front of the pump. The options that are available to the user are, however, constrained by the configuration options and features that were loaded into the EEPROM from the PC. For
15 example, if the only mode that is configured is mL/hr, then the user of the pump can only select this option when the pump is turned on (unless, of course, the user enters the configuration set mode and turns on the other mode options). The following description assumes that
20 all modes and features are turned on.

The sequence of entries required from the user for the different modes are summarized in Fig. 24. The pump prompts the user to select a mode from among the available modes on the pump, to then identify the syringe
25 manufacturer from among those listed in the pump and finally to specify a syringe size from among the sizes listed in the pumps memory (see row 200 in Fig. 24). After supplying those three entries, the sequence of events differs depending upon the mode that the user
30 selected.

If the selected mode is mL/hr (column 220), the pump prompts the user to specify an infusion rate in mL/hr (row 206). Then, the pump prompts the user to enter a volume limit in mL, if one is to be used (row
35 208). In response to the <BOLUS> key, the pump prompts

5 the <START> key is pressed to initiate an infusion according to the program that was entered. Since the rate is entered as mL/hr, the pump simply implements the rate supplied.

10 If the mode is Units/hr (column 222), after specifying the manufacturer and syringe size, the user enters the concentration of the drug that is in the syringe in Units per milliliter (row 204). Once the concentration has been specified, the user is prompted to enter an infusion dose in units/hr (row 206). Then, the user is permitted to optionally specify a bolus size in Units (row 210). At that point, the user may start the program. The pump computes the rate at which it must deliver the fluid in mL/hr and it delivers the drug at that computed rate.

20 If the mode is mcg/min (column 224), the user performs the same sequence of events as are performed for programming the Units/hr mode, except that the drug concentration is specified in mg/mL, the dose is entered as mcg/min and the bolus size is specified in mg. The pump computes the appropriate drug delivery rate in mL/hr.

30 For the mcg/kg/min mode (column 226), after syringe size is specified, the pump prompts the user to enter the patient's body weight in kg (row 202). Then, the user enters drug concentration, dose and bolus size in that order and using the units appropriate to this mode. The pump computes the drug delivery rate required to achieve the specified dose level.

35 Referring again to Fig. 19a, if the Drug Library option is enabled and at least one drug has been

5 the drug delivery information, may be supplied by the drug library entry.

If an identification field is configured, the identification field is displayed during the reading of the drug library index data, otherwise the pump displays
10 "LOADNG DRUGS".

During the process of reading the drug library index, the pump performs a checksum on the data. If the pump detects a checksum failure, a "DRUGS CORRUPT" error response is displayed to the user. After the 2 second
15 text display, the drug selection programming step is skipped, and the pump proceeds with mode selection.

Assuming that the drug library index has been read without any detected errors, the pump prompts the user to select a drug (step 308). The user enters and moves
20 through the list of drugs stored in the customized drug library by using the arrow keys. The <Up Arrow> key moves in the forward alphabetical direction and the <Down Arrow> moves in the reverse alphabetical direction. Where the pump enters the list of drugs depends upon
25 whether drug default mode is set. Thus, to determine the pump's response to the user's first arrow key press, the pump checks whether the drug default is on (step 310). If the drug default is on, the first drug that is displayed is the last drug that was run on the pump (step
30 312). If the drug default is off, the first drug that is displayed is the first drug in the alphabetically organized drug library (step 314).

As each drug appears on the pump's display screen, the predefined Concentration is displayed along with the
35 assigned drug name. If no predefined Concentration

5 Once the desired drug is found, the user selects it by pressing the <CONFIRM> key. In response to the confirm key, the pump selects the drug appearing on the display and prompts the user for the next selection (step 316).

10 If "GENERAL" is selected (step 318), the pump proceeds to mode selection, and subsequently behaves as if the drug library feature is disabled until it is next powered up (step 320).

15 In the case of drug entries having identical names and Concentrations but differing in assigned modes, the drug is displayed as one drug entry.

20 When the <CONFIRM> key is pressed to select a drug entry, if the selected drug entry has more than one assigned mode (step 322), the pump proceeds to mode selection, allowing the user to select between the modes assigned to the drug (step 324). The Concentration field remains displayed during mode selection. If the Drug Default option has been configured (step 326), and the last used drug has been selected, the pump presents the last used mode in response to the first arrow keypress (step 328). Otherwise, the pump displays the first option on the list of available modes (step 330)

30 The <CONFIRM> key is pressed to select the mode, the pump then reads additional drug library data for the selected drug from the EEPROM (step 334).

35 If the selected drug has only one assigned mode (in step 322), the pump defaults to that mode and mode selection is skipped (332). The pump then reads additional drug library data for the selected drug from the EEPROM. The assigned mode prompt is displayed in the

5 the predefined Concentration (if any) remains displayed
after a drug has been selected. The pump first
determines whether there is more than one option
configured (step 336). If only one manufacturer has been
programmed into the pump, the pump defaults to this
10 option and asks the user to verify that choice (step
338). If there is more than one option, the pump prompts
the user to select a manufacturer (step 340). As before,
the user presses the arrow keys to enter and move through
the list of options. To determine how to respond to the
15 first arrow key press, the pump checks whether the
manufacturer default is configured on (step 342). If it
is configured on, the pump responds to the first arrow
key press by displaying the manufacturer used in the last
run (step 344). If the manufacturer default is
20 configured off, the pump responds to the first arrow key
press by displaying the first option on the list of
options (step 346). When the user has identified the
manufacturer of the syringe that is to be used, it is
selected by pressing <CONFIRM> (step 348).

25 After the manufacturer has been selected, the pump
checks whether syringe recognition is configured on (step
350). If syringe recognition is configured on, the pump
determines the diameter of the syringe barrel and then
uses a lookup table for the selected manufacturer to
30 translate that measurement to syringe size. The pump
displays the syringe size and prompts the user to verify
that size or select a different size (step 352). If
syringe recognition is not configured on, the pump
prompts the user to select a size (step 354). The user
35 enters the list of options by pressing an arrow key. To

5 the syringe size last run in the pump (step 358). If
syringe default is configured off, the pump responds to
the first arrow key press by displaying the first (i.e.,
smallest) option on the list of available syringe sizes
(step 360). When the user has identified the syringe
10 size that is to be used, it is selected by pressing
<CONFIRM> (step 362).

After the syringe size has been selected, the pump
determines whether the selected drug has a predefined
concentration (364). If there is a predefined
15 concentration for the selected drug, programming of the
concentration field is skipped (step 366). The
predefined concentration is assumed to have been selected
in the drug selection step and the concentration is
displayed in the concentration field of the display.
20 Further, the user will not subsequently be allowed to
edit the predefined Concentration field.

If no Concentration is predefined for the selected
drug and mode, the pump prompts the user to specify a
concentration (step 368).

25 After the entry in the Concentration field has
been established the pump prompts the user to enter a
Dose or Rate value (step 370). The predefined default
Dose or Rate is displayed.

The user may employ the arrow keys to adjust the
30 displayed value. Or a digit keypress replaces the
default value display with the selected digit, allowing
direct entry of the desired value. The user may also use
the <CLR> key to reset the displayed value to dashes.

- 5 but out of range for the selected drug, the pump will display "DOSE [or RATE] > nnn" or if the previously programmed value was also out of range for the drug, and in the same direction, it will display "DOSE [or RATE] < nnn" for 2 seconds (where nnn is the drug limit value).
- 10 The pump then sounds a beep and accepts the confirmed value. If the previous value was not out of range for the drug, or was out of range in the opposition direction, the pump instead sounds a beep, and displays "VERIFY > nnn" or "VERIFY < nnn" (where nnn is the drug
- 15 limit value). The user may press <CONFIRM> to verify the desired value, or use <CLR>, or digit or arrow keys to change the displayed value. Once the Dose or Rate has been successfully confirmed, the drug name reappears in the text display.
- 20 Bolus programming proceeds according to the following rules. If the Bolus function is allowed for the selected drug, and a valid <BOLUS> key is pressed, the pump normally displays the Bolus size. If no Bolus size has been programmed, dashes are displayed in the
- 25 Bolus size field, and "PRESS EDIT TO SET BOLUS SIZE" will be displayed in the bottom line of the text field as a scrolled prompt. If a Bolus size value has been programmed, it is displayed in the Bolus size field, and "BOLUS READY" is displayed in the text field.
- 30 The "BOLUS READY" prompt times out in 10 seconds if no valid key is pressed (the "PRESS EDIT TO SET BOLUS SIZE" prompt will time out in 20 seconds if no valid key is pressed) and the normal Run or Standby state display is restored. However, if the Bolus Size field contains
- 35 dashes and <START> is pressed, a "DATA MISSING" error

5 immediately.

If the Bolus Size field does not contain dashes, <START> may be pressed following <BOLUS> to initiate Bolus delivery. If <EDIT> is pressed following <BOLUS>, the pump opens the Bolus size field for editing. "BOLUS
10 SIZE" is then displayed in the text field. If the Bolus size field was displayed as dashes, it is initialized to the predefined default Bolus size for the selected drug.

The <CLR>, arrow or digit keys may be used to edit the Bolus size value. The Bolus size may be set to any
15 value within the pump's limits, as well as to dashes.

If the <EDIT> key is pressed again during Bolus size editing, the pump restores the Bolus size field and text display to their contents when the field was opened, and the Bolus size field is closed.

20 If an arrow keypress increments or decrements the Bolus size field to a value out of the pump's range, the pump displays "PUMP LIMIT" and substitute the nearest acceptable value.

If the Bolus size field is open for editing, and
25 the value displayed is within both the pump's range and the predefined limits for the selected drug, <CONFIRM> may be pressed to store the Bolus size and close the Bolus size field, or <START> may be pressed to store the Bolus size and initiate Bolus delivery.

30 If either <CONFIRM> or <START> is pressed and the displayed Bolus size is out of the pump's range, the pump displays "PUMP LIMIT" and substitutes the nearest acceptable value. The Bolus size field remains open, and the key will otherwise be ignored.

5 previously programmed Bolus size exceeded the same
predefined drug limit, it displays "BOLUS < nnn" for 1.5
seconds (where nnn is the predefined drug limit). The
pump then sounds a beep, the Bolus size value is stored,
and the Bolus size field is closed (<CONFIRM>) or the
10 Bolus initiated (<START>).

If the previously programmed Bolus size was not
out of range for the drug, or was out of range in the
opposite direction, the pump instead sounds a beep, and
displays "VERIFY > nnn" or "VERIFY < nnn" (where nnn is
15 the drug limit value). The <CONFIRM> or <START> key will
otherwise be ignored. The <CLR>, digit or arrow keys may
be used to change the displayed value, or <CONFIRM> or
<START> may be pressed to store the Bolus size, and close
the Bolus size field (<CONFIRM>) or initiate the Bolus
20 (<START>).

If the Bolus size field is closed by the <EDIT> or
<CONFIRM> key and the final displayed value is dashes,
the "PRESS EDIT TO SET BOLUS SIZE" scrolling prompt will
be displayed. If the value is not dashes, "BOLUS READY"
25 will be displayed. <CONFIRM> and <BOLUS> may be used to
reopen the field, as described above. If "BOLUS READY"
is displayed, <START> may be pressed to initiate Bolus
delivery.

The "BOLUS READY" prompt times out in 10 seconds
30 if no valid key is pressed (and the "PRESS EDIT TO SET
BOLUS SIZE" prompt time outs in 20 seconds if no valid
key is pressed) and the normal Run or Standby state
display is restored.

If the Bolus function is allowed for the selected
35 drug when a valid <BOLUS> key is pressed, but the maximum

5 selected drug and an otherwise valid <BOLUS> key is pressed, the pump issues a "NOT ALLOWED" error response to the <BOLUS> key.

10 If a maximum bolus rate is prespecified for the selected drug, the pump selects the lesser of the maximum bolus rate and the pump maximum rate for the selected syringe, for bolus delivery. If the maximum bolus rate is less than the minimum rate for the selected syringe, the pump issues an "OUT OF RANGE" error response to the <BOLUS> key.

15 Referring again to Fig. 19c, after the dose (or rate and volume limit) has been appropriately programmed, the user presses the <START> key to begin an infusion. The pump responds differently depending on whether syringe detect is on or off (step 372). If the syringe
20 detect is on, the pump checks whether the syringe is properly mounted before proceeding (step 374). If the syringe is not properly mounted, it alerts the user (step 376). If the syringe is detected as being properly mounted, it begins delivering the drug at the programmed
25 rate and according to the programmed schedule (step 378).

Other Pump Operational Features

The pump has two configuration modes, each of which is selected by entering a special access code immediately after the power-up lamp test. There is a
30 Configuration Set Mode and a Configuration Review Mode. Configuration Set Mode allows the pump configuration to be modified. Configuration Review Mode enables the user to review the current pump configuration but does not allow the user to change the configuration.

5	Select Modes?	Limits the number of modes available to the user.
	Select Manufacturers?	The pump prompts only for the brands of syringe actually used.
10	Select Defaults?	The pump can be set to default to the drug, mode, manufacturer, and syringe size previously used.
	Select Misc?	A number of features can be selected including:
15	Drug Library	The drug library feature can be toggled on/off.
	Syringe Recognition	If configured on, the pump automatically determines the size of the syringe.
20	Syringe Detection	If configured on, enables the pump to warn of an improperly mounted syringe.
	PSI Range	Fine tunes the occlusion alarm by tailoring for the appropriate range of pressures (<u>H</u> igh, <u>M</u> edium, <u>L</u> ow).
25	Rate Range	Limits the maximum delivery rate to <u>H</u> igh, <u>M</u> edium, or <u>L</u> ow range.
	Auto Lock	Automatically locks the keyboard when the keyboard becomes idle.
30	Volume Limit	Is available in mL/hr mode only and it sounds an alarm when the Volume Limit counts down from the programmed value to zero.
35	Silent Running	Toggles certain alarms on/off.
	Idle Alarm	Selects the type of idle alarm that will be sounded.

5 procedure is only available to authorized users who have
been given the code. This prevents changes being entered
by unauthorized persons. To select the "Configuration
Set" Mode, the user enters the special code immediately
after the lamp test and the identification has been
10 displayed.

Once in the configuration set mode, the test
display area prompts for each option. The user response
field (the single-character digit in Field #1) shows the
response that is pending. The arrow keys (<▲>, <▼>)
15 enable the user to step through the available choices
(including Yes, No, High, Medium, or Low) and pressing
the <CONFIRM> key locks in the pending selection.

The first prompt for each option group is a
"SELECT | (group name) ?" query, where (group name
20 identifies the relevant configurable option. To begin
configuring the group, the user selects a pending
response prompt of "Y" (yes) and then presses <CONFIRM>.
To skip ahead to the next group, the user sets the
pending response prompt to "N" (no), and then presses
25 <CONFIRM>.

Once a group has been opened for configuration,
every option within that group must be configured. After
the final option within a group has been configured, the
display read "UPDATING" for a few seconds while the
30 pump's configuration memory is updated, and then it
displays the next "SELECT | (group name) ?" query.

The following example helps illustrate this
procedure. Following mode configuration, the next prompt
is "SELECT MFRS?". A flashing "Y" appears in the user
35 response field on the top line of the LCD screen.

5 filed of the top line. Pressing <▲> or <▼> toggles the user response between "Y" and "N". Pressing <CONFIRM> enters the selection and causes the next manufacturer to be displayed. After the user has made a selection for all manufacturers, the pump exits "SELECT MFRS?" group
10 and displays the "SELECT DEFAULTS?" prompt, enabling the user to perform the same selection process for the defaults..

Note that the pump program requires that the pump configuration must include at least one mode and
15 manufacturer. The user cannot exit either one of these groups unless there is at least one option selected.

After the last option group has been configured or skipped, the pump terminates the configuration set process by initiating a normal power-up restart.

20 Configuration Review Mode

The Configuration Review mode allows the pump configuration to be checked without risk of accidental alteration. To review the pump's configuration, the user enters another special access code after the power-up

25 Lamp Test.

The configuration sequence displays the category being reviewed in the lower screen field, followed by a question mark (for example: "VIEW MODES ?"). The upper screen field displays a "Y" (for "yes"). Pressing
30 <CONFIRM> begins reviewing the options within this category. The text field displays only the options that are configured. Pressing either <▲> or <▼> changes the "Y" to "N" (for "no"), indicating that review of this

The user can also input relevant information into the pump through touch memory contacts 33, shown in Fig. 1. The user activates this feature through a special key sequence on the control panel. This is done either at the beginning of the process of programming the pump for a particular drug or after the pump has been programmed. Once activated, the contents of the touch memory label transfer into the pump's memory. The transferred information includes, minimally, the drug expiration date, the drug concentration, the manufacturer and the size of the syringe, and the identity of the person who prepared the syringe. An program internal to the pump then performs a number of operations using the transferred information.

