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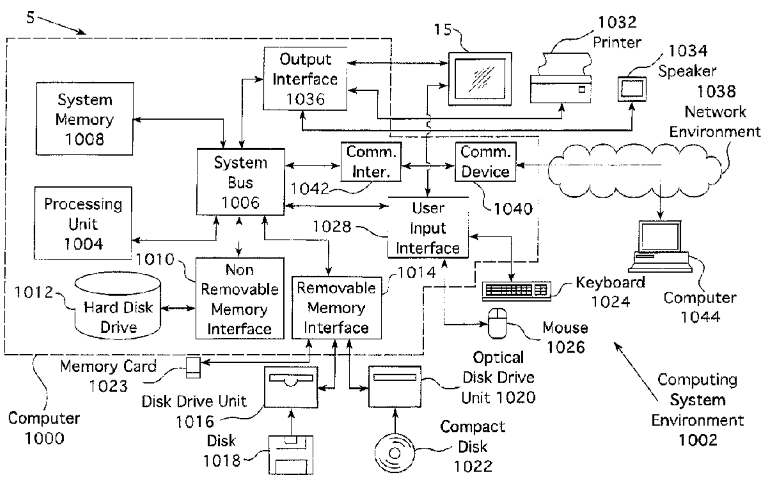
(54) **Titre : SYSTEME ET PROCEDE POUR LA PLANIFICATION ET LE CONTROLE D'UTILISATION DE PRODUITS PHARMACO-RADIOACTIFS A DOSES MULTIPLES SUR DES INJECTEURS DE PRODUITS PHARMACO-RADIOACTIFS**

(54) **Title: SYSTEM AND METHOD FOR PLANNING AND MONITORING MULTI-DOSE RADIOPHARMACEUTICAL USAGE ON RADIOPHARMACEUTICAL INJECTORS**



(57) **Abrégé/Abstract:**

A method for planning and monitoring radio pharmaceutical usage during a plurality of radio pharmaceutical injection procedures includes: providing a schedule of the plurality of radio pharmaceutical injection procedures to produce a planned patient schedule; based on the planned patient schedule, calculating a multi-dose container configuration for use during the plurality of radio pharmaceutical injection procedures; transferring the planned patient schedule to a radio pharmaceutical fluid delivery system; loading the multi-dose patient configuration into the radio pharmaceutical fluid delivery system; and conducting the plurality of radio pharmaceutical injection procedures based on the planned patient schedule.

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(54) **Title**: SYSTEM AND METHOD FOR PLANNING AND MONITORING MULTI-DOSE RADIOPHARMACEUTICAL USAGE ON RADIOPHARMACEUTICAL INJECTORS

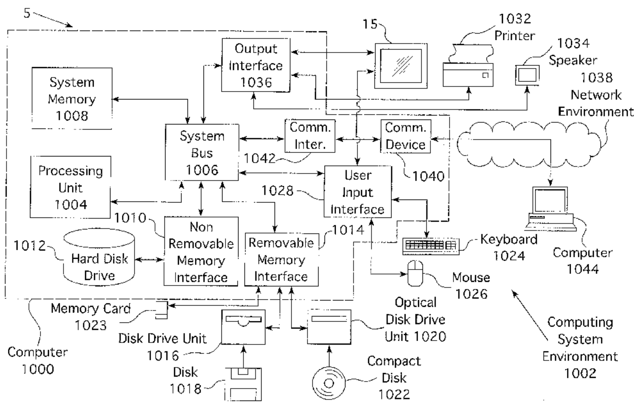

FIG. 1F

(57) **Abstract**: A method for planning and monitoring radio pharmaceutical usage during a plurality of radio pharmaceutical injection procedures includes: providing a schedule of the plurality of radio pharmaceutical injection procedures to produce a planned patient schedule; based on the planned patient schedule, calculating a multi-dose container configuration for use during the plurality of radio pharmaceutical injection procedures; transferring the planned patient schedule to a radio pharmaceutical fluid delivery system; loading the multi-dose patient configuration into the radio pharmaceutical fluid delivery system; and conducting the plurality of radio pharmaceutical injection procedures based on the planned patient schedule.

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SYSTEM AND METHOD FOR PLANNING AND MONITORING MULTI-DOSE RADIOPHARMACEUTICAL USAGE ON RADIOPHARMACEUTICAL INJECTORS

CLAIM OF PRIORITY

[0001] The present application claims priority to U.S. Provisional Application Serial No. 61/351,463, filed June 4, 2010 and entitled "System and Method for Planning and Monitoring Multi-Dose Radiopharmaceutical Usage on Radiopharmaceutical Injectors".

BACKGROUND

Technical Field

[0002] This disclosure relates to the administration of pharmaceutical substances, typically intrinsically harmful or toxic pharmaceutical substances such as radioactive pharmaceutical substances, generally known as radiopharmaceuticals, to human and animal subjects and, more specifically, to a method of and a system for planning and monitoring multi-dose radiopharmaceutical usage on radiopharmaceutical injectors.

Description of Related Art

[0003] Administration of radioactive pharmaceutical substances or drugs, generally termed radiopharmaceuticals, is often used in the medical field to provide information or imagery of internal body structures and/or functions including, but not limited to, bone, vasculature, organs and organ systems, and other tissue. Additionally, such radiopharmaceuticals may be used as therapeutic agents to kill or inhibit the growth of targeted cells or tissue, such as cancer cells.

[0004] Two types of imaging procedures utilizing radiopharmaceuticals are positron emission tomography (PET) or single-photon emission computerized tomography (SPECT) procedures. PET and SPECT are noninvasive, three-dimensional, imaging procedures that provide information regarding physiological and biochemical processes in patients. PET and SPECT images of, for example, the brain or another organ, are produced by injecting the patient with a dose of a radiopharmaceutical and then creating an image based on the radiation emitted by the radiopharmaceutical. The radiopharmaceutical generally includes a radioactive substance, such as a radioisotope, that can be absorbed by certain cells in the brain or other organs, concentrating it there.

[0005] Radioisotopes, especially those with short half-lives, can be relatively safely administered to patients in the form of a labeled substrate, ligand, drug, antibody, neurotransmitter, or other compound or molecule that is normally processed or used by the body (for example, glucose). The radioisotope acts as a tracer of specific physiological or biological processes. For example, fluorodeoxyglucose (FDG) is a normal molecule of glucose, the basic energy fuel of cells, to which is attached a radioisotope or radioactive fluorine (*i.e.*, ^{18}F). The ^{18}F radioisotope is produced in a cyclotron equipped with a unit to synthesize the FDG molecule.

[0006] Cells (for example, in the brain) that are more active in a given period of time after an injection of FDG will absorb more FDG because they have a higher metabolism and require more energy. The ^{18}F radioisotope in the FDG molecule experiences a radioactive decay, emitting a positron. When a positron collides with an electron, annihilation occurs, liberating a burst of energy in the form of two beams of gamma rays in opposite directions. The PET scanner detects the emitted gamma rays to compile a three dimensional image.

[0007] To allow for cell uptake of the radiopharmaceutical, the patient typically rests for a period of time (45-90 minutes for FDG) after the radiopharmaceutical is injected. After sufficient time for cell uptake has elapsed, the patient is typically placed on a movable bed that slides into the PET (or SPECT), or other suitable scanner. The PET scanner includes several rings of radiation detectors. Each detector emits a brief pulse of light every time it is struck with a gamma ray coming from the radioisotope within the patient's body. The pulse of light is amplified by, for example, a photomultiplier, and the information is sent to the computer for forming images of the patient.

[0008] To minimize the radiation dose to patients, radiopharmaceuticals containing radioisotopes, such as Flourine-18, Technetium-99, Carbon-11, Copper-64, Gallium-67, Iodine-123, Nitrogen-13, Oxygen-15, Rubidium-82, Thallium-201, Chromium-51, Iodine-131, Iodine-151, Iridium-192, Phosphorus-32, Samarium-153, and Yttrium-90, having relatively short half-lives are typically used for PET and SPECT imaging procedures and other radio-therapies. ^{18}F, for example, has a half-life of 109.7 minutes.

[0009] Because of its short half-life, the radioactivity level of the radioisotope will quickly decrease after it is manufactured in a cyclotron or a reactor. Consequently, the elapsed time (and corresponding decrease in radioactivity level of the radioisotope) after synthesis of the radiopharmaceutical must be factored into calculating the volume of radiopharmaceutical required to be injected into the patient to deliver the desired radioactivity dose. If the time delay after synthesis is long in relation to the radioisotope's half-life or if the calculated volume of radiopharmaceutical to be injected into the patient is insufficient to deliver the desired radioactivity dose, the delivered radioactivity dose may be too low to provide diagnostic-quality images, resulting in wasted time and effort and exposing the patient and medical personnel to unnecessary radiation.

[0010] In addition, radiopharmaceutical agents used in imaging procedures and therapeutic procedures are hazardous to attending medical personnel. These agents are toxic and can have physical and/or chemical effects for attending medical personnel such as clinicians, imaging technicians, nurses, and pharmacists. Excessive radiation exposure is harmful to attending medical personnel due to their occupational repeated exposure to the radiopharmaceuticals. However, due to the short half-life of typical radiopharmaceutical agents and small applied dosages, the radiation exposure risk-to-benefit ratio for individual patients is acceptable. The constant and repeated exposure of medical personnel to radiopharmaceuticals over an extended period of time is a significant problem in the nuclear medicine field.

[0011] With the foregoing background in place, exemplary current practice of generating, preparing, and administration of radiopharmaceuticals will now be described. Typical radiopharmaceutical treatment practice in the United States includes having the radiopharmaceutical agent initially generated off-site from a treatment location, typically a hospital, by an outside nuclear medicine facility and then delivered to the treatment location for further preparation, for example, individual dosing and administration. The treatment location, for example, a hospital, orders specific radioactive substances to be ready at specific times for specific patients. These substances are prepared by the outside nuclear medicine facility and with sufficient radioactivity that they will have the desired radioactivity level at the targeted time. For example, the outside nuclear medicine provider may have a facility equipped with a cyclotron or radioisotope generator in, for example, a lead-shielded enclosure wherein the radiopharmaceutical agent, namely, a radioactive isotope is generated or created. Further refining or dose preparation steps, namely, placing the radioisotope in injectable form, may occur at the off-treatment site. Thus, the outside provider may provide a radiopharmaceutical substance to the treatment site having a desired radioactivity level at the targeted time. Further "individual" dose preparation of the radiopharmaceutical agent may occur at the treatment site. Alternatively, the outside provider may provide a "finished" radiopharmaceutical agent ready for injection to a specified patient at a specified time so that treatment site personnel are only required to confirm that the correct radioactive dosage is present in the radiopharmaceutical agent, for example, in a stand-alone radiation dosimetry device as described previously. During the forgoing process, there is frequent close-proximity contact with radioactive materials by personnel and, as described previously, handling and transport shielding devices are needed for the protection of these personnel.

[0012] Transport pigs are commonly employed to transport the radiopharmaceutical agents, which are individual doses prepared for individual patients, to the treatment facility. At the treatment facility, data about each unit dose is entered into a facility computer either manually or through reading a bar code, floppy disk, or other similar data format, which may accompany or be on the transport pig or the radiopharmaceutical agent container. When it is time to deliver a specified unit dose to a specified patient, treatment facility personnel must remove, for example, a syringe containing the radiopharmaceutical agent from the transport pig and confirm that the dose in the syringe is within the range prescribed for that patient. Alternatively, the attending personnel must transfer the radiopharmaceutical agent to a shielded syringe as identified previously and confirm dosage. If the dose is too high, some is discarded into a shielded waste container. If the dose is too low, either a different syringe is used and/or additional agent is loaded into the syringe if available. While it is possible for the attending treatment site personnel to be involved with dosage preparation, typical United States practice is to have the radiopharmaceutical agent delivered to the treatment site which will have the desired radioactivity level at the targeted time. Manual manipulation of the radiopharmaceutical agent at the treatment site is limited at the treatment site due to this procedure. Nonetheless, various manual checks are required to confirm that a correct radiopharmaceutical dose is ready for injection into a specific patient. These manual checks include visual inspections and radioactivity measurements as noted above.

[0013] As an example of the foregoing, in PET imaging, an injectable radiopharmaceutical agent such as, for instance, FDG (fluorodeoxyglucose) is fabricated in a cyclotron device at an outside nuclear medicine facility. Thereafter, the FDG is processed to be in a radiopharmaceutical form and is transferred in an individual dose container (*i.e.*, container, bottle, syringe, etc.) and the container is loaded into a transport pig to prevent unnecessary radiation exposure to personnel, such as the radio-pharmacist, technician, and driver responsible for creation, handling, and transport of the FDG from the cyclotron site to the PET imaging site. Since the half-life of FDG is short, approximately 110 minutes, it is necessary to quickly transport the FDG to the PET imaging site. Depending upon the elapsed transport time and the initial radioactivity level of the FDG at the time of fabrication, the radioactivity level of the FDG may need to be re-measured at the PET imaging site. As an example, if the radioactivity level is too high, the transport radio-pharmacist or a radio-pharmacist at the PET imaging site may be required to dilute the FDG with a dilutent such as, for instance, saline solution, and remove part of the volume or extract fluid to reduce radioactivity prior to patient injection. During this entire process, the handling of FDG from creation to patient injection may be entirely manual. Within this process, shielding products, as described previously (*i.e.*, transport pigs, syringe shields, L-blocks, etc.) are used to shield individuals from FDG. While shielding may reduce the radiation exposure of the radio-pharmacist, the radio-pharmacist may still be exposed to emissions from the radiopharmaceutical agent during the manual mixing, volume reduction, and/or dilution process needed to obtain the required dose. After injection and often after an additional delay to allow the radiopharmaceutical to reach and be absorbed by the desired regions of interest in the body, the patient is typically placed on a moveable bed that slides by remote control into a circular opening of an imaging scanner referred to as the gantry. Positioned around the circular opening and inside the gantry are several rings of radiation detectors. In one type of radiation detector, each detector emits a brief pulse of light every time it is struck with a gamma ray coming from the radionuclide within the patient's body. The pulse of light is amplified by a photomultiplier converted to an electronic signal and the information is sent to the computer that controls the apparatus and records imaging data.

[0014] Clinical sites that inject radiopharmaceuticals typically do so using single-use doses provided for each patient. Sites order unit doses assayed to the planned injection time for each planned patient. These doses are often ordered with a sufficient activity margin to accommodate radiopharmaceutical decay due to slight differences between planned and actual injection times. Sites typically order extra unit doses to handle add-on patients or to mitigate drastic schedule variations within their planned patient set.

[0015] However, it is becoming more common to have radiopharmaceutical agents delivered in a multi-dose format to the treatment site. A multi-dose container provides all scheduled patient doses in a single container. A patient's dose is extracted from the multi-dose container at the time of injection. Ideally the multi-dose container will service all patients, including planned patients that are not dosed at their scheduled time and possibly unplanned for patients.

[0016] When determining the container configuration for their patient schedule, clinicians must trade off minimizing cost with being able to handle schedule deviations. As such, the container configuration will typically only account for a typical schedule variation for a given clinician's site. There will be times when extreme schedule variations will render the ordered multi-dose container inadequate to service the planned patient schedule. Clinicians must take corrective actions, such as ordering more doses, when they are going to have activity shortfalls. Due to the long turn-around time when ordering doses, it is imperative that clinicians are made aware of a suspected shortfall in their multi-dose container as early as possible. Accordingly, a need exists for a system and a method to quickly and easily determine a multi-dose container configuration that meets a planned patient schedule with a sufficient margin to account for reasonable schedule variation while minimizing multi-dose container cost.

[0017] Furthermore, when determining the container configuration for their patient schedule, clinician's must trade off minimizing cost with being able to handle schedule deviations. As such, the container configuration will typically only account for typical schedule variation for a given clinicians site. There will be times when extreme schedule variations will render the ordered multi-dose container inadequate to service the planned patient schedule. Clinicians must take corrective actions, such as ordering more doses, when they are going to have activity shortfalls. Due to the long turn-around time when ordering doses, it is imperative that clinicians are made aware of a suspected shortfall in their multi-dose container as early as possible. Accordingly, a further need exists for a system and method for monitoring multi-dose container usage and predicting a likely shortfall at the earliest possible moment.

SUMMARY

[0018] Therefore, it is an object of the present disclosure to provide a method and system that overcome some or all of the drawbacks and deficiencies evident in the prior art. More specifically, the systems and methods described herein allow for a clinician to quickly and easily determine a multi-dose container configuration that meets a planned patient schedule with a sufficient margin to account for reasonable schedule variation while minimizing multi-dose container cost. In addition, the systems and methods of the present disclosure allow for the monitoring of multi-dose container usage and predict a likely shortfall at the earliest possible moment.

[0019] Accordingly, provided is a method for planning and monitoring radiopharmaceutical usage during a plurality of radiopharmaceutical injection procedures. The method includes: providing a schedule of the plurality of radiopharmaceutical injection procedures to produce a planned patient schedule; based on the planned patient schedule, calculating a multi-dose container configuration for use during the plurality of radiopharmaceutical injection procedures; transferring the planned patient schedule to a radiopharmaceutical fluid delivery system; providing the multi-dose container configuration to the radiopharmaceutical fluid delivery system; and conducting the plurality of radiopharmaceutical injection procedures based on the planned patient schedule.

[0020] The schedule may include the time of an injection procedure for each patient and an activity removed from the multi-dose container of radiopharmaceutical for each patient. The step of providing the schedule may include at least one of: manually entering the time and activity for each patient into a computer; retrieving the time and activity for each patient from a memory device associated with the computer; and retrieving the time and activity for each patient from a remotely located patient device over a network. The planned patient schedule may be provided such that it is editable after being initially provided to accommodate add-on patients, cancellations, time modifications to patients already provided on the planned patient schedule, modifications to an activity removed from the multi-dose container of radiopharmaceutical to patients already provided on the planned patient schedule, or any combination thereof.

[0021] The method may further include the steps of: monitoring the multi-dose container configuration during the plurality of radiopharmaceutical injection procedures; determining if there is a risk that at least one of the plurality of radiopharmaceutical injection procedures may not be completed properly; and alerting an operator if there is risk that at least one of the plurality of radiopharmaceutical injection procedures may not be completed. The step of monitoring the multi-dose container configuration may include: determining remaining radiopharmaceutical activity and volume of the multi-dose container configuration to provide a remaining activity estimation; and adjusting the remaining activity estimation based on isotope decay. The step of determining the remaining radiopharmaceutical activity of the multi-dose container configuration may be performed by one of an ionization chamber, a CZT crystal detector, a Geiger-Müller counter, and a scintillating counter.

[0022] The method may further include the step of displaying the planned patient schedule on a graphical user interface of the radiopharmaceutical fluid delivery system. The step of alerting an operator may include highlighting one of the plurality of radiopharmaceutical injection procedures in the planned patient schedule. The method may also include the step of updating the planned patient schedule to accommodate a maximum number of the plurality of radiopharmaceutical injection procedures if there is risk that at least one of the plurality of radiopharmaceutical injection procedures may not be completed.

[0023] Further provided is an article having a machine-readable storage medium containing instructions that, if executed, enable a processor to: load a schedule of a plurality of radiopharmaceutical injection procedures to produce a planned patient schedule; and based on the planned patient schedule, calculate a multi-dose container configuration for use during the plurality of radiopharmaceutical injection procedures.

[0024] The article may also include instructions that, if executed, enable the processor to transfer the planned patient schedule to a radiopharmaceutical fluid delivery system. The schedule may include time of an injection procedure for each patient and an activity removed from the multi-dose container of radiopharmaceutical for each patient. The step of providing the schedule may include at least one of manually entering the time and activity for each patient into a computer, retrieving the time and activity for each patient from a memory device associated with the computer, and retrieving the time and activity for each patient from a remotely located patient device over a network. The planned patient schedule may be editable after initial loading to accommodate add-on patients, cancellations, time modifications to patients already provided on the planned patient schedule, modifications to an activity removed from the multi-dose container of radiopharmaceutical to patients already provided on the planned patient schedule, or any combination thereof.

[0025] Also provided is a planning and monitoring software stored on a storage medium to plan and monitor radiopharmaceutical usage during a plurality of radiopharmaceutical injection procedures. The software includes programming instructions that, if executed, enable a processor to: load a schedule of a plurality of radiopharmaceutical injection procedures to produce a planned patient schedule; and based on the planned patient schedule, calculate a multi-dose container configuration for use during the plurality of radiopharmaceutical injection procedures.

[0026] The planning and monitoring software may further include instructions that, if executed, enable the processor to transfer the planned patient schedule to a radiopharmaceutical fluid delivery system. The schedule may include time of an injection procedure for each patient and an activity removed from the multi-dose container of radiopharmaceutical for each patient.

The step of providing the schedule may include at least one of manually entering the time and activity for each patient into a computer, retrieving the time and activity for each patient from a memory device associated with the computer, and retrieving the time and activity for each patient from a remotely located patient device over a network. The planned patient schedule may be provided such that it is editable after initial loading to accommodate add-on patients, cancellations, time modifications to patients already provided on the planned patient schedule, modifications to an activity removed from the multi-dose container of radiopharmaceutical to patients already provided on the planned patient schedule, or any combination thereof.

[0027] Further provided is a radiopharmaceutical fluid delivery device for performing a radiopharmaceutical injection procedure. The radiopharmaceutical fluid delivery device includes: a disposable administration set for allowing fluid flow from a radiopharmaceutical source of the radiopharmaceutical fluid delivery device to a patient; a pumping mechanism in fluid communication with the disposable administration set and the radiopharmaceutical source to pump fluid from the radiopharmaceutical source and through the disposable administration set to the patient; a control unit operatively coupled to the pumping mechanism and configured to: a) receive a schedule of a plurality of radiopharmaceutical injection procedures; and b) control the pumping mechanism to conduct the plurality of radiopharmaceutical injection procedures based on the schedule; and a display unit operatively coupled to the control unit for displaying the schedule to an operator.

[0028] The control unit may be further configured to: c) monitor the multi-dose container configuration during the plurality of radiopharmaceutical injection procedures; d) determine if there is a risk that at least one of the plurality of radiopharmaceutical injection procedures may not be completed properly; and e) alert an operator if there is risk that at least one of the plurality of radiopharmaceutical injection procedures may not be completed.

[0029] The disposable administration set may be a multipatient disposable administration set that includes a medical fluid component; a radiopharmaceutical component; a coil component coupled to the medical fluid component and the radiopharmaceutical component; and a waste component coupled to the medical fluid component, the coil component, and the radiopharmaceutical component.

[0030] Also provided is a method for optimizing a schedule of a plurality of radiopharmaceutical injection procedures. The method includes the steps of: providing a schedule of the plurality of radiopharmaceutical injection procedures to produce a planned patient schedule; transferring the planned patient schedule to a radiopharmaceutical fluid delivery system; changing the planned patient schedule; and suggesting changes in at least one of radioactive dose and infusion time for at least one future patient in the planned patient schedule. The method may also include the step of: determining a new, optimized patient schedule based on the changes suggested.

[0031] The schedule may include the time of an injection procedure for each patient and an activity removed from the multi-dose container of radiopharmaceutical for each patient. The step of providing the schedule may include at least one of: manually entering the time and activity for each patient into a computer; retrieving the time and activity for each patient from a memory device associated with the computer; and retrieving the time and activity for each patient from a remotely located patient device over a network. The planned patient schedule may be provided such that it is editable after being initially provided to accommodate add-on patients, cancellations, time modifications to patients already provided on the planned patient schedule, modifications to an activity removed from the multi-dose container of radiopharmaceutical to patients already provided on the planned patient schedule, or any combination thereof.

[0031a] According to one aspect of the present invention, there is provided a radiopharmaceutical fluid delivery system comprising: a radiopharmaceutical source; a disposable administration set configured to allow fluid flow from the radiopharmaceutical source to a patient; a pumping mechanism in fluid communication with the disposable administration set and the radiopharmaceutical source, and configured to pump fluid from the radiopharmaceutical source through the disposable administration set to the patient; a control unit operatively coupled to the pumping mechanism, and configured to receive a patient schedule of a plurality of radiopharmaceutical injection procedures, determine a multi-dose container configuration for use during the plurality of radiopharmaceutical injection procedures, control the pumping mechanism to conduct the plurality of radiopharmaceutical injection procedures based on the patient schedule, monitor the multi-dose container configuration during the plurality of radiopharmaceutical injection procedures, determine whether there is a risk that at least one of the plurality of radiopharmaceutical injection procedures may not be completed properly due to one or more patient schedule changes, and provide an alert in response to the risk being determined; and a display unit operatively coupled to the control unit for displaying the patient schedule.

[0032] These and other features and characteristics of the present disclosure, as well as the methods of operation and functions of the related elements of structures and the combination of parts and economies of manufacture, will become more apparent upon consideration of the following description and the appended claims with reference to the accompanying drawings, all of which form a part of this specification, wherein like reference numerals designate corresponding parts in the various figures. It is to be expressly understood, however, that the drawings are for the purpose of illustration and description only and are not intended to limit the scope of this disclosure. As used in the specification and the claims, the singular form of "a", "an", and "the" include plural referents unless the context clearly dictates otherwise.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] FIG. 1A is a perspective view of a fluid delivery system according to an embodiment;

[0034] FIG. 1B is another perspective view of the fluid delivery system of **FIG. 1A** with the shielded cover thereof in a retracted position;

[0035] FIG. 1C is a top plan view of the fluid delivery system shown in **FIGS. 1A** and **1B** with various fluid path components positioned therein;

[0036] FIG. 1D is a cross-sectional view taken along line **1D-1D** of **FIG. 1A;**

[0037] FIG. 1E is a cross-sectional view taken along line **1E-1E** of **FIG. 1A;**

[0038] FIG. 1F is a block diagram illustrating a control system for use with the fluid delivery system of **FIG. 1A;**

[0039] **FIG. 2A** is a schematic illustration of the multi-patient fluid path set and components thereof according to an embodiment;

[0040] **FIG. 2B** is an exploded view showing the multi-patient fluid path set shown in **FIG. 2A** connected to a fluid source and disposed above the fluid delivery system shown in **FIGS. 1A-1E**;

[0041] **FIG. 3A** is an elevational view of a preferred embodiment of a coil assembly according to an embodiment;

[0042] **FIG. 3B** is a partial cross-sectional view of **FIG. 3A**;

[0043] **FIG. 3C** is a plan view (in partial cross-section) taken along line **3C-3C** of **FIG. 3A**;

[0044] **FIG. 3D** is a cross-sectional view taken along line **3D-3D** of **FIG. 3A**;

[0045] **FIG. 3E** is a perspective view of the core element of the coil assembly shown in **FIG. 3A**;

[0046] **FIG. 3F** is an enlarged view of **FIG. 1D** showing the coil assembly in the ionization chamber of the fluid delivery system;

[0047] **FIG. 4A** is an elevational view of preferred embodiments of a container shield carrying system and a container access system according to an embodiment;

[0048] **FIG. 4B** is a perspective view showing the container shield, the container shield carrying system, and the container access system of **FIG. 4A**;

[0049] **FIG. 4C** is an elevational view of a pharmaceutical container that may be used in the fluid delivery system according to an embodiment;

[0050] **FIG. 5** is a simplified schematic illustration of the fluid delivery system of **FIG. 1A** in a first state of operation according to an embodiment;

[0051] **FIG. 6** is a simplified schematic illustration of the fluid delivery system of **FIG. 1A** in a second state of operation according to an embodiment;

[0052] **FIG. 7** is a simplified schematic illustration of the fluid delivery system of **FIG. 1A** in a third state of operation according to an embodiment;

[0053] **FIG. 8** is a simplified schematic illustration of the fluid delivery system of **FIG. 1A** in a fourth state of operation according to an embodiment;

[0054] **FIG. 9** is a simplified schematic illustration of the fluid delivery system of **FIG. 1A** in a fifth state of operation according to an embodiment;

[0055] **FIG. 10** is a flow diagram of a process for implementing an injection procedure according to an embodiment;

[0056] **FIG. 11** is a bar graph showing the levels of activity measured in various stages of an injection procedure according to an embodiment;

[0057] **FIGS. 12-18** are various depictions of a display of a computer running software for planning multi-dose radiopharmaceutical usage on radiopharmaceutical according to an embodiment; and

[0058] **FIGS. 19-26** are various depictions of a graphical user interface for use in injection procedures according to an embodiment.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0059] For purposes of the description hereinafter, the terms "upper", "lower", "right", "left", "vertical", "horizontal", "top", "bottom", "lateral", "longitudinal", and derivatives thereof shall relate to the orientation of embodiments disclosed in the drawing figures. However, it is to be understood that embodiments may assume alternative variations and step sequences, except where expressly specified to the contrary. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed herein are not to be considered as limiting.

