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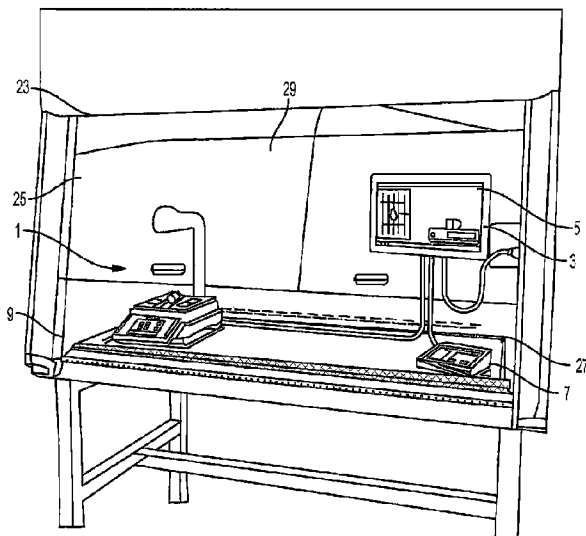
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(57) Abrégé/Abstract:

A system for reviewing and verifying preparation of a pharmaceutical compound comprising: processor to receive information comprising at least one image of at least one step of the preparation of a pharmaceutical compound and gravimetric measurement information provided by a scale during at least one step of the preparation of the pharmaceutical compound; and a computing device comprising a user interface connected to the processor and configured to display, based on instructions from the at least one processor, the image of the at least one step of the preparation of the pharmaceutical compound and an indication of whether a concentration of the pharmaceutical compound is within an acceptable tolerance range based on the gravimetric measurement information.

ABSTRACT

A system for reviewing and verifying preparation of a pharmaceutical compound comprising: processor to receive information comprising at least one image of at least one step of the preparation of a pharmaceutical compound and gravimetric measurement information provided by a scale during at least one step of the preparation of the pharmaceutical compound; and a computing device comprising a user interface connected to the processor and configured to display, based on instructions from the at least one processor, the image of the at least one step of the preparation of the pharmaceutical compound and an indication of whether a concentration of the pharmaceutical compound is within an acceptable tolerance range based on the gravimetric measurement information.

SYSTEM AND METHOD FOR PREPARING A PHARMACEUTICAL COMPOUND

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present disclosure is generally directed to systems and methods for preparing and administering a prescribed fluidic pharmaceutical compound, such as a chemotherapy compound and, more specifically, to systems and methods that allow a physician to enter a prescription for a patient that is subsequently verified for accuracy, prepared based on computer-aided instruction, verified based on a measured weight, substantially automatically provided with visual documentation, and administered to a patient.

Description of Related Art

[0002] Many technical functions involving the preparation and distribution of drugs may be performed in a pharmacy by a pharmacy technician or licensed nurse. When a non-pharmacist performs such functions, a pharmacist must generally verify their work. Various systems have been developed that take images of the various steps of the preparation of a pharmaceutical compound by a non-pharmacist technician to allow a pharmacist to later review the preparation. Such systems typically require the technician to take some type of active step in order to capture an image of the drug preparation step. For instance, the user may be required to use a touch screen or foot pedal to trigger image capture.

[0003] However, since such systems require an active step by the non-pharmacist technician to capture the appropriate image, errors may occur that prevent the supervising pharmacist from properly verifying the prescription. In addition, such prior art systems do not include any other mechanism for verifying the prescription and rely solely on the images obtained during the preparation of the prescription for verification.

[0004] In addition, systems have also been developed that utilize gravimetric information, checked by a methodology, to confirm the proper drug concentration. However, there is not a current system that combines information from an image verification system and a gravimetric verification system to ensure that a drug has been appropriately compounded.

[0005] Accordingly, a need exists for a system that triggers an image capturing step when certain criteria of the drug preparation have been met and moves to the next step of the drug preparation without any additional user input. A further need exists for a system that displays both image information and gravimetric measurements obtained during drug preparation steps to a reviewing pharmacist in a clear and easily readable manner, such that the pharmacist can quickly approve or reject a particular drug preparation.

SUMMARY OF THE INVENTION

[0006] According to one aspect of the invention, provided is a system for preparing a pharmaceutical compound. The system comprises: a computing device comprising a user interface providing an operator with instructions for preparing the pharmaceutical compound and at least one processor operatively connected to the user interface; a scale operatively connected to the at least one processor; and an image capture device operatively connected to the at least one processor and the scale and positioned to capture an image of at least one of a component used in preparing the pharmaceutical compound and the pharmaceutical compound. In one embodiment, the scale may be configured to transmit a signal to the at least one processor indicating that a weight detected thereby has changed when the at least one component is placed thereon and, based on the signal, the at least one processor triggers the image capture device to capture the image of the at least one component. Alternatively, the scale may be configured to transmit a signal to the at least one processor to verify that a correct amount of at least one component used in preparing the pharmaceutical compound has been drawn by the operator based on a weight of the at least one component and the at least one processor triggers the image capture device to capture the image of the at least one component when the at least one processor verifies the correct amount of the at least one component.

[0007] The image capture device may be triggered to capture the image of the at least one component once the weight of the at least one component on the scale has stabilized. The image of the at least one component may be displayed on the user interface for review by the operator. A removal of the at least one component from the scale may cause the at least one processor to accept the image, associate the image with a data record, and provide instruction on the user interface to allow the operator to move to a next step of the instructions for preparing the pharmaceutical compound. The data record and images may be provided to a pharmacist for verification. If the image is deemed to be unacceptable by the operator, the user interface may be configured to provide the operator with the capability to recapture the image.

[0008] An upper surface of the scale may be provided with a visual indication to the operator of a center of an image produced by the image capture device. The visual indication may be a cross recess formed in the upper surface of the scale. A scanner may be operatively coupled to the user interface. The scanner may be configured to scan a barcode provided on the at least one component and provide the user interface with information regarding the at least one component.

[0009] According to another aspect of the invention, provided is a system for preparing a pharmaceutical compound. The system comprises: a computing device comprising a user interface providing an operator with instructions for preparing the pharmaceutical compound and at least one processor operatively connected to the user interface; a scale operatively connected to the at least one processor; and an enclosure comprising an image capture device having a field of view positioned to capture an image of an object positioned on the scale during the preparation of the pharmaceutical compound. The image capture device is operatively connected to the at least one processor. The scale transmits a signal to the at least one processor to verify a correct amount of at least one component of the pharmaceutical compound based on a weight of the at least one component. The image capture device captures an image of the object positioned on the scale when the at least one processor verifies the correct amount of the at least one component.

[0010] The enclosure may be positioned above the scale, and may further comprise a barcode scanner. The barcode scanner may be angled with respect to the scale. The barcode scanner may include a sensor that is offset with respect to the scale. The enclosure may have a streamlined shape to minimize flow disturbance within a flow hood.

[0011] Another object of the system of the present disclosure is to allow a pharmacist to accurately review the steps taken by a technician preparing a prescribed fluidic pharmaceutical compound in which the system displays both image information and gravimetric measurements obtained during drug preparation steps to the pharmacist in a clear and easily readable manner, such that the pharmacist can quickly approve or reject a particular drug preparation. Overlaying two different information types (i.e., image and gravimetric information) gives the pharmacist valuable insights regarding the compounding procedure and the opportunity to better judge quality of preparations and technicians performing the preparations.

[0012] Such a system guides a pharmacist or technician through the different compounding steps to prepare a medication order in a pharmacy by giving step-by-step instructions on a computer screen and verifying the different compounding steps by measuring the weight of the compounded liquids with a scale. The measured weight is then analyzed with a mathematical methodology which checks if the necessary compounding accuracy has been accomplished. Every time an item is placed on the scale, a picture of the top of the scale is captured to create a visual documentation trail of the compounding process. The pictures are stored together with the recorded measurements from the scale and the methodology result in a log file. If a measured weight of a drug is not in the predefined tolerance range of the

expected weight, the software generates instructions to change the amount of the drug to bring it within the acceptable tolerance range. The software will not proceed to the next compounding step as long as the required tolerance of the present step has not been accomplished.

[0013] In particular, the system includes a pharmacist review module where the pharmacist can review pictures of a particular drug preparation and either approve or disapprove the preparation for the release to the patient. The captured images are shown with the corresponding compounding instructions and an indication of whether the concentration of a drug is inside or outside of the acceptable tolerance range as determined by the mathematical methodology. Accordingly, the pharmacist review module provides visual information (i.e., the pictures of each step of the preparation) overlaid with quantitative measurements collected with the scale and verified by the mathematical methodology to adhere to predefined acceptance criteria.

[0014] More particularly, provided is a system for reviewing a verifying preparation of a pharmaceutical compound. The system comprises: a processor configured to receive information regarding the preparation of the pharmaceutical compound. The information comprises at least one image of at least one step of the preparation of the pharmaceutical compound and gravimetric measurement information provided by a scale during at least one step of the preparation of the pharmaceutical compound. The system also includes a user interface operatively connected to the processor and configured to display, based on instructions from the processor, the at least one image of the at least one step of the preparation of the pharmaceutical compound and an indication of whether a concentration of the pharmaceutical compound is within an acceptable tolerance range based on the gravimetric measurement information.

[0015] The at least one image of the at least one step of the preparation of the pharmaceutical compound may include an image of each step of the preparation of the pharmaceutical compound, and that the user interface includes an area that displays thumbnail images of each step. A graphical indication may be overlaid onto each of the thumbnail images to identify whether the concentration of the pharmaceutical compound is within the acceptable tolerance range for the step of the preparation of the pharmaceutical compound illustrated in each of the thumbnail images. The user interface may also include an area that displays the instructions for the preparation of the pharmaceutical compound that correspond to the at least one image of the at least one step of the preparation of the pharmaceutical compound that is displayed.

[0016] These and other features and characteristics of the present invention, 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 as a definition of the limits of the invention. 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

[0017] FIG. 1 is a flow chart of sequential computer-implemented modules for preparing and administering a prescribed fluidic pharmaceutical compound in accordance with the present disclosure;

[0018] FIG. 2 is a perspective view of a scale and enclosure housing in a flow hood in accordance with an embodiment of the present disclosure;

[0019] FIG. 3 is a perspective view of the scale and enclosure housing of FIG. 2 in accordance with an embodiment of the present disclosure;

[0020] FIG. 4 is a flow chart describing the manner in which a pharmaceutical compound is prepared in accordance with an embodiment of the present disclosure;

[0021] FIGS. 5A-5D, 6A-6D, 7A-7B, 8A-8D, 9A-9D, 10A-10C, 11A-11D, 12A-12C, and 13A-13C are exemplary screen shots provided at a user interface of the system of FIG. 3 provided during the preparation of a pharmaceutical compound;

[0022] FIG. 14A is a flow chart describing the manner in which a pharmaceutical compound is prepared in accordance with another embodiment of the present disclosure;

[0023] FIG. 14B is a flow chart describing the manner in which a pharmaceutical compound is prepared, which continues from FIG. 14A, in accordance with another embodiment of the present disclosure;

[0024] FIG. 15 is a schematic diagram of a pharmacy final verification module in accordance with an embodiment of the present disclosure;

[0025] FIG. 16 is an exemplary screen shot provided at the pharmacy final verification module allowing a pharmacist to review the preparation of the pharmaceutical compound in accordance with the present disclosure; and

[0026] **FIG. 17** is another exemplary screen shot provided at the pharmacy final verification module in accordance with the present disclosure.

DESCRIPTION OF THE INVENTION

[0027] 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 invention as it is oriented in the drawing figures. However, it is to be understood that the invention may assume various alternative variations, except where expressly specified to the contrary. It is also to be understood that the specific devices illustrated in the attached drawings, and described in the following specification, are simply exemplary embodiments of the invention. Hence, specific dimensions and other physical characteristics related to the embodiments disclosed herein are not to be considered as limiting.

[0028] With reference to **FIG. 1**, the system of the present disclosure employs several sequential computer-implemented modules for preparing and administering a prescribed fluidic pharmaceutical compound, such as a chemotherapy compound. The modules each include code allowing for input from a user, generating output, and calculating and determining instructions for the preparation and administration of the pharmaceutical compound that may be implemented on one or more processor(s) **101** of one or more suitable computing device(s). More specifically, the system allows a physician to enter a prescription for a patient that is subsequently verified for accuracy, prepared based on computer-aided instruction, verified based on a measured weight, and administered to a patient. Such a system includes specific modules described in detail below. The modules include: (A) a computerized physician ordering entry (CPOE) module **100**; (B) a pharmacist verification module **200**; (C) a pharmacy preparation module **300**; (D) a pharmacy final verification module **400**; and (E) a bedside (*e.g.*, administration) module **500**. These modules may each be implemented on a single processor or multiple processors provided on a single computing device or may each be implemented on an independent computing device having its own processor where data and information is communicated between the computing devices using any suitable wired or wireless communication protocol, such as, but not limited to Ethernet, WiFi, cellular, Bluetooth, or the like.

[0029] **A. CPOE Module**

[0030] The CPOE module **100** enables physicians to input prescribed treatment orders for patients that include prescribed pharmaceuticals associated with particular patients. In

particular, the physician enters prescription information for a patient into a computer, and the data is transmitted over an intra-hospital network and stored for retrieval and use by the subsequent modules described herein. The prescription information can include one or more pharmaceuticals and the corresponding dosage/quantities for those pharmaceuticals. The CPOE module 100 is an optional component and may not be utilized in every instance in which the overall system is implemented.

[0031] B. Pharmacist Verification Module

[0032] The pharmacist verification module 200 of the system enables pharmacists to view the prescription information data input by the physician in the CPOE module 100 or from some other source in circumstances when the CPOE module 100 is not utilized, and manually verify the prescribed treatment for a particular patient. As discussed above, the pharmacist verification module 200 may be implemented on the same computing device as the CPOE module 100. Alternatively, the pharmacist verification module 200 may be implemented on a computing device that is remote from the computing device that implements the CPOE module 100.

[0033] C. Pharmacy Preparation Module

[0034] With reference to FIGS. 2 and 3, the pharmacy preparation module 300 includes software and associated hardware, such as pharmacy preparation system 1, to guide a pharmacist or non-pharmacist technician through the steps of preparing a prescribed fluidic pharmaceutical compound, such as a chemotherapy compound. The pharmacy preparation system 1 assists pharmacists or non-pharmacist technicians in preparing a syringe or intravenous (IV) bag with one or more prescribed pharmaceutical compounds. The pharmacy preparation system 1 is operatively connected to a computing device 4 that includes a user interface 3 having a display 5 and a user input device 7, such as a keyboard, mouse, etc. Optionally, the display 5 of the user interface 3 may be implemented as a small LED projector provided on a portion of the pharmacy preparation system 1 for projecting the displayed information on a back wall of a laminar flow hood 25, thereby removing the need of a monitor for the display 5 as shown in FIG. 2. A scale 9 having a scale output interface 11 may be operatively connected to the user interface 3. The scale 9 may be implemented as any suitable device for detecting a change in mass or weight when an object is placed thereon. Accordingly, the scale 9 may simply be configured as a device that sends a signal when the mass or weight of an object is greater or less than a predetermined threshold or a high-precision scale that provides an accurate reading of the weight of an object placed thereon.

