Title: METHODS AND SYSTEMS FOR MONITORING AN AUTOMATED INFUSION SYSTEM

Abstract: Methods and systems for monitoring an automated radiopharmaceutical infusion apparatus are disclosed. A user interface graphically representing infusion apparatus components may be presented on a display device. Multiple sensors may be arranged within an infusion apparatus to measure property information associated with infusion apparatus components, including fluid pathways. The property information may include radioactivity and flow information. The property information may be compared with expected results. If the property information does not match the expected results, a fault condition may be indicated on the display device. The user interface may provide information and/or functions to manage the fault conditions.
METHODS AND SYSTEMS FOR MONITORING AN AUTOMATED INFUSION SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of United States Application No. 13/764,426, filed February 11, 2013 and entitled "Methods and Systems for Monitoring an Automated Infusion System," and which is incorporated herein in its entirety.

BACKGROUND

[0002] Radiopharmaceuticals are radioactive drugs or contrast agents used to treat disease and diagnose medical problems. They may be administered to patients using various methods, such as orally or by injection. Certain procedures, such as positron emission tomography (PET), use automated infusion systems to deliver carefully measured doses of the radiopharmaceutical to patients. Maintenance and proper operation of infusion systems are critical to ensure the safe and efficient injection of each dose. In addition, medical personnel who routinely work with these systems must be protected from prolonged exposure to radiation from the radiopharmaceutical.

[0003] Conventional infusion systems do not provide adequate information regarding system components during the infusion process, particularly the multiple fluid channels used to move the radiopharmaceutical and other fluids throughout the infusion system. Consequently, it is difficult for medical personnel to know the status of internal components in real-time and to observe them without being exposed to radiation.

SUMMARY

[0004] The invention described in this document is not limited to the particular systems, methodologies or protocols described, as these may vary. The terminology used
herein is for the purpose of describing particular embodiments only, and is not intended to limit the scope of the present disclosure.

[0005] It must be noted that as used herein and in the appended claims, the singular forms "a," "an," and "the" include plural reference unless the context clearly dictates otherwise. Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art. As used herein, the term "comprising” means "including, but not limited to.”

[0006] In an embodiment, a system for monitoring an automated radiopharmaceutical infusion apparatus may comprise a plurality of fluid pathways and a plurality of sensors positioned to measure at least one property associated with the plurality of fluid pathways. At least one of the plurality of fluid pathways may comprise a radiopharmaceutical source pathway, and the at least one property may comprise radioactivity. The system may further comprise a display device, a processor in communication with the plurality of sensors and the display device, and a non-transitory, computer-readable storage medium in operable communication with the processor. The computer-readable storage medium may contain one or more programming instructions that, when executed, cause the processor to receive property information from the plurality of sensors, present an apparatus display graphically representing apparatus components based on the property information on the display device, compare the property information with expected results, generate a fault condition responsive to property information not matching the expected results, and graphically represent the fault condition on the apparatus display.

[0007] In an embodiment, a system for monitoring an automated radiopharmaceutical infusion apparatus may comprise a plurality of fluid pathways and a plurality of sensors positioned to measure at least one property associated with the plurality of fluid pathways. At least one of the plurality of fluid pathways may comprise a
radiopharmaceutical source pathway, and the at least one property may comprise radioactivity. The system may further comprise a display device, a processor in communication with the plurality of sensors and the display device, and a non-transitory, computer-readable storage medium in operable communication with the processor. The computer-readable storage medium may contain one or more programming instructions that, when executed, cause the processor to receive property information from the plurality of sensors, present an apparatus display graphically representing apparatus components based on the property information on the display device, compare the property information with expected results, generate a fault condition responsive to property information not matching expected results, and graphically represent the fault condition on the apparatus display. The property information may comprise fluid flow information.

[0008] In an embodiment, a system for monitoring an automated radiopharmaceutical infusion apparatus may comprise a plurality of fluid pathways and a plurality of sensors positioned to measure at least one property associated with the plurality of fluid pathways. At least one of the plurality of fluid pathways may comprise a radiopharmaceutical source pathway, and the at least one property may comprise radioactivity. The system may further comprise a display device, a processor in communication with the plurality of sensors and the display device, and a non-transitory, computer-readable storage medium in operable communication with the processor. The computer-readable storage medium may contain one or more programming instructions that, when executed, cause the processor to receive property information from the plurality of sensors, present an apparatus display graphically representing apparatus components based on the property information on the display device, compare the property information with expected results, generate a fault condition responsive to property information not matching expected results, and graphically represent the fault condition on the apparatus display. The
property information may comprise information indicating the presence of a fluid in a fluid pathway.

[0009] In an embodiment, a system for monitoring an automated radiopharmaceutical infusion apparatus may comprise a plurality of fluid pathways and a plurality of sensors positioned to measure at least one property associated with the plurality of fluid pathways. At least one of the plurality of fluid pathways may comprise a radiopharmaceutical source pathway, and the at least one property may comprise radioactivity. The system may further comprise a display device, a processor in communication with the plurality of sensors and the display device, and a non-transitory, computer-readable storage medium in operable communication with the processor. The computer-readable storage medium may contain one or more programming instructions that, when executed, cause the processor to receive property information from the plurality of sensors, present an apparatus display graphically representing apparatus components based on the property information on the display device, compare the property information with expected results, generate a fault condition responsive to property information not matching expected results, and graphically represent the fault condition on the apparatus display. The apparatus components may comprise at least one fluid pathway.

[0010] In an embodiment, a system for monitoring an automated radiopharmaceutical infusion apparatus may comprise a plurality of fluid pathways and a plurality of sensors positioned to measure at least one property associated with the plurality of fluid pathways. At least one of the plurality of fluid pathways may comprise a radiopharmaceutical source pathway, and the at least one property may comprise radioactivity. The system may further comprise a display device, a processor in communication with the plurality of sensors and the display device, and a non-transitory, computer-readable storage medium in operable communication with the processor. The
computer-readable storage medium may contain one or more programming instructions that, when executed, cause the processor to receive property information from the plurality of sensors, present an apparatus display graphically representing apparatus components based on the property information on the display device, compare the property information with expected results, generate a fault condition responsive to property information not matching expected results, and graphically represent the fault condition on the apparatus display. The apparatus components may comprise a radiopharmaceutical source.

[0011] In an embodiment, a system for monitoring an automated radiopharmaceutical infusion apparatus may comprise a plurality of fluid pathways and a plurality of sensors positioned to measure at least one property associated with the plurality of fluid pathways. At least one of the plurality of fluid pathways may comprise a radiopharmaceutical source pathway, and the at least one property may comprise radioactivity. The system may further comprise a display device, a processor in communication with the plurality of sensors and the display device, and a non-transitory, computer-readable storage medium in operable communication with the processor. The computer-readable storage medium may contain one or more programming instructions that, when executed, cause the processor to receive property information from the plurality of sensors, present an apparatus display graphically representing apparatus components based on the property information on the display device, compare the property information with expected results, generate a fault condition responsive to property information not matching expected results, and graphically represent the fault condition on the apparatus display. The apparatus component may comprise a dose meter.

[0012] In an embodiment, a system for monitoring an automated radiopharmaceutical infusion apparatus may comprise a plurality of fluid pathways and a plurality of sensors positioned to measure at least one property associated with the plurality
of fluid pathways. At least one of the plurality of fluid pathways may comprise a radiopharmaceutical source pathway, and the at least one property may comprise radioactivity. The system may further comprise a display device, a processor in communication with the plurality of sensors and the display device, and a non-transitory, computer-readable storage medium in operable communication with the processor. The computer-readable storage medium may contain one or more programming instructions that, when executed, cause the processor to receive property information from the plurality of sensors, present an apparatus display graphically representing apparatus components based on the property information on the display device, compare the property information with expected results, generate a fault condition responsive to property information not matching expected results, and graphically represent the fault condition on the apparatus display. The apparatus components may comprise a dispensing element.