If this function is invoked at the beginning of the programming sequence, the program performs the operations shown in Fig. 25. First, the pump receives the contents of the touch memory into its own memory (step 400). Then, the pump checks the syringe's expiration date against the current date (step 402). If the syringe date has expired, the pump rejects the syringe and alerts the user of the expired date (step 404). If the date on the syringe has not expired, the pump program searches its internal drug library for a match with the drug in the syringe (step 406). If no match is found, the pump alerts the user that the drug is not in the library (step 408). The user can continue using the syringe by programming the pump manually without the aid of the drug library. The pump prompts the user to verify whether programming will continue manually (step 410). If the user chooses to continue

5 bolus size, etc. (step 414). After the pump is fully configured, the pump is ready to run the drug.

If a match is found in the pump's drug library, the pump selects that drug from the drug library (step 416) and configures itself using whatever information has
10 been stored in the library for that drug (step 418). Then, the program further configures the pump using additional information that might be available from the touch memory (e.g. manufacturer, syringe size, etc.). Finally, the pump prompts the user for whatever
15 additional information is required (step 420). Once that information is entered, the pump is ready to run the drug.

As should be readily apparent, by using the touch memory to provide further information useful to
20 configuring the pump (e.g. the inputs previously supplied by the user, see Figs. 19a-c), the users task in programming the pump can be greatly simplified.

If the touch memory feature is used after the pump has been configured for a particular drug, the pump then
25 performs a verification function as illustrated in Fig. 26. After the contents of the touch memory label have been transferred into the pump's memory (step 430), the pump compares the label information with the pump configuration (step 432). If inconsistencies are found,
30 the pump reports those inconsistencies to the user and disables the pump from running the drug until the user either overrides the program or in some other way satisfactorily reconciles the inconsistency (step 434).

5 history of program and alarm events with a time stamp for
each indicating when the event occurred. Only a
preselected number of events is remembered. When the
preselected number of recorded events is reached, the
record of each new event displaces the oldest event
10 record from memory. The pump uses the event log to
record program parameters that were run on the pump,
including when infusions were started, when they were
stopped, when a bolus was run, when an alarm occurred and
the nature of the alarm.

15 This information can be retrieved from the pump
with the aid of the user interface previously described.
Referring to Fig. 7, to read the event log, the user
selects "LOAD LOG FILE FROM PUMP". In response, the
program downloads the contents of the event log into the
20 PC computer from where it can be stored on disk. The
event log enables one to reconstruct how a pump has been
used in the event that a problem arises that requires
such a reconstruction.

Other embodiments are within the following claims.

25 What is claimed is:

5 a drug library containing a plurality of drug
entries, there being associated with each drug entry a
set of associated drug delivery parameters and/or drug
delivery protocols for configuring the drug infusion
pump;
10 means for selecting a set of drug entries from
among said plurality of drug entries in said drug
library;
means for adding the selected drug entries along
with the sets of drug delivery information associated
15 therewith to a customized library; and
loading means for causing the system to
electronically load said customized library into the drug
infusion pump.

2. The system of claim 1 wherein each of the
20 associated sets of drug delivery parameters includes
information selected from a group of parameters including
drug concentration, drug delivery rate, drug dose, and
bolus size.

3. The system of claim 2 wherein the said group
25 of parameters includes minimum, default and maximum drug
delivery rate.

4. The system of claim 2 wherein the said group
of parameters includes minimum, default and maximum dose.

5. The system of claim 2 wherein the said group
30 of parameters includes minimum, default and maximum bolus
size.

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for creating a drug configuration within the customized
5 library that does not exist in the drug library.

8. The system of claim 1 further comprising means
for editing an existing drug configuration in the
customized library.

9. The system of claim 1 further comprising a
10 graphical tool that generates a graph for display on a
computer screen, said graph enabling the user to select
an appropriate drug concentration for a given body
weight.

10. The system of claim 9 wherein said graph is a
15 two-dimensional log-log graph wherein one axis is body
weight and the other axis is fluid flow rate.

11. The system of claim 9 wherein one or more
curves are plotted on said graph, said one or more curves
being for a given drug concentration and different doses.

20 12. The system of claim 11 wherein the one or
more curves are of the form:

$$\text{Body Weight} = \text{Rate} \times \frac{\text{Concentration}}{\text{Dose}} \times K ,$$

where K is a positive number.

13. The system of claim 11 further comprising
25 means for moving said one or more curves about on said
graph.

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5 customized library, said modes specifying the units available for expressing the drug delivery information and said identified modes being the modes that will be available in the infusion pump when said customized library is loaded into said infusion pump.

10 15. The system of claim 14 wherein said available mode options include milliliter/hour, units/hour, micrograms/minute, and micrograms/kilogram/minute.

 16. The system of claim 1 further comprising a list of names of syringe manufacturers, means for
15 selecting names of syringe manufacturers from said list of names of syringe manufacturers and means for adding said selected names of syringe manufactures to said customized library, said selected names of syringe manufacturers identifying syringes that can be used in
20 the drug infusion pump when said customized library is loaded into said infusion pump.

 17. The system of claim 1 further comprising a list of syringe sizes, means for one or more syringe sizes from said list of syringe size and means for adding
25 said selected syringe sizes to said customized library, said selected syringe sizes identifying syringes that can be used in the drug infusion pump when said customized library is loaded into said infusion pump.

 18. The system of claim 1 further comprising
30 means for representing a set of features within the customized library, each of which can be toggled on or

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features includes a drug library enable flag, wherein the
5 drug library enable flag either enables or disables,
depending upon the condition of the drug library enable
flag, access to the drug entries within the customized
library when the customized library is loaded into said
drug infusion pump.

10 20. The system of claim 18 wherein said set of
features includes a syringe recognition flag, wherein the
syringe recognition flag either enables or disables,
depending upon the condition of the syringe recognition
flag, a syringe recognition capability within said drug
15 infusion pump when the customized library is loaded into
said drug infusion pump.

21. The system of claim 18 wherein said set of
features includes a syringe detection flag, wherein the
syringe detection flag either enables or disables,
20 depending upon the condition of the syringe detection
flag, a syringe detection capability within said drug
infusion pump when the customized library is loaded into
said drug infusion pump.

22. The system of claim 18 wherein said set of
25 features includes a volume limit detection flag, wherein
the volume limit flag either enables or disables,
depending upon the condition of the volume limit flag, a
function within the pump that enables the user to specify
a volume limit for a drug delivery configuration when the
30 customized library is loaded into said drug infusion
pump.

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24. The system of claim 1 wherein said means for
5 selecting is normally disabled and said system further
comprises password protection logic that serves to enable
said selection means but only if a system user supplies a
preselected password to said password protection logic.

25. The system of claim 24 wherein there are
10 defined a plurality of access levels, each of said access
levels corresponding to a different set of access
privileges for said system and wherein said system
further comprises a table associating each of a plurality
of users with a corresponding one of said plurality of
15 access levels and wherein said password protection logic
uses said table to assign access privileges to the system
user.

26. The system of claim 1 further comprising an
access control means for controlling access to said
20 loading means, wherein said access control means permits
access to said loading means if a system user satisfies a
set of preconditions and denies access to said loading
means if the system user fails to satisfy the set of
preconditions.

25 27. The system of claim 26 wherein said access
control means comprises a sign-off table for recording a
sign-off and wherein said access control means permits
access to said loading means if a valid approval sign-off
exists in said sign-off table and denies access to said
30 loading means if a valid approval sign-off does not exist
in said sign-off table.

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5 a last modification of said customized file by said
system user occurred and wherein said access control
means permits access to said loading means if said
approval date and time is later than said system user
date and time and denies access to said loading means if
10 said approval date and time is later than said system
user date and time.

29. A system for use with a computer, said system
comprising:

a storage medium containing a drug library, said
15 drug library containing a plurality of drug entries,
there being associated with each drug entry a set of
associated drug delivery information for configuring a
programmable drug infusion pump, said storage medium
being readable by the computer,

20 a program that runs on said computer, said program
comprising:

means for enabling a user of said computer to
select a set of drug entries from among said plurality of
drugs entries in said drug library;

25 means for enabling the user to add the selected
drug entries along with the sets of drug delivery
information associated therewith to a customized library;
and

means for enabling the user to cause said computer
30 to electronically load the customized library into the
drug infusion pump.

30. The system of claim 29 further comprising
means for enabling the user to create a drug

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means for enabling the user to edit an existing drug
5 configuration in the customized library.

32. The system of claim 29 further comprising a
graphical tool that generates a graph for display on a
computer screen, said graph enabling the user to select
an appropriate drug concentration for a given body
10 weight.

33. A drug infusion pump for use with a container
containing a particular drug, said pump comprising:
a drive mechanism for causing the particular drug
to be delivered to a patient from the container;
15 a programmable controller controlling the drive
mechanism;
an electronically loadable memory inside the pump;
input circuitry through which the electronically
loadable memory can be electronically loaded with a drug
20 library, said drug library containing a plurality of drug
entries, there being associated with each drug entry a
set of associated drug delivery parameters and/or drug
delivery protocols for configuring the drug infusion
pump;
25 a user interface enabling a user to program the
programmable controller, said user interface comprising:
means for enabling the user to select a drug entry
from the electronically loaded drug library; and
means for configuring the programmable controller
30 with the set of drug delivery parameters associated with
the selected drug.

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35. The drug infusion pump of claim 33 wherein
5 said electronically loadable memory is non-volatile
memory.

36. The drug infusion pump of claim 35 wherein
said electronically loadable memory is EEPROM.

37. The drug infusion pump of claim 33 wherein
10 said user interface comprises a control panel through
which the user can program the programmable controller
and a display screen for displaying drug entries from the
drug library.

38. The drug infusion pump of claim 33 wherein
15 each of the associated sets of drug delivery parameters
includes information selected from a group of parameters
including drug concentration, drug delivery rate, drug
dose, and bolus size.

39. The drug infusion pump of claim 38 wherein
20 the said group of parameters includes minimum, default
and maximum drug delivery rate.

40. The drug infusion pump of claim 38 wherein
the said group of parameters includes minimum, default
and maximum dose.

25 41. The drug infusion pump of claim 38 wherein
the said group of parameters includes minimum, default
and maximum bolus size.

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said electronically loaded drug library contains a list
5 of available mode options, said mode options specifying
the units available for expressing drug delivery
information, and wherein said drug infusion pump offers
the user the list of available mode options from which to
make a selection when the electronically loaded drug
10 library is in said pump.

44. The drug infusion pump of claim 43 wherein
said list of available mode options includes selection
made from the group including milliliter/hour,
units/hour, micrograms/minute, and
15 micrograms/kilogram/minute.

45. The drug infusion pump of claim 33 wherein
said electronically loaded drug library contains a list
of names of syringe manufacturers, said names of syringe
manufacturers identifying syringes that can be used in
20 the drug infusion pump, and wherein said drug infusion
pump offers the user the list of names of syringe
manufacturers from which to make a selection when the
electronically loaded drug library is in said pump.

46. The drug infusion pump of claim 33 wherein
25 said electronically loaded drug library contains a list
of syringe sizes, said selected syringe sizes identifying
syringes that can be used in the drug infusion pump, and
wherein said drug infusion pump offers the user the list
of syringe sizes from which to make a selection when the
30 electronically loaded drug library is in said pump.

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5 the features from among the set of features that are
toggled on when the electronically loaded drug library is
in said pump.

48. The drug infusion pump of claim 47 wherein
said set of features includes a drug library enable flag,
10 wherein the drug library enable flag either enables or
disables, depending upon the condition of the drug
library enable flag, access to the drug entries within
the drug library in said drug infusion pump.

49. The drug infusion pump of claim 47 wherein
15 said set of features includes a syringe recognition flag,
wherein the syringe recognition flag either enables or
disables, depending upon the condition of the syringe
recognition flag, a syringe recognition capability within
said drug infusion pump when the drug library is in said
20 drug infusion pump.

50. The drug infusion pump of claim 47 wherein
said set of features includes a syringe detection flag,
wherein the syringe detection flag either enables or
disables, depending upon the condition of the syringe
25 detection flag, a syringe detection capability within
said drug infusion pump when the drug library is in said
drug infusion pump.

51. The drug infusion pump of claim 47 wherein
said set of features includes a volume limit detection
30 flag, wherein the volume limit flag either enables or
disables, depending upon the condition of the volume

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5 52. A drug infusion pump for use with a container
containing a given drug, said container including a
machine readable label, the label specifying an
identifier of the given drug and possibly other
information about the given drug, said pump comprising:
10 a drive mechanism for causing the given drug to be
delivered to a patient from the container;
 a programmable controller controlling the drive
mechanism;
 a memory for storing a drug library, said drug
15 library containing a plurality of drug entries, there
being associated with each drug entry a set of associated
drug delivery parameters for configuring the drug
infusion pump;
 a label reader for reading the contents of the
20 label on the container;
 means responsive to the label reader for
identifying an entry in the drug library that corresponds
to the given drug;
 means for configuring the programmable controller
25 by using the set of drug delivery parameters associated
with the identified entry from the drug library; and
 means for causing the controller to run the drive
mechanism using the set of drug delivery parameters
associated with the identified entry from the drug
30 library.

53. The drug infusion pump of claim 52 wherein
said container is a syringe and said drive mechanism
operates said syringe.

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said configuring means also uses information from said
5 label to configure the programmable controller.

56. The drug infusion pump of claim 52 wherein
the label includes an expiration date for the given drug
and wherein said pump further comprises:

- an internal clock indicating a current date;
- 10 means for comparing the expiration date as read by
the label reader to the current date as indicated by the
internal clock; and
- means for issuing a warning if the current date is
later than the expiration date.

- 15 57. The drug infusion pump of claim 56 further
comprising means for preventing the controller from
running the drive mechanism if the current date is later
than the expiration date.

58. A drug infusion pump for use with a container
20 containing a given drug, said pump comprising:

- a drive mechanism for causing the given drug to be
delivered to a patient from the container;
- a programmable controller controlling the drive
mechanism;
- 25 a memory containing an event log;
- means for configuring the programmable controller
to deliver the given drug in accordance with a set of
drug delivery parameters;
- a user interface for operating the pump;
- 30 and

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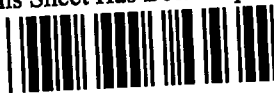
59. The drug infusion pump of claim 58 wherein
5 the events that are recorded in said event log include
occurrences of alarms, said alarms warning of a problem
requiring user attention.

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system including a drug library containing a plurality of drug entries, there being associated with each drug entry a set of associated drug delivery parameters and/or drug delivery protocols for configuring the drug infusion
10 pump; a tool for selecting a set of drug entries from among the plurality of drug entries in said drug library; a tool for adding the selected drug entries along with the sets of drug delivery information associated therewith to a customized library; and a loading tool for
15 causing the system to electronically load the customized library into the drug infusion pump.