[0035] In one embodiment, a barcode scanner 13 may be operatively connected to at least one of the user interface 3 and the scale 9, such that the barcode scanner 13 may scan a medication vial having a barcode that is placed onto a portion of the scale 9. In another embodiment, an image capture device 15 may be operatively connected to at least one of the user interface 3 and the scale 9, such that the image capture device 15 may take a picture of an item, such as a medication vial, IV bag, or syringe placed onto a portion of the scale 9. In one embodiment, the image capture device 15 may capture a plurality of still images or running video of items placed onto a portion of the scale 9 throughout the medication compounding process for documentation and/or subsequent review of the medication compounding process.

[0036] In still another embodiment, at least one of the barcode scanner 13 and the image capture device 15 may be at least partially enclosed within an enclosure housing 17. In certain configurations, the housing 17 may fully enclose the barcode scanner 13 and the image capture device 15. Optionally, the housing 17 may include only one of the barcode scanner 13 and the image capture device 15.

[0037] The housing 17 may be positioned above a portion of the scale 9, such as supported by a supporting arm 19. As shown in FIG. 2, the pharmacy preparation system 1 may be positioned within a laminar flow hood 25 having an inlet air source 23 and an outlet air port 27 for creating a laminar flow of air within an interior 29 of the laminar flow hood 25. An exterior surface 21 of the housing 17 may have a streamlined shape and/or profile which is optimized to reduce disruption of the flow of air within the laminar flow hood 25.

[0038] This aerodynamically streamlined housing 17 as shown in FIG. 3 is designed in such a way to minimize the airflow disturbance that is created by having a device in a laminar airflow stream. This configuration allows the device to be placed in the upstream vicinity of a scale and still have an acceptable gravimetric accuracy (i.e. +/-0.05g) and stabilization time (i.e. no more than 2 additional seconds) for verifying medication preparation purposes.

[0039] The smaller and/or more streamlined housing 17 results in a smaller flow disturbance and therefore a higher likelihood of meeting accuracy and stability requirements. The streamlined housing 17 has a form that minimizes flow disruption and drag, allowing for stable and accurate gravimetric readings that are required for medication preparation purposes. In addition, housing 17 allows for required gravimetric scale accuracy and stability, while placing the input devices (i.e., image capture device 15 and barcode scanner 13) in the upstream airflow vicinity relative to the scale 9. Placing these objects within the scale 9 vicinity is typically the ideal area for a number of reasons. A secondary advantage to the

streamlined housing 17 is to provide and maintain a clean working environment for the sterile preparation of medications. In use, the purpose of the air stream in a flow hood is to create a clean zone for sanitary reasons. A turbulent zone created by objects near, or upstream of the airflow, may result in a potential contamination hazard during medication preparation. As a result, having an aerodynamically shaped housing for input devices minimizes the amount of laminar airflow disruption and decreases the chances of any type of contamination.

[0040] With continued reference to FIG. 3, the scale 9 may include a platen 31, such as a portion of the weighing surface of the scale 9, which may provide a visual indication, such as a cross recess 35, to the technician of a center of an image to be captured by the image capture device 15. This allows a technician to properly position drug compounding related medications 37 and related supplies within the field of view of the image capture device 15, such as the image capture device enclosed within the housing 17 positioned above the platen 31 of the scale 9. An upper surface 41 of the platen 31 may define a plurality of recessed grooves 39 and/or protrusions extending from a surface of the platen 31 to frictionally restrain drug compounding related medications 37 and related supplies on the upper surface 41 of the platen 31. In another configuration, the upper surface 41 of the platen 31 may include a tackifier or other frictionally enhancing surface to similarly restrain drug compounding related medications 37 and related supplies on the upper surface 41 of the platen 31. The arrangement of grooves 39 and/or protrusions may easily indicate to a user the center of the platen 31 which may be arranged to coincide with the center of the field of view of the image capture device 15.

[0041] The plurality of recessed grooves 39 and/or protrusions extending from a surface of the platen 31 may be configured to restrain any liquid material that is accidentally spilled on the upper surface 41 of the platen 31 during a drug compounding procedure. The plurality of recessed grooves 39 may define a receiving well 47 which serves to collect and restrain accidentally spilled material in a confined area within the platen 31 until proper disposal techniques may be employed. The surface of the platen 31 may be coated with a durable composition that resists degradation caused by exposure to caustic agents, such as chemotherapy compounds and drugs, as well as cleaning agents, such as bleach, isopropyl alcohol, and the like. In certain configurations, the durable composition may be an epoxy or epoxy-based paint or coating.

[0042] With reference to FIGS. 4, 14A, and 14B, in operation, the pharmacist/technician is prompted through a series of display screens provided on the display 5 of the user interface 3 as shown in one or more of FIGS. 5A-5D, 6A-6D, 7A-7B, 8A-8D, 9A-9D, 10A-10C, 11A-

11D, 12A-12C, and 13A-13C to take the following steps to prepare the pharmaceutical compound. FIG. 4 provides a flow chart of a first phase of the preparation in which an active ingredient is reconstituted. First, the operator scans a first barcode with the barcode scanner 13 on a medication container including a drug to be reconstituted to prepare the prescribed pharmaceutical compound (block 301) as shown in FIG. 5C. Then, the medication container is placed on the scale 9 (block 302). A representation of this step is displayed on display 5 of user interface 3 as shown in FIG. 6A. Once the weight stabilizes, the system verifies that the measured weight is meeting the weight target plus/minus a predetermined tolerance. In addition, the image capture device 15 takes an image of the medication container and displays it to the user on the display 5 of the user interface 3 (block 304) as shown in FIG. 6B. The user then removes the medication container and the image is saved to the data record of the drug preparation (block 306).

[0043] Next, the technician scans a second barcode of a fluid container of fluid that is to be mixed with the drug to be reconstituted (block 308) as shown in FIG. 6C. The fluid container is then placed on the scale 9 (block 310) and, once the weight stabilizes, the image capture device 15 takes an image of the fluid container and displays it to the user on the display 5 of the user interface 3 (block 312) as shown in FIG. 6D. The user then removes the fluid container and the image is saved to the data record of the drug preparation (block 314).

[0044] Thereafter, the user mixes the drug to be reconstituted with the fluid in the fluid container by injecting the fluid from the fluid container into the medication container (block 316) as shown in FIG. 7A. The medication container is then returned to the scale 9 and the weight of the medication container is verified (block 318) as shown in FIG. 7B. Once the weight is stabilized and verified (block 320), the image capture device 15 automatically takes an image of the medication container based on a signal received from the scale and displays the image on the display 5 of the user interface 3 (block 322). If the technician decides the image was not meeting certain requirements, there is the option to request a new or additional image (block 324). Requesting another picture will automatically switch the image capture device 15 into a "live video mode" displayed at the user interface 3 (block 326). The technician can now move the medication container on the scale 9 to a preferred position and trigger the image capture through the user interface 3 (block 328). As before, the captured image will be shown at the user interface 3 and by removing the item from the scale 9, the technician accepts the image and the system automatically moves to the next compounding step (block 330).

[0045] Once the drug preparation is complete, the system prints a barcode label for placement on the reconstituted drug preparation.

[0046] With reference to FIGS. 14A and 14B, a second phase of the preparation of the pharmaceutical compound using the pharmacy preparation module 300 will be described. First, the operator scans a barcode with the barcode scanner 13 on the reconstituted drug preparation (block 332) as shown in FIG. 8A. Then, the reconstituted drug preparation is placed on the scale 9 (block 334) and an empty syringe is added to the scale 9 (block 336) as shown in FIG. 8C. Once the weight stabilizes, the system verifies that the measured weight is meeting the weight target plus/minus a predetermined tolerance. In addition, the image capture device 15 takes an image of the medication container and displays it to the user on the display 5 of the user interface 3 (block 338) as shown in FIG. 8D. The user then removes the reconstituted drug preparation and the empty syringe and the image is saved to the data record of the drug preparation (block 340).

[0047] Next, the technician is instructed to withdraw a predetermined amount from the reconstituted drug preparation with the syringe (block 342) as shown in FIG. 9A and places the syringe back on the scale 9 (block 344). The weight is then verified (block 346) and an image is captured (block 348) as shown in FIG. 9B. If the weight is determined to be too low as shown in the flow chart of FIGS. 14A and 14B, the technician is instructed to remove the syringe (block 350 and FIG. 9C) and withdraw an additional amount of the reconstituted drug preparation (block 352 and FIG. 9D).

[0048] Once the additional amount of the reconstituted drug preparation is withdrawn into the syringe, the syringe is placed back on the scale 9 (block 354) as shown in FIG. 10A. The weight is then verified (block 356) and an image is captured (block 358) as shown in FIG. 10B. The syringe is then removed from the scale (block 360).

[0049] The technician then scans a barcode of a fluid container having a saline solution therein, such as an IV bag (block 362). The fluid container is then placed on the scale 9 (block 364) and, once the weight stabilizes, the image capture device 15 takes an image of the fluid container and displays it to the user on the display 5 of the user interface 3 (block 366). If the technician decides the image was not meeting certain requirements, there is the option to request a new or additional image (block 368). Requesting another picture will automatically switch the camera into a "live video mode" displayed at the user interface 3 (block 370). The technician can now move the medication container on the scale 9 to a preferred position and trigger the image capture through the user interface 3 (block 372). As before, the captured image will be shown at the user interface 3 and by removing the item

from the scale 9, the technician accepts the image (block 374) and the system automatically awaits authorization from a pharmacist to precede (block 376). The screen shots in FIGS. 11A-11C illustrate this procedure.

[0050] Once pharmacist authorization has been provided (block 378), the user injects the contents of the syringe into the fluid container (block 380) as shown in FIG. 12A. The medication container is then returned to the scale 9 and the weight of the medication container is verified (block 382). Once the weight is stabilized and verified (block 384) as shown in FIG. 12B, the image capture device 15 automatically takes an image of the medication container based on a signal received from the scale and displays the image on the display 5 of the user interface 3 (block 386) as shown in FIG. 12C. As before, the captured image will be shown at the user interface 3 and by removing the item from the scale 9, the technician accepts the image (block 388). Once the drug preparation is complete, the system prints a barcode label for placement on the completed drug preparation that includes encoded information representing the name of the pharmaceutical and patient information.

[0051] The pharmacy preparation module 300 also includes software instructions that cause the processor of the computing device 4 to perform the following actions during the drug preparation: (i) retrieve the prescription information data input by the physician in the CPOE module 100 from the intra-hospital network; (ii) verify that the scanned barcode corresponds with the prescription information; (iii) determine if the weight of the syringe and/or IV bag is within a predetermined threshold accuracy level for the amount of the pharmaceutical to be administered; (iv) determine what adjustments must be made if the weight is not accurate; and (v) transmit data relating to the weight of the syringe and/or IV bag back to the intra-hospital network.

[0052] D. Pharmacy Final Verification Module

[0053] Subsequent to preparing the prescribed pharmaceutical, the pharmacy final verification module 400 allows the pharmacist to review the data and/or documentation created by the pharmacy preparation module 300 including the images taken by the image capture device 15 and either approve or disapprove the preparation for the release to the patient. As described hereinabove, the pharmacist final verification module 400 may be implemented on the same computing device as the pharmacy preparation module 300. Alternatively, the pharmacist final verification module 400 may be implemented on a computing device that is remote from the computing device of the pharmacy preparation module 300. Such a remote configuration is illustrated schematically in FIG. 15. With reference to FIG. 15, the pharmacist final verification module 400 includes a system 401

having a processor **402** configured to receive information from the pharmacy preparation module **300** regarding the preparation of the pharmaceutical compound. The information comprises at least one image of at least one step of the preparation of the pharmaceutical compound and gravimetric measurement information provided by the scale **9** during at least one step of the preparation of the pharmaceutical compound. The system **401** also includes a user interface **403** operatively connected to the processor **402** and configured to display, based on instructions from the processor **402**, the at least one image of the at least one step of the preparation of the pharmaceutical compound and an indication of whether a concentration of the pharmaceutical compound is within an acceptable tolerance range based on the gravimetric measurement information.

[0054] An exemplary screen shot provided at the pharmacy final verification module **400** is provided in **FIG. 16**. On this exemplary screen, the captured images are shown with the corresponding compounding instructions and an indication of whether the concentration of a drug is inside or outside of the acceptable tolerance range as determined by the mathematical methodology. Accordingly, the pharmacy final verification module **400** provides visual information (i.e., the pictures of each step of the preparation) overlaid with quantitative measurements collected with the scale and verified by the mathematical methodology to adhere to predefined acceptance criteria.

[0055] As illustrated in **FIGS. 16** and **17**, the pharmacy final verification module **400** includes a review window **420** having a first portion **422** that displays a selected image **424** of a particular drug preparation step, a second portion **426** that displays thumbnail images of each of the drug preparation steps, and a third portion **428** that displays the compounding instructions for the particular drug preparation step along with the result of the quantitative measurement provided by the scale, and an indication provided by the mathematical methodology that the concentration of a drug is either inside or outside of the acceptable tolerance. In addition, an icon **430** may be associated with the thumbnail of the particular drug preparation step to provide an indication to the pharmacist that the tolerance requirements of the particular drug preparation step were met. For instance, a green check mark may be provided if the tolerance requirements were met or a red exclamation point may be provided if the tolerance requirements were not met. The review window **420** may also include a fourth portion **432** that displays icons **434** allowing the pharmacist to either confirm or reject the drug preparation.

[0056] With continued reference to **FIGS. 16** and **17**, the mouse pointer was hovering over the fifth thumbnail from the left in the second portion **426** of the review window **420**. For this

particular thumbnail, the enlarged picture is shown above the thumbnail row in the first portion 422 of the review window 420 and below the thumbnails, the corresponding compounding instructions 435 along with the result of the quantitative measurement 436 and methodology check 438 (see also the exemplary screenshot provided in FIG. 2) are shown in the third portion 428 of the review window 420. The third portion 428 may also include other statistical information regarding the drug preparation such as, but not limited to, how often compounding steps had to be repeated to meet tolerance targets or if particular compounding steps took more time than usual compared to other cases.