[0060] It is to be understood that the disclosed embodiments may assume various alternative variations and step sequences, except where expressly specified to the contrary. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments.

[0061] An exemplary radiopharmaceutical fluid delivery system for use with the system disclosed herein is disclosed in United States Patent Application Publication No. 2008/0177126 to Tate et al., the disclosure of which is incorporated herein by reference. More specifically, **FIGS. 1A-1F** show an exemplary embodiment of such a radiopharmaceutical fluid delivery system **10**. The fluid delivery system **10** may be configured as a cart-like apparatus **9** having wheels **13** and/or casters **12** for allowing the system to be movable. One or more of the wheels **13** may be lockable to prevent the system **10** from moving once it is in position. The system **10** also preferably includes one or more handles **14** for allowing an operator to move or position the system **10**. Alternately, the fluid delivery system **10** may be a stand-alone or fixed-position apparatus.

[0062] The fluid delivery system **10** includes a display or graphical user interface (GUI) **15** for programming and operating the system **10**. The GUI display **15** may be attached to one of the handles **14** (as shown) of the system **10**. The display **15** may be a color display and incorporate touch-screen capability, as known in the art, for ease of use. The display **15** may be fixed, but is preferably pivotally connected to the fluid delivery system **10** (as shown), by means of a movable arm **11** that is pivotally connected to a joint **16**. Further, the display **15** may be tilted or swiveled with respect to the arm **11** to allow for optimal positioning of the display **15** by an operator.

[0063] With specific reference to **FIG. 1F**, GUI touch-screen display **15** may be part of a control system **5** embodied as a computer **1000** in a computing system environment **1002** used for controlling an injection procedure of the fluid delivery system **10**. While any suitable computing device may be used to control the fluid delivery system **10**, an exemplary embodiment of one computing system and computing system environment **1002** will be discussed hereinafter with reference to **FIG. 1F**. This computing system environment **1002** may include, but is not limited to, at least one computer **1000** having certain components for appropriate operation, execution of code, and creation and communication of data. For example, the computer **1000** includes a processing unit **1004** (typically referred to as a central processing unit or CPU) that serves to execute computer-based instructions received in the appropriate data form and format. Further, this processing unit **1004** may be in the form of multiple processors executing code in series, in parallel, or in any other manner for appropriate implementation of the computer-based instructions.

[0064] In order to facilitate appropriate data communication and processing information between the various components of the computer **1000**, a system bus **1006** is utilized. The system bus **1006** may be any of several types of bus structures, including a memory bus or memory controller, a peripheral bus, or a local bus using any of a variety of bus architectures. In particular, the system bus **1006** facilitates data and information communication between the various components (whether internal or external to the computer **1000**) through a variety of interfaces, as discussed hereinafter.

[0065] The computer **1000** may include a variety of discrete computer-readable media components. For example, this computer-readable media may include any media that can be accessed by the computer **1000**, such as volatile media, non-volatile media, removable media, non-removable media, etc. As a further example, this computer-readable media may include computer storage media, such as media implemented in any method or technology for storage of information such as computer-readable instructions, data structures, program modules, or other data, random access memory (RAM), read only memory (ROM), electrically erasable programmable read only memory (EEPROM), flash memory, or other memory technology, CD-ROM, digital versatile disks (DVDs), or other optical disk storage, magnetic cassettes, magnetic tape, magnetic disk storage, or other magnetic storage devices, or any other medium which can be used to store the desired information and which can be accessed by the computer **1000**. Further, this computer-readable media may include communications media, such as computer-readable instructions, data structures, program modules, or other data in a modulated data signal such as a carrier wave or other transport mechanism and include any information delivery media, wired media (such as a wired network and a direct-wired connection), and wireless media (such as acoustic signals, radio frequency signals, optical signals, infrared signals, biometric signals, bar code signals, etc.). Of course, combinations of any of the above should also be included within the scope of computer-readable media.

[0066] The computer **1000** further includes a system memory **1008** with computer storage media in the form of volatile and non-volatile memory, such as ROM and RAM. A basic input/output system (BIOS) with appropriate computer-based routines assists in transferring information between components within the computer **1000** and is normally stored in ROM. The RAM portion of the system memory **1008** typically contains data and program modules that are immediately accessible to or presently being operated on by processing unit **1004**, *e.g.*, an operating system, application programming interfaces, application programs, program modules, program data, and other instruction-based computer-readable code.

[0067] The computer **1000** may also include other removable or non-removable, volatile or non-volatile computer storage media products. For example, the computer **1000** may include a non-removable memory interface **1010** that communicates with and controls a hard disk drive **1012**, *i.e.*, a non-removable, non-volatile magnetic medium, a removable, non-volatile memory interface **1014** that communicates with and controls a magnetic disk drive unit **1016** (which reads from and writes to a removable, non-volatile magnetic disk **1018**), an optical disk drive unit **1020** (which reads from and writes to a removable, non-volatile optical disk, such as a CD ROM **1022**), a Universal Serial Bus (USB) port for use in connection with a removable memory card **1023**, etc. However, it is envisioned that other removable or non-removable, volatile or non-volatile computer storage media can be used in the exemplary computing system environment **1002**, including, but not limited to, magnetic tape cassettes, DVDs, digital video tape, solid state RAM, solid state ROM, etc. These various removable or non-removable, volatile or non-volatile magnetic media are in communication with the processing unit **1004** and other components of the computer **1000** via the system bus **1006**. The drives and their associated computer storage media discussed above and illustrated in **FIG. 1F** provide storage of operating systems, computer-readable instructions, application programs, data structures, program modules, program data, and other instruction-based computer-readable code for the computer **1000** (whether duplicative or not of the information and data in the system memory **1008**).

[0068] Desirably, an operator of the fluid delivery system **10** will enter commands, information, and data into the computer **1000** using the touch-screen of the GUI display **15** via an operator input interface **1028**. However, it has been envisioned that an operator may enter commands, information, and data into the computer **1000** using other attachable or operable input devices, such as a keyboard **1024**, a mouse **1026**, etc., via the operator input interface **1028**. Of course, a variety of such input devices may be utilized, *e.g.*, a microphone, a trackball, a joystick, a touchpad, a scanner, etc., including any arrangement that facilitates the input of data and information to the computer **1000** from an outside source. As discussed, these and other input devices are often connected to the processing unit **1004** through the operator input interface **1028** coupled to the system bus **1006**, but may be connected by other interface and bus structures, such as a parallel port, game port, or a USB. Still further, data and information can be presented or provided to an operator in an intelligible form or format through certain output devices, such as the GUI display **15** (to visually display this information and data in electronic form), a printer **1032** (to physically display this information and data in print form), a speaker **1034** (to audibly present this information and data in audible form), etc. All of these devices are in communication with the computer **1000** through an output interface **1036** coupled to the system bus **1006**. It is envisioned that any such peripheral output devices be used to provide information and data to the operator.

[0069] The computer **1000** may operate in a network environment **1038** through the use of a communications device **1040**, which is integral to the computer or remote therefrom. This communications device **1040** is operable by and in communication with the other components of the computer **1000** through a communications interface **1042**. Using such an arrangement, the computer **1000** may connect with or otherwise communicate with one or more remote computers, such as a remote computer **1044** of a hospital information system, which typically includes many or all of the components described above in connection with the computer **1000**.

Using appropriate communications devices **1040**, *e.g.*, a modem, a network interface, or adapter, etc., the computer **1000** may operate within and communicate through a local area network (LAN) and a wide area network (WAN), but may also include other networks such as a virtual private network (VPN), an office network, an enterprise network, an intranet, the Internet, etc. It will be appreciated that the network connections shown are exemplary and other means of establishing a communications link between the computers **1000**, **1044** may be used.

[0070] As used herein, the computer **1000** includes or is operable to execute appropriate custom-designed or conventional software to perform and implement the processing steps of the methods and systems disclosed herein, thereby forming a specialized and particular computing system. Accordingly, the presently-invented methods and systems may include one or more computers **1000** or similar computing devices having a computer-readable storage medium capable of storing computer-readable program code or instructions that cause the processing unit **1004** to execute, configure, or otherwise implement the methods, processes, and transformational data manipulations discussed herein. Still further, the computer **1000** may be in the form of a personal computer coupled to the fluid delivery system **10**, a processor formed integrally with the fluid delivery system **10**, a computer provided remotely from the fluid delivery system **10**, or any other type of computing device having the necessary processing hardware to appropriately process data to effectively implement the presently-invented computer-implemented method and system.

[0071] Returning to **FIGS. 1A-1E**, the fluid delivery system **10** may include a retractable lid or cover **20** having a primary handle including a latch release **1** (*see* **FIGS. 1D** and **1E**) and a secondary handle **21**. The lid **20** may cover an upper surface **103** that defines a number of recessed portions, such as wells and troughs, into which a container or container (*see* **902** in

FIG. 4C) of a pharmaceutical or a radiopharmaceutical (discussed in more detail below) and various components of a multi-patient fluid path set **200** (hereinafter MPDS, discussed in more detail below) may be positioned during an injection procedure. A locking mechanism, such as a combination or a key lock (not shown), may be used to lock the lid **20** in a closed position to, for example, prevent use or access of the system **10** by unauthorized personnel. In another embodiment, the locking mechanism may be a software-implemented lock, such as a password-protected access point, that is accessible through the display **15** and is adapted to lock the cover in a closed position and/or to prevent unauthorized personnel from accessing or operating the system **10**.

[0072] The lid **20** is slidable or retractable (by, for example, using primary handle and latch release **1**) with respect to the cart **9** to allow for insertion and removal of the container or container **902** and MPDS **200** from the fluid delivery system **10**. The lid **20**, upper surface **103**, and various other portions of the cart **9** preferably include suitable radioactive shielding (such as lead) for minimizing potential radiation exposure from the radiopharmaceutical to the operator. In this manner, the radiopharmaceutical container **902** and the components of the MPDS **200** can lie below the plane of surface **103**, whereupon the surface **103** or one or more portions thereof can be covered by the lid **20** during use to limit radiation exposure to the operator or other medical personnel. Further, instead of a retractable lid **20**, surface **103** itself could be disposed on a portion of the fluid delivery system **10** (*e.g.*, a drawer-type mechanism) that slidably displaces with respect to a remainder of the fluid delivery system **10**.

[0073] As further shown in **FIGS. 1A**, **1B**, and **1D**, the fluid delivery system **10** includes a pumping mechanism, such as a peristaltic pump **22**, a removable/replaceable source of medical fluid **23** (such as saline), an output device such as printer **1032**, and an interrupt button

25. The peristaltic pump **22** is shown in a closed position in **FIG. 1A**, but may be opened (*see* **FIGS. 1B**, **1C**, and **2B**) to receive a length of tubing **27** (*see* **FIGS. 1C** and **2A**) in fluid connection with the source of medical fluid **23** to inject the fluid into a patient (discussed in more detail below). While a peristaltic pump **22** is currently preferred, any suitable type of pumping mechanism, such as a piston-driven syringe pump, gear pump, rotary pump, or in-line pump, may be used.

[0074] The printer **1032** may be used to generate records of the injection and/or imaging procedures performed on patients, for inclusion in patients' medical records or for billing or inventory purposes. The printer **1032** may be pivotally connected to the system **10** (*see* **FIG. 1B**) to allow an operator to load paper or labels into the printer **1032**.

[0075] The interrupt button **25** allows an operator to quickly and easily pause or abort an injection procedure in the event of, for example, patient discomfort or an emergency, without having to resort to the GUI display **15** (which also can be manipulated to pause or abort an injection procedure). The interrupt button **25** may be connected to LEDs and/or a printed circuit board to provide visual and/or auditory alarms when the interrupt button **25** has been activated.

[0076] Turning to **FIGS. 1C-1F**, **2A**, and **2B**, additional features and components of the fluid delivery system **10**, including the upper surface **103**, the MPDS **200**, a container access system **600**, and a single-patient fluid path set **700** (hereinafter SPDS), will be discussed.

[0077] As shown in **FIG. 1C**, the upper surface **103** generally defines wells and recesses or troughs into which various components of the MPDS **200** are situated. Specifically, a first recess or trough **107** accommodates a first tubing section **204** of the MPDS **200** and a tubing holder **150** for holding the tubing section **204** and preventing it from getting kinked or tangled with, for example, the SPDS **700**. The first tubing section **204** may also include the tubing length

27 that is placed within the peristaltic pump **22** and is in fluid connection with the medical fluid source **23**.

[0078] The first trough **107** leads into a second recess or trough **113** that accommodates a second pumping mechanism **180**, such as a peristaltic pump, and a T-connector **205** (including check valves **214**, **215**) of the MPDS **200**. As shown in **FIG. 1**C, the second trough **113** also leads to a first well **111** that accommodates a container access system **600** and a radiopharmaceutical vial or container **902** disposed in a container shield or PIG **554** (discussed in more detail below) and to a second well **121** that accommodates a dose calibrator or ionization chamber **160** for the fluid delivery system **10**. As shown in **FIGS. 1D** and **3F**, the ionization chamber **160** preferably accommodates a coil assembly **400** of the MPDS **200** (discussed in more detail below). Although the system is described as including an ionization chamber **160** for detecting activity of the radiopharmaceutical fluid, this is not to be considered as limiting the scope of this disclosure as any suitable activity detector may be used such as, but not limited to, a CZT crystal detector, a Geiger-Müller counter, a scintillating counter, and a parabolic detector, such as the parabolic sensor disclosed in United States Patent Application No. 12/664,653, which is hereby incorporated by reference.

[0079] A third recess or trough **125** extends from the second well **121** to a third well **127** and further along the surface **103** of the fluid delivery system **10**. The trough **125** accommodates a T-connector **222** of the MPDS **200**, two pinch valves **170**, **172**, an air detector **174**, and a mount or retainer **176** for holding the connector end **228** of the MPDS **200**. The pinch valves **170, 172** may be powered and controlled by the fluid delivery system **10**, but alternately could be manually-operated. In another alternate embodiment, the pinch valves **170**, **172** and the T-connector **222** of the MPDS **200** may be replaced with a manual or automated 3-way stopcock.

[0080] The third well **127** accommodates a waste receptacle or bag **224** for receiving medical fluid and/or pharmaceutical that is discarded during, for example, a priming procedure (discussed in more detail below) to prepare the system **10** for an injection procedure.

[0081] As shown in **FIG. 1C**, the SPDS **700** includes a length of tubing (preferably coiled, as shown) having a first end **702** that is attachable to the connector end **228** of the MPDS **200**, and a patient end **704** having a luer connector that is attachable to, for example, a catheter (not shown) placed in a venous structure of a patient. As discussed in more detail below, the MPDS **200** may be used for multiple patients but the SPDS **700** is intended to be used on a per-patient basis and discarded after use with a single patient to prevent, for example, cross-contamination between patients.

[0082] As can be appreciated after reviewing **FIG. 1A-1E**, the secondary handle **21** of lid **20** overlies the tubing holder **150** and the mount **176** when the lid **20** and handle **21** are closed to cover the MPDS **200**. The secondary handle **21** may be flipped open (from the closed position as shown in **FIG. 1A**) without retracting the cover **20** to allow an operator to connect the SPDS **700** to the MPDS **200** (as discussed in more detail below). As best shown in **FIG. 1C**, the SPDS **700** may be placed under the secondary handle **21** when it is closed.

[0083] The fluid delivery system **10** further includes the system controller **5** (*see* **FIGS. 1D** and **1E**) in communication with the various components thereof, including the GUI **15**, the pumps **22**, **180**, the dose calibrator or ionization chamber **160**, the interrupt button **25**, the air detector **174**, the printer **1032**, and motors **30**, **31** (*see* **FIG. 3F**) for pinch valves **170**, **172**, respectively, for controlling the operation of the system **10**. The system controller **5** may be embodied as the computer **1000** as discussed in greater detail hereinabove with reference to **FIG. 1F**.

[0084] As can be appreciated, the wells and troughs formed in the upper surface **103** can be sized, configured, or arranged as suitable for the length, design, or configuration of the MPDS **200** or other components thereof, including the radiopharmaceutical container **902**, container shield **554**, container access system **600**, ionization chamber **160**, waste receptacle **224**, etc.

[0085] It should be understood that **FIG. 1C** in no way is intended to convey dimensions or relative dimensions of the aforementioned recessed portions or MPDS components; instead, **FIG. 1C** conveys general positional relationships of such recessed portions with respect to one another.

[0086] It should further be understood and appreciated that the recessed portions shown and described with respect to **FIG. 1C** are encased throughout with suitable radioactive shielding to further minimize exposure to an operator.

[0087] Turning now to **FIGS. 2A** and **2B**, an embodiment of the MPDS **200** and components thereof will be discussed. In addition, specific details of the coil assembly **400** employed in the MPDS **200** are shown and described with respect to **FIGS. 3A-3F** and **FIG. 1D**.

[0088] By way of a general overview, the MPDS **200** in accordance with at least one embodiment allows for FDG (or other radiopharmaceutical) to be drawn from a bulk radiopharmaceutical container **902** and placed into a coil assembly **400** that allows an ionization chamber **160** to measure the amount of activity in the coil assembly **400**. Once the system prepares a dose having the desired activity level, the fluid delivery system **10** will deliver the FDG dose to the patient (through the SPDS **700**).

[0089] Generally, the MPDS **200** can be considered in terms of four components: (1) a medical fluid or saline component; (2) an FDG or pharmaceutical component; (3) a coil assembly component; and (4) a waste component. The saline component draws saline out of a bulk source **23** (*e.g.*, via peristaltic pump **22**). This is then used to prime the MPDS **200** (*i.e.*, remove air therefrom), position FDG in the coil assembly **400** in the ionization chamber **160**, and then deliver the dose to the patient.

[0090] The FDG component serves to draw FDG out of bulk radiopharmaceutical container **902** (*e.g.*, via peristaltic pump **180**) and place the same into the fluid path to the ionization chamber **160**.

[0091] The coil assembly component is employed to position the radiopharmaceutical to allow its radioactivity level to be optimally measured by the ionization chamber **160**. Through the arrangement of the coil assembly **400** (as discussed in more detail below), the radiopharmaceutical can be optimally oriented and located within the "linear region" of the ionization chamber **160** to more accurately measure its activity level and prepare an optimal dose for injection into a patient.

[0092] The waste component holds the saline fluid and/or radiopharmaceutical that are discarded during the prime and dose preparation procedures, which are conducted to prepare the fluid path and the pharmaceutical dose for injection into a patient.

[0093] **FIG. 2A** schematically illustrates the MPDS **200** according to an embodiment. The MPDS **200** shown in **FIG. 2A** may be pre-connected as shown and may originally be stored in a sterile packet or container for use in an injector apparatus, such as fluid delivery system **10**, when desired. For a non-restrictive and illustrative appreciation of a manner in which MPDS **200** can be incorporated in an injector apparatus, simultaneous reference may be made to **FIGS. 1A-1E** and **2B** (and the discussion thereof hereinabove).

[0094] Primary components of MPDS **200** include, as shown: a spike **202** for connecting the MPDS **200** to the medical fluid or saline source **23**; a vented cannula **208** for connecting with a source of FDG or other radiopharmaceutical; a coil assembly **400**; a T-connector **205** with check valves **214**, **215** for fluidly connecting the saline source **23**, the radiopharmaceutical source, and the coil assembly **400**; a waste bag **224**; a connector end **228**; and a T-connector **222** for fluidly connecting the coil assembly **400**, the waste bag **224**, and the connector end **228**.

[0095] In general, MPDS **200** and fluid delivery system **10** are configured for priming (*i.e.*, purging air from) the MPDS **200**, delivering pharmaceutical (*e.g.*, FDG) to a patient, and providing a saline flush, while minimizing or eliminating exposure of administering or operating personnel to the detrimental effects of the pharmaceutical and minimizing or eliminating creation of contaminated waste. Moreover, MPDS **200** and other elements disclosed herein also facilitate safe delivery of the pharmaceutical to multiple destinations (for example, dose delivery to a series of patients).

[0096] A T-connector **205** and check valves **214**, **215** accommodate a first tubing section **204** that is in fluid connection with spike **202** and a second tubing section **210** in fluid connection with cannula **208**. The check valves **214**, **215** may be integrally formed with the T-connector **205** or may be separate components, or they could be combined into a single dual check valve. The check valves **214**, **215** prevent saline from being pumped by peristaltic pump **22** into second tubing section **210** and the pharmaceutical from being pumped by peristaltic pump **180** into the first tubing section **204**.

[0097] A third tubing section **216** leads to coil assembly **400** (including tube coil **444**), and a fourth tubing section **220** leads from the coil assembly **400** to the T-connector **222**. As described below, the tube coil **444** is formed from a tubing section **217** that has dimensions different from those of the third tubing section **216** and the fourth tubing section **220**.

[0098] A fifth tubing section **226** leads from the T-connector **222** to the waste receptacle **224** and a sixth tubing section **230** leads from the T-connector **222** to the connector end **228**. As shown above in **FIG. 1C**, the connector end **228** mates with the first end **702** of the SPDS **700** for delivery of a pharmaceutical to a patient.

[0099] The connector end **228** may be a swabable luer valve (Part No. 245204024 provided by Halkey-Roberts Corporation of St. Petersburg, Fla.) that is biased to close or seal off the connector end **228** of the MPDS **200** when the SPDS **700** is not connected thereto. The swabable luer valve prevents the MPDS **200** from being contaminated and allows an operator to swab or clean (by, for example, an alcohol wipe) the connector end **228** prior to connecting an SPDS **700** thereto. Alternately, however, the connector end **228** may be a standard luer connector as known in the art.

[0100] As schematically shown in **FIG. 2A**, the tubing length **27** of the first tubing section **204** can be placed within pump **22** (indicated by dotted lines) to pump saline or other medical fluid from source **23** and a portion of the second tubing section **210** can be placed within pump **180** (indicated by dotted lines) to pump a radiopharmaceutical from a radiopharmaceutical source.

[0101] Absolute and relative dimensions of the components shown in **FIG. 2A**, including tubing, may be chosen to best suit the applications at hand. The first tubing section **204** may be approximately 56.75 inches in length, has an outer diameter (OD) of approximately 0.188 inches and an inner diameter (ID) of approximately 0.062 inches, and has a 45 durometer. The second tubing section **210** may be approximately 8.75 inches in length and is formed of microbore tubing having an OD of about 0.094 inches and an ID of about 0.032 inches and a 45 durometer. The third tubing section **216** may be approximately 15 inches in length, has an OD of approximately 0.163 inches and an ID of approximately 0.062 inches, and has a 60 durometer. The fourth tubing section **220** may be approximately 12 inches in length, has an OD of approximately 0.163 inches and an ID of approximately 0.062 inches, and has a 60 durometer. The fifth tubing section **226** and the sixth tubing section **230** may each be approximately 5 inches in length, have an OD of approximately 0.163 inches and an ID of approximately 0.062 inches, and have a 60 durometer. The tubing in tube coil **444** may be approximately 41 inches in length, has an OD of about 0.218 inches and an ID of about 0.156 inches and an 80 durometer. All of these dimensions are provided for exemplary purposes only and are not to be construed as limiting the present disclosure.

[0102] The microbore tubing of second tubing section **210** may be formed of, for example, silicone, C-Flex, or silicone-like PVC material. Essentially, the use of microbore tubing in second tubing section **210** improves volume accuracy and thereby improves measured activity accuracy (*i.e.*, of pharmaceutical delivered to the patient) and reduces radiopharmaceutical waste.

[0103] By way of tubing material for the other tubing sections **204**, **216**, **220**, **226**, **230** and tube coil **444**, essentially any suitable polymeric material, including standard PVC or pump tubing, may be employed.

[0104] Referring again to **FIGS. 1A-2B**, the placement of the MPDS **200** in the fluid delivery system **10** and the connection of the SPDS **700** will now be discussed. To set up the system **10** at, for example, the beginning of the day, the operator lifts the secondary handle **21**, grasps the primary handle and latch release **1**, and retracts the lid **20** to reveal the upper surface

103 of the system **10**. If a used MPDS **200** is present in the system **10**, the operator will remove and discard it.

[0105] A new MPDS **200** may be removed from its (typically sterile) packaging and placed in the system **10** as shown in **FIG. 1C**. This includes placing the waste receptacle **224** into well **127**, placing coil assembly **400** into ionization chamber **160**, placing second tubing section **210** into operative connection with pump **180**, placing the tubing length **27** of the first tubing section **204** into operative connection with pump **22** and tubing holder **150**, placing vented cannula **208** into fluid connection with radiopharmaceutical source or container **902** located in well **111**, placing fifth tubing section **226** in operative connection with pinch valve **170**, and placing sixth tubing section **230** in operative connection with pinch valve **172**, air detector **174**, and mount **176**. A saline source **23** may be hung on a hook **6** (*see* **FIGS. 1A**, **1B**, and **2B**) or otherwise mounted on fluid delivery system **10**, and spike **202** is inserted into port **7** (*see* **FIGS. 1A**, **1B**, and **2B**) of source **23** to fluidly connect the MPDS **200** to the source **23**. Of course, this installation procedure does not need to be completed in the order described above, but may be completed in any suitable order consistent with the description or drawings hereof.

[0106] After the MPDS **200** is installed and primed (as discussed below), the first end **702** of the SPDS **700** is connected to the connector end **228** of the MPDS **200** and the SPDS **700** is primed to provide a wet connection at the patient end **704** of the SPDS **700**, which is then connected to a catheter (not shown) located in a patient. The SPDS **700** may be a coiled tubing formed of standard PVC, approximately 60 inches in length and having an OD of approximately 0.100 inches and an ID of approximately 0.060 inches and a 90 durometer.

[0107] As shown in **FIGS. 2A** and **2B**, the MPDS **200** includes a coil assembly **400**. In the broadest sense, coil assembly **400** may include a section of tubing (including portions of third and fourth tubing sections **216**, **220**) that is simply gathered (in a coiled or an uncoiled, amorphous fashion) and placed inside ionization chamber **160**.

[0108] As shown in **FIGS. 3A-3F**, however, a more desirable embodiment of coil assembly **400** includes a (preferably thermoformed) core element or structure **446** that is preferably configured for allowing tubing section **217** to be wrapped thereupon and to assume the coiled tube section indicated at **444**. As such, the coiled tube section or tube coil **444** may be formed on the core element **446** to facilitate optimal positioning of the tube coil **444** within the ionization chamber **160**.

[0109] To facilitate positioning of the tube coil **444**, the core element **446** may include a tube channel **410** defined by shoulders **412**, **414** (*see* **FIG. 3B**) that retain tube coil **444** therebetween to hold the tube coil **444** in position and to prevent tube kinking. Further, the upper surface **420** of core element **446** defines an inlet channel or groove **422** and an outlet channel or groove **424** to accommodate third tubing section **216** and fourth tubing section **220**, respectively.

[0110] The core element **446** preferably may be self-centering when inserted into the sleeve **162** of the ionization chamber **160** of the fluid delivery system **10** to thereby facilitate optimal performance (*see* **FIG. 3F**). This may be achieved either through structural features of the coil assembly **400**, the structure of core element **446** itself, or a combination thereof when used with the sleeve **162** of the ionization chamber **160**.

[0111] As best shown in **FIG. 3E**, the core element **446** may be formed by folding two elements (**450**, **452**) together along an integral hinge **455**. Suitable form-locking mechanisms can be molded onto the core element **446** to facilitate clasping of the elements **450**, **452** together.

[0112] **FIGS. 1C**, **1D**, and **3F** show coil assembly **400** positioned concentrically in the sleeve **162** of the ionization chamber **160**. The core element **446** and the tube coil **444** are sized and dimensioned so that the coil assembly **400** is optimally positioned within the "linear region" of the ionization chamber **160** so that the ionization chamber **160** can accurately determine the activity level of one or more volumes of radiopharmaceutical that is located within the tube coil **444**. The "linear region" of an ionization chamber is the region in which activity level measurements are repeatable and predictable. For an exemplary ionization chamber (Model IK-102 Short Ionization Chamber provided by Veenstra Instruments) used in system **10**, the "linear region" is located within a window of 5 mm to 65 mm measured from the base or bottom wall **160a** of the ionization chamber **160** (*see* **FIG. 3F**).

[0113] The tube coil **444** may be comprised of approximately 7 turns (*see* **FIGS. 3A** and **3B**) formed from a length of tubing that is approximately 41.0 inches. As shown in **FIG. 3B**, the height **h** of the tube coil **444** is approximately 1.53 inches and the diameter **w** of the tube coil **444** is approximately 1.95 inches. The tube coil **444** is preferably formed from a tube having an OD of 0.218 inches and an ID of 0.156 inches. Further, based on the length and ID of the tubing, the tube coil **444** preferably has a volume capacity of approximately 12.5 ml.

