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(73) Patenthaver: **Pharma Integration S.R.L., Strada Del Petriccio e Belriguardo No. 35, 53100 Siena, Italien**

(72) Opfinder: **BECHINI, Claudio, , 53100 Siena, Italien**

(74) Fuldmægtig i Danmark: **Dennemeyer & Associates S.A, P.O. Box 700425, DE-81304 Munich, Tyskland**

(54) Benævnelse: **MASKINE TIL FARMACEUTISKE ELLER BIOTEKNOLOGISKE PROCESSER, ENHED OG FREMGANGSMÅDE TIL REALISERING AF MASKINEN**

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DESCRIPTION

Description

FIELD OF THE INVENTION

[0001] The present invention concerns the technical sector relating to the handling of material in chambers having a controlled and/or classified and/or certified atmosphere for realising one or more of the required operations in the life cycle of pharmaceutical or biotechnological articles, such as, for example, handling pharmaceutical or biotechnological material, handling containers and the closing means thereof, verifying or predisposing.

DESCRIPTION OF THE PRIOR ART

[0002] In the technical sector of reference, use is known of process chambers having controlled atmosphere which are located internally of a containment structure such as, for example, an isolator or a RABS (acronym of *Restricted-Access Barrier System).*

[0003] The isolators are completely closed and sealed, thus enabling the complete isolation of the chamber. They offer a high level of protection against contamination, especially useful for particularly sensitive, dangerous and/or toxic materials. Further, they enable extensive decontamination or cleanliness processes, for example using hydrogen peroxide or other aggressive decontaminants. Isolators usually comprise a transparent wall for enabling observation of the chamber from the outside environment and the wall, or another, can comprise gloves and/or doors for enabling interventions internally of the chamber.

[0004] The isolators are typically made of steel, do not envisage entry of personnel and commonly have a volume as small as possible with respect to the needs of the process, even considering the fact that they are expensive to operate.

[0005] Usually, RABS comprise a containing wall which surrounds the apparatus but which remains open towards the white chamber. The containing wall can include gloves and/or doors to allow interaction with the work apparatus. The air treatment system can be integral with the one for the white chamber.

[0006] It is specified that, using the common terminology in the reference technical sector, in the present patent application the term "air" is not limited to a particular mixture, for example the mixtures can be equally identified as ambient air or nitrogen. However, in the description of

the invention the more generic term "fluid" will be used.

[0007] In a larger structure, such as a RABS, there is in general the possibility of accessing the chamber directly by personnel or by other machines.

[0008] Typically these processes take place internally of cleanrooms, or clean areas, which are designed, maintained and controlled so as to prevent particle contamination of the articles. By way of example, standard ISO 14644-1, as well as European good manufacturing practice, includes a classification of cleanrooms. At present, in cleanrooms, the control of the atmosphere is done by injecting filtered air, for example using HEPA filters.

[0009] Machines are known having a horizontal plane, which use suction of air on both sides of the plane or, if wall-mounted, on one side only. The air is used as an airborne transport for any contaminant substances or particles from the cleaner zones towards the recovery areas. The machines often have shady areas or turbulence areas which prevent formation of a single and substantially unidirectional flow. The horizontal plane also acts as a barrier and deposit for contaminant substances or particles. Likewise the members arranged internally of the chambers modify the flow and intercept it, reducing the effects of the flow at least locally. To obviate these drawbacks, solutions are known for the specific configuration, which, however, do not adapt well in the event of a variation of the system configuration, for example modifications in the station or of the containment structure.

[0010] The drawbacks of the machines with the horizontal plane are in part obviated by the machines illustrated in patent application EP 3939896 A1 and in patent EP 3335844 B1 which give examples of a chamber with a controlled atmosphere internally of a containment structure. Both chambers are licked by an air flow, in a top-downwards direction, which intends to limit/prevent the deposit of particles on the exposed surfaces of the process chamber. The air is generally filtered both in inlet and outlet and the flow is usually laminar, or substantially laminar, at least over a portion thereof. The deposit of particles is further limited by the arrangement of the robots on a wall, so as to avoid the use of bases. As in the most widespread use, here and in the rest of this document the term "wall" described an element that extends in a vertical direction.

[0011] However, in the machine disclosed in patent application US 4696902 A and also in the solutions discussed in EP 3939896 A1 and in patent EP 3335844 B1 there is a continuous presence of limited deposits of particles or, in any case the cleanliness of the process chamber is not fully satisfactory, especially in the light of the tendency to use substances that are more toxic and/or make the regulations more stringent.

[0012] Further, all the discussed solutions require design and realisations that are ad *hoc,* so as to be difficult to design and/or manufacture, as well as to customise in good time or at low cost.

SUMMARY OF THE INVENTION

[0013] The present invention intends to obviate one or more drawbacks of the solutions of the prior art.

[0014] A first aim of the present invention is to provide a machine that facilitates maintenance of the chamber in clean conditions required by pharmaceutical or biotechnological processes.

[0015] A second aim of the present invention is to guarantee high cleanliness conditions also in the areas which are typically more subject to deposits of contaminant substances or particles.

[0016] An aim of some embodiments is to have available a space in proximity of the process stations for housing means for supplying energy or means for supplying materials.

[0017] A further aim of some embodiments is to facilitate the integration of the ventilation means as well as the openings for the passage of materials.

[0018] A non-secondary aim of the invention is to facilitate the construction of the machine, so that it can be rapidly available and/or quickly customisable, as well as preferably being inexpensive.

[0019] These and other aims, which will be obvious to the expert in the sector from a reading of the following text, are attained by means of a machine for pharmaceutical or biotechnological processes, an assembly and a method for realising the machine according to the claims.

[0020] In accordance with the teachings of the present document, the machine comprises a structure, ventilation means and movement means.

[0021] The structure has an upper part, a lower part and, between them, walls comprising a first wall and a second wall opposite the first wall. The upper part, the lower part and the walls delimit a chamber.

[0022] The movement means for moving materials and/or instruments are configured to move the materials and/or the instruments in an operating space internally of the chamber.

[0023] The ventilation means comprise at least a fluid injection mouth internally of the chamber, superiorly of the operating space, at least a fluid extraction mouth from the chamber, inferiorly of the operating space, and at least a fluid treatment unit suitable for pharmaceutical or biotechnological processes upstream of the at least an injection mouth. The ventilation means move a fluid from the at least an injection mouth to the at least an extraction mouth.

[0024] The structure is configured so that the horizontal section of the chamber is constant, or

substantially constant, or diminishes while descending from the at least an injection mouth to the at least an extraction mouth.

[0025] Advantageously the first wall comprises a first part, a second part distanced from the first part according to a horizontal direction and an inclined part which extends between the first part and the second part, inferiorly of the second part and superiorly of the first part and which is contiguous with the first part and with the second part so as to confine the chamber.

[0026] The operating space extends, at least partly, above the inclined part and/or and/or in a volume arranged superiorly of the first part and in front of the inclined part. At least in part this means that the operating space can also embrace other areas.

[0027] The inclined part is inclined with respect to a horizontal plane so that the horizontal section of the chamber crossed by the fluid diminishes when falling towards the first part.

[0028] As illustrated in the following, the assembly comprises components that are essential for carrying out the pharmaceutical or biotechnological processes and can be coupled to remaining components so as to form the machine of the invention, as illustrated in the method.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] Specific embodiments of the invention will be described in the following part of the present description, according to what is set down in the claims and with the aid of the accompanying figures, in which:

- figure 1 is a frontal view of an embodiment of a machine for pharmaceutical or biotechnological processes according to the invention;
- figure 2 is a rear view of a figure 1;
- figures from 3 to 9 illustrate transversal sections of embodiments of a machine for pharmaceutical or biotechnological processes according to the invention which exemplify some of the possible combinations of characteristics according to the present description;
- figure 10 is an axonometric frontal view of an embodiment of an assembly according to the invention;
- figures 11 and figure 12 are axonometric rear views of an embodiment of an assembly according to the invention that is substantially similar to the embodiment of figure 10;
- figure 13 is a frontal view, with a trace line of the cutting plane of the following figure, of another embodiment of a machine for pharmaceutical or biotechnological processes according to the invention which has further chambers;
- figure 14 is a section view of figure 13.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0030] With reference to the appended figures, reference numeral 1 denotes a machine for pharmaceutical or biotechnological processes.

[0031] An embodiment of the machine (1) comprises a structure (10), movement means for moving materials and/or instruments and ventilation means (2).

[0032] The structure (10) has an upper part (11), a lower part (12) and, between them, walls (13, 14, 15, 16). The walls comprise a first wall (13) and a second wall (14) which is opposite the first wall (13).

[0033] The upper part (11), the lower part (12) and the walls (13, 14, 15, 16) delimit a chamber (100).

[0034] The movement means are configured to move the materials and/or the instruments in an operating space (100a) internally of the chamber (100).

[0035] The ventilation means (2) comprise at least a fluid injection mouth (21a, 21b) internally of the chamber (100) superiorly of the operating space (100a), at least a fluid extraction mouth (25a, 25b) of fluid from the chamber (100) inferiorly of the operating space (100a) and at least a fluid treatment unit (221) suitable for pharmaceutical or biotechnological processes upstream of the at least an injection mouth (21a, 21b).

[0036] The ventilation means (2) move a fluid from the at least an injection mouth (21a, 21b) to the at least an extraction mouth (25a, 25b).

[0037] The structure (10) is configured so that the horizontal section (A) of the chamber (100) is constant, or substantially constant, or diminishes descending from the at least an injection mouth (21a, 21) to the at least an extraction mouth (25a, 25b).

[0038] The first wall (13) advantageously comprises a first part (131), a second part (132) distanced from the first part (131) according to a horizontal direction (O) and an inclined part (133) which extends between the first part (131) and the second part (132), inferiorly of the second part (132) and superiorly of the first part (131) and which is contiguous with the first part (131) and with the second part (132) so as to confine the chamber (100).

[0039] The operating space (100a) extends, at least partly, above the inclined part (133) and/or and/or in a volume arranged superiorly of the first part (131) and in front of the inclined part (133).