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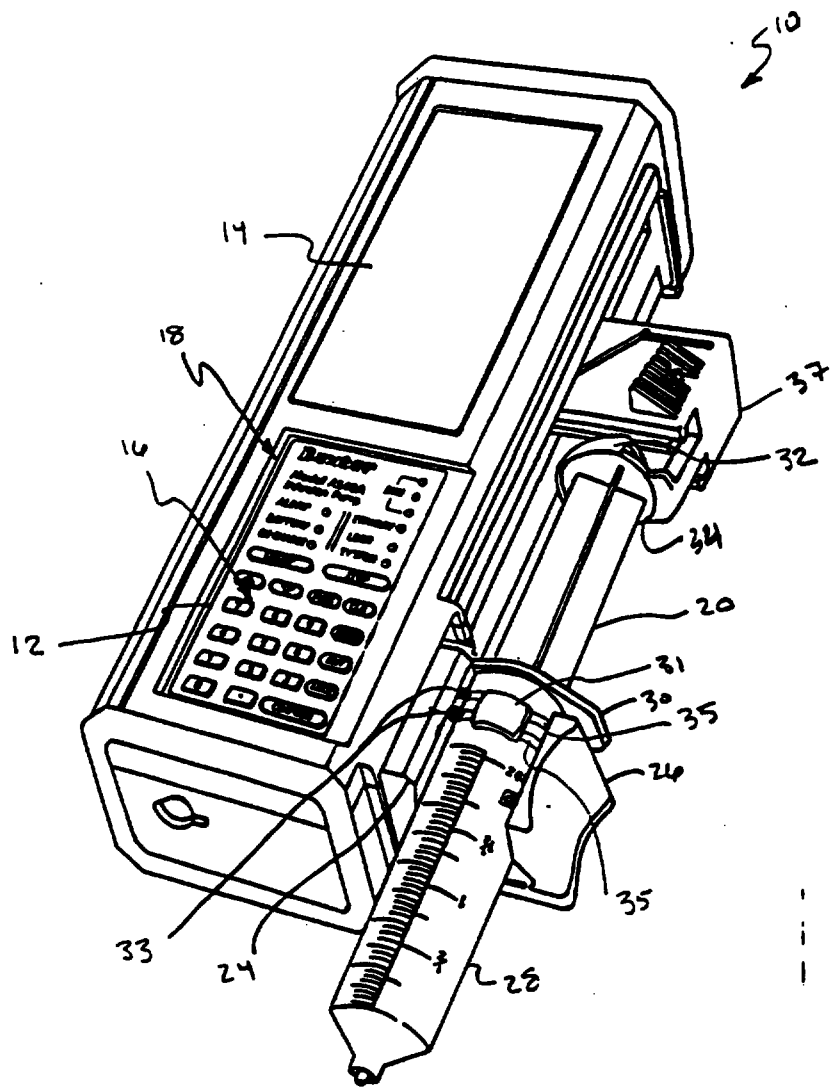
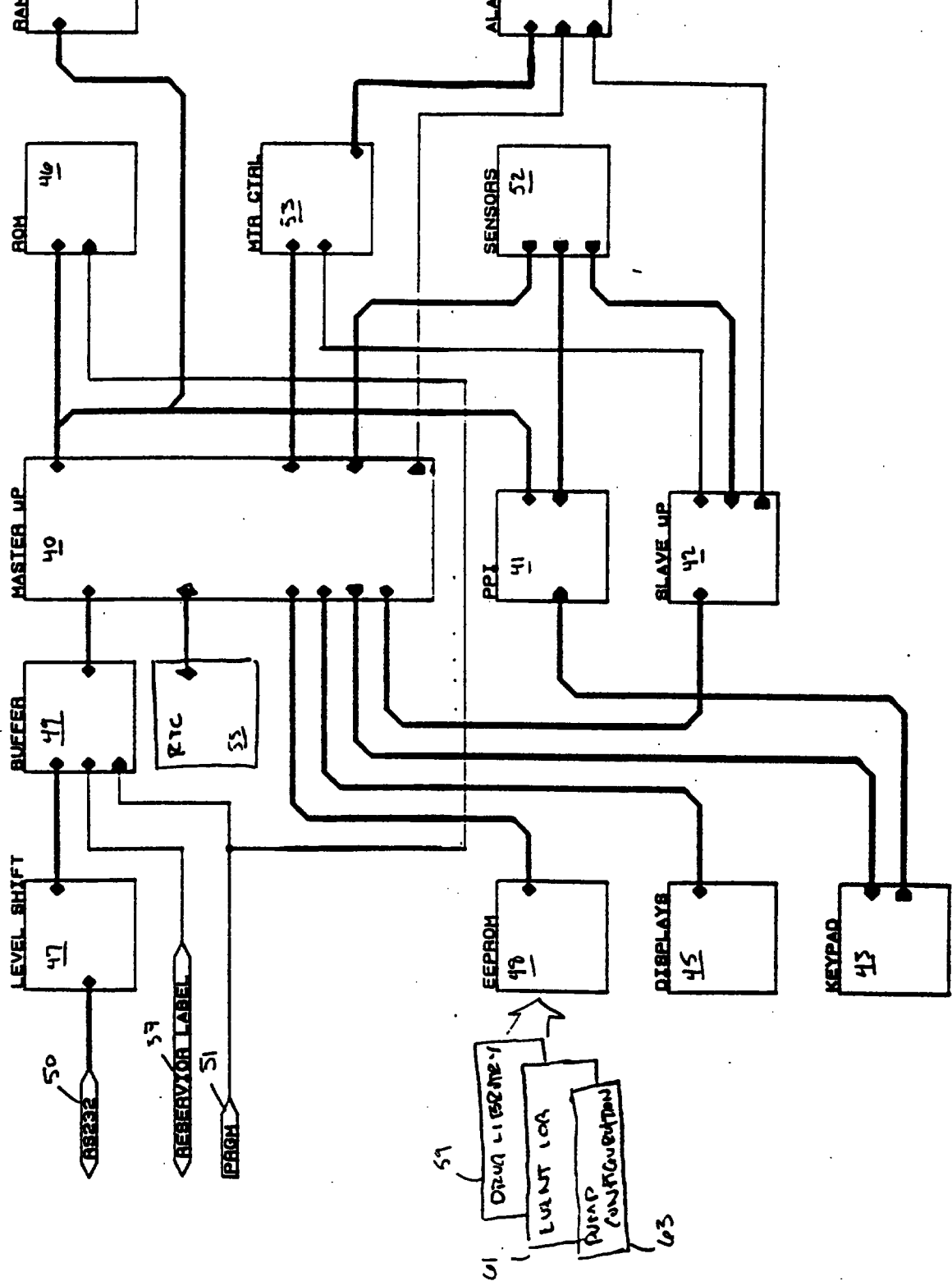


FIG 1

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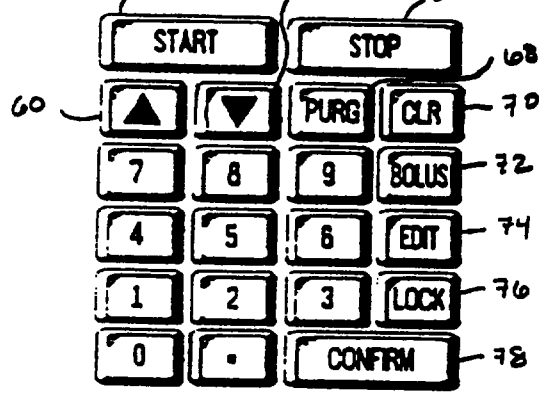


FIG. 3

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FIELD 1	SYRINGE mfr/size	☒ / 18.8
FIELD 2	INFUSE RATE	8.8.8 mL/hr
FIELD 3	OVER BODY WT	8.8:8.8 kg hr/min
FIELD 4	EVERY CONC.	8.8:8.8 Units mg/mL hr/min
FIELD 5	NEXT DOSE IN	8.8:8.8 mg/L/hr mcg/kg hr/min
FIELD 6	TOTAL VOL LIMIT	8.8.8 mgrams mL mcg
FIELD 7	TOTAL	8.8.8 mL
FIELD 8	☒ ☒ ☒ ☒ ☒ ☒ ☒ ☒	

FIG. 4

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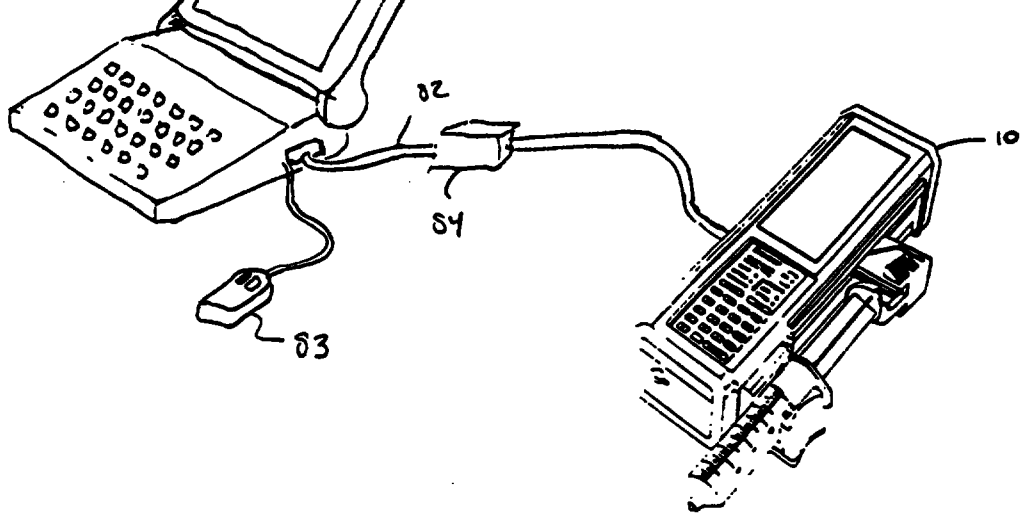


Fig. 5

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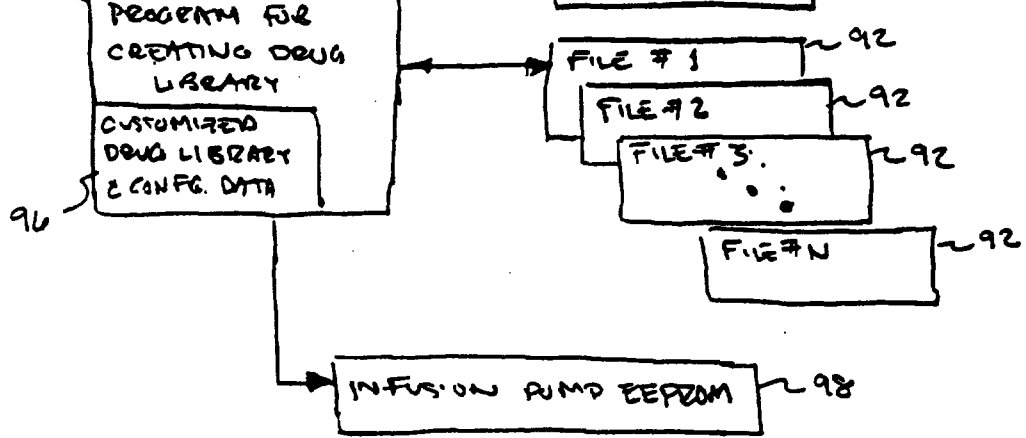


FIG. 6

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CONFIGURE MPRS
CONFIGURE SYRINGES
CONFIGURE DEFAULTS
CONFIGURE MISC
CONFIGURE IDENT
READ FROM FILE
WRITE TO FILE
WRITE TO FILE WITH APPROVAL
GET FROM PUMP
LOAD PUMP
VIEW/PRINT DRUG LIBRARY/CONFIGURATION
VIEW/PRINT ACTIVITY LOG
LOCK
GRAPHICAL TOOL
EXIT

△	= Previous choice
▽	= Next choice
ENTER	= Select

FIG. 7

1 of 39		DRUG LIST		
DRUG NAME & CONCENTRATION	T Y P E	min def max DOSE	min def max BOLUS	MAX. BOLUS RATE & CONFIG ON IN PUMP
* alfentan .25 ug/ml	S	.5 ug/kg/min 1.5 3	25 ug/kg 75 175	50 ug/kg/min Config: Y

F1 = Help F2 = Edit a custom drug F3 = Create a custom drug F4 = Delete a custom drug F7 = Toggle config. F9 = Graphical Tool * = Indicates Drug selected	(SPACEBAR) = Select/deselect drug ENTER = Save and return to main menu HOME = First drug END = Last drug △ = Previous drug ▽ = Next drug
---	---

Lower case drug name indicates pediatric drug

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FIG. 8

CONCENTRATION	E	min	max	min	max	CONFIG ON IN PUMP
* _____	C	_____ mcg/kg/min	_____	_____ mcg/kg	_____	_____ mcg/kg/min
_____ mg/ml		_____		_____		Config: Y

F1 = Help F5 = Toggle drug mode F6 = Toggle pediatric/adult ESC = Cancel changes F9 = Graphical Tool * = Indicates drug selected	TAB = Next field LEFT ARROW = Previous character RIGHT ARROW = Next character DEL = Delete character ENTER = Save and return to drug list
--	--

Fig. 9

CREATE/EDIT A CUSTOM DRUG						
DRUG NAME & CONCENTRATION	T Y P E -	min def max	DOSE	min def max	BOLUS	MAX. BOLUS RATE & CONFIG ON IN PUMP
* NEW DRUG	C	100	mcg/kg/min	1	mcg/kg	400 mcg/kg/min
25 mg/ml		200		2		
		300		3		Config: Y

F1 = Help F5 = Toggle drug mode F6 = Toggle pediatric/adult ESC = Cancel changes * = Indicates drug selected	TAB = Next field LEFT ARROW = Previous character RIGHT ARROW = Next character DEL = Delete character ENTER = Save and return to drug list
---	--

FIG. 10

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LEFT ARROW = Previous character
 RIGHT ARROW = Next character
 DEL = Delete character
 ESC = Cancel and return to main menu

FIG. 11

MODE MENU	
ML/HR	Y
UNITS/HR	Y
SINGLE DOSE	Y
MANUAL SCHEDULE	Y
AUTO SCHEDULE	Y
MCG/MIN	Y
MCG/KG/MIN	Y
Δ = Previous mode ▽ = Next mode (SPACEBAR) = Change configuration ENTER = Save and return to main menu	

FIG. 12

MANUFACTURERS	
B-D	Y
MONOJECT	Y
TERUMO	Y
Δ = Previous manufacturer ▽ = Next manufacturer (SPACEBAR) = Change configuration ENTER = Save and return to main menu	

FIG. 14

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ML/HR

FIG. 13a

UNITS/HR

FIG. 13b

SINGLE
DOSE

FIG. 13c

INFUSE _____ mL
OVER _____ hr:min
EVERY _____ hr:min

MANUAL
SCHEDULE

FIG 13d

INFUSE _____ mL
OVER _____ hr:min
EVERY _____ hr:min

AUTO
SCHEDULE

FIG 13e

CONC. _____ mg/mL
DOSE _____ $\frac{\text{mg}}{\text{min}}$

MCg/MIN

FIG 13f

BODY
WT _____ kg
CONC. _____ mg/mL
DOSE _____ $\frac{\text{mg/kg}}{\text{min}}$

MCg/KG
/MIN

FIG. 13g

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B-D 10ML Y
B-D 20ML Y
B-D 30ML Y
B-D 60ML Y

MONOJECT 10ML Y
MONOJECT 20ML Y
MONOJECT 35ML Y
MONOJECT 60ML Y

TERUMO 10ML Y
TERUMO 20ML Y
TERUMO 30ML Y
TERUMO 60ML Y

▽ = Previous syr

△ = Next syr

(SPACEBAR) = Change configuration

ENTER = Save and return to main menu

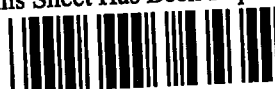
FIG. 15

DEFAULTS MENU	
DRUG DEFAULT	Y
MODE DEFAULT	Y
MFR DEFAULT	Y
SYRINGE DEFAULT	Y

▽ = Previous default
△ = Next default
(SPACEBAR) = Change configuration
ENTER = Save and return to main menu

FIG. 14

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SYRINGE DETECTION	Y
PSI RANGE	M
RATE RANGE	H
AUTO LOCK	N
VOLUME LIMIT	Y
SILENT RUNNING	N
IDLE ALARM	N

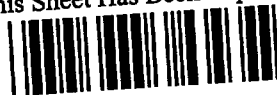
▽ = Previous feature
 △ = Next feature
 (SPACEBAR) = Change configuration
 ENTER = Save and return to main menu