[0057] Additionally, the icon 430 in the thumbnail indicates if the tolerance requirements of the particular compounding step were met, giving the pharmacist a quick guidance to where in the compounding procedure problems occurred. A gray box (not shown) around multiple thumbnails provides an indication to the pharmacist that the image representing this compounding step was retaken.

[0058] The overlay of a captured image with verification information generated by a mathematical methodology from gravimetric data allows the pharmacist to quickly review very different types of information. The visual information content of the image allows the pharmacist to check very apparent information such as, but not limited to, the drug color, the syringe type, or whether the system was used improperly (e.g., the user used an additional object to generate the necessary weight to pass the tolerance requirements of the methodology). The icon 430 in the thumbnail representing the methodology check outcome is binary information telling the pharmacist that the amount of drug was either inside or outside of the tolerance requirements for the particular compounding step. An accumulation of icons 430 on thumbnails in the form of red exclamation marks provides a quick indication to the pharmacist that the technician needed several iterations to meet tolerance requirements and may trigger additional scrutiny when reviewing such a drug preparation.

[0059] **E. Bedside Module**

[0060] Prior to administering the prescribed pharmaceutical to a patient, the bedside module 500 allows for a final verification. A barcode scanner located proximate to a patient is used by a nurse or other technician to scan the barcode label on the syringe and/or IV bag. The barcode scanner is in communication with a computer, which verifies the information encoded on the second barcode with patient information and/or prescription information retrieved from the intra-hospital network.

[0061] While specific embodiments of the invention have been described in detail, it will be appreciated by those skilled in the art that various modifications and alternatives to those

details could be developed in light of the overall teachings of the disclosure. Accordingly, the particular arrangements disclosed are meant to be illustrative only and not limiting as to the scope of invention which is to be given the full breadth of the claims appended and any and all equivalents thereof.

CLAIMS

1. A system for reviewing and verifying preparation of a pharmaceutical compound comprising:

a pharmacy workstation comprising:

a scale;

an image capture device; and

at least one processor configured to cause the image capture device to capture at least one image of at least one step of the preparation of the pharmaceutical compound and to receive, from the scale, gravimetric measurement information during preparation of the pharmaceutical compound; and

a computing device comprising a user interface operatively connected to pharmacy workstation and configured to display for an operator, based on instructions from the at least one processor, a review window, the review window comprising:

a first portion displaying the at least one image of the at least one step of the preparation of the pharmaceutical compound and an indication of whether a concentration of the pharmaceutical compound is within an acceptable tolerance range based on the gravimetric measurement information; and

a second portion displaying one or more thumbnail images of each step of the preparation of the pharmaceutical compound.

2. The system of claim 1, wherein a graphical indication is overlaid onto each of the thumbnail images to identify whether the concentration of the pharmaceutical compound is within the acceptable tolerance range for the step of the preparation of the pharmaceutical compound illustrated in each of the thumbnail images.

3. The system of claim 1, wherein the user interface includes an area that displays the instructions for the preparation of the pharmaceutical compound that corresponds to the at least one image of the at least one step of the preparation of the pharmaceutical compound that is displayed.

4. The system of claim 1, wherein the indication is a check mark.
5. The system of claim 1, wherein the indication is an exclamation point.
6. The system of claim 1, wherein the user interface includes an area that displays icons allowing the operator to either confirm or reject the pharmaceutical compound.
7. The system of claim 1, wherein the user interface includes an area that displays information relating to how often the at least one step of the preparation of the pharmaceutical compound was repeated and/or an elapsed time for performance of the at least one step of the preparation of the pharmaceutical compound.

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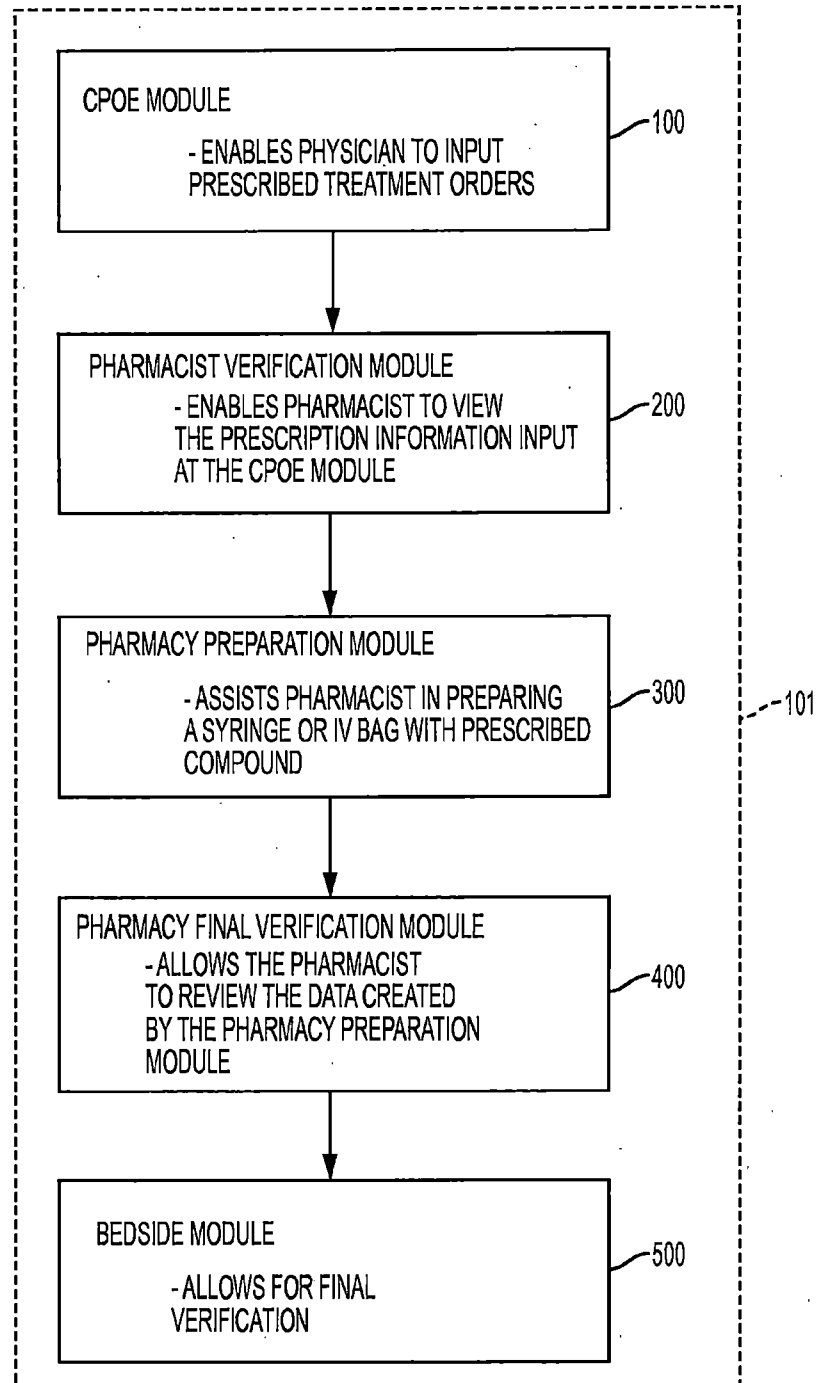


FIG. 1

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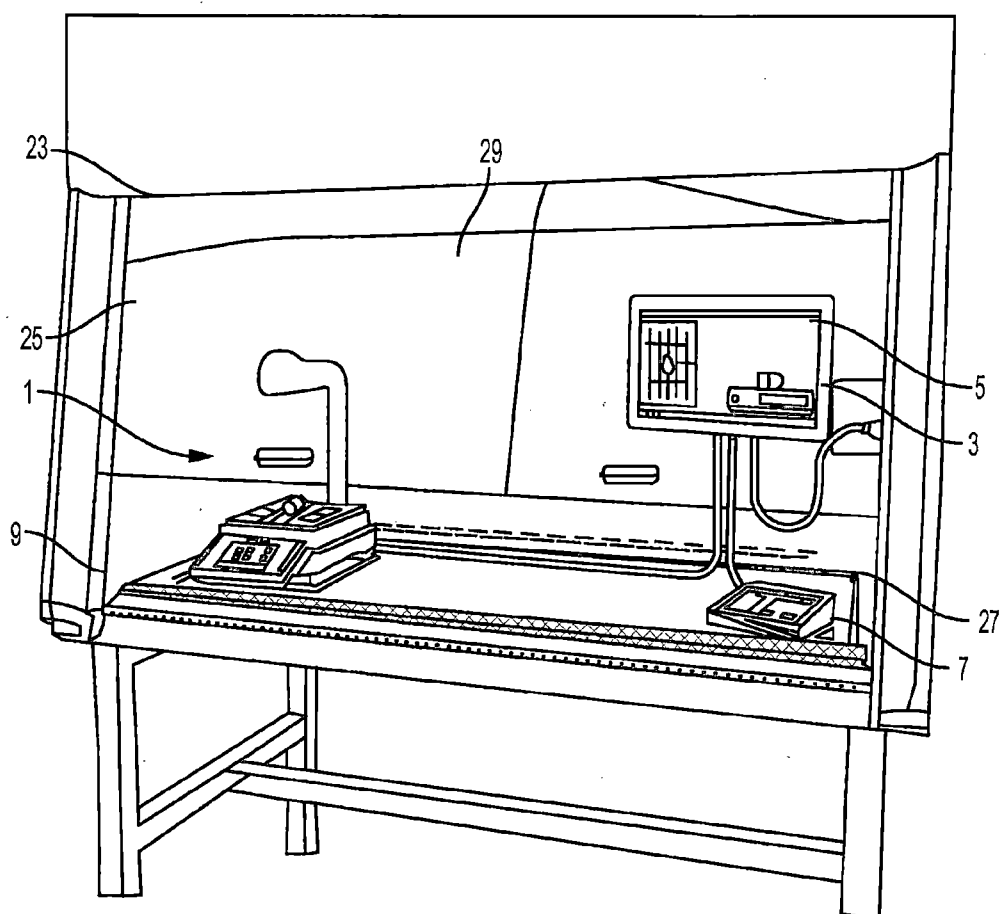


FIG. 2

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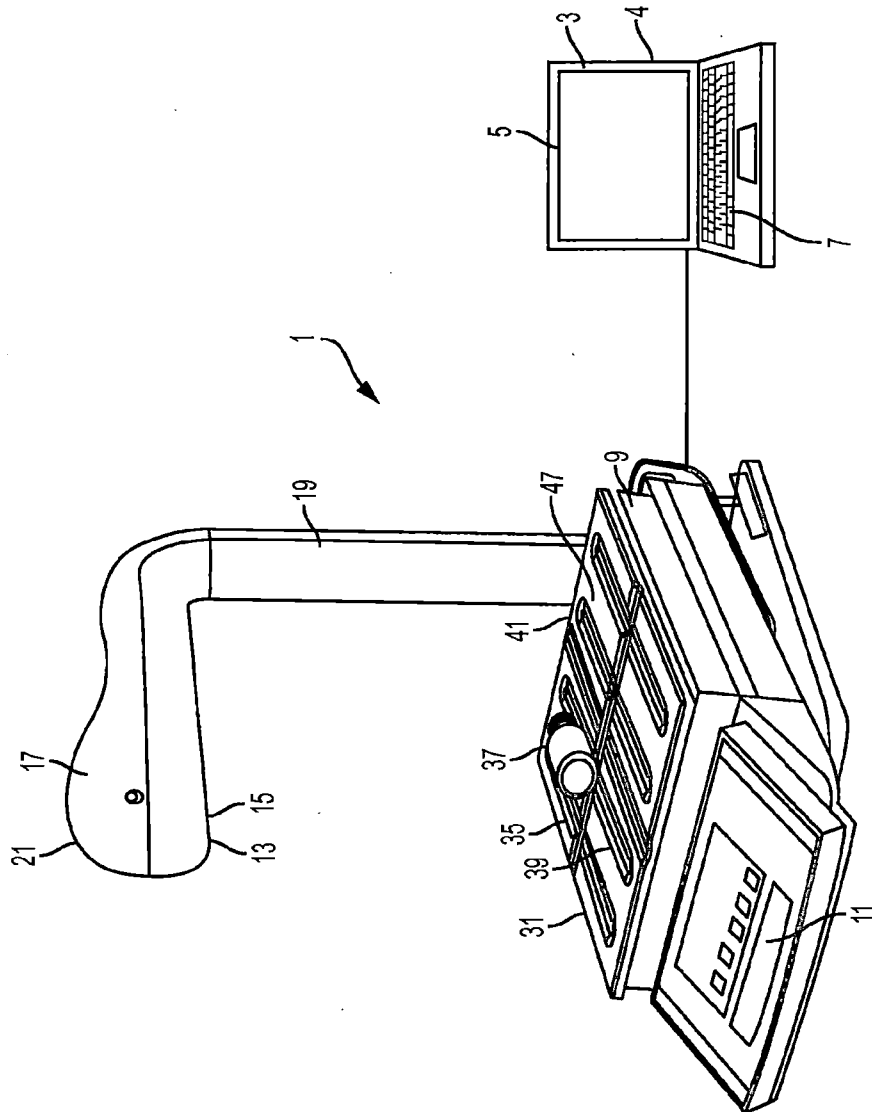