[0040] The inclined part (133) is inclined with respect to a horizontal plane (H) so that the horizontal section (A) of the chamber (100) crossed by the fluid diminishes when falling

towards the first part (131).

[0041] The machine (1) of the invention avoids fluid stagnation areas descending towards the at least an extraction mouth (25a, 25b) and facilitates an acceleration of the fluid so as to prevent deposits of contaminant substances or particles and facilitate airborne transport thereof. In particular the advantages are appreciable at the inclined part (133) and around the movement means which are often the cause of obstacles, shaded areas and/or sources of emission of contaminant substances or particles from the mechanical parts of the movement means. Benefits alike to the ones obtained for the movement means are also attained with respect to any functional units (99) of the process, typically arranged on the inclined part (133) and/or brought from the first part (131), as will be discussed in more detail below.

[0042] Typically the materials and/or the instruments are moved to realise one or more pharmaceutical or biotechnological processes.

[0043] Figures 6, 7 and 8 are examples of some operating spaces (100a) and illustrate how the operating space (100a) does not necessarily correspond to the space that the movement means can reach but to the space where the materials and/or the instruments are in motion.

[0044] By way of example, the operating space (100a) represented in figure 7 comprises, with respect to the one of figure 8, a volume arranged superiorly of the first part (131) and in front of the inclined part (133); in other words arranged between the inclined part (133) and the second wall (14).

[0045] Also in figures 6, 7 and 8 it can be observed how the inclined part (133) is underlying the operating space (100a), i.e. above the inclined part (133).

[0046] The operating space (100a) preferably extends, at least partly, above the inclined part (133).

[0047] Minimal increasing variations of the horizontal section (A) of the chamber (100) may not influence the velocity of the flow and on the ability thereof to perform airborne transport, in this sense the horizontal section (A) can be substantially constant.

[0048] The first wall (13) and the second wall (14) preferably move towards one another, inferiorly of the inclined part (133) and superiorly of the at least an extraction mouth (25a, 25b).

[0049] The above-mentioned effects, connected to the increase of the flow velocity, further facilitate airborne transport of the contaminants collected superiorly and the cleanliness of the space involved, where of the movement means or parts of the functional units (99) are often located devices.

[0050] Clearly the nearing movement can be determined by the attitude of the first wall (13) and/or of the second wall (14).

[0051] The second wall (14) preferably has a part (not illustrated), at the height of the inclined part (133), which is inclined so as to reduce the horizontal section (A).

[0052] A further restriction of the horizontal section (A) determined by the second wall (14) internally of the portion corresponding to the inclined part (133) further facilitates the increase of flow velocity with the above-described benefits.

[0053] The second part (132) preferably comprises an opening (130) for introducing or removing materials into/from the chamber (100). The machines for pharmaceutical or biotechnological processes are usually provided with similar openings (130) which are often arranged in proximity of the operating space (100a).

[0054] The inclined part (133) thus enables directing the flow that laps the opening (130), as well as the contaminants from the materials that can pass through it, towards the at least an extraction mouth (25a, 25b), while at the same time accelerating the contaminants so as to avoid deposits. In this away a high level of cleanliness can be maintained notwithstanding the presence of areas that are openable towards the outside environment or being passed through.

[0055] The at least an extraction mouth (25a, 25b) can be made on the first wall (13), as can be seen in figure 8, or on the second wall (14), as shown by way of example in figure 6, or on both, as shown by way of example in figure 7. In combination or alternatively, the at least an extraction mouth (25a, 25b) can be made on the lower part (12). The positioning on the first wall (13) or on the second wall (14) is more convenient especially in the case of filters (222) arranged at the at least an extraction mouth (25a, 25b).

[0056] An extraction mouth (25a) is preferably made on the second wall (14).

[0057] The extraction from the side opposite to the inclined part (133), inclined, inferiorly thereof, not only facilitates the directionality of the flow, it enables arranging a greater volume beneath the inclined part (133), useful for the installation of apparatus. For example, means for supplying energy (6) and/or means for supplying materials (7) can be installed on the movement means, useful for the pharmaceutical or biotechnological processes that are carried out internally of the chamber (100).

[0058] Although the at least an extraction mouth (25a, 25b) can be made on the first wall (13), when realised on the second wall (14) it generally allows affording a greater volume for the filters (222), useful especially on increasing the volume of the chamber (100) and/or for connections to components of the ventilation means (2) arranged on the external side of the second wall (14). This is advantageous in applications where it is difficult to identify further space, beyond the space normally available for the ventilation means (2) above the upper part (11).

[0059] With reference to figures 4 and 5, given same conditions, the chamber (100) of figure 4 requires a filter (222) of greater volume with respect to the filter (222) of the chamber (100) of figure 5.

[0060] The first wall (13) is preferably connected to the lower part (12) with a fillet and/or the second wall (14) is connected to the lower part (12) with a fillet, the fillet (R) is conformed so as to direct the flow towards the at least an extraction mouth (25a, 25b), consequently improving airborne transport towards the outside of the chamber (100).

[0061] More preferably, in the presence of an extraction mouth (25a) realised on the second wall (14), the first wall (13) is connected to the lower part (12) with a fillet, and, in the presence of an extraction mouth (25b) realised on the first wall (13), the second wall (14) is connected to the lower part (12) with a fillet.

[0062] As can be observed in figures 3, 4, 6 and 8, it is preferable for the curvature radius of the fillet (R) to be such that the fillet (R) fronts the at least an extraction mouth (25a, 25b).

[0063] The ventilation means (2) preferably comprise a filter (222) suitable for pharmaceutical or biotechnological processes arranged at an extraction mouth (25a, 25b), so as to clean the fluid from the airborne contaminant substances or particles.

[0064] The ventilation means (2) preferably comprise a recirculation conduit (23) which connects at least an extraction mouth (25a, 25b) to at least an injection mouth (21a, 21b), as schematically illustrated in figures 4, 7, and 8. More preferably the recirculation conduit (23) passes by the side of the second wall (14), instead of by the side of the first wall (13), as occurs in the known solutions.

[0065] The upper part (11) typically houses the at least an injection mouth (21a, 21b) and preferably the ventilation means (2) are configured in such a way that the flow is laminar, or substantially laminar, at least in a first portion (F), and directed perpendicularly to a horizontal plane (H).

[0066] Laminar flows are often used in cleanrooms because of the directional aspect thereof and, in the case of the machine (1) of the invention, ensure good airborne transport for a first portion (F) typically free of obstacles, then to be channelled towards extraction. Preferably, especially in the case of a laminar flow, or substantially laminar, at least in a first portion (F), the machine (1) comprises a separator wall (9) of the chamber (100); the separator wall (9) extends from the upper part (11)
towards the lower part (12) to a height of the first part (131).

[0067] The separator wall (9) thus realises a configuration alike to a RABS, with a part of the chamber (100) not suffering contaminations of the part of chamber (100) in which the movement means are installed and in which the inclined part (133) is present as well as, possibly, the opening (130).

[0068] Preferably, especially in the case of a laminar flow, or substantially laminar, at least in a first portion (F), the at least an injection mouth (21a, 21b) extends, or extends substantially, over all the horizontal section (A) of the chamber (100).

[0069] As can be seen especially in figures from 3 to 9, it is preferable that the flow covers the whole horizontal section (A) so as to prevent the presence of areas of contaminant accumulation.

[0070] In other words, the at least an injection mouth (21a, 21b) preferably extends, or extends substantially, from the first wall (13) to the second wall (14) and, more preferably, also from another of the walls (15, 16) adjacent to the first wall (13) and the second wall (14).

[0071] Especially in the case of a laminar flow, or a substantially laminar flow, at least in a first portion (F), the first wall (13) and the second wall (14) preferably both have a flat vertical part (134, 141) which descends from the upper part (11) and lies on a respective vertical plane (Z). In this way stagnation areas, and possibly the laminar flow does not deviate, modifying the directionality thereof.

[0072] Typically, though not necessarily, the walls (15, 16) adjacent to the first wall (13) and the second wall (14) are flat and vertical, i.e. they lie on vertical planes, as in figure 14; in other embodiments they can contribute to reducing the horizontal section (A).

[0073] The movement means can comprise transporters or conveyors, such as, for example, conveyor belts, mechanical arms, robotic arms and/or other known devices.

[0074] The movement means preferably comprise an arm (33). The machine (1) of the invention advantageously avoids contaminant accumulation and guarantees airborne transport even in the presence of the arm (33). The arm (33) can be a mechanical arm or a robotic arm.

[0075] The movement means typically also comprise a contact part (34), borne by a respective arm (33), which contacts the materials and/or the instruments internally of the operating space (100a).

[0076] The movement means can comprise devices borne by the walls (13, 14, 15, 16) and/or by the upper part (11) and/or by the inclined part (133).

[0077] Typically, though not necessarily, the movement means comprise a plurality of devices.

[0078] The movement means preferably comprise at least a robot (31, 32). More preferably each robot (31, 32) comprises an arm (33) and a contact part (34) and is configured to move the contact part (34) into the operating space (100a).

[0079] The movement means, or the at least a robot (31, 32), preferably comprise a part (35)

that is coupled to or crosses the first part (131) and/or the inclined part (133) so as to be able to easily receive energy and/or materials.

[0080] The machine (1) preferably comprises means for supplying energy (6) to the movement means and/or means for supplying materials (7) to the movement means arranged at the first part (131) or at the inclined part (133) on the side opposite the chamber (100), so that they are in proximity of the operating space (100a).

[0081] More preferably, the means for supplying energy (6) and/or the means for supplying materials (7) are located below the inclined part (133), internally of a volume which in the prior art solutions was typically exploited for the passage of air conduits.

[0082] The machine (1) preferably comprises at least a functional group (99) which cooperates with the movement means to realise a pharmaceutical or biotechnological process.