[0114] As discussed heretofore, a source, container, or container **902** (*see* **FIG. 4C**) of a pharmaceutical or radiopharmaceutical is placed into the fluid delivery system **10** (*e.g.*, in well **111** formed in upper surface **103**) to prepare and perform an injection procedure. A radiopharmaceutical container or container **902** is typically placed in a conventional container shield or PIG **554** for transport by personnel.

[0115] Turning now to **FIGS. 4A** and **4B**, an exemplary embodiment of a container shield carrying device or system **500** and a container access system **600** are shown. Container access system **600** is removably disposed within well **111** of fluid delivery system **10** and operates to hold container shield **554** and to access the contents of the container **902** contained therein.

[0116] As best shown in **FIG. 4A**, the container shield **554** (containing a radiopharmaceutical container **902**) includes a flange **504** formed along a top end thereof and a removable septum cap **562** that is securely and removably engaged with the container shield **554** (*e.g.*, via threading) to allow insertion and removal of the container **902** therefrom.

[0117] As shown in **FIGS. 4A** and **4B**, the carrying system **500** includes a collar unit **502** that removably engages the flange **504** formed on the container shield **554**. The collar **502** may be formed in two pieces **506, 508** that are pivotally connected together (*e.g.*, at one end thereof) to allow the collar **502** to engage and disengage the flange **504**.

[0118] The collar **502** includes two elongated slots **510** formed in a top surface therein. As best shown in **FIG. 4B**, the slots **510** each include a pin **512** disposed therein and extending between two opposing walls **514** thereof.

[0119] The carrying system **500** further includes a handle unit **520** that engages with the collar unit **502** and the septum cap **562** to allow the container shield **554** (and container **902**) to be carried and installed in the fluid delivery system **10**. The handle unit **520** includes a handle **556** that is rigidly connected to a generally U-shaped cross piece **564a**. The cross piece **564a** defines two downwardly extending arms **530** having slots **532** formed thereon.

[0120] The slots **532** each form a slight hook on the ends thereof and are adapted to engage and retain a second cross piece **564b** that supports a plunger **566** having a generally frustoconical shape that mates with a generally frustoconical recess of the septum cap **562** (*see* **FIG. 4B**).

[0121] The second cross piece **564b** is also generally U-shaped and defines two downwardly extending arms **534** having hooks **536** formed therein. The open ends of the hooks **536** are formed on opposite ends of the arms **534** and are adapted to accept and retain the pins **512** in slots **510** of collar **502**. The slots **510** are sized to provide sufficient clearance for the arms **534** to be inserted thereinto (in a downward direction) and for the hooks **536** to engage pins **512** (through rotation of handle **556**).

[0122] The plunger **566** is connected to the second cross piece **564b** by means of a connector (such as a screw **540**) and a spring **538**. The plunger **566** is biased by spring **538** to ensure a tight fit between the plunger **566** and the septum cap **562**.

[0123] To engage and carry the container shield **554**, the collar **502** is connected to the flange **504** of the container shield **554** as described above. The handle unit **520** is then moved into proximity to the container shield **554** (by an operator grasping the handle **556** and moving the unit **520** into position) and the arms **534** are lowered into the slots **510** of the collar **502**. At substantially the same time, the plunger **566** is engaged with the septum cap **562**, with the spring **538** ensuring a tight fit between the two. The operator then turns the handle unit **520** in a clockwise direction (*see* arrow **AA** in **FIG. 4A**) to seat the pins **512** in slots **510** into the hooks **536** of arms **534**.

[0124] The operator then lifts the combined container shield **554** and container carrying system **500** (by moving the handle unit **520** in an upward direction) and transports it to, for example, the fluid delivery system **10**. The operator then lowers the container shield **554** into the container access system **600** disposed in well **111** (*see* **FIG. 4A**) and rotates the handle unit **520** in a counter-clockwise direction to disengage the hooks **536** from the pins **512**. The operator then lifts the handle **556** in an upward direction to remove the arms **534** from the slots **510** and the plunger **566** from the septum cap **562**, thereby leaving the container shield **554** (with septum cap **562** and collar **502**) in container access system **600** in well **111** (*see* **FIG. 4B**).

[0125] In an exemplary embodiment, the plunger **566** includes radioactive shielding (such as lead) to shield the operator from radiation that would otherwise leak through or be emitted from the septum of the septum cap **562**. Together with the container shield **554** and the septum cap **562**, the plunger **566** of the container carrying system **500** shields the operator from the radiation emitted by the radiopharmaceutical and prevents unnecessary radiation exposure. Further, by extending the handle **556** from the container shield **554**, the distance between the two functions to lessen any possible radiation exposure to the operator.

[0126] As discussed above with respect to **FIGS. 4A-4B**, the fluid delivery system **10** includes a container access system **600** that is removably disposed within well **111** of fluid delivery system **10** and is adapted to hold container shield **554** and to provide access to the contents of the container **902** within container shield **554**.

[0127] Because containers (such as container **902** described herein) typically come in various sizes, such as 10 ml, 15 ml, 20 ml, and 30 ml, the fluid delivery system **10** is intended to accommodate various container sizes. To do so, the fluid delivery system **10** may include one or more container shields and container access systems. Thus, depending on the size of the container used at a clinical site or for a particular procedure, an operator of the fluid delivery system **10** can select the appropriate container shield and container access system and place it in the well **111** of the fluid delivery system to enable a fluid injection procedure.

[0128] Referring again to **FIGS. 1C** and **2A**, once the MPDS **200** is installed in the fluid delivery system **10**, the spike **202** is placed in fluid connection with the saline source **23** and the cannula **208** is inserted into the container **902** and placed in fluid connection with the pharmaceutical therein, and an injection procedure can be implemented.

[0129] An exemplary injection procedure is discussed hereinafter with reference to **FIGS. 5-11**. Many variations on the injection procedure may be implemented within the scope of this disclosure. For instance, the container **902** of radiopharmaceutical may be any suitable multi-dose container configuration. This multi-dose container configuration may include a dose of radiopharmaceutical for a plurality of patients provided in any suitable container for storing radiopharmaceuticals. The multi-dose container configuration may include a dose of radiopharmaceutical for a plurality of patients provided in a syringe. In addition, the multi-dose container configuration may be a plurality of containers suitable for storing radiopharmaceuticals where each container stores a certain amount of a radiopharmaceutical composition. A micro-fluidic device or other radiopharmaceutical generation technology capable of real-time generation of a certain amount of a radiopharmaceutical may also be utilized as the multi-dose container configuration. Furthermore, the multi-dose container configuration may be a plurality of suitable containers each holding a different radiopharmaceutical fluid. The multi-dose container configuration may also be a pre-loaded amount of radiopharmaceutical fluid in a coil of tubing of an administration set. Alternatively, a single dose container may also be utilized. Accordingly, the injection procedure described hereinafter is not to be construed as limiting this disclosure and while a container **902** is described hereinafter, this is not to be construed as limiting as any variety of radiopharmaceutical container may be used. Furthermore, the following procedure describes the use of a first volume, bolus, or slug **800** and a second volume, bolus, or slug **802** of radiopharmaceutical delivered to a patient. This also is not to be construed as limiting injection processes to the injection procedure disclosed herein as any suitable number of slugs may be delivered to the patient.

[0130] An exemplary injection procedure can generally be divided into five phases. In an initialization phase **910**, the device is brought into a well-defined initial state. In a calibration phase **920**, steps are performed for calibrating the radioactivity in container **902**. In a delivery phase **930**, the radiopharmaceutical is delivered to the destination. In a step **940**, it is decided whether another injection shall be performed. If yes, operation will continue again with the calibration phase **920**. If no, a shutdown phase **950** will follow.

[0131] Before starting the operation, the operator will have to determine two quantities: the desired activity **Ar** to be injected to the patient; and the estimated concentration of activity in the container (activity per unit of volume, *e.g.*, expressed in MBq/ml) **Cv**. These data are provided to the system controller **5**. Operation then starts with the initialization period **910**.

[0132] The initialization period **910** comprises the following steps:

[0133] Step **911** (Initial filling of radiopharmaceutical to point **C**): In a first step, the complete tubing is filled with saline, thereby excluding air from the tubing system. For this, T-connector **205**, check valve **214**, and check valve **215** (hereinafter valve **V1**) are placed in a state that connects ports "**c**" and "**b**", while T-connector **222**, pinch valve **170**, and pinch valve **172** (hereinafter valve **V2**) are placed in positions "**d**" and "**e**". Pump **22** flushes saline up to point **B** (*see* **FIG. 5**). Then the tubing section **210** is inserted into a container containing saline. Valve **V1** is brought into a state that connects ports "**a**" and "**b**", while valve **V2** still connects "**d**" and "**e**". Pump **180** now flushes saline until the tubing is completely filled with saline from point **A** (*see* **FIG. 5**) to the destination beyond valve **V2**, and air is thus completely purged from the system. The tubing section **210** is then inserted into the container **902** containing the radiopharmaceutical. Valve **V1** is brought into a state that connects ports "**a**" and "**b**", while valve **V2** connects ports "**d**" and "**f**". Pump **180** is operated to pump radiopharmaceutical in container **902** from inlet point **A** and past point **B** at valve **V1** to some point **C** in the third tubing section **216**. The volume of radiopharmaceutical between points **B** and **C** in the third tubing section **216** does not need to be known exactly; it suffices to ensure that the section of tubing from **A** to **B** is filled completely with radiopharmaceutical, and that the activity in the volume between **B** and **C** is not larger than the desired end activity **Ar**. The situation at the end of step **911** is illustrated in **FIG. 5**, where the volume of radiopharmaceutical between points **B** and **C** is designated by reference number **800**.

[0134] Step **912** (Flushing of offset volume to dose calibrator): Valve **V1** is now switched to a state in which it connects ports "**c**" and "**b**". Pump **22** is operated to pump saline from the source **23** towards valve **V1**. The volume to be pumped is slightly larger than the volume in the third tubing section **216**, *i.e.*, slightly larger than the volume between points **B** and **D**. This volume need not be known exactly. Thereby, the "offset volume" **800** is moved into the coil section **444**. The situation at the end of this step is illustrated in **FIG. 6**.

[0135] Step **913** (Initial determination of activity): The activity of volume **800** in the coil section **444** is measured by the ionization chamber **160** (measurement **M1**). This activity will be called the "offset activity" **A1**. The system controller **5** now calculates the missing activity **Am** required to reach a total activity of **Ar** as shown in Equation 1 hereinafter:

$$Am = Ar - A1 \qquad \text{(Equation 1)}$$

[0136] This is illustrated in **FIG. 11** in the leftmost column. From this and the estimated concentration of activity in the container, **Cv**, the estimated missing volume **Va1** still to be delivered is calculated as shown in Equation 2 hereinafter:

$$Va1 = \frac{Am}{Cv} \qquad \text{(Equation 2)}$$

[0137] It is important to note that this calculation is still based on the estimate of the concentration of activity in the container, and the result cannot be expected to be highly accurate. It is further important to note that no knowledge about the offset volume **800** is required in this calculation. In addition, ionization chamber **160** may be any suitable activity detector. Such detectors include standard Geiger-Müller counters, scintillating counters, an ionization chamber, a cadmium zinc telluride (CZT) crystal detector, etc., which should be calibrated to yield a sufficiently precise measure of the actual activity in the coil section **444**. Desirably, the activity detector is an ionization chamber.

[0138] This step concludes initialization **910**. In the following calibration phase **920**, the following steps are performed:

[0139] Step **921** (Filling of radiopharmaceutical to point **C**): Valve **V1** is switched to a state in which it connects ports "**a**" and "**b**". Pump **180** is operated to pump a volume **Vc'** through valve **V1**, filling the fill-in section to point **C**. This situation is illustrated in **FIG. 7**, where this volume is designated by reference number **802**. Volume **Vc'** is chosen to be approximately half of the estimated missing volume **Va1** as set forth hereinafter in Equation 3:

$$Vc' \approx \frac{Va1}{2} \qquad \text{(Equation 3)}$$

[0140] It is important to note that volume **Vc'** is known exactly in system internal units. The exact nature of these units depends on the type of pump used, *e.g.*, the units could be pump revolutions, pump cycles, etc. If a volume flow meter is placed in-line with the pump, the units provided by the flow meter can be used as system internal units. Depending on the type of pump and the type of tubing, the resolution of volume in this step can be very small, and even small volumes can be delivered accurately. In addition, the predictive flow rate determination system as discussed in greater detail hereinafter may be used as system internal units.

[0141] Step **922** (Flushing of volume **Vc'** to the ionization chamber **160**): Valve **V1** is switched to connect ports "**c**" and "**b**". Pump **22** is operated to pump slightly more than the volume between points **B** and **D** of saline through valve **V1**. Thereby, volume **802**, which is equal to **Vc'**, of radiopharmaceutical is moved into the coil section **444**. The situation at the end of this step is illustrated in **FIG. 8**.

[0142] Step **923** (Calibration of activity): The activity in the coil section **444** is measured by the ionization chamber (measurement **M2**). This activity level will be called **A2**. It corresponds to the sum of the offset activity **A1** and the activity of the volume **Vc'**, which will be called the "reference activity" **Ac'**. This is illustrated in the second column of **FIG. 11**. Now the activity concentration in the container in system internal units, **Cs**, is calculated as set forth hereinafter in Equation 4:

$$Cs = \frac{Ac'}{Vc'} = \frac{(A2 - A1)}{Vc'} \quad \text{(Equation 4)}$$

[0143] The system is now calibrated in system internal units. Thereafter the volume **Vc''** is determined. The activity **Ac''** still required to reach a total activity of **Ar** is determined as set forth in Equation 5:

$$Ac'' = Ar - A2 \qquad \text{(Equation 5)}$$

[0144] From this, the volume **Vc''** still to be delivered is calculated in system internal units as set forth in Equation 6 hereinafter:

$$Vc'' = \frac{Ac''}{Cs} = \frac{(Ar - A2)}{Cs} = \frac{(Ar - A2)}{(A2 - A1)Vc'} \qquad \text{(Equation 6)}$$

[0145] This completes the calibration phase **920**. In the following delivery phase **930**, the following steps are performed:

[0146] Step **931** (Filling of radiopharmaceutical to point **C"**): Valve **V1** is switched to a state in which it connects ports "**a**" and "**b**". Pump **180** is operated to pump the volume **Vc"** through valve **V1**, filling third tubing section **216** to point **C"**. This situation is illustrated in **FIG. 9**, where this volume is designated by reference number **804**.

[0147] Step **932** (Flushing of volume **Vc"** to ionization chamber **160**): Valve **V1** is switched to connect ports "**c**" and "**b**". Pump **22** is operated to pump slightly more than the volume between points **B** and **D** of saline through valve **V1**. Thereby, volume **804**, which is equal to **Vc"**, of radiopharmaceutical is moved into the coil section **444**. Alternatively, the total activity in the coil section **444** is now measured (optional measurement **M3**, *see* right column of **FIG. 11**). It should correspond exactly to the total desired activity **Ar**, provided that the volume of the coil section **444** is large enough to hold all three volumes **800**, **802**, and **804** within this section. The latter condition can always be fulfilled if the volume of the coil section **444** is at least five times the volume of the third tubing section **216**. If a significant discrepancy is detected, the system is stopped.

[0148] Step **933** (Delivery to injection catheter): Valve **V2** is switched to connect ports "**d**" and "**e**". Pump **22** is operated to pump at least the volume of the coil section **444**, plus the volume of the tubing from the coil section **444** to the injection catheter and of the injection catheter itself, of saline through valve **V1**. Thereby, all liquid in the coil section **444** is flushed to the patient, and exactly the required dose of radioactivity is delivered to the patient.

[0149] This completes the delivery phase **930**. If another injection of the same radiopharmaceutical (to the same or a different patient) is required, operation continues by repeating the calibration and delivery phases **920** and **930**. Otherwise, operation stops by a suitable shutdown procedure, which may involve additional cycles of flushing with saline.

[0150] When repeating calibration phase **920**, no additional initialization as in phase **910** is necessary, since the coil section **444** has been flushed with saline, and the radiopharmaceutical extends exactly to point **B**. No activity is present in the coil section **444**. Therefore, in the above calculations, **A1** can be set to zero in this case, and **Am** is set to **Ar**. No further changes are necessary. The three-phase procedure with phases **910**, **920**, and **930** now simplifies to a two-phase procedure with phases **920** and **930** only.

[0151] It will be appreciated that the various embodiments of the disclosed device and the associated methods of operation provide a number of inherent safety features. Specifically, there is a high degree of redundancy in the operation of the device, such that even in case of failure of one component, such as a pump or a valve, it is impossible that more than the desired dose will be delivered to the patient. Specifically, by its design the system will only allow the dose present within the coil section **444** to be delivered to the patient. This is because during the actual delivery of the radiopharmaceutical, there is no connection between the container **902** and the fluid delivery line. The discrete nature of the sequential measurements of activity within the coil section **444** is another feature which increases safety. In step **932**, the activity in the coil section **444** is actually known beforehand, and measurement **M3** just serves to confirm that the right amount of activity is present in the coil section **444**. If significant discrepancies are detected between the expected result and the actual measurement, operation will be stopped immediately, and an alarm will be given.

[0152] It will also be appreciated that, in normal operation, no radiopharmaceutical will enter the waste reservoir **224**. Thus, generation of radioactive waste is minimized.

[0153] The disclosure now turns to particular embodiments, as illustrated in **FIGS. 12-23**, that could conceivably be employed in programming and operating a fluid delivery system as broadly contemplated herein.

[0154] With reference to **FIGS. 12-18**, screen captures of a program used for determining a multi-dose container configuration that meets a planned patient schedule with a sufficient margin to account for reasonable schedule variation while minimizing multi-dose container cost are illustrated. Upon initiating the multi-dose container planning software on a computer, such as computer **1044**, a clinician will be presented with a screen **1300** as illustrated in **FIG. 12**. A schedule **1302** is then provided as input to the multi-dose container planning. This schedule **1302** represents the patient load expected to be serviced by a multi-dose radiopharmaceutical container, such as container **902**. The schedule **1302** may include the time of an injection procedure (entered into the column **1304** labeled time) for each patient, and an activity (entered in the column **1306** labeled activity) removed from the multi-dose container **902** of radiopharmaceutical for each patient.

[0155] The schedule **1302** may be entered by: manually entering time and activity for each patient into the computer **1044** using an input device, such as a keyboard; retrieving the time and activity for each patient from a memory device associated with the computer; or retrieving the time and activity for each patient from a remotely located patient device over a network. While the a computer may be used to enter the schedule **1302**, this is not to be construed as limiting the present disclosure as any suitable computing device, such as, but not limited to, a cellular phone, a Personal Digital Assistant (PDA), or the control system **5** of the injector, may be utilized to enter the schedule **1302**. In addition, while schedule **1302** has been described hereinabove as the schedule of injection procedures for a day. This is not to be construed as limiting the present disclosure as any period of time may be used such as a week, a month, or a year.

[0156] The Time of Prime block **1308** allows the clinician to enter a time, preferably immediately before the first scheduled patient, at which the clinician will be preparing the fluid delivery system **10** for use as described hereinabove. At this time, a small amount of activity may be removed from the container **902** to validate the container **902** contents or for the automatic injection system to remove air from the MPDS **200** and the SPDS **700**. The activity associated with this action is not provided by the clinician.

[0157] Once the clinician has entered the schedule **1302** and entered the time of priming using the Time of Prime block **1308**, the clinician presses the update chart button **1310**. With specific reference to **FIG. 13**, the update chart button **1310** allows the processor of the computer **1044** to run an algorithm to determine various valid container configurations and plots these container configurations as blocks **1312** on graph **1314**. The x-axis of the graph may be volume of the container **902** and the y-axis may be activity of the radiopharmaceutical fluid within the container **902**. For instance, point **1316** would represent a container having a volume of 20 mL and containing a radiopharmaceutical fluid having an activity level of 700 mCi.

[0158] The system determines the correct placement of blocks **1312** on graph **1314** as follows. A radiopharmaceutical container order is typically specified with four parameters: (1) radiopharmaceutical/radioisotope; (2) assay time; (3) assay volume; and (4) assay activity. The radiopharmaceutical is generally set by the application (*e.g.*, FDG for PET). The assay time is the time at which the container contains the specified assay activity. The assay time is generally prescribed based on normal delivery schedules and can be defined by the clinician. The unknown factors that must be determined are the assay volume and assay activity. When the system determines these factors, all available solutions are plotted on graph **1314** as blocks **1312** as shown in **FIG. 13**.

[0159] These values are determined by calculating all container volume and activity pairs at a specified assay time that can meet the given schedule taking into account injection system constraints to produce blocks **1312** on graph **1314**.

[0160] The following system constraints are considered in the model: (1) Prime Volume: volume removed from the container to complete system setup operations that cannot be used for patient dosing; (2) Minimum Dose Volume **1316**: the minimum volume of radiopharmaceutical fluid in a single patient dose; (3) Maximum Dose Volume **1318**: the maximum volume of radiopharmaceutical fluid in a single patient dose; (4) Unextractable Volume **1320**: volume of radiopharmaceutical fluid the system is unable to remove from the container; (5) Maximum Container Activity **1322**: maximum activity in a container that can be inserted in the system (separate values may be used for priming **1322a** and for patient dosing **1322b**); (6) Maximum Container Concentration **1324**: maximum activity concentration that is expected from the radiopharmaceutical fluid; (7) Maximum Container Volume **1326**: the maximum volume the container can reasonably hold; and (8) Decay Constant: radioactive decay value for the radiopharmaceutical of interest. These values can be adjusted and changed by accessing the options menu **1328** from the tools pull-down menu **1330** as shown in **FIG. 18**.

[0161] For the purposes of making calculations tenable, the clinician can provide the system with a prescribed Volume Step **1332** (*e.g.*, 0.5 ml) and Activity Step **1334** (*e.g.*, 10 mCi) that provide reasonable precision with respect to the overall solution space. These values can also be adjusted and changed by accessing the options menu **1328** from the tools pull-down menu **1330** as shown in **FIG. 19**.

[0162] Based on the constraints listed above, it should be clear that only container volumes in the range from Unextractable Volume **1320** to Maximum Container Volume **1326** in increments of Volume Step **1332** need be considered, and container activities in the range from zero to Maximum Container Activity at Priming **1322a**, referenced to the given assay time, in increments of Activity Step **1334** need be considered by the system.

[0163] Given this operating range constraint, the rules for determining the container activity/container volume pairs as represented by blocks **1312** in **FIG. 13** that meet the schedule are as follows:

[0164] First, Starting Concentration must be determined as Container Activity divided by Container Volume, referenced by the container assay time. Thereafter, first patient activity is determined as follows: calculating activity remaining after priming by decaying the Starting Concentration to the Planned Injection Time, and calculating activity pursuant to the following equation: (concentration*(Container Volume – Prime Volume)). Then, this activity is decayed to the first patient's Planned Injection Time. Next, the volume required for each patient dose is determined by decaying the Starting Concentration to the Planned Injection Time, then calculating dose volume as Planned Dose/concentration.

[0165] The Container Volume/Container Activity pair is considered a valid solution if all the following hold: 1) the Starting Concentration is greater than the Maximum Container Concentration; 2) the Minimum Dose Volume is less than or equal to all dose volumes, which is less than or equal to the Maximum Dose Volume; 3) the difference between the Container Volume and the sum of the Prime Volume and all Dose Volumes is greater than the Unextractable Volume; and 4) the first patient activity is greater than the Maximum Container Activity at the first patient injection.

[0166] The shaded area provided by block **1312** in **FIG. 13** shows the typical solution space from the preceding algorithm for a given patient schedule **1302** and container assay time. With reference to **FIG. 14**, this solution space is constrained as follows: **B1)** this boundary represents the highest achievable concentration in the system. The slope of this line is the lesser of: a) the Maximum Container Concentration, and b) First Patient's Planned Dose/Minimum Dose Volume; **B2)** this boundary represents leaving exactly the Unextractable Volume remaining in the container **902** with the last patient (the last patient dose size is bounded by the remaining extractable volume in the system instead of the absolute Maximum Dose Size); **B3)** this boundary represents the minimum activity required to meet all scheduled patients and priming without other system constraints taking effect (for container configurations along this boundary, the last patient dose volume will be between the Minimum Dose Volume and Maximum Dose Volume and there will be a small amount of extractable activity left in the container); **B4)** this boundary represents the minimum concentration limit. The slope of this line is the last patient's Planned Dose/Maximum Dose Volume. For container configurations along this boundary, the last patient dose volume will be the Maximum Dose Volume and there may be a relatively large volume of radiopharmaceutical remaining in the container; **B5)** this boundary is the Maximum Vial Volume; and **B6)** this boundary represents absolute maximum vial activity limits. A slope at this boundary appears if there is a higher Maximum Vial Activity at priming than at dosing, and the first patient's Planned Injection Time is very near the Priming Planned Injection Time. Clinicians may choose any solution within the space provided by blocks **1312** to meet their schedule.

[0167] With reference to **FIG. 15**, the schedule **1302** is editable after being initially provided to accommodate add-on patients, cancellations, time modifications to patients already provided on the planned patient schedule, modifications to an activity removed from the multi-dose container of radiopharmaceutical to patients already provided on the planned patient schedule, or any combination thereof. For instance, a clinician may click on one of the activity values in the schedule **1302** using a mouse or any other suitable input device. A menu **1336** then appears allowing the user to change the activity value for a patient. Once the clinician has completed updating any values in schedule **1302** to produce a new schedule **1302′**, the update chart button **1310** is pressed and the algorithm discussed hereinabove is run on new schedule **1302′** to produce all container volume and activity pairs at a specified assay time that can meet the new schedule **1302′** taking into account injection system constraints as represented by blocks **1312′** on graph **1314** in **FIG. 16**.

[0168] With reference to **FIG. 17** activity units may be changed from mCi to MBq using menu **1338** to produce a new schedule **1302″** where the activity is measured in MBq. In addition, after the activity units have been changed to MBq, the clinician presses the update chart button **1310** such that the algorithm discussed hereinabove is run on new schedule **1302″** to produce all container volume and activity pairs at a specified assay time that can meet the new schedule **1302″** taking into account injection system constraints as represented by blocks **1312″** on graph **1314** in **FIG. 17**. The computer **1044** may be coupled to a printer such that a hardcopy (printout) may be generated of both the schedule **1302**, **1302′**, or **1302″** and the valid container configuration graph **1314**.

[0169] With reference to **FIG. 18**, the schedule **1302**, **1302′**, or **1302″** may be transferred to a radiopharmaceutical fluid delivery system **10** by selecting the Export button **1340** from the file drop-down menu. This causes the computer **1044** to either save the schedule to a removable memory storage device, such as a flash memory drive, or send the schedule to the fluid delivery system **10** over a network. The clinician then orders the correct multi-dose container configuration and provides the multi-dose container configuration to the radiopharmaceutical fluid delivery system **10** as described hereinabove.

[0170] With reference to **FIGS. 20-26**, a multi-dose container configuration monitoring system that forecasts multi-dose radiopharmaceutical usage over a pending patient schedule and alerts clinicians when there is a risk of not being able to dose the full schedule is described. Shown schematically in **FIGS. 20-26** are various incarnations of a touch screen arrangement **1100** displayed on a graphical user interface, such as GUI **15**, that could be employed with the fluid delivery system **10**. As a non-restrictive example, such a touch screen arrangement could be utilized in conjunction with the system controller **5** of any of a variety of fluid delivery systems as broadly contemplated herein.

[0171] In order to clearly and unambiguously communicate to an operator the current status of the fluid delivery system **10**, a GUI **15** with easily legible symbols and icons, including exceedingly operator-friendly data entry mechanisms, is broadly contemplated. An operator will thus be able to intuitively understand and undertake various tasks for operating fluid delivery system **10**.

[0172] While a touch screen arrangement is contemplated in connection with **FIGS. 20-26**, it is to be understood that other types of data entry arrangements are conceivable that would achieve an equivalent purpose. For example, soft or hard key entry could be used, as well as trackball arrangements, mouse arrangements, or a cursor control touch pad (remote from the screen).

[0173] With continued reference to **FIG. 20**, a main operator interface provided on a touch screen is illustrated before an injection procedure has been started and before a schedule has been transferred thereto. After the operator prepares the system **10** for a fluid delivery procedure, the system **10** generates the display **1100** shown in **FIG. 20** which indicates in the upper left hand side thereof that the "System is ready". The touch screen includes a saline field **1102** and a pharmaceutical or FDG field **1104** providing an indication of the amount of saline in source **23** and FDG in container **902**, respectively. For example, the saline field **1102** indicates that 664 ml of saline is available and the FDG field **1104** indicates that 372 mCi of FDG are available, as shown. Indicated at **1106** is a touch field showing requested activity (currently displayed as 15.0 mCi) for an injection procedure to be performed. When the system **10** is activated, the requested activity field **1106** may display a default activity value that can be pre-programmed into the system **10** or pre-set by the operator. Alternatively, the requested activity field **1106** can default to the last activity level that was programmed into the system **10**.