[0013] In an embodiment, a system for monitoring an automated radiopharmaceutical infusion apparatus may comprise a plurality of fluid pathways and a plurality of sensors positioned to measure at least one property associated with the plurality of fluid pathways. At least one of the plurality of fluid pathways may comprise a radiopharmaceutical source pathway, and the at least one property may comprise radioactivity. The system may further comprise a display device, a processor in communication with the plurality of sensors and the display device, and a non-transitory, computer-readable storage medium in operable communication with the processor. The computer-readable storage medium may contain one or more programming instructions that, when executed, cause the processor to receive property information from the plurality of sensors, present an apparatus display graphically representing apparatus components based on the property information on the display device, compare the property information with expected results, generate a fault condition responsive to property information not matching
expected results, and graphically represent the fault condition on the apparatus display. The fault condition may comprise a flow rate below a threshold value.

[0014] In an embodiment, a system for monitoring an automated radiopharmaceutical infusion apparatus may comprise a plurality of fluid pathways and a plurality of sensors positioned to measure at least one property associated with the plurality of fluid pathways. At least one of the plurality of fluid pathways may comprise a radiopharmaceutical source pathway, and the at least one property may comprise radioactivity. The system may further comprise a display device, a processor in communication with the plurality of sensors and the display device, and a non-transitory, computer-readable storage medium in operable communication with the processor. The computer-readable storage medium may contain one or more programming instructions that, when executed, cause the processor to receive property information from the plurality of sensors, present an apparatus display graphically representing apparatus components based on the property information on the display device, compare the property information with expected results, generate a fault condition responsive to property information not matching expected results, and graphically represent the fault condition on the apparatus display. The apparatus components may comprise a directional valve configured to connect at least two of the plurality of fluid pathways. The fault condition may comprise the presence of fluid in a dry pathway.

[0015] In an embodiment, a method for monitoring an automated radiopharmaceutical infusion apparatus may comprise providing a plurality of sensors, providing a processor operatively connected to the plurality of sensors and a display device, and causing the processor to enable monitoring the automated radiopharmaceutical infusion apparatus. The plurality of sensors may be positioned to measure at least one property associated with the plurality of fluid pathways. The plurality of pathways may comprise at
least one radiopharmaceutical fluid pathway, and the at least one property may comprise
radioactivity. The processor may monitor the automated radiopharmaceutical infusion
apparatus by receiving property information from the plurality of sensors, presenting an
apparatus display graphically representing apparatus components based on the property
information on the display device, comparing the property information with expected results,
generating a fault condition responsive to property information not matching the expected
results, and graphically representing the fault condition on the apparatus display.

[0016] In an embodiment, a method for monitoring an automated
radiopharmaceutical infusion apparatus may comprise providing a plurality of sensors,
providing a processor operatively connected to the plurality of sensors and a display device,
and monitoring the automated radiopharmaceutical infusion apparatus using the processor.
The plurality of sensors may be positioned to measure at least one property associated with
the plurality of fluid pathways. The plurality of pathways may comprise at least one
radiopharmaceutical fluid pathway, and the at least one property may comprise radioactivity.
The processor may monitor the automated radiopharmaceutical infusion apparatus by
receiving property information from the plurality of sensors, presenting an apparatus display
graphically representing apparatus components based on the property information on the
display device, comparing the property information with expected results, generating a fault
condition responsive to property information not matching expected results, and graphically
representing the fault condition on the apparatus display. The processor may present
information associated with the selected graphically represented fault condition.

[0017] In an embodiment, a method for monitoring an automated
radiopharmaceutical infusion apparatus may comprise providing a plurality of sensors,
providing a processor operatively connected to the plurality of sensors and a display device,
and monitoring the automated radiopharmaceutical infusion apparatus using the processor.
The plurality of sensors may be positioned to measure at least one property associated with the plurality of fluid pathways. The plurality of pathways may comprise at least one radiopharmaceutical fluid pathway, and the at least one property may comprise radioactivity. The processor may monitor the automated radiopharmaceutical infusion apparatus by receiving property information from the plurality of sensors, presenting an apparatus display graphically representing apparatus components based on the property information on the display device, comparing the property information with expected results, generating a fault condition responsive to property information not matching expected results, and graphically representing the fault condition on the apparatus display. Comparing the property information with expected results may comprises determining, by the processor, a stage of an infusion process and comparing the property information with expected results for the stage of the infusion process. The stage of the infusion process may comprise a dry tubing priming stage.

[0018] In an embodiment, a method for monitoring an automated radiopharmaceutical infusion apparatus may comprise providing a plurality of sensors, providing a processor operatively connected to the plurality of sensors and a display device, and monitoring the automated radiopharmaceutical infusion apparatus using the processor. The plurality of sensors may be positioned to measure at least one property associated with the plurality of fluid pathways. The plurality of pathways may comprise at least one radiopharmaceutical fluid pathway, and the at least one property may comprise radioactivity. The processor may monitor the automated radiopharmaceutical infusion apparatus by receiving property information from the plurality of sensors, presenting an apparatus display graphically representing apparatus components based on the property information on the display device, comparing the property information with expected results, generating a fault condition responsive to property information not matching expected results, and graphically
representing the fault condition on the apparatus display. Comparing the property
information with expected results may comprises determining, by the processor, a stage of an
infusion process and comparing the property information with expected results for the stage
of the infusion process. The stage of the infusion process may comprise a patient infusion
stage.

[0019] In an embodiment, a method for monitoring an automated
radiopharmaceutical infusion apparatus may comprise providing a plurality of sensors,
providing a processor operatively connected to the plurality of sensors and a display device,
and monitoring the automated radiopharmaceutical infusion apparatus using the processor.
The plurality of sensors may be positioned to measure at least one property associated with
the plurality of fluid pathways. The plurality of pathways may comprise at least one
radiopharmaceutical fluid pathway, and the at least one property may comprise radioactivity.
The processor may monitor the automated radiopharmaceutical infusion apparatus by
receiving property information from the plurality of sensors, presenting an apparatus display
d graphically representing apparatus components based on the property information on the
display device, comparing the property information with expected results, generating a fault
condition responsive to property information not matching expected results, and graphically
representing the fault condition on the apparatus display. The plurality of fluid pathways
may further comprise at least one of the following: a saline pathway, a dose meter inlet
pathway, a dose meter outlet pathway, and a waste pathway.

[0020] In an embodiment, a method for monitoring an automated
radiopharmaceutical infusion apparatus may comprise providing a plurality of sensors,
providing a processor operatively connected to the plurality of sensors and a display device,
and monitoring the automated radiopharmaceutical infusion apparatus using the processor.
The plurality of sensors may be positioned to measure at least one property associated with
the plurality of fluid pathways. The plurality of pathways may comprise at least one radiopharmaceutical fluid pathway, and the at least one property may comprise radioactivity. The processor may monitor the automated radiopharmaceutical infusion apparatus by receiving property information from the plurality of sensors, presenting an apparatus display graphically representing apparatus components based on the property information on the display device, comparing the property information with expected results, generating a fault condition responsive to property information not matching expected results, and graphically representing the fault condition on the apparatus display. The plurality of radioactivity sensors may further comprise at least one of a silicon diode, a silicon PIN diode, an avalanche diode, a scintillator, a photomultiplier, a solid state crystal, a semiconductor, Geiger tubes, an ionization-chamber, a silicon photodiode, a microdischarge-based sensor, a sodium iodide crystal sensor, a bismuth tri-iodide crystal sensor, a cadmium tellurium crystal semiconductor, a cadmium zinc tellurium semiconductor, and combinations thereof.

In an embodiment, a method for monitoring an automated radiopharmaceutical infusion apparatus may comprise providing a plurality of sensors, providing a processor operatively connected to the plurality of sensors and a display device, and monitoring the automated radiopharmaceutical infusion apparatus using the processor. The plurality of sensors may be positioned to measure at least one property associated with the plurality of fluid pathways. The plurality of pathways may comprise at least one radiopharmaceutical fluid pathway, and the at least one property may comprise radioactivity. The processor may monitor the automated radiopharmaceutical infusion apparatus by receiving property information from the plurality of sensors, presenting an apparatus display graphically representing apparatus components based on the property information on the display device, comparing the property information with expected results, generating a fault condition responsive to property information not matching expected results, and graphically
representing the fault condition on the apparatus display. The property information may comprise fluid flow information.