[0083] The at least a functional group (99) can comprise weighing systems, collecting systems, container-closing systems, ring-sealing stations, liquid or powder dosing systems, parking areas for containers or caps, carousels, centrifuges or other devices commonly used in the pharmaceutical or biotechnological industry.

[0084] The inclined part (133) more preferably accommodates or supports at least a functional group (99) and/or the first part (131) supports at least a functional group (99).

[0085] In figures 6 and 7 the operating space (100a) enables the movement means to operate above the inclined part (133) and on any functional units (99) born by the first part (131). The definition of the operating space (100a) takes account of the position of the at least a functional group (99) which involves the pharmaceutical or biotechnological process to be carried out.

[0086] The ventilation means (2) preferably comprise at least a ventilator (24). Often a ventilator (24) is arranged above the upper part (11) and other ventilators (24) can be introduced to manage overpressure or depression internally of the inside of the chamber (100) as well as the volumes of suction, emission towards the outside and recovery. For example other ventilators (24) are arranged on the side of the second wall (14) in figures from 3 to 9 and enable dynamic management of the recirculation and the pressure internally of the chamber (100).

[0087] The at least a fluid treatment unit (221) preferably comprises a filter, more preferably of the HEPA type for pharmaceutical or biotechnological processes.

[0088] The ventilation means (2) typically comprise a filter (222) for filtering the air in outlet to the chamber (100), preferably of the HEPA type suitable for pharmaceutical or biotechnological processes.

[0089] The ventilation means (2) commonly also comprise a filter (223) for filtering the air in

towards the outside or from the outside, preferably of the HEPA type for pharmaceutical or biotechnological processes.

[0090] The at least a fluid treatment unit (221) preferably comprises a fluid cooling and/or heating unit.

[0091] The means for supplying energy (6) can comprise electric cables, electrical control units, conduits for pressurised fluids or other devices commonly used in the pharmaceutical, biotechnological or robotic industry.

[0092] The means for supplying materials (7) can comprise pipes for fluids, such as for example water, air or nitrogen, or mechanical parts for openings and/or drawers and/or compartments, pumps, valves or other devices commonly used in the pharmaceutical or biotechnological industry. By way of example, in figure 10 a compartment open towards the chamber is partially visible, in a dotted line, openable towards the chamber (100).

[0093] The materials can comprise containers or parts thereof, pharmaceutical products, biotechnological products, products for tests, or other materials used for pharmaceutical or biotechnological processes.

[0094] The instruments can comprise gripping organs, such as, for example pincers, measuring instruments, pick-up devices, filling devices or other instruments used for pharmaceutical or biotechnological processes.

[0095] The invention also relates to an assembly (0) for manufacturing the machine (1) according to the present description.

[0096] An embodiment of the assembly (0) comprises:

- parts of wall for delimiting a chamber (100) comprising a first part (131) and an inclined part (133);
- at least a further wall (4);
- a base (5) which supports the first part (131) and the at least a further wall (4);
- movement means for moving materials and/or instruments, which are configured to move the materials and/or the instruments in an operating space (100a);
- means for supplying energy (6) to the movement means and/or means for supplying materials (7) to the movement means;

wherein:

- the base (5), the first part (131), the inclined part (133) and the at least a further wall (4) delimit, though not necessarily close, a volume (V) which houses the means for supplying energy (6) and/or the means for supplying materials (7);
- the inclined part (133) is contiguous to the first part (131) and rises from the first part (131) in an oblique direction (D) with respect to a horizontal plane (H).

[0097] The assembly (0) according to the invention facilitates the construction of the machine (1) as it comprises components essential for realising pharmaceutical or biotechnological processes in a chamber (100) with the above-delineated advantages.

[0098] The assembly (0) can be, for example, pre-validated or pre-qualified and subsequently transported to another place for assembly with the other parts of structure so as to build the machine (1) of the invention.

[0099] The assembly (0) can easily be integrated into very different structures to one another, while guaranteeing high levels of cleanliness internally of the chamber (100).

[0100] The assembly (0) is further more easily transportable than the whole machine (1) and transport means for delicate or fragile objects can more easily be used.

[0101] The parts of wall preferably also comprise a second part (132), more preferably comprising an opening (130), as can be observed for example in figure 10. This can be useful for further limiting the successive operations and maximising the operations before obtaining the prefabricated assembly (0).

[0102] The movement means preferably comprise a part (35) that is coupled to or crosses the first part (131) and/or the inclined part (133) so as to be on the opposite side to the volume (V) and to be easily energised or to be able to easily receive materials.

[0103] The assembly (0) preferably comprises a separation part (8) and the movement means comprise a first device and a second device.

[0104] The separation part (8) is arranged above the inclined part (133) between the first device and the second device and has a first oblique surface (81) and a second oblique surface (82) facing on opposite sides and which broaden towards the inclined part (133) in the conjoining direction (C) of the first device and of the second device.

[0105] The separation part (8) can interface with or accommodate a wall (15, 16) so as to delimit therewith the chamber (100) thus facilitating the distancing of the flow from the wall (15, 16) due to the oblique surface, for the same reasons already adopted by the inclined part (133). Likewise, the advantages increase when the wall (15, 16) comprises an opening.

[0106] The invention also relates to a method for manufacturing the machine (1) according to the present description.

[0107] An embodiment of the method comprises steps of:

- providing an assembly (0) according to the present description, i.e. according to one of

the described embodiments;

- providing parts comprising an upper part (11), a lower part (12), walls (13, 14, 15, 16) and a second part (132) of wall configured to form a structure (10) together with the parts of wall, with the upper part (11), the lower part (12) and the walls (13, 14, 15, 16) delimiting the chamber (100);
- providing ventilation means (2) which comprise at least a fluid treatment unit (221) suitable for pharmaceutical or biotechnological processes, at least a fluid injection mouth (21a, 21b) and at least a fluid extraction mouth (25a, 25b);
- connecting the parts to the assembly (0) so as to realise a first wall (13) comprising a first part (131), a second part (132) distanced from the first part (131) according to a horizontal direction (O) and an inclined part (133) which is contiguous with the second part (132) which extends between the first part (131) and the second part (132), inferiorly of the second part (132) and superiorly of the first part (131) and so as to realise a structure (10) having a horizontal section (A) of the chamber (100) which is constant, or substantially constant, or diminishes descending from the installation area of the at least an injection mouth (21a, 21b) to the installation area of the at least an extraction mouth (25a, 25b);
- installing the ventilation means (2) so as to have the at least a fluid injection mouth (21a, 21b) superiorly of the operating space (100a) and the at least a fluid extraction mouth (25a, 25b) from the chamber (100) inferiorly of the operating space (100a) and so as to move a fluid from the at least an injection mouth (21a, 21b) to the at least an extraction mouth (25a, 25b).

[0108] The above-described method enables exploiting the advantages of having a prefabricated assembly (0), typically pre-qualified, to form a chamber (100) suitable for the specific requirements of the particular pharmaceutical or biotechnological process. The machine (1) of the invention thus becomes available rapidly and/or can be personalised quickly, as well as having lower costs with respect to those deriving from zero design and manufacturing operations.

[0109] Further, the improvements on the assembly (0) can have direct repercussions on all the machines (1) that will be made.

[0110] In the step of providing an assembly (0), an assembly is preferably provided that comprises a separation part (8), with the movement means comprising a first device and a second device.

[0111] The separation part (8) is arranged above the inclined part (133) between the first device and the second device and has a first oblique surface (81) and a second oblique surface (82) facing on opposite sides and which broaden towards the inclined part (133) in the conjoining direction (C) of the first device and of the second device.

[0112] Further, in the step of connecting the parts to the assembly (0), a separation part (8) is connected to a wall (13, 14, 15, 16) in such a way that the wall (13, 14, 15, 16) extends between the first oblique surface (81) and the second oblique surface (82). The above-illustrated advantages are obtained in this way.

[0113] The accompanying figures enable clarification with examples and, possible, to detail the above-illustrated teachings.

[0114] Figure 1 illustrates accesses, for example for maintenance, not strictly necessary. Figure 2 illustrates some openings (130) and the in-view wall provided with openings of the RTP type, an acronym for *Rapid Transfer Port.*

[0115] The machine (1) of the invention can comprise further chambers. For example starting from the assembly (0) of figure 10 a single chamber (100) can be realised or a chamber (100) and further chambers, three in the case of figure 14.

[0116] The machine (1) realised can comprise three further chambers with an outer conformation that can be the one illustrated in figure 1.

[0117] The assembly (0), illustrated in the following, can be made with a "modular" approach guaranteeing one or more stations.

[0118] With reference to the machine (1) of figure 3 substantially four areas of fluid velocity or horizontal strips can be observed, starting from above: a first area reaching to the inclined part (133), a second area at the inclined part (133), a third area beneath the inclined part (133) and reaching to the end of the inclination of the second wall (14) and a fourth lower area.

[0119] The opening (130) is represented in figure 3, but this might also be present in the other embodiments, as can the fillet (R).

[0120] In figures 5 and 6 on the side of the first wall (13) opposite the chamber (100) there is a space in the machine (1) which might be used to arrange a further white chamber or one having a controlled atmosphere, but, also, for the return of the fluid towards the at least an injection mouth (21a, 21b). The teachings of the present invention, with the greater efficiency in cleanliness at the opening (130) also enable reducing the size of the machine (1) on the side of the first wall (13) opposite the chamber (100).

[0121] In figure 10, the base (5) comprises, though this is not strictly necessary, a platform which extends from the first part (131). The platform facilitates the transport and management of the assembly (0) before realising the machine (1), while protecting the area with the movement means and, possibly, the functional units (99).

[0122] In the same figure 10, as in the following figures 11 and 12, it can be seen how easy it is to access the volume (V) and an electric cable of the means for supplying energy (6) can

also been seen.

[0123] As illustrated in figures 11 and 12 the assembly (0) can be easily integrated with functional units (99), i.e. modules or devices commonly used in the pharmaceutical or biotechnological industry, ensuring, among other things, a greater facility of access during the installation with respect to installation on a machine (1).

