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(54) APPARATUS AND METHOD FOR PREPARING DRUGS

(57) An apparatus (10) for preparing drugs in a safe and controlled environment, comprising a casing or frame (12) comprising two zones adjacent to each other and defined by a warehouse zone or area (18) and a set-up zone or area (20) which are separate from each other and communicating, the warehouse zone or area (18) defining an area assigned for the loading and storage by means of a warehouse (26) of materials required for the pharmaceutical preparations and the set-up zone or area (20) defining an area in which the drug preparation is carried out with the materials picked up from the warehouse zone or area by means of a first robotic manipulator (30) and a second robotic manipulator (31) simultaneously cooperating with each other and with functional devices for the pharmaceutical preparation, carrying out mutually different actions to perform set-up and preparation operations in "masked time".

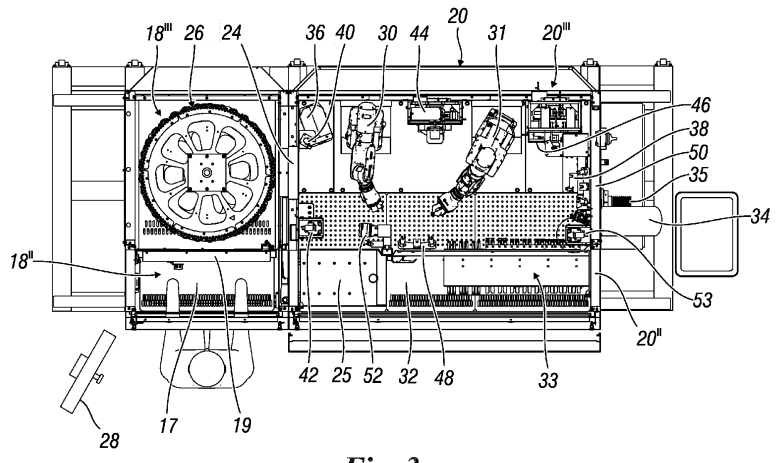

Fig. 3

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Description

[0001] The present invention relates to an apparatus and a method for preparing drugs.

[0002] More in particular, the present invention relates to an automated type apparatus and the related method for preparing (or compounding) injectable pharmaceutical solutions in a safe and controlled environment and, more in particular (but not exclusively), for preparing chemotherapy drugs and/or any injectable type drug based on the specific needs of hospital facilities and the like (e.g., intravitreal syringes, monoclonal antibodies, state-of-the-art antibiotics, vaccine partitioning, and the like) .

[0003] As known, traditionally the preparation of drugs is carried out in hospital pharmacies by means of a manual method (or compounding) and consists of a series of method steps comprising the insertion of the prescriptions related to the patient in the hospital's computer system by the doctors, a validation by the pharmacist and a set-up of the production of said drug by the assigned operator.

[0004] The drugs are prepared manually in a sterile environment and, in particular, under a vertical laminar air flow hood so as to safeguard the safety of the operator, the sterility conditions of the preparations and, consequently, the quality thereof.

[0005] However, the traditional manual preparation method includes the establishment of possible sources of error and problems, with a consequent impact on the quality of the finished product.

[0006] A further drawback of manual preparation (or compounding) is the lack of ensured safety for the operator assigned to the preparation, who may be exposed to cytotoxic and mutagenic substances which can be very harmful to health.

[0007] A further drawback of the traditional preparation method is represented by an incomplete traceability of the production process.

[0008] A further drawback is the difficulty, if not impossibility, of carrying out checks on the correctness of drug dosages. A further drawback is represented by the fact that the rules for a good preparation of drugs include the presence of two operators (one operator at each hood), of which one is responsible for the preparation and the other for checking the correctness of the process; therefore, the manual control which can be subject to errors and the need to employ at least two operators entails increases in cycle times as well as in the related costs.

[0009] A further and not negligible drawback is represented by the fact that a manual preparation is subject to contamination related precisely to the manual handling of the components necessary for the preparations.

[0010] To try to remedy such drawbacks, automated devices have been developed which allow ensuring greater safety for the operator and greater safety and quality for the pharmaceutical preparation.

[0011] Such apparatuses comprise a functional storage area or warehouse for receiving and storing the components necessary for a preparation and a work area in which a manipulator operates to pick up the components from the storage area and combine them to form the finished product. However, such types of automatic apparatus have a drawback linked to a non-optimal level of automation and, therefore, to a non-optimal production process by virtue of the fact that they allow making only one preparation at a time.

[0012] A further drawback of such known automated apparatuses is represented by the fact that they require a substantial contribution from the operator to insert the material necessary to prepare the individual preparation into the machine, to constantly unload the finished preparations and for various and repeated operations next to the machine.

[0013] A further drawback of such known apparatuses is represented by the fact that the material loading and unloading operations are linked to the individual pharmaceutical preparation and, in particular, for each individual preparation the operator must load all the necessary materials into the apparatus and must also unload the finished product; therefore, the presence of the operator next to the machine is always necessary and, moreover, it is not possible to carry out several preparations in the same cycle since, as described, each cycle includes loading the material necessary for a single preparation.

[0014] A further drawback which affects the production capacity of the known apparatuses is represented by the fact that the materials necessary for a pharmaceutical preparation can only be loaded in the face of a specific prescription, for example a prescription by the hospital computer system or the like; therefore, once receiving the prescription, the operator views the material to be loaded in the storage area and labels it with a specific and unique code prior to the insertion thereof in the warehouse, thereby without being able to pre-load the warehouse of the storage area. More in particular, when the material is loaded, it is already linked to a specific prescription and, therefore, to a specific patient and this implies that, to make a preparation, it is always necessary to have a specific medical prescription and it is not possible to generically pre-load material during the preparation step to proceed with a material-prescription association after loading.

[0015] A further drawback is represented by the fact that the known automatic apparatuses use syringes with a needle and this, as is known, involves nebulization and dispersion problems of the drugs being prepared and, consequently, increases the contamination risk of the preparations, of the work surfaces and of the assigned staff; in fact, such apparatuses use syringes with a needle for the purpose of withdrawing the components from the drug bottles according to the prescribed doses and for each preparation, the elastomer of the drug bottle is punctured by means of the needle, the component is withdrawn and the needle is subsequently extracted from

the bottle, consequently, there is an inevitable dispersion of the component both by nebulization and by the repeated puncturing of the elastomer

[0016] A further drawback of the traditional automatic apparatuses is represented by a lack of flexibility regarding the management of materials in different formats, and as there are dimensional constraints for the gripper of the manipulator which is not capable of gripping very small sizes (for example, small volume drug bottles).

[0017] The above drawbacks contribute to a further and important drawback characterizing the traditional apparatuses, which is represented by the low hourly productivity which is indeed comparable to that of the manual type; in fact, the traditional apparatuses also do not carry out different operations/preparations simultaneously.

[0018] The known automatic apparatuses for preparing drugs also have dimensional drawbacks in terms of footprint, ergonomics, lay-out management, installation difficulties, handling, maintenance and the like.

[0019] A further drawback is represented by the fact that the known apparatuses always need to have a sterile and aseptic environment, for example a clean room, or to have to equip suitable spaces for the purpose, with consequent increases in costs and time.

[0020] An example of such a type of apparatus is described in CA2725622 which refers to an automated workstation for preparing, starting from different substances each of which is contained in a vessel, a final product for medical or pharmaceutical use packaged in a container, comprising at least one isolated chamber delimiting several internal functional areas, a loading area comprising rapid decontamination means, a locking device for the introduction of the vessels and containers into the loading area, an area for the storage of the filled vessels and containers which communicates with the loading area, a transfer area, an area for preparing final products which communicates at least with said storage area through said transfer area and comprising rapid decontamination means, a locking device for unloading final products from the workstation; and at least one robot or a programmable logic controller for handling the objects contained in the storage area and/or in the preparation area.

[0021] A further drawback of the known automatic apparatuses is represented by the fact that the bottles containing the active ingredients, the bags or containers containing the diluents necessary for the pharmaceutical preparations have an overfilling with respect to the declared nominal volume and, in the case of the bags containing the diluents, such overfilling can result in a deviation of the desired concentrations for the pharmaceutical preparation.

[0022] More in particular, the drawback mentioned above in reference to overfilling is linked to a difficulty in the optimal management thereof which leads to producing preparations with imprecise concentrations; in fact, with the traditional systems, if a diluent removal becomes necessary before inserting the drug into the bottle/bag, the exact overfilling value cannot be evaluated and, therefore, the overfilling is not removed.

[0023] A further drawback of the known apparatus is represented by the fact that they require channeling the air flows expelled from the machine and, therefore, are characterized by structural constraints.

[0024] A further drawback is represented by the fact that the traditional apparatuses, due to the problems related to the management of the condensate which forms as a result of the heating of the appliance, have considerable dimensions and require tanks for collecting water due to the formation of said condensate.

[0025] A further drawback of the traditional apparatuses is represented by the fact that they are not modular and, therefore, generate difficulties both during installation and during transport.

[0026] A further drawback is represented by the fact that the traditional apparatuses are not ergonomic, and the operator is always forced to work standing up, with all the disadvantages which such a situation entails.

[0027] It is the object of the present invention to obviate the drawbacks disclosed above.

[0028] More in particular, it is the object of the present invention to provide an apparatus and a method for the automated preparation of drugs and, in particular, for preparing chemotherapy drugs and, in general, any injectable drug in a safe and controlled environment.

[0029] It is a further object of the present invention to provide an apparatus for preparing drugs adapted to ensure an optimal automation such as to allow the production of even several different preparations within the same production cycle.

[0030] It is a further object of the present invention to provide an automated apparatus which does not use needles and which, therefore, does not generate problems related to product nebulization and dispersion and which simultaneously does not generate dripping or the like.

[0031] It is a further object of the present invention to provide an automated apparatus suitable for using commercial closed systems (i.e., not dedicated material) in compliance with industry regulations.