[0022] In an embodiment, a method for monitoring an automated radiopharmaceutical infusion apparatus may comprise providing a plurality of sensors, providing a processor operatively connected to the plurality of sensors and a display device, and monitoring the automated radiopharmaceutical infusion apparatus using the processor. The plurality of sensors may be positioned to measure at least one property associated with the plurality of fluid pathways. The plurality of pathways may comprise at least one radiopharmaceutical fluid pathway, and the at least one property may comprise radioactivity. The processor may monitor the automated radiopharmaceutical infusion apparatus by receiving property information from the plurality of sensors, presenting an apparatus display graphically representing apparatus components based on the property information on the display device, comparing the property information with expected results, generating a fault condition responsive to property information not matching expected results, and graphically representing the fault condition on the apparatus display. The property information may comprise information indicating the presence of a fluid in a fluid pathway.

[0023] In an embodiment, a method for monitoring an automated radiopharmaceutical infusion apparatus may comprise providing a plurality of sensors, providing a processor operatively connected to the plurality of sensors and a display device, and monitoring the automated radiopharmaceutical infusion apparatus using the processor. The plurality of sensors may be positioned to measure at least one property associated with the plurality of fluid pathways. The plurality of pathways may comprise at least one radiopharmaceutical fluid pathway, and the at least one property may comprise radioactivity. The processor may monitor the automated radiopharmaceutical infusion apparatus by receiving property information from the plurality of sensors, presenting an apparatus display
graphically representing apparatus components based on the property information on the display device, comparing the property information with expected results, generating a fault condition responsive to property information not matching expected results, and graphically representing the fault condition on the apparatus display. The apparatus components may comprise a radiopharmaceutical source.

[0024] In an embodiment, a method for monitoring an automated radiopharmaceutical infusion apparatus may comprise providing a plurality of sensors, providing a processor operatively connected to the plurality of sensors and a display device, and monitoring the automated radiopharmaceutical infusion apparatus using the processor. The plurality of sensors may be positioned to measure at least one property associated with the plurality of fluid pathways. The plurality of pathways may comprise at least one radiopharmaceutical fluid pathway, and the at least one property may comprise radioactivity. The processor may monitor the automated radiopharmaceutical infusion apparatus by receiving property information from the plurality of sensors, presenting an apparatus display graphically representing apparatus components based on the property information on the display device, comparing the property information with expected results, generating a fault condition responsive to property information not matching expected results, and graphically representing the fault condition on the apparatus display. The apparatus components may comprise a dose meter.

[0025] In an embodiment, a method for monitoring an automated radiopharmaceutical infusion apparatus may comprise providing a plurality of sensors, providing a processor operatively connected to the plurality of sensors and a display device, and monitoring the automated radiopharmaceutical infusion apparatus using the processor. The plurality of sensors may be positioned to measure at least one property associated with the plurality of fluid pathways. The plurality of pathways may comprise at least one
radiopharmaceutical fluid pathway, and the at least one property may comprise radioactivity. The processor may monitor the automated radiopharmaceutical infusion apparatus by receiving property information from the plurality of sensors, presenting an apparatus display graphically representing apparatus components based on the property information on the display device, comparing the property information with expected results, generating a fault condition responsive to property information not matching expected results, and graphically representing the fault condition on the apparatus display. The apparatus components may comprise a dispensing element.

[0026] In an embodiment, a method for monitoring an automated radiopharmaceutical infusion apparatus may comprise providing a plurality of sensors, providing a processor operatively connected to the plurality of sensors and a display device, and monitoring the automated radiopharmaceutical infusion apparatus using the processor. The plurality of sensors may be positioned to measure at least one property associated with the plurality of fluid pathways. The plurality of pathways may comprise at least one radiopharmaceutical fluid pathway, and the at least one property may comprise radioactivity. The processor may monitor the automated radiopharmaceutical infusion apparatus by receiving property information from the plurality of sensors, presenting an apparatus display graphically representing apparatus components based on the property information on the display device, comparing the property information with expected results, generating a fault condition responsive to property information not matching expected results, and graphically representing the fault condition on the apparatus display. The method may further comprise changing, by the processor, the position of the directional valve responsive to user input received by the processor.

[0027] In an embodiment, a method for monitoring an automated radiopharmaceutical infusion apparatus may comprise providing a plurality of sensors,
providing a processor operatively connected to the plurality of sensors and a display device, and monitoring the automated radiopharmaceutical infusion apparatus using the processor. The plurality of sensors may be positioned to measure at least one property associated with the plurality of fluid pathways. The plurality of pathways may comprise at least one radiopharmaceutical fluid pathway, and the at least one property may comprise radioactivity. The processor may monitor the automated radiopharmaceutical infusion apparatus by receiving property information from the plurality of sensors, presenting an apparatus display graphically representing apparatus components based on the property information on the display device, comparing the property information with expected results, generating a fault condition responsive to property information not matching expected results, and graphically representing the fault condition on the apparatus display. The fault condition may comprise the presence of fluid in a dry pathway.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] FIG. 1 depicts an illustrative automated infusion apparatus according to an embodiment.

[0029] FIG. 2 depicts an illustrative infusion apparatus user interface according to some embodiments.

[0030] FIG. 3 depicts a flow diagram of a method of monitoring an automated radiopharmaceutical infusion apparatus according to an embodiment.

[0031] FIG. 4 depicts a block diagram of illustrative internal hardware that may be used to contain or implement program instructions according to an embodiment.

[0032] FIG. 5 depicts a generalized signal and threshold relationship graphed with respect to time according to an embodiment.

DETAILED DESCRIPTION

-15-
[0033] The terminology used in the description is for the purpose of describing the particular versions or embodiments only, and is not intended to limit the scope.

[0034] The present disclosure is directed toward obtaining and presenting information associated with the operation of an automated infusion apparatus, and a system configured to inject a radiopharmaceutical in particular. In one embodiment, the information may be associated with the fluids delivered through the infusion apparatus and/or the fluid channels used to move the fluids within and outside of the infusion apparatus. The information may be obtained through one or more sensors positioned throughout the infusion apparatus. Illustrative and non-restrictive examples of sensors include radioactivity, flow and optical sensors. A processor may be configured to receive the information. The processor may be connected to a display device and may execute one or more software applications configured to present a graphical display of the infusion apparatus on the display device. The one or more software applications may also compare the information with expected values. In an embodiment, if the information is not within the range of an expected value, a fault condition may be generated and visually represented on the graphical display. The sensor information may also be used to assess the radioactivity in the unit to enable the user to take appropriate actions or precautions if the system shielding needs to be opened while significant radiopharmaceutical is contained in the system.

[0035] This may be useful in the case of system malfunction or suspected leakage, whether the radiopharmaceutical is in the fluid path or elsewhere. The present disclosure is not limited to the embodiments described herein. For example, other embodiments may pertain to fluids containing cells or fluids containing non-radioactive drugs. Fluids containing cells may be monitored for important parameters such as concentration of cells or percentage of live cells. For other drugs similar monitoring and checking systems and methods can be useful, for example when the system has the capability for drawing a dose.
and delivering one drug to multiple patients, or multiple drugs to one or more patients, or when dilution or mixing is involved.

[0036] Other embodiments can be used to deliver cells in suspension to a target, either into the bloodstream or into tissue of a person, animal, tissue scaffolding, or other material. According to this example, it may be useful to know the number of cells, and in certain embodiments, the number of living or healthy cells and/or control the delivery so that the desired number of cells is delivered. According to this embodiment, a sensor may counts cells, for example using the Coulter principle, or using optical or fluorescence as in cell sorters, using other optical properties as applicable, and/or optionally using, for example, magnetic particles or other properties if the cells are tagged or labeled in a way that can be assessed by the specific sensor. Detecting cell death or percentage of viable cells before delivery can provide important information and may prevent, for example, useless or damaging treatments.