[0124] It is understood that the above has been described by way of non-limiting example and that any constructional variants are considered to fall within the protective scope of the present technical solution, as claimed in the following.

REFERENCES CITED IN THE DESCRIPTION

Cited references

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Patent documents cited in the description

- EP3939896A1 [0010] [0011]
- EP3335844B1 [0010] [0011]
- US4696902A [0011]

MASKINE TIL FARMACEUTISKE ELLER BIOTEKNOLOGISKE PROCESSER, ENHED OG FREMGANGSMÅDE TIL REALISERING AF MASKINEN

PATENTKRAV

1) Maskine (1) til farmaceutiske eller bioteknologiske processer, som omfatter:
   - en struktur (10) som har en øvre del (11), en nedre del (12) og, mellem den øvre del (11) og nedre del (12), vægge (13, 14, 15, 16) som omfatter en første væg (13) og en anden væg (14) overfor den første væg (13) og den øvre del (11), den nedre del (12) og væggene (13, 14, 15, 16) afgrænser et kammer (100);
   - bevægelsesmidler til bevægelse af materialer og/eller instrumenter, som er konfigureret til at bevæge materialerne og/eller instrumenterne i et driftsområde (100a) indvendigt i kammeret (100);
   - ventilationsmidler (2) som omfatter mindst en væskeinjektionsmunding (21a, 21b) indvendigt i kammeret (100) ovenover driftsområdet (100a), mindst en væskeudtræksmunding (25a, 25b) til væske fra kammeret (100) nedenunder driftsområdet (100a) og mindst en væskebehandlingsenhed (221), der er egnet til farmaceutiske eller bioteknologiske processer opstrøms af den mindst ene injektionsmunding (21a, 21b), hvor ventilationsmidlerne (2) bevæger en væske fra den mindste ene injektionsmunding (21a, 21b) til den mindst ene udtræksmunding (25a, 25b);

hvor

den første væg (13) omfatter en første del (131), en anden del (132) og en hældet del (133) som strækker sig mellem den første del (131) og den anden del (132), nedenunder den anden del (132) og ovenover den første del (131), og som er sammenhængende med den første del (131) og med den anden del (132) således at den indelukker kammeret (100);

- driftsområdet (100a) strækker sig, mindst delvist, over den hældede del (133) og/eller i en volumen anbragt ovenover den første del (131) og foran den hældede del (133);
- den hældede del (133) er hældet i forhold til et horisontalt plan (H) således at den horisontale sektion (A) af kammeret (100), som krydses af væsken, reduceres mens den falder mod den første del (131), og

maskinen er kendetegnet ved at den strukturen (10) er konfigureret således at den horisontale sektion (A) af kammeret (100) er konstant, eller grundlæggende konstant, eller mindskes mens den falder fra den mindst ene injektionsmunding (21a, 21b) til den

mindste ene udtræksmunding (25a, 25b); og ved at den anden del (132) er distanceret fra den første del (131) ifølge en horisontal retning (O).

2) Maskine ifølge det foregående krav, hvor den første væg (13) og den anden væg (14) er tæt ved hinanden, nedenunder den hældede del (133) og ovenover den mindst ene udtræksmunding (25a, 25b).

3) Maskine (1) ifølge ethvert af de foregående krav, hvor den anden del (132) omfatter en åbning (130) til introduktion eller fjernelse af materialer ind i eller fra kammeret (100) og hvor driftsområdet (100a) strækker sig, mindst delvist, over den hældede del (133).

4) Maskine (1) ifølge ethvert af de foregående krav, hvor en udtræksmunding (25a) er udført på den anden væg (14).

5) Maskine (1) ifølge ethvert af de foregående krav, hvor den mindst ene udtræksmunding (25a, 25b) er udført på den første væg (13) og/eller ifølge krav 4, og hvor henholdsvis den anden væg (14) og/eller den første væg (13) er tilsluttet til den nedre del (12) med en runding, hvor rundingen (R) er tilpasset således at den leder flowet mod den mindst ene udtræksmunding (25a, 25b).

6) Maskine (1) ifølge ethvert af de foregående krav, hvor den øvre del (11) huser mindst en injektionsmunding (21a, 21b) og hvor ventilationsmidlerne (2) er konfigureret på en sådan måde, at strømningen er laminar, eller grundlæggende laminar, mindst i en første andel (F), og ledes vinkelret til et horisontalt plan (H).

7) Maskine (1) ifølge det foregående krav, som omfatter en separatorvæg (9) af kammeret (100) hvor separatorvæggen (9) strækker sig fra den øvre del (11) mod den nedre del (12) til en højde af den første del (131).

8) Maskine (1) ifølge ethvert af de foregående krav, hvor den mindst ene injektionsmunding (21a, 21b) strækker sig, eller grundlæggende strækker sig, over hele den horisontale sektion (A) af kammeret (100).

9) Maskine (1) ifølge ethvert af de foregående krav, hvor den første væg (13) og den anden væg (14) begge har en flad vertikal del (134, 141) som falder fra den øvre del (11) og ligger på et tilhørende vertikalt plan (Z).

10) Maskine (1) ifølge ethvert af de foregående krav, hvor væggene (15, 16) tilstødende til den første væg (13) og den anden væg (14) er flade og vertikale.

11) Maskine (1) ifølge ethvert af de foregående krav, hvor bevægelsesmidlerne omfatter en del (35) der er koblet til eller krydser den første del (131) og/eller den hældede del (133).

12) Maskine (1) ifølge ethvert af de foregående krav, som omfatter midler til forsyning af energi (6) til bevægelsesmidlerne og/eller midler til forsyning af materialer (7) til bevægelsesmidlerne anbragt på den første del (131) eller på den hældede del (133) på siden overfor kammeret (100),
hvor midlerne til forsyning af energi (6) og/eller midlerne til forsyning af materialer (7) er placeret under den hældede del (133).

13) Maskine (1) ifølge ethvert af de foregående krav, som omfatter mindst en funktionel gruppe (99) som samarbejder med bevægelsesmidlerne for at realisere en farmaceutisk eller bioteknologisk proces,
hvor den hældede del (133) rummer eller understøtter mindst en funktionel gruppe (99) af den mindst ene funktionelle gruppe (99) og/eller
hvor den første del (131) understøtter mindst en funktionel gruppe (99) af den mindst ene funktionelle gruppe (99).

14) Enhed (0) til realisering af maskinen (1) ifølge ethvert af de foregående krav, som omfatter:

- vægdele til afgrænsning af et kammer (100) som omfatter en første del (131) og en hældet del (133);
- mindst en yderligere væg (4);
- en base (5) som understøtter den første del (131) og den mindst ene yderligere væg (4);

- bevægelsesmidler til bevægelse af materialer og/eller instrumenter, som er konfigureret til at bevæge materialerne og/eller instrumenterne i et driftsområde (100a);
- midler til forsyning af energi (6) til bevægelsesmidlerne og/eller midler til forsyning af materialer (7) til bevægelsesmidlerne;

hvor:

- den hældede del (133) er sammenhængende til den første del (131) og stiger fra den første del (131) i en skrå retning (D) i forhold til et horisontalt plan (H),

enheden (O) er kendetegnet ved at basen (5), den første del (131), den hældede del (133) og den mindst ene yderligere væg (4) afgrænser en volumen (V) som huser midlerne til forsyning af energi (6) og/eller midlerne til forsyning af materialer (7).

15) Enhed (0) ifølge det foregående krav, som omfatter en separationsdel (8), hvor:

- bevægelsesmidlerne omfatter et første apparat og et andet apparat;
- separationsdelen (8) er anbragt over den hældede del (133) mellem det første apparat og det andet apparat og har en første skrå overflade (81) og en anden skrå overflade (82) som sidder overfor hinanden og som udvides i bredden mod den hældede del (133) i den forbundne retning (C) af det første apparat og det andet apparat.

16) Metode til realisering af maskinen (1) ifølge ethvert af de foregående krav fra 1 til 13, som omfatter trin med:

- tilvejebringelse af en enhed (0) som i krav 14 eller 15;
- tilvejebringelse af dele, som omfatter en øvre del (11), en nedre del (12), vægge (13, 14, 15, 16) og en anden vægdel (132) konfigureret til at danne en struktur (10) sammen med vægdelene, med den øvre del (11), den nedre del (12) og væggene (13, 14, 15, 16) der afgrænser kammeret (100);
- tilvejebringelse af ventilationsmidler (2) som omfatter mindst en væskebehandlingsenhed (221), der er egnet til farmaceutiske eller bioteknologiske processer, mindst en væskeinjektionsmunding (21a, 21b) og mindst en væskeudtræksmunding (25a, 25b);
- tilslutning af delene til enheden (0) for at realisere en første væg (13) som omfatter en første del (131), en anden del (132) distanceret fra den første del (131) ifølge en horisontal retning (O) og en hældet del (133) som er sammenhængende med den anden del (132) og som strækker sig mellem den første del (131) og den anden del (132), nedenunder den anden del (132) og ovenover den første del (131) og for at

realisere en struktur (10) med en horisontal sektion (A) af kammeret (100) som er konstant, eller grundlæggende konstant, eller mindskes mens den falder fra installationsområdet af den mindst ene injektionsmunding (21a, 21b) til installationsområdet af den mindst ene udtræksmunding (25a, 25b);

- installation af ventilationsmidlerne (2) for at have den mindst ene væskeinjektionsmunding (21a, 21b) ovenover driftsområdet (100a) og den mindst ene væskeudtræksmunding (25a, 25b) fra kammeret (100) nedenunder driftsområdet (100a) og for at bevæge en væske fra den mindst ene injektionsmunding (21a, 21b) til den mindst ene udtræksmunding (25a, 25b).

17) Metode ifølge det foregående krav, hvor der i trinnet med tilvejebringelse af en enhed (0) tilvejebringes en enhed (0) ifølge krav 15, og hvor der i trinnet med tilslutning af delene til enheden (0) tilsluttes en separationsdel (8) til en væg (13, 14, 15, 16) således at væggen (13, 14, 15, 16) strækker sig mellem den første skrå overflade (81) og en anden skrå overflade (82).

