(19) DANMARK

(10) **DK/EP 3335844 T3**

Patent- og Varemærkestyrelsen

(12) Oversættelse af europæisk patentskrift

(51) Int.Cl.: ***B 25 J 21/00 (2006.01)*** ***B 08 B 15/02 (2006.01)*** ***B 65 B 3/00 (2006.01)***
B 65 B 7/28 (2006.01) ***B 65 B 43/46 (2006.01)*** ***B 65 B 43/54 (2006.01)***
B 65 B 55/02 (2006.01) ***B 65 B 55/04 (2006.01)*** ***B 65 B 63/00 (2006.01)***

(45) Oversættelsen bekendtgjort den: **2020-01-06**

(80) Dato for Den Europæiske Patentmyndigheds bekendtgørelse om meddelelse af patentet: **2019-10-30**

(86) Europæisk ansøgning nr.: **16405035.3**

(86) Europæisk indleveringsdag: **2016-12-15**

(87) Den europæiske ansøgnings publiceringsdag: **2018-06-20**

(84) Designerede stater: **AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR**

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(54) Benævnelse: **KONSTRUKTIV STRUKTUR AF EN INDESLUTNING BESTEMT TIL AUTOMATISERET PRODUKTION AF FARMACEUTISKE ELLER BIOTEKNISKE ARTIKLER**

(56) Fremdragne publikationer:
US-A1- 2006 136 095
US-A1- 2012 191 243
US-A1- 2016 136 052
US-A1- 2016 326 573

Constructive assembly of a containment means, intended for the automated production of pharmaceutical or biotechnical articles

Field of use of the invention

The invention relates to the constructive assembly of a containment means intended for the automated production of pharmaceutical or biotechnical articles which, as an end product, in each case comprise a plurality of article parts. The containment means is typically configured as an open or closed restricted access barrier system (RABS) or as an isolator, in each case equipped with an air treatment device and having a clean-room classification. The containment means is surrounded by a housing within which there is an inner chamber with at least one through-opening. Further generic features of the assembly are that at least one robot is installed in the chamber, said robot having, on its pivotable arm, at least one manipulating element which is movable within a pivot range, wherein the chamber is suitable for installation of at least one process unit for the production of the articles. Several such containment means can be linked to each other in a production line in order to form a containment means chain.

Prior art

In the previously known containment means for automated production of pharmaceutical or biotechnical articles, washing, filling and closing stations are installed in the containment means, and conveyor belts, with carousel conveyors arranged between them, extend through the containment means and deliver the article parts that are to be processed to the respective machine station. For this purpose, the following are known for example from the company Bosch: "Universal washing machines RRN/RRU", "FLC – Filling and closing machine for vials and infusion bottles", "Closing machine for overseal caps VRU/VRT/VRK", "Drying and Sterilizing Tunnel HQL Series" and "FXS – Filling and sealing machine for presterilized syringes".

The document US 2016/0326573 A1 also discloses a containment for the automated production of pharmaceutical or biotechnical articles.

Object of the invention

The object of the invention is to propose a constructive assembly of a containment means for the automated production of pharmaceutical or biotechnical articles, in the work chamber of which containment means the development of undesired particles, e.g. caused by abrasion on receptacles and/or on transport means, is reduced. At the same time, the design concept is intended to ensure that the laminar airflow guided through the work chamber is disturbed to a lesser extent by installed add-on structures. These objects have the ultimate aim of reducing the error rate of articles not treated according to regulations. Finally, it is an object of the design concept to permit modular adaptation to specific production requirements, also for interconnected chains of containment means.

Overview of the invention

The constructive assembly of a containment means is intended for the automated production of pharmaceutical or biotechnical articles, As end product, an article in each case comprises a plurality of article parts. The containment means is surrounded by a housing within which there is an inner chamber having at least one through-opening. At least one robot is installed in the chamber, which robot has at least one manipulating element on its pivotable arm, which can move within a pivot range. The chamber is suitable for the installation of at least one process unit for production of the articles.

Further to the above list of features forming the preamble, the constructive assembly has the following additional features. The chamber comprises a process space for the production of the articles, and a tub-shaped base space for anchoring the foot of the at least one robot to one of the side faces inside the base space. The process space is arranged above the base space, and both adjoin each other in a congruent and open manner. The manipulating element has the functions of gripping means and transporting means for the articles or article parts and/or for inspection of the articles or article parts and/or for production of the articles. The pivot range of the at least one manipulating element on the at least one robot extends in a horizontal plane and a vertical plane within a working

region, which is defined between a minimum working height and a maximum working height.

Particular embodiments of the invention are defined below. Within the pivot range, at least one transfer region is provided which is intended to pick up or position articles or article parts by means of the manipulating element of the at least one robot.

Alternatively, two transfer regions are advantageously provided within the pivot range. Here, the first transfer region is intended for picking up articles or article parts by means of the manipulating element of the at least one robot, and the second transfer region is intended for positioning articles or article parts by means of the manipulating element of the at least one robot.

A first containment means is connected to a second containment means, in each of which a robot is installed, and one of the transfer regions lies in the pivot range of the manipulating elements of both robots.

Alternatively, at least two robots are advantageously installed in the containment means, wherein a transfer region lies in each case in the pivot range of the manipulating elements of two adjacent robots.

At least one process unit for production of the articles is installed in the process space of the containment means, in the pivot range of the manipulating element of the at least one robot. The process unit is configured as a washing station, drying station, sterilizing station, filling station, closing station, assembly or disassembly station, identification station or test station. The test station is set up for optical inspection and/or weight control. A plurality of process units with various functions can be installed in the process space.

In order to form a modular system of containment means, a predefined positioning grid is provided for anchoring the foot of the at least one robot to the side faces inside the base space of the respective containment means.

The base space is delimited by an inclined bottom face which promotes the removal of an airflow, preferably of a laminar nature, flowing through the chamber and of liquids that arise in the process space during the production of the articles.

Moreover, at least one transfer station for interim positioning of article parts and/or articles and/or at least one storage means for storing article parts are arranged in the process space.

The manipulating elements have a pick-up grid for picking up a grouped number of article parts or articles. The storage means can be assigned a magazine for filling a manipulating element, according to its pick-up grid, with a grouped number of article parts. A respective pick-up grid of the process units and transfer station is configured to simultaneously handle a grouped number of article parts or articles in a manner numerically and geometrically matching the pick-up grid of the manipulating elements. The manipulating element can additionally be equipped with an assembly or disassembly device, an inspection device and/or a closing device and/or an identification device.

A replaceable exchange module, which is equipped with function-specific process units, is insertable into one of the housing faces delimiting the process space. The exchange module can have, in addition to the process units, a lock device for loading/unloading article parts or articles. Functionally identical process units can be arranged in mutually staggered cascades.

A first containment means is linked to further containment means in a production line to form a containment means chain. The respective base space and the respective process space can be equipped in a task-specific manner with robots, manipulating elements and/or process units and/or transfer stations and/or storage means. The pivot range of the at least one manipulating element on the at least one robot extends in a horizontal plane at least beyond one of the vertical faces of the process space.

Inside a containment means chain, the first containment means has a first through-opening via which article parts, in the form of receptacles placed in a tray systematically according to a sorting grid, are delivered to the process space. Thus, a grouped number of the receptacles can be gripped by the manipulating element of the first robot and brought to the first process unit in order to carry out the first production step. The first containment means has a second through-opening or is open toward an adjacent containment means for the purpose of transferring the article parts, processed thus far, into the process space of the next containment means in order to carry out subsequent production steps by means of further robots and further process units. The final containment means of the containment means chain, with the final robots and final process units installed therein, is intended for carrying out final production steps. This final containment means has a second through-opening through which the finished produced articles can be output.

The pick-up grid of the manipulating elements is designed to be adjustable by an adjustment mechanism, in order to establish compatibility if the sorting grid initially deviates from the pick-up grids of the process units and transfer station.

The finished produced article comprises as article parts:

- a receptacle;
- a pharmaceutical or biotechnical filling as liquid or powder introduced into the receptacle through the filling opening of the latter;
- a first closure in the form of a stopper or of a thermally produced closure; and
- an optional second closure in the form of an element, e.g. a crimped cap, engaging with a form fit over the first closure and serving to secure the first closure.

A process unit has the form of a weighing station which is supported on a foundation outside the chamber or directly outside the containment means and is thus insulated from shocks.

The weighing station has a weighing tray with a pick-up grid which is compatible with the other pick-up grids and which is intended:

- for the insertion of a grouped number of receptacles provided with the filling and deposited by the manipulating element; and
- for individual weight measurement of each one of the filled receptacles.

The storage means is provided with a vibration device for the purpose of filling the magazine and is supported outside the chamber in order to avoid interference vibrations.

A tunnel extends through the individual containment means and the containment means chain and serves to ensure that the trays emptied of receptacles at the first through-opening bypass the chamber and are made available again at the second through-opening in order to pick up the finished produced articles and, after emptying, are returned to the first through-opening.

The containment means is configured as:

- an open or closed restricted access barrier system (RABS) with an air treatment device of clean-room classification; or
- an isolator with an air treatment device of clean-room classification and a decontamination device.

The air treatment device has an inflow air filter, which is arranged above the process space, and an outflow air filter, which is installed in a seat present at the base space.