[0037] Additional similar embodiments may be used to deliver one or more non-radioactive drugs or fluids, where the total dose and/or concentration over a specific time is a necessary parameter to control or achieve. In this case, the sensor may measure concentration, presence, or absence of the desired drug by a variety of means, for example optical refraction, fluid density in a Coriolis effect, a property of sound transmission in the fluid, viscosity, conductivity, light transmission, scatter or absorption, or color, or a combination of any of these means depending up the drugs being used. For example, according to one embodiment, a source of ionizing radiation may measure the radiation absorption of the fluid, for example if the desired measurement is the density of X-ray contrast. Additional embodiments may be used to deliver and assess cells as well as monitor the delivery or lack of delivery of drugs, such as cell preservation buffers that should only be injected in relatively low concentrations.
Various embodiments of this system may be used to safely and accurately deliver controlled doses of fluid to multiple patients from a bulk source, multiple times to a single patient, and continually to a single patient over time with adjustments made based upon the condition of the drug (e.g. cell death or radioactive decay), for example as determined by the system described herein.

FIG. 1 depicts an illustrative automated infusion apparatus according to an embodiment. As shown in FIG. 1, an automated infusion system 100 may include an infusion apparatus 105 configured to deliver a medical fluid to a patient. The infusion apparatus 105 may have a radiopharmaceutical bulk container 130 arranged therein and configured to hold a volume of the radiopharmaceutical in liquid or substantially liquid form. In a radiopharmaceutical infusion system, the radiopharmaceutical bulk container 130 may be in the form of a shielded vial, commonly referred to as a "pig," such as a lead or tungsten shielded vial. Other medical fluid containers 115 may also be positioned within the infusion apparatus 105. A non-limiting example of a medical fluid stored in the other medical containers 115 is saline, which may be used for various purposes known to those having ordinary skill in the art. For instance, saline may be used to dilute the radiopharmaceutical to a specified concentration, as a "chaser" to the radiopharmaceutical, to push the radiopharmaceutical through the automated infusion system 100, and combination thereof. A dose meter 120 may be provided that operates to verify the dose of the radiopharmaceutical that will be delivered to the patient through the dispensing element 125. The dose meter 120 may be comprised of various dose meters known to those having ordinary skill in the art, such as an ionization chamber. The dispensing element 125 may comprise any type of element capable of delivering the dose to the patient, such as intravenously through a syringe, catheter, needle, or automated injection system. A waste container 135 may be provided for receiving liquid waste within the system, such as excess saline or portions of the
radiopharmaceutical outside of the radiopharmaceutical bulk container 130 after infusion is complete or has been stopped.

[0040] The infusion apparatus 105 includes multiple fluid pathways 160, 165, 170, 175, 180, 185 that allow various fluids to travel within the apparatus. The fluid pathways 160, 165, 170, 175, 180, 185 may include a flexible and deformable tube, such as a polyvinyl chloride (PVC) tube. In an embodiment, the fluid pathways 160, 165, 170, 175, 180, 185 may be comprised of generally disposable tubing that is replaced at various times, such as between infusions, daily, weekly, or when new radiopharmaceutical is placed in the infusion apparatus 105.

[0041] An infusion pump (not shown) may be used to pump the various fluids within the fluid pathways 160, 165, 170, 175, 180, 185. The fluid pathways 160, 165, 170, 175, 180, 185 may be connected to various valves and other components within the infusion apparatus. The fluid pathways 160, 165, 170, 175, 180, 185 may connect with a directional valve 140 configured to join one or more of the pathways in fluid communication. For example, the fluid pathway 165 for saline in the medical fluid container 115 may be joined with the fluid pathway 185 for the radiopharmaceutical, for instance, as a chaser and/or to dilute the radiopharmaceutical before delivery to the patient. The saline-radiopharmaceutical pathway 165, 185 may be joined with the inlet pathway 170 for the dose meter 120. The resulting saline-radiopharmaceutical-dose meter pathway 165, 185, 170 provides a channel for a dose of radiopharmaceutical to be measured by the dose meter 120. As shown in FIG. 1, the radiopharmaceutical may flow from the exit pathway 175 for the dose meter 120 to the pathway 180 for the dispensing element 125. The saline-radiopharmaceutical pathway 165, 185 may also be joined directly with the pathway 180 to the dispensing element 125. In this manner, two or more of the pathways 160, 165, 170, 175, 180, 185 may be joined in fluid communication and disconnected as needed during operation of the infusion apparatus 105.
One or more sensors 110 may be positioned within the infusion apparatus 105 to collect information associated with the apparatus pathways 160, 165, 170, 175, 180, 185 and apparatus elements 115, 130, 130. The sensors 110 may comprise any type of sensor capable of measuring a property of interest, including, without limitation, concentration, radioactivity, salinity, conductance, optical properties, analyte concentration, flow, and combinations thereof. Illustrative sensors 110 include, but are not limited to, temperature sensors, pressure sensors, radioactivity sensors, optical sensors, analyte sensors, concentration sensors, flow sensors, electro-resistive devices, electro-capacitive devices, ultrasound devices, and combinations thereof. For example, one or more sensors 110 may provide information concerning the volume of a medical fluid in a medical fluid container 115. In another example, one or more sensors 110 may provide information concerning the level of radioactivity associated with one or more of the pathways 160, 165, 170, 175, 180, 185. In a further example, one or more sensors 110 may provide information concerning the level of flow (e.g., cubic meters/second) of a fluid through one or more of the pathways 160, 165, 170, 175, 180, 185.

The infusion apparatus 105 may generally comprise one or more processors 195 and a non-transitory memory 190 or other storage device for storing programming instructions, one or more software programs (e.g., infusion apparatus control application) data or information regarding one or more applications, and other hardware, which may be the same or similar to the central processing unit (CPU) 405, read only memory (ROM) 410, random access memory 415, communication ports 440, controller 420, and/or memory device 425 depicted in FIG. 4 and described below in reference thereto.

The processors 195 may be in communication with various elements of the infusion apparatus 105, including, without limitation, the dispensing element 125, the dose meter 120, the directional valve 140, the radiopharmaceutical bulk container 130, the medical
fluid containers 115, and sensors 110 arranged within the infusion apparatus and described in more detail below. The processors 195 may be in direct communication with the aforementioned elements or may be in communication with sensors 110 associated therewith. For example, for the radiopharmaceutical bulk container 130 and the medical fluid containers 115, the processors 195 may be in communication with sensors 110 configured to determine the remaining volume of fluids stored in the containers. In another example, the dose meter 120, directional valve 140, and dispensing element 125 may have internal elements (e.g., control circuits, transceivers, microprocessors, etc.) that may transmit/receive signals and information to/from the processor 195. For example, the processors 195 may transmit a signal to change the position of the directional valve 140.

[0045] The processors 195 may execute one or more software programs, such as an infusion apparatus control application, for operating the infusion apparatus 105 or particular aspects thereof. The infusion apparatus control application may operate to present an infusion apparatus user interface, such as the user interface 210 depicted in FIG. 2 and described in more detail below, on a display device 150. The infusion apparatus control application may receive information from the sensors 110. In one embodiment, the infusion apparatus control application may operate to display sensor 110 information on a user interface. In another embodiment, the infusion apparatus control application may analyze the sensor 110 information to determine one or more operating conditions of the infusion apparatus 105 and flow of fluids through the various fluid pathways 160, 165, 170, 175, 180, 185.

[0046] In one embodiment, the sensors 160 may comprise one or more radiation sensors positioned along the fluid pathways 160, 165, 170, 175, 180, 185. Non-limiting examples of sensors include silicon diodes, silicon PIN diode radiation sensors, avalanche diodes, scintillators, photomultipliers, solid state crystals, semiconductors, Geiger tubes,
ionization-chamber radiation detectors, silicon photodiodes, microdischarge-based radiation
detectors, sodium iodide crystal radiation detectors, bismuth tri-iodide crystal radiation
detectors, or cadmium tellurium and cadmium zinc tellurium semiconductor crystal radiation
detectors, and combinations thereof.

[0047] One of the challenges with using multiple detectors in a system is that the
response of the detector may depend upon many parameters of the detector and the system in
addition to the property being measured. For example, the output signal of a radiation
detector may depend upon one or more of the radiation energy & type (e.g. isotope) being
emitted and detected, the detector material absorption and efficiency of conversion of energy
to charge, the electronics used to amplify and present the signal, the geometry of the
relationship of the detector to the fluid, and the specifics of the various materials surrounding
fluid, the detector and relevant adjacent space, which may affect absorption, scatter,
secondary photon and electron creation. Thus it can be very expensive to have multiple
detectors that are calibrated so that the system can correctly ensure that the operation is
proceeding as it should. In addition, some properties such as tubing inner diameter (ID) are
not easily or well controlled using cost efficient manufacturing processes, so there may be
some variation in response even with well calibrated and expensive detectors.