FIG. 3

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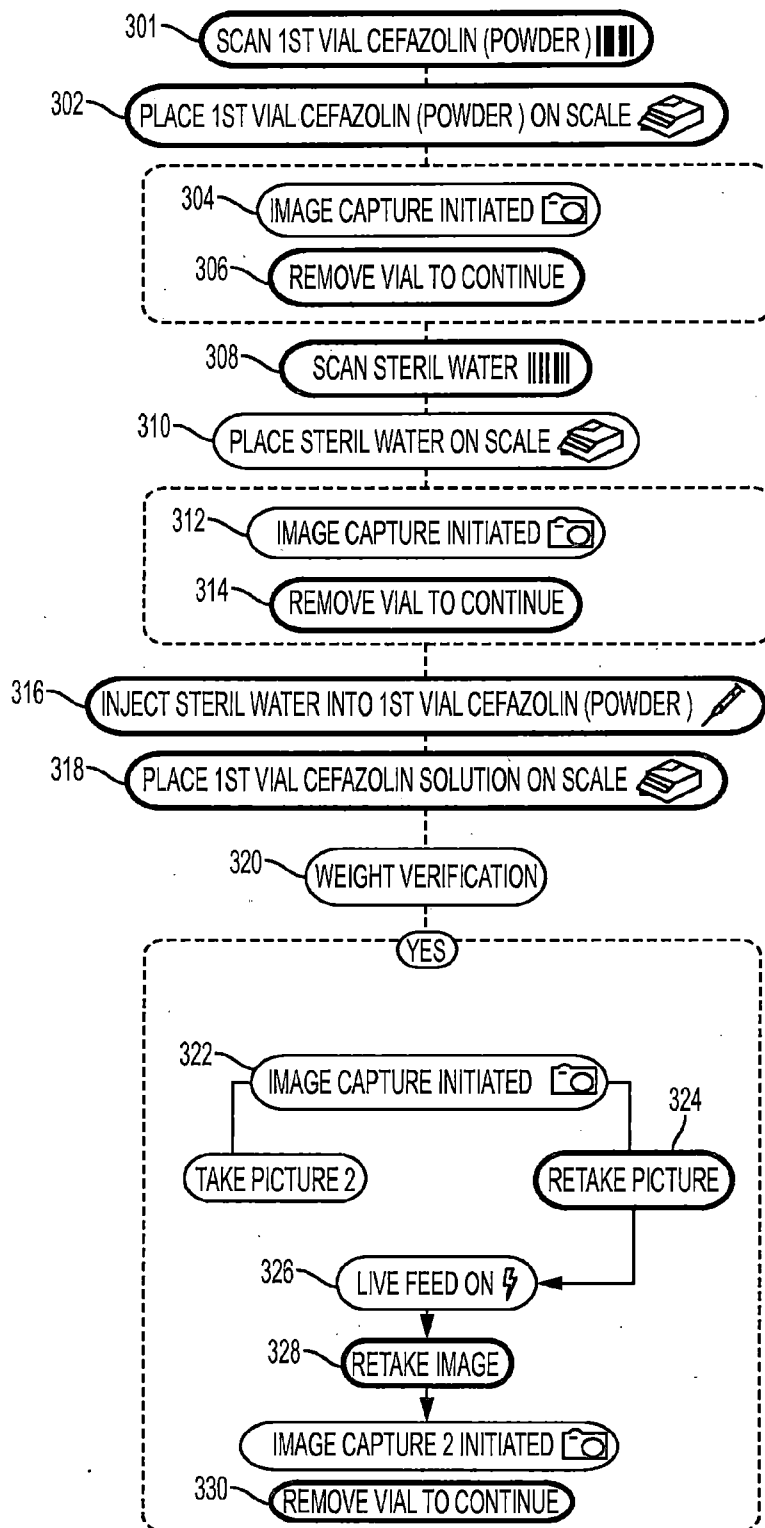


FIG. 4

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FIG. 5A

File Edit View Preparation History Data Reports	
Set Up Preparations	
<Enter>: Confirm Preparation <Escape>: Do not Perform Preparation <F7>: Modify Proposal <F8>: Reset Proposal	
Available Stocks	
☐ Display remainders in all storages	
Test Product	
Required Active Ingredient Mass: 16.9mg Prepared Remnant 3.1mg	
Existing Remainers:	
☐ #938, 3.06mg 0.5mg/ml, Exp.: 06/11/2013 11.52	
1x 20mg	
1x of SAMPLE LOT Use Bef.: 07/01/2013	
Diluent:	
20 ml diluent	
100ml bag	
Dil. Lot # TB 24	
Expected number of required syringes:	
For diluent: 1x 20ml	
For Withdrawal: 1x 50ml	
Vehicle:	
193342: SAMPLE, John in 100ml NaCl (100ml PVC Bag)	
Veh Lot # NC0004	

Prepare Volumetrically	
Confirm Parts List	
Do Not Perform Preparation	
EC/Al Lots	

Parts List	Preparation Instructions
Parts List for Preparation Number 66138	
Oral Medication With Test Product Triubit	
Med. #94462 SAMPLE; Test Product in 100ml NaCl 0.9% (100ml PVC Bag)	

Required Vials:	
1x Vial Test Product 20mg	
Required Vehicle:	
1x 100ml NaCl 0.9%, PVC Bag	
Required diluent:	
20ml diluent	
Required Syringes:	
For diluent 1x is 20ml	
For Withdrawal is 50ml	

Start

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FIG. 5B

Help					
Preparations					
Please select a verified preparation:					
Prod. No.	Product(s)	Administration	Patient(s)	Ward(s)	Medication(s)
6613B	Test product Trsutat		Sample	SA - Ward 1	1 193362
Details for selected preparation					
# 1: Med. #193362. Bmg Test Product Trsubst (33.6ml in NaC10.9% 100ml Bag PVC, Sample, (Sa - Ward 1)					
Prepare <ENTER>			Cancel interrupted preparation <F6> Start preparation directly (bar code):		
Assistant Check:			Set up Preparation <F4> Reconstitute in advance <F7>		
Start					

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Scan 20mg vial

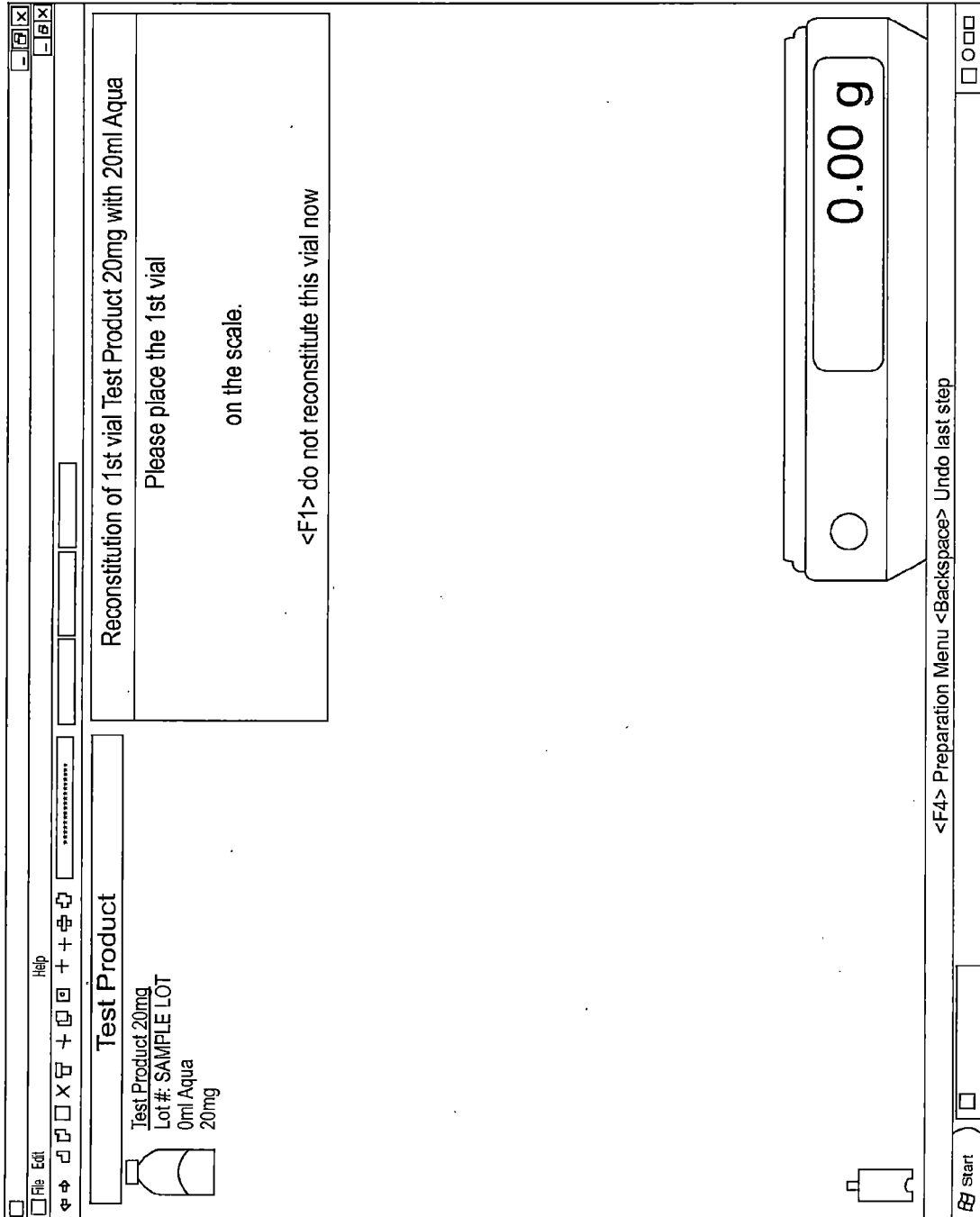


File Edit Help		Test Product Test Product 20mg Lot #: SAMPLE LOT 0ml Aqua ad Ing. 20mg		Reconstitution of 1st vial Test Product 20mg with 20ml Aqua Scan barcode of vial 1st, Test Product 20mg (Lot: SAMPLE LOT). <F1> do not reconstitute this vial now <F5> Confirm correct product manually		0.00 g		<F4> Preparation Menu <0> Tare Scale <Backspace> Undo last step Start	
---	--	---	--	--	--	---	--	--	--

FIG. 5C

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REPLACEMENT SHEET
SUBSTITUTE SHEET (RULE 26)

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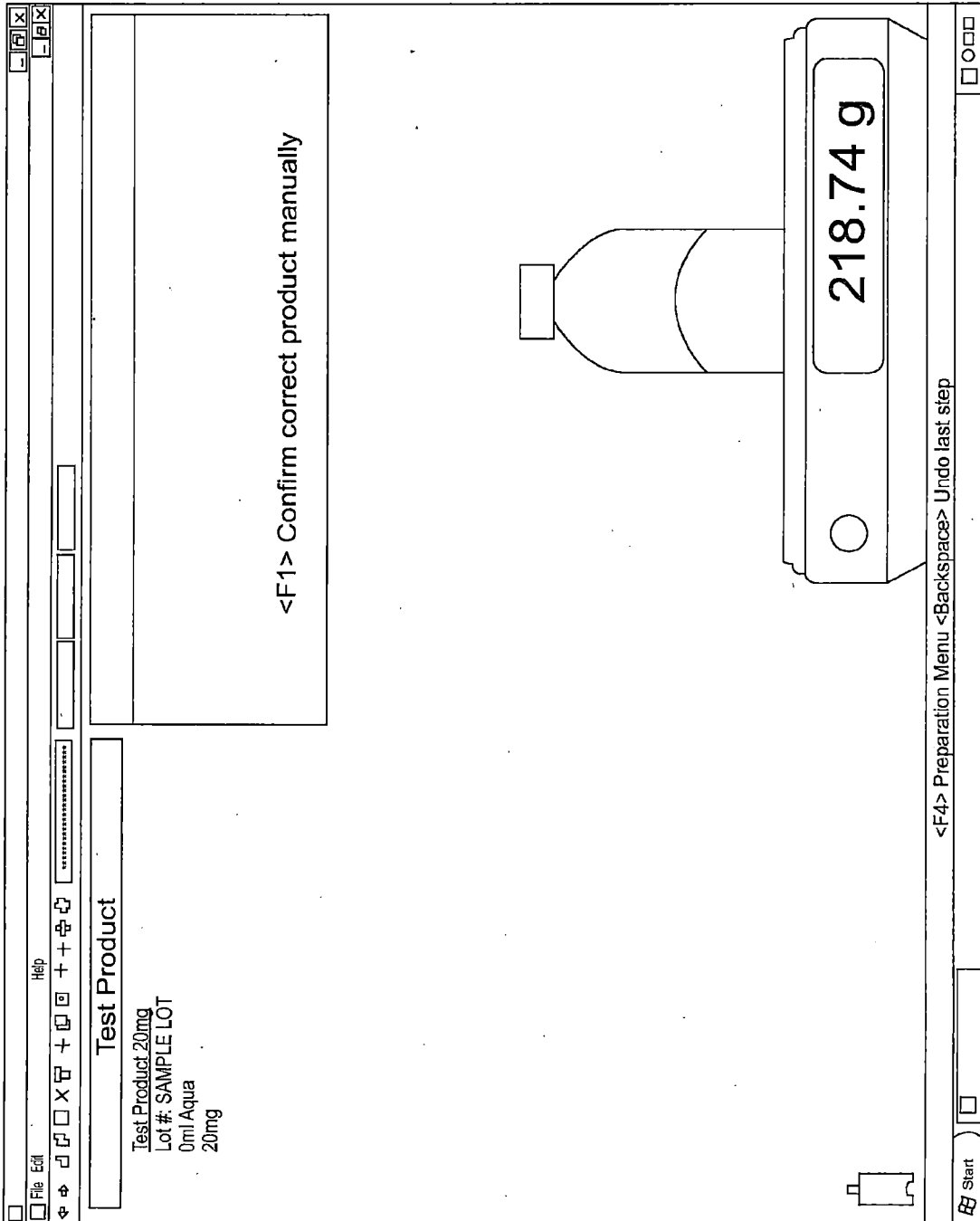