Brief description of the attached drawings

In the drawings shows:

Figure 1A – a side view of a containment means, for example in the form of an isolator, only as a housing in vertical section;

Figure 1B – a front perspective view of the containment means according to Figure 1A, equipped with robots, process units, an exchange module, a lock device, through-openings, and receptacles made available in a tray;

Figure 1C – the arrangement according to Fig. 1B in a front view;

Figure 1D – the vertical section on the line A–A in Figure 1C;

Figure 1E – the vertical section on the line B–B in Figure 1D;

Figure 2A – a front perspective view of the arrangement according to Figure 1B without the lock device, with both robots in the operating mode (washing and drying);

Figure 2B – the arrangement according to Figure 2A in a front view;

Figure 2C – the vertical section on the line C–C in Figure 2B;

Figure 2D – the vertical section on the line D–D in Figure 2C;

Figure 3A – a front view of a complete article;

Figure 3B – the vertical section on the line E–E in Figure 3A;

Figure 3C – the complete article according to Figure 3A in an exploded perspective view;

Figure 3D – the vertical section on the line F–F in Figure 3C;

Figure 4A – a schematic perspective view of the interaction of two robots in the transfer/ acceptance of articles or article parts;

Figure 4B – the assembly according to Figure 4A in a perspective plan view;

Figure 4C – the first robot from Figure 4A, in a perspective view of the manipulating element;

Figure 4D – an enlarged perspective view of the manipulating element of the first robot from Figure 4A with receptacles, in the form of vials, gripped at the necks;

Figure 5 – a perspective view of the assembly according to Figure 2A, with an approaching exchange module;

Figure 6A – the exchange module according to Figure 5 in an enlarged perspective view;

Figure 6B – a perspective view of an alternative exchange module with a process unit in the form of a capping device for applying second closures;

Figure 7A – a perspective plan view of the containment means according to Figure 1A, equipped with two robots in the operating mode (filling and plugging), a process unit, a parts magazine with first closures, receptacles made available in the tray at the first through-opening, a tray with closed receptacles at the second through-opening;

Figure 7B – the assembly according to Figure 7A in a front view;

Figure 7C – a perspective plan view of the arrangement according to Figure 7A, supplemented with a weighing station, with both robots in the operating mode (filling, weighing and plugging);

Figure 7D – the assembly according to Figure 7C in a front view;

Figure 7E – a perspective view of the weighing station from Figure 7D; and

Figure 8 – a containment means chain, with five interlinked containment means for carrying out different production cycles.

Illustrative embodiment

The constructive assembly of a containment means according to the invention, intended for the automated production of pharmaceutical or biotechnical articles, is described in detail below with reference to the appended drawings.

The following stipulation applies to the entirety of the rest of the description. Where reference numbers appear in a figure in order to avoid ambiguity, but are not explained in the directly associated text of the description, their mention in a preceding description of a figure is incorporated by reference. In the interests of clarity, component parts are generally not designated again in subsequent figures, provided that it is unambiguously clear from the drawing that these are “recurring” component parts.

Figure 1A

The containment means **9**, here in the form of an isolator, is first of all shown only in a substantially empty assembly with the housing **90** in order to explain the spatial division and walls. A transparent pane **911** usually sits in the front wall **910**, while an exchange module **95** is inserted into the rear wall **912**. The housing **90**

moreover comprises an upper wall and a lower wall which, together with the front wall **910** and rear wall **912**, delimit the containment means **9** from the outside. Inside the containment means **9** is the inner chamber **91**, which is constructed as a process space **93** and, beneath the latter, as a tub-shaped base space **92** which, at the bottom, terminates at a beveled bottom face **914**, beneath which the bottom space **97** is located. Process space **93** and base space **92** adjoin each other in an open and congruent manner. At its lowest point, the bottom face **914** has a water removal opening **920**, adjacent to which an outflow air filter **940** is inserted into the rear wall **912** and protrudes into the rear space **99**. The tunnel **990** extends through the rear space **99**. Extending inside the process space **93** is a vertical working range a, which is defined between a minimum working height a_{min} and a maximum working height a_{max}. At the top, the chamber **91** and process space **93** terminate at a ceiling face **915**, on which there is installed an inflow air filter **94** that protrudes into the roof space **98**. During the operation of the containment means **9**, a typical laminar airflow **L** is introduced from above through the inflow air filter **94** into the chamber **91**, which airflow **L** flows out of the chamber **91** at the bottom via the outflow air filter **940**.

Figures 1B to 1E

This sequence of figures illustrates the containment means **9** equipped with two robots **1**,**2**, two process units **3**, an exchange module **95**, a lock device **96**, the input-side through-opening **917** and the output-side through-opening **919**. Receptacles **70** made available in a sorting grid **800** in a tray **8** are brought to the through-opening **917** at the input side. There is nothing present at this moment at the through-opening **919** at the output side. On the side of the exchange module **95** directed toward the process space **93**, the process units **3** are installed, e.g. in a cascade formation, and washing and drying nozzles are arranged in a pick-up grid **30**. Collecting basins **39** for collecting washing liquid are arranged under the process units **3**. The lock device **96** (see Figures 1B,1C) integrated in the exchange module **95** is located between the two process units **3**.

The feet **10**,**20** of the robots **1**,**2** are anchored to the rear wall **912** in the base space **92**; the robot arms **11**,**21**, with the manipulating elements **12**,**22** arranged at

the very front (see also Figures 2C and 2D), protrude upward into the process space **93**. In order to form a modular system of containment means **9**, a predefined positioning grid is provided for anchoring the feet **10**, **20** of the robots **1**,**2** to the side faces **910**,**912**,**916**,**918** inside the base space **92** of the respective containment means **9**. The manipulating element **12**,**22** has the function of gripping and transporting means for the articles **6** or article parts **7**;**70–72** and/or of inspecting the articles **6** or article parts **7**;**70–72** and/or producing the articles **6** (see also Figure 2A). Moreover, in addition to the purely gripping or holding function, the manipulating element **12**,**22** could also be equipped with an assembly or disassembly device, an inspection device and/or a closing device and/or an identification device. In addition or alternatively to the lock device **96**, the exchange module **95** can support a transfer station **4**, which has the pick-up grid **40** (see Figure 1E).

The pivot range ($\mathbf{R_1}$,$\mathbf{R_2}$) of the manipulating elements **12**,**22** on the robot arms **1**, **2** extends in a horizontal plane and a vertical plane, namely in a vertical plane within a working range a having the minimum working height and maximum work heighting $\mathbf{a_{min}}$, $\mathbf{a_{max}}$ (see Figure 1A). In the horizontal plane, the pivot range ($\mathbf{R_1}$,$\mathbf{R_2}$) is preferably sufficiently dimensioned across the side faces **916**,**918** in order to be able to grasp the receptacles **70** standing systematically in the sorting grid **800** in the tray **8** at the input-side through-opening **917** and, after treatment of the receptacles **70**, to position them in the output-side through-opening 919. Within the pivot range ($\mathbf{R_1}$,$\mathbf{R_2}$), at least one transfer region is provided which is intended, by means of the manipulating element **12**,**22** of at least one robot **1**,**2**, for picking up or positioning articles **6** or article parts **7**;**70–72**. In a further embodiment, two transfer regions are provided within the pivot range ($\mathbf{R_1}$,$\mathbf{R_2}$). In this case, the first transfer region is intended for picking up articles **6** or article parts **7**;**70–72** by means of the manipulating element **12**,**22** of at least one robot **1**, **2**. By contrast, the second transfer region would be provided for positioning articles **6** or article parts **7**;**70–72** by means of the manipulating element **12**,**22** of at least one robot **1**,**2** (see also Figures 2A and 3A–3C).

Extending through the individual containment means **9** and the containment means chain **9'** is the tunnel **990**, which serves to ensure that the trays **8** emptied of receptacles **70** at the input-side through-opening **917** bypass the chamber **91** and are made available again at the second through-opening **919** in order to receive the finished produced articles **6** and are brought back in the opposite direction to the input-side through-opening **917** after emptying (see also Figure 8).

Figures 2A to 2D

This sequence of figures illustrates the containment means **9** with both robots **1**,**2** in the operating mode. The arm **11** of the first robot **1** pivots toward the input-side through-opening **917** in order, by means of the associated manipulating element **12**, to pick up a grouped number of empty and open receptacles **70** (e.g. the very front row of receptacles **70**) from the tray **8** standing there, which tray **8** is loaded with the receptacles **70** in the sorting grid **800**, and to deliver them to the adjacent process unit **3**. This process unit **3** could be a first washing station. In an interim step, the first robot **1** had placed the group of receptacles **70** previously washed at the washing station onto the transfer station **4** in the pick-up grid **40** thereof. The group standing on the transfer station, serving as transfer region, is grasped by the manipulating element **22** of the second robot **1** and delivered firstly to the associated process unit **3**, which could be a second washing station. After the second cleaning procedure, the second robot **2** transports the now twice cleaned group of receptacles onto the tray **8** standing at the output-side through-opening **919** in the sorting grid **800** for further processing, usually inside a plurality of containment means **9** linked to one another in a production line to form a containment means chain **9'**.

Figures 3A to 3D

A finished produced article **6** comprises, as article parts **7**, firstly a receptacle **70**, here in the form of a typical vial, which has a filling opening **73** for introducing a pharmaceutical or biotechnical filling **79** as liquid or powder into the receptacle **70**. Moreover, the complete article **6** has a first closure **71**, here in the form of a stopper. A stopper could also be produced by thermal means. Finally, the complete article **6** can comprise an optional second closure **72**, namely in the form

of an element, e.g. a crimped cap, which engages over the first closure **71** with a form fit and secures the first closure **71**.

Figures 4A to 4D

This sequence of figures illustrates the interaction of two robots **1**,**2** and their manipulating elements **12**,**22** in the transfer/acceptance, taking the example of a grouped number of receptacles **70** which are delivered and still held by the manipulating element **12** of the first robot **1** at a spatially floating transfer region and are now gripped by the manipulating element **22** of the second robot **2** for acceptance. For example, the manipulating element **12** of the first robot **1** holds a group of receptacles **70** suspended by their vial necks in accordance with pick-up grid **120**. The group of receptacles **70** is accepted by being grasped by the manipulating element **22** of the second robot **2** according to pick-up grid **120** and held like tongs between their bottoms and upper ends. Then, by movement of the arm **21** of the second robot **2**, the group of receptacles **70** thus gripped is as it were lifted out of the pick-up grid **120** from the manipulating element **12** of the first robot **1** and transported onward.