[0048] One approach to solve this problem is to use the expensive sensors to less
than their full capability, effectively degrading their possible performance to account for the
unknowns in the system configuration, for example to use them as broad range detectors with
the criteria being presence or absence of radiation rather than to their full capability, such as
determining the concentration or amount of radiation. An improved approach according to
certain embodiments herein may involve using all the sensors to their utmost capability and
having the system adjust the thresholds either during a system calibration or system test state
or phase and/or during normal operation. This last option can compensate for parameters that
affect sensor response that can change from disposable set to disposable set or even over
time, such as tubing swelling or interfering radiation increasing slightly as the waste bag fill
with radioactive waste.

[0049] An alternative embodiment which benefits from the system’s ability to
optionally adjust thresholds is to have one or a plurality of the total number of sensors be the
relatively expensive, accurate, and calibratable sensor, for example the dose meter 120. Then
the other sensors 110 can be less expensive and less accurate detectors such as silicon diode
detectors operated as current detectors. In this embodiment, one or more injections are made
in the factory or under the control of service personnel to allow the system to measure the
sensor’s response to a characterized flow of drug, such as a radiopharmaceutical or other
drug. This then allows the system to determine the ratio or other more sophisticated
functional relationship between the sensor response and the property that the sensor is
measuring.

[0050] In certain embodiments, the one or more calibratable sensor may be
calibratable with a solid check source. For example, if the dose meter 120 is a well type
ionization counter, it may be calibrated with commercially available national standards
traceable check sources. Once one sensor in the system is calibrated, performing one or more
injections of a radiopharmaceutical allows the system to calibrate one or more other sensors
using the system’s model of the fluid path and information about the injection, for example
flow rate over time. According to certain embodiments, this may be done, for example, by
comparing the integral of the flow signal in a flow through transducer to the dose
measurement made when the full dose is in the dose meter 120 and setting the response
constant of the flow through meter appropriately. If multiple calibration runs are performed,
accuracy of the calibration may be increased. Further, if multiple calibration runs are
performed under different test conditions, the system model may also be checked and
updated. In some embodiments, the first run of the day can be used to assess whether there are significant deviations from disposable set to disposable set, or multiple injections or every injection may be monitored for changes that indicate a malfunction or impending malfunction.

[0051] The processor 195 may receive information from the radiation sensors, which may be analyzed by the infusion apparatus control application. For example, the radiation sensor information may be analyzed to determine whether the radiopharmaceutical is traveling through the correct pathway. The infusion apparatus control application may be configured to expect radiation and/or certain levels of radiation at radiation sensors located at certain positions within the infusion apparatus 105. As such, if there is not an adequate radioactivity detected in radiopharmaceutical delivery paths 180 and 185 (and/or paths 170 and 175 if the dose meter 120 is being used) when the infusion apparatus 105 is infusing a patient with the radiopharmaceutical, this may indicate one or more fault conditions. For instance, it may indicate a leak, blockage, break, or other problem with the pathway, or that the pathway is not properly connected to the source container (e.g., 130). In another instance, inadequate radioactivity may indicate that the radiopharmaceutical container 130 does not have an adequate supply of the radiopharmaceutical. In a further instance, inadequate radioactivity may indicate that the infusion pump is not operating properly. Additional example faults which may be detected include pump slippage (which means that the volume delivered per time or per rotation is less than expected), pump failure, or the presence of air or a bubble in the system where it should not be. According to various embodiments, pumps may include, for example, push only syringe pumps, pull/push syringe pumps, peristaltic pumps, gravity, or other fluid motive methods know in the art.

[0052] In the alternative, if the radioactivity in the radiopharmaceutical delivery paths (e.g., 180, 185 and/or 170, 175) is above an expected level, this may indicate one or
more other fault conditions. Non-limiting examples of such fault conditions include an inadequate amount of saline, the directional valve being out of position, the saline is not properly diluting the radiopharmaceutical, and/or the radiopharmaceutical container supplying radiopharmaceutical with an incorrect radioactivity level. In addition, radioactivity detected in an unexpected pathway, such as saline pathway, may indicate a general tubing leak.

[0053] The infusion apparatus control application may be configured to compare the level of radioactivity detected at the radiopharmaceutical source path with the level of radioactivity detected at the delivery path. If the infusion protocol requires the radiopharmaceutical to be diluted with saline, then the radioactivity level at path should be higher than the level at path after the radiopharmaceutical has been diluted with saline. If the radioactivity level at path is not lower by a threshold amount than the radioactivity level at path, the infusion apparatus control application may indicate a fault condition.

[0054] In another embodiment, the infusion apparatus control application may have values for the length of the various fluid pathways and combinations thereof and the expected infusion flow rate. The sensors may comprise one or more sensors for detecting flow through the fluid pathways and combinations thereof. The infusion apparatus application may compare the flow rate received from the flow rate sensors and compare them with the expected flow rate. Discrepancies may be indicative of one or more fault conditions, such as a flow rate below a threshold value, a tubing leak, improper infusion pump operation, or detection of fluid in a dry pathway. For instance, saline may be used as a "chaser" to the radiopharmaceutical dispensed to the patient. A fault condition may occur if the detected level of flow in the
saline 165 fluid pathway is below a threshold amount when the infusion apparatus 105 is
supposed to be dispensing the saline to the patient.

[0055] According to some embodiments, the processor 195 may be
communicatively coupled with one or more infusion apparatus 105 components, such as the
infusion pump. In this manner, the infusion apparatus control application may use the
component information to analyze sensor information indicating a fault condition. For
instance, the infusion apparatus control application may check whether the infusion pump is
working properly responsive to an indication of a low radioactivity condition. In another
instance, the infusion apparatus control application may check the fluid level of saline in the
medical fluid container 130 responsive to a fault condition indicating a high radioactivity
condition to determine whether there is an adequate volume of saline to dilute the
radiopharmaceutical. In a further instance, if the flow in the radiopharmaceutical delivery
path is indicated as being low, the infusion apparatus control application may check whether
the directional valve 140 is properly positioned to allow for the proper flow of the
radiopharmaceutical and any other fluids (e.g., saline) required for a proper flow level.

[0056] The sensors 160 may comprise one or more optical sensors that may be used,
among other things, for the presence of fluid in the fluid pathways 160, 165, 170, 175, 180,
185. Fluid fill detection may be used during certain steps in the infusion process, such as the
dry tubing priming stage of the infusion process. The optical sensors may be used to detect
fluid motion through dispersion or diffraction measurements across the tubing. The infusion
apparatus control application may be configured to analyze information received from the
optical sensors to make determinations about the presence of fluid. For instance, the
detection of a fluid meniscus passing an optical detector may indicate the motion of fluid
through a particular section of the fluid pathway 160, 165, 170, 175, 180, 185. In an
embodiment, the infusion apparatus control application may be configured to determine if a
bubble is in the fluid pathway 160, 165, 170, 175, 180, 185, for instance, as compared to a meniscus. In this embodiment, the detection of two menisci passing within a certain threshold time frame may be indicative of a bubble.

[0057] The infusion apparatus control application may be configured to analyze the fluid detection information to determine whether any fault conditions exist. For example, a fault condition may exist if fluid is detected in a section of the fluid pathway 160, 165, 170, 175, 180, 185 at an unexpected stage of the infusion process. Alternatively, a fault condition may be generated based on the absence of fluid in a section of the fluid pathway 160, 165, 170, 175, 180, 185 when required, such as the lack of radiopharmaceutical in the radiopharmaceutical source pathway 185 during the infusion process or a lack of saline in the saline pathway 165 when the infusion process requires dilution of the radiopharmaceutical.