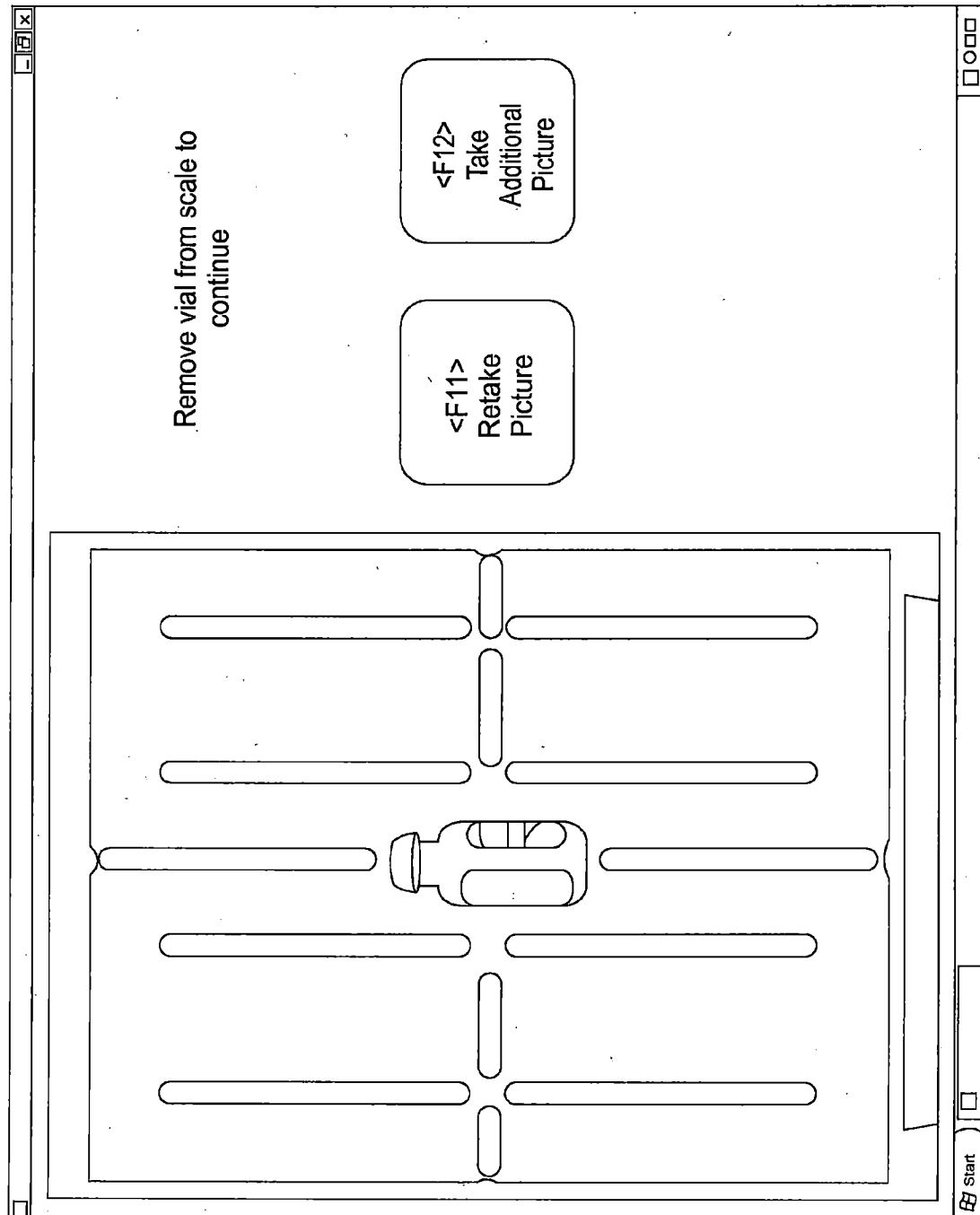
FIG. 6A

REPLACEMENT SHEET

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FIG. 6B



REPLACEMENT SHEET

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Scan 20mg vial



File Edit Help

Test Product

Test Product 20mg
Lot #: SAMPLE LOT
0ml Aqua
20mg

Reconstitution of 1st vial Test Product 20mg with 20ml Aqua

Scan the barcode of the diluent
Aqua 100ml (Lot TB24)

<F1> Confirm correct product manually

Start

<F4> Preparation Menu <Backspace> Undo last step

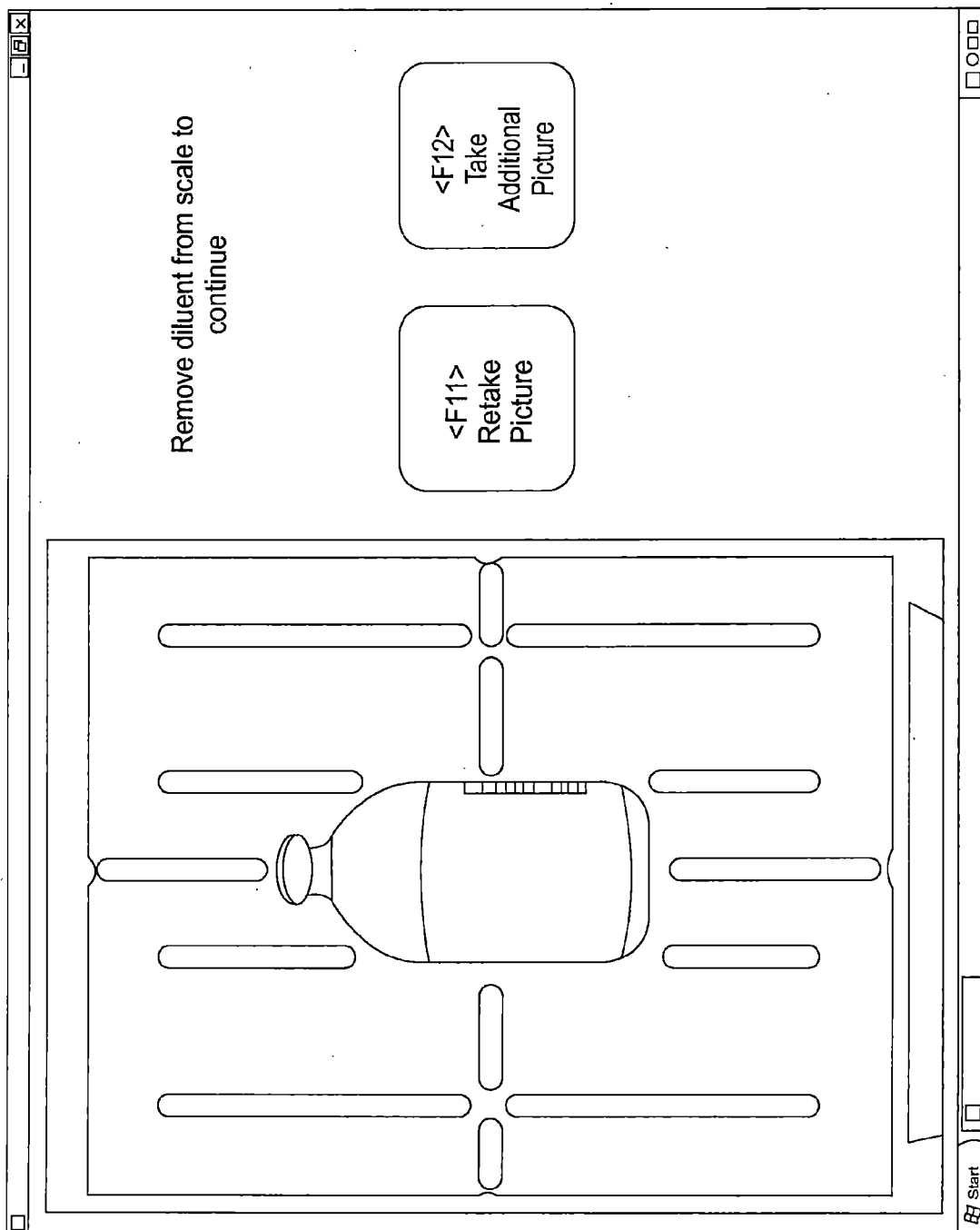
FIG. 6C

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FIG. 6D



REPLACEMENT SHEET

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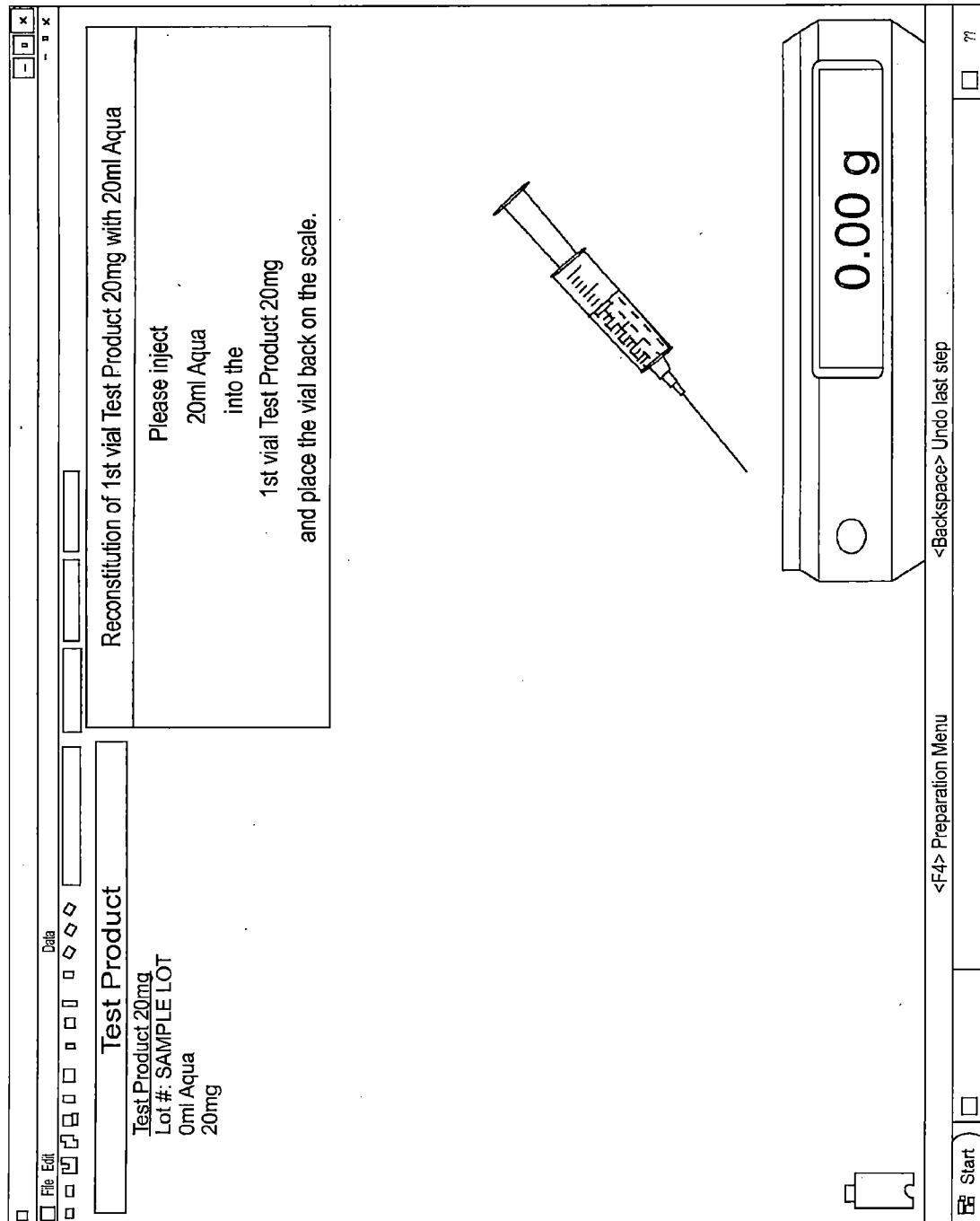


FIG. 7A

FIG. 7B

[illegible]

REPLACEMENT SHEET

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Scan 20mg vial



	Test Product Test Product 20mg Lot # SAMPLE LOT 20ml Aqua 20mg (4kg)	Date Time	☐ File Edit ☐ ☐ AS withdrawn Prescribed: 16.9mg Achieved: 0mg 0% Scan barcode of vial 1st, Test Product 20mg (Lot: SAMPLE LOT). <F2> do not use this vial <F5> Confirm correct product manually <F3> to skip this medication
		<Backspace> Undo last step	

FIG. 8A

REPLACEMENT SHEET

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FIG. 8B

[illegible]

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FIG. 8C

Test Product Test Product 20mg Lot #: SAMPLE LOT 20ml Aqua 20mg	16.9mg Test Product (33.8ml) in NaCl 0.9% 100ml Bag PVC, Sample <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; border-bottom: 1px solid black;">Achieved: 0mg</td> <td style="width: 33%; border-bottom: 1px solid black;">AS withdrawn</td> <td style="width: 33%; border-bottom: 1px solid black;">Prescribed: 16.9mg</td> </tr> <tr> <td style="border-bottom: 1px solid black;"></td> <td style="border-bottom: 1px solid black;">0%</td> <td style="border-bottom: 1px solid black;"></td> </tr> </table> To be withdrawn from this vial: approx. 33.8ml (33.8g) Please place an empty 50ml Syringe on the scale. <F3> to skip this medication	Achieved: 0mg	AS withdrawn	Prescribed: 16.9mg		0%	
Achieved: 0mg	AS withdrawn	Prescribed: 16.9mg					
	0%						



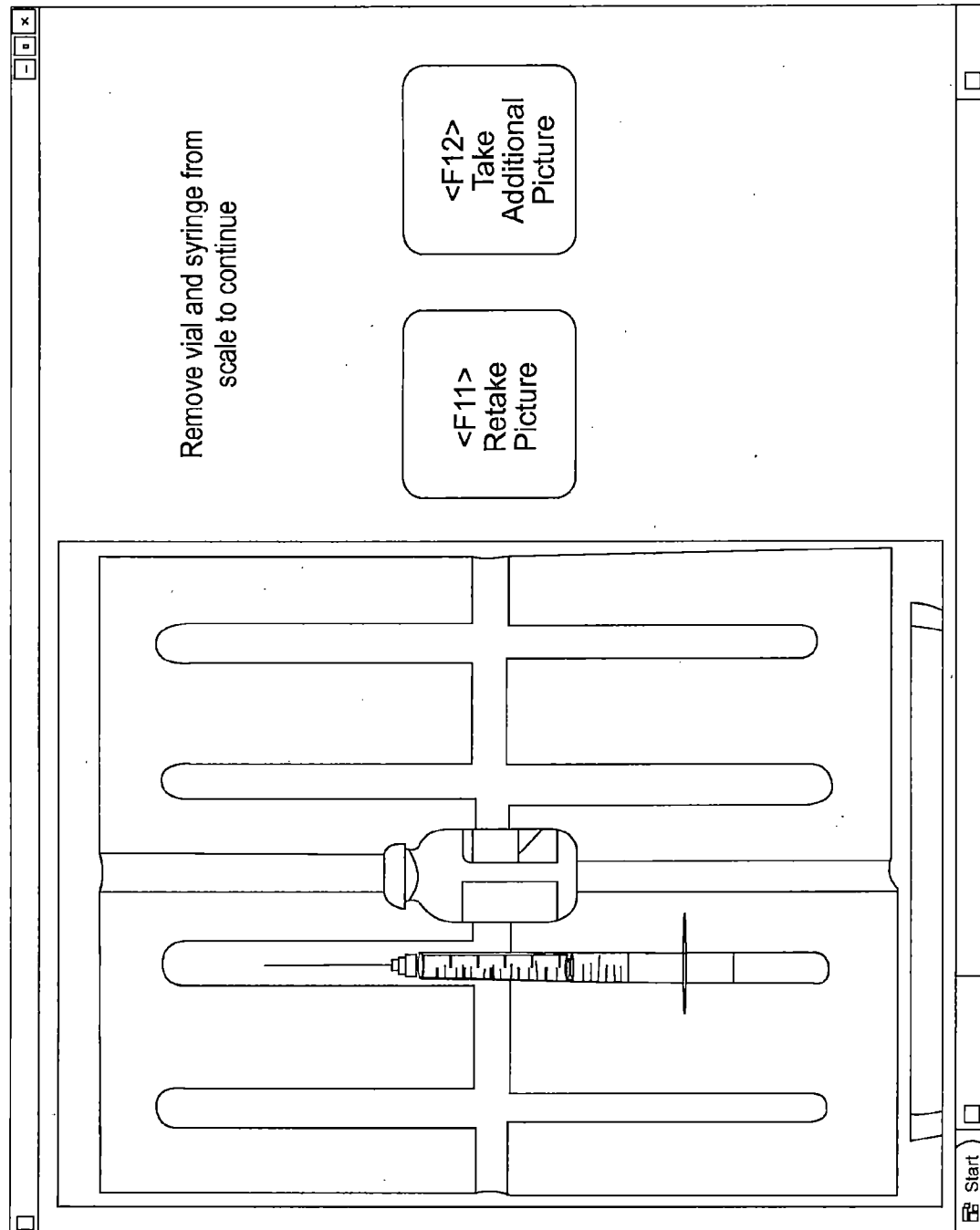
<F4> Preparation Menu
<Backspace> Undo last step

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FIG. 8D



REPLACEMENT SHEET

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File Edit Data

Test Product

Test Product 20mg
Lot #: SAMPLE LOT
20ml Aqua
20mg

16.9mg Test Product (33.8ml) in NaCl 0.9% 100ml Bag
PVC, Sample

Achieved: 0mg

AS withdrawn

Prescribed: 16.9mg

Prescribed Active Ingredient: 16.9mg, Amt. Attained: 0mg

withdraw approx. 33.8ml (33.8g) solution.
Then place the syringe back on the scale.