The sorting grid **800** in the trays **8**, the pick-up grid **30** of the process units **3** and the pick-up grid **40** of the transfer station **4** are not always compatible from the outset with the pick-up grids **120**,**220** of the manipulating elements **12**,**22**. To establish compatibility, the pick-up grids **120**,**220** of the manipulating elements **12**, **22** are designed to be adjustable by means of an adjustment mechanism.

Figures 5 and 6A

A replaceable exchange module **95** is insertable into one of the housing faces **910**,**912**,**916**,**918** delimiting the process space **3**, here preferably into a recess **913** of the rear wall **912**. In the example shown, two cascade-shaped process units **3** with their pick-up grids **30** are provided alongside each other. A collecting basin **39** is arranged under each of them. Both process units **3** could be washing stations; the right-hand one could also be configured as a drying station. A transfer station **4** with the pick-up grid **40** is installed between the two process units **3**. This replaceability of the exchange module **95**, with the possibility of being equipped in

a function-specific manner with process units **3**, permits modular and thus production-efficient assembly of individual containment means **9**, and also of a plurality of containment means **9** linked to one another to form a containment means chain **9'**.

In addition to the process units **3**, the exchange module **95** can have a lock device **96** for the loading and/or unloading of article parts **7** or articles **6** (see Figure 1A). The individual process unit **3** can be configured as a washing station, drying station, sterilizing station, filling station, closing station, assembly or disassembly station, identification station or test station. A test station is set up for optical inspection and/or weight control.

Figure 6B

On this exchange module **95**, a process unit **3** is installed in the form of a capping device with its pick-up grid **30** for applying the second closures **762** over the previously applied first closures **71**. The second closures **72** serve to secure the first closure **71** and engage over the latter in the manner of a crimped cap.

Figures 7A and 7B

This sequence of figures illustrates the production steps by which receptacles **70** in a containment means **9** are filled and subsequently closed. The empty receptacles **70** made available in the tray **8** according to sorting grid **800** are located at the input-side through-opening **917**. The two robots **1**,**2**, running in the operating mode, are once again present in the chamber **91**. A process unit **3** with its pick-up grid **30** is installed as a filling station on the exchange module **95**. It is assumed that the receptacles **70** provided with the filling **79** at the process unit **3** and suspended in the associated manipulating element **12** have been transported by the first robot **1** to a floating transfer region, which the second robot 2 approaches with its manipulating element **22**. First closures **71**, e.g. stoppers, are gripped in this manipulating element **22** according to the pick-up grid **220**, in order to close the filled receptacles **70** in a subsequent production step.

The closures **71** are made available from a storage means **5** which is present in the process space **93** and in which the closures **71** are stored. The storage means **5** is assigned a magazine **50** for filling the manipulating element **22** with a grouped number of closures **71** according to its pick-up grid **220**. The storage means **5** is provided with a vibration device for filling the magazine **50**. Preferably, the storage means **5** is supported outside the chamber **91** in order to avoid interference vibrations.

After the first closures **71** have been placed on the filled receptacles **70**, in a simple case the articles **6** could be regarded as finished and would be delivered as such from the second robot **2** to the output-side through-opening **919** and onto the tray **8** standing there, in the sorting grid **800**.

Figures 7C to 7E

Before the filled receptacles **70** are closed, a check to verify the correct filling quantity is often made by means of a process unit **3** in the form of a weighing station **35** which is configured to individually measure the weight of each of the filled receptacles **70** and is preferably supported outside the chamber **91**, or directly outside the containment means **9**, on a foundation F and is thus insulated from shocks. The weighing station **35** has a weighing tray **36** with a pickup grid **30**, which should be compatible with the other pick-up grids **120**,**220**;**30**,**40**.

Figure 8

The containment means chain **9'** shown by way of example consists of five interconnected containment means **9** for carrying out different production steps, beginning with the making available of empty receptacles **70** at the input-side through-opening **917**, through to the ejection of the finished articles **6** at the output-side through-opening **919**. Between these lie the cleaning of the containers **70**, the introduction of the filling **79**, the weight control, and the application of the first closures **71** and, if appropriate, also the second closures **72**.

The base space **92** and the process space **93** of the individual containment means **9** are each equipped, in a task-specific manner, with robots **1**,**2** having

manipulating elements **12**,**22** and/or with process units **3** and/or transfer stations **4** and/or storage means **5**.

The first containment means **9** has the first through-opening **917** via which article parts **7** in the form of receptacles **70**, arranged in a tray **8** systematically according to a sorting grid **800**, are delivered to the process space **93**. In this way, a grouped number of the receptacles **70** can be grasped by the manipulating element **12** of the first robot **1** and brought to the first process unit **3** for carrying out the first production step. The first containment means **9** moreover has a second through-opening **919** or is open toward a next containment means **9** for the purpose of transferring the processed article parts **7** into the process space **93** of the next containment means **9** in order to carry out subsequent production steps by means of further robots **2** and further process units **3**. The final containment means **9** of the containment means chain **9'**, with the final robots **2** and final process units **3** installed therein, is intended for carrying out final production steps. This final containment means **9** has the second through-opening **919** through which the finished produced articles **6** can be output and positioned on a tray **8**.

After the trays **8** have been emptied of the finished produced articles **6**, the trays **8** can be returned through the tunnel **990** to the starting position at the first through-opening **917** on the first containment means **9** for the subsequent delivery of receptacles **80** set up systematically according to the pick-up grid **800**.

P A T E N T K R A V

1. Konstruktiv struktur af en indeslutning (9) bestemt til automatiseret produktion af farmaceutiske eller biotekniske artikler (6), hvor:

a) en artikel (6) som slutprodukt hver omfatter flere artikeldele (7);

b) indeslutningen (9) er omgivet af et hus (90), og der deri befinder sig et indre kammer (91) med mindst ét gennemløb (917, 919);

c) der i kammeret (91) er installeret mindst én robot (1, 2), som på sin svingbare arm (11, 21) besidder mindst ét manipuleringsorgan (12, 22), hvilket kan bevæges indenfor et svingområde (R_1, R_2), og

d) kammeret (91) er egnet til installation af mindst én procesenhed (3) til produktion af artiklerne (6), hvor

e) kammeret (91) omfatter:

ea) et procesrum (93) til produktion af artiklerne (6); og

eb) et baljeformet basisrum (92) til forankring af foden (10, 20) af den mindst ene robot (1, 2) til en af sidefladerne (910, 912, 916, 918) indvendigt i basisrummet (92); hvor

ec) procesrummet (93) er anbragt oven over basisrummet (92), og de begge grænser kongruent åbent op til hinanden;

f) manipuleringsorganet (12, 22) har de følgende funktioner:

fa) griber og transportmiddel for artiklerne (6) eller artikeldelene (7); og/eller

fb) inspektion af artiklerne (6) eller artikeldelene (7); og/eller

fc) produktion af artiklerne (6); og

g) svingområdet (R_1, R_2) af det mindst ene manipuleringsorgan (12, 22) ved den mindst ene robot (1, 2) udstrækker sig i det horisontale og vertikale plan, nemlig i det vertikale plan inden for et arbejdsområde (a), som definerer sig mellem en minimal arbejdshøjde (amin) og en maksimal arbejdshøjde (amax).

2. Konstruktiv struktur ifølge krav 1, k e n d e t e g n e t ved, at der inden for svingområdet (R_1, R_2) er tilvejebragt mindst et overleveringsområde bestemt til ved hjælp af manipuleringsorganet (12, 22) af den mindst ene robot (1, 2) at opsamle eller at positionere artikler (6) eller artikeldele (7; 70-72).

3. Konstruktiv struktur ifølge krav 1, k e n d e t e g n e t ved, at der inden for svingområdet (R_1, R_2) er tilvejebragt to overleveringsområder; hvor

a) det første overleveringsområde er bestemt til ved hjælp af manipuleringsorganet (12, 22) af den mindst ene robot (1, 2) at opsamle artikler (6) eller artikeldele (7; 70-72); og

b) det andet overleveringsområde er bestemt til ved hjælp af manipuleringsorganet (12, 22) af den mindst ene robot (1, 2) at positionere artikler (6) eller

artikeldele (7; 70-72).

4. Konstruktiv struktur ifølge mindst ét af kravene 1 til 3, k e n d e t e g n e t ved, at

a) en første indeslutning (9) er forbundet med en anden indeslutning (9), i hver af hvilke der er installeret en robot (1, 2); og

b) et af overleveringsområderne ligger i svingområdet (R_1, R_2) af manipuleringsorganerne (12, 22) af begge robotter (1, 2).

5. Konstruktiv struktur ifølge mindst ét af kravene 1 til 3, k e n d e t e g n e t ved, at

a) der i indeslutningen (9) er installeret mindst to robotter (1, 2); og

b) et respektive overleveringsområde ligger i svingområdet (R_1, R_2) af manipuleringsorganerne (12, 22) af to ved siden af hinanden anbragte robotter (1, 2).

6. Konstruktiv struktur ifølge mindst ét af kravene 1 til 5, k e n d e t e g n e t ved, at der i procesrummet (93) af indeslutningen (9) i svingområdet (R_1, R_2) af manipuleringsorganet (12, 22) af den mindst ene robot (1, 2) er installeret mindst en procesenhed (3) til produktion af artiklerne (6).

7. Konstruktiv struktur ifølge mindst ét af kravene 1 til 6, k e n d e t e g n e t ved, at

a) procesenheden (3) er udformet som vaskestation, tørrestation, sterilisationsstation, påfyldningsstation, lukkestation, montage- eller demontagestation, markeringsstation eller efterprøvningsstation; hvor

b) efterprøvningsstationen er tilvejebragt til optisk inspektion og/eller vægtkontrol; og

c) der i procesrummet (93) kan installeres flere procesenheder (3) med forskellige funktioner.

8. Konstruktiv struktur ifølge mindst ét af kravene 1 til 7, k e n d e t e g n e t ved, at der til dannelse af et byggeklodssystem af indeslutninger (9) er tilvejebragt en forud defineret positionsraster til forankringen af foden (10, 20) af den mindst ene robot (1, 2) på sidefladerne (910, 912, 916, 918) indvendigt på basisrummet (92) af den respektive indeslutning (9).