[0058] As mentioned herein, the threshold for declaring the existence of a condition or out of bounds state may involve readings being above or below a single level, which can be termed a single sided threshold. A second option is a double sided threshold or boundary, which comprises an upper bound and a lower bound. The measured signal may then either between the boundaries, above the upper limit, or below the lower limit. Depending upon the parameter being measured and the system action, when within limits involves one response, mostly commonly that of being OK or no response, when above the upper bound causing a second response from the system, for example alerting the user to the condition, and finally when below the lower bound causing a third response, for example declaring a sensor fault and possibly halting the system. This double sided thresholding may be generalized to allow for more sophisticated operation (multiple bands outside of each other, or multiple levels with response states depending up which level's the measurement is between. In an embodiment, the initial system response upon a threshold level being traversed may be to continue monitoring or measuring more closely because signals such as radioactivity are by their
nature noisy. Thus, the length of time for which a threshold is exceeded may be a parameter that affects the action that the system takes.

[0059] FIG. 5 shows a generalized signal and threshold diagram. The scale of the figure is chosen only for clarity of reference and does not reflect actual amplitudes or levels. The vertical axis 911 is the amplitude of the sensor signal and the horizontal axis 912 is time, delivered volume, or some other scale of progression of the system operation. Curve 900 is the signal measured by the sensor. Curve 901 represents the single level threshold mentioned above. If signal 900 exceeds curve 901, then the system takes an action. Alternatively, for other sensors, the fault may be if the measured signal 900 falls below a threshold, for example curve 902, at which time the system takes some action. Curves 901 and 902 may be used simultaneously to perform the double sided thresholding mentioned elsewhere. In this case, if the signal 900 is between curves 901 and 902, the system operates normally and the display shows normal operation, for example by tracing the curve in green or black. If the signal 900 exceeds curve 901, the system action may be taken, for example alerting the operator to a higher than expected condition because this is not a severe condition, for example by coloring the measurement number or curve on the display yellow or red. Alternatively, as mentioned elsewhere, the initial thresholds may not require alerting the user but may be used by the system in self-test, self-adjustment, or continuous adaptive thresholding. Further, if the signal 900 moves below threshold 902, the system may again alert the operator through a color change or other means.

[0060] Another embodiment has one or more additional thresholds above threshold 901. The farther the signal curve 900 deviates from the expected range, which may be, for example, between curve 901 and 902, the more severe or abrupt is the system response. For example if the signal 900 exceeds curve 903, a sound can be used to get the operators attention. In another embodiment with an additional threshold 905 can be used to indicate
that a significant leak or the failure of the sensor has occurred. The system may then
optionally sound an alarm, stop delivery, or otherwise act to promote the safety of the
operator and the patient. An alternative action, if this sensor is redundant or not essential, is
to declare the sensor faulty and continue operation with no effect.

[0061] Another embodiment has one or more additional thresholds below threshold
902. Similarly to what was discussed herein, as signal 900 goes below the thresholds, the
system may take the programmed appropriate, escalating actions up to and including stopping
operation or declaring the sensor inactive. As mentioned above, FIG. 5 is a generalized
diagram so the zero amplitude signal axis can be at any level. In the simplest embodiment,
there is just one threshold level and action may be taken depending whether the signal 900 is
above or below that threshold. In progressively sophisticated embodiments, there is a
hierarchy of fault states with their associated appropriate actions, optionally with user input
on the actions to be taken.

[0062] For embodiments with radiation sensors, used when the system has a
radiopharmaceutical in it, there should always be some radiation impinging on the sensor.
This is termed background or residual radiation. There may also be some radiation leaking
through the shielding from the source. This can be used to set level 906 and thus provide a
check that the sensor is at least operational. For cells, there is not necessarily a level of cells
in the priming or flushing fluid, so such a determination of sensor functionality cannot
necessarily be made. For some drug measurements such as optical density or IR absorption
for contrast assessment, water will have some non-zero signal and again sensor functionality
can be assessed by having a signal within a broad defined range.

[0063] The time course in FIG. 5 shows the sensor response curve 900 changing
over time as, for example, radiation flows through the tubing near the sensor. There are
various phases or segments of the operation, 951 to 956. Response curve 900' represents the
sensor response if the radioactive fluid were to get to the sensor and then a variety of faults occurs, for example, a spill occurs in the proximity of the sensor, the pump stops while pushing or pulling fluid, or a line breaks and so there is no flushing fluid. As is evident, server response curve 900' (shown by dashed line) represents a case where sensor response exceeds threshold 901 sometime in phase 954 or 955. This triggers the programmed appropriate system response. An alternative sensor response curve may be 900", which could occur for example if the reservoir or radiopharmaceutical is empty, or if there is a break in the radiopharmaceutical fluid pathway upstream and away from the sensor such that radiation does not reach the sensor.

[0064] In certain embodiments, the system software may contain a model of the system fluid path, sensor location, radioactive fluid locations, and radiation shielding parameters. For example, the model may be used to communicate graphically the status of the system and where an alert or alarm is occurring. In another embodiment of the model, intervening volumes or transit times are known so that delays in propagation of the drug can be assessed. This enables the system to adjust the thresholds during operation, for example over time or volume delivered, as is illustrated in FIG. 5, phases 951, 952, and 953 and then again in phases 953, 954, and 955. In additional embodiments, the model may include the expected position of valving elements and the expected flow path of the fluid where the system has multiple paths. Optionally sensors may measure the valve position directly, or expected or actual valve position may be used in the model to set the threshold curve and determine if the valve is in the wrong position or malfunctioning, for example, if the fluid motion is different than expected and a threshold exceeded.

[0065] Additional embodiments of the models of the system may allow the system to calibrate relatively less accurate or inexpensive sensor by moving a known fluid through the system and assessing the sensor response to the known fluid. This can optionally be
done at the factory at the time of assembly or when the equipment is serviced. In another embodiment, the calibration and adjustment of the sensors may be done by the operator periodically, for example monthly or daily by delivering a volume of fluid to a fluid container and then confirming the dose delivered in a dose calibrator.

[0066] In additional embodiments, the thresholds may be adjusted from injection to injection. For example, where the system software has information about the fluid path geometry, radiation shield properties, and dose locations, the system may then adjust thresholds and levels to account for the installation of a new bulk vial which increases the leakage radiation signal. Optionally, the system may adjust thresholds as drug is delivered or over time as it undergoes radioactive decay in recognition of the decrease in radiation coming to the sensor from the bulk vial. This may be necessary in a system that is small and compact for ease of transport and operator convenience. In some embodiments, the system may also record and recognize if the sensor operates predominately near, although not exceeding one threshold and optionally adjust the threshold, as this may be caused by sensor drift. An alternative reason for sensor drift is the build-up of radio pharmaceuticals adhering to the fluid path and/or one or more of the elements. If this build-up over deliveries is within system defined limits, then the thresholds are adjusted and the operator is not alerted. This build-up may depend upon the properties of the tubing used and/or the radiopharmaceutical, such that optionally providing the system with this type of information allows it to decide upon the desired course of action. If the build-up is beyond expected limits, then the user is alerted as this could indicate a leak of the radiopharmaceutical. As described herein, in certain embodiments, the system may optionally use a variety of information, for example about the drug, the fluid path element properties, the system and fluid path geometries, and the presence and quantity of drugs to adapt the thresholds to maximize the appropriate indication of true positive events and reduce the inappropriate indication of false positive events. While
doing this, the adaptability of the system enables the adjustment and selection of thresholds to reduce false negatives.

[0067] Embodiments are not limited to the particular sensors and/or fault conditions described above as these are provided as illustrative and non-restrictive examples. Any sensor and/or fault condition capable of operating according to the described embodiments is contemplated herein.

[0068] As shown in FIG. 1, the infusion apparatus 105 may comprise one or more communication ports (not shown) that provide communication with a computing device 145 and/or networks 155. The communications ports may provide a connection to the computing device 145 or networks 155 through communication protocols known to those having ordinary skill in the art, such as serial, Ethernet and Wi-Fi connections. The communication ports may be the same or substantially similar to communications port 440 depicted in FIG. 4 and described below. According to some embodiments, the infusion apparatus user interface may be accessible through a display device 150 coupled to the computing device 145 or available through the network 155 (e.g., over the Internet and/or through a web application). The computing device 145 may comprise various types of computing devices, including, without limitation, a server, personal computer (PC), tablet computer, computing appliance, or smart phone device. Non-restrictive examples of networks 155 include communications networks or health information networks (e.g., picture archiving and communications system (PACS)). In this manner, information associated with and control of the infusion apparatus 105 may be accessible by systems remotely located from the infusion apparatus.