<F3> to skip this medication

Start

<F4> Preparation Menu

<Backspace> Undo last step

278.24 g

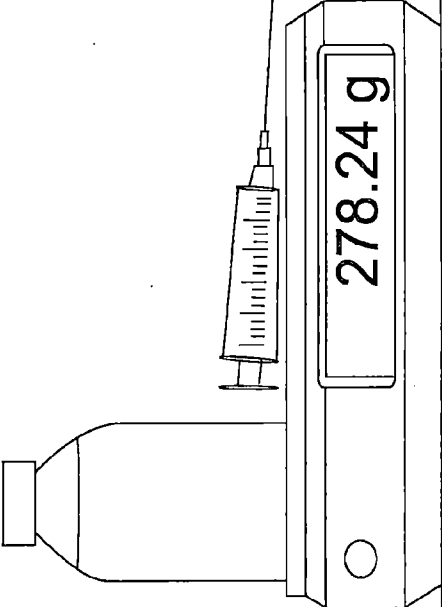


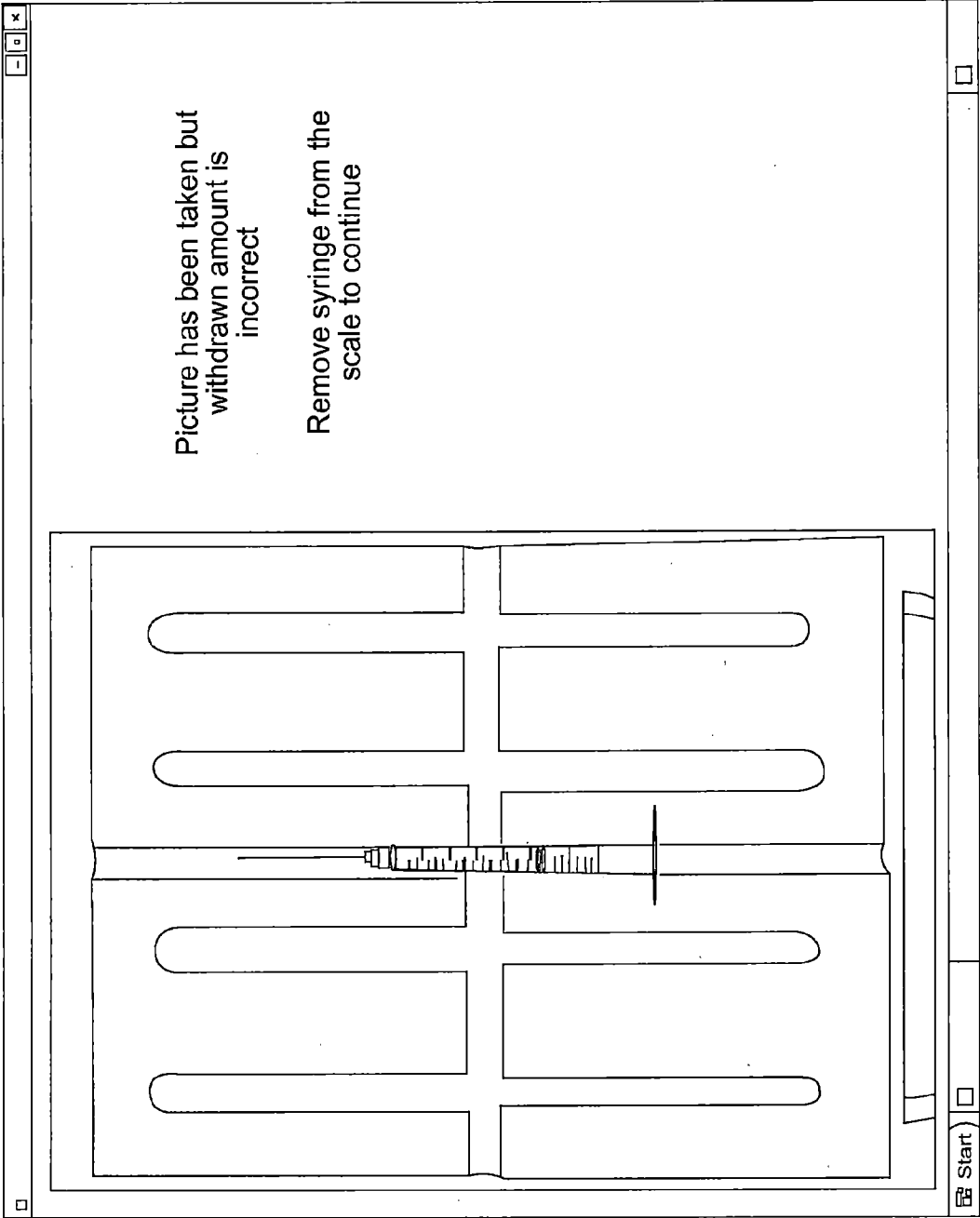
FIG. 9A

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FIG. 9B



REPLACEMENT SHEET

SUBSTITUTE SHEET (RULE 26)

[illegible]

REPLACEMENT SHEET

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File Edit Data ←→ ↺ ↻ □ □ □ □ □	Test Product Test Product 20mg Lot #: SAMPLE LOT 20ml Aqua 20mg 16.9mg Test Product (33.8ml) in NaCl 0.9% 100ml Bag PVC, Sample Achieved: 18mg AS withdrawn 48.4% Prescribed: 16.9mg Prescribed Active Ingredient: 16.9mg, Amt. Attained: 0mg withdraw an additional 17.4g solution. 33.8ml solution should be in the syringe after that. Then place the syringe back on the scale. <F1> if no more withdrawal possible	 0.00 g
<F4> Preparation Menu <Backspace> Undo last step		

REPLACEMENT SHEET

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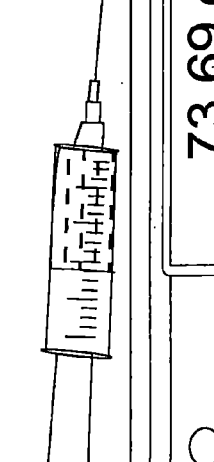
Test Product
 Test Product 20mg
 Lot #: SAMPLE LOT
 20ml Aqua
 20mg

16.9mg Test Product (33.8ml) in NaCl 0.9% 100ml Bag
 PVC, Sample

Achieved: mg	AS withdrawn	Prescribed: 16.9mg
101.1%		

Current Amount of Active Ingredient: 17.09mg
 Prescribed Amount of Active Ingredient: 16.9mg
 Achieved Quantity: 101.1%

Take the syringe from the scale.



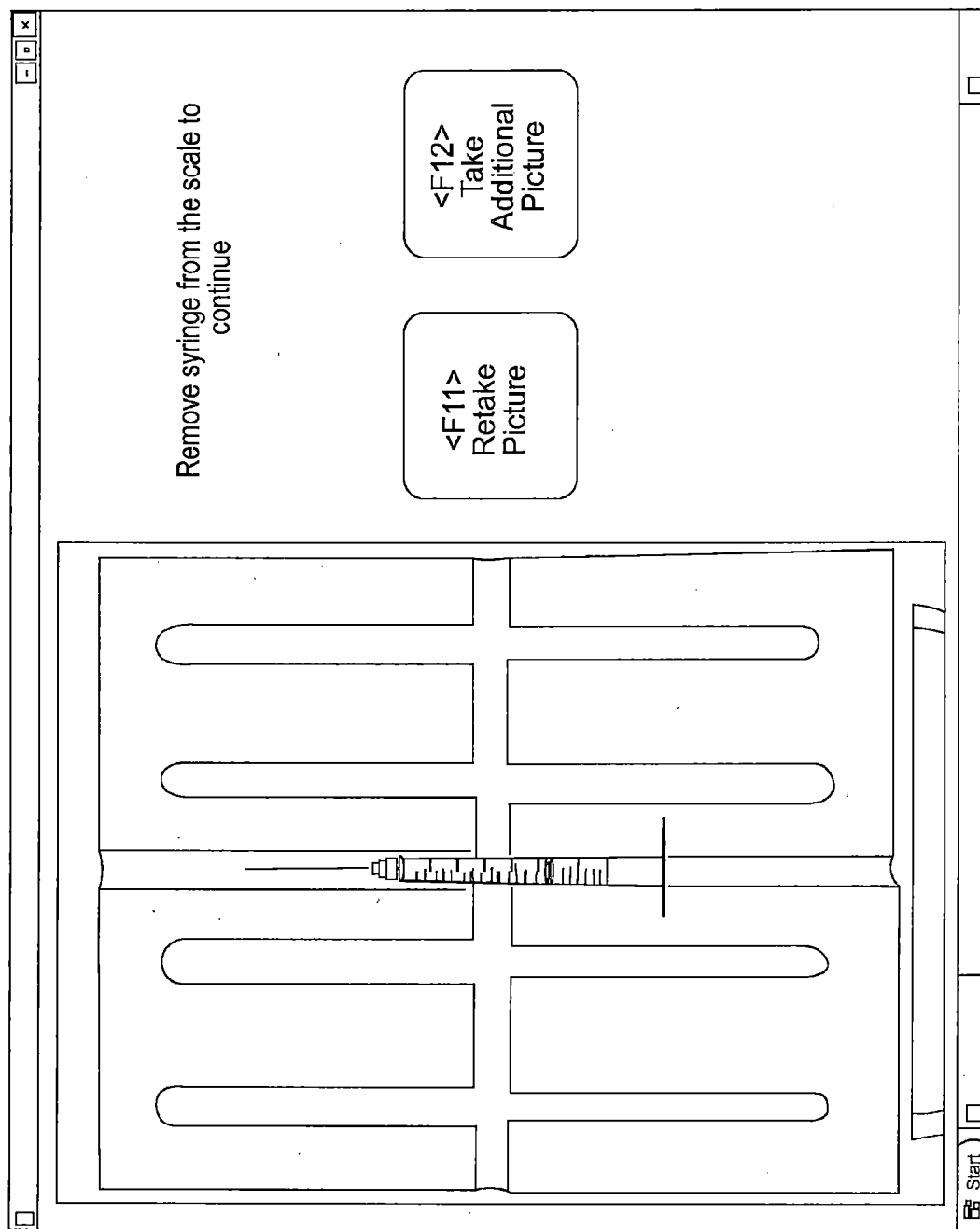
<F4> Preparation Menu
<Backspace> Undo last step

REPLACEMENT SHEET

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FIG. 10B



Scan IV bag

[illegible]

FIG. 10C

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FORCE TAKE ADDITIONAL IMAGE CAPTURE