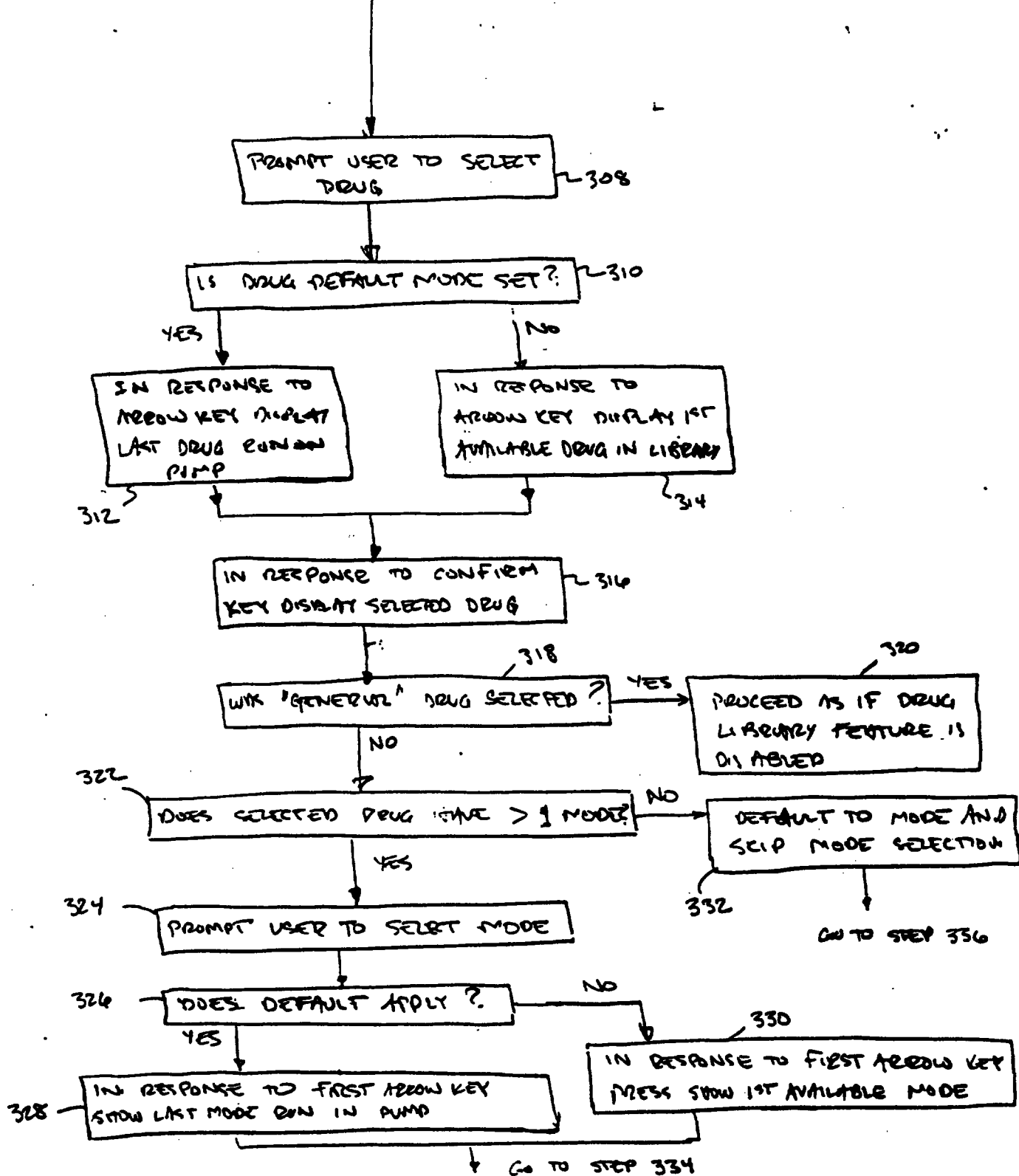
FIG. 19

CREATE/EDIT PUMP IDENTIFIER
Type in Identifier and press ENTER (Legal char's: A-Z, 0-9, dash & space) ESC = Cancel changes DEL = Delete character LEFT ARROW = Previous character RIGHT ARROW = Next character

FIG. 18

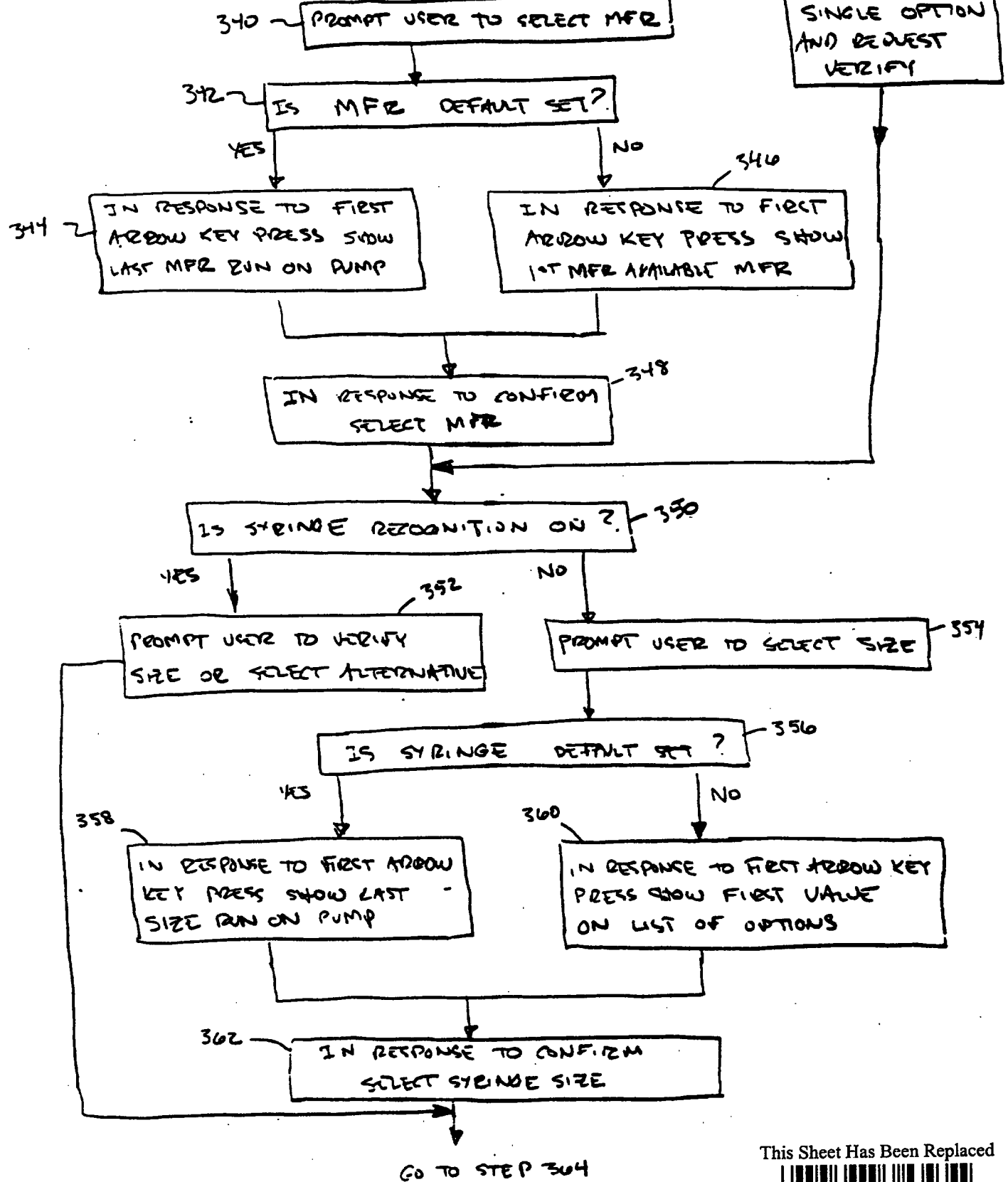
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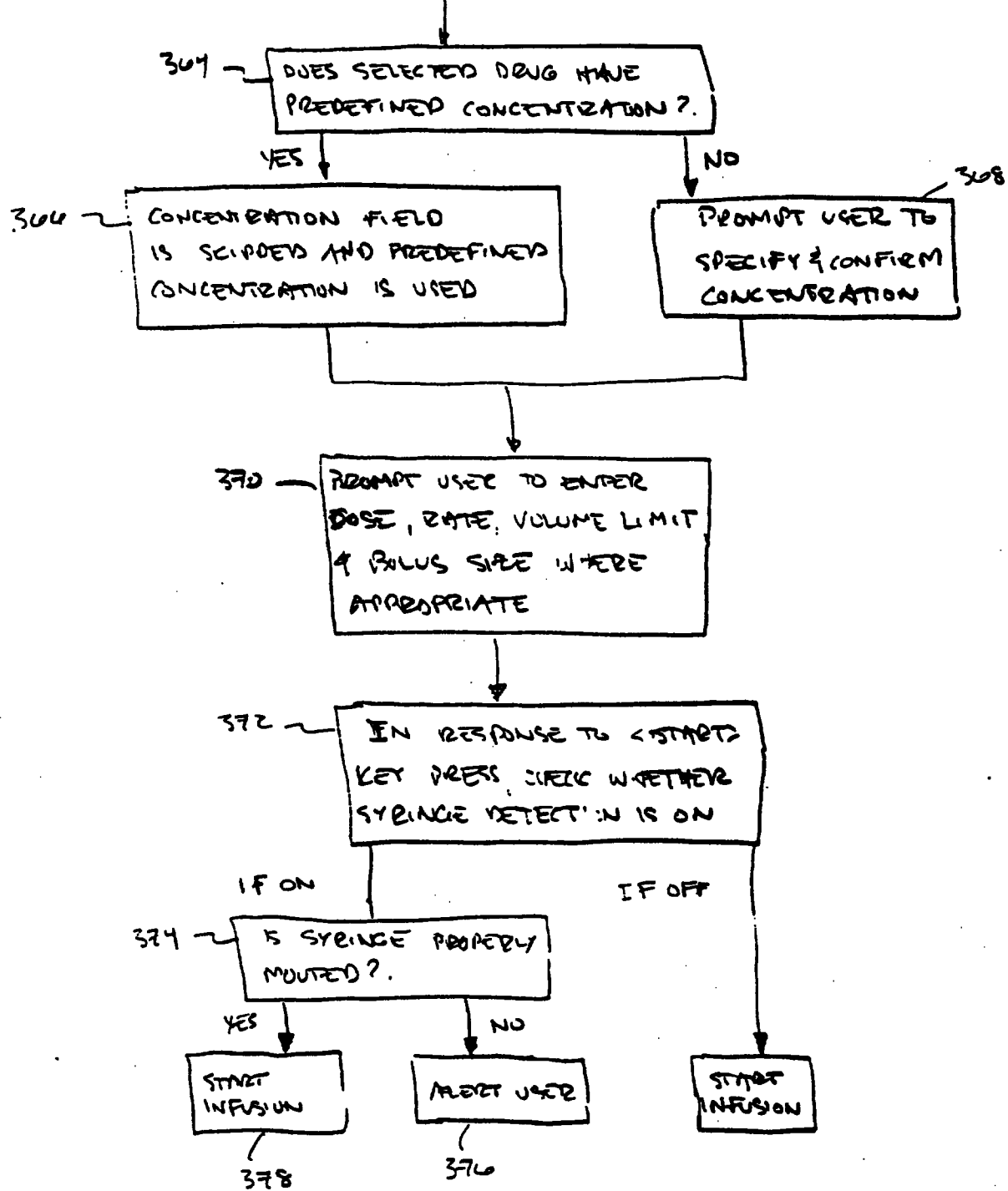
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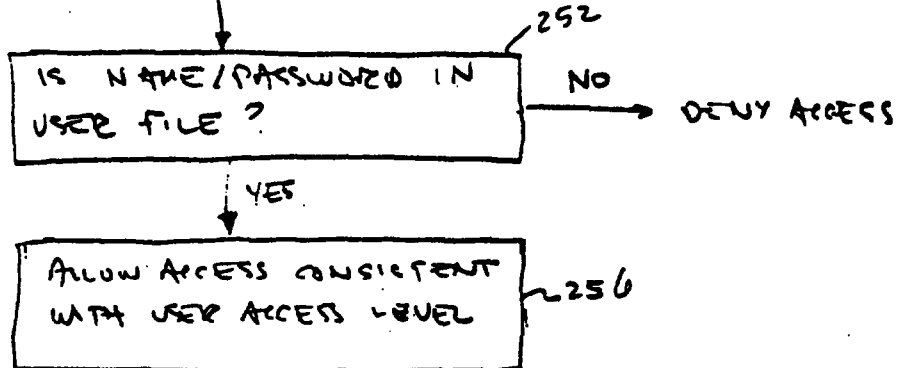


FIG. 21

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204 ~	USER NAME # 2	DATE # 2	TIME # 2
206 ~	USER NAME # 3	DATE # 3	TIME # 3

FIG. 22

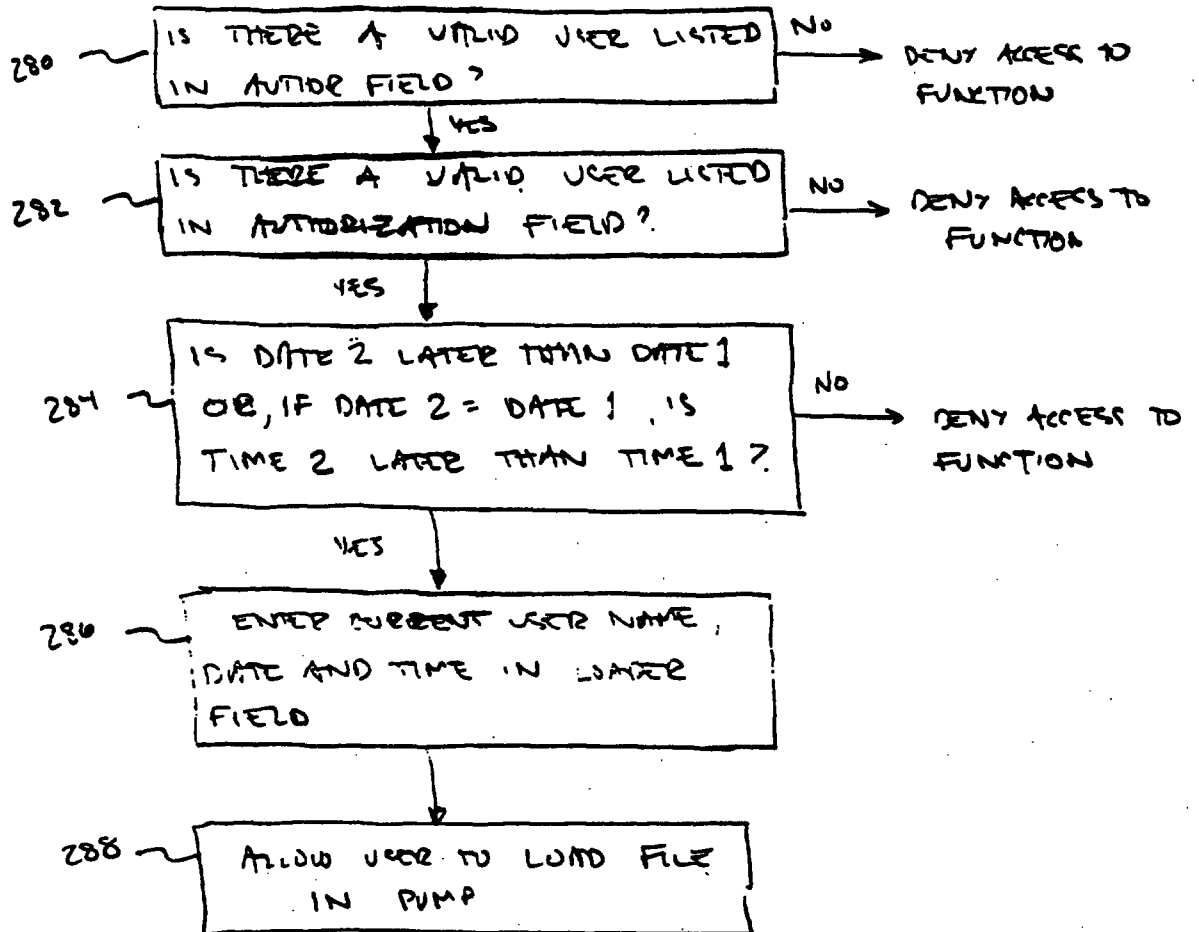
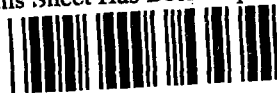


FIG. 23

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	Syringe size, Syringe Size	Syringe size, Syringe Size	Syringe size, Syringe Size	Syringe size, Syringe Size
202				Enter the patient's body weight in kilograms (kg)
204		Enter the drug concentration in Units per milliliter (U/mL)	Enter the drug concentration in milligrams per milliliter (mg/mL)	Enter the drug concentration in milligrams per milliliter (mg/mL)
206	Enter the infusion RATE in milliliters per hour (mL/hr)	Enter the infusion DOSE in Units per hour (U/hr)	Enter the DOSE in micrograms per minute (mcg/min)	Enter the DOSE in micrograms per kilogram per minute (mcg/kg/min)
208	Enter the Volume Limit (mL)			
210	Enter the bolus size in milliliters (mL)	Enter the bolus size in Units	Enter the bolus size in milligrams (mg)	Enter the bolus size in micrograms per kilogram of body weight (mcg/kg)
212	PURGE system	PURGE system	PURGE system	PURGE system
214	Press <START>	Press <START>	Press <START>	Press <START>