[0069] FIG. 2 depicts an illustrative infusion apparatus user interface according to some embodiments. As shown in FIG. 2, an infusion apparatus user interface ("user interface") 210 may comprise a dynamic graphical user interface (GUI) presented on a display device 205 (e.g., display monitor or touch screen device). As described above, the
user interface 210 may be presented by an infusion device control application and may depict various components of the infusion apparatus. For instance, the user interface may present visual representations of the radiopharmaceutical source 220, the saline source 225, the dose meter 240, the waste container 230, the dispensing element 235, the directional valve 215, and the various fluid pathways 250.

[0070] The user interface 210 may be used to graphically represent information to an operator of an infusion apparatus. For example, the user interface 210 may indicate the status of infusion apparatus components, including, without limitation, the radiopharmaceutical source 220, the saline source 225, the dose meter 240, the waste container 230, the dispensing element 235, the directional valve 215, and the various fluid pathways 250 connecting the components. The status may be based on information transmitted from the components, data elements associated with any of the components or fluid path elements, and/or the sensors (e.g., sensors 110 depicted in FIG. 1) to the processor (e.g., processor 195 depicted in FIG. 1). The transmitted information may be input into the infusion apparatus control application and analyzed to determine a status. For example, a dispensing element may provide a signal indicating whether it is active in dispensing a medical fluid to a patient. In another example, a saline source container may provide information of the amount of saline remaining in the container. In a further example, sensors configured to determine flow may provide information about the flow of fluid in a particular section of the fluid pathway. The data elements associated with a component or fluid path element can also be used to set up the model and response function adjustments for sensors or other parts of the system as described in U.S. Patent No. 5,739,508, incorporated herein by this reference.

[0071] Infusion apparatus information and component status may be represented in various forms through the user interface 210. For example, status and information may be
represented by colors, flashing GUI elements, numerical elements, and text. Fluid flow may be indicated by a fluid flow GUI element 260. The sensors configured to detect and/or measure flow for a particular section of a flow pathway may transmit flow information to the infusion apparatus processor. The flow information may be analyzed by the infusion apparatus control application that is being executed by the infusion apparatus processor to generate flow information. The infusion apparatus control application may present the flow information in one or more various formats on the user interface 210 through one or more designated GUI elements (e.g., 260). In the illustrative embodiment depicted in FIG. 2, the flow information is displayed as a flow rate. However, embodiments provide that the flow information may be presented in various other formats, such as a flow/no flow indicator (e.g., one color for flow, another color for no flow through the section of the fluid pathway 250), or other real-time flow indicators. Information associated with other components may be similarly presented on the user interface 210.

[0072] In an embodiment, the position of the directional valve may be represented by a directional valve element 215 as well as the pathways connected through the directional valve may be indicated on the user interface 210. For example, connected pathways may be highlighted and similarly colored.

[0073] The user interface 210 may be configured to indicate fault conditions within the infusion apparatus. For example, components associated with a fault condition may be highlighted, such as with a flashing red boundary or enclosed within a GUI element indicating a fault condition. In FIG. 2, a dose meter fault condition GUI element 255 has been activated to indicate that there is a fault condition associated with the dose meter 240. A pathway or portions of a pathway may be highlighted to indicate a fault condition associated therewith, such as the highlighted region 265 depicted in FIG. 2. The fault condition associated with the highlighted region may indicate various conditions, including, without
limitation, improper flow, a potential leak or improper connection, or radioactivity detected in an unexpected area. According to some embodiments, the fault conditions may be accompanied by other alert mechanisms, such as an audio alert, a tactile alert, or the transmission of messages (e.g., email, short message service (SMS), etc.) to one or more computing devices. In certain embodiments, if the fault condition and alert continues for sufficient time with no acknowledgement or response from the operator, the system will stop operation. In other more serious instances, for example, when the sensor values are significantly above/below threshold values, the system will automatically stop and alert the operator, without the operator having the ability to have the system continue operation.

[0074] A message GUI element 245 may be presented on the user interface 210 to provide messages to operators of the infusion apparatus. For instance, the message GUI element 245 may be configured to present messages associated with the progress of the infusion process (e.g., infusion initiated, amount of dose administered, etc.). The message GUI element 245 may also be configured to present fault conditions and/or alarms as generated by the infusion apparatus control application based on information received from sensors and/or infusion apparatus components. The message GUI element 245 may operate in combination with other fault condition indicators presented on the user interface 210. For example, the dose meter fault condition GUI element 255 may indicate that there is a fault condition associated with the dose meter and descriptive text related to the fault condition, such as "low flow into dose meter," may be presented at the message GUI element 245.

[0075] The user interface 210 may provide functionality for a user to select a GUI component for more information or to perform a function. For example, a user may select the highlighted region 265 to receive information or functions related to the associated fault condition, such as through a window presented responsive to selection of the highlighted region. The information may comprise a more detailed assessment of the fault, while the
functions may provide actions that may be taken in response to the fault condition (e.g., stop flow, stop infusion process, turn directional valve to close pathway, etc.). In an embodiment, the display device **205** may be a touch screen such that a user may select a component or fault by touching the associated area on the touch screen.

**[0076]** As depicted in FIG. 1, the infusion apparatus **105** may be communicatively connected with a computing device **145** and/or a network **155**. The user interface **210** may be presented on one or more computing devices connected to the infusion apparatus directly or through a network **155**. In an embodiment, the user interface **210** may be available as a web service, for example, as a web page available through the Internet. In another embodiment, multiple user interfaces **210** may be displayed simultaneously at a remote computing device, for example, at a central location of a healthcare facility having multiple infusion apparatuses. In this embodiment, a user may select to focus on one or more of the multiple user interfaces **210**.

**[0077]** FIG. 3 depicts a flow diagram of a method of monitoring an automated radiopharmaceutical infusion apparatus according to an embodiment. As shown in FIG. 3, sensors may be provided **305** that are positioned to measure property information associated with infusion apparatus fluid pathways. The property information may comprise any information associated with the infusion apparatus fluid pathways, such as radioactivity, flow, temperature, and pressure. For example, radiation sensors may be positioned along each fluid pathway to measure radioactivity in and around the fluid pathway. In another example, sensors and/or combinations of sensors configured to measure the presence of fluid in a fluid pathway may be positioned within the infusion apparatus.

**[0078]** An apparatus display may be presented **310** that represents infusion apparatus components and conditions based on the property information. For example, a user interface may be presented on a display device that comprises GUI elements representing
components of the infusion apparatus and information associated therewith. Each infusion apparatus component, including, without limitation, a dispensing element, a dose meter, at least one of the fluid pathways, a directional valve configured to connect at least two of the plurality of fluid pathways, and an infusion pump may be represented by a GUI element. According to some embodiments, each GUI element may be selected by a user (e.g., using a touch screen, mouse, stylus, keyboard, etc.) and the apparatus display may present operational information about the selected GUI element (e.g., operating conditions, fault conditions, etc.).

[0079] The property information may be compared with expected results. For example, an infusion apparatus control application may be executed on a processor of the infusion apparatus. The infusion apparatus control application may be configured to maintain and/or calculate expected results for the property information. The processor may receive the property information and transmit it to the infusion apparatus control application for comparison with the expected results. For example, during an infusion process, the infusion apparatus control application may compare the flow of the radiopharmaceutical through a radiopharmaceutical dispensing pathway with the expected results. The infusion apparatus control application may be configured to compare any available property information and/or to make determinations based on the property information. For instance, the infusion apparatus control application may determine that there is a potential leak or defective connection in the saline line if there is no flow in the saline source pathway and the volume of saline in the saline container is above a specified threshold.

[0080] A fault condition may be generated responsive to property information that does not match an expected result. For example, the infusion apparatus control application may trigger a fault condition if it receives property information that does not conform to an expected result. For example, the infusion apparatus control application may
be configured to expect radioactivity in the saline source pathway to be below a certain threshold. If the property information for the saline source pathway indicates a level of radioactivity above the threshold, a fault condition may be triggered as this may indicate a fault within the infusion apparatus (e.g., a leak in the radiopharmaceutical source pathway). According to some embodiments, the comparisons may not be rigid; rather, certain of the comparisons may determine whether a measured property is within a specified range or above/below a threshold value.