[0032] It is a further object of the present invention to provide a highly flexible apparatus for preparing drugs as concerns handling consumables used for the preparations, with particular reference to vial and syringe formats.

[0033] It is a further object of the present invention to provide an apparatus for preparing drugs which allows easily managing the over-filling of the drug components and diluents.

[0034] It is a further object of the present invention to provide an apparatus and a related method for preparing drugs adapted to ensure a reduction in downtime and, consequently, a high productivity (in particular hourly productivity).

[0035] It is a further object of the present invention to

provide a highly flexible and easily installable apparatus for preparing drugs without footprint and lay-out problems and easily moveable within the dedicated spaces.

[0036] It is a further object of the present invention to provide an apparatus for preparing drugs adapted to ensure optimal operation in accordance with industry regulations.

[0037] It is a further object of the present invention to provide an ergonomically optimized apparatus for preparing drugs. It is a further object of the present invention to provide an apparatus for preparing drugs which is optimized from an automation point of view and free from constant and continuous reliance on the operator technician.

[0038] It is a further object of the present invention to provide an apparatus for preparing drugs characterized by high safety for both the operator and for the products being prepared (with reference to the sterility of the environments).

[0039] It is a further object of the present invention to provide an apparatus for preparing drugs which allows better optimized organization of the operator's work as well as a flexibility of use and adaptability to the needs thereof. It is a further object of the present invention to provide an apparatus for preparing drugs adapted to ensure high reliability and durability over time and moreover, such that it can be easily made.

[0040] These and other objects are achieved by the invention having the features according to in claim 1.

[0041] According to the invention, an apparatus for preparing drugs is provided, more in particular for the automated preparation (or compounding) of injectable pharmaceutical solutions in a safe and controlled environment, comprising a casing or frame comprising two zones adjacent to each other and defined by a warehouse zone or area and a set-up zone or area which are separate from each other and communicating, the warehouse zone or area defining an area assigned for the loading and storage, via a warehouse, of the materials required for pharmaceutical preparations of the drug and diluent type and the set-up zone or area defining an area in which the preparation of the drug is carried out with the materials picked up from the warehouse zone or area by means of a first robotic manipulator and a second robotic manipulator simultaneously cooperating with each other and with functional devices for the pharmaceutical preparation, carrying out mutually different actions to perform set-up and preparation operations in "masked time".

[0042] The constructive and functional features of the apparatus and method for preparing drugs of the present invention can be better understood from the following detailed description in which reference is made to the accompanying drawings which illustrate an embodiment thereof given only by way of explanation and in which:

figure 1 diagrammatically shows an axonometric view of the apparatus for preparing drugs of the invention;

figure 2 diagrammatically shows a front view of the apparatus for preparing drugs of the invention;

figure 3 diagrammatically shows a partially sectioned top view of the apparatus of the invention;

figure 4 diagrammatically shows a front view, partially sectioned according to a vertical plane, of the apparatus for preparing drugs of the invention;

figure 5 diagrammatically shows a front view, partially sectioned according to a further vertical plane, of the apparatus for preparing drugs of the invention;

figures 6 and 7 diagrammatically show axonometric views of two components of the apparatus of the invention and, in particular, of two dosing devices;

figure 8 diagrammatically shows an axonometric view of a drug/diluent type product component warehouse of the apparatus of the invention;

figure 9 diagrammatically shows an axonometric view of a component adapted to form a syringe warehouse of the apparatus of the invention.

[0043] The apparatus for preparing drugs of the invention, indicated overall with 10 in the aforementioned figures, comprises a casing or frame 12 resting on the ground by means of a support base 14 provided with wheels 16 (or equivalent movement means) adapted to allow movements of said casing or frame 12.

[0044] The casing or frame 12 comprises two mutually adjacent zones (as better detailed below) and defined by a warehouse zone or area 18 and a set-up zone or area 20 which are separated from each other by a wall 22 and which are communicating by means of an opening 24 formed in said wall 22.

[0045] The warehouse zone or area 18 forms the area assigned for the loading and storage of the materials necessary for the preparations, while the set-up zone or area forms the area in which the drug preparation is carried out with the materials picked up from the warehouse zone or area.

[0046] The warehouse zone or area 18 is closed by means of a hatch 18' and the set-up zone or area 20 is closed by means of a further hatch 20', with said hatch 18' and further hatch 20' openable/closable automatically by means of actuators 21.

[0047] The warehouse zone or area 18 comprises a front part 18" provided with a work surface 17 for an operator who carries out product loading and unloading actions and a rear part 18"' comprising a warehouse 26 consisting of a rotating structure (or revolver) better described below.

[0048] Furthermore, the front part 18" is separated from the external environment by means of a glass panel (not depicted in the drawings) which only leaves free a sufficient space for the operator operating at said warehouse zone or area 18 to introduce his/her hands; such a glass panel can be sliding in an automated manner by means of guides stabilized at the hatch 18'.

[0049] The front part 18", in which the work surface 17 is present, is hit by a vertical laminar air flow under which

the operator carries out the material loading and unloading procedures

The vertical laminar air flow is also present in the rear part 18"' and is different with respect to the one characterizing the front part with reference to speed; by way of example, the laminar air flow in said rear part can have a speed of 0.4 m/s (meters per second), while the laminar air flow in the front part 18" can have a speed of 0.25 m/s (meters per second).

[0050] Furthermore, the air is partly expelled and partly recirculated, with the intrinsic filtration system of the apparatus which ensures the possibility of not channeling said air, but of expelling it into the environment.

[0051] Always by way of explanation, the internal air can be 70% recirculated while 30% is expelled by means of an exhausted air filter; the expelled volume is supplemented by a continuous supply of 30% air from the front opening of the glass with the air which is circulated by means of motor fans (not depicted) and which is continuously decontaminated by passing through H14 HEPA (High Efficiency Particulate Air) filters.

[0052] At said warehouse zone or area 18 and externally thereto, a monitor 28 is stabilized defining a human-machine interface for operator use.

[0053] The front part 18" and the rear part 18"' of the warehouse zone or area are separated from each other by a hinged openable door consisting of an intermediate openable door 19 between two perforated panels 19'; the openable door 19 is transparent and openable in an automated sliding manner, while the panels are perforated to allow a passage of air and are integral with the hinged openable door.

[0054] Said front part 18", as described above and with reference to the preferred embodiment referred to in the figures, comprises a work surface 17 for loading and unloading actions carried out by an operator and, on the left inner wall, comprises three pairs of hooks (not depicted) placed at different heights and functional to allow the operator to organize the materials necessary for the preparations, while on the right inner wall there is a door which allows the extraction of a trolley 25 carrying completed preparations in bottle or bag format as better described below (the trolley 25 is a removable type trolley on which a manipulator (described below) deposits bottles containing the ready-made preparation and which is extracted by the operator for picking up the finished products).

[0055] In the front part 18" there is a code reader 23 (barcode or QR code or similar) for a recognition of the diluent bottles by means of the special label with which they are provided.

[0056] The warehouse 26 is housed in the same rear part 18"', consisting of a rotating structure (or revolver) which is formed by one or more discs on top of and parallel to each other and stabilized with respect to a central rotating shaft 26A arranged vertically, with said discs being provided with inserts for loading the materials required to prepare the drugs and, more in particular, functional for housing drugs and diluents; the number of discs in the warehouse 26 is a function of the specific production needs.

[0057] By way of explanation and with non-limiting reference to the embodiment of the figures (figure 8), the warehouse 26 (or revolver) can comprise a first disc 26B stabilized at an upper end of the shaft 26A, a second disc 26C arranged below the first disc 26B, a third disc 26D arranged below the second disc 26C, a fourth disc 26E arranged below the third disc 26D, a fifth disc 26F arranged below the fourth disc 26E, with said discs arranged parallel to each other and at different distances along the longitudinal extension of the shaft 26A.

[0058] The described discs of the warehouse 26 comprise inserts or pockets, formed on the outer circumferential extension of each disc and functional for the housing of bottles/bags or drugs; for example and with reference to the preferred embodiment, the second disc 26C and the fifth disc 26F comprise inserts 26G for housing diluents, the third disc 26D and the fourth disc 26E comprise inserts 26H for housing drugs and the first disc 26B comprises inserts or pockets 26L for housing reusable-type drugs, as better described below (said first disc, as better described below is used only by a manipulator described below).

[0059] The set-up zone or area 20 likewise comprises a front part 20" and a rear part 20"' which are separated from each other by openable doors 27 of the hinge type; the front part 20" defines a work zone for the operator, while the rear part 20"' forms a work zone for anthropomorphic-type manipulators (defined by a first manipulator 30 and by a second manipulator 31); said front part 20" and rear part 20"', like the front part 18" and rear part 18"' of the warehouse zone or area 18, are hit by a vertical laminar air flow, with said air flow being different for the two front and rear parts.

[0060] The front part 20", as previously described for the front part 18" of the warehouse zone or area 18, is separated from the external environment by means of a glass panel (not depicted in the figures) which only leaves sufficient space for the operator operating at said set-up zone or area 20 to introduce his/her hands; said glass panel can be sliding in an automated manner by means of guides stabilized at the hatch 20'.

[0061] Outside the set-up zone or area 20, at a right-side wall, there is an unloading device for used or exhausted materials defined by a cylindrical duct 34 to which a bag (not depicted) for the collection of hazardous waste and a sanitizing device 35 of known type are fastened.

[0062] The front part 20" comprises a work surface 32 for handling syringes and syringe preparations, a syringe warehouse 33 (stabilized at the openable door 27) which consists of an IN syringe warehouse 33' (input syringes) and an OUT syringe warehouse 33" (output syringes) as better described below.