DRAWINGS

Drawing

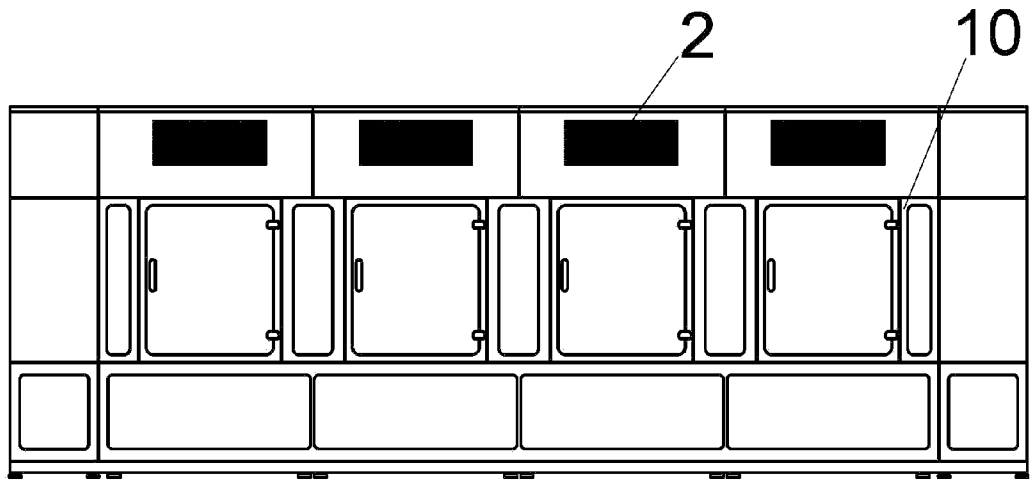

FIG. 1

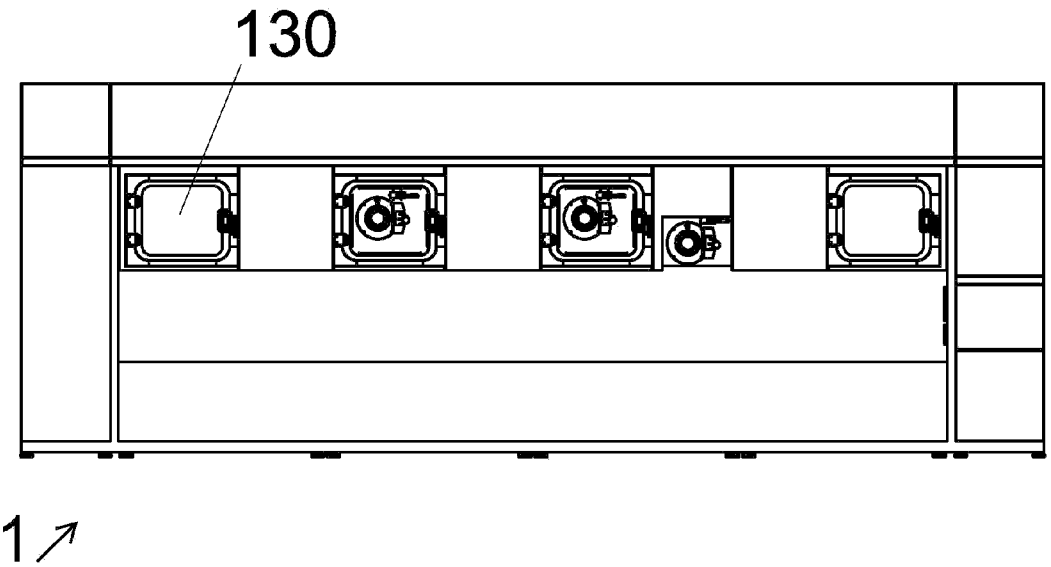

FIG. 2

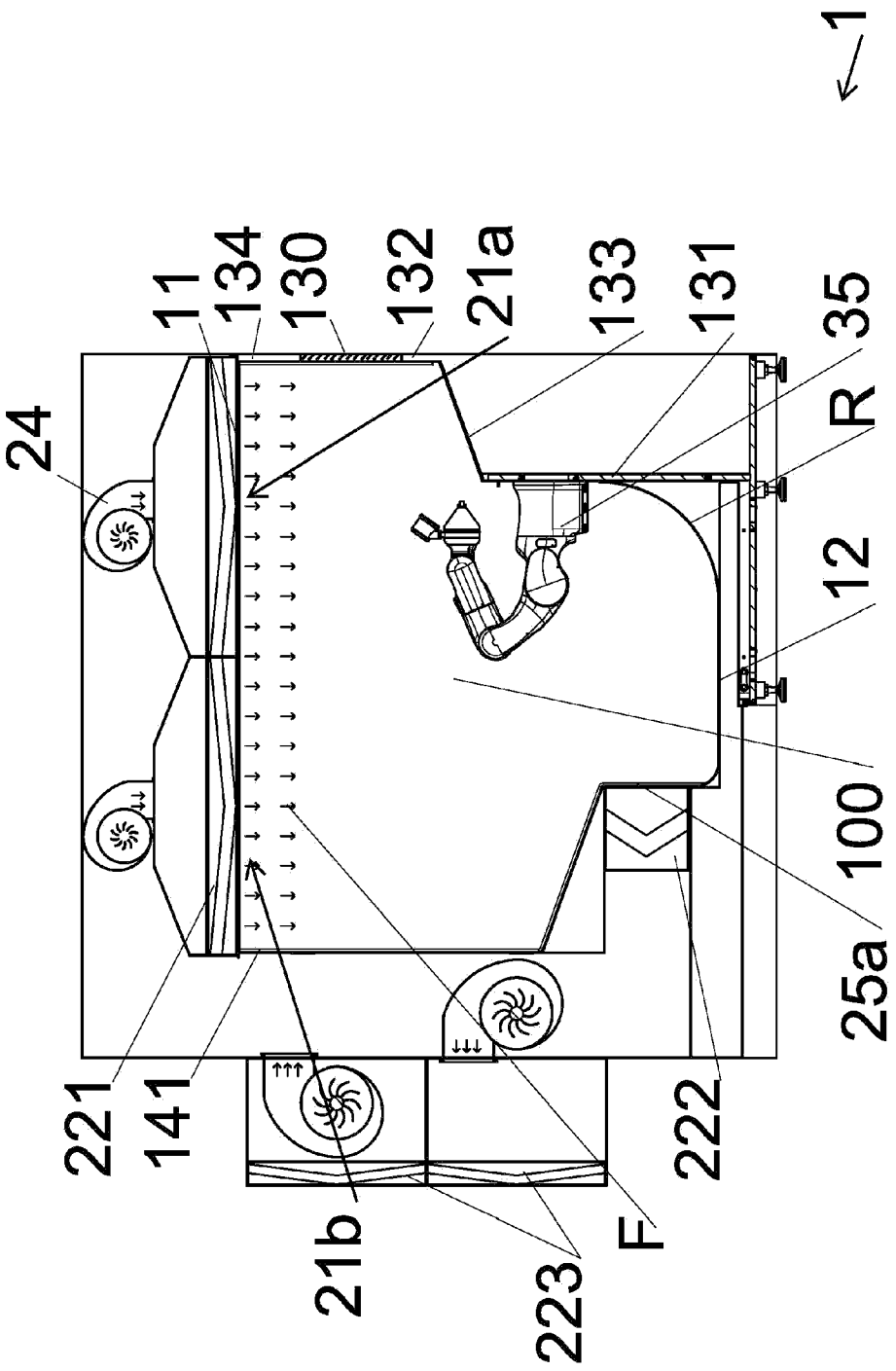
1
11
134
130
132
21a
133
131
35
R
24
12
100
25a
221
141
21b
223
F
222