9. Konstruktiv struktur ifølge mindst ét af kravene 1 til 8, k e n d e t e g n e t ved, at basisrummet (92) er begrænset af en hældende bundflade (914), som begunstiger en transport af en gennem kammeret (91) strømmende luftstrømning (L), fortrinsvis af laminar karakteristik, og i procesrummet (93) ved produktionen af artiklerne (6) opstående væsker.

10. Konstruktiv struktur ifølge mindst ét af kravene 1 til 9, k e n d e t e g n e t ved, at der i procesrummet (93) desuden er anbragt:

a) mindst én transferstation (4) til mellempositionering af artikeldele (7) og/eller artikler (6); og/eller

b) mindst ét lager (5) til lagerforsyning af artikeldele (7); hvor

c) manipuleringsorganerne (12, 22) omfatter en optageraster (120, 220) til optag af et grupperet antal af artikeldele (7) eller artikler (6); og

d) lageret (5) kan være tilordnet et magasin (50) til påfyldning af et manipuleringsorgan (12, 22) i overensstemmelse med dettes optageraster (120, 220) med et grupperet antal af artikeldele (7).

11. Konstruktiv struktur ifølge mindst ét af kravene 1 til 10, k e n d e t e g n e t ved, at

a) en respektive optageraster (30, 40) af procesenhederne (3) og transferstationen (4) til samtidig håndtering af et grupperet antal af artikeldele (7) eller artikler (6) er udformet talmæssigt og geometrisk komplementær til optagerasteren (120, 220) af manipuleringsorganerne (12, 22); og

b) manipuleringsorganet (12, 22) desuden kan være udrustet med en montage- eller demontageindretning, en inspektionsindretning og/eller en lukkeindretning og/eller en markeringsindretning.

12. Konstruktiv struktur ifølge mindst ét af kravene 1 til 11, k e n d e t e g n e t ved, at

a) der i en husflade (910, 912, 916, 918), som afgrænser procesrummet (93) kan indsættes et udskifteligt udvekslingsmodul (95), der er udrustet med funktionsspecifikke procesenheder (3);

b) udvekslingsmodulet (95) ud over procesenhederne (3) kan omfatte en sluseindretning (96) til ind- og/eller udslusning af artikeldele (7) eller artikler (6); og

c) funktionsmæssigt ensartede procesenheder (3) kan være anbragt i kaskader forsat i forhold til hinanden.

13. Konstruktiv struktur ifølge mindst ét af kravene 1 til 12, k e n d e t e g n e t ved, at

a) en første indeslutning (9) er anbragt forbundet med yderligere indeslutninger (9) i en produktionslinje til en indeslutningskæde (9'); hvor

b) det respektive basisrum (92) og det respektive procesrum (93) kan besidde en respektive opgavespecifik udrustning med robotter (1, 2), manipuleringsorganer (12, 22) og/eller procesenheder (3) og/eller transferstationer (4) og/eller lagre (5).

14. Konstruktiv struktur ifølge mindst ét af kravene 1 til 13, k e n d e t e g n e t ved, at svingområdet (R_1, R_2) af det mindst ene manipuleringsorgan (12, 22) ved den mindst ene robot (1, 2) i det horisontale plan udstrækker sig i det mindste indtil henover én af de vertikale flader (910, 912, 916, 918) af procesrummet (93).

15. Konstruktiv struktur ifølge mindst ét af kravene 13 og 14, k e n d e t e g n e t ved, at

a) den første indeslutning (9) har et første gennemløb (917) til levering af artikeldele (7) i udformning som i en bakke (8) systematisk i overensstemmelse med en sorteringsraster (800) indstillede beholdere (70) til procesrummet (93), og dermed lader et grupperet antal af beholderne (70) sig gribe af manipuleringsorganet (12) af den første robot (1), og kan føres hen til den første procesenhed (3) til gennemførsel af det første produktionstrin;

b) den første indeslutning (9) har et andet gennemløb (919), eller er åbent mod en anden indeslutning (9), til formål for overførsel af de så vidt bearbejdede artikeldele (7) til procesrummet (93) af den næste indeslutning (9) til gennemførsel af det næste produktionstrin ved hjælp af yderligere robotter (2) og yderligere procesenheder (3);

c) den sidste indeslutning (9) af indeslutningskæden (9') med de deri installerede sidste robotter (2) og sidste procesenheder (3) er bestemt til gennemførsel af afsluttende produktionstrin; og

d) denne sidste indeslutning (9) besidder et andet gennemløb (919), gennem hvilket de færdigproducerede artikler (6) lader sig udlevere.

16. Konstruktiv struktur ifølge mindst ét af kravene 11 til 15, k e n d e t e g n e t ved, at optagerasteren (120, 220) af manipuleringsorganet (12, 22) er udformet indstilleligt ved hjælp af en indstillingsmekanik, for at tilvejebringe kompatibilitet ved indledningsvis forhånden værende afvigelse af sorteringsrasteren (800) fra optagerasterne (30, 40) af procesenhederne (3) og transferstationen (4).

17. Konstruktiv struktur ifølge mindst ét af kravene 1 til 16, k e n d e t e g n e t ved, at de færdigproducerede artikler (6) som artikeldele (7) omfatter:

a) en beholder (70);

b) en i beholderen (70) gennem dennes påfyldningsåbning (73) appliceret farmaceutisk eller bioteknisk fyldning (79) som væske eller pulver;

c) et første lukke (71) i udformning som en prop eller et termisk opnået lukke; og

d) et valgfrit andet lukke (72) i udformning som et hen over det første lukke (71) formsluttende gribende element, f.eks. en kreppet kappe, som sikring af det første lukke (71).

18. Konstruktiv struktur ifølge mindst ét af kravene 1 til 17, k e n d e t e g n e t ved, at

a) en procesenhed (3) har udformning som en vejestation (35), som støtter sig mod et fundament (F) udenfor kammeret (91) eller direkte udenfor indeslutningen (9), og dermed er isoleret mod rystelser;

b) vejestationen (35) har en vejebakke (36) med en til de øvrige optagerastere (120, 220; 30 40) kompatibel optageraster (30), hvilken vejebakke er bestemt til:

ba) indsættelse af et af manipuleringsorganet (12, 22) afsat grupperet antal af de med fyldningen (79) forsynede beholdere (70); og

bb) er bestemt il individuel vægtmåling af hver enkelt af de flydte beholdere (70); og

c) lageret (5) er forsynet med en vibrationsindretning til formål for påfyldningen af magasinet (50); hvor

d) lageret (5) er støttet udenfor kammeret (91) til forhindring af forstyrrende vibrationer.

19. Konstruktiv struktur ifølge mindst ét af kravene 1 til 18, k e n d e t e g n e t ved, at

a) der gennem den enkelte indeslutning (9) og indeslutningskæden (9') udstrækker sig en tunnel (990); og

b) tunnelen (990) tjener dertil, at de ved det første gennemløb (917) for beholderne (70) tømte bakker (8) ved omgåelse af kammeret (91) atter står klar ved det andet gennemløb (919) til optag af de færdigproducerede artikler (6).

20. Konstruktiv struktur ifølge mindst ét af kravene 1 til 19, k e n d e t e g n e t ved, at indeslutningen (9) er udformet som:

a) åbent eller lukket barrieresystem med begrænset adgang< (RABS = Restricted Access Barrier System) med en luftbehandlingsindretning med renrumsklassifikation; eller

b) isolator med en luftbehandlingsindretning med renrumsklassifikation og dekontamineringsindretning; hvor

c) luftbehandlingsindretningen har et indløbsluftfilter (94), som er anbragt oven over procesrummet (93), og omfatter et udløbsluftfilter (940), der er installeret i et på basisrummet (92) forhåndenværende optag.

Fig. 1A

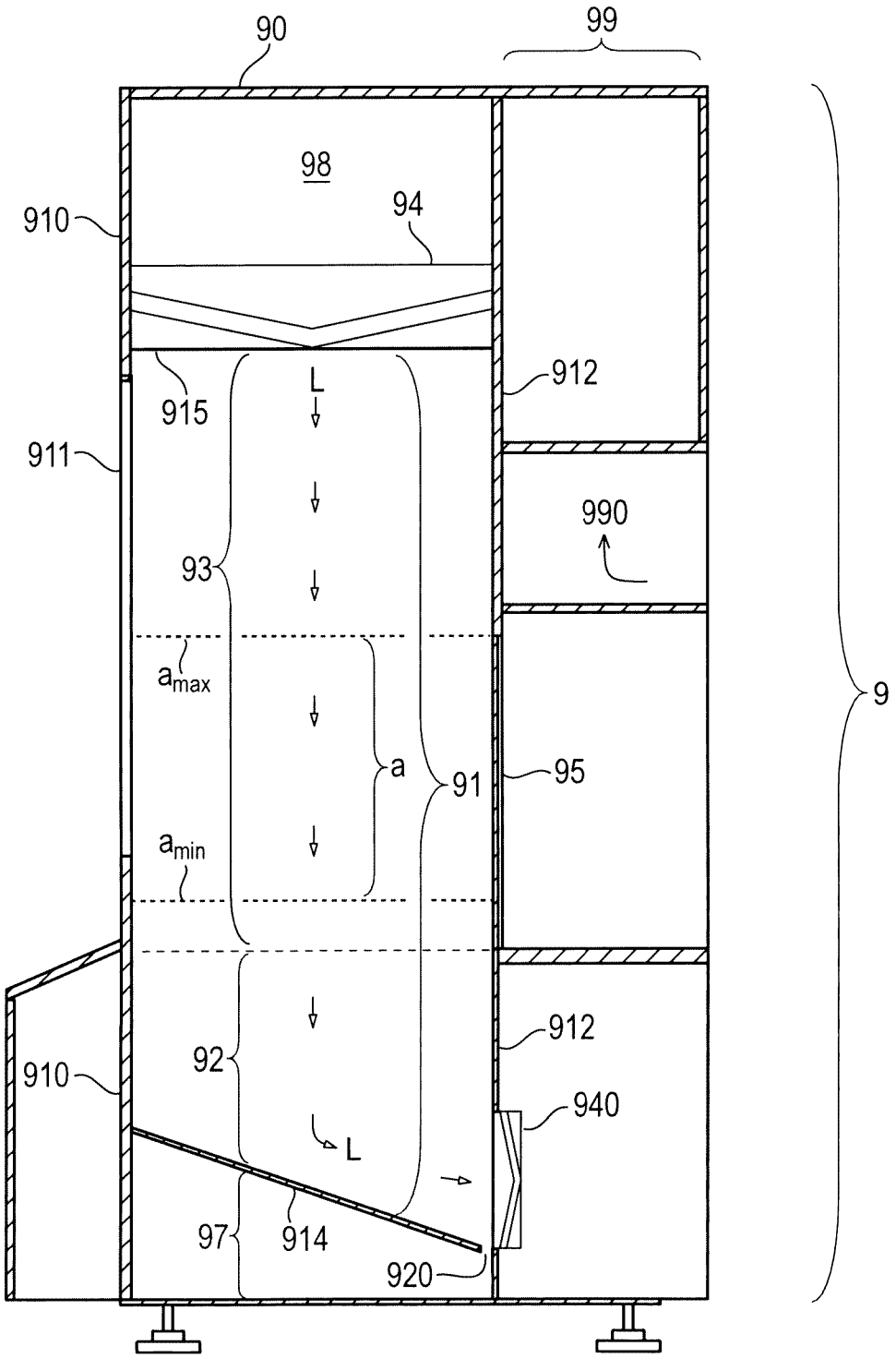
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Fig. 1B