[0063] The IN-syringe warehouse 33' comprises a plurality of guides 51 (in the preferred embodiment re-

ferred to in the figures (figure 9), there are nine such guides, of which two dedicated to 60 ml (milliliter) syringes, one for 30 ml syringe, two are dedicated to 20 ml syringes, a further two are dedicated to 10 ml syringes, one guide is functional to 3 ml syringes and, finally, one is functional to 1 ml syringes) preferably inclined downwards in the direction of the rear part 20"' to allow a feed (slide) in the rear part for the use of the manipulators as better described below. The OUT syringe warehouse 33' comprises guides 52 for the storage of syringes filled with the preparation and, therefore, with the finished product; such guides are preferably inclined downwards from the rear part 20"' to the front part 20".

[0064] The rear part 20"' defines the drug set-up/preparation area in which the two manipulators (first manipulator 30 and second manipulator 31) are arranged parallel to each other and in which the functional devices for a cooperation with said manipulators are present.

[0065] More in particular, the functional devices for a cooperation with the aforementioned manipulators comprise a first scale 36 arranged at the partition wall 22 between the warehouse zone or area 18 and the set-up zone or area 20, a second scale 38 arranged at a right wall of said set-up zone or area opposite to the partition wall 22, a diluent rack 40 arranged at the first scale 36 (it is a stand-by station for a diluent in any format consisting of a "U" hook where the first manipulator 30 rests the diluent between one processing step and the next as better described below), a bottle-drug turntable 42 (defines a rotating support on which the first manipulator rests the drug bottle for scanning the drug label thereof, with the rotation allowing a visual acquisition means to scan the entire label), a first dosing device 44 arranged between the first manipulator 30 and the second manipulator 31, a second dosing device 46, a first rack 48 stabilized at the openable door 27 on the internal front facing said rear part 20"' (said first rack 48 defines a stand-by station consisting, preferably but not exclusively, of four drug bottle coupling sites, one per syringe which is used as an exchange area between the two manipulators), a second rack 50 arranged at the second scale 38 (such a second rack 50 defines a stand-by station consisting, preferably, of four coupling sites for drug bottles and one for syringes and defines a station with which the second manipulator 31 cooperates which, as better described below, positions the drug or syringe there between one step and the next of the preparation when there is another product in processing), a first visual acquisition means (or first camera) 52 arranged frontally (or in any case in the working area of the first manipulator 30), a syringe-turntable 53 arranged at a right side wall of said set-up zone or area 20 opposite to the partition wall 22 (it defines a rotating support on which the second manipulator 31 rests the syringe for scanning the barcode, so that the rotation of said syringe allows a second visual acquisition means to scan the entire label), a second visual acquisition means (or second camera) 54 arranged at the syringe-turntable 53, a spike 56 arranged at the vial-drug turntable 42 and therebelow), the dispensing device has the function of removing diluent if the volume of drug to be inserted is such to require a previous emptying of the bottle of the same volume of diluent (for precise concentrations, the dispensing device not only removes the volume of drug, but also the amount of overfilled diluent; if necessary it always removes both the volume of drug and the overfilled amount and this allows to always obtain precise concentrations).

[0066] With reference to the preferred embodiment in the figures, but not exclusively, the dispensing device can consist of a group comprising three nozzles and three peristaltic pumps for the removal of diluent (in particular, a nozzle is included for each treated diluent to avoid cross-contamination (saline, glucose solution and water)); the features of the dispensing device can vary according to specific production needs.

[0067] The first scale 36 forms a high precision gravimetric control group for weighing diluents, while the second scale 38 forms a high precision gravimetric control group for weighing drug bottles and syringes.

[0068] The first dosing device 44 is shown in greater detail in figure 6 and defines a functional device for infusing (infusion dosing) the drug contained in the pre-filled syringe of the second dosing device 46 (described below) into the diluent or drug bottle (in the event of a preparation method including the reconstitution of powdered drugs).

[0069] More specifically, the first dosing device 44 comprises a base body 58 stabilized at an internal bottom wall of the rear part 20"' of the set-up area or zone 20 and defining a support body for functional means to empty a vertically arranged syringe and comprising an engagement assembly 60 for a syringe 59 (shown in dashed line in figure 6), a screwing assembly 61 arranged at the bottom with respect to the engagement assembly 60 and functional to rotate the syringe stabilized at the engagement assembly, a housing assembly 62 for diluents/drugs arranged below the screwing assembly 61 and a pusher assembly 64 arranged above the engagement assembly 60 movable vertically downward and upward (as indicated by the arrow "Y" in figure 6) in the direction of the syringe stabilized to the engagement assembly 60, with said assemblies being arranged along a same vertical line.

[0070] The second dosing device 46, diagrammed in greater detail in figure 7, forms a functional device to a withdrawal, by means of a syringe, of a drug from a mother bottle containing it (extraction dosing device).

[0071] Said second dosing device 46 comprises a base body 64 stabilized at an internal bottom wall of the rear part 20"' of the set-up area or zone 20 to which the functional means to carry out the aforementioned extraction operation are stabilized and which comprise a drug bottle housing assembly 66, a syringe engagement assembly 68 for a syringe 59 (shown in dashed line in figure 7), a screwing assembly 69 adapted to rotate a syringe to be filled with the contents of a drug bottle

arranged in-between the drug bottle housing assembly 66 and the syringe engagement assembly 68 and a pusher assembly 70 comprising a pusher 70' vertically movable upwards/downwards (as indicated by the arrow "Y" in figure 7) and a pusher engagement site 70" movable according to a horizontal direction (as indicated by the arrow "X" in figure 7) and provided with an engagement element for the syringe (specifically for the plunger of the syringe) and with said pusher engagement site 70" coupled to the pusher 70', said pusher assembly 70 arranged below the syringe engagement assembly 68; the described assemblies of the second dosing device are all arranged along the same vertical axis.

[0072] The transfer of the drug between the mother bottle and the syringe and between the syringe and the diluent/reconstituted bottle (which occurs in the first dosing assembly and in the second dosing assembly) is actuated by means of a closed coupling system by screwing between a "spike" connector affixed to the drug/diluent bottle and a "luer-lock" connector affixed to the syringe (such connectors, being known, are not described and are not depicted in the figures) and the passage of the drug from the mother bottle to the syringe and from the syringe to the diluent is subject to a screwing between the "spike" connector and the "luer-lock" connector.

[0073] The operation of the two described dosing devices is described in detail below.

[0074] As described above, the extraction dosing device or second dosing device 46 has the function of preparing a withdrawal, by means of a syringe, of a drug from a mother bottle containing it and the operation thereof comprises the steps of:

- coupling a syringe to the syringe engagement assembly 68 by means of the second manipulator 31;
- locking the luer-lock connector of the syringe on the screwing assembly 69;

positioning a drug bottle on the drug bottle housing assembly 66;

- vertically sliding the drug bottle housing assembly 66 downwards to bring the spike connector into contact with the luer-lock connector of the syringe;
- operating the screwing assembly 69 to screw the luer-lock connector onto the spike connector;
- operating the pusher assembly 70 with vertical upwards movement of the pusher 70' and horizontal movement of the pusher engagement site 70" so as to bring the pusher 70' close to the syringe and with the pusher engagement site 70" engaging the plunger of the syringe;
- operating the pusher 70' with vertical downwards movement to withdraw the preset drug dose from the bottle (in this step the pusher 70' carries out small upward/downward movements to remove any bubbles withdrawn from the drug bottle);
- operating the pusher engagement site 70" to release the plunger of the syringe;
- operating the pusher assembly 70 downwards;
- operating the screwing assembly 69 to unscrew the luer-lock connector from the spike connector;
- operating the drug bottle housing assembly 66 vertically upwards;
- removing the drug bottle;
- operating the screwing assembly 69 vertically upwards;
- removing the syringe from the syringe engagement assembly 68.

[0075] The infusion dosing device or first dosing device 44, as described above, has the function of infusing the liquid product withdrawn with the second dosing unit into a diluent bottle (or any other type of diluent container) or into a drug bottle with the steps of:

- positioning the diluent on the housing assembly 62 for diluents/drugs (by means of the first manipulator 30);
- positioning the syringe on the engagement assembly 60;
- raising the screwing assembly 61 in the direction of the engagement assembly 60 and locking the luer-lock connector of the syringe;
- vertically raising the housing assembly 62 for diluents/drugs to define a coupling between the spike connector of a drug/diluent 63 and the luer-lock connector of the syringe 59;
- operating the screwing assembly 61 to rotate the syringe and define a complete screwing between the luer-lock connector and the spike connector;
- operating the pusher assembly 64 vertically downwards to crush the plunger of the syringe 59 for the infusion of the contents thereof in the diluent or reconstituted drug 63;
- operating the pusher assembly 64 upwards;
- operating the screwing assembly 61 for a decoupling between syringe and diluent;
- withdrawing the final medicated container 63.

[0076] The described extraction dosing device, prior to operation, defines an automatic calibration step which can be started by the operator.

[0077] For all syringe volumes, a dosing and weighing cycle is carried out and, based on the actual weight recorded, an automatic calibration of the dosing device stroke is carried out to always ensure an optimal dosing.

[0078] Such an automatic calibration procedure allows maximizing the precision of the apparatus and makes the machine flexible and automatically adaptable in the use of any brand of syringe and this because, automatically recalibrating, it would eliminate dosing inaccuracies due to different shape, size and processing tolerances which different brands of syringes inherently possess.

[0079] As regards the method defining the working

cycle for preparing drugs by means of the apparatus of the invention, it is detailed below.

[0080] Said work cycle consists of a series of macro-operating steps defined by a preparation and loading macro-step, as set-up macro-step and an unloading macro-step.

[0081] The preparation and loading macro-step comprises automated preparation operations of the apparatus (calibration of the processing devices) and the subsequent manual preparation of the material and guided loading thereof into the apparatus for preparing drugs.

[0082] More in particular, in such a first macro-step the operator views the validated prescriptions present in the hospital computer system on a monitor, defines the priority to be assigned and starts the process, sees the products and materials required for the productions started and prepares them, prints and applies a unique internal barcode (or QR code) to each bottle, selects the drug bottles to be loaded and carries out the guided manual loading on the warehouse 26 according to the coordinates established by the system, reads the barcode (or QR code) of the diluent labels and carries out the manual loading on the warehouse 26 according to the coordinates established by the system, loads the syringe warehouse 33 taking care to apply the internal barcode (or QR code) on each syringe.