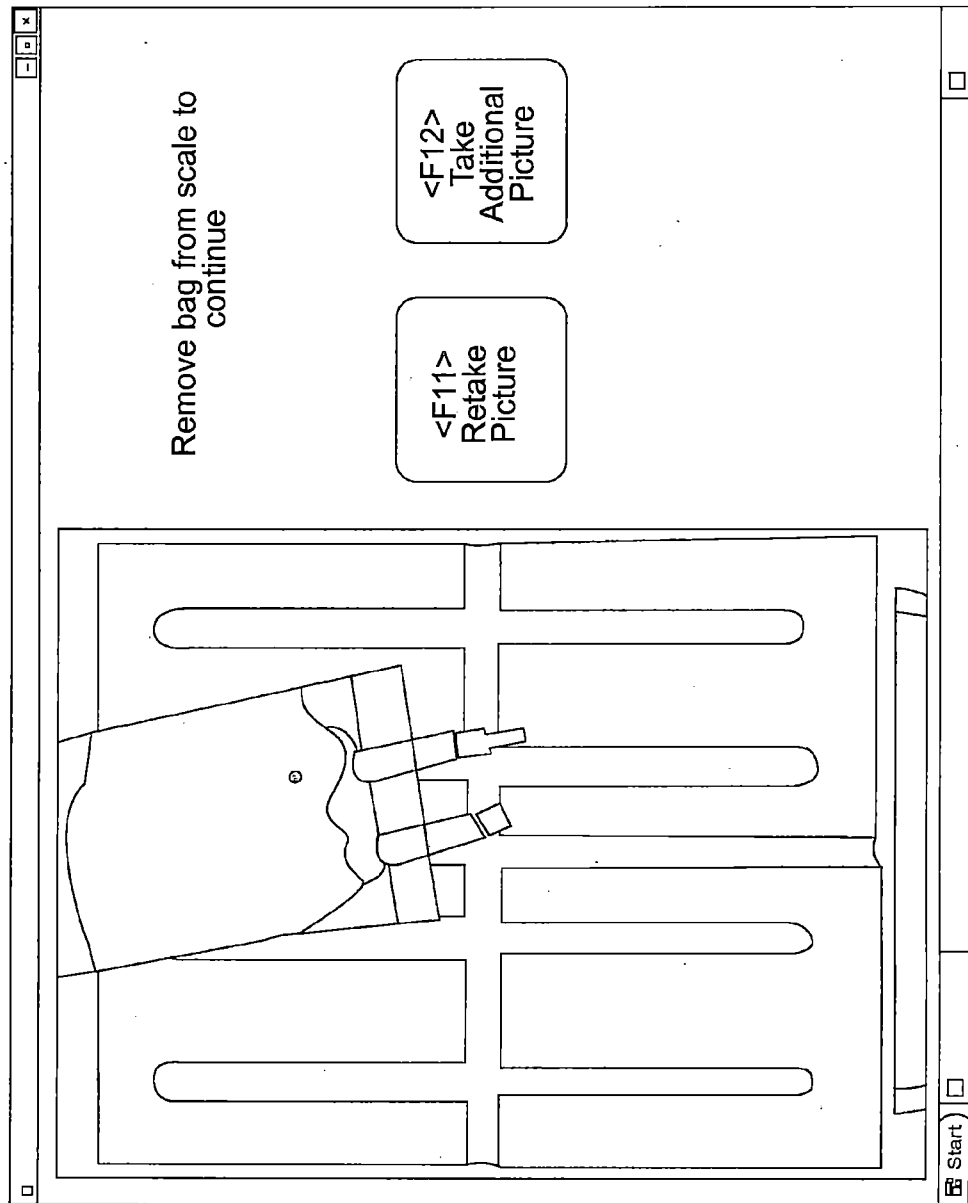
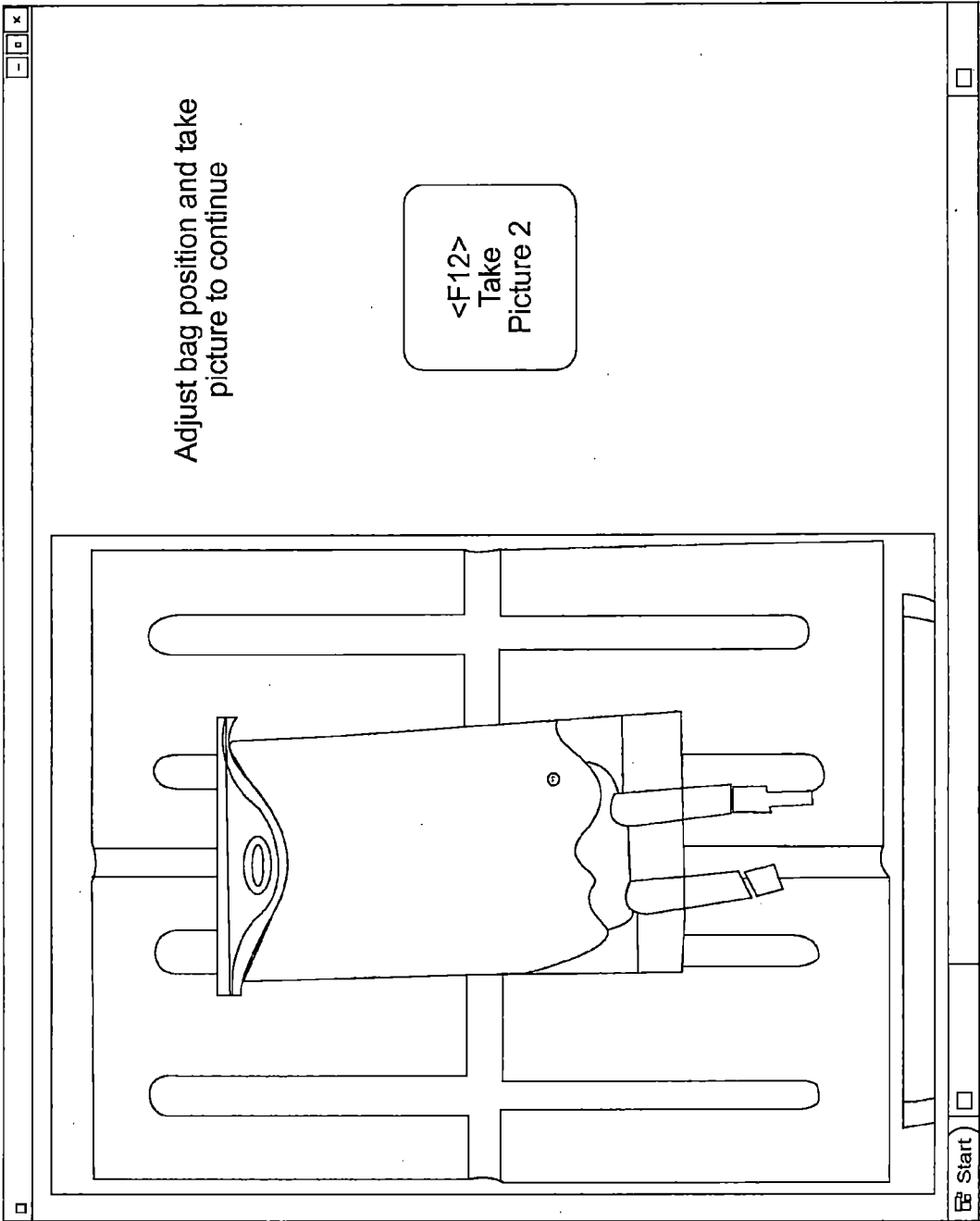


FIG. 11A

REPLACEMENT SHEET

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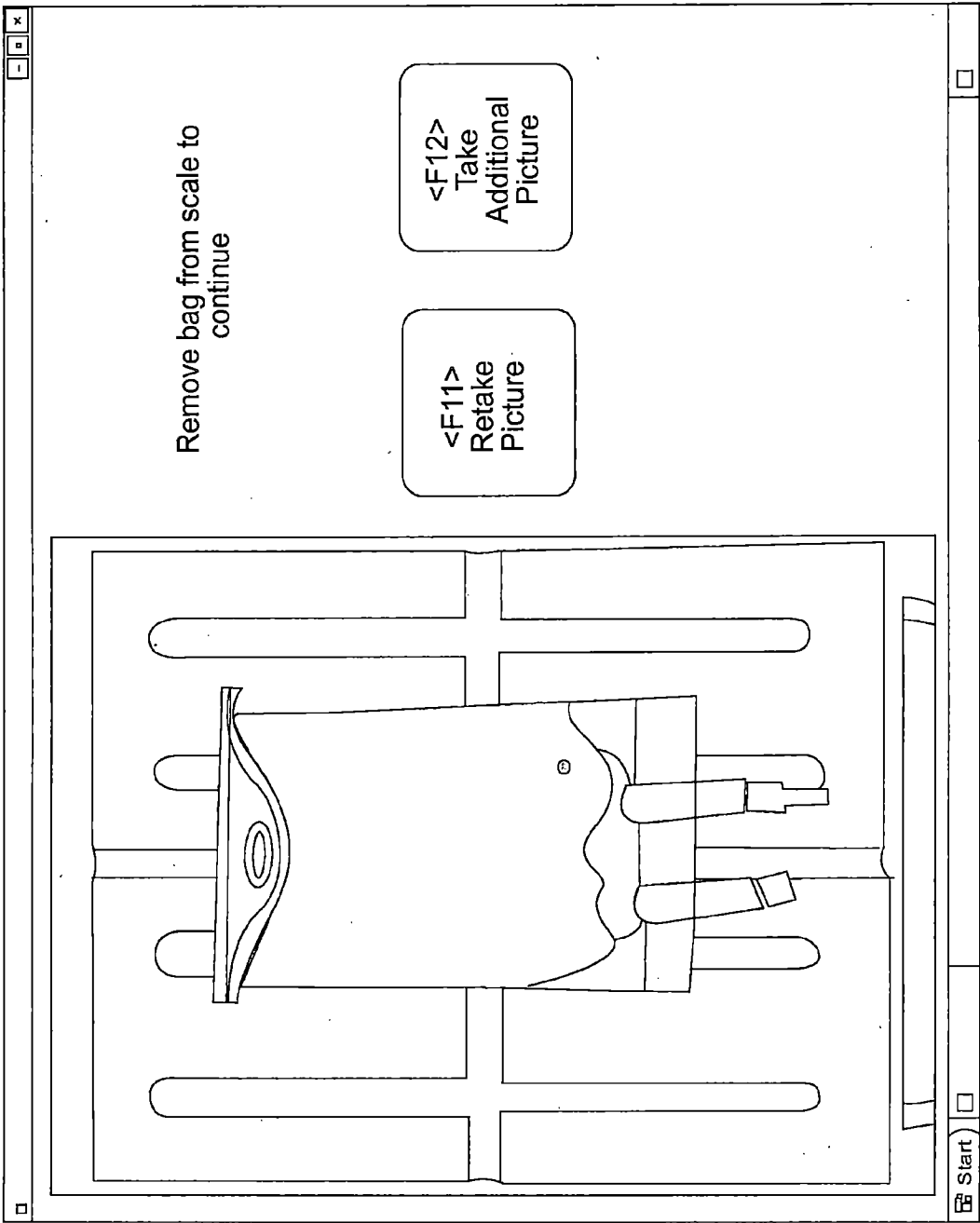
FIG. 11B



REPLACEMENT SHEET

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FIG. 11C



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FIG. 11D

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FIG. 12B

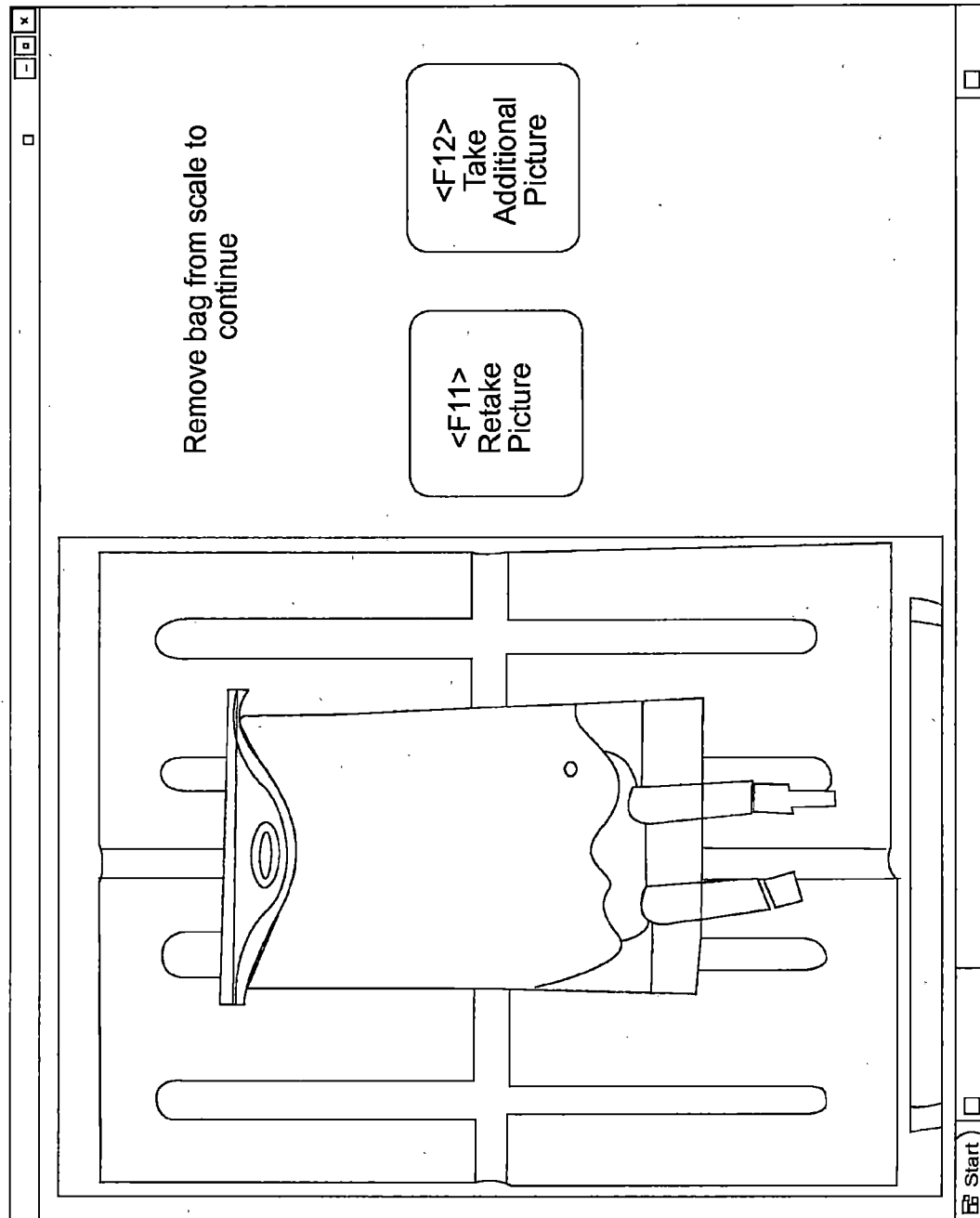
☐ File ☐ Edit ☐ Data <-> ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐							
Test Product Test Product 20mg Lot #: SAMPLE LOT 20ml Aqua 2.91mg	16.9mg Test Product (33.8ml) in NaCl 0.9% 100ml Bag PVC, Sample <table style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 33%; border-right: 1px solid black; padding: 5px;">Achieved: 17.08mg</td> <td style="width: 33%; border-right: 1px solid black; padding: 5px;">AS Injected</td> <td style="width: 33%; padding: 5px;">Prescribed: 16.9mg</td> </tr> <tr> <td colspan="3" style="padding: 5px; text-align: center;"> 101% </td> </tr> </table> Injected Mass: 34.1g (= 17.08mg) Current Amount of Active Ingredient: 17.08mg Prescribed Amount of Active Ingredient: 16.9mg Deviation: 1 % YOU ARE WITHIN TOLERANCE! Please remove the Bag from the scale.	Achieved: 17.08mg	AS Injected	Prescribed: 16.9mg	101%		
Achieved: 17.08mg	AS Injected	Prescribed: 16.9mg					
101%							
<F4> Preparation Menu <Backspace> Undo last step							