FIG. 3

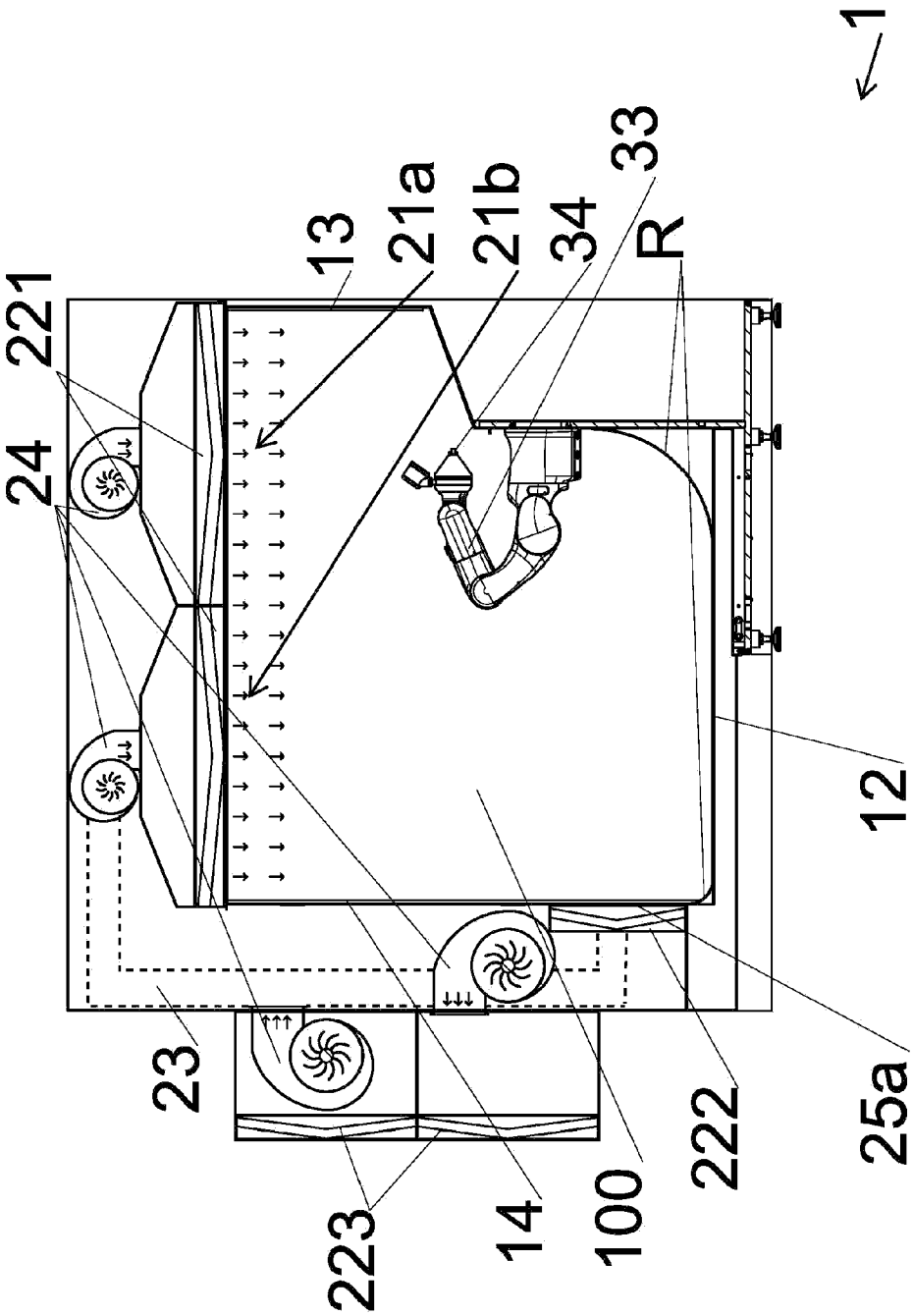

FIG. 4

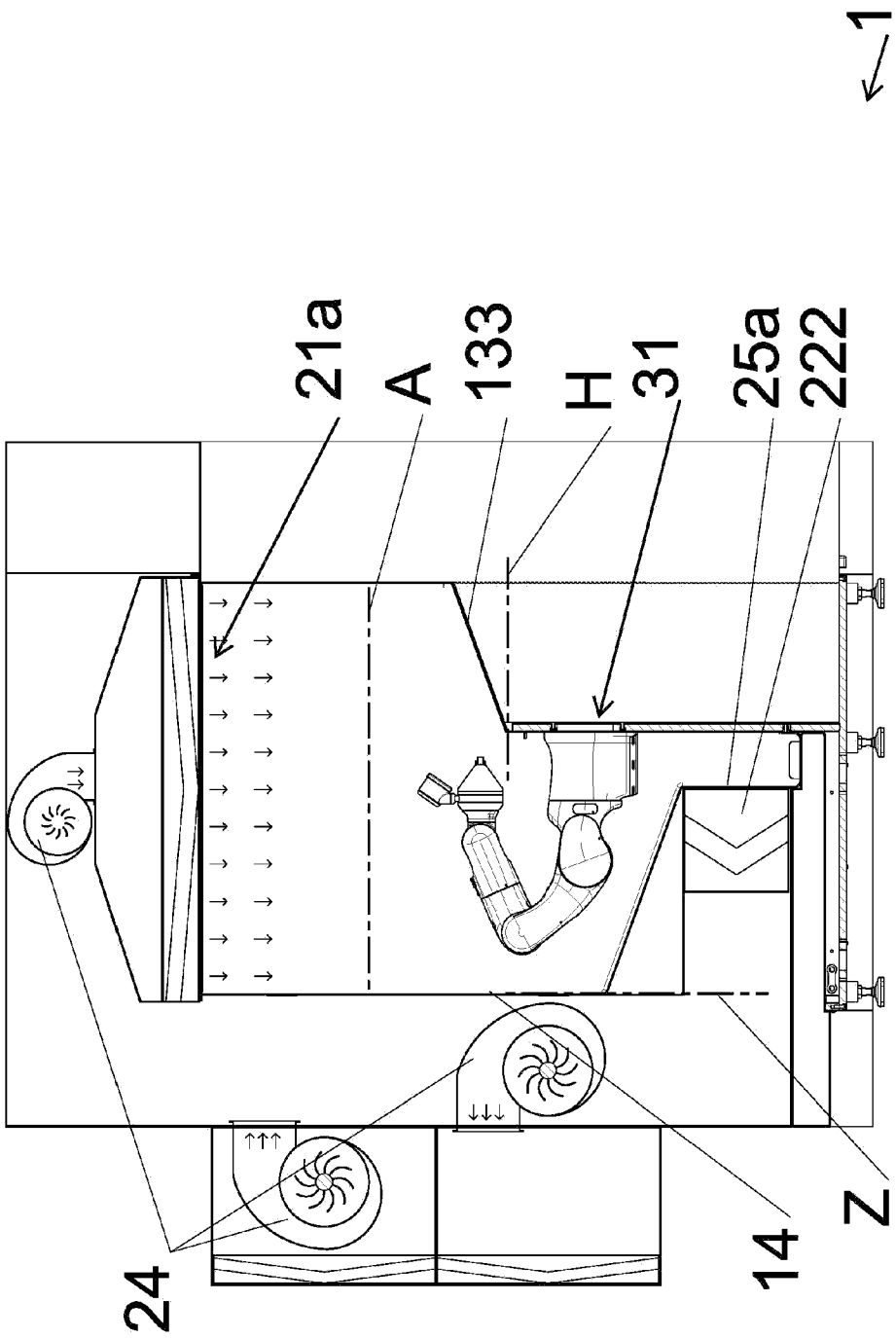

FIG. 5

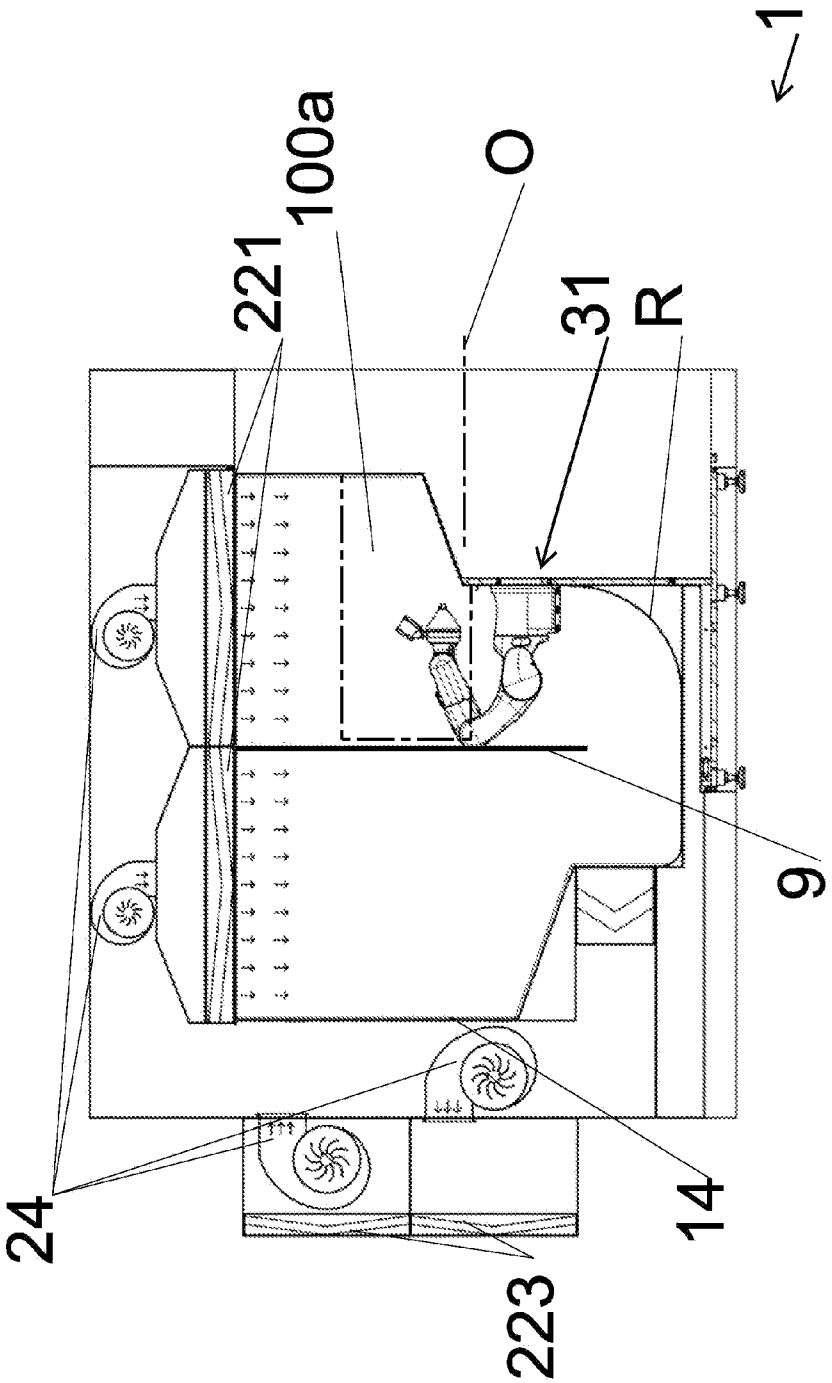

FIG. 6

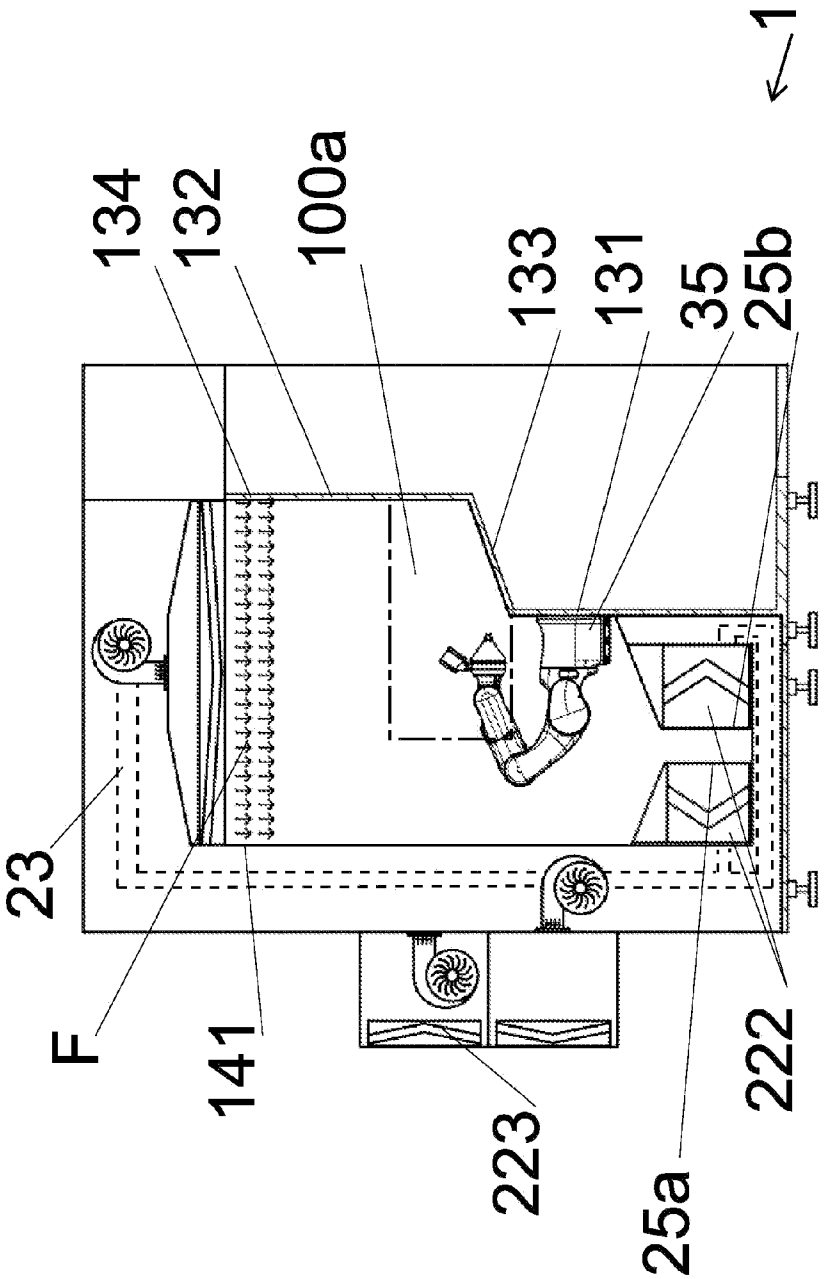