[0174] Indicated at **1112**, **1114**, **1116**, and **1118**, respectively, in **FIG. 20** are circular status icons that provide quick and easy reference to different aspects of system status and, as such, will highlight when an aspect of system status is "on" or "active", or provide status information on the system **10**. Thus, icons **1112-1118** from left to right, respectively, convey information on the following system aspects: activity present **1112**, fluid motion/injection status **1114**, check for air/priming status **1116**, and system battery status **1118**.

[0175] The system battery (not shown) provides power to the system controller **5** and to the ionization chamber **160** (to maintain the ionization chamber at its normal operating state) in the event that the system **10** is disconnected from an AC power source. The system battery is charged while the system **10** is connected to an AC power source.

[0176] **FIG. 20** also shows four additional touch fields **1120-1123** along the bottom thereof. Reset button **1120** is activated to reset or clear information, such as case identification information, desired activity level, etc., from the treatment screens. Configuration button **1121** is activated to access the configuration screens for the system **10**. Schedule button **1122** is activated to access a scheduling interface to allow an operator to schedule a plurality of injection procedures into the system **10**. Treatment button **1123** is activated to access the injection control screen shown in **FIG. 19**. In addition, the operator can input case information including patient identification and injection site information into the system **10**. When the operator activates the edit button **1208** in the case ID field **1206**, a "Case Information" pop-up display is provided for inputting a patient or other identification number and an injection site at which the radiopharmaceutical will be administered or injected.

[0177] If the operator desires to schedule one or more injection procedures, he activates schedule button **1122**, thereby generating pop-up **1126** shown in **FIG. 21**. At this point, the operator may import a schedule **1302**, **1302′**, or **1302″** generated as described hereinabove by pressing the import schedule button **1128**. The operator can alter this schedule **1302**, **1302′**, or **1302″** or generate a new schedule by pressing the add appointment button **1130**. The operator can also clear any schedule that is already in the system **10** by pressing the clear schedule button **1132**. Once the schedule is imported, it appears in schedule window **1134**. The operator can review the schedule and make any appropriate changes with the add appointment button **1130**. Once the operator is satisfied with the schedule, he presses the treatment button **1123** and is returned to a main operating screen **1101** with the schedule pane **1136** populated with the imported schedule as shown in **FIG. 22**. If for some reason during operation, the system determines that the current multi-dose container configuration will not be able to provide a scheduled patient with the scheduled activity at the scheduled time, the system will provide a warning to the operator in information pane **1142** and highlight the scheduled injection procedure **1144** in the schedule window **1134** as shown in **FIG. 23**. The system controller **5** may suggest resolutions to the schedule to be able to acceptably infuse the patient which may include adjusting the time of the injection procedure or adjusting the activity of the scheduled does such as by presenting the operator with a range of activity levels **1146** that are available to the patient. For instance, an operator attempted to schedule an injection procedure at 16:00 that required a radiopharmaceutical having an activity level of 925 MBq. If the current multi-dose container configuration is unable to accommodate such an injection procedure, the scheduled injection procedure **1144** is highlighted and a range of activity levels **1146**, such as 18-430 MBq, is presented to the operator that would allow the operator to schedule a patient at 16:00. This range represents the Minimum Dose Activity and Maximum Dose Activity achievable for that patient. If this activity level is acceptable to operator, the operator can adjust the injection procedure at 16:00 to have an activity level anywhere between 18-430 MBq. If this level is unacceptable, the operator must cancel the procedure or adjust the infusion time.

[0178] The system may also be able to recommend or suggest changes in radioactive dose and/or infusion times for future patients in the schedule collectively to maximize the ability of the system and operator to infuse all of the patients in the schedule. The suggested changes may be for each future patient or for the entire schedule. Any suggested changes in the schedule must be approved by an operator.

[0179] With reference to **FIG. 24**, the operator, after priming the system as discussed hereinabove, then activates the Infuse button (not shown) to begin the injection procedures provided in the schedule pane **1136**.

[0180] The system **10** further includes a multi-dose container configuration monitoring system that forecasts multi-dose radiopharmaceutical usage over a pending patient schedule and alerts clinicians when there is a risk of not being able to dose the full schedule. Proper functioning of the monitoring algorithm requires several preconditions to be met. If any of these preconditions are not met, in lieu of forecasting container usage per the schedule the monitor should indicate to the user that it is unable to provide a radiopharmaceutical usage forecast until the precondition has been satisfied.

[0181] The preconditions are as follows. First, the monitoring requires, as input, a patient schedule to be imported as discussed hereinabove. The schedule is editable after initial entry to accommodate add-on patients, cancellations, and time/dose modifications to scheduled patients. For the monitor to work properly, the operator must have scheduled priming entry and times/doses scheduled for all patients.

[0182] The next precondition is that the monitor requires an estimate of the remaining extractable radiopharmaceutical activity and volume at the present time. This is typically based on the original multi-dose container assay information, less fluid removed from the multi-dose container, and adjusted for unextractable volume and isotope decay. An activity monitoring device, such as an ionization chamber, a CZT crystal detector, a Geiger-Müller counter, or a scintillating counter, may be used to determine this information.

[0183] The third precondition comes from the fact that the monitor algorithm is intended to forecast dosing for future patients. It is feasible for one patient to be past due, in which case the monitor can realistically associate that patient with the current time. However, reliable forecasting is not possible if more than one patient is past due. Accordingly, the monitor requires that no more than one patient pending dosing is scheduled in the past.

[0184] If all preconditions are met, the monitor uses the following algorithm to determine if a given patient schedule can be met. The monitor uses the same system constraints discussed hereinabove, as well as: 1) Extractable Volume: volume remaining in the multi-dose container available for dosing (it is the total volume remaining in the multi-dose container less the Unextractable Volume); and 2) Extractable Activity: activity remaining in the multi-dose container available for dosing. Given these parameters, the monitor will determine the viability of meeting the given schedule with the multi-dose container per the following algorithm: 1) establish initial parameter values such as, Start Concentration and Start Time; and 2) for each item in the schedule that has not yet been executed (*e.g.*, priming, undosed patients), take the following action in order according to scheduled injection time: 2.1) set Delta Time to the higher of the difference between the scheduled injection time and the start time or zero; 2.2) set the Current Concentration by decaying the Start Concentration by Delta Time; 2.3) for patient items, set Dose Activity to the Planned Dose and for priming items, set the Dose Activity to Prime Volume multiplied by the Current Concentration; 2.4) for patient items, calculate Dose Volume as Dose Activity divided by Current Concentration, and for priming items, set the Dose Volume to the Prime Volume; 2.5) calculate the Maximum Dose Activity as Current Concentration multiplied by the lesser of Maximum Dose Volume or Extractable Volume; 2.6) calculate the Minimum Dose Activity as Minimum Dose Volume multiplied by Current Concentration; and 2.7) if any of the following are true, mark the current and all subsequent items in the schedule as at risk for dosing with the current multi-dose container **902**:

a. Dose Activity less than Minimum Dose Activity; and

b. Dose Activity greater than Maximum Dose Activity.

[0185] If the step 2.7 determined that the scheduled item was at risk, the processing must be halted and the operator must be notified. Otherwise, parameters for processing the next item in the schedule are updated by updating Extractable Volume by subtracting from it the Dose Volume.

[0186] The items in the schedule may be marked by highlighting the items within the schedule pane **1136** as shown in **FIG. 25** by reference numeral **38** to alert the operator action is likely required on their part. Furthermore, the first at risk item in the schedule should present the Minimum Dose Activity and Maximum Dose Activity achievable for that patient, thereby giving the operator sufficient information to determine the best course of action for this item. For example, the clinician may elect to dose the patient with the current container **902** even if the patient is at risk if the shortfall is still within acceptable dosing limits.

[0187] In addition, as items are completed, the schedule is updated with actual injection times and doses. This provides the clinician with a history of injections performed with the current container. In addition, an icon, such as a green check mark **1140** for a completed injection procedure and a yellow P **1138** for a partial injection procedure, may be placed next to each item in the schedule in the schedule pane **1136** as shown in **FIG. 26**.

[0188] The main objective of the planning and monitoring of multi-dose pharmaceutical procedures is to optimize a schedule of injection procedures to minimize the amount of radiopharmaceutical that is wasted and maximize the number of injection procedures that are performed with a given radiopharmaceutical configuration. Accordingly, the system utilizes a two step procedure to achieve this objective. First, an operator loads a schedule of injection procedures into the system that includes a time and a required activity level for each of the procedures and provides a user with a plurality of multi-dose radiopharmaceutical container configurations that can be used to meet his needs as discussed hereinabove with reference to **FIGS. 12-19**. Along with the time and required activity level for each of the injection procedures, the system may also consider at least one of the following factors in determining the plurality of multi-dose radiopharmaceutical container configurations that are presented to the user: 1) delivery logistics; 2) distance from the radiopharmaceutical production facility; 3) container size; 4) flexibility of the radiopharmaceutical; 5) production schedule of the radiopharmaceutical production facility; 6) injection system loses (e.g., waste, priming, etc.); and 7) radiopharmaceutical half-life. However, these factors are not to be construed as limiting the present disclosure as the system may also consider a variety of other factors may need to be considered in this determination. Thereafter, the operator selects an appropriate multi-dose radiopharmaceutical container configuration and begins the scheduled injection procedures.

[0189] The second step of the procedure is if the schedule changes during the injection procedures, the system then recommends a new schedule that optimizes the number of patient scans and/or injections that can be performed by suggesting changes in the radioactive dose and/or the infusions times for each future patient or for the entire schedule. This maximizes the systems ability to infuse all of the patients in the schedule and minimizes radiopharmaceutical waste.

[0190] Although various embodiments have been described in detail for the purpose of illustration, it is to be understood that such detail is solely for that purpose and that the disclosure is not limited to the disclosed embodiments, but, on the contrary, is intended to cover modifications and equivalent arrangements. For example, it is to be understood that this disclosure contemplates that, to the extent possible, one or more features of any embodiment can be combined with one or more features of any other embodiment.

CLAIMS:

1. A radiopharmaceutical fluid delivery system comprising:

a radiopharmaceutical source;

a disposable administration set configured to allow fluid flow from the radiopharmaceutical source to a patient;

a pumping mechanism in fluid communication with the disposable administration set and the radiopharmaceutical source, and configured to pump fluid from the radiopharmaceutical source through the disposable administration set to the patient;

a control unit operatively coupled to the pumping mechanism, and configured to receive a patient schedule of a plurality of radiopharmaceutical injection procedures, determine a multi-dose container configuration for use during the plurality of radiopharmaceutical injection procedures, control the pumping mechanism to conduct the plurality of radiopharmaceutical injection procedures based on the patient schedule, monitor the multi-dose container configuration during the plurality of radiopharmaceutical injection procedures, determine whether there is a risk that at least one of the plurality of radiopharmaceutical injection procedures may not be completed properly due to one or more patient schedule changes, and provide an alert in response to the risk being determined; and

a display unit operatively coupled to the control unit for displaying the patient schedule.

2. The radiopharmaceutical fluid delivery system of claim 1, wherein the disposable administration set is a multi-patient disposable administration set.

3. The radiopharmaceutical fluid delivery system of claim 1 or 2, wherein the disposable administration set comprises:

a medical fluid component;

a radiopharmaceutical component;

a coil component coupled to the medical fluid component and the radiopharmaceutical component; and a waste container coupled to the medical fluid component, the coil component, and the radiopharmaceutical component.

4. The radiopharmaceutical fluid delivery system of any one of claims 1 to 3, wherein the patient schedule comprises, for each of a plurality of patients, a time of a radiopharmaceutical injection procedure for the patient, and an activity removed from the multi-dose container of radiopharmaceutical for the patient.

5. The radiopharmaceutical fluid delivery system of any one of claims 1 to 4, wherein, when the control unit receives a patient schedule, the control unit receives as least one of the following:

the time and activity for a radiopharmaceutical injection procedure for the patient from a user via a computer;

the time and activity for a radiopharmaceutical injection procedure for patient from a memory device associated with the computer; and

the time and activity for a radiopharmaceutical injection procedure for patient from a remotely located patient device over a network.

6. The radiopharmaceutical fluid delivery system of any one of claims 1 to 5, wherein the control unit further comprises an edit function for editing the patient schedule, to add an additional patient, cancel a patient, modify a time for a patient on the patient schedule, modify an activity of radiopharmaceutical removed from the multi-dose container for a patient on the patient schedule, or any combination thereof.

7. The radiopharmaceutical fluid delivery system of claim 6, wherein upon receiving a change in the patient schedule, the control unit updates the patient schedule to accommodate a maximum number of the plurality of radiopharmaceutical injection procedures in response to the risk being determined.

8. The radiopharmaceutical fluid delivery system of any one of claims 1 to 7, wherein when the control unit monitors the multi-dose container configuration during the plurality of

radiopharmaceutical injection procedures, the control unit determines a remaining activity and volume of radiopharmaceutical in the multi-dose container configuration to provide a remaining activity estimation; and adjusts the remaining activity estimation based on isotope decay.

9. The radiopharmaceutical fluid delivery system of any one of claims 1 to 8, further comprising at least one radiation detector selected from the group consisting of an ionization chamber, a CZT crystal detector, a Geiger-Muller counter, and a scintillating counter.

10. The radiopharmaceutical fluid delivery system of any one of claims 1 to 9, wherein the display unit comprises a graphical user interface which displays at least the patient schedule.

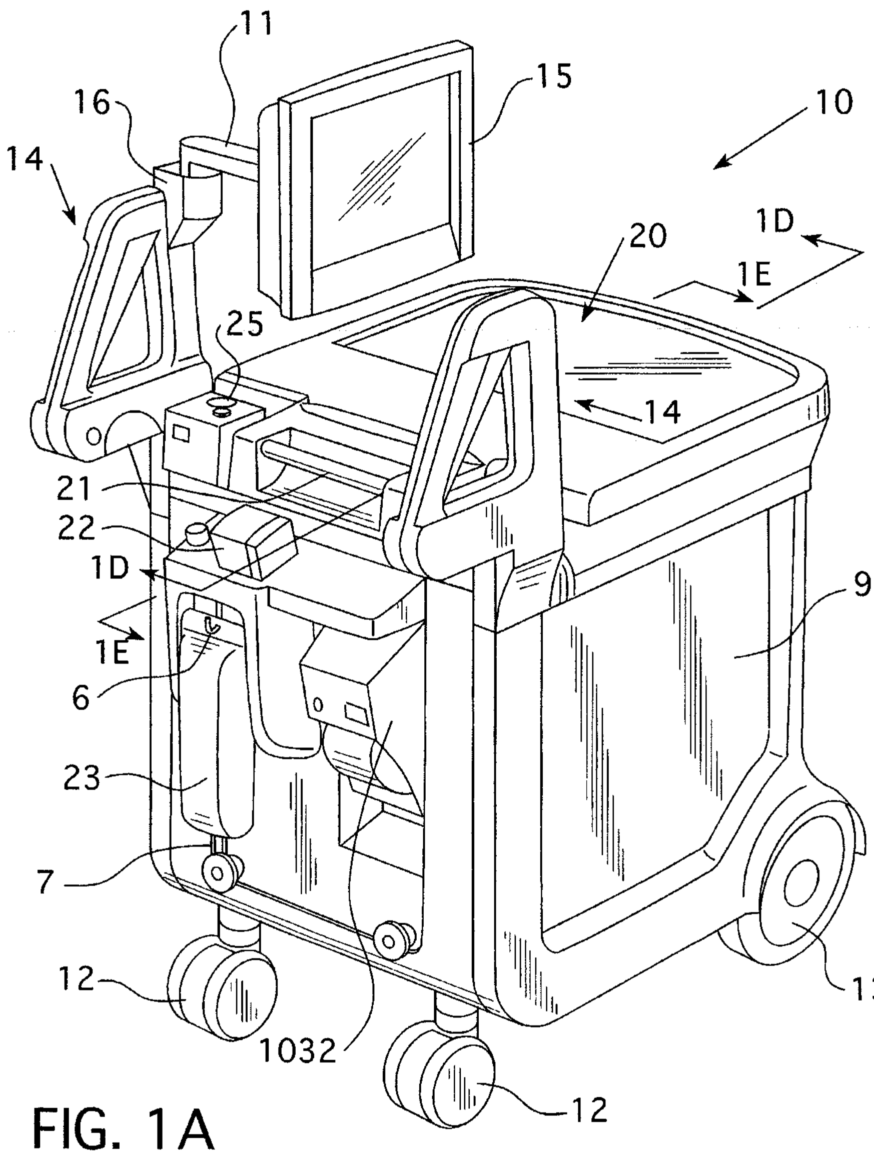


FIG. 1A

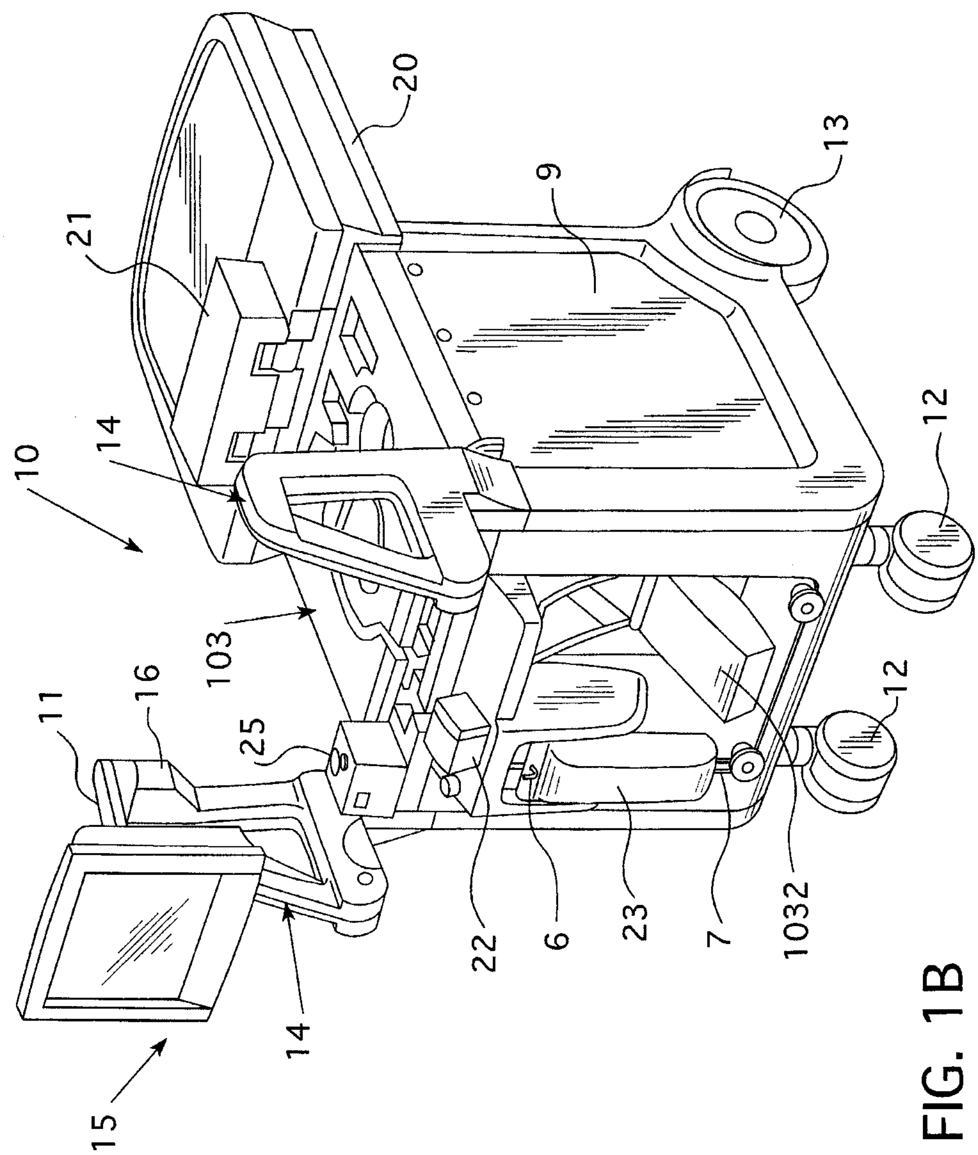
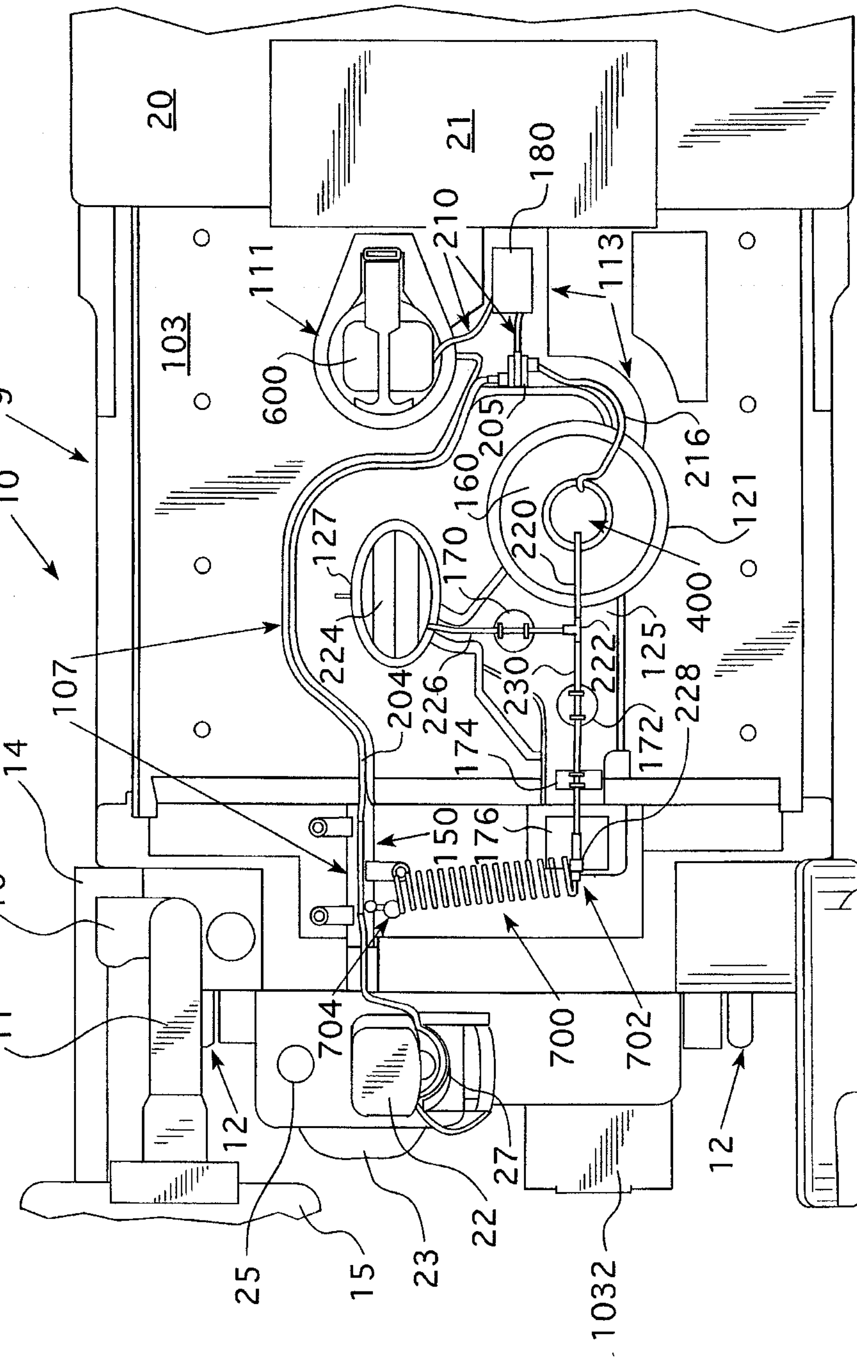


FIG. 1B

3/33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210
111
113
103
600
205
216
9
10
160
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220
400
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125
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222
226
230
228
204
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16
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11
704
700
702
12
27
22
23
25
15
1032