REPLACEMENT SHEET

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FIG. 12C



REPLACEMENT SHEET

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Test Product

Test Product 20mg
Lot #: SAMPLE LOT
20ml Aqua
2.91mg

Weighing remainders

Place 1st vial Test Product 20mg on the scale.
<F1> to reject remnant

0.00 g

File Edit Data

Start

<F4> Preparation Menu <Backspace> Undo last step

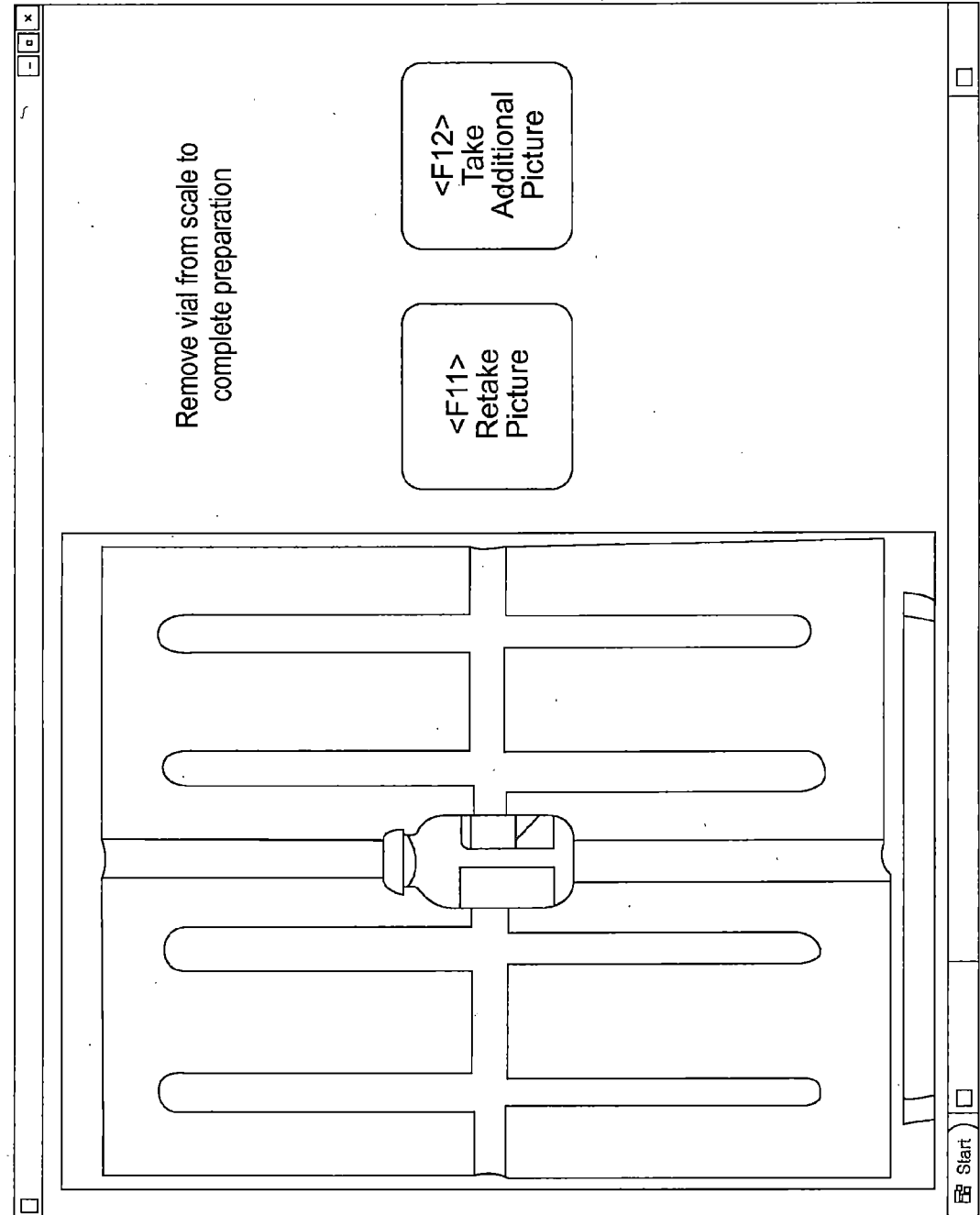
REPLACEMENT SHEET

SUBSTITUTE SHEET (RULE 26)

REPLACEMENT SHEET

SUBSTITUTE SHEET (RULE 26)

FIG. 13C



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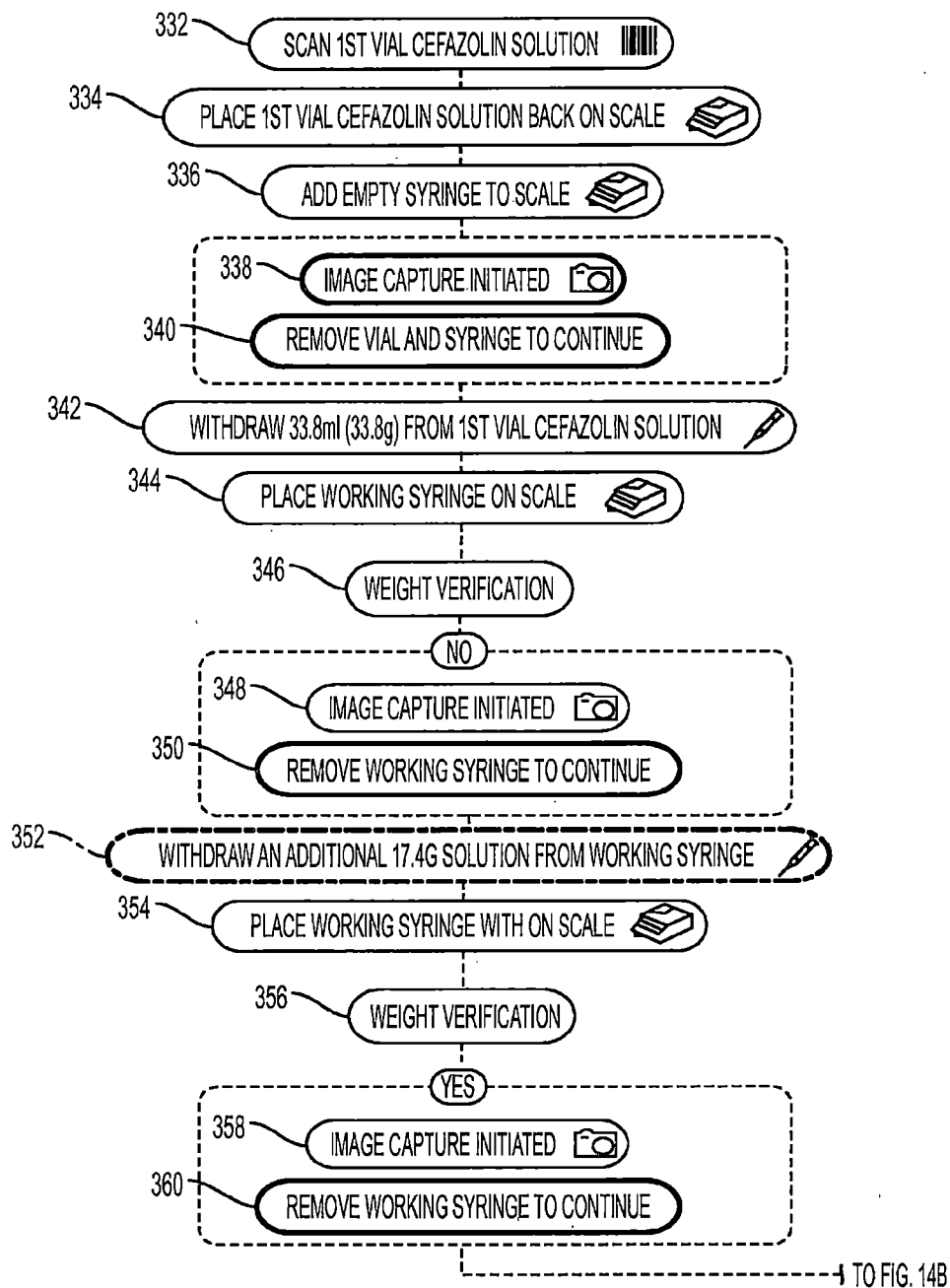


FIG. 14A

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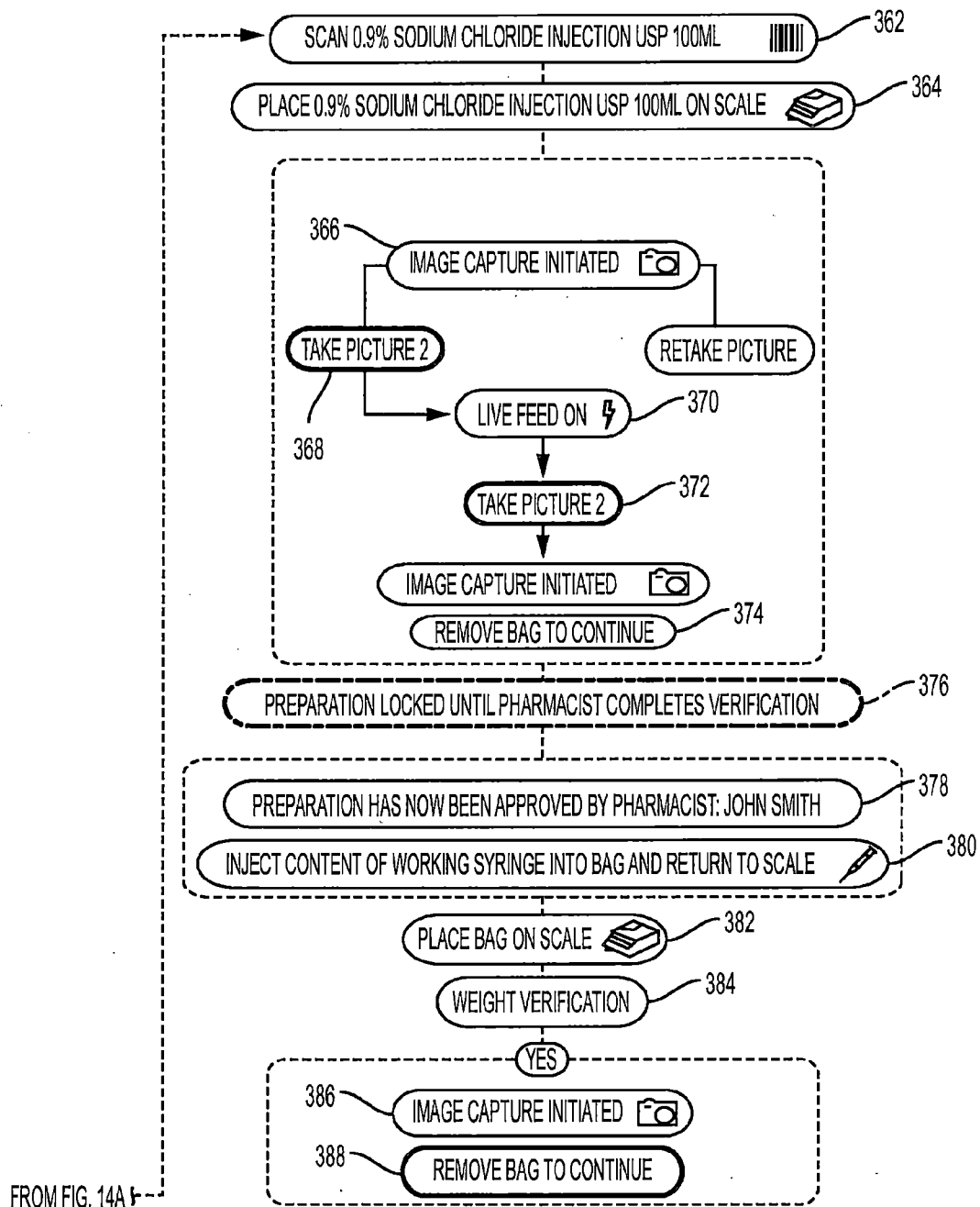


FIG. 14B

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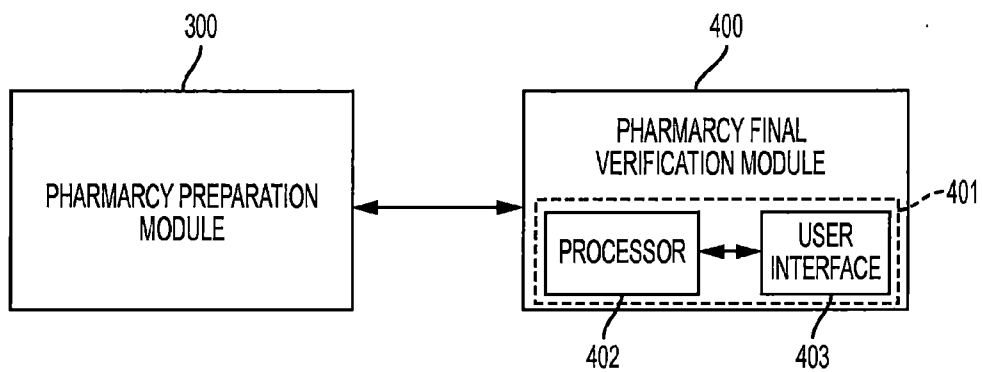


FIG. 15

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Name

>

Skip to Next Patient

Back to Cue

More Details

16.9mg Test Product in 100ml Nacl 0, 9%

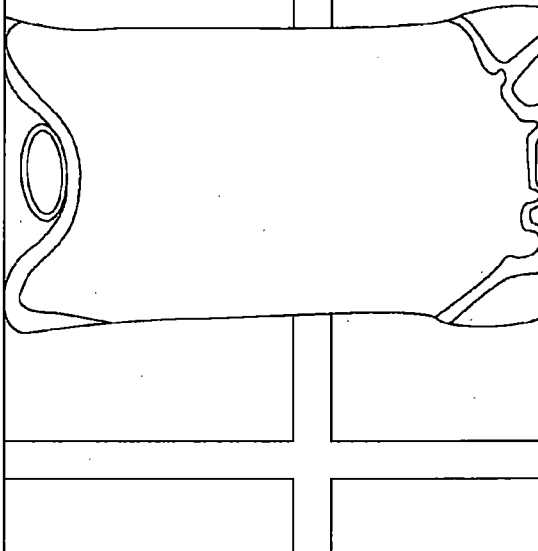


Image Viewing Tools

254.52 g

1 - Reconstitute Test Product

2 - Add Active Ingredient

3 - Weigh Remnant

Injected Mass: 33.9g = (16.85mg AS)

Current amount of active ingredient: 16.85mg

Prescribed amount of active ingredient: 16.9mg

Deviation: -0.3 %

You are within Tolerance.

Please remove the bag from the scale.

Reason for Task

Description of Task

Add notes

Approve Task

Decline

FIG. 16

REPLACEMENT SHEET

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FIG. 17

422

430

426

428

420

432

434

434

424

2 - Transfer of STESKKBZ Trsubst 40mg

Weight after withdrawal

Deviation + 10,1%

Preparation protocol

Pharmacist Review

Order number
unknown

Case number
unknown

Ward

Patient Name

Date

bst. 40MG in NaCl 0.9% 100ml

X Exit Pharmacist Review

✓ Confirm prescription

⊗ Reject prescription

The diagram shows a pharmacist review station. At the top, there is a header 'Pharmacist Review' with fields for 'Order number', 'Case number', 'Ward', 'Patient Name', and 'Date'. Below this, there is a large area with various icons and labels. On the left, there is a label 'bst. 40MG in NaCl 0.9% 100ml'. In the center, there is a large icon of a pharmacist. To the right of the pharmacist, there is a row of icons representing different medical procedures or equipment. Below this row, there is a label '2 - Transfer of STESKKBZ Trsubst 40mg'. At the bottom right, there are two boxes labeled 'Weight after withdrawal' and 'Deviation + 10,1%'. On the far right, there is a box labeled 'Preparation protocol'. On the left side of the diagram, there are three labels: '422', '430', and '426'. At the top right, there are three labels: '420', '432', and '434'. At the bottom right, there is a label '428'.

REPLACEMENT SHEET

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