[0083] Once such a method has been completed, the operator who has viewed the list of preparations received in input from the hospital system will start production and the machine will send the manipulators the processes (or "jobs") necessary to make the required pharmaceutical preparations; such an organization and execution logic of work cycles does not require a pre-loading and loading of the products strictly linked to a specific prescription.

[0084] The set-up macro-step starts once the preparation and loading macro-step has been completed and is a fully automated step in which the manipulators described operate, mutually cooperating and with the preparation devices of which a detailed description has been given above; as better described below, the manipulators pick up diluents, drugs and syringes following an order of priority defined by the programming of the production cycle respecting, for example, the order of arrival of the prescriptions; however, there is no pre-established order in the "jobs" which the apparatus will carry out.

[0085] In more detail, the set-up macro-step takes place as described below with the two manipulators (first manipulator 30 and second manipulator 31) operating simultaneously, carrying out different actions with respect to each other (in a logic of parallelization of the production process, optimization of cycle times and production) so as to carry out the set-up and preparation operations in "masked time" with consequent advantages from a production cycle time perspective.

[0086] During the set-up macro-step, the above-described overfilling is also managed, with the possibility of weighing the initial materials and knowing the exact value of the internal volumes.

[0087] The unloading macro-step comprises the step of the operator picking up the finished product which can consist of the bottle of finished product (which the operator picks up from the trolley 25 that moves by sliding from the front part 20" of the set-up zone or area 20 to the front part 18" of the warehouse zone or area 18" and/or from the syringe filled with the drug which is picked up from the OUT syringe warehouse 33" of the syringe warehouse 33; the unloading of the finished product in this macro-step occurs separately and independently, i.e., there is the possibility of unloading multiple productions of drugs in both diluent containers and syringes.

[0088] It should be understood that, while the operator unloads the finished products, the manipulators can continue with the set-up and preparation of further drugs in accordance with the planned production cycles.

[0089] Once the step described above has been completed, a label is generated with all the information related to the prescription to be used during the validation step of the prepared drug. Such a label includes a data matrix containing all the information related to a specific patient and the prescriptions associated therewith; the association of such a data matrix to the preparation, readable by the infusion pumps used for administration in the wards, allows the preparation to be tracked from the set-up thereof to the infusion to the patient, eliminating possible administration errors which can occur in the ward with the traditional labels not provided with such a data matrix.

[0090] The following describes, by way of explanation, a drug preparation cycle in accordance with the apparatus of the invention.

[0091] In the preparation and loading macro-step, on the work surface 17 of the front part 18" of the warehouse zone or area 18, the operator manually prepares the diluent containers, the drug bottles and applies spike connectors thereto and loads everything into the warehouse 26.

[0092] The operator also prints the internal barcodes (or QR codes), applies them to the diluents already provided with an identification barcode thereof on the label, scans the barcodes of the label and loads them into the warehouse in the position dedicated thereto; with regard to the drug bottles, the operator follows the same method without the application of the internal barcode (or QR code) and without scanning the barcode of the label.

[0093] As for the syringes, the operator prints the dedicated internal barcodes (or QR codes) and applies them on the syringes, applies them to the same luer-lock connectors and loads them in the syringe warehouse 33 of the set-up zone or area 20 and in particular in the IN syringe warehouse 33'.

[0094] The steps of the drug set-up cycle, with reference to an exemplary preparation cycle, are described below.

[0095] The first manipulator 30 picks up a drug bottle from the warehouse 26, positions it on the vial-drug turntable 42 and the first visual acquisition means (or first camera) 52 detects the label of said drug, verifying

the specifications thereof (batch, expiration, correctness of the drug contained, etc.) and after reading, the first manipulator 30 picks up the above-mentioned drug from the vial-drug turntable 42 and deposits it on the first rack 48.

[0096] Simultaneously, the second manipulator 31 picks up a syringe from the IN syringe warehouse 33' of the syringe warehouse 33, weighs it on the second scale 38 for empty weight detection and then positions it on the second dosing device 46.

[0097] The second manipulator 31 picks up the drug bottle from the first rack 48 and positions it on the second scale 38 which detects the weight of the bottle which is then picked up by the second manipulator and positioned on the second dosing device 46.

[0098] Meanwhile, the first manipulator 30 picks up a diluent from the warehouse 26 and positions it for verification by the first visual acquisition means (or first camera) 52 which detects the batch, the expiration and the internal barcode (or QR code) affixed and associates the latter with a specific prescription/patient and subsequently positions it on the first scale 36 which detects the weight thereof and, if the volume contained in the diluent was different from that required for the drug preparation cycle, the first manipulator picks up said diluent and positions it on the spike 56 which removes the excess volume from said diluent container which is then picked up by the first manipulator and positioned again on the first scale 36 for a new control and, subsequently, is positioned on the first dosing device 44.

[0099] While the first manipulator 30 operates as described above, the second manipulator 31, operating as described above, positions the drug bottle on the second dosing device 46 to which the syringe is connected, which is filled with the contents of the bottle in the preset amount and, subsequently, the second manipulator 31 picks up the drug bottle and deposits it on the second scale 38 to verify the weight thereof, picks up the syringe from the second dosing device and positions it on the second scale 38 which detects the weight thereof and, subsequently, picks up the bottle from the second scale 38 and positions it on the second rack 50 and, subsequently picks up the syringe from the second scale 38 and positions it on the first dosing device 44 where the contents of the syringe are placed in the preset diluent container.

[0100] The medicated container filled with the contents of the syringe is then picked up by the first manipulator and deposited on the first scale 36 which checks the weight thereof and, subsequently, the same first manipulator 30 picks up the final product from the first scale and positions it on the trolley 25 for the finished product unloading operations as described below.

[0101] While the first manipulator 30 carries out the described operations, the second manipulator 31 picks up the empty syringe from the first dosing device and transports it to the used or depleted material unloading device defined by the cylindrical conduit 34 and, subsequently, picks up the drug bottle from the second rack 50 and transports it to the used or depleted material unloading device or to the first rack 48 depending on whether said bottle is empty or still contains drug and, in this case, the non-empty bottle is then picked up by the first manipulator 30 and deposited in the warehouse 26.

[0102] The operator will then pick up the finished product from the trolley 25 and finalize the product preparation by removing the spike element and affixing a possible tail, reading the internal barcode (or QR code) affixed and displaying the information related to the specific preparation carried out, printing and affixing a label (containing hospital information related to the patient and the prescription both in written form and as a QR code) and will carry out a new simultaneous scan of the two labels for a verification of correctness and matching of the information related to the product with consequent validation of the production.

[0103] The unloading of the finished product in this macro-step takes place separately and independently, i.e., there is the possibility of unloading multiple drug productions of the type unloading drugs in diluent containers and unloading syringes.

[0104] The apparatus of the invention, for which a production cycle has been described by way of example and referred to the preparation of drugs diluted in a bottle, is also used for the preparation of drugs in a syringe which has all the procedural steps described above and differs in that the internal barcode (or QR code) is applied to the syringe and is read by the second visual acquisition means (or second camera) 54 and the syringe, once filled with the drug, is deposited by the second manipulator 31 in the OUT syringe warehouse 33' of the syringe warehouse 33.

[0105] As can be seen from the foregoing, the advantages achieved by the apparatus and method for preparing drugs of the invention are evident.

[0106] The apparatus for preparing drugs of the invention and the related method advantageously allows the automated preparation of chemotherapy drugs and, in general, of any injectable drug in a safe and controlled environment.

[0107] A further advantage of the apparatus of the invention is represented by the fact that the automation characterizing it and the simultaneity in executing the operations allows the production of even several different preparations within the same production cycle and this is also linked to the presence of two manipulators working simultaneously and in "masked time" and which are managed in accordance with a "job" logic.

[0108] A further advantage of the apparatus of the invention is represented by the fact that the dosing (dispensing and infusion) devices do not use needles and, therefore, no problems arise related to product nebulization and dispersion, and, at the same time, there is no dripping or the like of the substances.

[0109] A further advantage is that the apparatus of the invention is highly flexible as regards handling the consumables used for the preparations with particular re-

ference to the formats of drug bottles and syringes.

[0110] A further advantage is that the apparatus of the invention allows managing the overfilling of the drug components and diluents.

[0111] Another advantage is that it allows, by virtue of the manipulators working simultaneously and in "masked time", managing the warehouse and other elements/-components, a reduction in downtime and, consequently, a high productivity (in particular an hourly productivity).

[0112] A further advantage of the apparatus of the invention is that it is highly flexible and easily installable without problems of footprint and lay-out, is easily movable within the dedicated spaces and, moreover, is improved and optimized with reference to aspects related to ergonomics. A further advantage of the apparatus of the invention is a high operating autonomy (by virtue of the high automation, the possibility of being able to carry out different preparations within the same cycle without the need for machine stops, etc.) and by a remote control (by virtue also of the presence of colored LED warning lights which make it possible to distinguish between the warehouse zone or area and the set-up zone or area - for example, white light indicating regular operation, orange light if warning an alert state that does not affect the normal working cycle of the apparatus (as in the case of the outgoing bottle warehouse defined by the sliding trolley 25 which, if full or almost full, requires intervention by the operator to provide the emptying thereof), red light if an alarm is in progress (the lights are integrated in the two warehouse and set-up zones or areas).

[0113] Further advantageous is the fact that the apparatus of the invention comprises an internal work architecture with an order of actions not defined a priori and this allows an optimization of the process ("job" type process logic). Further advantageous is the fact that the apparatus of the invention comprises a diluent warehouse and a syringe warehouse which are mutually separated (the diluent warehouse located in the warehouse zone or area and the syringe warehouse in the set-up zone or area) and this allows simultaneous processing and the production of several different preparations within the same production cycle as well as optimizing spaces to increase capacity and ensure operating autonomy.