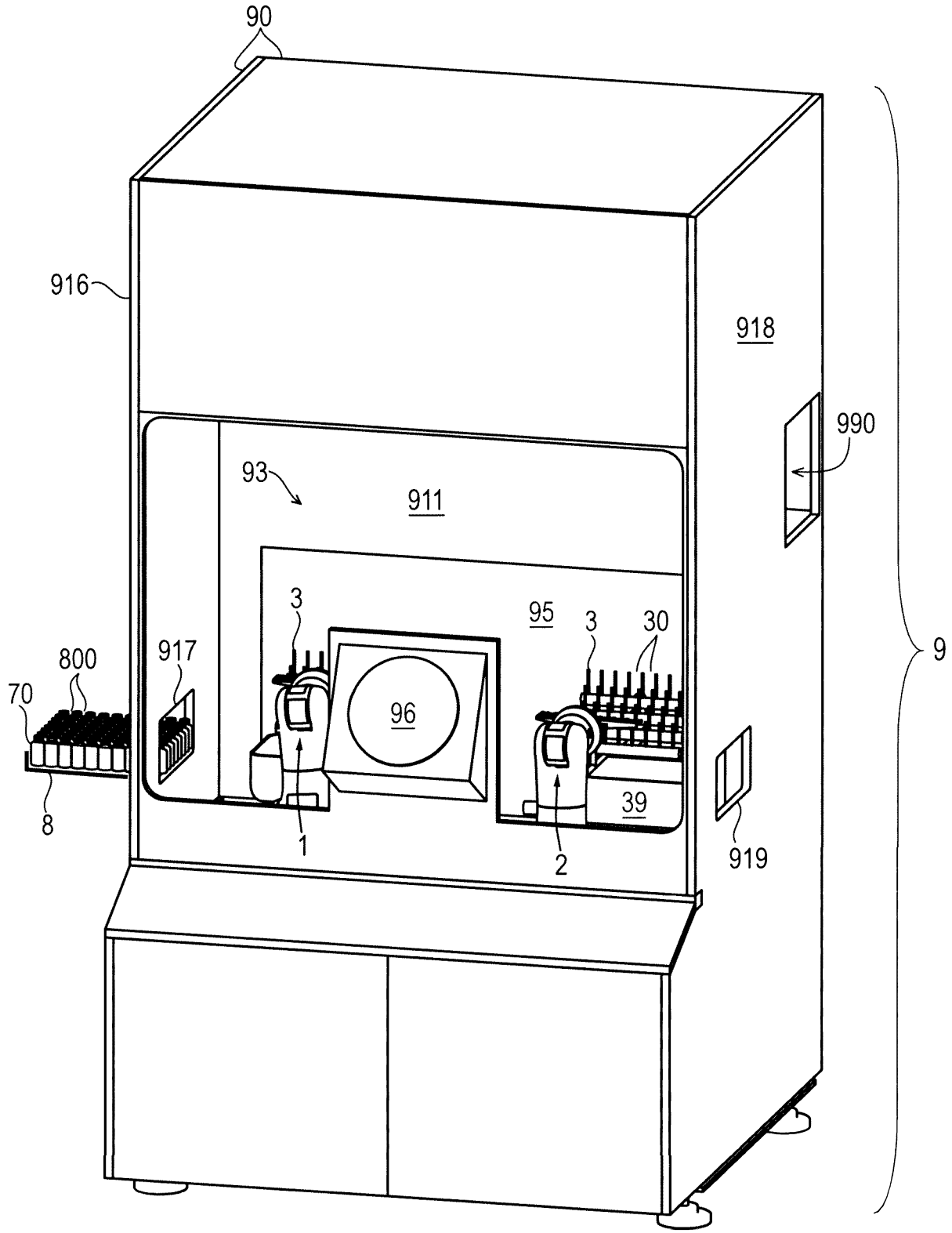

Fig. 1C

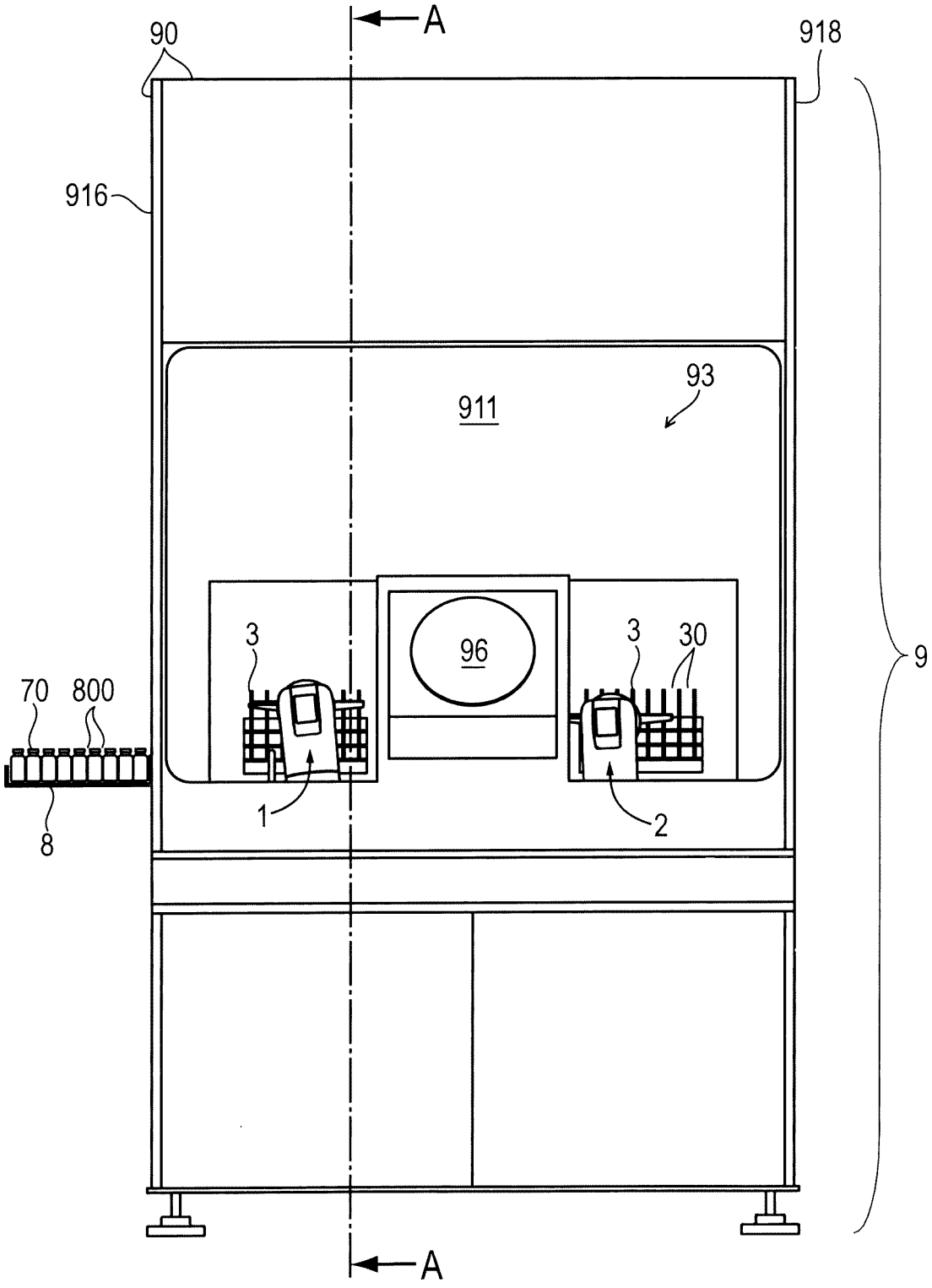

Fig. 1D

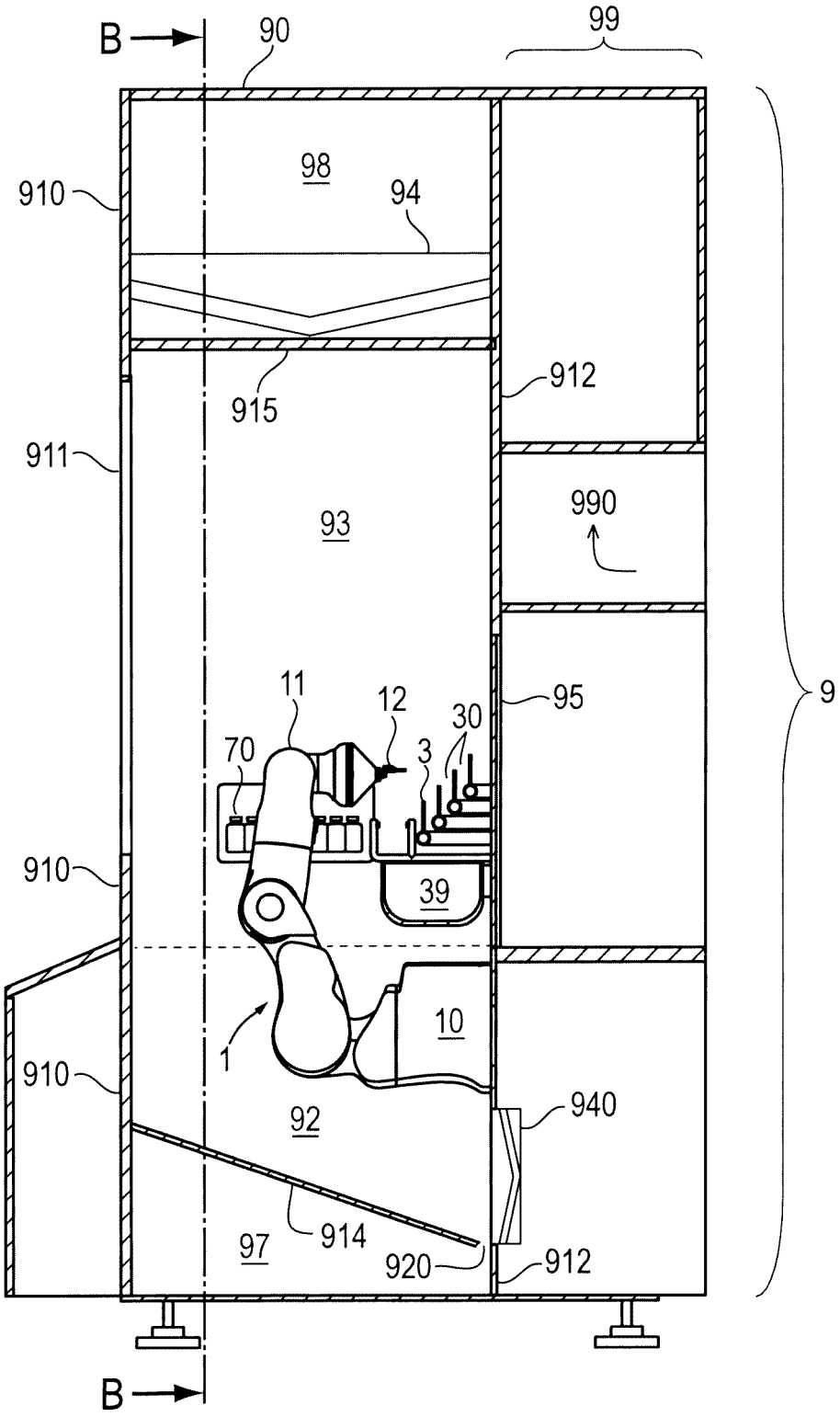
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Fig. 1E