FIG. 1C

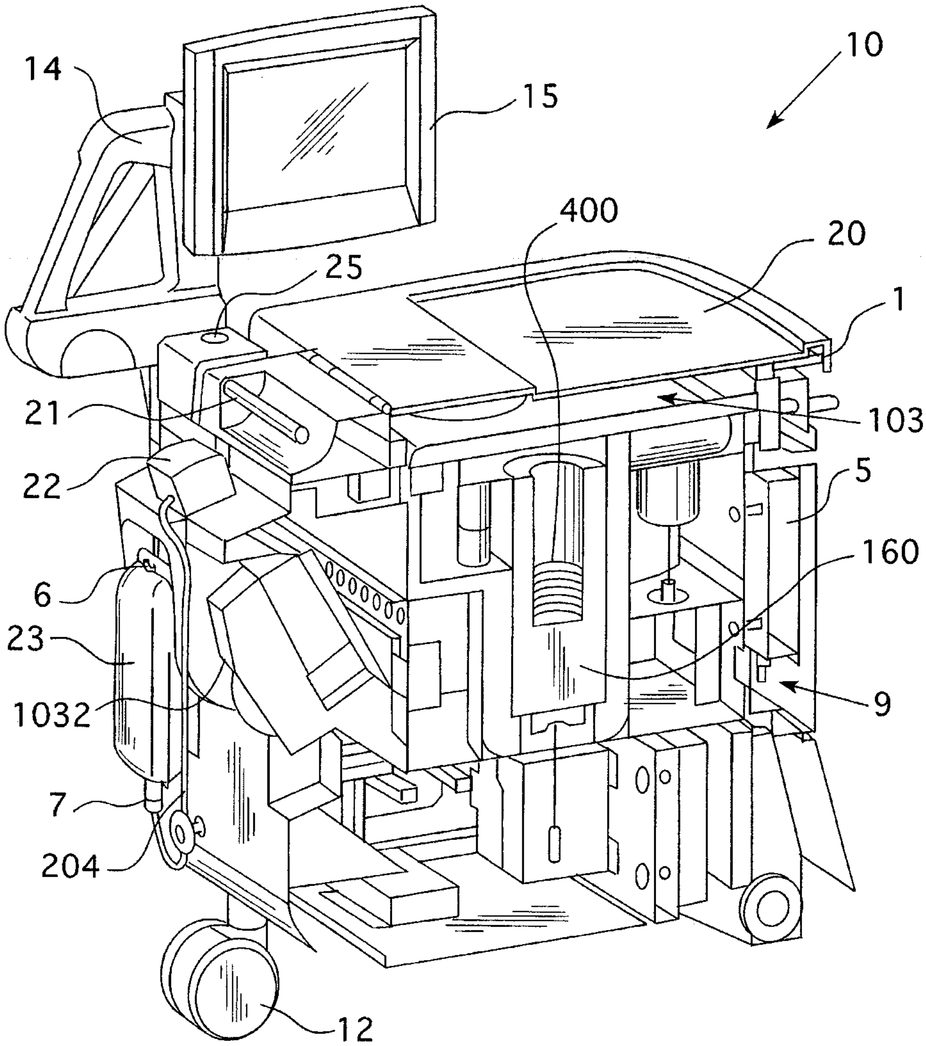


FIG. 1D

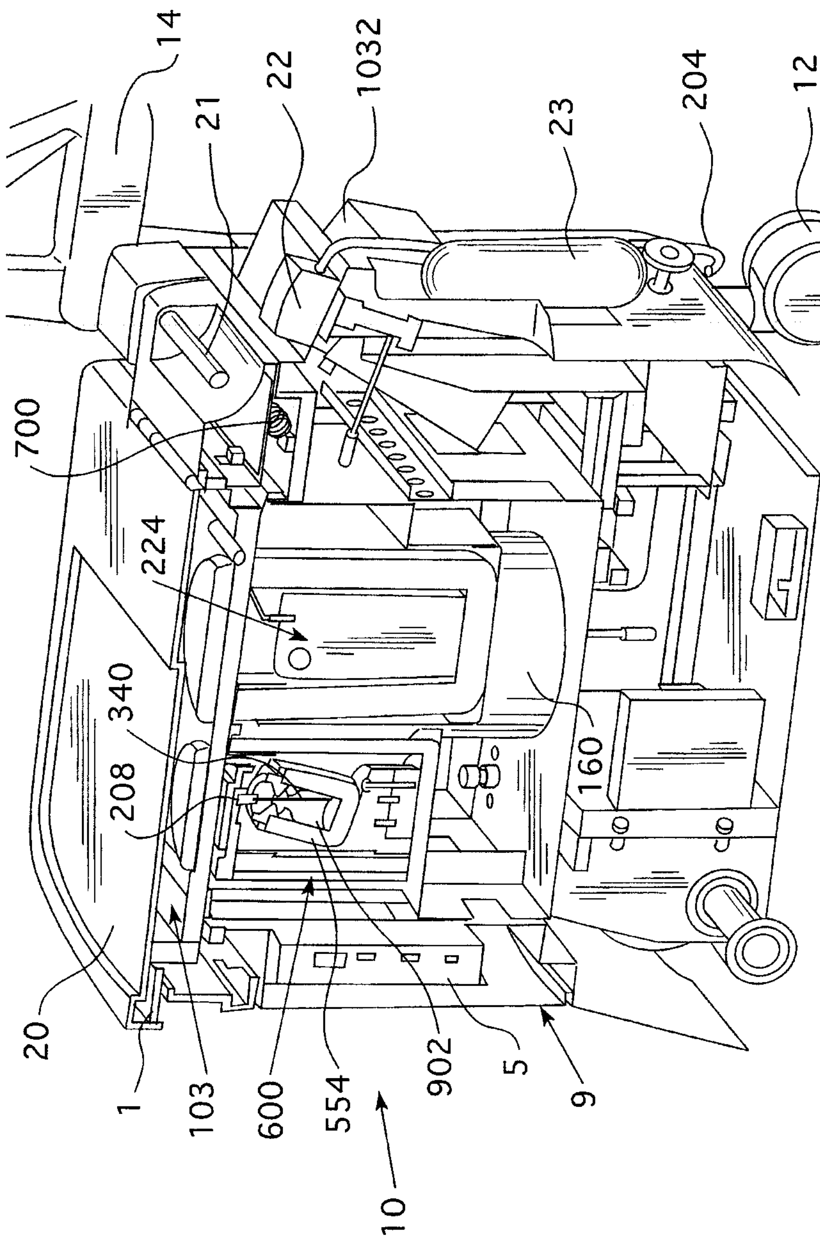
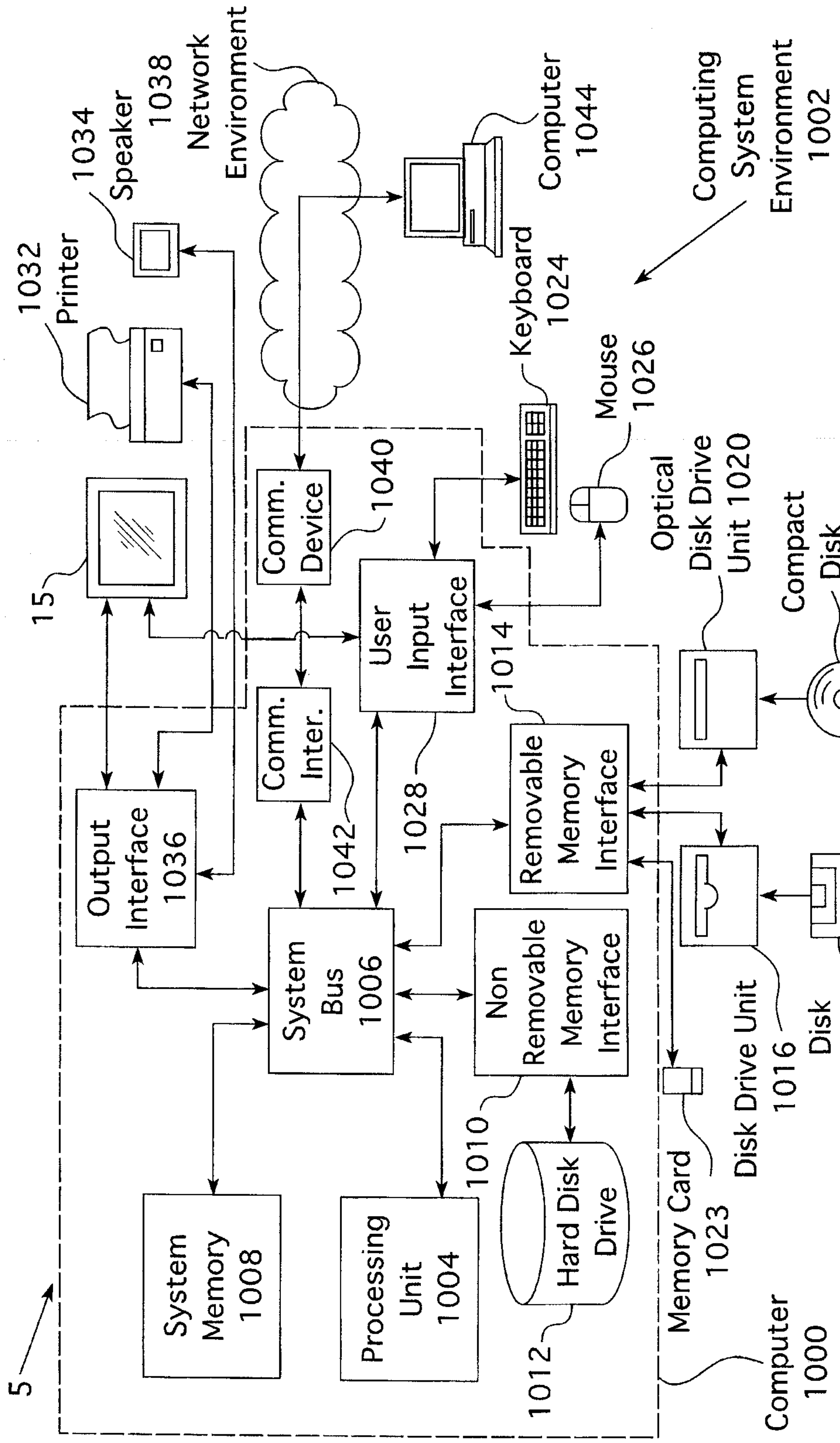

14
21
22
1032
23
204
12
700
224
340
208
160
20
1
103
600
554
902
5
9
10

FIG. 1E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Printer
1034
Speaker
1038
Network
Environment
Computer
1044
Computing
System
Environment
1002
Keyboard
1024
Mouse
1026
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Device
1040
User
Input
Interface
1014
Optical
Disk Drive
Unit 1020
Compact
Disk
1022
Output
Interface
1036
Comm.
Inter.
1042
1028
Removable
Memory
Interface
System
Bus
1006
Non
Removable
Memory
Interface
1010
Disk Drive Unit
1016
Disk
1018
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Memory
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Processing
Unit
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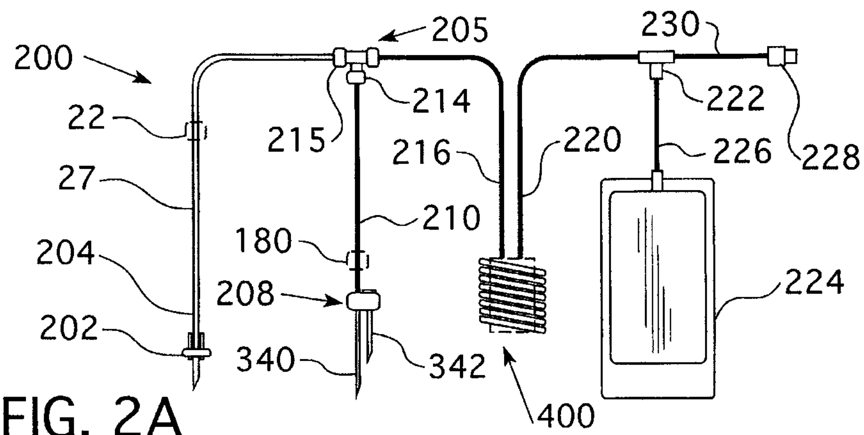
Hard Disk
Drive
1012
Memory Card
1023
5
Computer
1000

FIG. 1F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210
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204
208
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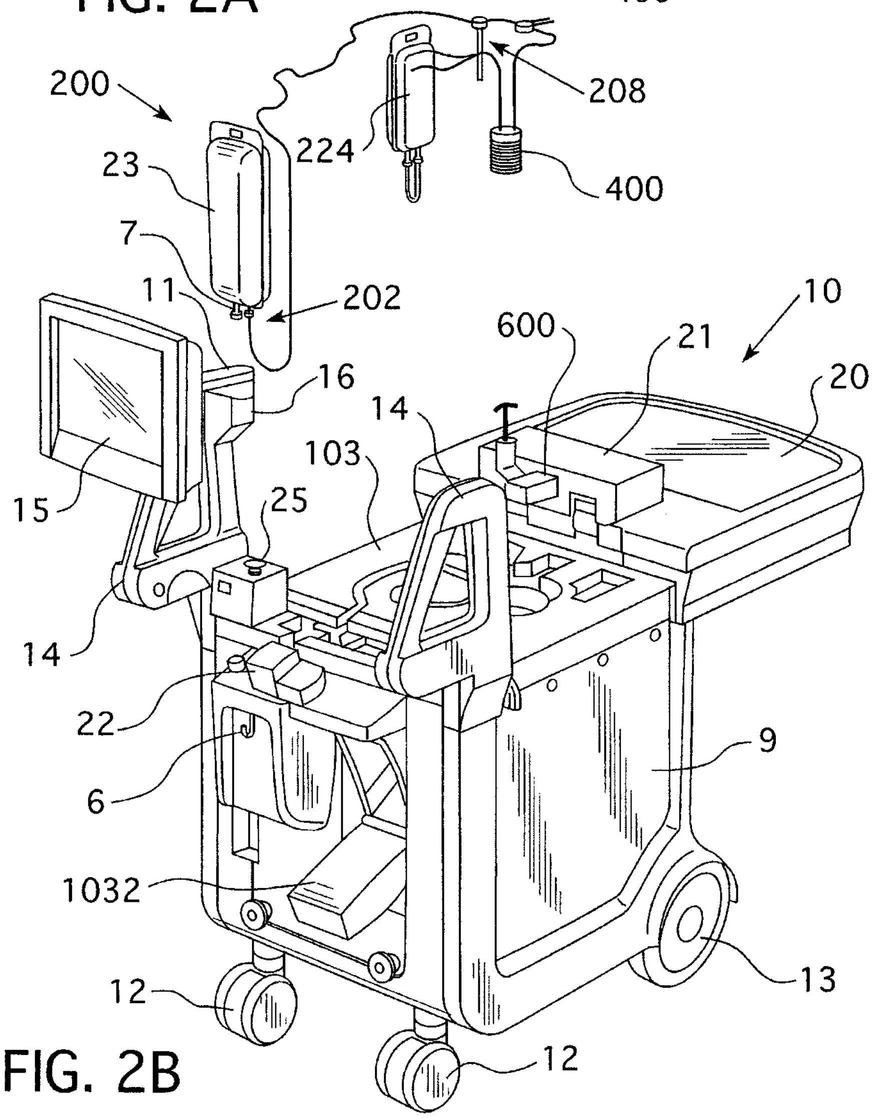
400

FIG. 2A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13
12
12

FIG. 2B

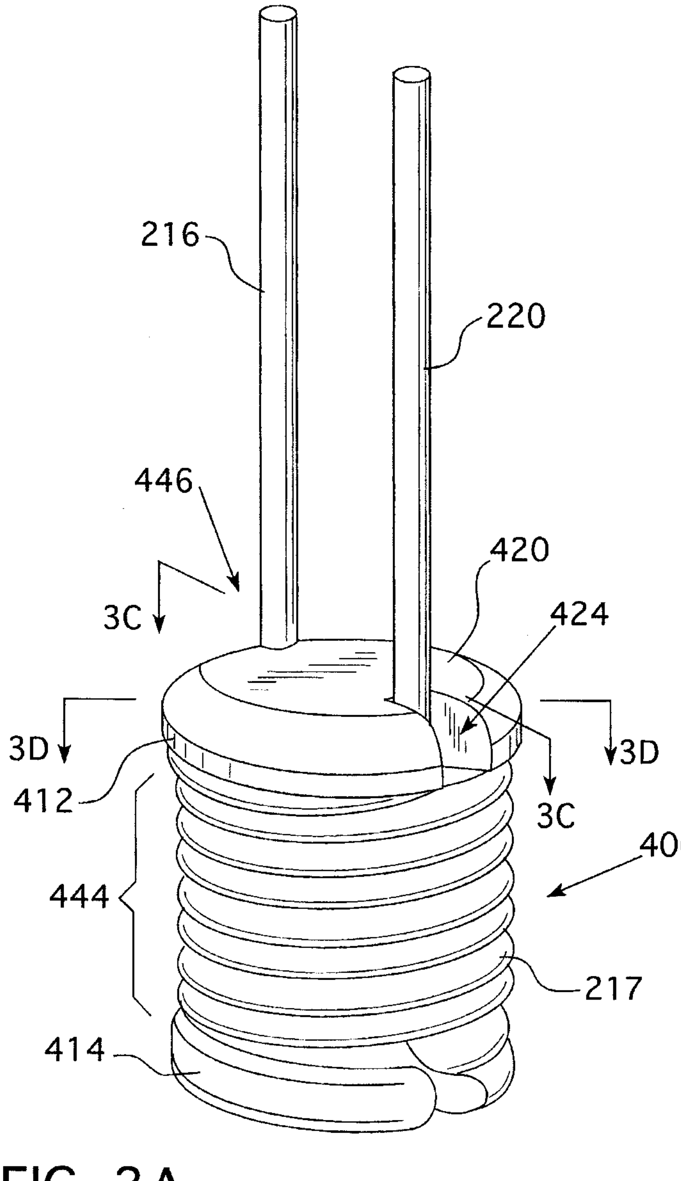
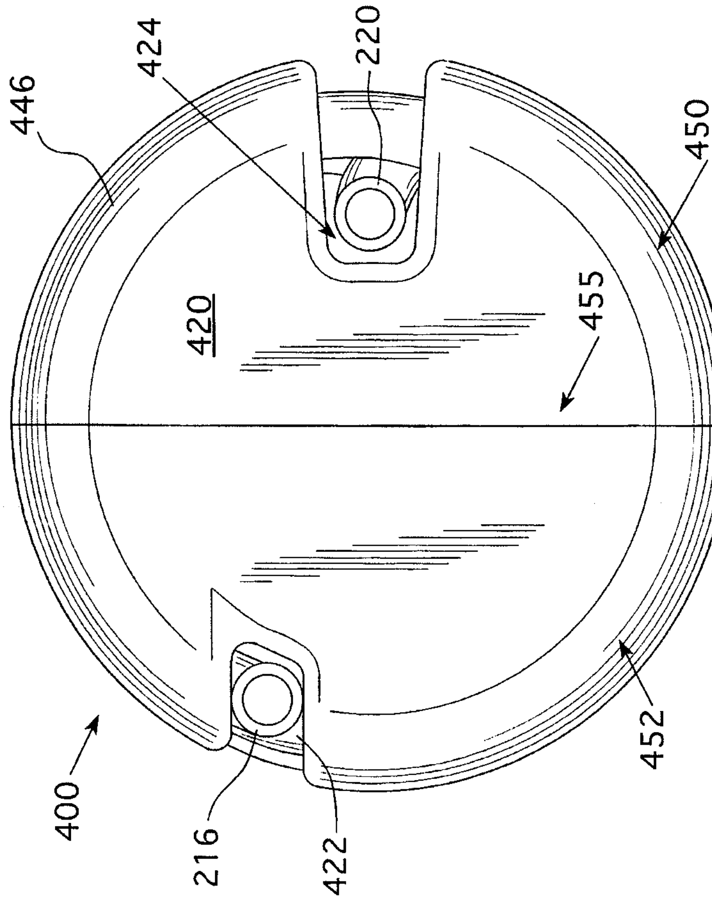


FIG. 3A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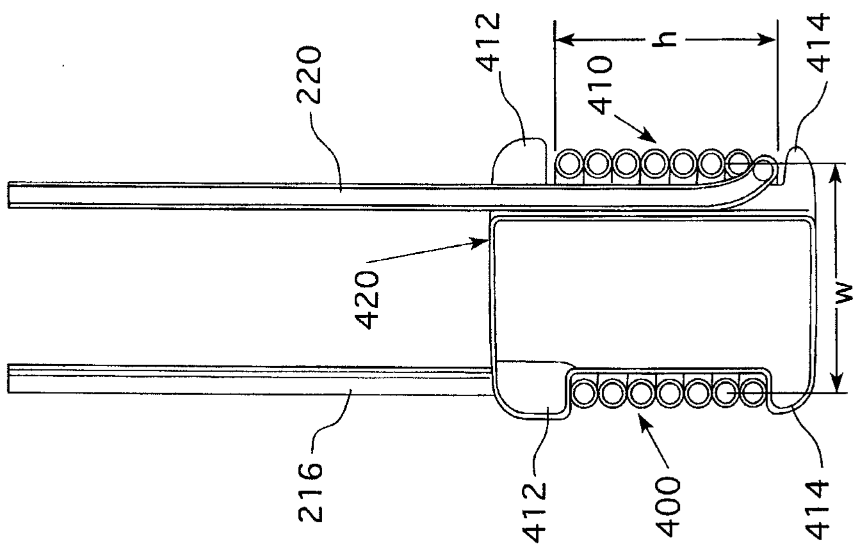
450
420
455
400
216
422
452

FIG. 3C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414

FIG. 3B

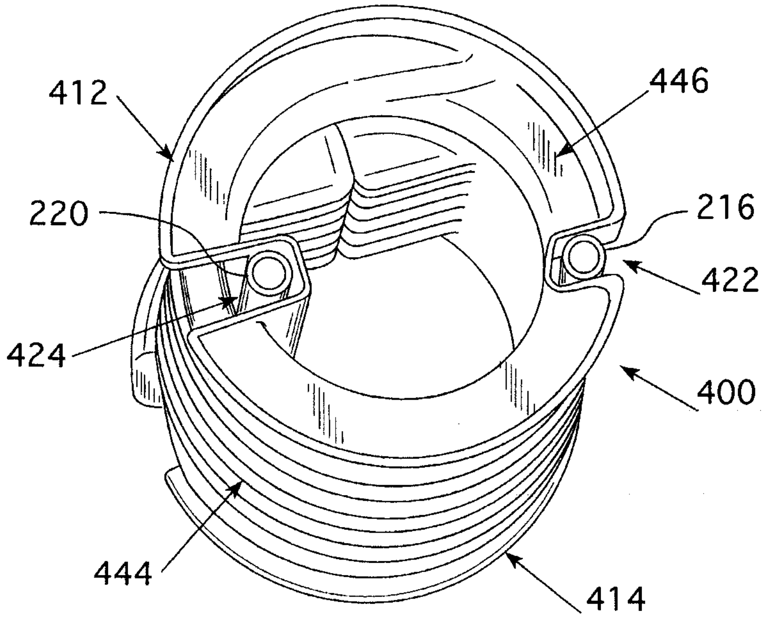
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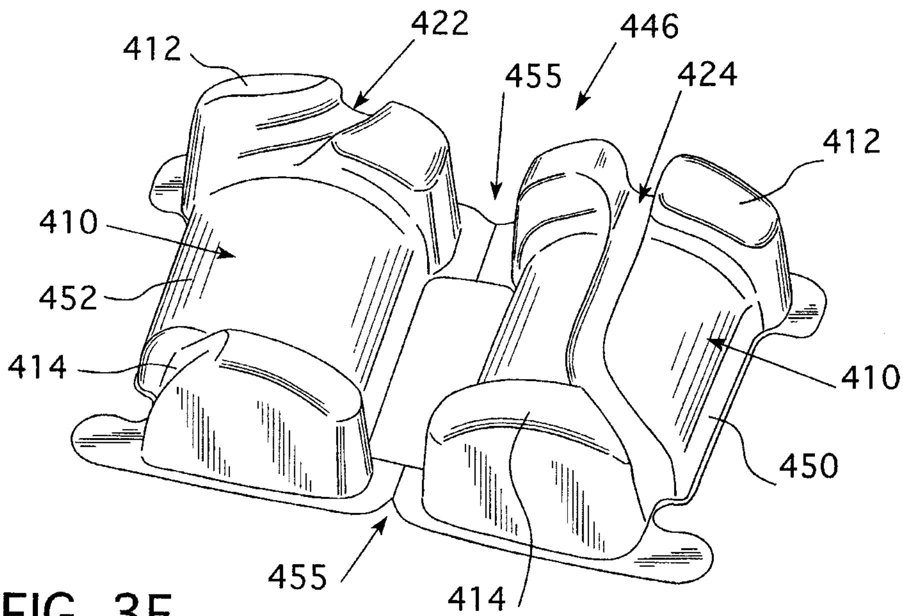
FIG. 3D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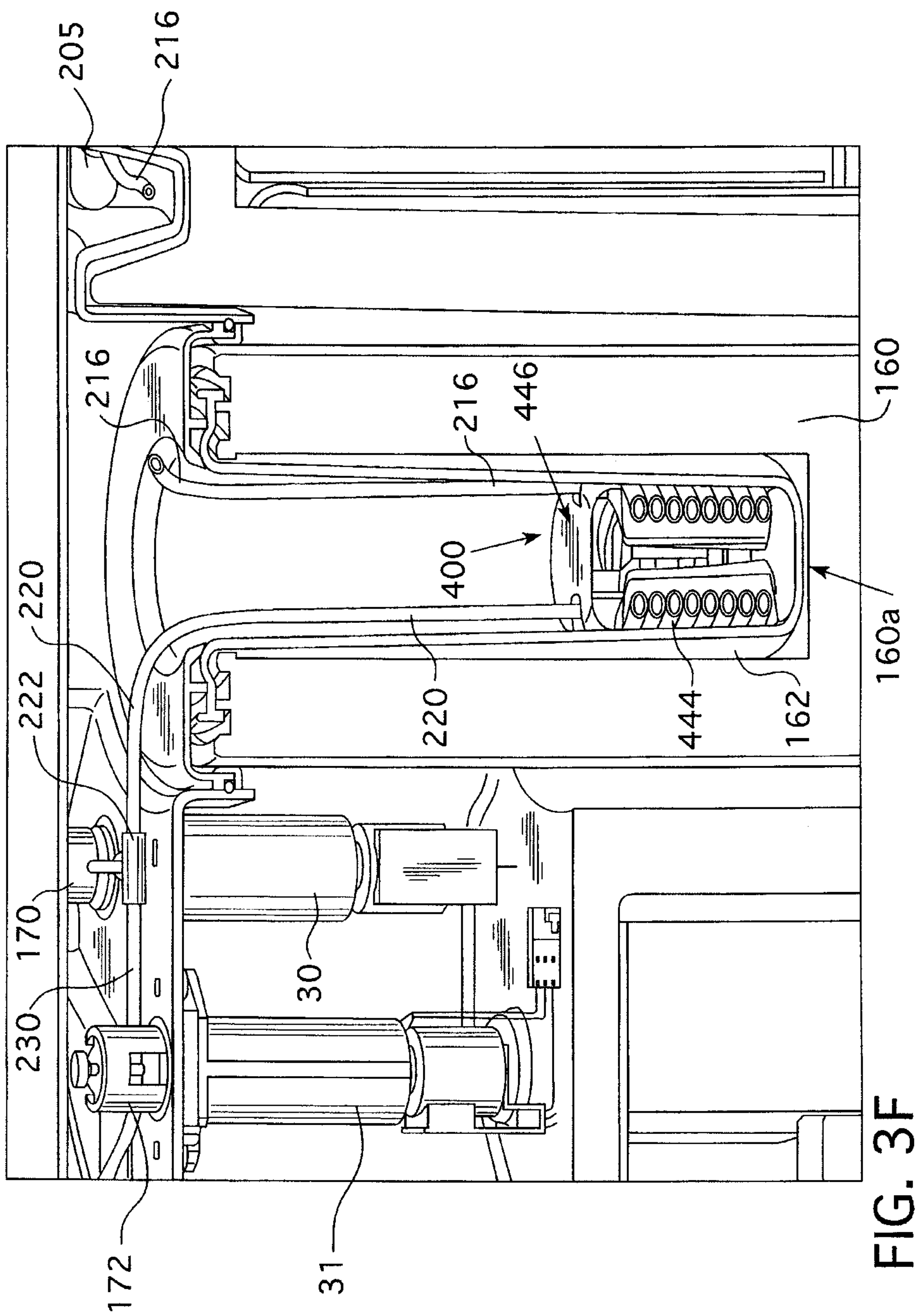
450
455
414

FIG. 3E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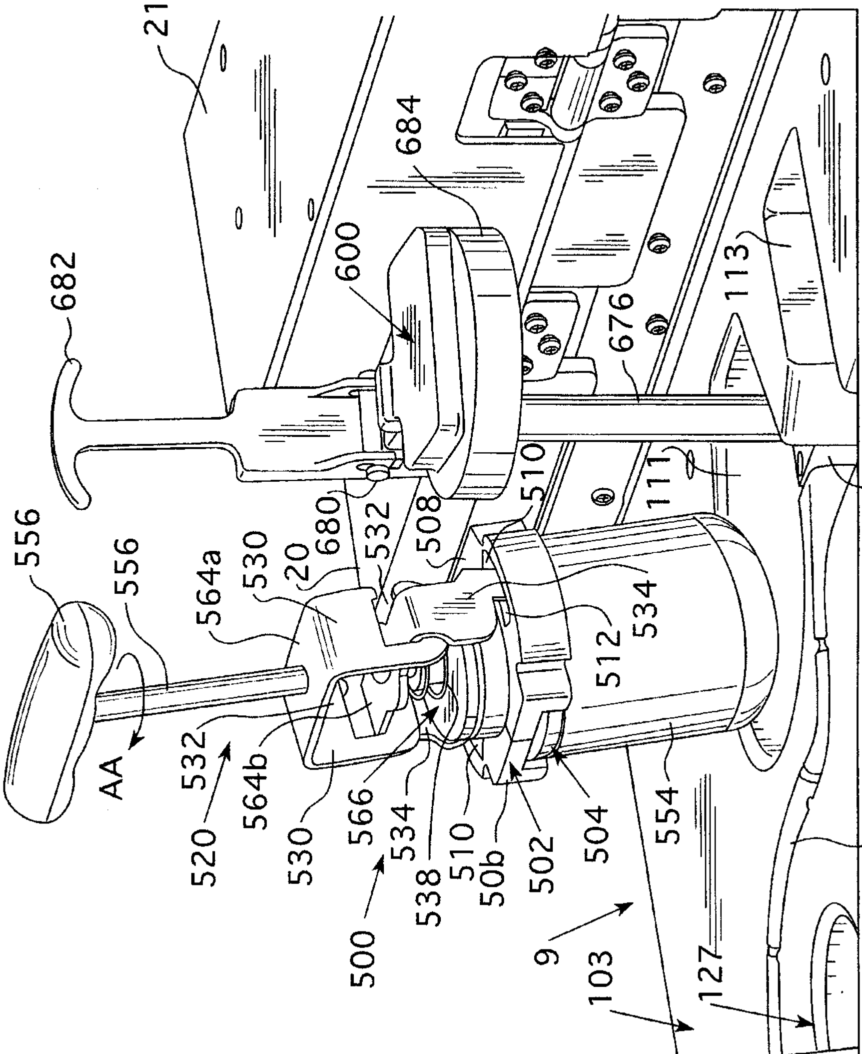
31