FIG 24

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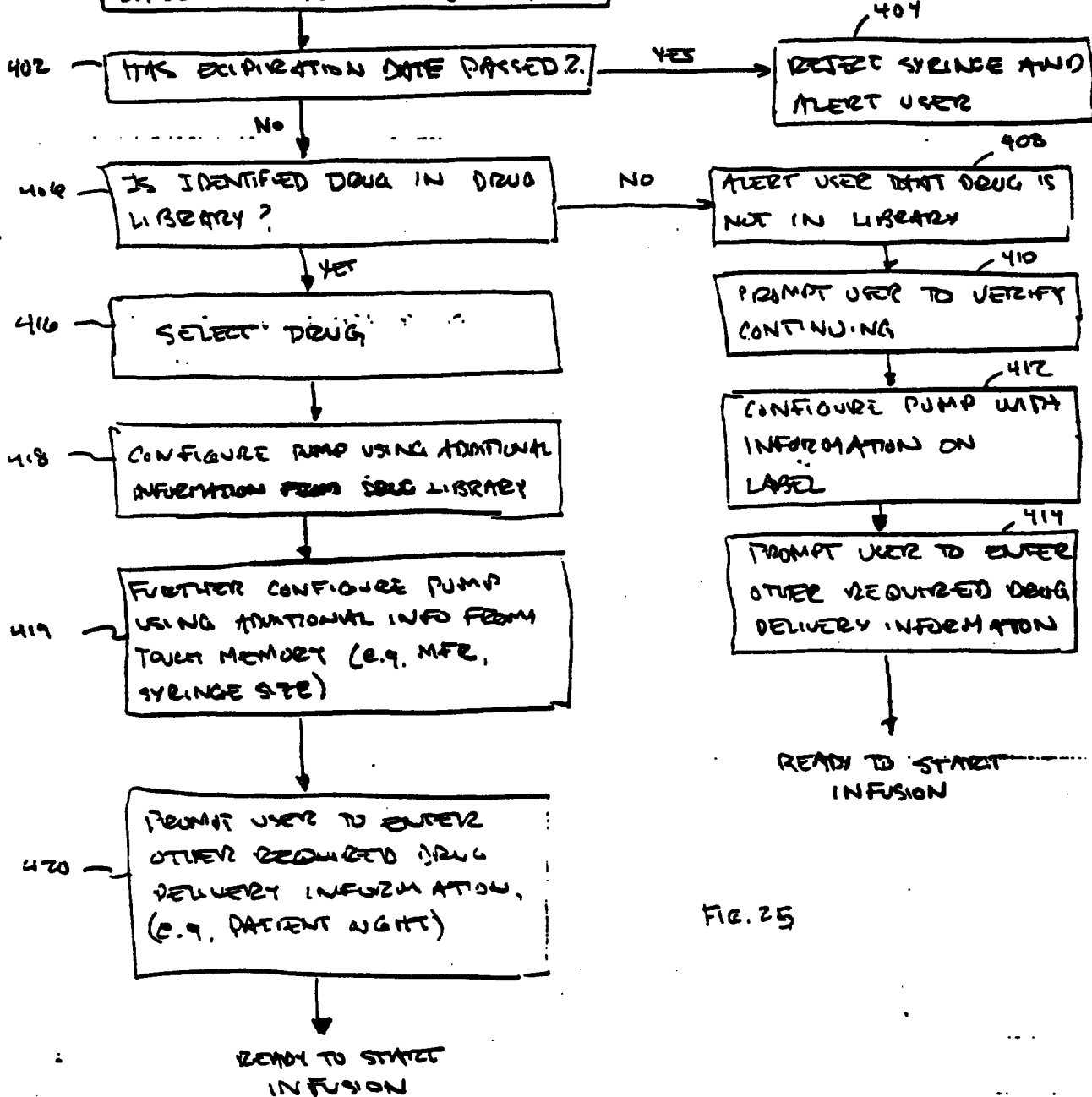


FIG. 25

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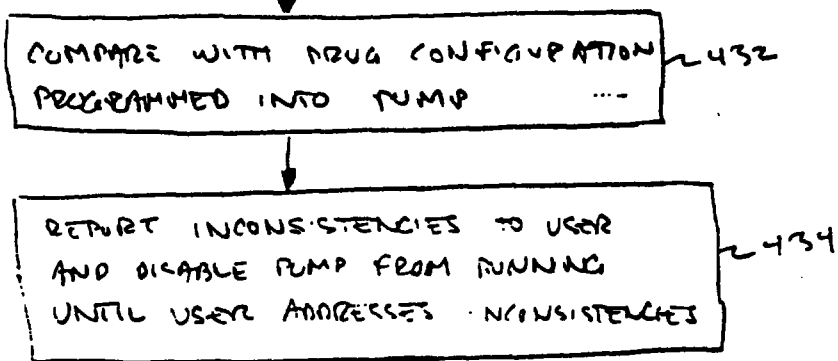


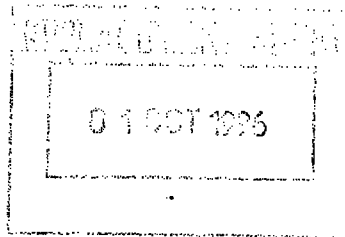
FIG 26

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drug entries, there being associated with each drug entry a set of associated drug delivery parameters and/or drug delivery protocols for configuring the drug infusion pump; a tool for selecting a set of drug entries from among the plurality of drug entries in said drug library; a tool for adding the selected drug entries along with the sets of drug delivery information associated therewith to a customized library; and a loading tool for causing the system to electronically load the customized library into the drug infusion pump.

Fig. 5



electronically loadable drug infusion pump, said system comprising: .

- 5 a drug library containing a plurality of drug entries, there being associated with each drug entry a set of associated drug delivery parameters and/or drug delivery protocols for configuring the drug infusion pump;

means for selecting a set of drug entries from among said
10 plurality of drug entries in said drug library;

means for adding the selected drug entries along with the sets of drug delivery information associated therewith to a customized library; and

loading means for causing the system to electronically
15 load said customized library into the drug infusion pump.

2. The system of claim 1 wherein each of the associated sets of drug delivery parameters includes information selected from a group of parameters including drug concentration, drug delivery rate, drug dose, and bolus size.

20 3. The system of claim 1 further comprising means for creating a drug configuration within the customized library that does not exist in the drug library, and/or comprising means for editing an existing drug configuration in the customized library.

25 4. The system of claim 1 further comprising a graphical tool that generates a graph for display on a computer screen, said graph enabling the user to select an appropriate drug concentration for a given body weight.



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$$\text{Body Weight} = \text{Rate} \times \frac{\text{Concentration}}{\text{Dose}} \times K,$$

wherein K is a positive number, and/or the system further comprising means for moving said one or more curves about on
10 said graph.

6. The system of claim 1 further comprising a list of available mode options, means for identifying one or more modes from said list of available mode options and means for adding said identified modes to said customized library, said modes
15 specifying the units available for expressing the drug delivery information and said identified modes being the modes that will be available in the infusion pump when said customized library is loaded into said infusion pump.

7. The system of claim 1 further comprising a list of names
20 of syringe manufacturers, means for selecting names of syringe manufacturers from said list of names of syringe manufacturers and means for adding said selected names of syringe manufacturers to said customized library, said selected names of syringe manufacturers identifying syringes that can be
25 used in the drug infusion pump when said customized library is loaded into said infusion pump, and/or wherein the system further comprises a list of syringe sizes, means for one or more syringe sizes from said list of syringe size and means for adding said selected syringe sizes to said customized
30 library, said selected syringe sizes identifying syringes that can be used in the drug infusion pump when said customized library is loaded into said infusion pump.

8. The system of claim 1 further comprising means for representing a set of features within the customized library, each



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enable flag either enables or disables, depending upon the
5 condition of the drug library enable flag, access to the drug
entries within the customized library when the customized
library is loaded into said drug infusion pump; and/or inclu-
ding a syringe recognition flag, wherein the syringe recogni-
tion flag either enables or disables, depending on the con-
10 dition of the syringe recognition flag, a syringe recognition
capability within said drug infusion pump when the customized
library is loaded into said drug infusion pump; and/or inclu-
ding a syringe detection flag, wherein the syringe detection
flag either enables or disables, depending on the condition
15 of the syringe detection flag, a syringe detection capability
within said drug infusion pump when the customized library is
loaded into said drug infusion pump.

9. The system of claim 1 further comprising means for causing
said system to read pump configuration information from the
20 drug infusion pump.

10. The system of claim 1 wherein said means for selecting is
normally disabled and said system further comprises password
protection logic that serves to enable said selection means
but only if a system user supplies a preselected password to
25 said password protection logic.

11. The system of claim 1 further comprising an access con-
trol means for controlling access to said loading means,
wherein said access control means permits access to said
loading means if a system user satisfies a set of precondi-
30 tions and denies access to said loading means if the system
user fails to satisfy the set of preconditions.

12. A system for use with a computer, said system comprising:



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5 infusion pump, said storage medium being readable by the computer,

a programme that runs on said computer, said programme comprising:

10 means for enabling a user of said computer to select a set of drug entries from among said plurality of drug entries in said drug library;

means for enabling the user to add the selected drug entries along with the sets of drug delivery information associated therewith to a customized library; and

15 means for enabling the user to cause said computer to electronically load the customized library into the drug infusion pump.

13. The system of claim 12 further comprising means for enabling the user to create a drug configuration within the
20 customized library that does not exist in the drug library, and/or comprising means for enabling the user to edit an existing drug configuration in the customized library.

14. A drug infusion pump for use with a container containing a particular drug, said pump comprising:

25 a drive mechanism for causing the particular drug to be delivered to a patient from the container;

a programmable controller controlling the drive mechanism;

an electronically loadable memory inside the pump;



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being associated with each drug entry, a list of associated
5 drug delivery parameters and/or drug delivery protocols for
configuring the drug infusion pump;

a user interface enabling a user to program the
programmable controller, said user interface comprising:

means for enabling a user to select a drug entry from the
10 electronically loaded drug library; and

means for configuring the programmable controller with
the set of drug delivery parameters associated with the
selected drug.

15 15. The drug infusion pump of claim 14 wherein said container
is a syringe, said drive mechanism operates said syringe,
and/or said electronically loadable memory is non-volatile
memory.

16. The drug infusion pump of claim 14 wherein each of the
associated sets of drug delivery parameters includes informa-
20 tion selected from a group of parameters including drug
concentration, drug delivery rate, drug dose, and bolus size.

17. The drug infusion pump of claim 14 wherein said electro-
nically loaded drug library contains a list of available mode
options, said mode options specifying the units available for
25 expressing drug delivery information, and wherein said drug
infusion pump offers the user the list of available mode
options from which to make a selection when the electronical-
ly loaded drug library is in said pump.

18. The drug infusion pump of claim 14 wherein said electro-
30 nically loaded drug library contains a list of names of
syringe manufacturers, said names of syringe manufacturers

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5 said pump, and/or wherein said electronically loaded drug
library contains a list of syringe sizes, said selected
syringe sizes identifying syringes that can be used in the
drug infusion pump, and wherein said drug infusion pump
offers the user the list of syringe sizes from which to make
10 a selection when the electronically loaded drug library is in
said pump.

19. A drug infusion pump for use with a container containing
a given drug, said container including a machine readable
label, the label specifying an identifier of the given drug
15 and possibly other information about the given drug, said
pump comprising:

a drive mechanism for causing the given drug to be
delivered to a patient from the container;

a programmable controller controlling the drive mecha-
20 nism;

a memory for storing a drug library, said drug library
containing a plurality of drug entries, there being associ-
ated with each drug entry a set of associated drug delivery
parameters for configuring the drug infusion pump;

25 a label reader for reading the contents of the label on
the container;

means responsive to the label reader for identifying an
entry in the drug library that corresponds to the given drug;

means for configuring the programmable controller by
30 using the set of drug delivery parameters associated with the
identified entry from the drug library; and



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20. The drug infusion pump of claim 19 wherein said container
5 is a syringe, said drive mechanism operates said syringe,
and/or said machine readable label is a touch memory, and/or
said configuring means also uses information from said label
to configure the programmable controller.

21. The drug infusion pump of claim 19 wherein the label
10 includes an expiration date for the given drug and wherein
said pump further comprises:

an internal clock indicating a current date;

means for comparing the expiration date as read by the
label reader to the current date as indicated by the internal
15 clock; and

means for issuing a warning if the current date is later
than the expiration date.

22. A drug infusion pump for use with a container containing
a given drug, said pump comprising:

20 a drive mechanism for causing the given drug to be deli-
vered to a patient from the container;

a programmable controller controlling the drive mecha-
nism;

a memory containing an event log;

25 means for configuring the programmable controller to
deliver the given drug in accordance with a set of drug
delivery parameters;



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the operation and/or programming of the pump.

- 5 23. The drug infusion pump of claim 22 wherein the events that are recorded in said event log include occurrences of alarms, said alarms warning of a problem requiring user attention.



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comprising: .

- 5 a drug library containing a plurality of drug entries,
there being associated with each drug entry a set of associa-
ted drug delivery parameters and/or drug delivery protocols
for configuring the drug infusion pump;

means for selecting a set of drug entries from among said
10 plurality of drug entries in said drug library;

means for adding the selected drug entries along with the
sets of drug delivery information associated therewith to a
customized library; and

loading means for causing the system to electronically
15 load said customized library into the drug infusion pump.

2. The system of claim 1 wherein each of the associated sets
of drug delivery parameters includes information selected
from a group of parameters including drug concentration, drug
delivery rate, drug dose, and bolus size.

20 3. The system of claim 1 further comprising means for creat-
ing a drug configuration within the customized library that
does not exist in the drug library, and comprising means
for editing an existing drug configuration in the customized
library.

25 4. The system of claim 1 further comprising a graphical tool
that generates a graph for display on a computer screen, said
graph enabling the user to select an appropriate drug concen-
tration for a given body weight.

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$$\text{Body Weight} = \text{Rate} \times \frac{\text{Concentration}}{\text{Dose}} \times K,$$

wherein K is a positive number, and the system further comprising means for moving said one or more curves about on
10 said graph.

6. The system of claim 1 further comprising a list of available mode options, means for identifying one or more modes from said list of available mode options and means for adding said identified modes to said customized library, said modes
15 specifying the units available for expressing the drug delivery information and said identified modes being the modes that will be available in the infusion pump when said customized library is loaded into said infusion pump.

7. The system of claim 1 further comprising a list of names
20 of syringe manufacturers, means for selecting names of syringe manufacturers from said list of names of syringe manufacturers and means for adding said selected names of syringe manufacturers to said customized library, said selected names of syringe manufacturers identifying syringes that can be
25 used in the drug infusion pump when said customized library is loaded into said infusion pump, and wherein the system further comprises a list of syringe sizes, means for one or more syringe sizes from said list of syringe size and means for adding said selected syringe sizes to said customized
30 library, said selected syringe sizes identifying syringes that can be used in the drug infusion pump when said customized library is loaded into said infusion pump.

8. The system of claim 1 further comprising means for representing a set of features within the customized library, each



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5 condition of the drug library enable flag, access to the drug
entries within the customized library when the customized
library is loaded into said drug infusion pump; and inclu-
ding a syringe recognition flag, wherein the syringe recogni-
tion flag either enables or disables, depending on the con-
10 dition of the syringe recognition flag, a syringe recognition
capability within said drug infusion pump when the customized
library is loaded into said drug infusion pump; and inclu-
ding a syringe detection flag, wherein the syringe detection
flag either enables or disables, depending on the condition
15 of the syringe detection flag, a syringe detection capability
within said drug infusion pump when the customized library is
loaded into said drug infusion pump.

9. The system of claim 1 further comprising means for causing
said system to read pump configuration information from the
20 drug infusion pump.

10. The system of claim 1 wherein said means for selecting is
normally disabled and said system further comprises password
protection logic that serves to enable said selection means
but only if a system user supplies a preselected password to
25 said password protection logic.

11. The system of claim 1 further comprising an access con-
trol means for controlling access to said loading means,
wherein said access control means permits access to said
loading means if a system user satisfies a set of precondi-
30 tions and denies access to said loading means if the system
user fails to satisfy the set of preconditions.

12. A system for use with a computer, said system comprising:



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delivery information for configuring a programmable drug infusion pump, said storage medium being readable by the computer,

a program that runs on said computer, said programme comprising:

means for enabling a user of said computer to select a set of drug entries from among said plurality of drug entries in said drug library;

means for enabling the user to add the selected drug entries along with the sets of drug delivery information associated therewith to a customized library; and

means for enabling the user to cause said computer to electronically load the customized library into the drug infusion pump.

13. The system of claim 12 further comprising means for enabling the user to create a drug configuration within the customized library that does not exist in the drug library, and comprising means for enabling the user to edit an existing drug configuration in the customized library.

14. A drug infusion pump for use with a container containing a particular drug, said pump comprising:

a drive mechanism which is operable to cause the particular drug to be delivered to a patient from the container;

a programmable controller controlling the drive mechanism, said programmable controller comprising:



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associated drug delivery parameters for configuring the drug infusion pump; and

an interface through which the drug library is loadable by the user into the electronically customizable memory, the interface including circuitry through which a drug entry is selectable by the user from the drug library and thereby the programmable controller is configurable with the set of drug delivery parameters associated with the selected drug.

15. The drug infusion pump of claim 14 wherein said container is a syringe, said drive mechanism operates said syringe, and said electronically loadable memory is non-volatile memory.

16. The drug infusion pump of claim 14 wherein each of the associated sets of drug delivery parameters includes information selected from a group of parameters including drug concentration, drug delivery rate, drug dose, and bolus size.

17. The drug infusion pump of claim 14 wherein said electronically loaded drug library contains a list of available mode options, said mode options specifying the units available for expressing drug delivery information, and wherein said drug infusion pump offers the user the list of available mode options from which to make a selection when the electronically loaded drug library is in said pump.