[0081] The fault condition may be graphically represented 325 on the apparatus display. In this manner, an operator of the infusion apparatus may be alerted to potential fault conditions within the infusion apparatus. The fault condition may be represented as a text-based alarm and/or the components associated with the fault condition may be highlighted on the apparatus display. Representations of the fault condition are not limited to any particular forms, as embodiments provide that fault conditions may be represented in any manner capable of being graphically represented on the apparatus display.

[0082] FIG. 4 depicts a block diagram of exemplary internal hardware that may be used to contain or implement program instructions, such as the process steps discussed above in reference to FIG. 3, according to an embodiment. A bus 400 serves as the main information highway interconnecting the other illustrated components of the hardware. CPU 405 is the central processing unit of the system, performing calculations and logic operations required to execute a program. CPU 405, alone or in conjunction with one or more of the other elements disclosed in FIG. 1, is an exemplary processing device, computing device or processor as such terms are using in this disclosure. Read only memory (ROM) 410 and random access memory (RAM) 415 constitute exemplary memory devices.

[0083] A controller 420 interfaces with one or more optional memory devices 425 to the system bus 400. These memory devices 425 may include, for example, an external or
internal DVD drive, a CD ROM drive, a hard drive, flash memory, a USB drive or the like. As indicated previously, these various drives and controllers are optional devices.

[0084] Program instructions, software or interactive modules for providing the digital marketplace and performing analysis on any received feedback may be stored in the ROM 410 and/or the RAM 415. Optionally, the program instructions may be stored on a tangible computer readable medium such as a compact disk, a digital disk, flash memory, a memory card, a USB drive, an optical disc storage medium, such as a Blu-ray™ disc, and/or other recording medium.

[0085] An optional display interface 430 may permit information from the bus 400 to be displayed on the display 435 in audio, visual, graphic or alphanumeric format. Communication with external devices may occur using various communication ports 440. An exemplary communication port 440 may be attached to a communications network, such as the Internet or an intranet. Other exemplary communication ports 440 may comprise a serial port, a RS-232 port, and a RS-485 port.

[0086] The hardware may also include an interface 445 which allows for receipt of data from input devices such as a keyboard 450 or other input device 455 such as a mouse, a joystick, a touch screen, a remote control, a pointing device, a video input device, and/or an audio input device.

[0087] It will be appreciated that various of the above-disclosed and other features and functions, or alternatives thereof, may be desirably combined into many other different systems or applications. It will also be appreciated that various presently unforeseen or unanticipated alternatives, modifications, variations or improvements therein may be subsequently made by those skilled in the art which alternatives, variations and improvements are also intended to be encompassed by the following claims.
CLAIMS

What Is Claimed Is

1. A system for monitoring an automated radiopharmaceutical infusion apparatus, the system comprising:

   a plurality of fluid pathways comprising a radiopharmaceutical source pathway;
   a plurality of sensors positioned to measure at least one property associated with the plurality of fluid pathways, the at least one property comprising radioactivity;
   a display device;
   a processor in communication with the plurality of sensors and the display device; and
   a non-transitory, computer-readable storage medium in operable communication with the processor, wherein the computer-readable storage medium contains one or more programming instructions that, when executed, cause the processor to:

      receive property information from the plurality of sensors,
      present an apparatus display graphically representing apparatus components based on the property information on the display device,
      compare the property information with expected results,
      generate a fault condition responsive to property information not matching the expected results, and
      graphically represent the fault condition on the apparatus display.

2. The system of claim 1, wherein the plurality of fluid pathways further comprise at least one of a saline pathway, a dose meter inlet pathway, a dose meter outlet pathway, and a waste pathway.
3. The system of claim 1, wherein the plurality of sensors comprise at least one radioactivity sensor.

4. The system of claim 3, wherein the at least one radioactivity sensor comprises at least one of a silicon diode, a silicon PIN diode, an avalanche diode, a scintillator, a photomultiplier, a solid state crystal, a semiconductor, Geiger tubes, an ionization-chamber, a silicon photodiode, a microdischarge-based sensor, a sodium iodide crystal sensor, a bismuth tri-iodide crystal sensor, a cadmium tellurium crystal sensor, a cadmium zinc tellurium semiconductor sensor, and combinations thereof.

5. The system of claim 1, wherein the plurality of sensors comprise at least one of temperature sensors, pressure sensors, radioactivity sensors, optical sensors, analyte sensors, concentration sensors, flow sensors, electro-resistive devices, electro-capacitive devices, ultrasound devices, and combinations thereof.

6. The system of claim 1, wherein the property information comprises radioactivity information.

7. The system of claim 1, wherein the fault condition comprises radioactivity above a threshold value.

8. A method for monitoring an automated radiopharmaceutical infusion apparatus, the method comprising:
providing a plurality of sensors positioned to measure at least one property associated with a plurality of fluid pathways comprising a radiopharmaceutical fluid pathway, wherein the at least one property comprises radioactivity;

providing a processor operatively connected to a display device and the plurality of sensors; and

causing the processor to enable monitoring of the automated radiopharmaceutical infusion apparatus, wherein monitoring comprises:

- receiving property information from the plurality of sensors,
- presenting an apparatus display graphically representing apparatus components based on the property information on the display device,
- comparing the property information with expected results,
- generating a fault condition responsive to property information not matching the expected results, and
- graphically representing the fault condition on the apparatus display.

9. The method of claim 8, wherein monitoring further comprises receiving, by the processor, selection of one or more of the apparatus components.

10. The method of claim 8, wherein monitoring further comprises receiving, by the processor, selection of a graphically represented fault condition.

11. The method of claim 8, wherein monitoring further comprises presenting, by the processor, at least one function for managing the graphically represented fault condition.
12. The method of claim 11, wherein the at least one function comprises at least one of stopping infusion and closing at least one of the plurality of fluid pathways.

13. The method of claim 8, wherein comparing the property information with expected results comprises:
   determining, by the processor, a stage of an infusion process, and
   comparing the property information with expected results for the stage of the infusion process.

14. The method of claim 8, wherein the plurality of sensors comprise at least one radioactivity sensor.

15. The method of claim 8, wherein the plurality of sensors comprise at least one of temperature sensors, pressure sensors, radioactivity sensors, optical sensors, analyte sensors, concentration sensors, flow sensors, electro-resistive devices, electro-capacitive devices, ultrasound devices, and combinations thereof.

16. The method of claim 8, wherein the property information comprises radioactivity information.

17. The method of claim 8, wherein the apparatus components comprise at least one fluid pathway.

18. The method of claim 8, wherein the apparatus components comprise a directional valve configured to connect at least two of the plurality of fluid pathways.
19. The method of claim 8, wherein the fault condition comprises radioactivity above a threshold value.

20. The method of claim 8, wherein the fault condition comprises a flow rate below a threshold value.
Fault Conditions

No RP Flow
Low Saline Volume
Dose Error

FIG. 2
Provide Sensors Positioned to Measure Property Information Associated with Infusion Apparatus Fluid Pathways

Present an Apparatus Display Representing Infusion Apparatus Components and Conditions Based on the Property Information

Compare the Property Information with Expected Results

Generate a Fault Condition Responsive to Property Information not Matching Expected Results

Graphically Represent the Fault Condition on the Apparatus Display

FIG. 3
INTERNATIONAL SEARCH REPORT

International application No. PCT/US14/15732

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61M 5/142, 5/145 (2014.01)

USPC - 417/63; 604/93.01, 131, 151, 152

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61M 5/142, 5/145 (2014.01)

USPC - 417/63; 604/93.01, 131, 151, 152

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)


C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>US 2009/0312635 A1 (SHIMCHUK, G. G., et al.) December 17, 2009; figure 1; paragraphs [0040], [0046], [0047], [0052]-[0054], [0058], [0059]</td>
<td>1-20</td>
</tr>
</tbody>
</table>

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referred to in an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

Document member of the same patent family

Date of the actual completion of the international search: 09 May 2014 (09.05.2014)

Date of mailing of the international search report: Z2 MAY 2014

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandra, Virginia 22313-1450
Facsimile No. 571-272-3201

Form PCT/ISA/210 (second sheet) (July 2009)