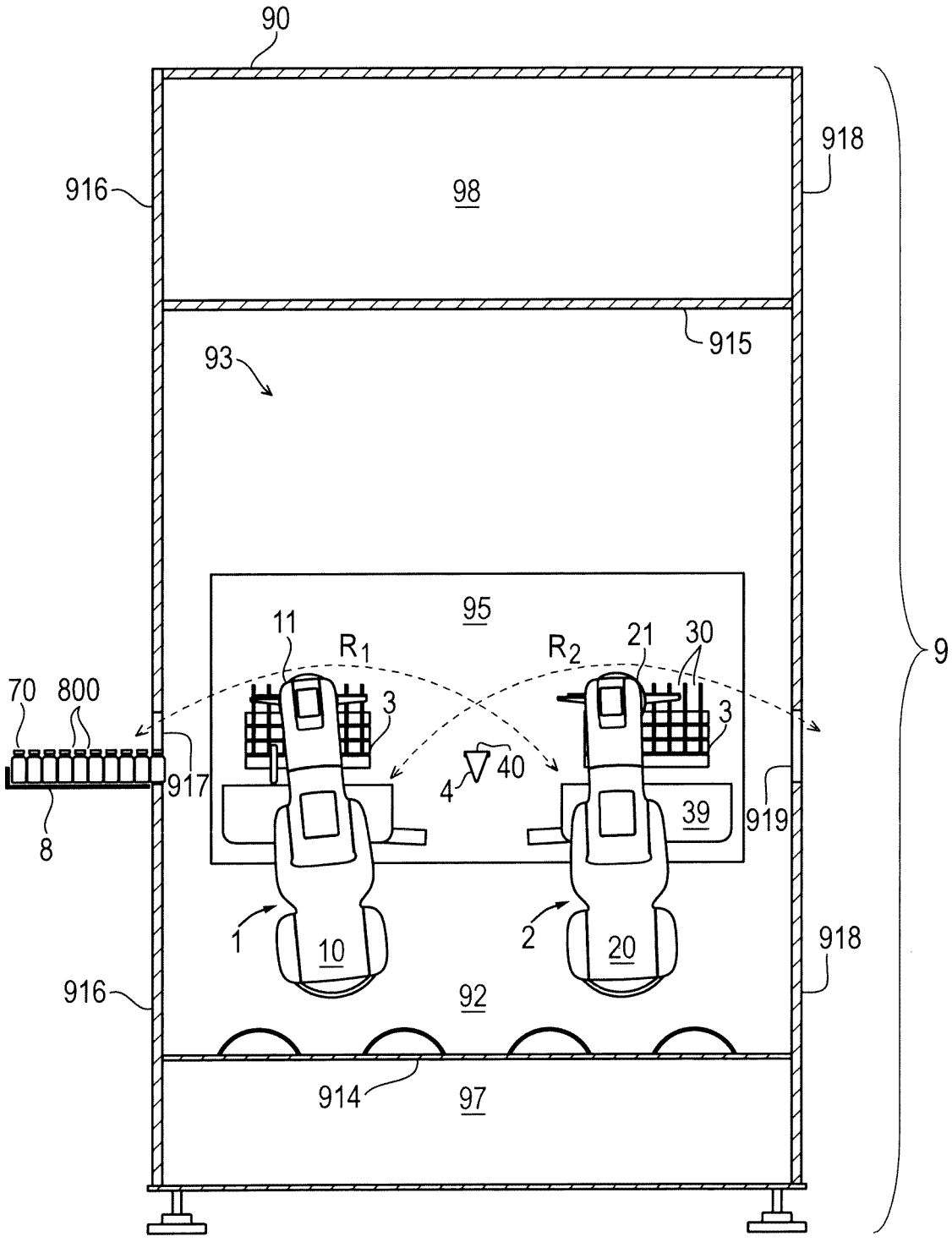
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Fig. 2A

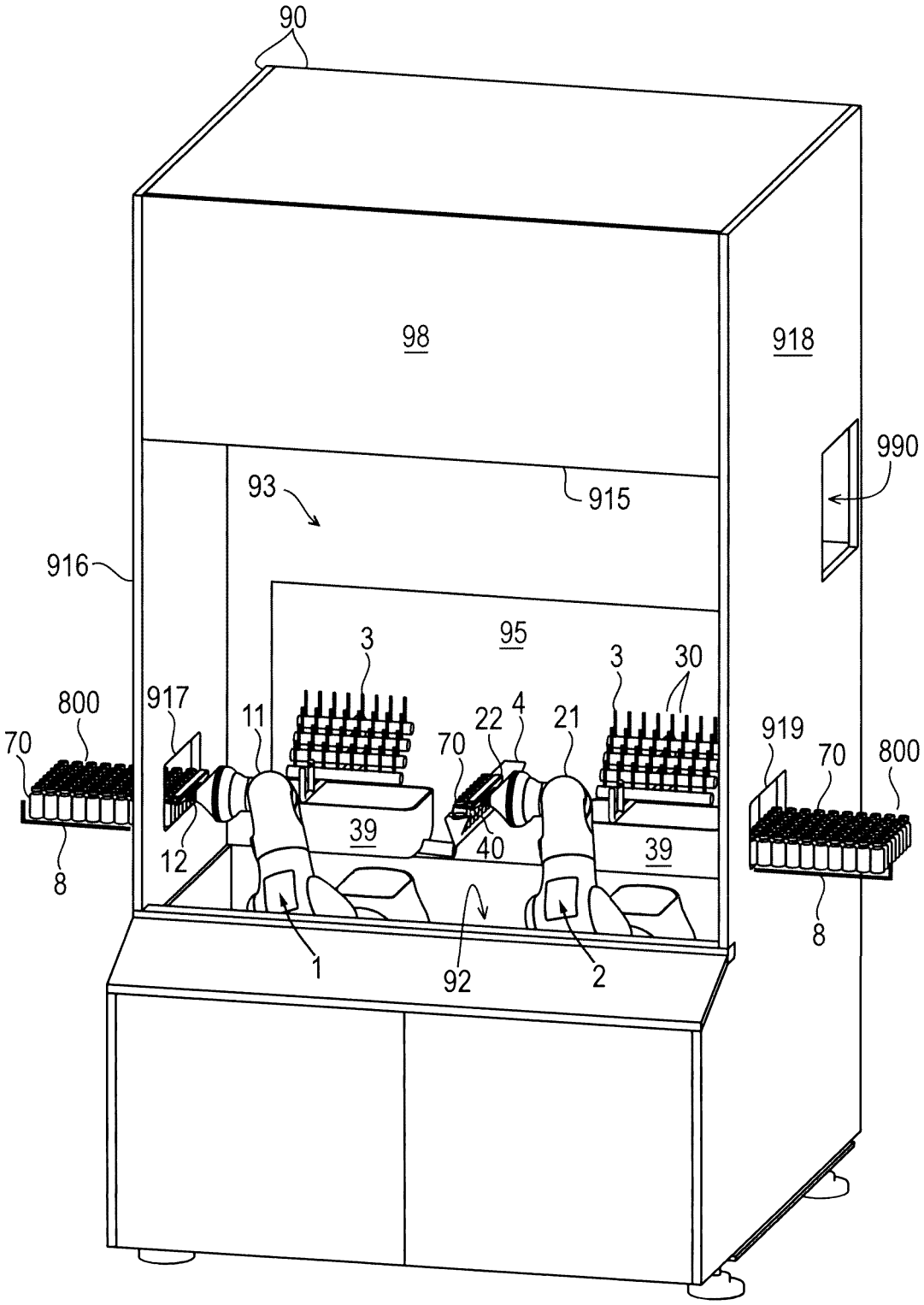
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Fig. 2B