18. The drug infusion pump of claim 14 wherein said electronically loaded drug library contains a list of names of syringe manufacturers, said names of syringe manufacturers



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library contains a list of syringe sizes, said selected syringe sizes identifying syringes that can be used in the drug infusion pump, and wherein said drug infusion pump offers the user the list of syringe sizes from which to make
10 a selection when the electronically loaded drug library is in said pump.

19. A drug infusion pump for use with a container containing a given drug, said container including a machine readable label, the label specifying an identifier of the given drug
15 and possibly other information about the given drug, said pump comprising:

a drive mechanism for causing the given drug to be delivered to a patient from the container;

a programmable controller controlling the drive mechanism;
20

a memory for storing a drug library, said drug library containing a plurality of drug entries, there being associated with each drug entry a set of associated drug delivery parameters for configuring the drug infusion pump;

25 a label reader for reading the contents of the label on the container;

means responsive to the label reader for identifying an entry in the drug library that corresponds to the given drug;

means for configuring the programmable controller by
30 using the set of drug delivery parameters associated with the identified entry from the drug library; and



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nism using the set of drug delivery parameters associated with the identified entry from the drug library.

20. The drug infusion pump of claim 19 wherein said container
5 is a syringe, said drive mechanism operates said syringe,
and said machine readable label is a touch memory, and ~~for~~
said configuring means also uses information from said label
to configure the programmable controller.

21. The drug infusion pump of claim 19 wherein the label
10 includes an expiration date for the given drug and wherein
said pump further comprises:

an internal clock indicating a current date;

means for comparing the expiration date as read by the
label reader to the current date as indicated by the internal
15 clock; and

means for issuing a warning if the current date is later
than the expiration date.

20

25



This is the replacement sheet

Date: 16 DEC 1996

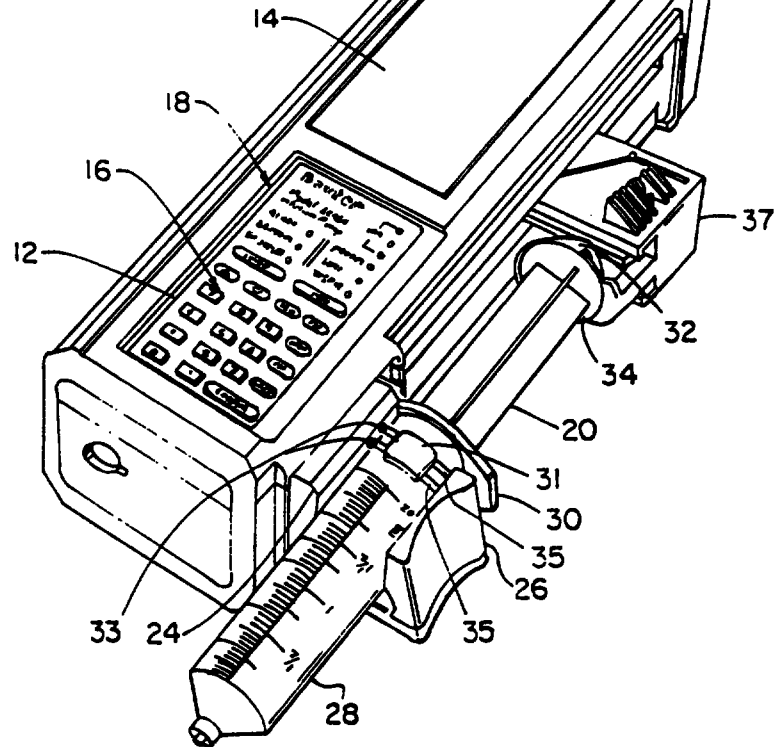


FIG 1

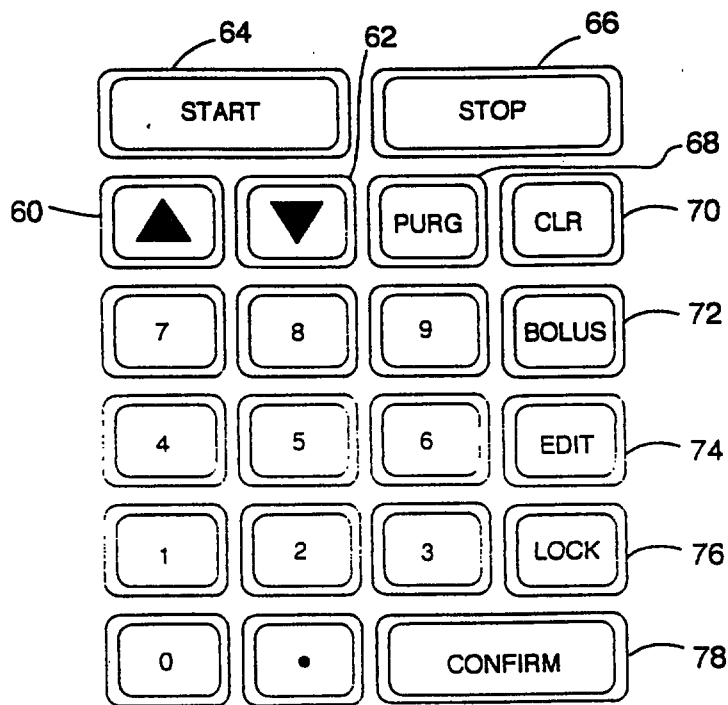


FIG 3

This is the replacement sheet

Date: 16 DEC 1998

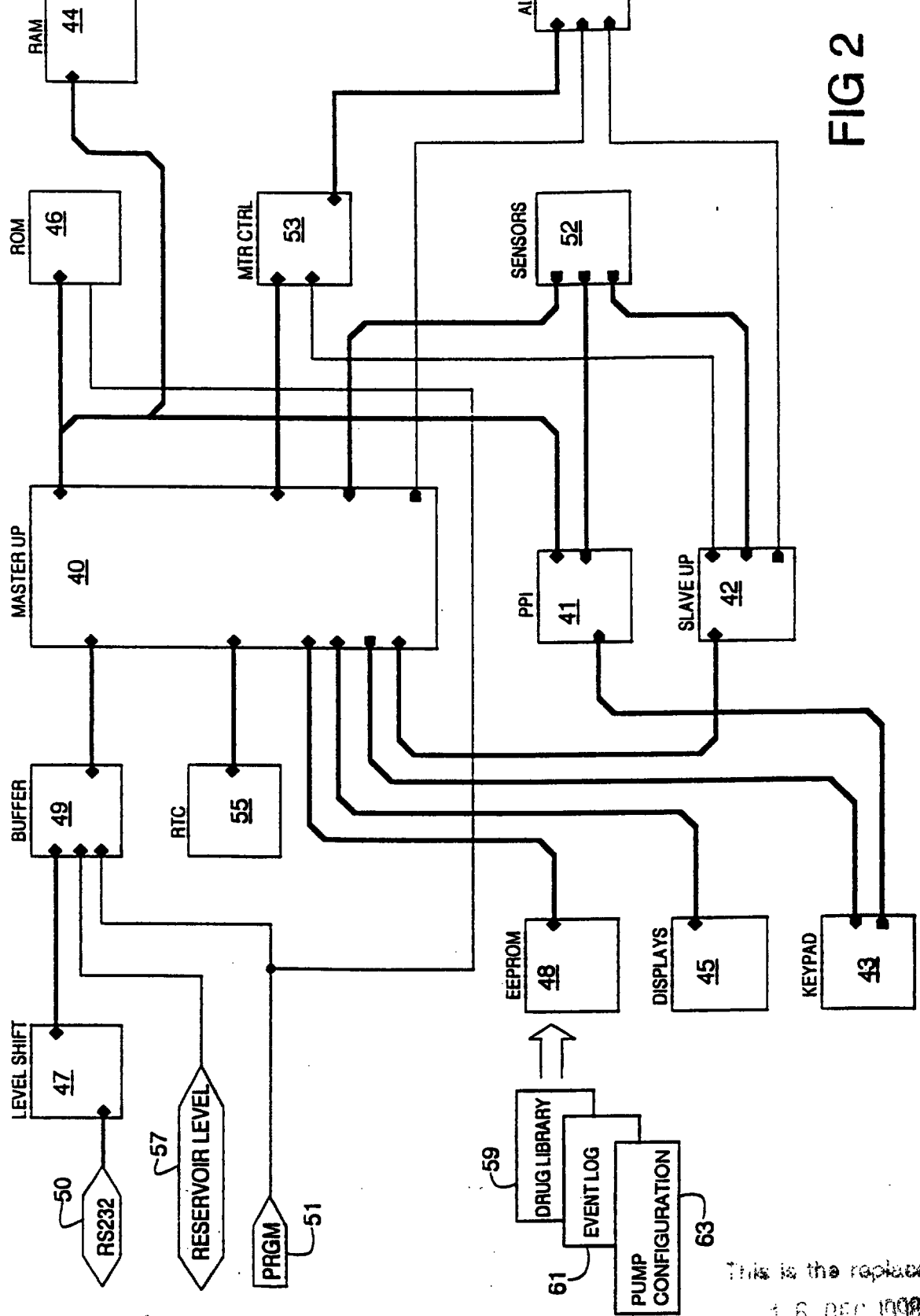


FIG 2

This is the replacement sheet
 Date: 16 DEC 1998

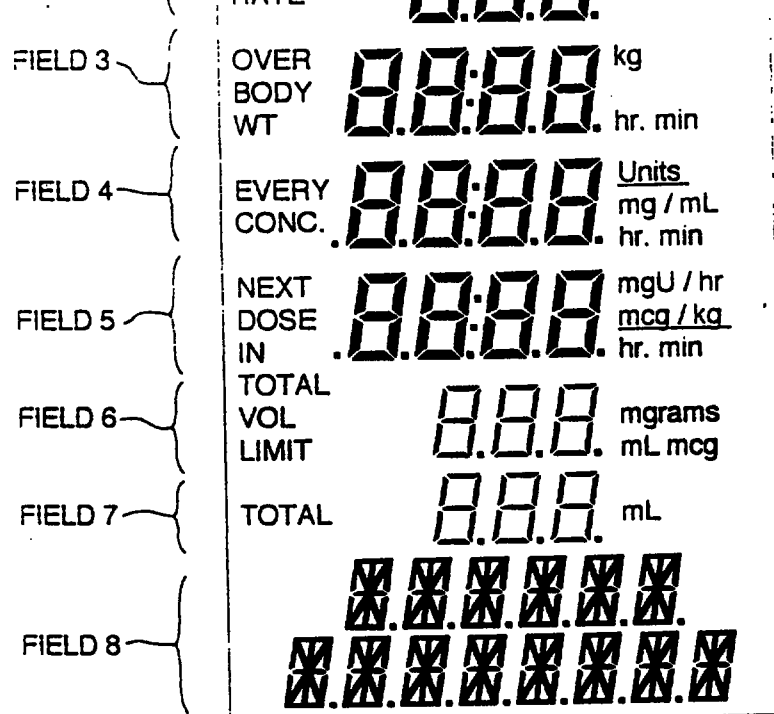


FIG 4

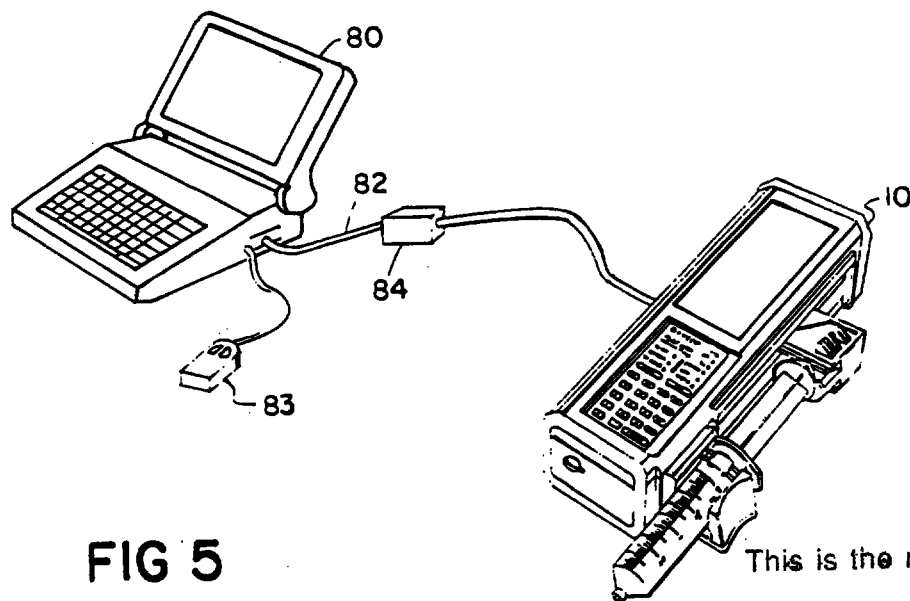


FIG 5

This is the replacement sheet

Date: 16 DEC 1998

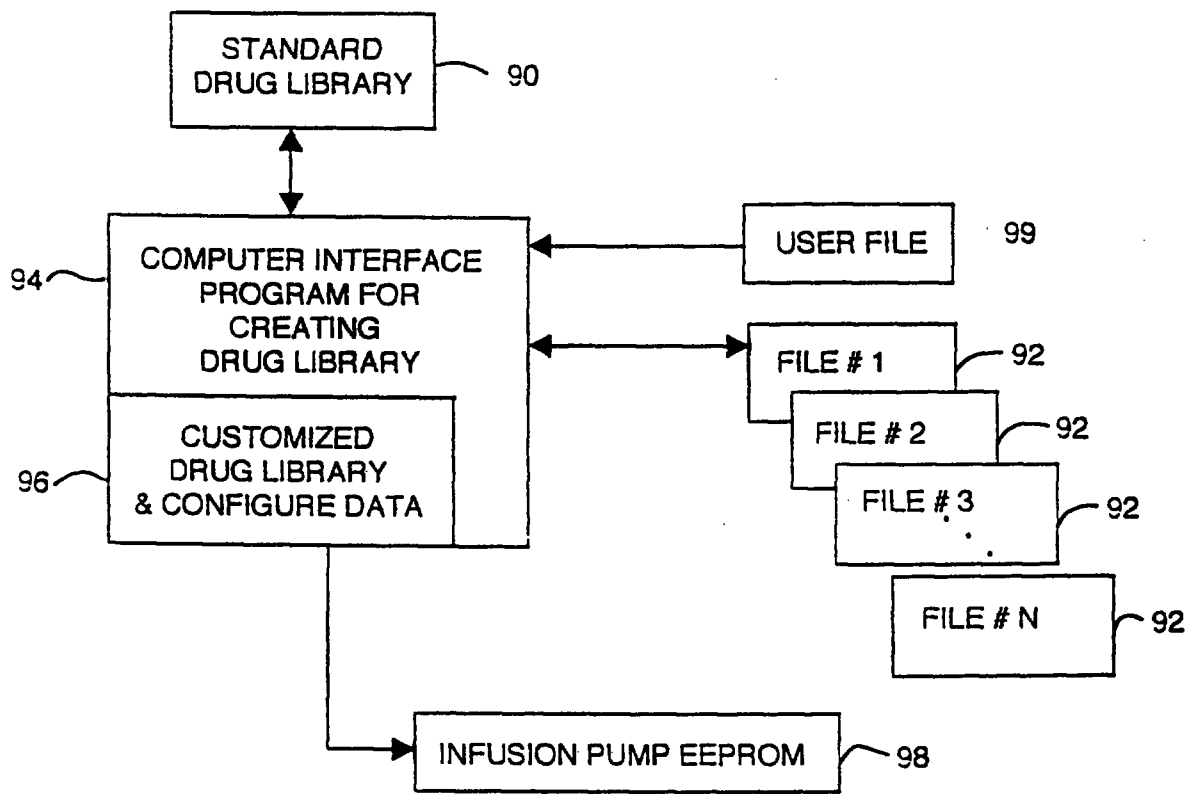


FIG 6

This is the replacement sheet

Date: 1 6 DEC 1998

DRUG LIBRARY
 CONFIGURE MODES 102
 CONFIGURE MFRS
 CONFIGURE SYRINGES
 CONFIGURE DEFAULTS
 CONFIGURE MISC
 CONFIGURE IDENT
 READ FROM FILE
 WRITE TO FILE
 WRITE TO FILE WITH APPROVAL
 GET FROM PUMP
 LOAD PUMP
 VIEW / PRINT DRUG LIBRARY / CONFIGURATION
 VIEW / PRINT ACTIVITY LOG
 LOCK
 GRAPHICAL TOOL
 EXIT