FIG. 3F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113
111
678
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508
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532
20
530
564a
556
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534
512
107
554
504
502
50b
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566
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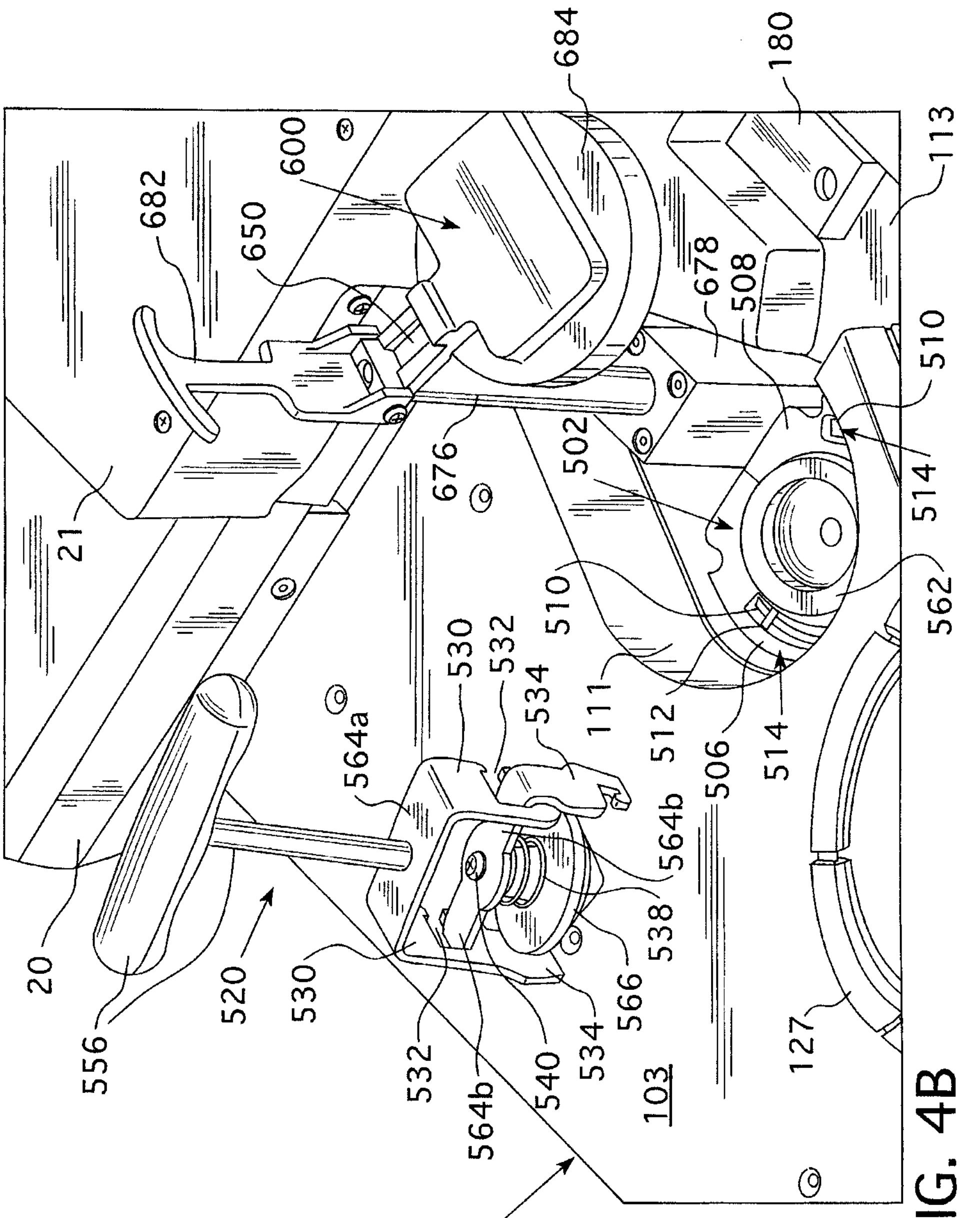
520
AA
500
9
103
127

FIG. 4A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103
127
9

FIG. 4B

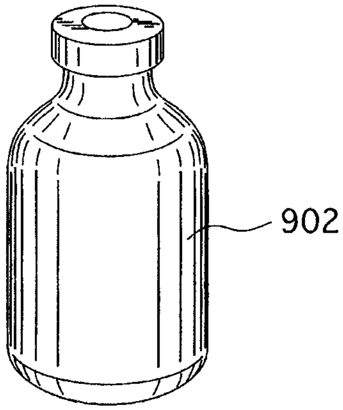

902

FIG. 4C

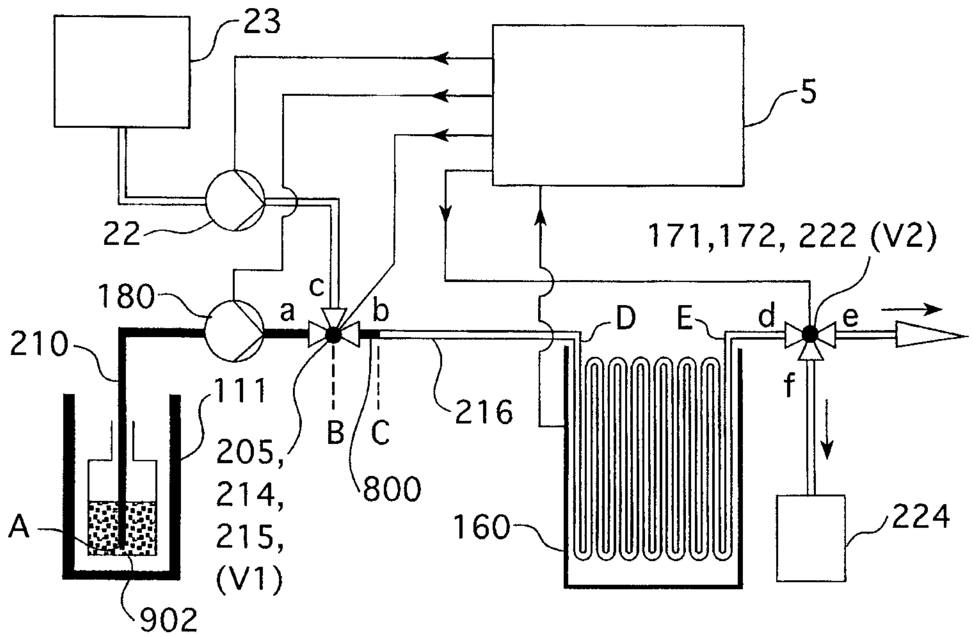

23
5
22
171,172, 222 (V2)
180
c
a
b
D
E
d
e
210
111
f
216
B
C
205,
214,
215,
(V1)
800
A
160
224
902

FIG. 5

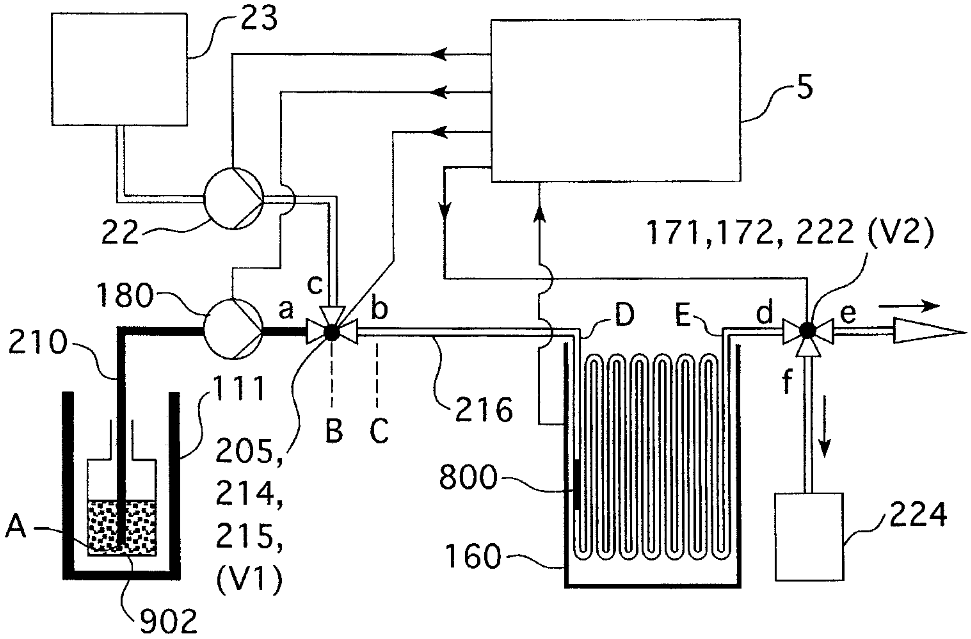

23
5
22
171,172, 222 (V2)
180
c
a
b
D
E
d
e
210
111
216
f
B
C
205,
214,
215,
(V1)
800
A
160
224
902

FIG. 6

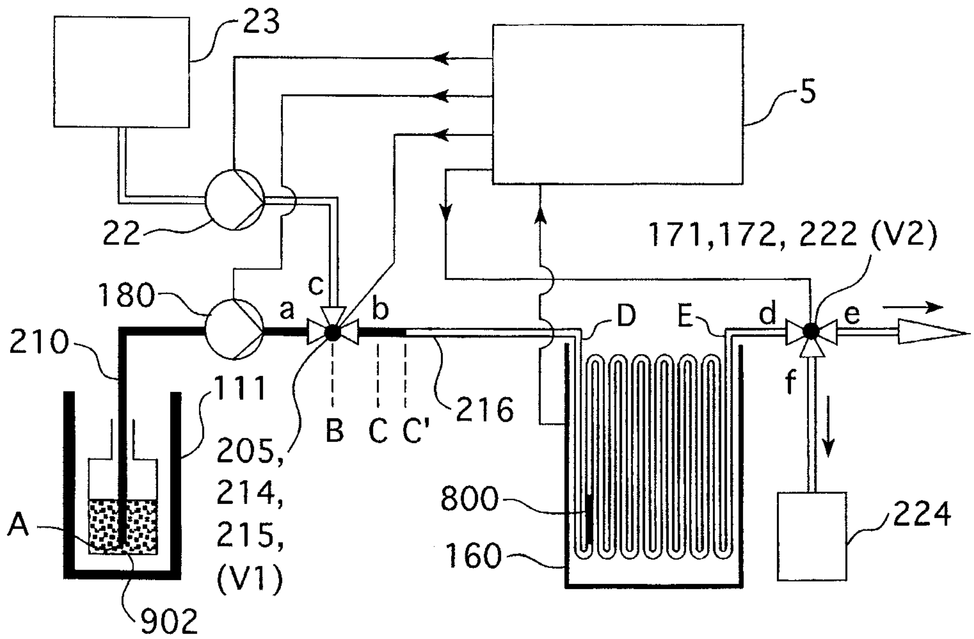

23
5
22
171,172, 222 (V2)
180
c
a
b
D
E
d
e
210
111
216
f
B
C
C'
205,
214,
215,
(V1)
800
A
160
224
902

FIG. 7

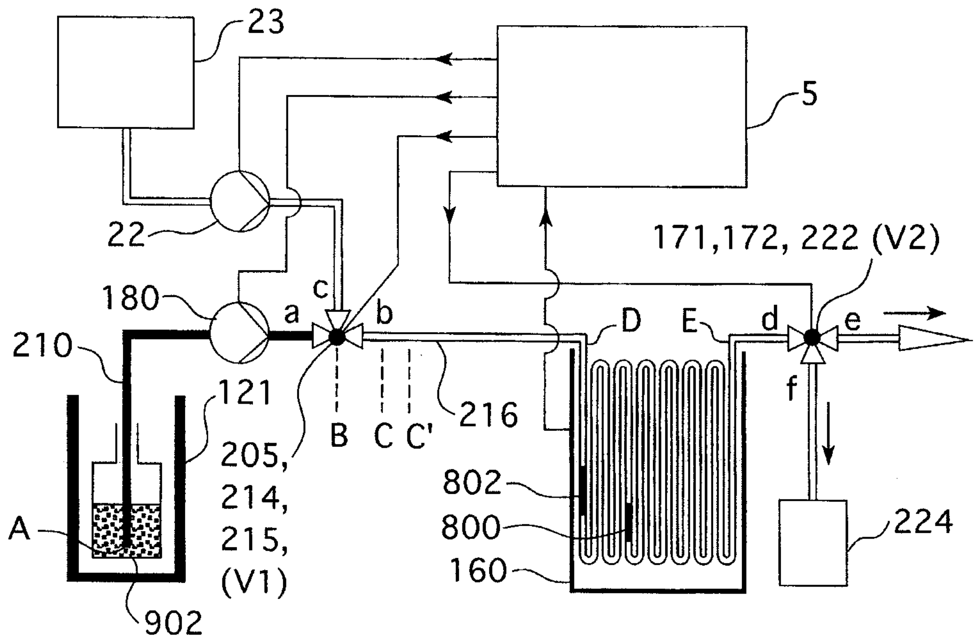

23
5
22
171,172, 222 (V2)
180
c
a
b
D
E
d
e
210
121
f
216
B
C C'
205,
214,
215,
(V1)
802
800
160
A
902
224

FIG. 8

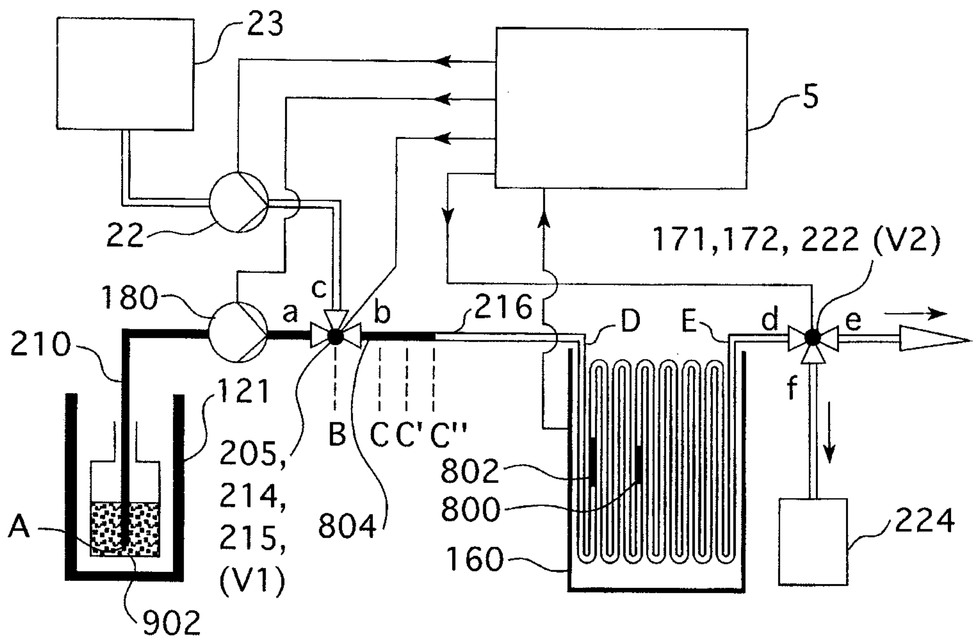

23
5
22
171,172, 222 (V2)
180
c
a
b
216
D
E
d
e
210
121
f
B
C C' C''
205,
214,
215,
(V1)
804
802
800
160
A
902
224

FIG. 9

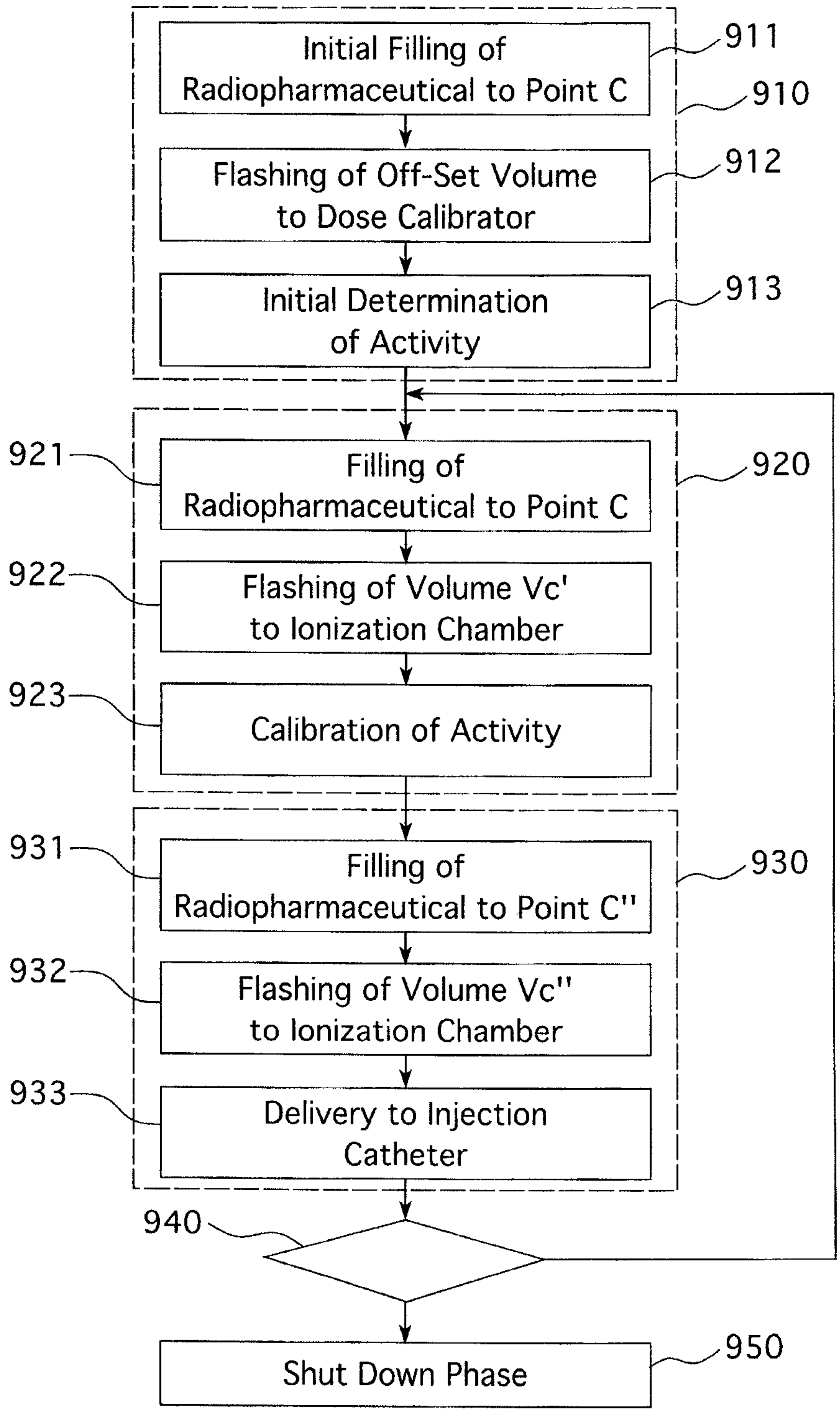

Initial Filling of Radiopharmaceutical to Point C
911
910
Flashing of Off-Set Volume to Dose Calibrator
912
Initial Determination of Activity
913
921
Filling of Radiopharmaceutical to Point C
920
922
Flashing of Volume Vc' to Ionization Chamber
923
Calibration of Activity
931
Filling of Radiopharmaceutical to Point C''
930
932
Flashing of Volume Vc'' to Ionization Chamber
933
Delivery to Injection Catheter
940
Shut Down Phase
950

FIG. 10

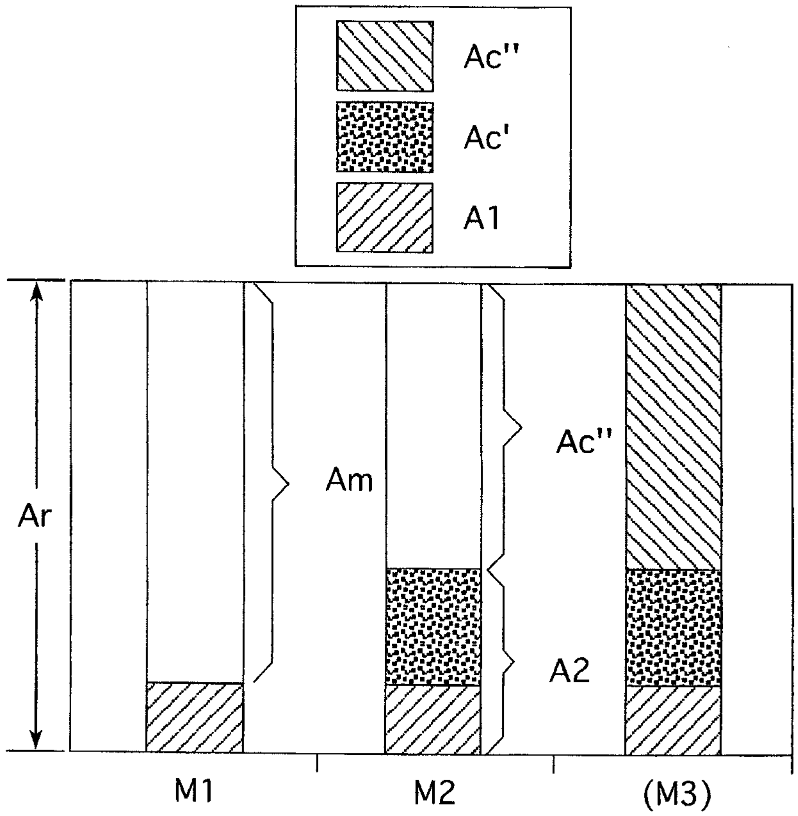


FIG. 11

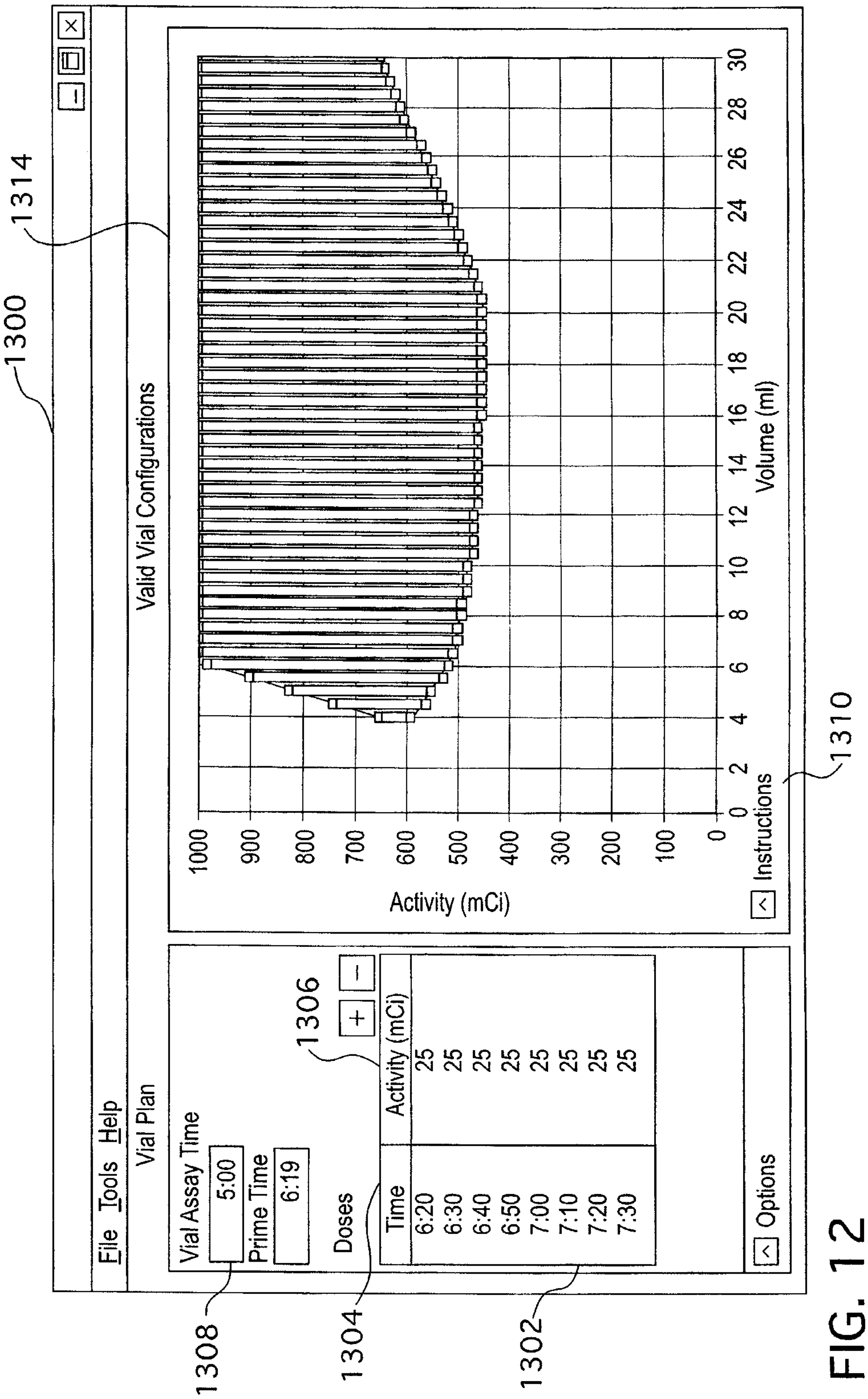

1300
1314
File Tools Help
Vial Plan
Vial Assay Time
5:00
Prime Time
6:19
Doses
+
–
Time
Activity (mCi)
6:20 25
6:30 25
6:40 25
6:50 25
7:00 25
7:10 25
7:20 25
7:30 25
Options
Valid Vial Configurations
Activity (mCi)
1000
900
800
700
600
500
400
300
200
100
0
0 2 4 6 8 10 12 14 16 18 20 22 24 26 28 30
Volume (ml)
Instructions
1310
1306
1308
1304
1302

FIG. 12

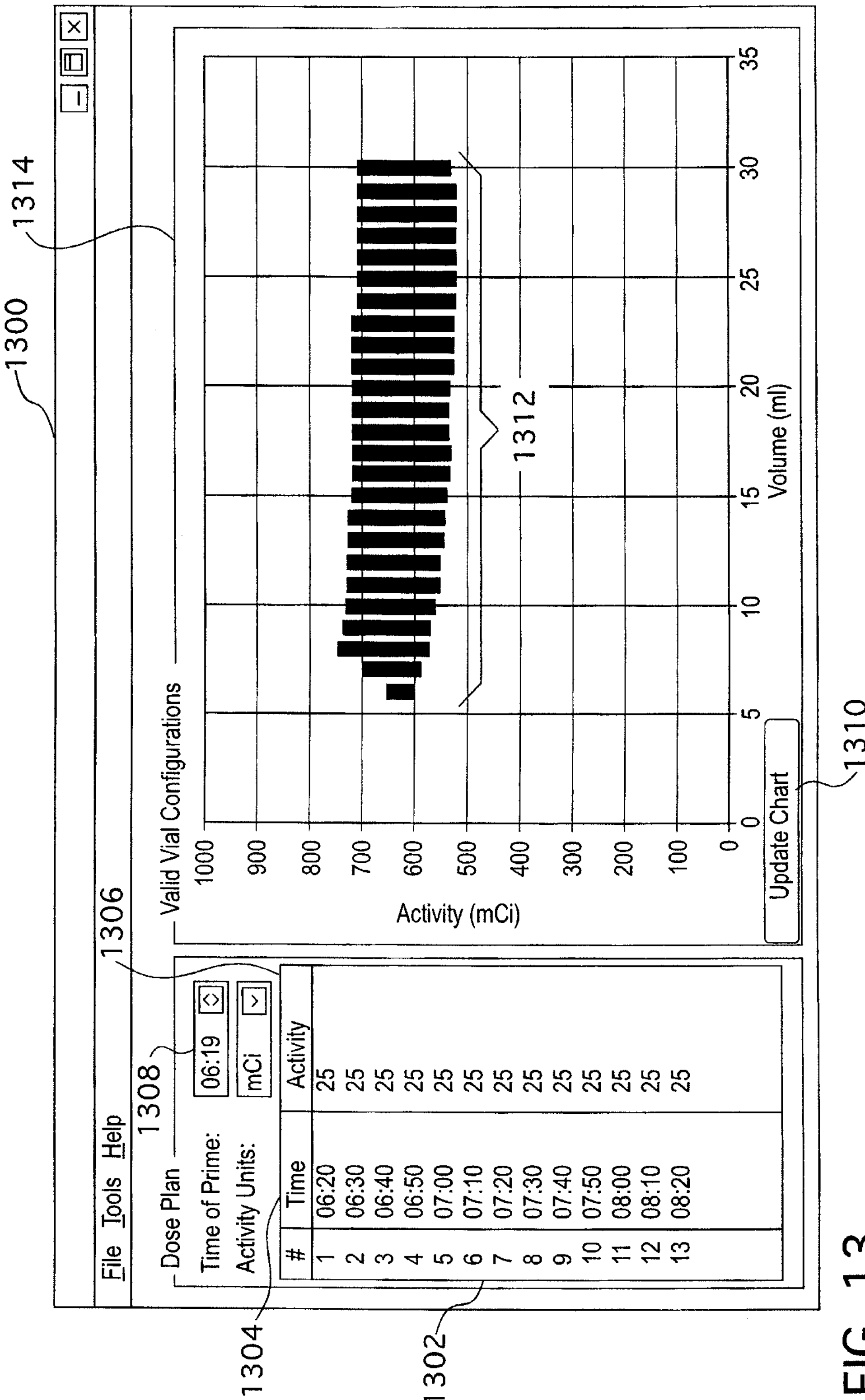

1300
1314
File Tools Help
Valid Vial Configurations
Activity (mCi)
1000
900
800
700
600
500
400
300
200
100
0
0
5
10
15
20
25
30
35
Volume (ml)
1312
Update Chart
1310
1306
1308
Dose Plan
Time of Prime:
06:19
Activity Units:
mCi
#
Time
Activity
1 06:20 25
2 06:30 25
3 06:40 25
4 06:50 25
5 07:00 25
6 07:10 25
7 07:20 25
8 07:30 25
9 07:40 25
10 07:50 25
11 08:00 25
12 08:10 25
13 08:20 25
1304
1302