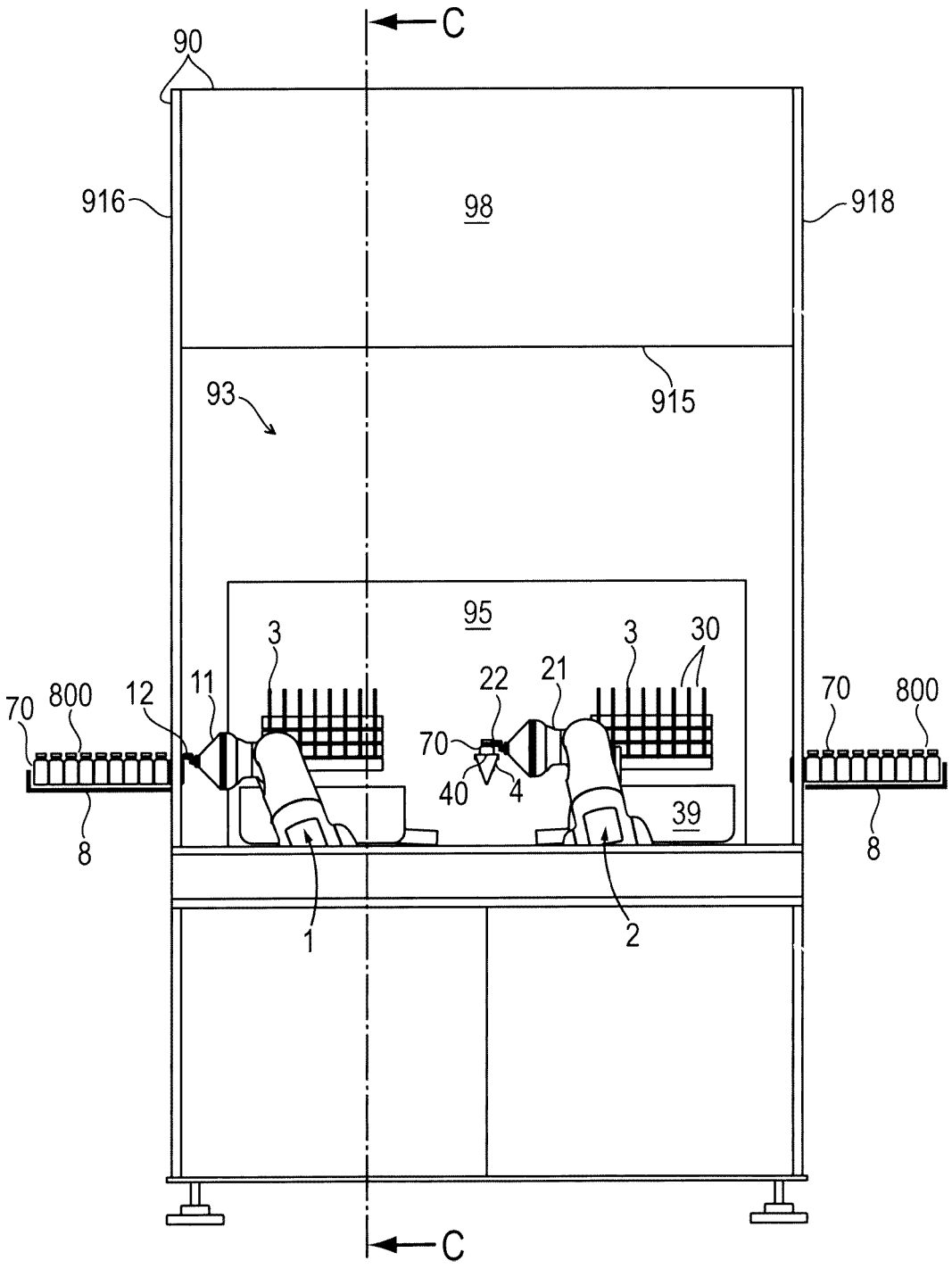
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Fig. 2C

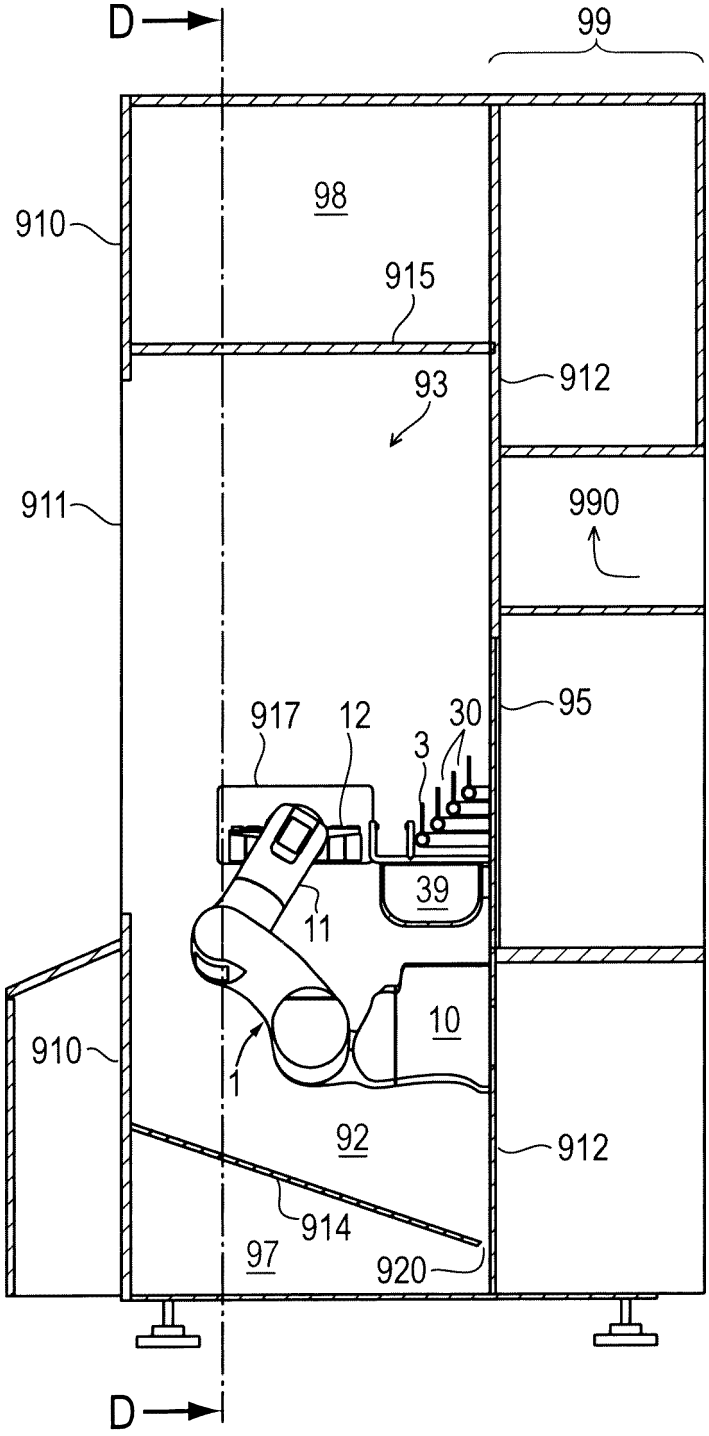
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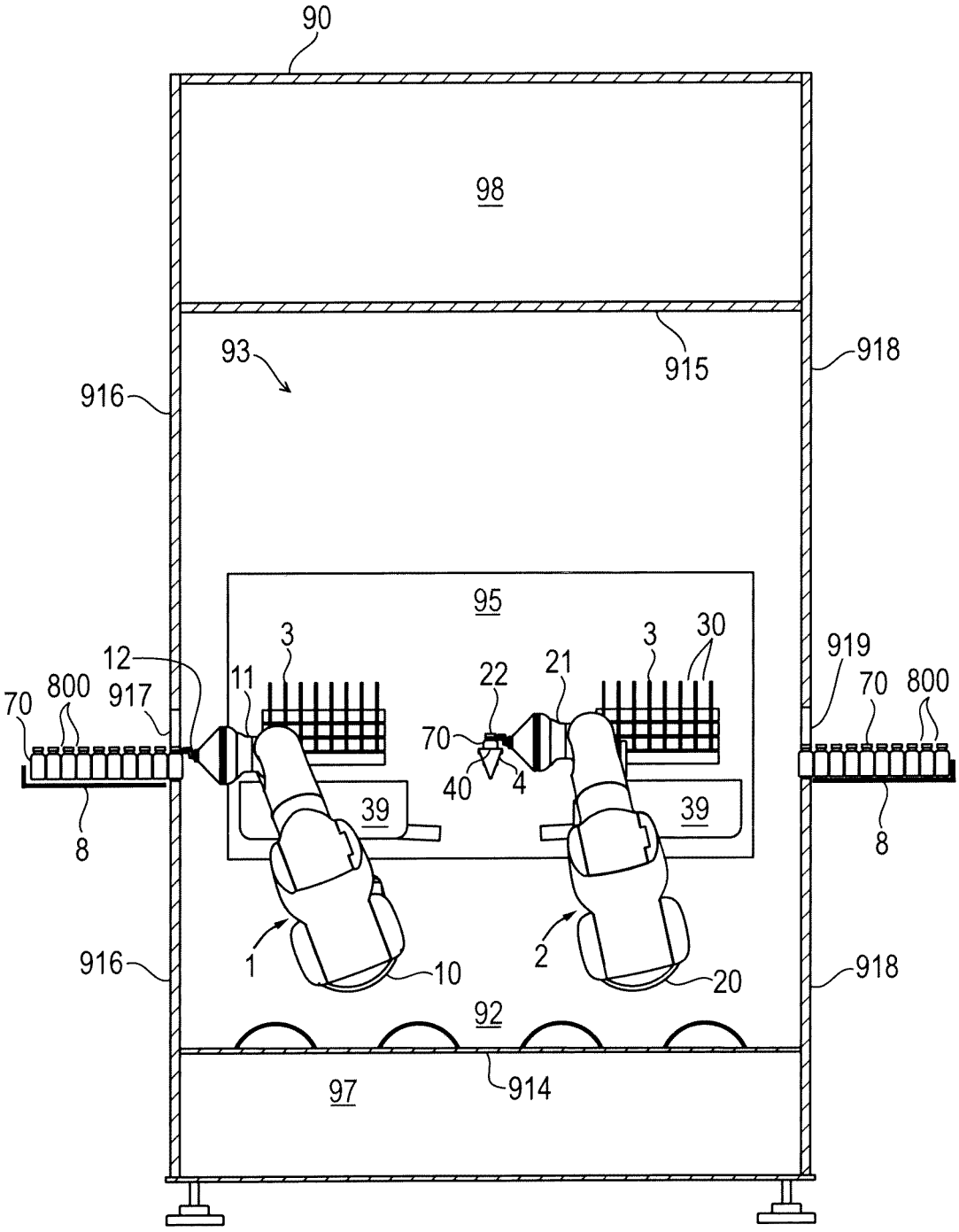
Fig. 2D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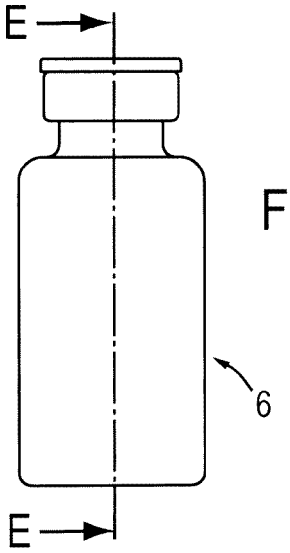