[0114] A further advantage of the apparatus of the invention is the separation of the loading and unloading areas which allows unloading several preparations simultaneously (bottles and syringes) without the need to interrupt the normal operations of the apparatus.

[0115] A further advantage of the apparatus of the invention is that it allows handling even small format drug bottles.

[0116] A further advantage of the apparatus of the invention is that the apparatus of the invention is ergonomic with reference to the structuring of the warehouse zone or area and the set-up zone, allowing the operator to be able to work seated.

[0117] A further advantage of the apparatus of the invention is the spacious warehouse of the warehouse zone or area and the separation between the environments (between the warehouse zone or area and the set-up zone or area and between the front parts and the rear part of each of such zones) which allow optimizing the work cycle management.

[0118] A further advantage is that the apparatus of the invention, by virtue of the configuration described above and the work cycle organization and execution logic ("job" logic) allows the pre-loading and association of materials for drug preparation for the patient not a priori, but in-machine.

[0119] A further advantage deriving from the advantages listed above is fact that the apparatus of the invention is highly flexible, with easy mobility in the installation spaces by virtue of the presence of wheels and easy installation, making it unnecessary, for example, to modify the environments of the structures and the installation rooms of the apparatus (the modularity of the apparatus allows it to pass through standard-sized doors without the need for disassembly or variation thereof).

[0120] A further advantage of the apparatus of the invention is that it does not need to be installed in a sterile and aseptic chamber of the clean room type and the like (by virtue of the structure and features of the warehouse and set-up areas described above) and does not need to equip spaces suitable for the purpose and, moreover, does not need to channel the air flows expelled from the machine and, therefore, is not subject to structural constraints which, differently, characterize the known apparatuses.

[0121] A further advantage is that the apparatus of the invention has smaller dimensions with respect to the traditional apparatuses for preparing drugs and this is also a consequence of the absence of problems related to the formation of condensation caused by machine overheating which, for the traditional apparatuses, requires the presence of a management system thereof which requires positioning the apparatus at a certain distance from the walls of the installation room and which also requires the presence of water collection tanks with a consequent and further impact on the footprint of the structure and with the need for an operator to empty them.

[0122] Although the invention was described above with particular reference to an embodiment thereof, given by way of non-limiting example, several modifications and variations will be apparent to those skilled in the art in light of the above description. Therefore, the present invention aims to encompass all modifications and variants falling within the scope of the following claims.

Claims

1. An apparatus (10) for preparing drugs, more in particular for the automated preparation (or compounding) of injectable pharmaceutical solutions in a safe and controlled environment, **characterized in that** it

comprises a casing or frame (12) comprising two zones adjacent to each other and defined by a warehouse zone or area (18) and a set-up zone or area (20) which are separate from and communicating with each other, the warehouse zone or area (18) defining an area assigned for the loading and storage of materials necessary for the pharmaceutical preparations and the set-up zone or area (20) defining an area in which the drug preparation is carried out with the materials picked from the warehouse zone or area by means of a first robotic manipulator (30) and a second robotic manipulator (31) cooperating with each other and with devices functional to pharmaceutical preparation simultaneously carrying out different actions with respect to each other to perform set-up and preparation operations in "masked time", i.e., carried out in parallel with each other, the warehouse zone or area (18) comprises a front part (18") and a rear part (18"') separated from each other by an openable door with the front part (18") separated from the external environment by means of a glass panel which only leaves free a space for the introduction of an operator's hand, said front part (18") and rear part (18"') being hit by a different vertical laminar air flow between the two said parts, the set-up zone or area (20) comprising a front part (20") and a rear part (20"') separated from each other by an openable door (27) with the front part (20") separated from the external environment by means of a glass panel which only leaves free a space for the introduction of the operator's hands, said front part (20") and rear part (20"') being hit by a different vertical laminar air flow between the two said parts.

2. An apparatus according to claim 1, **characterized in that** in the warehouse zone or area (18) the front part (18") is provided with a work surface (17) for an operator and the rear part (18"') comprises a warehouse (26), the front part (20") and the rear part (20"') of the set-up zone or area (20), the front part (20") defining a work zone for the operator and the rear part (20"') defining a work zone for the first manipulator (30) and the second manipulator (31) and for the devices functional for preparation.

3. An apparatus according to the preceding claims, **characterized in that** the warehouse (26) arranged in the rear part (18"') of the warehouse zone or area (18) comprises a rotating structure (or revolver) consisting of one or more discs on top of and parallel to each other and stabilized with respect to a central rotating shaft (26A) arranged vertically, said one or more discs provided with inserts for loading the materials required to prepare the drugs.

4. An apparatus according to the preceding claims, **characterized in that** the front part (20") of the set-up zone or area (20) comprises a syringe warehouse (33) comprising an input syringe warehouse or IN syringe warehouse (33') and an output syringe warehouse or OUT syringe warehouse (33"), the IN syringe warehouse (33') comprising a plurality of inclined guides (51) for housing empty syringes to be filled and the OUT syringe warehouse (33') comprising inclined guides (52) for storing syringes filled with a drug preparation or finished product.

5. An apparatus according to the preceding claims, **characterized in that** the rear part (20"') of the set-up zone or area (20) comprises a first manipulator (30) and a second manipulator (31) and functional devices for a cooperation with said manipulators and comprising a first scale (36) arranged at a partition wall (22) between the warehouse zone or area (18) and the set-up zone or area (20), a second scale (38) arranged at a right wall of said set-up zone or area (20) opposite to the partition wall (22), a diluent rack (40) arranged at the first scale (36), a vial-drug turntable (42), a first dosing device (44) arranged between the first manipulator (30) and the second manipulator (31), a second dosing device (46), a first rack (48) stabilized at an openable door (27) on an internal front facing the direction of said rear part (20"'), a second rack (50) arranged at the second scale (38), a first visual acquisition means (or first camera) (52) arranged in the work area of the first manipulator (30), a syringe-turntable (53) arranged at a right wall of said set-up zone or area (20) opposite to the partition wall (22), a second visual acquisition means (or second camera) (54) arranged at the syringe-turntable (53), a dispensing system (56) arranged at the vial-turntable (42).

6. An apparatus according to claim 5, **characterized in that** the first dosing device (44) defines a dosing device for the infusion of a drug by means of a closed coupling system and comprises a base body (58) stabilized at an internal bottom wall of the rear part (20"') of the set-up area or zone (20) and forms a support body for means functional to fill a syringe (59), vertically arranged and comprising an engagement assembly (60) for a syringe (59), a screwing assembly (61) arranged at the bottom with respect to the engagement assembly (60) and functional to rotate the syringe stabilized at the engagement assembly (60) to allow coupling a commercial "luer-lock" connector thereof to a diluent/drug "spike" connector, a housing assembly (62) for diluents/drugs arranged below the screwing assembly (61) and a pusher assembly (64) arranged above the engagement assembly (60) vertically movable downwards and upwards with respect to the engagement assembly (60).

7. An apparatus according to claim 5, **characterized in**

that the second dosing device (46) defines an extraction dosing device by means of a closed coupling system comprising a base body (64) stabilized at an internal bottom wall of the rear part (20"') of the set-up area or zone (20) to which the functional means to carry out the extraction operation are stabilized, which comprise a drug bottle housing assembly (66), a syringe engagement assembly (68) for a syringe (59), a screwing assembly (69) adapted to rotate a syringe to allow coupling a commercial "luer-lock" connector thereof to a "spike" connector of the drug bottle to be filled with the contents of a drug bottle arranged in-between the drug bottle housing assembly (66) and the syringe engagement assembly (68) and a pusher assembly (70) comprising a pusher (70) vertically movable upwards/downwards and a pusher engagement site (70") movable according to a horizontal direction and provided with an engagement element for the syringe and with said pusher engagement site (70") coupled to the pusher (70'), said pusher assembly (70') arranged below the syringe engagement assembly (68).

8. A method for preparing drugs by means of the apparatus according to the preceding claims, **characterized in that** it comprises operating macro-steps comprising a preparation and loading macro-step, a set-up macro-step, and an unloading macro-step, said macro-steps being able to be carried out simultaneously.

9. A method according to claim 8, **characterized in that** the preparation and loading macro-step comprises operations for preparation of the apparatus with automated calibration of the processing devices, manual set-up of the material and guided loading thereof into the apparatus for preparing drugs, with an operator on the work surface (17) of the front part (18") of the warehouse zone or area (18) who prepares the diluent containers, the drug bottles, and applies commercial spike connectors thereto, and loads everything into the warehouse (26), and who prepares the syringes, loads them into the IN syringe warehouse (33') of the syringe warehouse (33) of the set-up zone or area (20).

10. A method according to claim 8, **characterized in that** the preparation of the material and the loading thereof into the machine occur without the necessary presence of validated prescriptions and comprises the step of printing internal bar codes (or QR codes) and the application thereof to the final containers (diluents and syringes) before insertion into the machine with the association with the specific prescription of the patient, which occurs in the set-up macro-step by means of visual acquisition systems (or cameras).

11. A method according to claim 8, **characterized in that** in said set-up macro-step, since the first manipulator (30) and the second manipulator (31) cooperate with each other and with the preparation devices, and since such elements carry out different actions with respect to each other but in a simultaneous manner, the set-up and preparation operations occur in "masked time" according to a production cycle execution logic which includes the completion of several preparations in the shortest possible time.

12. A method according to claim 10, **characterized in that** the set-up macro-step comprises an optional step of removing the diluent by means of a dispensing device (56) aimed at respecting the prescribed concentrations of active ingredient-diluent, by possibly removing the overfill.

13. A method according to claim 10, **characterized in that** the set-up macro-step comprises a step of automatically calibrating the stroke of the second dosing device (46) as a function of the actual weight recorded for the syringes.