FIG. 13

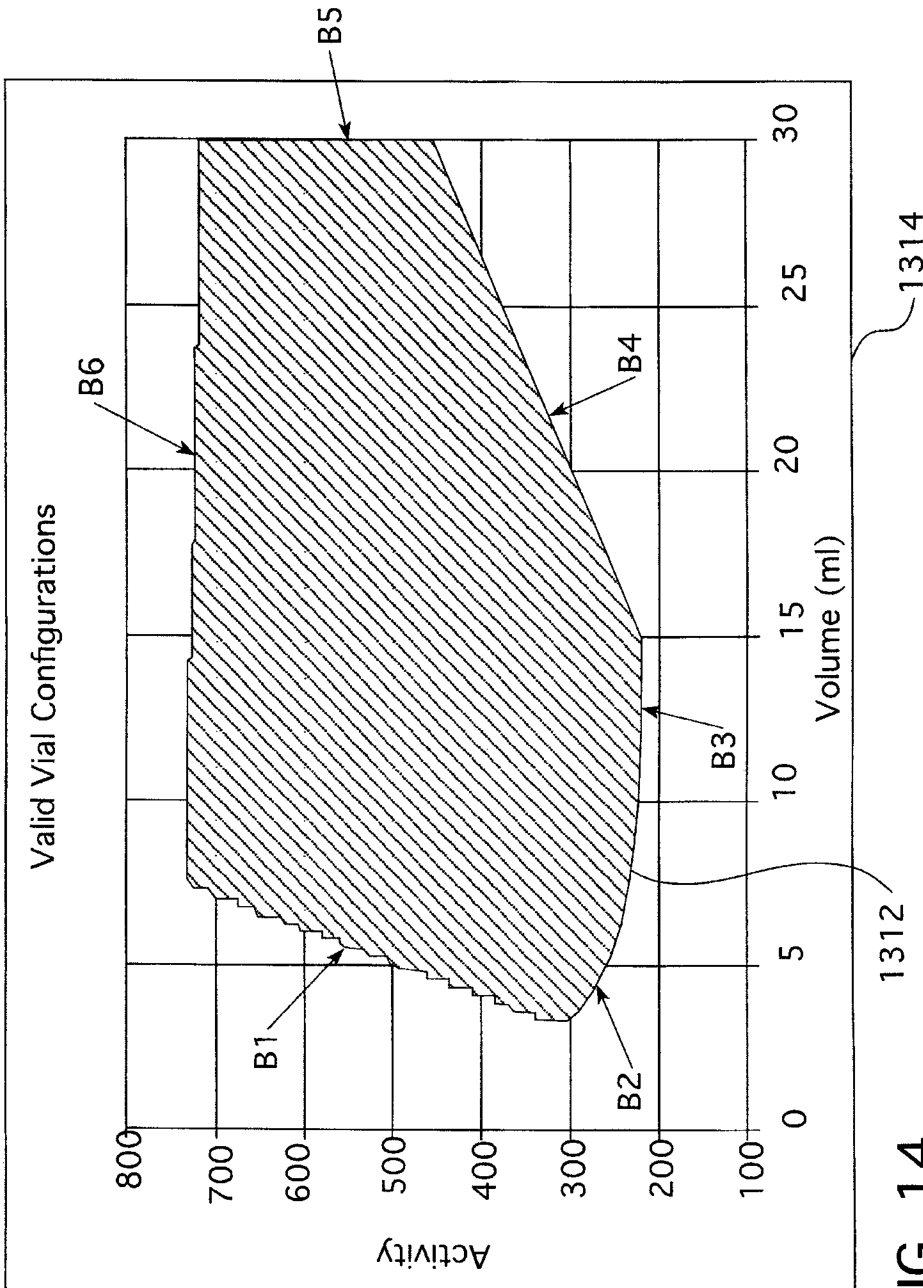

Valid Vial Configurations
Activity
800
700
600
500
400
300
200
100
0
5
10
15
20
25
30
Volume (ml)
B1
B2
B3
B4
B5
B6
1312
1314

FIG. 14

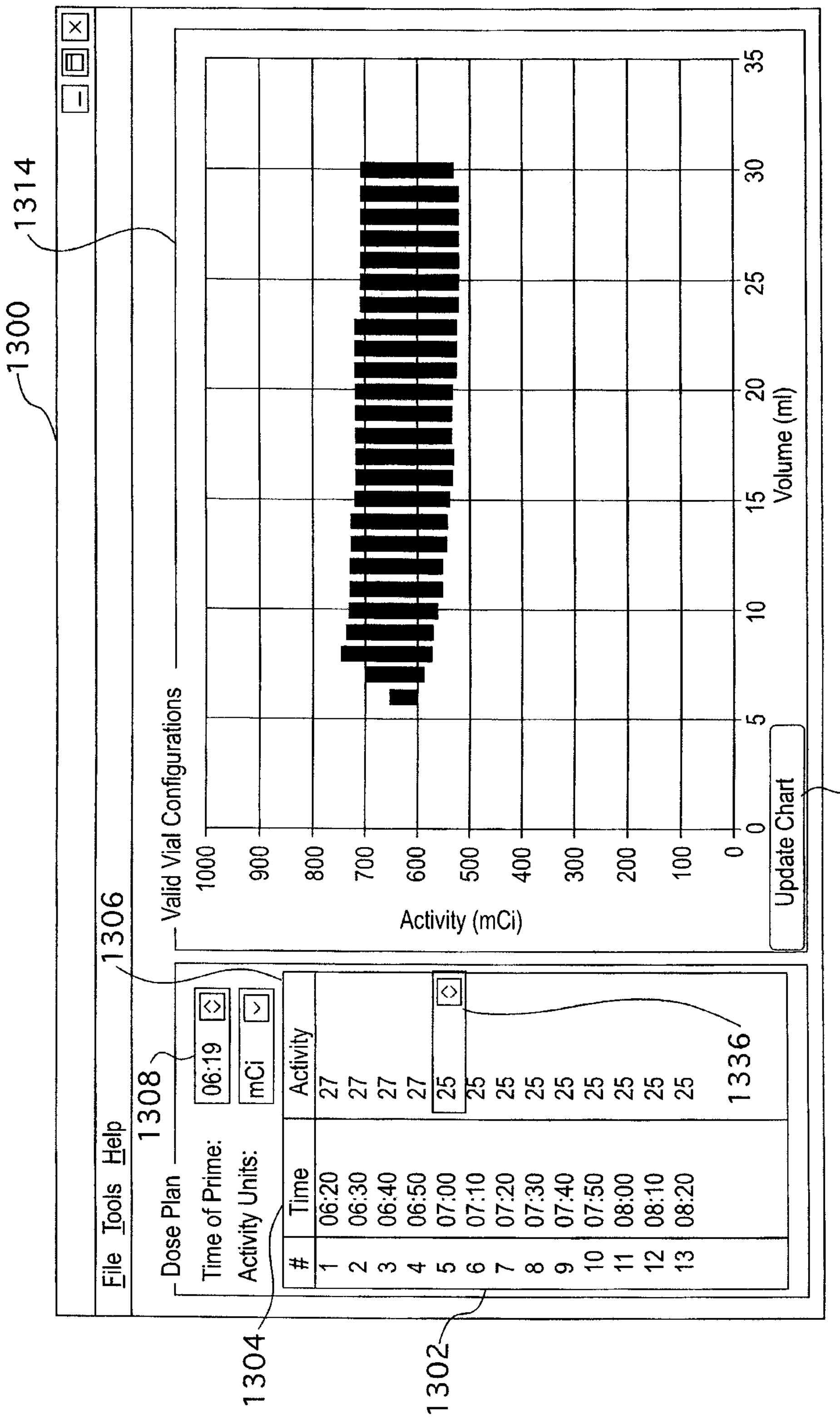

1300
1314
File Tools Help
Dose Plan
Time of Prime: 06:19
Activity Units: mCi
Time Activity
1 06:20 27
2 06:30 27
3 06:40 27
4 06:50 27
5 07:00 25
6 07:10 25
7 07:20 25
8 07:30 25
9 07:40 25
10 07:50 25
11 08:00 25
12 08:10 25
13 08:20 25
Valid Vial Configurations
Activity (mCi)
1000 900 800 700 600 500 400 300 200 100 0
0 5 10 15 20 25 30 35
Volume (ml)
Update Chart
1306
1308
1336
1304
1302
1310

FIG. 15

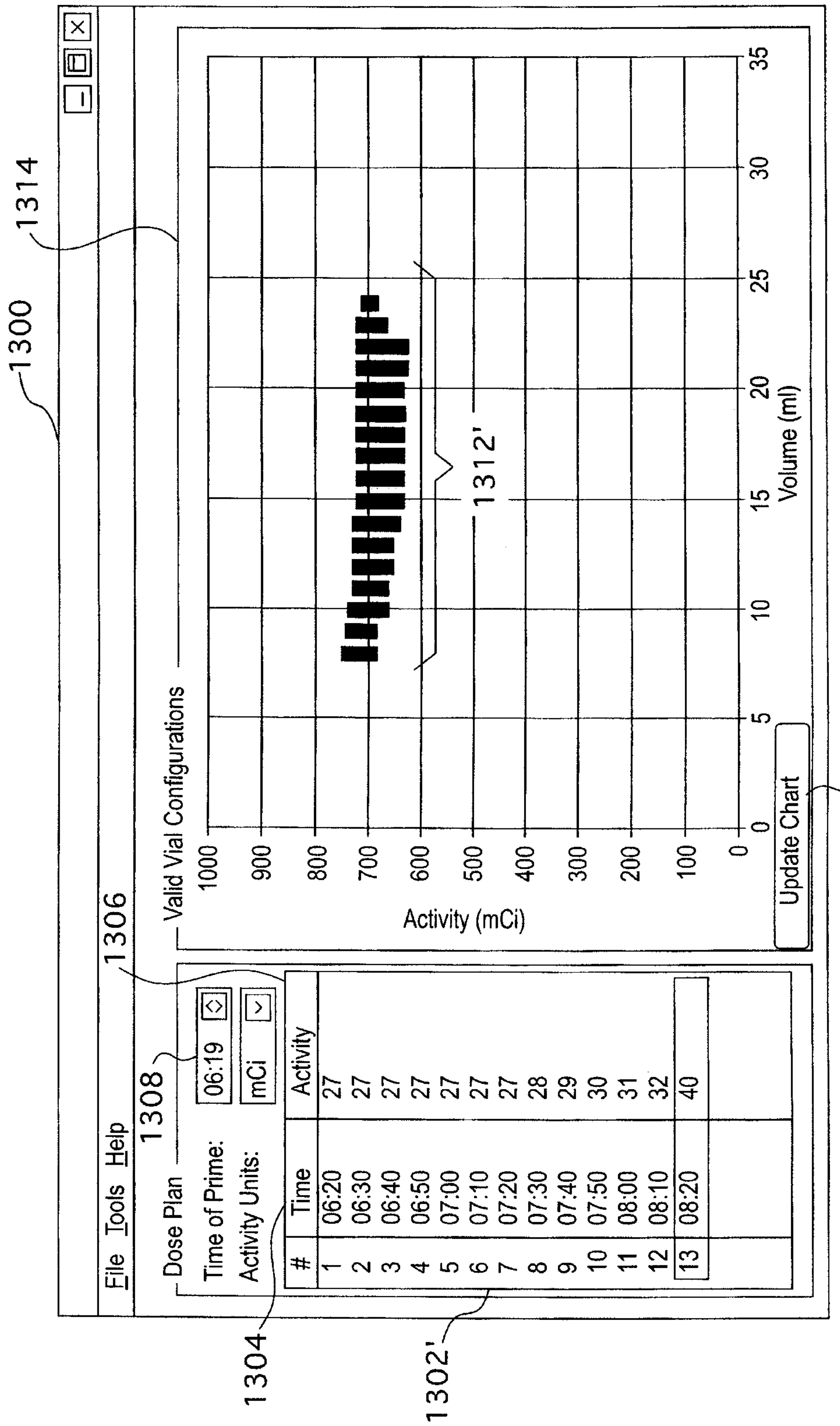

1300
1314
1306
1308
1304
1302'
1312'
1310
File Tools Help
Dose Plan
Time of Prime: 06:19
Activity Units: mCi
Time Activity
1 06:20 27
2 06:30 27
3 06:40 27
4 06:50 27
5 07:00 27
6 07:10 27
7 07:20 27
8 07:30 28
9 07:40 29
10 07:50 30
11 08:00 31
12 08:10 32
13 08:20 40
Valid Vial Configurations
Activity (mCi)
1000 900 800 700 600 500 400 300 200 100 0
0 5 10 15 20 25 30 35
Volume (ml)
Update Chart

FIG. 16

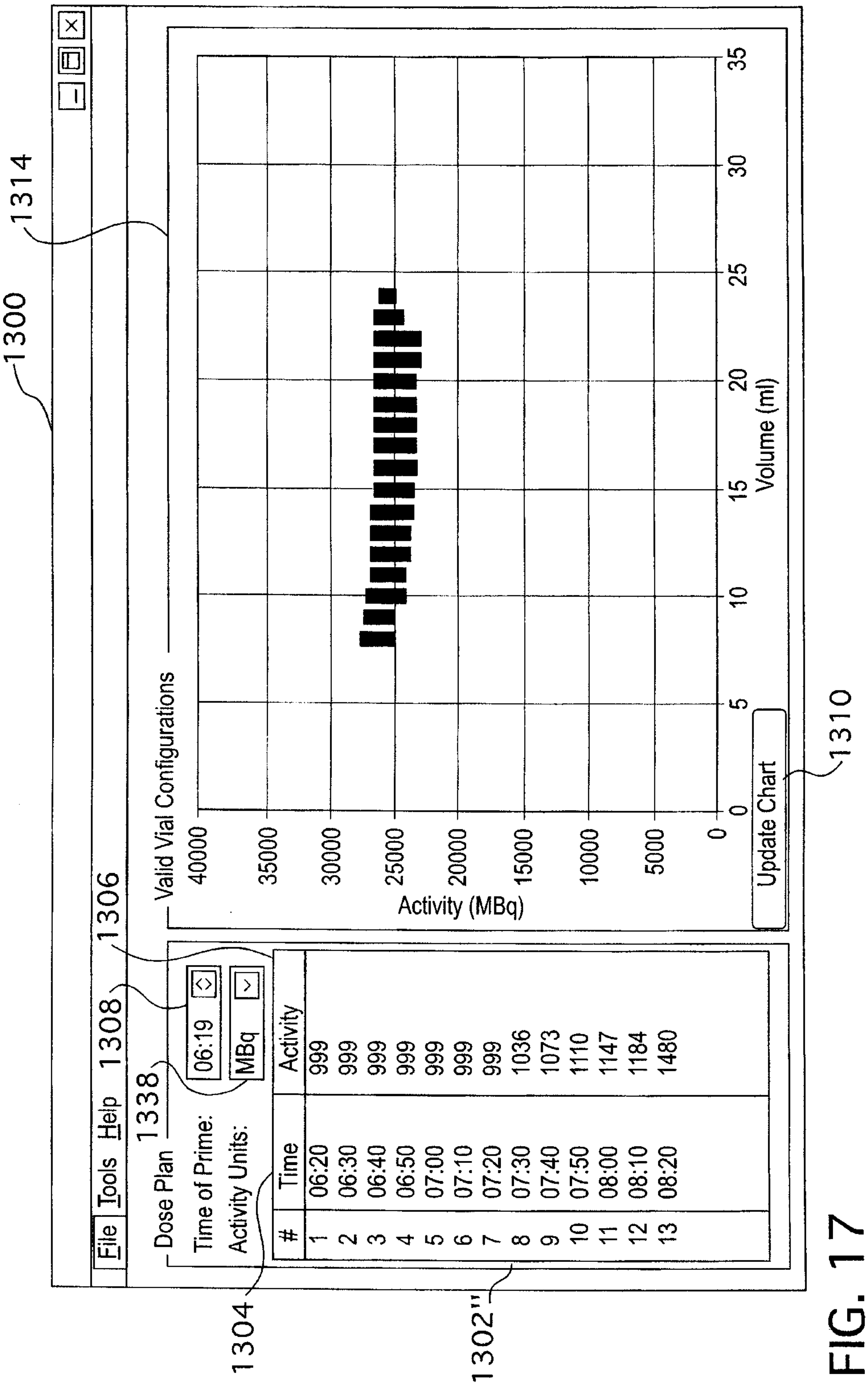

1300
1314
File Tools Help
Dose Plan
Time of Prime:
06:19
Activity Units:
MBq
Time Activity
1 06:20 999
2 06:30 999
3 06:40 999
4 06:50 999
5 07:00 999
6 07:10 999
7 07:20 999
8 07:30 1036
9 07:40 1073
10 07:50 1110
11 08:00 1147
12 08:10 1184
13 08:20 1480
Valid Vial Configurations
Activity (MBq)
40000
35000
30000
25000
20000
15000
10000
5000
0
0 5 10 15 20 25 30 35
Volume (ml)
Update Chart
1306
1308
1338
1304
1302''
1310

FIG. 17

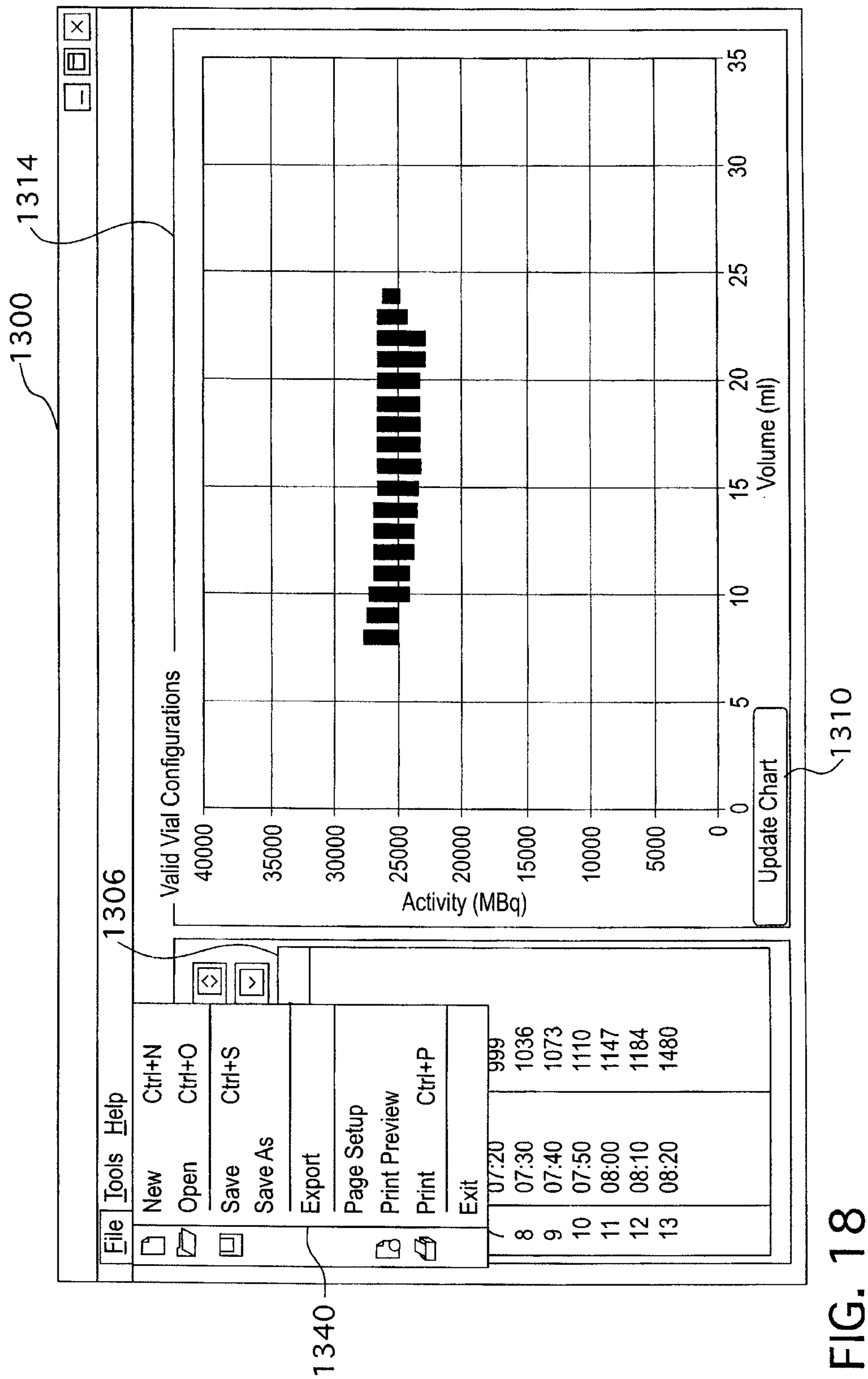

1300
1314
1306
1310
1340
File Tools Help
New Ctrl+N
Open Ctrl+O
Save Ctrl+S
Save As
Export
Page Setup
Print Preview
Print Ctrl+P
Exit
Valid Vial Configurations
Activity (MBq)
40000
35000
30000
25000
20000
15000
10000
5000
0
Volume (ml)
0
5
10
15
20
25
30
35
Update Chart
07:20 999
8 07:30 1036
9 07:40 1073
10 07:50 1110
11 08:00 1147
12 08:10 1184
13 08:20 1480

FIG. 18

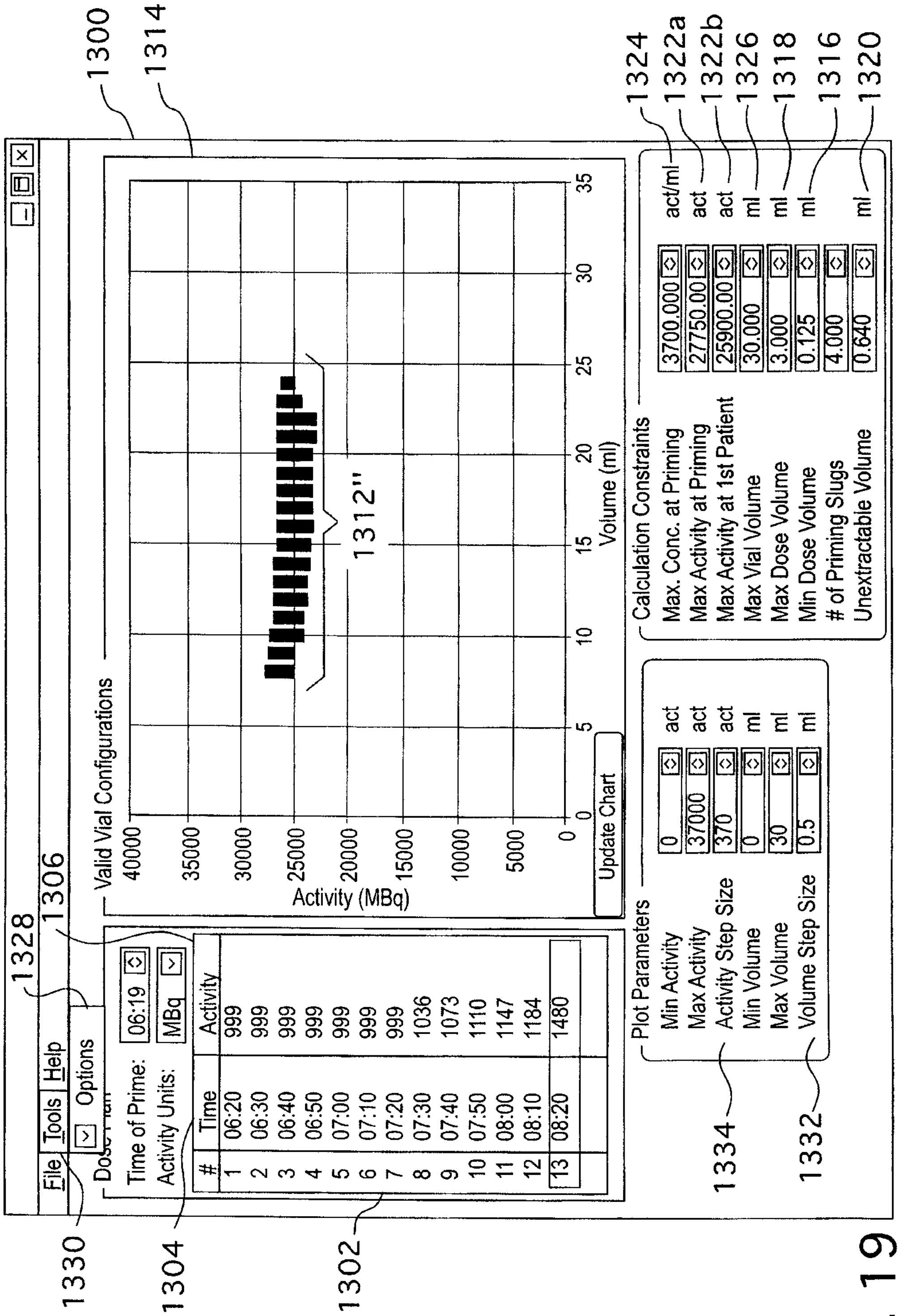

1300
1314
1324
1322a
1322b
1326
1318
1316
1320
1328
1306
1330
1304
1302
1334
1332
1312"
File Tools Help
Options
Time of Prime: 06:19
Activity Units: MBq
Time Activity
1 06:20 999
2 06:30 999
3 06:40 999
4 06:50 999
5 07:00 999
6 07:10 999
7 07:20 999
8 07:30 1036
9 07:40 1073
10 07:50 1110
11 08:00 1147
12 08:10 1184
13 08:20 1480
Valid Vial Configurations
Activity (MBq)
Volume (ml)
Update Chart
Plot Parameters
Min Activity 0 act
Max Activity 37000 act
Activity Step Size 370 act
Min Volume 0 ml
Max Volume 30 ml
Volume Step Size 0.5 ml
Calculation Constraints
Max. Conc. at Priming 3700.000 act/ml
Max Activity at Priming 27750.00 act
Max Activity at 1st Patient 25900.00 act
Max Vial Volume 30.000 ml
Max Dose Volume 3.000 ml
Min Dose Volume 0.125 ml
# of Priming Slugs 4.000
Unextractable Volume 0.640 ml

FIG. 19

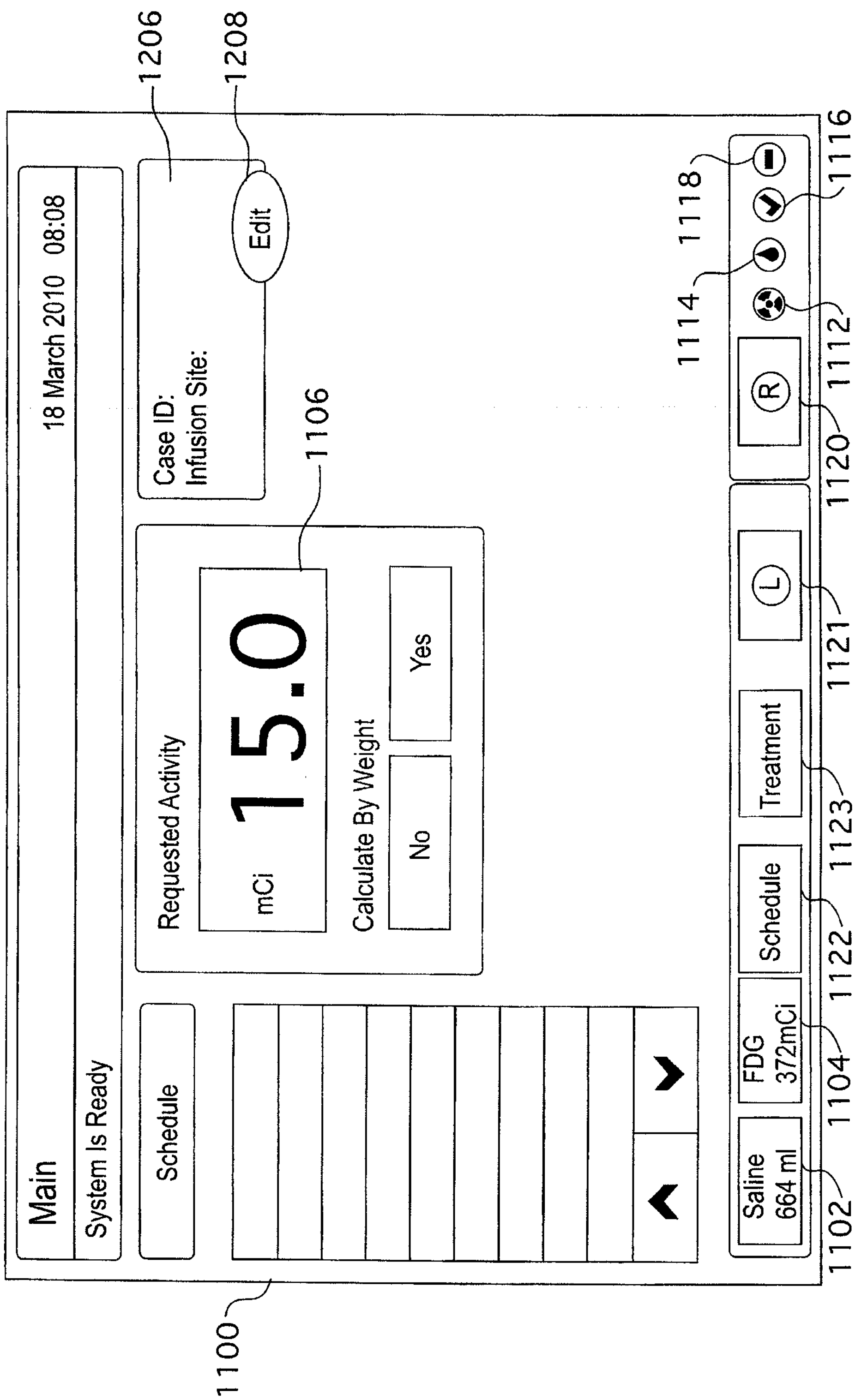

Main
18 March 2010 08:08
System Is Ready
Schedule
Requested Activity
mCi
15.0
Calculate By Weight
No
Yes
Case ID:
Infusion Site:
Edit
Saline
664 ml
FDG
372mCi
Schedule
Treatment
L
R
1100
1102
1104
1106
1112
1114
1116
1118
1120
1121
1122
1123
1206
1208