FIG. 7

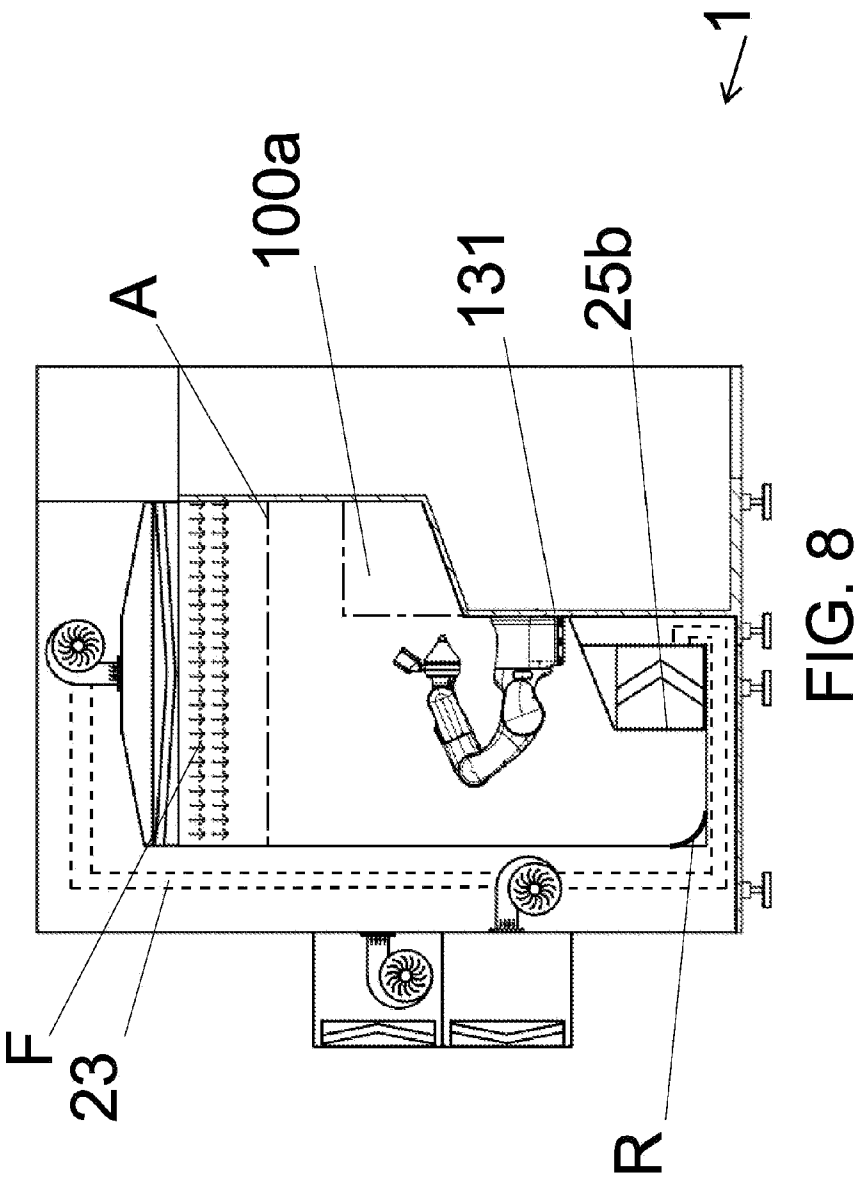

FIG. 8

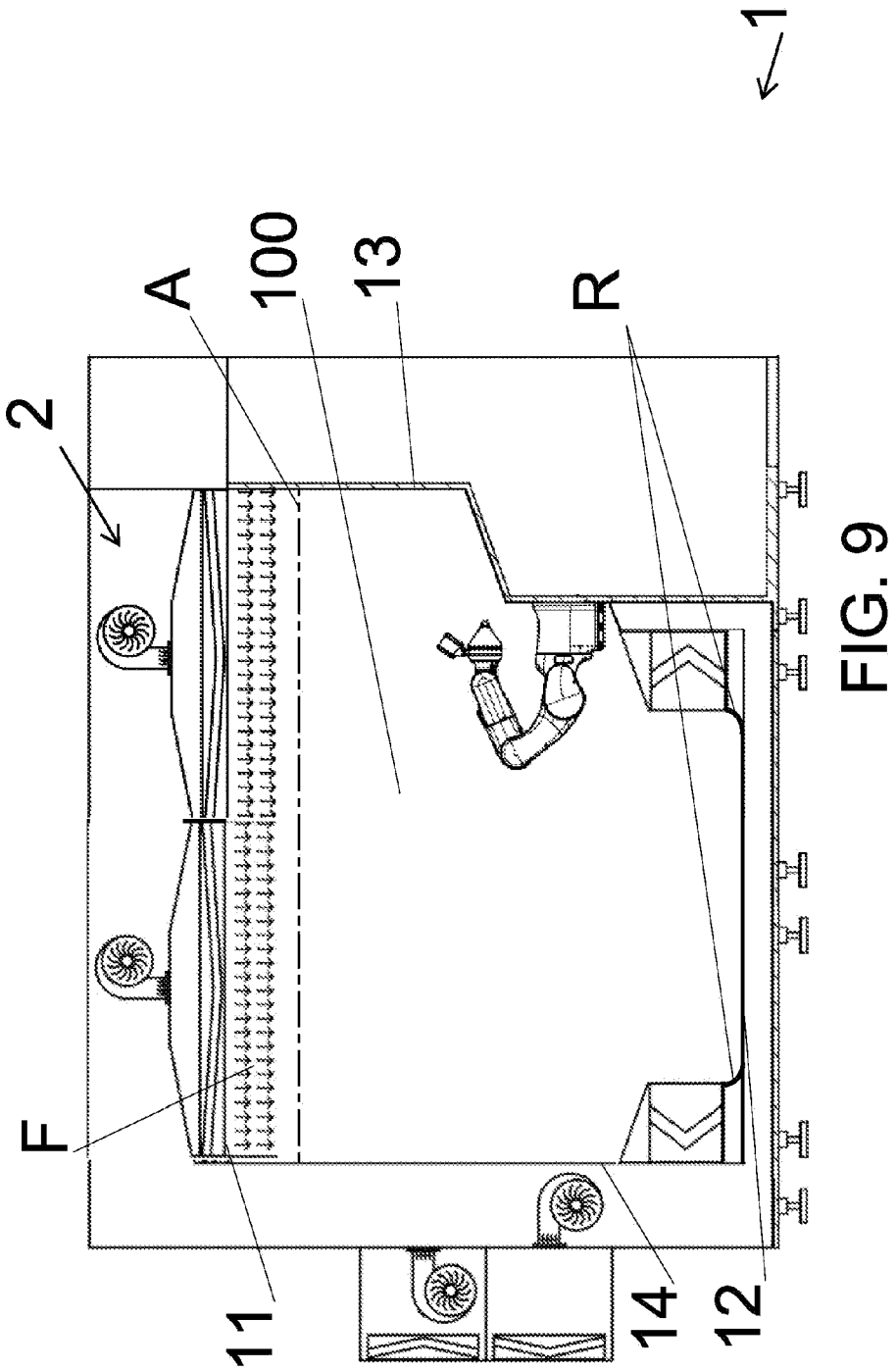

FIG. 9

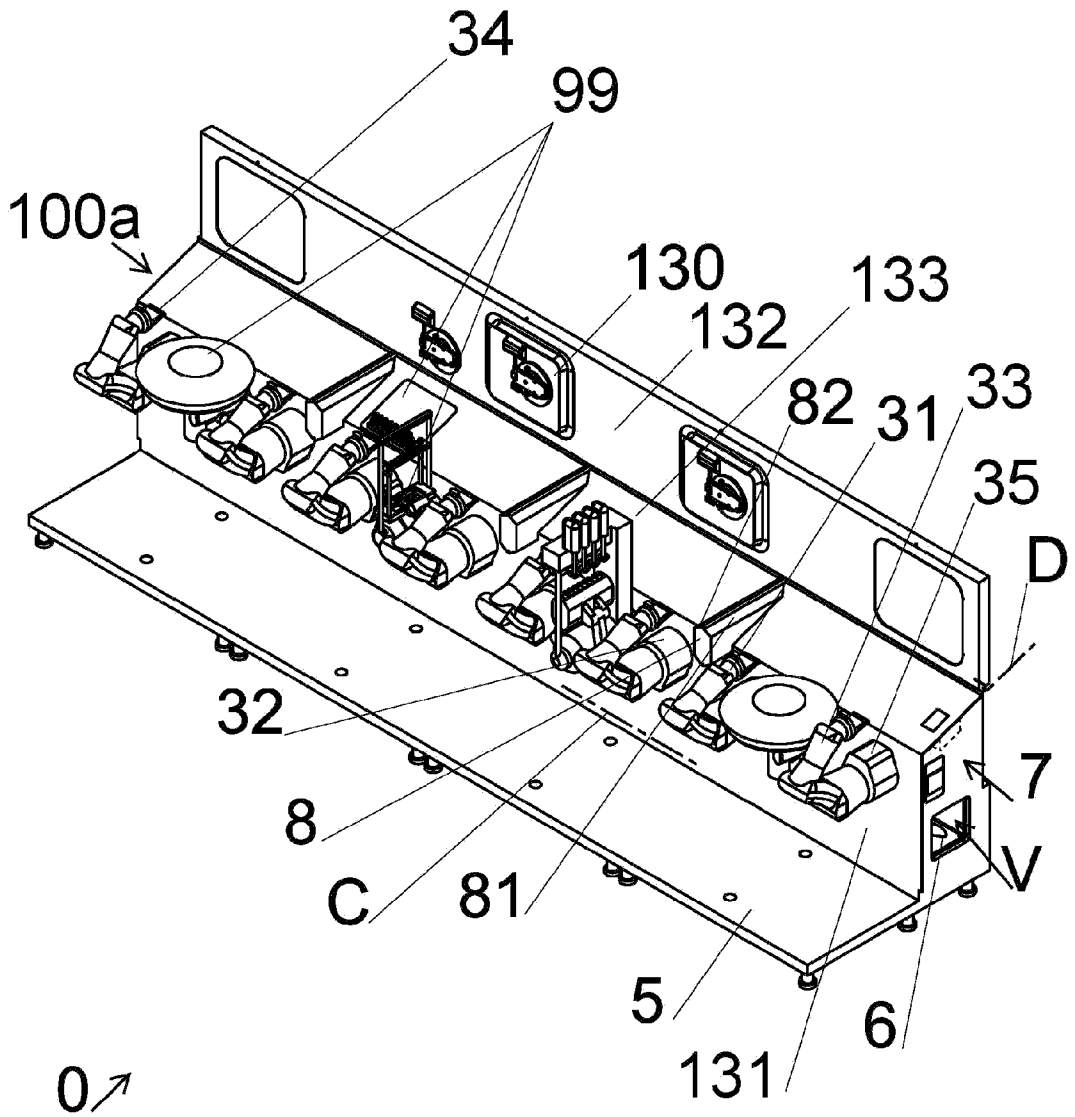

FIG. 10