14. A method according to claim 8, **characterized in that** the unloading macro-step comprises a step of picking up the finished product by the operator, which finished product, in the case of a finished product bottle, is picked up from the trolley (25) slidingly moved from the front part (20") of the set-up zone or area (20) to the front part (18") of the warehouse zone or area (18") and/or from the drug-filled syringe which is picked up from the OUT syringe warehouse (33") of the syringe warehouse (33).

15. A method according to claim 14, **characterized in that** the unloading of the finished product in this macro-step occurs separately and independently of the set-up with the possibility to unload multiple productions of final preparations in diluent containers and syringes.

16. A method according to claim 9 or 10, **characterized in that** the macro-step of unloading the finished product comprises a step of generating a label with all the information on the prescription to be used when validating the prepared drug, said label including a data matrix containing all the information on a specific patient and the prescriptions associable therewith, which is readable by the infusion pumps.

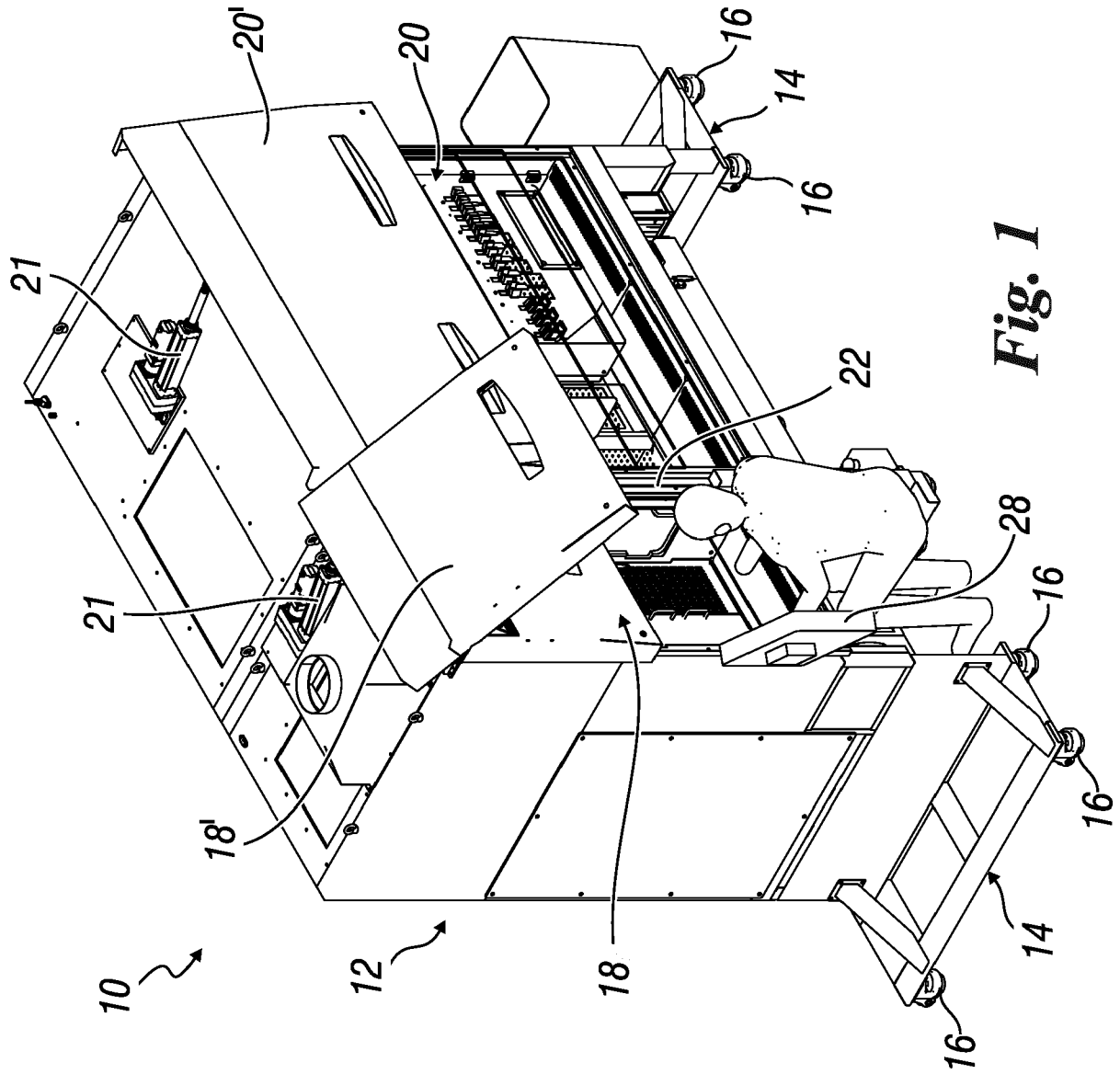

Fig. 1

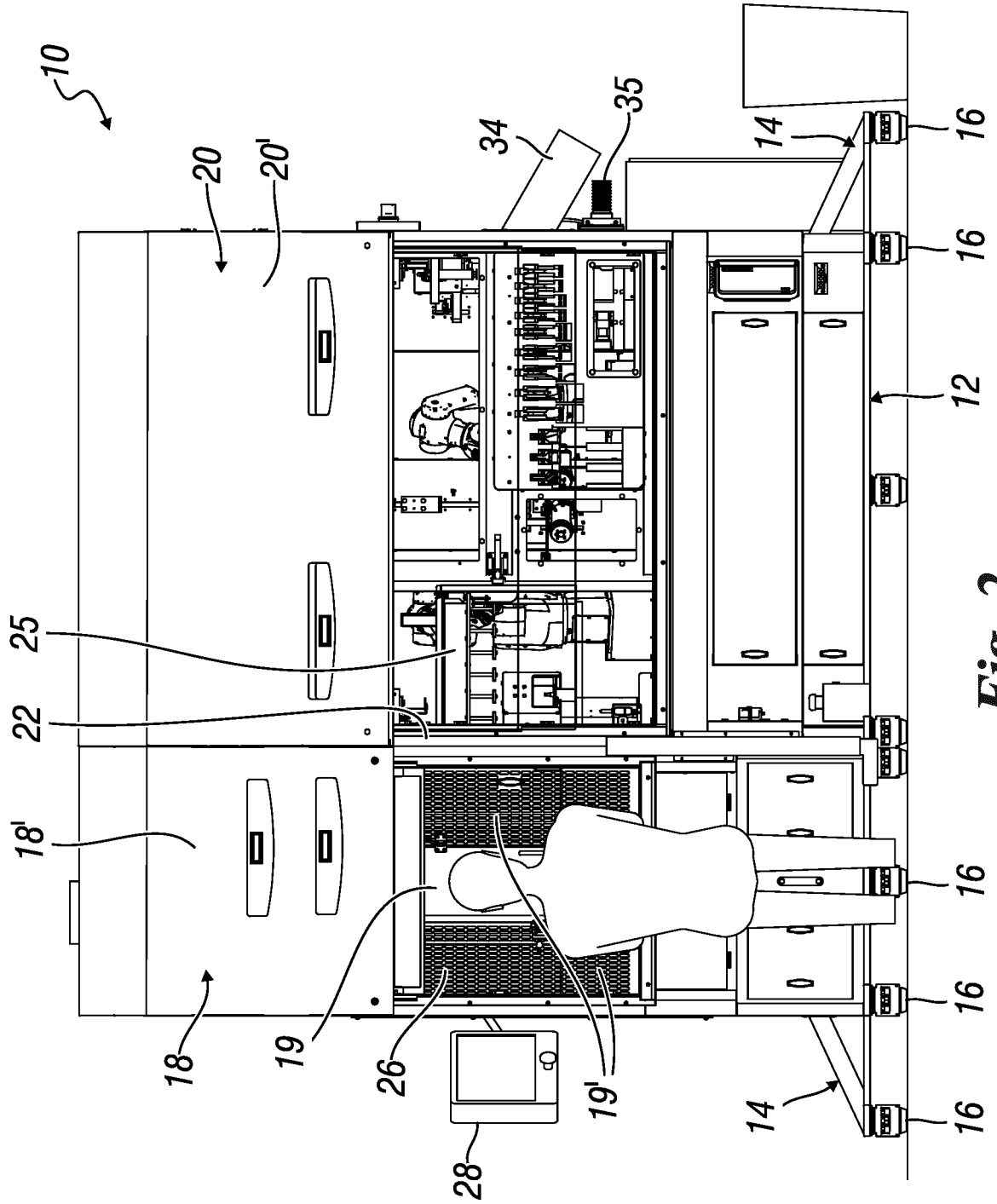

Fig. 2

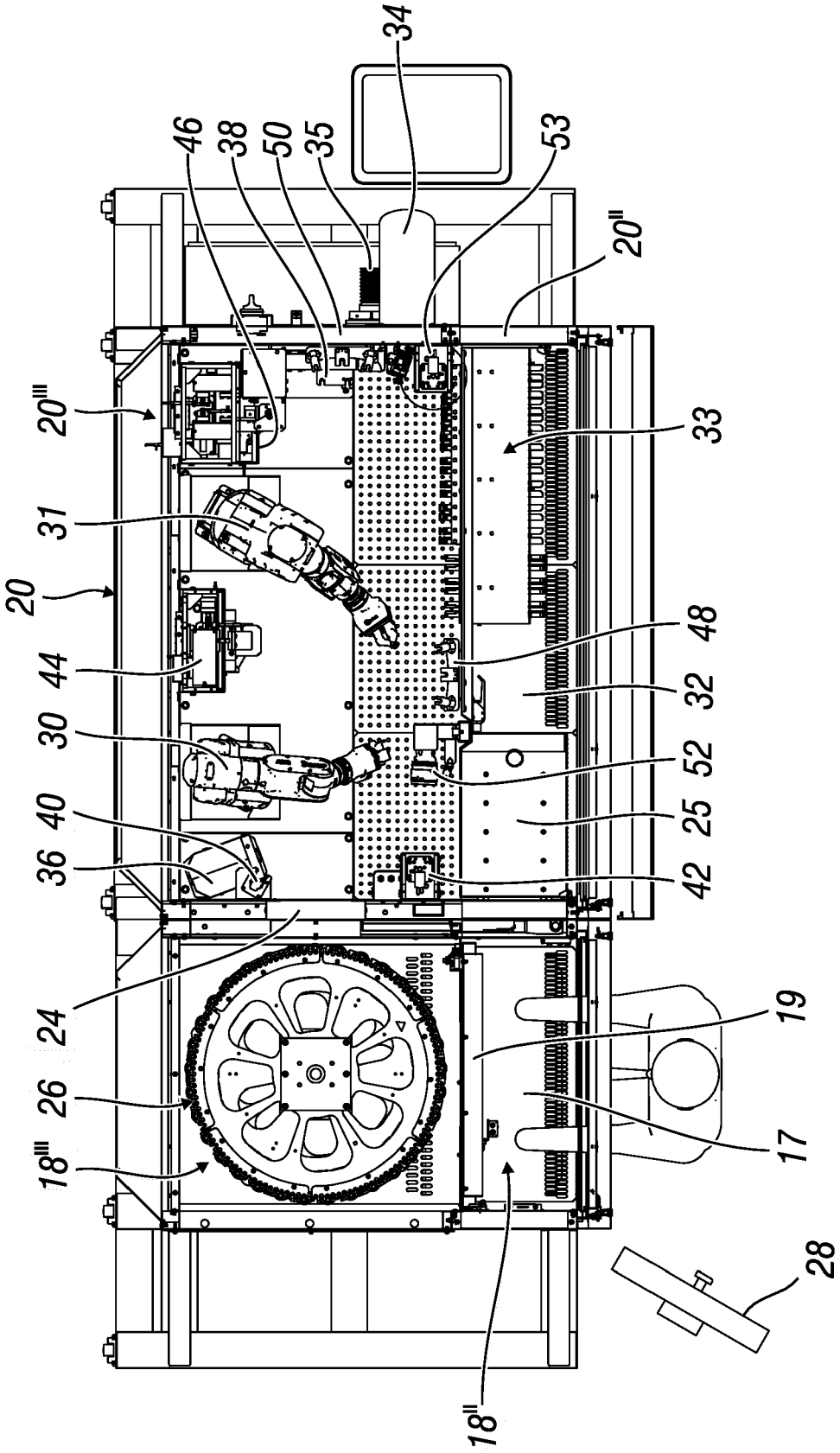
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Fig. 3