FIG. 20

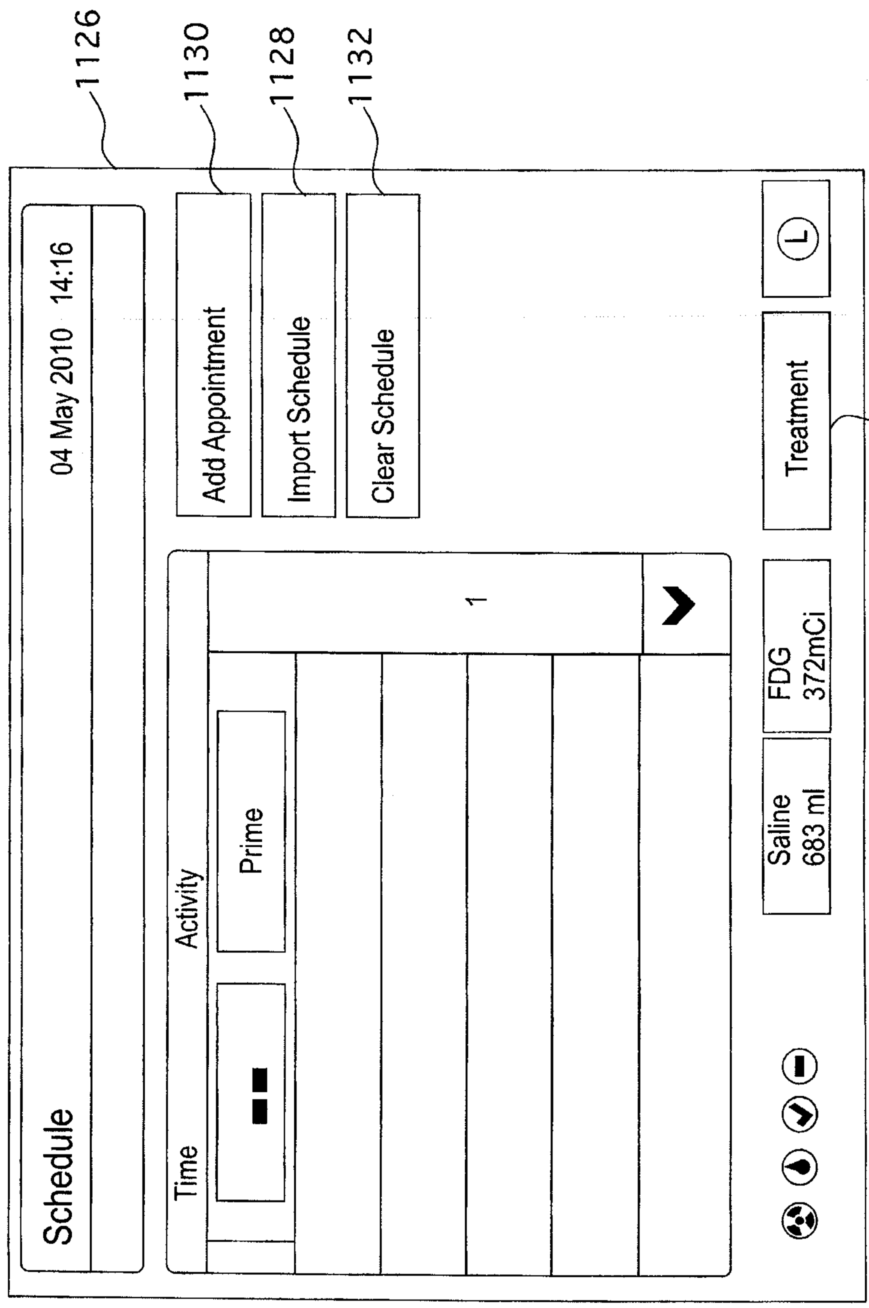

1126
1130
1128
1132
Schedule
04 May 2010 14:16
Add Appointment
Import Schedule
Clear Schedule
Time
Activity
Prime
1
Saline
683 ml
FDG
372mCi
Treatment
1123

FIG. 21

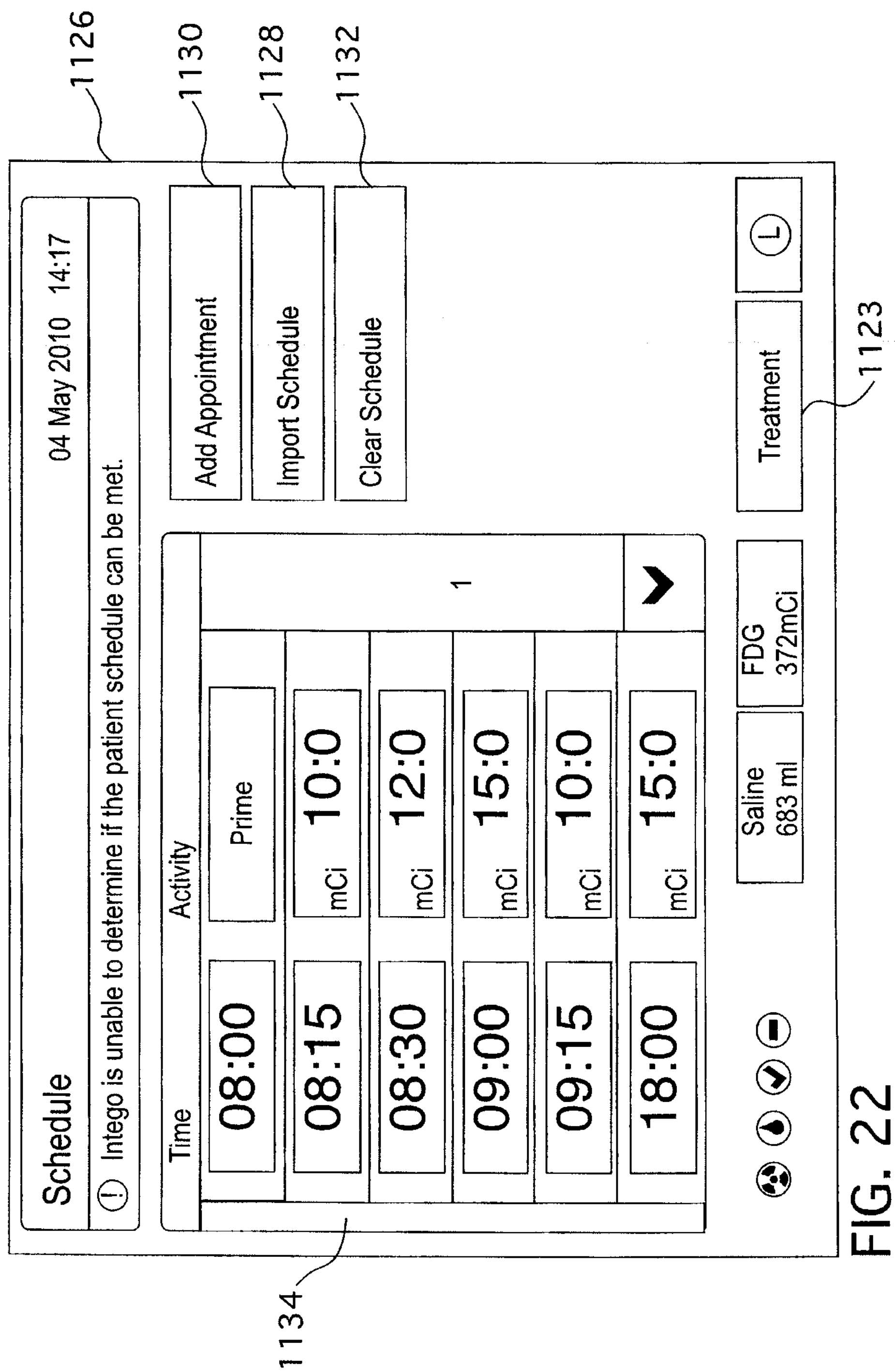

Schedule
04 May 2010 14:17
Intego is unable to determine if the patient schedule can be met.
Add Appointment
Import Schedule
Clear Schedule
Time
Activity
08:00
Prime
08:15
10:0 mCi
08:30
12:0 mCi
09:00
15:0 mCi
09:15
10:0 mCi
18:00
15:0 mCi
1
Saline 683 ml
FDG 372mCi
Treatment
1126
1130
1128
1132
1123
1134

FIG. 22

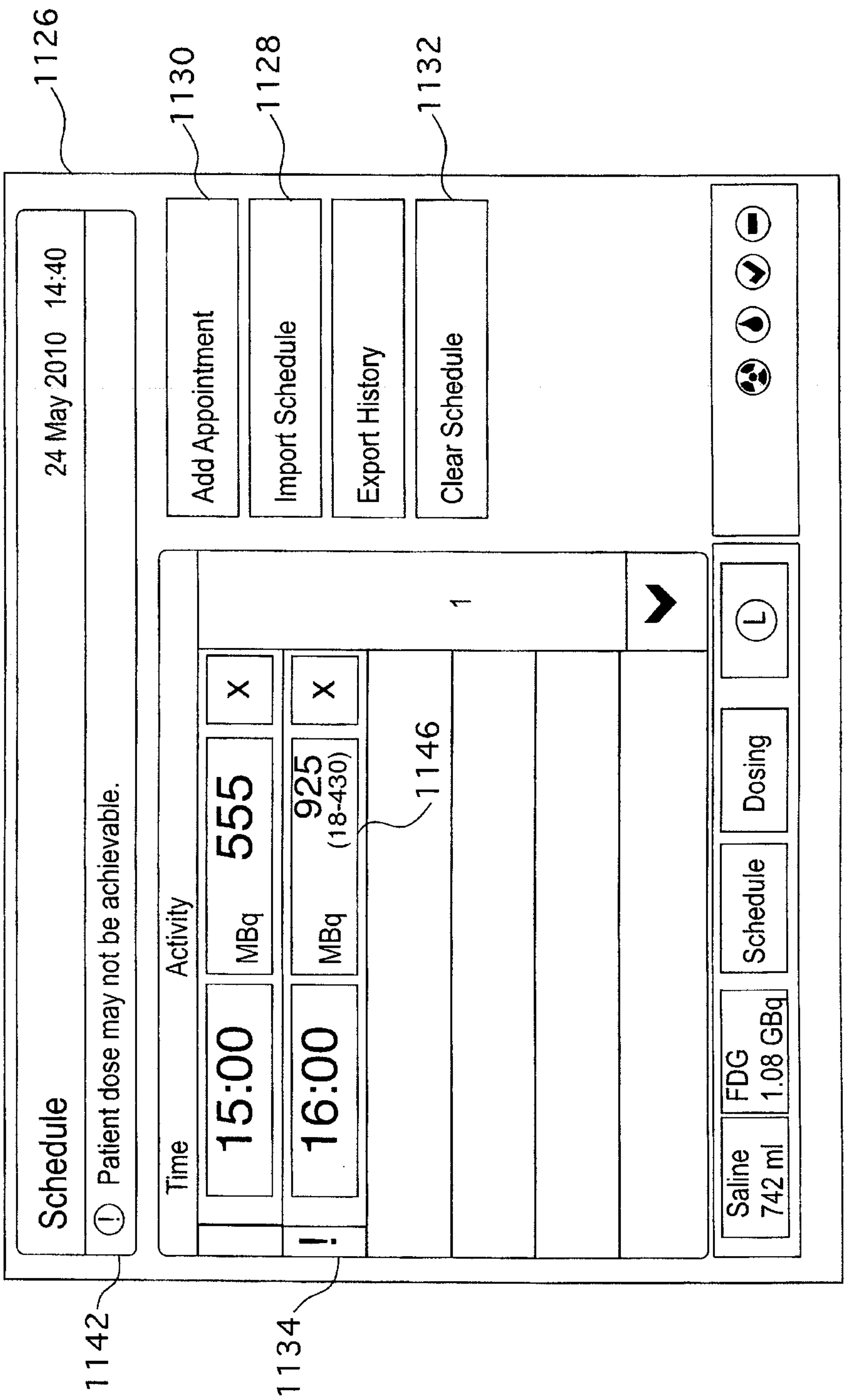

1126
1130
1128
1132
Schedule
24 May 2010 14:40
Patient dose may not be achievable.
Add Appointment
Import Schedule
Export History
Clear Schedule
Time
Activity
15:00
MBq
555
16:00
MBq
925
(18-430)
1146
Saline
742 ml
FDG
1.08 GBq
Schedule
Dosing
1142
1134

FIG. 23

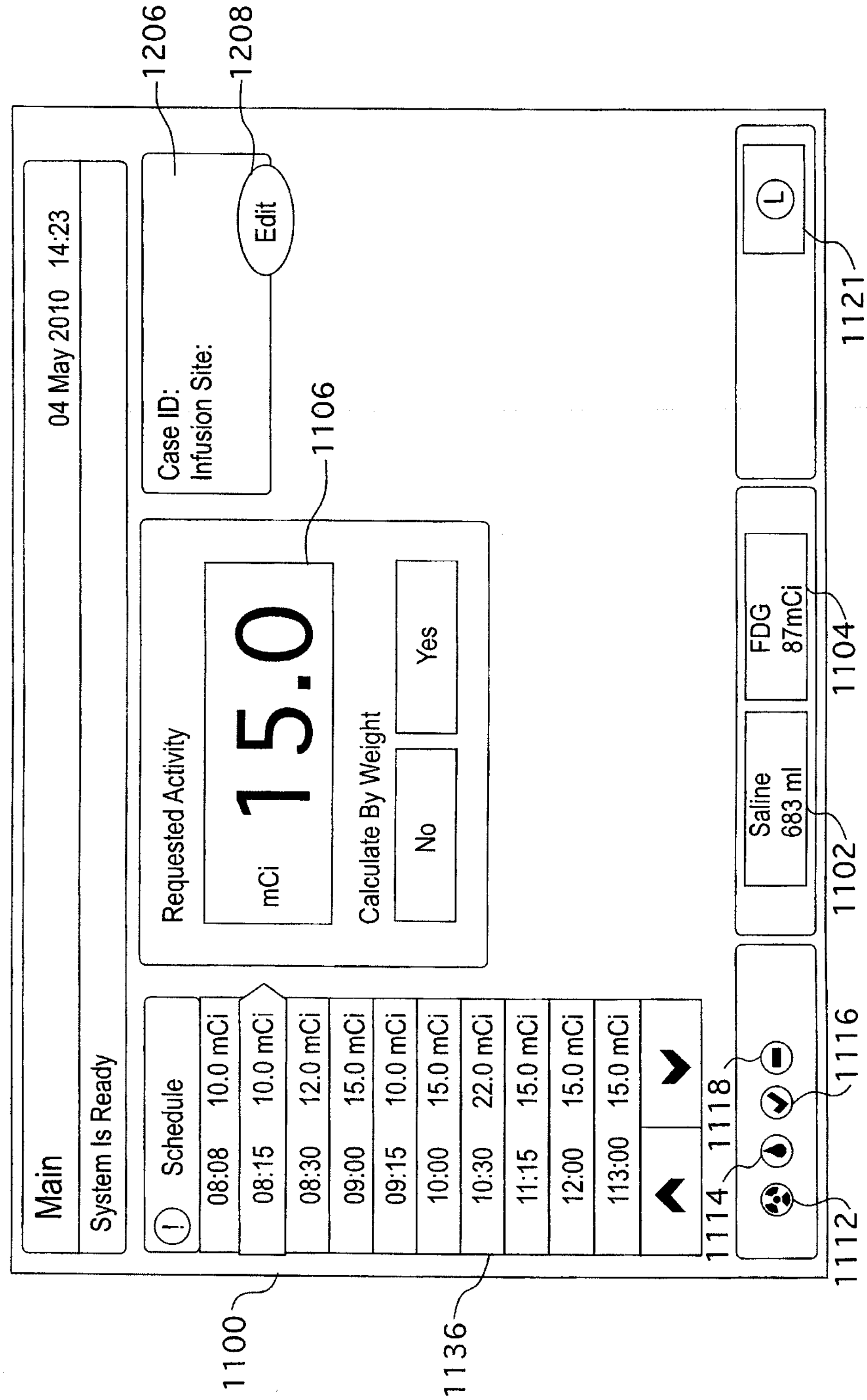

Main
System Is Ready
04 May 2010 14:23
Case ID:
Infusion Site:
Edit
Requested Activity
mCi
15.0
Calculate By Weight
No
Yes
Schedule
08:08 10.0 mCi
08:15 10.0 mCi
08:30 12.0 mCi
09:00 15.0 mCi
09:15 10.0 mCi
10:00 15.0 mCi
10:30 22.0 mCi
11:15 15.0 mCi
12:00 15.0 mCi
113:00 15.0 mCi
Saline
683 ml
FDG
87mCi
L
1100
1102
1104
1106
1112
1114
1116
1118
1121
1136
1206
1208

FIG. 24

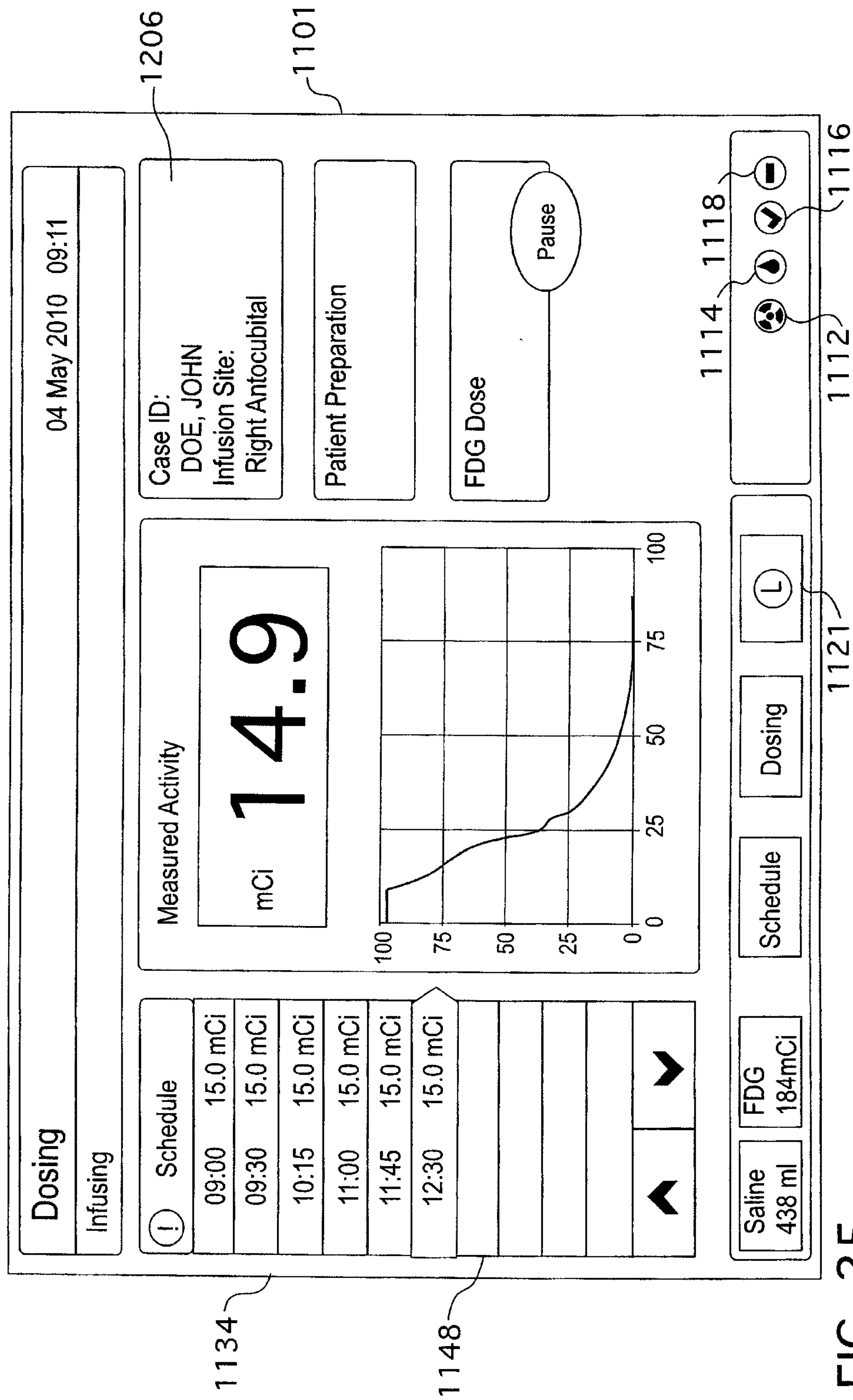

1206
1101
Dosing
Infusing
04 May 2010 09:11
Schedule
09:00 15.0 mCi
09:30 15.0 mCi
10:15 15.0 mCi
11:00 15.0 mCi
11:45 15.0 mCi
12:30 15.0 mCi
Measured Activity
mCi
14.9
Case ID:
DOE, JOHN
Infusion Site:
Right Antocubital
Patient Preparation
FDG Dose
Pause
Saline 438 ml
FDG 184mCi
Schedule
Dosing
1134
1148
1121
1114
1118
1112
1116

FIG. 25

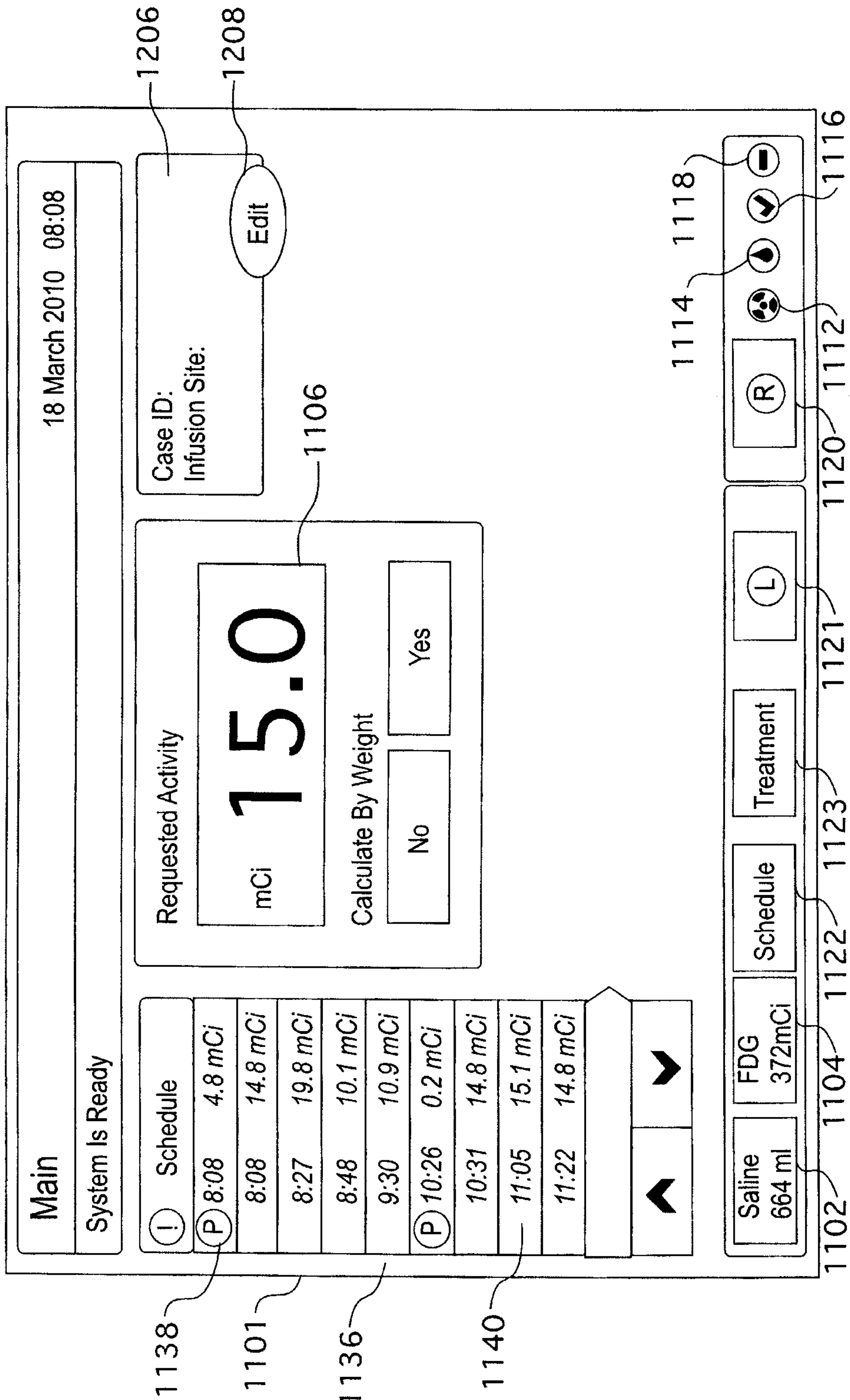
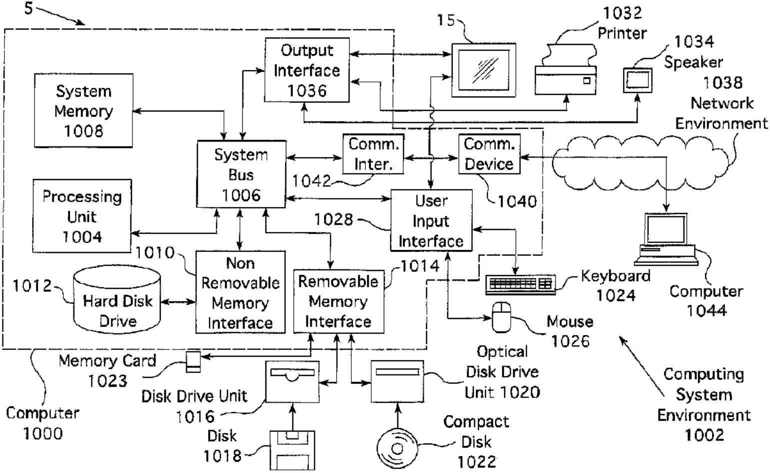

Main
System Is Ready
18 March 2010 08:08
Case ID:
Infusion Site:
Edit
Schedule
P 8:08 4.8 mCi
8:08 14.8 mCi
8:27 19.8 mCi
8:48 10.1 mCi
9:30 10.9 mCi
P 10:26 0.2 mCi
10:31 14.8 mCi
11:05 15.1 mCi
11:22 14.8 mCi
Requested Activity
mCi
15.0
Calculate By Weight
No
Yes
Saline 664 ml
FDG 372mCi
Schedule
Treatment
L
R
1206
1208
1106
1118
1114
1116
1112
1120
1121
1123
1122
1104
1102
1138
1101
1136
1140

FIG. 26


5
15
1032
Printer
1034
Speaker
1038
Network
Environment
Output
Interface
1036
System
Memory
1008
System
Bus
1006
Comm.
Inter.
Comm.
Device
1042
1040
Processing
Unit
1004
1028
User
Input
Interface
1010
Non
Removable
Memory
Interface
1014
Removable
Memory
Interface
1012
Hard Disk
Drive
Keyboard
1024
Computer
1044
Mouse
1026
Memory Card
1023
Optical
Disk Drive
Unit 1020
Disk Drive Unit
1016
Computer
1000
Disk
1018
Compact
Disk
1022
Computing
System
Environment
1002