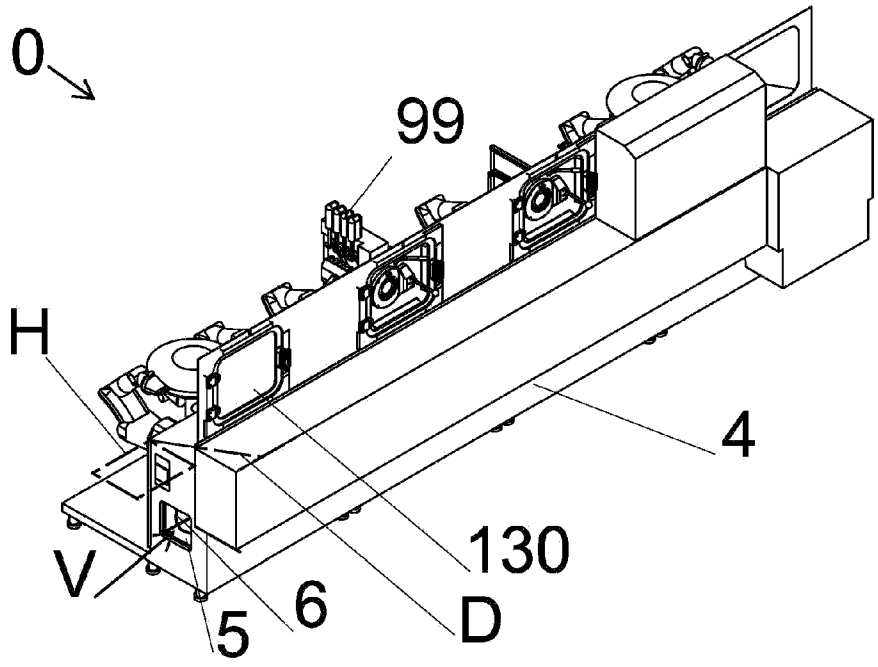

FIG. 11

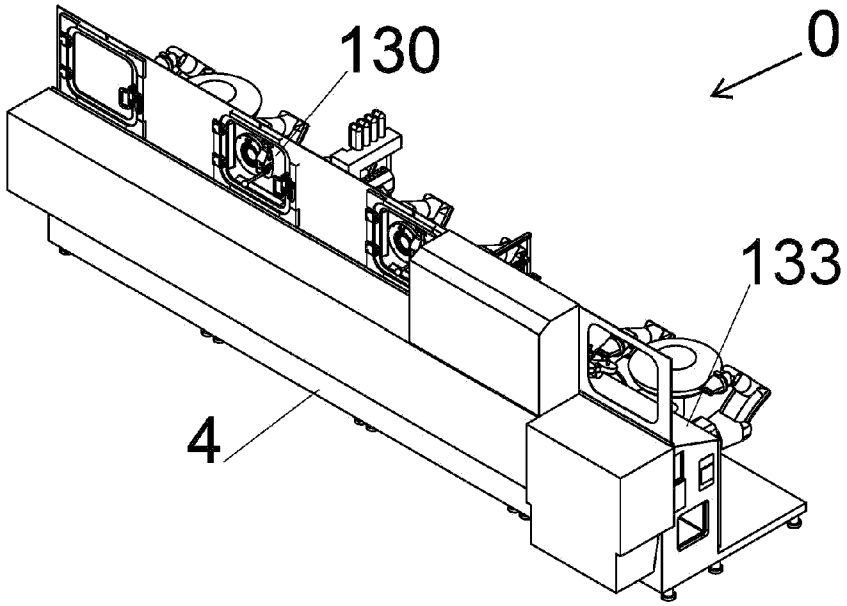

FIG. 12

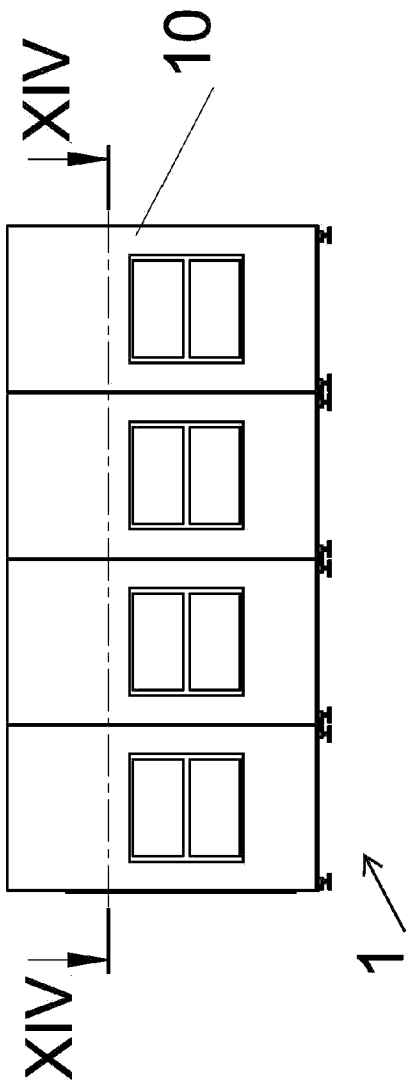

FIG. 13

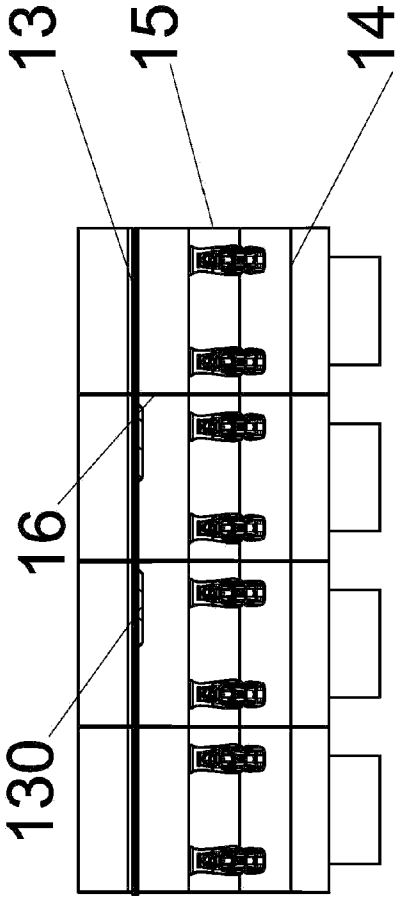

FIG. 14