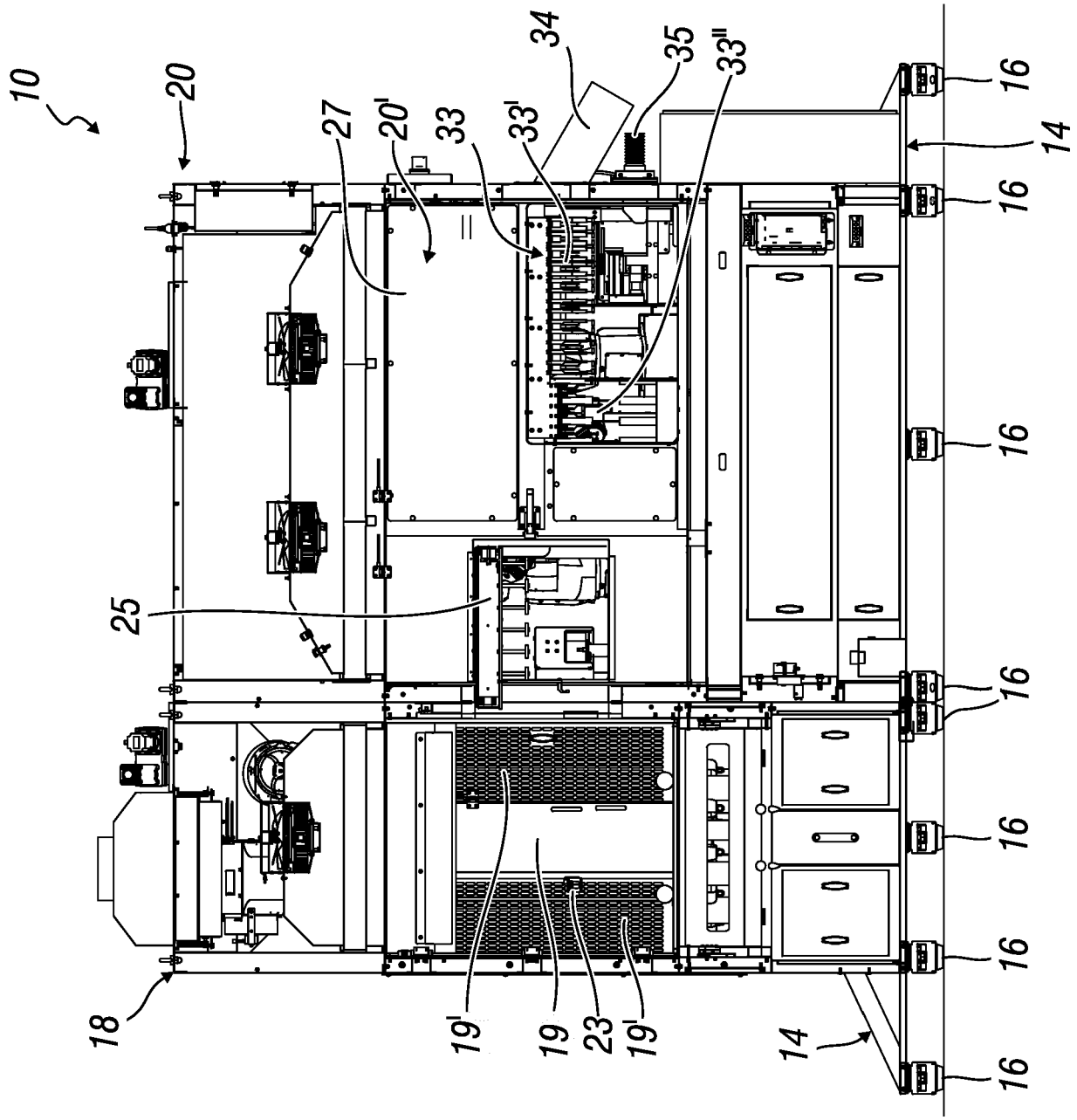

Fig. 4

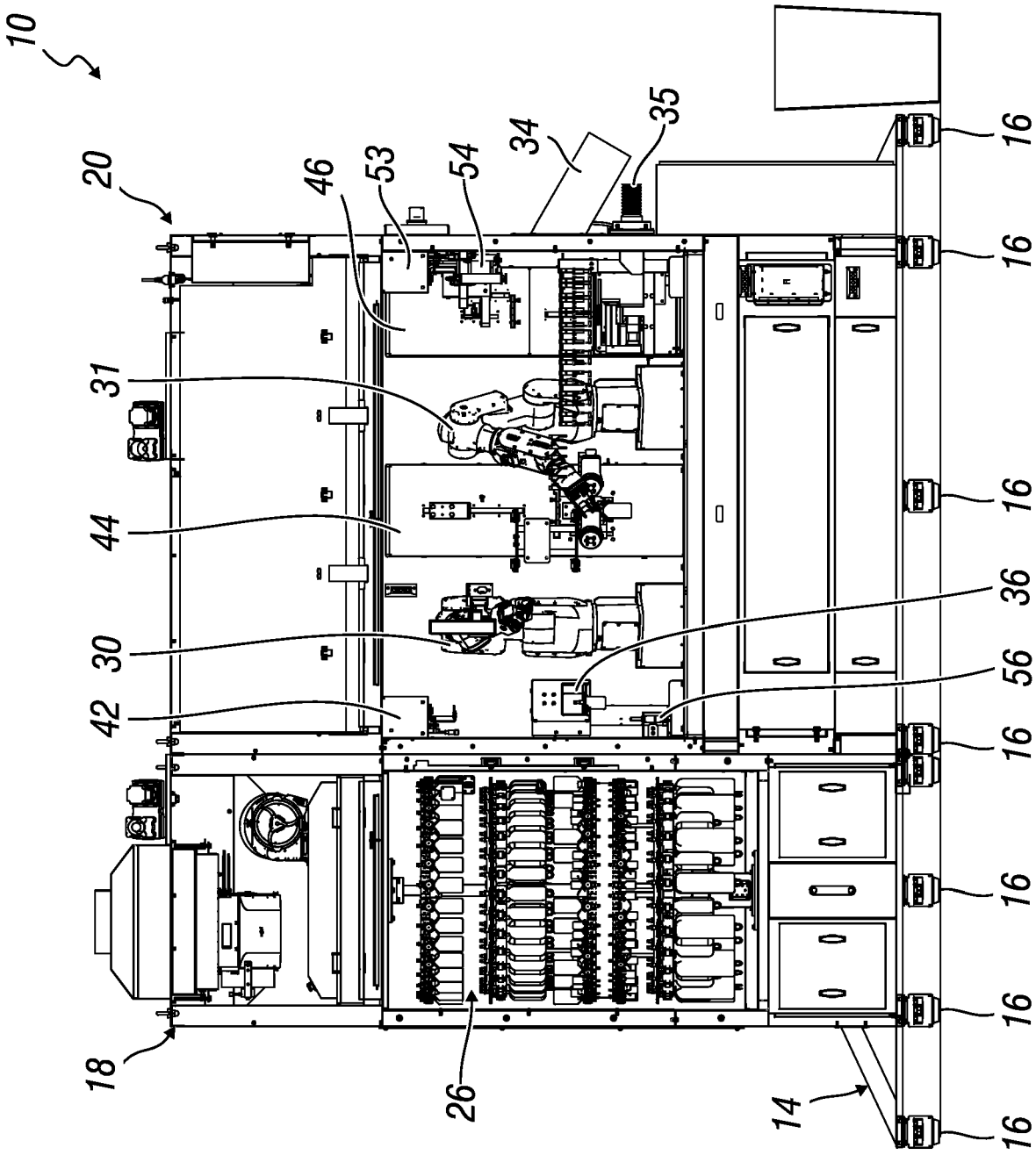

Fig. 5

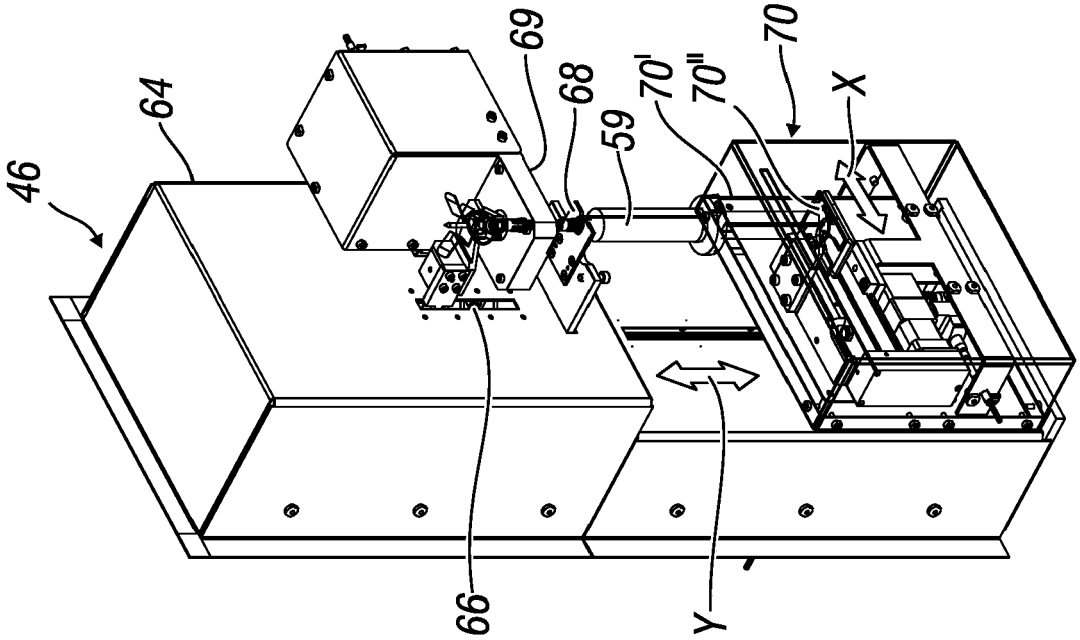

Fig. 7

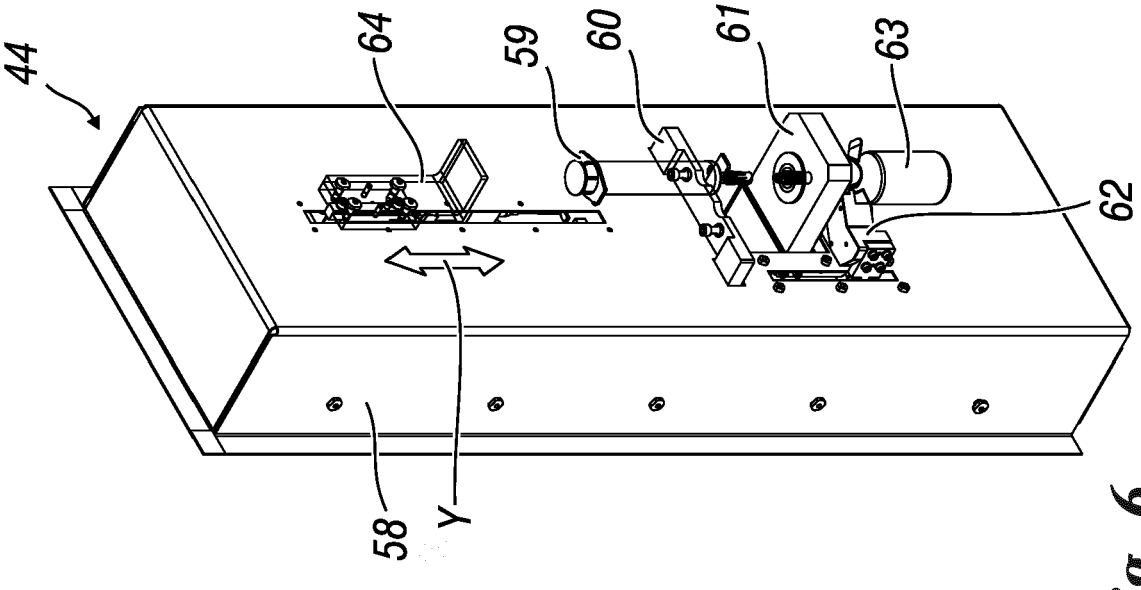

Fig. 6

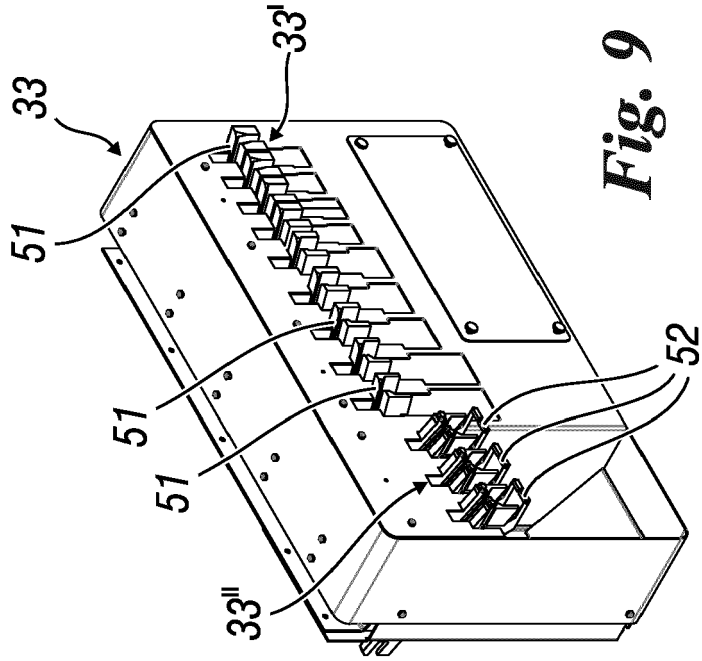

Fig. 9

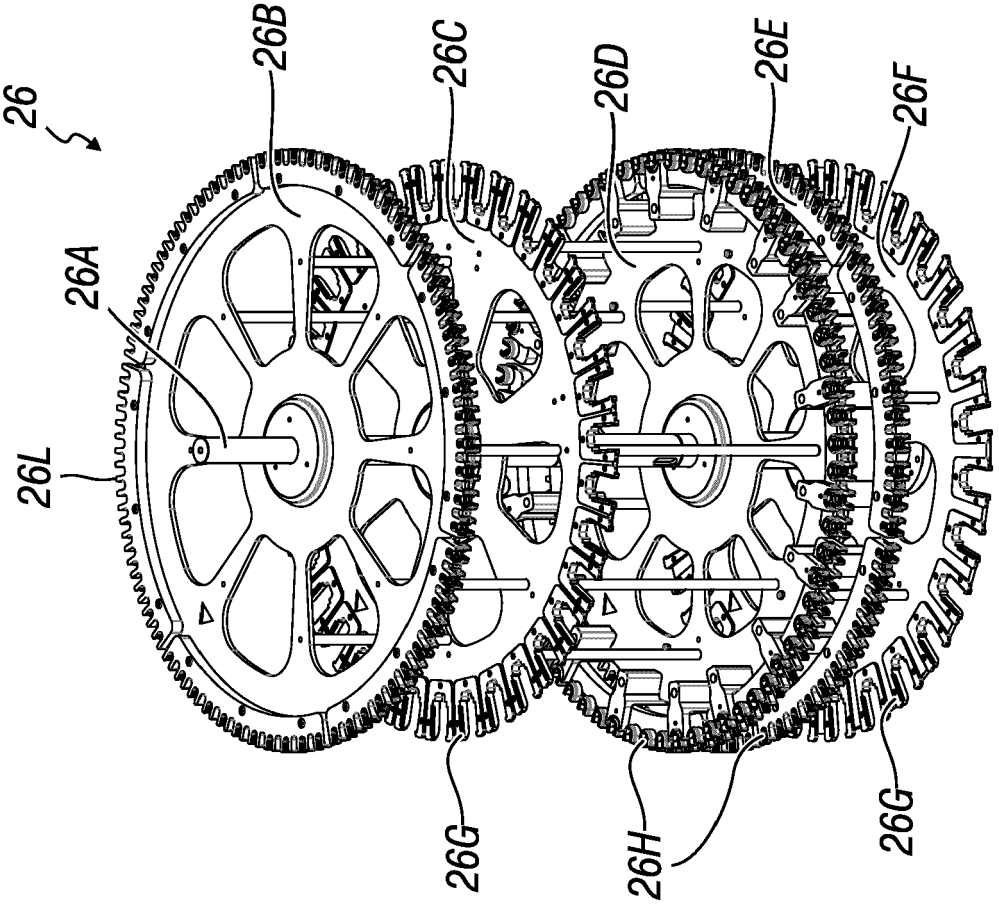

Fig. 8

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EUROPEAN SEARCH REPORT

Application Number
EP 24 19 0105

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	CA 2 725 622 A1 (PHARMED S A M [MC]) 10 December 2009 (2009-12-10) * paragraphs [0006], [0007], [0010]; figures 1-4,13,14 *	1-16	INV. A61J1/20 A61J1/22 A61J3/00 B65B3/00 G07F17/00
A	WO 2022/208099 A1 (3P INNOVATION LTD [GB]) 6 October 2022 (2022-10-06) * page 18, line 5 - page 20, line 10; figures 1-5 *	1-16	
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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	2 December 2024	Birlanga Pérez, J

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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D : document cited in the application
L : document cited for other reasons

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ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 24 19 0105

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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02-12-2024

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