△ = Previous choice
 ▽ = Next choice
 ENTER = Select

FIG 7

1 of 39 110		112 114 DRUG LIST			116
DRUG NAME & CONCENTRATION	T Y P E	min def max DOSE	min def max BOLUS	MAX. BOLUS RATE & CONFIG. ON IN PUMP	
122 alfentan 25 mg / ml	S	.5 mcg / kg / min 1.5 3	25 mcg / kg 75 175	50 mcg / kg / min	118
				Config: Y	120

F1 = Help
 F2 = Edit a custom drug
 F3 = Create a custom drug
 F4 = Delete a custom drug
 F7 = Toggle configuration
 F9 = Graphical tool
 * = Indicates drug selected

(SPACEBAR) = Select / deselect drug
 ENTER = Save and return to main menu

 HOME = First drug
 END = Last drug
 △ = Previous drug
 ▽ = Next drug

LOWER CASE DRUG NAME INDICATES PEDIATRIC DRUG

FIG 8

This is the replacement sheet

16 DEC 1998

Date:

CREATE / EDIT A CUSTOM DRUG				
DRUG NAME & CONCENTRATION	T Y P E	min — def — DOSE max —	min — def — BOLUS max —	MAX. BOLUS RATE & CONFIG. ON IN PUMP
* ——— mg / m	C	——— mcg / kg / min	——— mcg / kg	——— mcg / kg / min
				Config: Y

F1 = Help
F5 = Toggle drug mode
F6 = Toggle pediatric / adult
ESC = Cancel changes
F9 = Graphical tool
* = Indicates drug selected

TAB = Next field

LEFT ARROW = Previous character
RIGHT ARROW = Next Character
DEL = Delete character

ENTER = Save and return to drug list

FIG 9

CREATE / EDIT A CUSTOM DRUG				
DRUG NAME & CONCENTRATION	T Y P E	min — def — DOSE max —	min — def — BOLUS max —	MAX. BOLUS RATE & CONFIG. ON IN PUMP
* NEW DRUG 25 mg / ml	C	100 mcg / kg / min 200 300	1 mcg / kg 2 3	400 mcg / kg / min
				Config: Y

F1 = Help
F5 = Toggle drug mode
F6 = Toggle pediatric / adult
ESC = Cancel changes
* = Indicates drug selected

TAB = Next field

LEFT ARROW = Previous character
RIGHT ARROW = Next Character
DEL = Delete character

ENTER = Save and return to drug list

FIG 10

This is the replacement sheet

Date: 1 6 DEC 1998

NEWDRUGS.EEP
Type file name and press ENTER LEFT ARROW = Previous character RIGHT ARROW = Next character DEL = Delete character ESC = Cancel and return to main menu

FIG 11

MODE MENU	
ML / HR	Y
UNITS / HR	Y
SINGLE DOSE	Y
MANUAL SCHEDULE	Y
AUTO SCHEDULE	Y
MCG / MIN	Y
MCG / KG / MIN	Y
△ = Previous mode ▽ = Next mode (SPACEBAR) = Change configuration ENTER = Save and return to main menu	

FIG 12

MANUFACTURERS	
B-D	Y
MONOJECT	Y
TERUMO	Y
△ = Previous manufacturer ▽ = Next manufacturer (SPACEBAR) = Change configuration ENTER = Save and return to main menu	

FIG 14 This is the replacement sheet

Date: 1 6 DEC 1998

ML / HR

FIG 13a

CONC. — — — — Units
mL

DOSE — — — — U / hr

UNITS / HR

FIG 13b

OVER — — : — — hr / min

SINGLE
DOSE

FIG 13c

INFUSE — — — mL

OVER — — : — — hr: min

EVERY — — : — — hr: min

MANUAL
SCHEDULE

FIG 13d

INFUSE — — — mL

OVER — — : — — hr: min

EVERY — — : — — hr: min

AUTO
SCHEDULE

FIG 13e

CONC. — — — — mg / mL

DOSE — — — — mcg
min

MCG / MIN

FIG13f

BODY WT — — — — kg

CONC. — — — — mg / mL

DOSE — — — — mcg / kg
min

MCG / KG
/ MIN

FIG13g

This is the replacement sheet

Date: 16 DEC 1998

SYRINGES MENU								
B - D	1 ML	Y	MONOJECT	1 ML	Y	TERUMO	1 ML	Y
B - D	3 ML	Y	MONOJECT	3 ML	Y	TERUMO	3 ML	Y
B - D	5 ML	Y	MONOJECT	6 ML	Y	TERUMO	5 ML	Y
B - D	10 ML	Y	MONOJECT	12 ML	Y	TERUMO	10 ML	Y
B - D	20 ML	Y	MONOJECT	20 ML	Y	TERUMO	20 ML	Y
B - D	30 ML	Y	MONOJECT	35 ML	Y	TERUMO	30 ML	Y
B - D	60 ML	Y	MONOJECT	60 ML	Y	TERUMO	60 ML	Y

= Previous syr
 = Next syr

(SPACEBAR) = Change configuration
 ENTER = Save and return to main menu

FIG 15

DEFAULTS MENU	
DRUG DEFAULT	Y
MODE DEFAULT	Y
MFR DEFAULT	Y
SYRINGE DEFAULT	Y

= Previous default
 = Next default

(SPACEBAR) = Change configuration
 ENTER = Save and return to main menu

FIG 16

This is the replacement sheet

Date: 16 DEC 1998

MISCELLANEOUS FEATURES MENU	
DRUG LIBRARY ENABLE	Y
SYRINGE RECOGNITION	Y
SYRINGE DETECTION	Y
PSI RANGE	M
RATE RANGE	H
AUTO LOCK	N
VOLUME LIMIT	Y
SILENT RUNNING	N
IDLE ALARM	N

▽ = Previous feature △ = Next feature (SPACEBAR) = Change configuration ENTER = Save and return to main menu
--

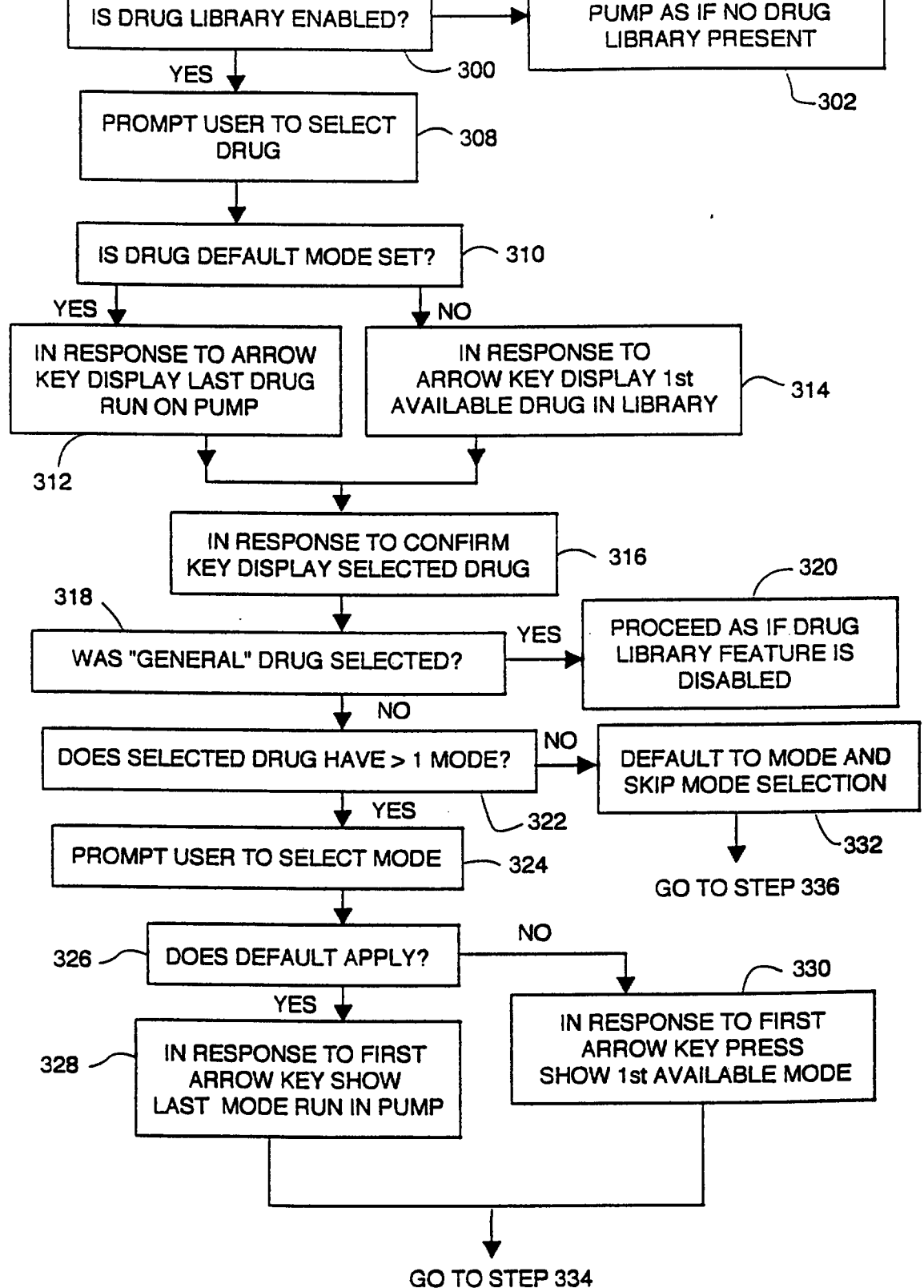
FIG 17

CREATE / EDIT PUMP IDENTIFIER
Type in identifier and press ENTER (Legal char's: A-Z, 0-9, dash & space) ESC = Cancel changes DEL = Delete character LEFT ARROW = Previous character RIGHT ARROW = Next character

FIG 18

This is the replacement sheet

Date: 16 DEC 1990



This is the replacement sheet **FIG 19a**

16 DEC 2000

Date:

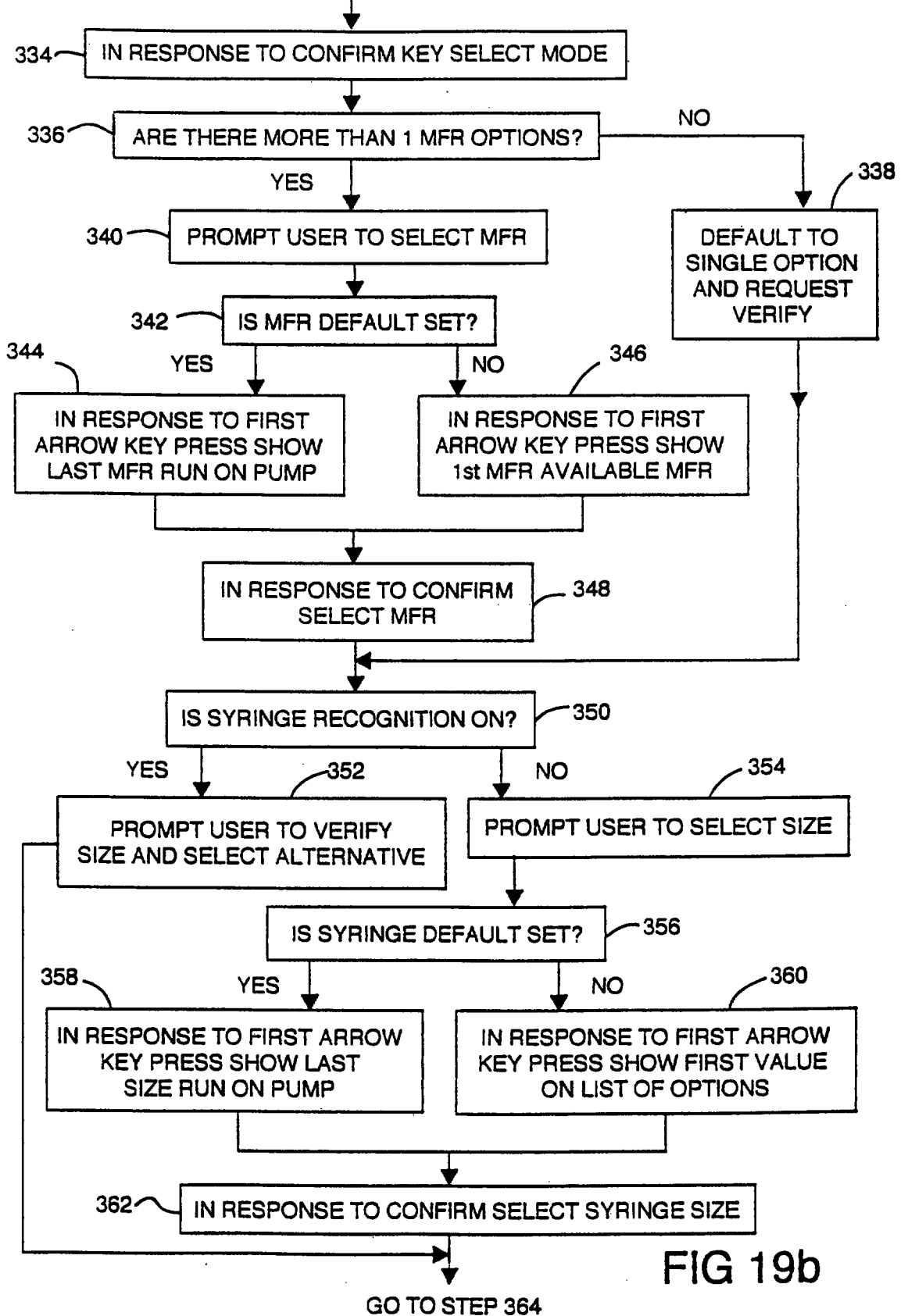


FIG 19b

GO TO STEP 364

This is the replacement sheet
1 6 DEC 1998

Date:

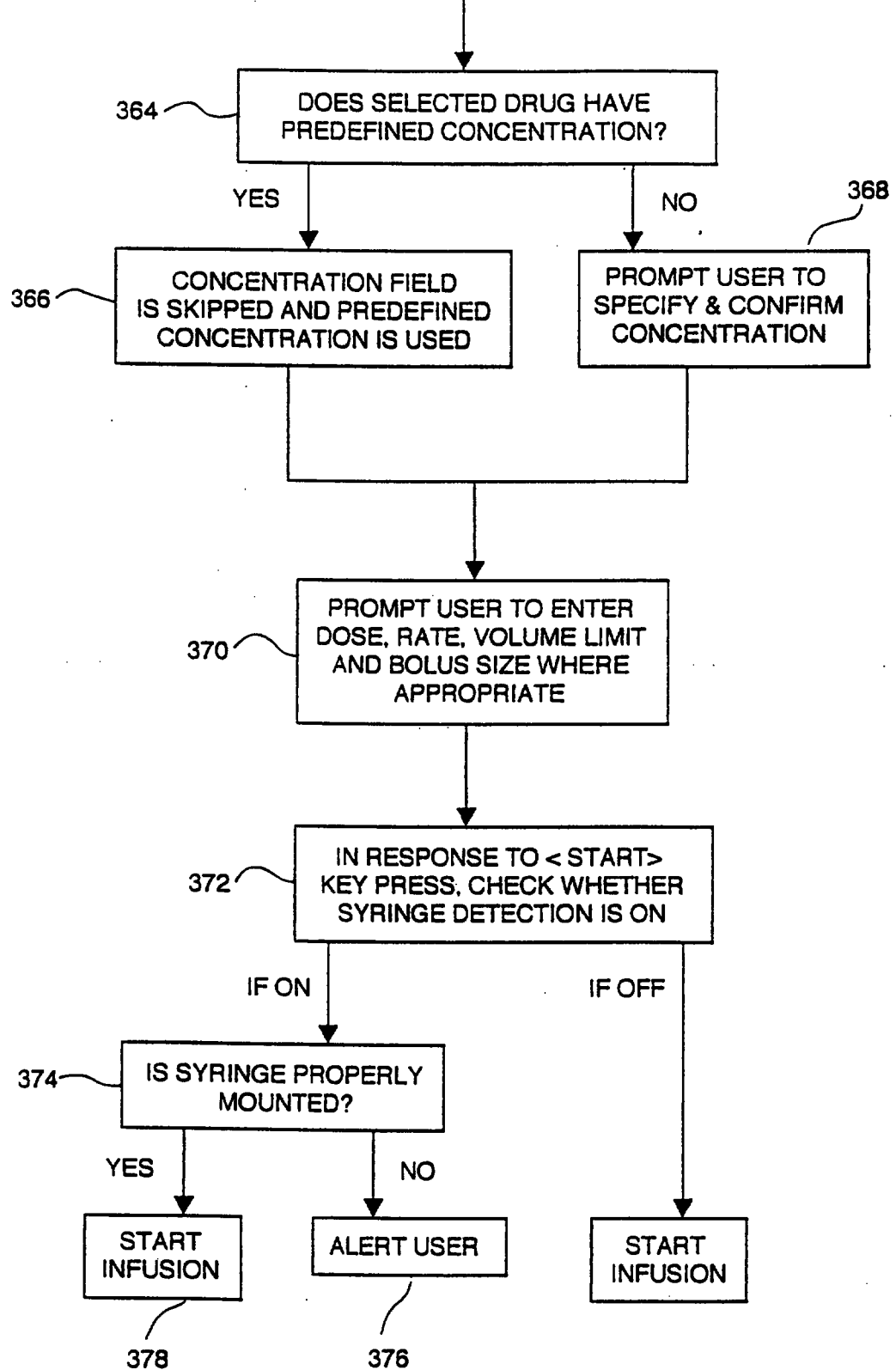


FIG 19c

This is the replacement sheet

Date: 1 6 DEC 1998

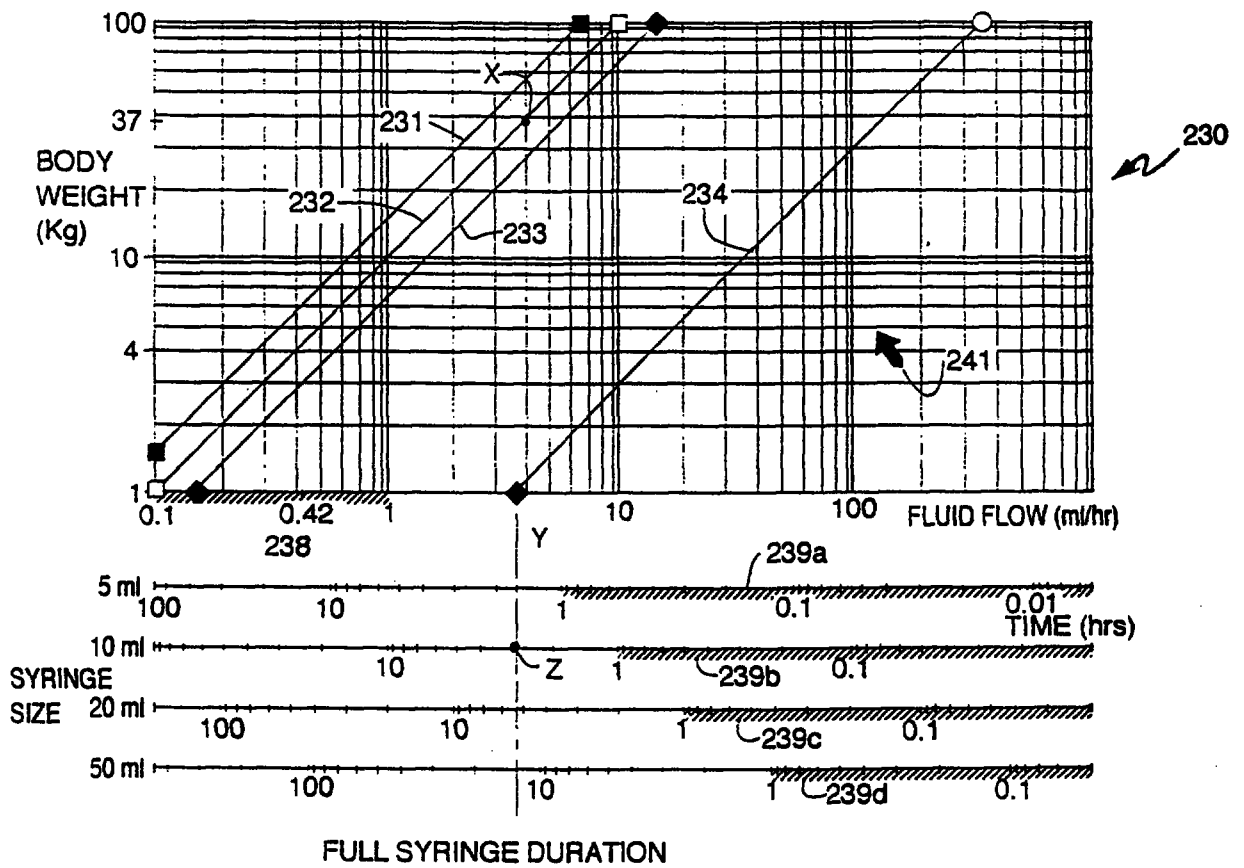


FIG 20

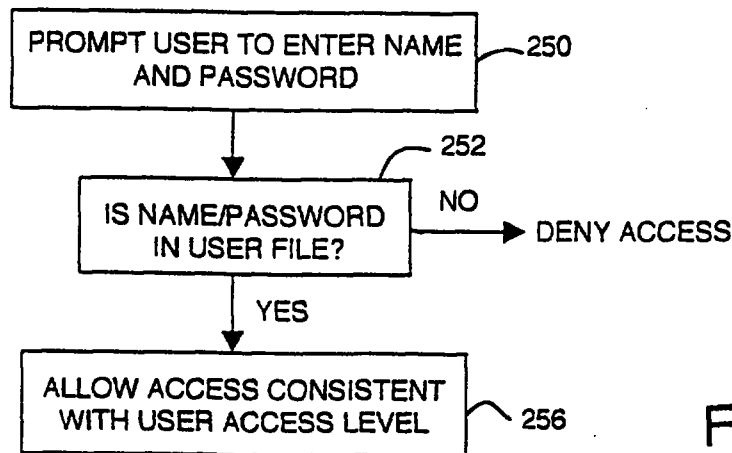


FIG 21

This is the replacement sheet

Date: 16 DEC 1991

262	USER NAME #1	DATE #1	TIME #1
264	USER NAME #2	DATE #2	TIME #2
266	USER NAME #3	DATE #3	TIME #3

FIG 22

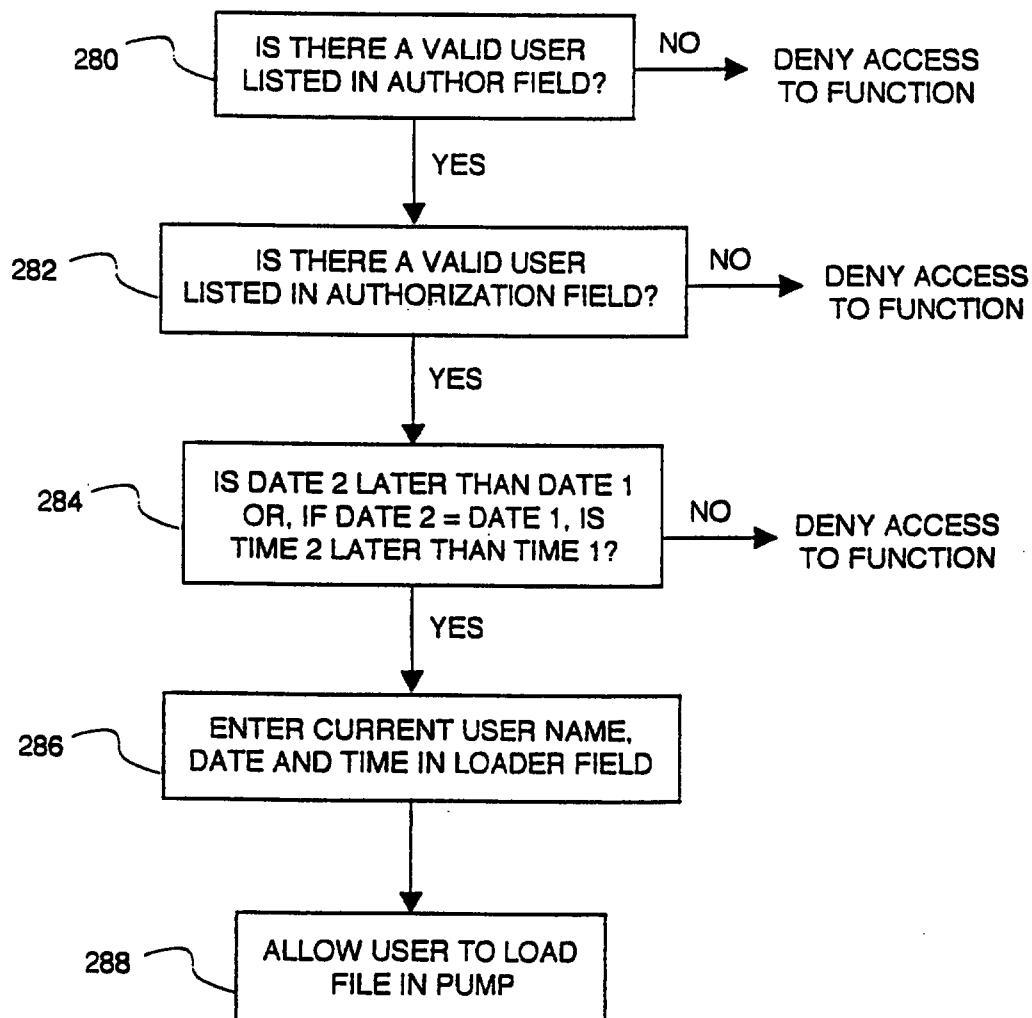


FIG 23

This is the replacement sheet

Date: 16 DEC 1998

	220	222	224	226
	mL / hr	Units / hr	mcg / min	mcg / kg / min
200	SELECT MODE. SYRINGE MFR. SYRINGE SIZE	SELECT MODE. SYRINGE MFR. SYRINGE SIZE	SELECT MODE. SYRINGE MFR. SYRINGE SIZE	SELECT MODE. SYRINGE MFR. SYRINGE SIZE
202				ENTER THE PATIENT'S BODY WEIGHT IN KILOGRAMS (kg)
204		ENTER THE DRUG CONCENTRATION IN UNITS PER MILLILITER (U / mL)	ENTER THE DRUG CONCENTRATION IN MILLIGRAMS PER MILLILITER (mg / mL)	ENTER THE DRUG CONCENTRATION IN MILLIGRAMS PER MILLILITER (mg / mL)
206	ENTER THE INFUSION RATE IN MILLILITERS per hour (mL / hr)	ENTER THE INFUSION DOSE IN UNITS PER HOUR (U / hr)	ENTER THE DOSE IN MICROGRAMS PER MINUTE (mcg / min)	ENTER THE DOSE IN MICROGRAMS PER KILOGRAM PER MINUTE (mcg / kg / min)
208	ENTER THE VOLUME LIMIT (mL)			
210	ENTER THE BOLUS SIZE IN MILLILITERS (mL)	ENTER THE BOLUS SIZE IN UNITS	ENTER THE BOLUS SIZE IN MILLIGRAMS (mg)	ENTER THE BOLUS SIZE IN MICROGRAMS PER KILOGRAM OF BODY WEIGHT (mcg / kg)
212				
214	PURGE system	PURGE system	PURGE system	PURGE system
	Press < START >	Press < START >	Press < START >	Press < START >

FIG 24

This is the replacement sheet

Date: 16 DEC 1998

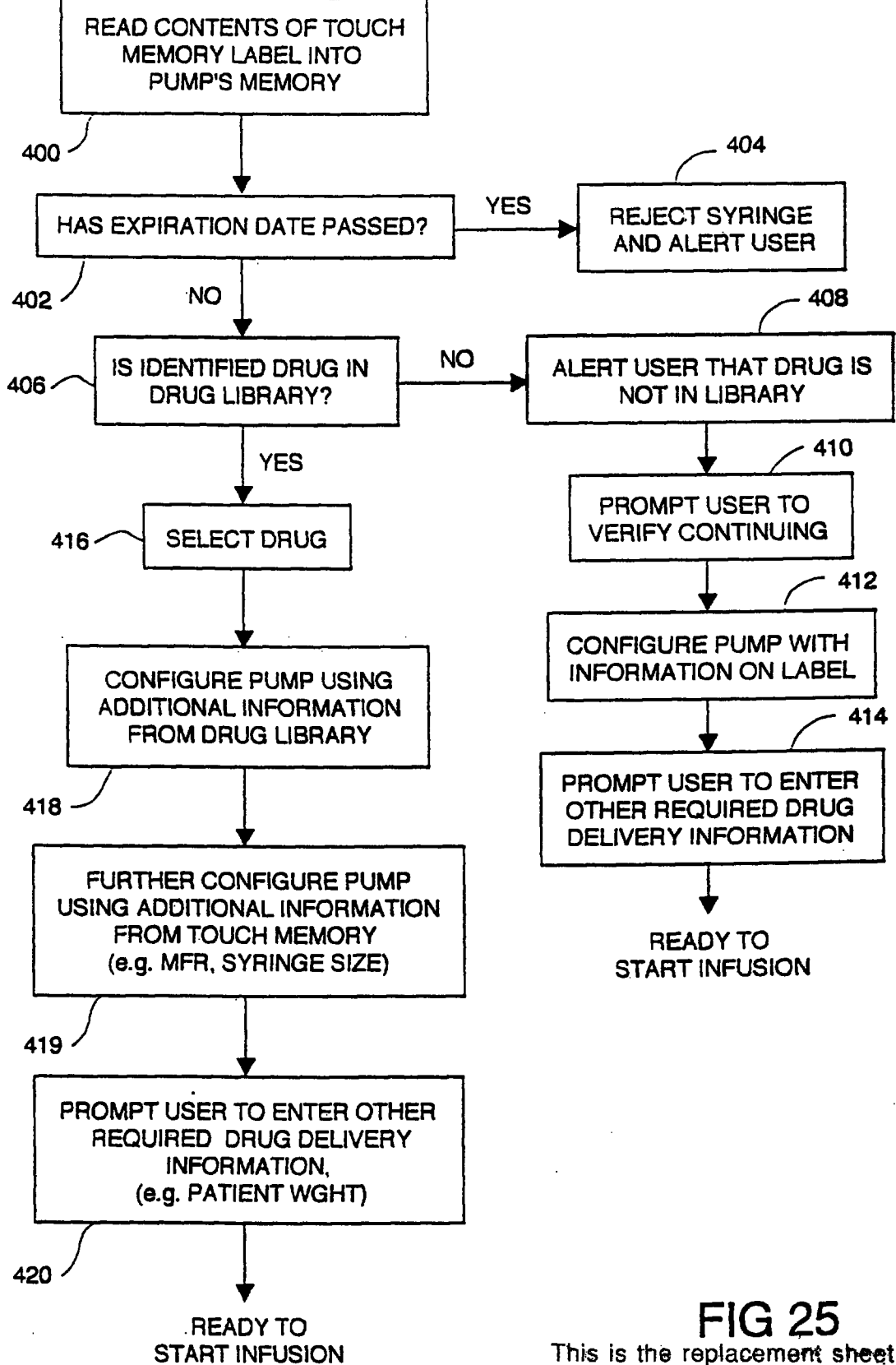


FIG 25

This is the replacement sheet

Date: 16 DEC 1990

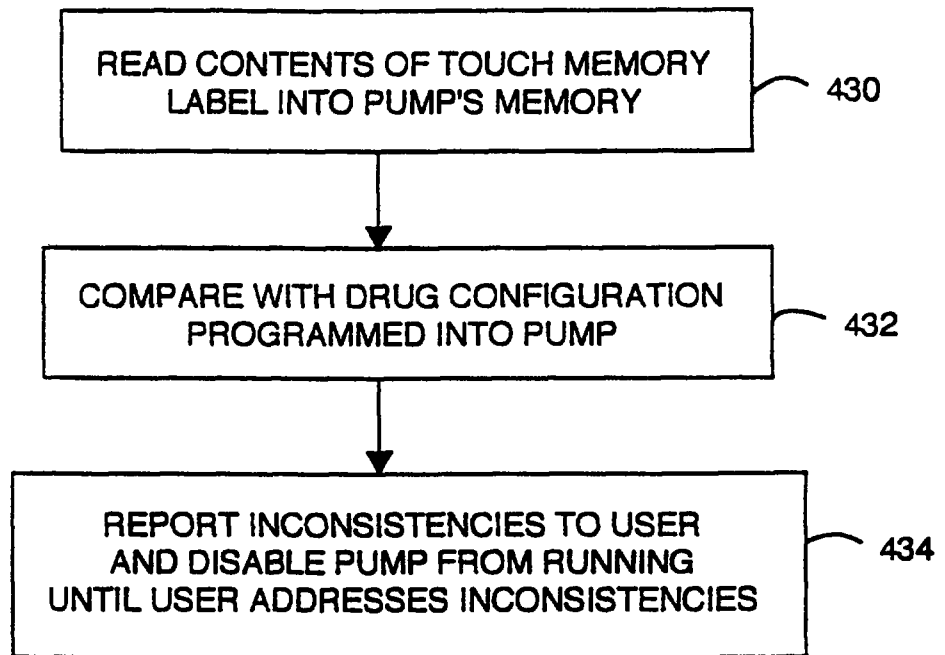


FIG 26

This is the replacement sheet

Date: 16 DEC 1998