Fig. 3A

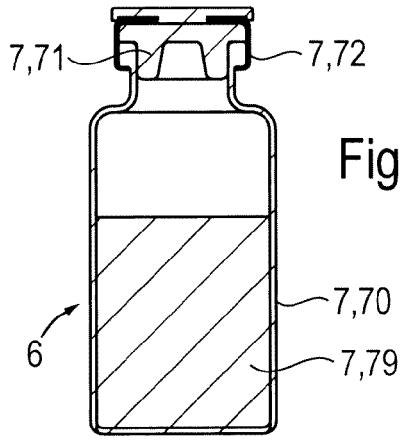


Fig. 3B

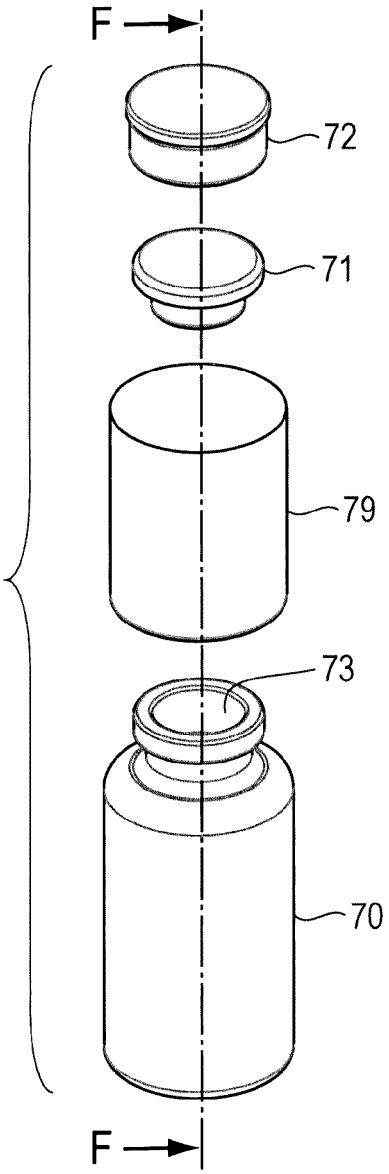


Fig. 3C

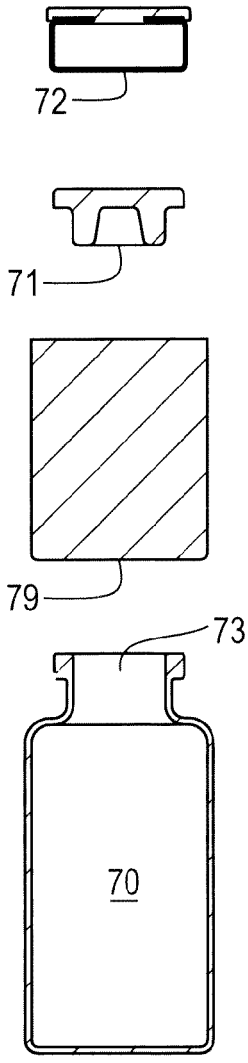


Fig. 3D

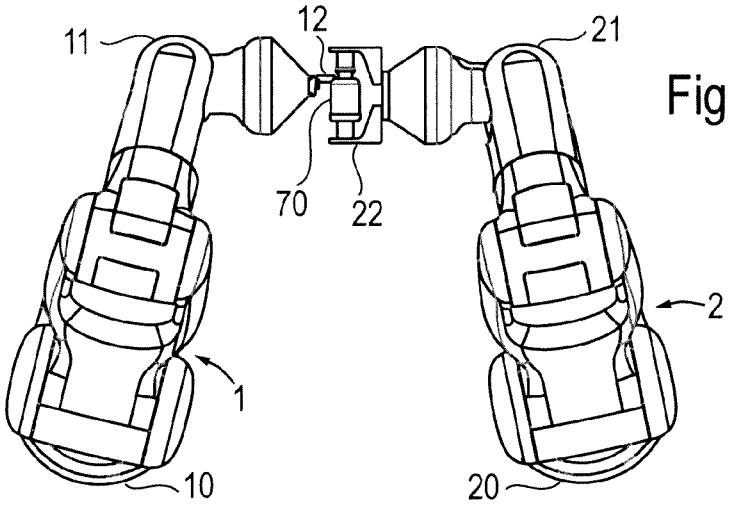


Fig. 4A

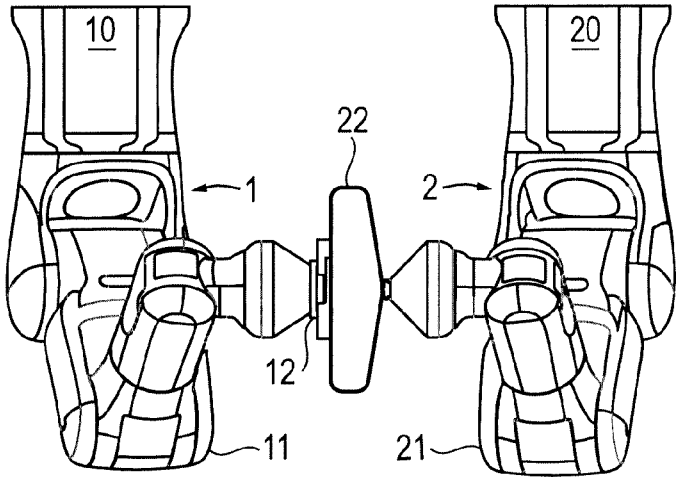
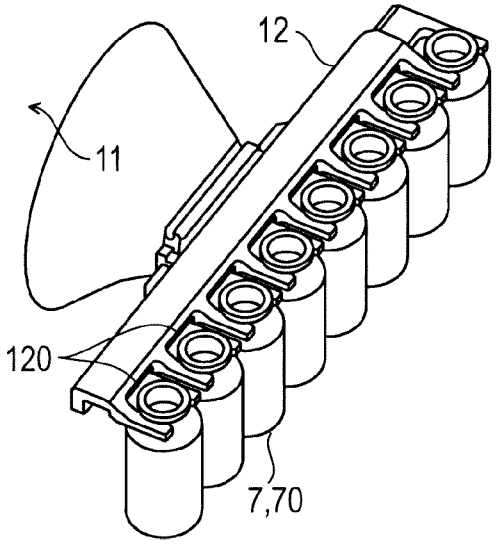


Fig. 4B

Fig. 4D



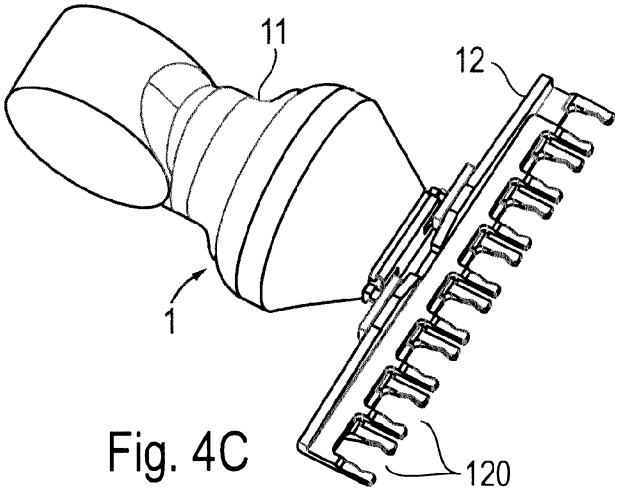


Fig. 4C

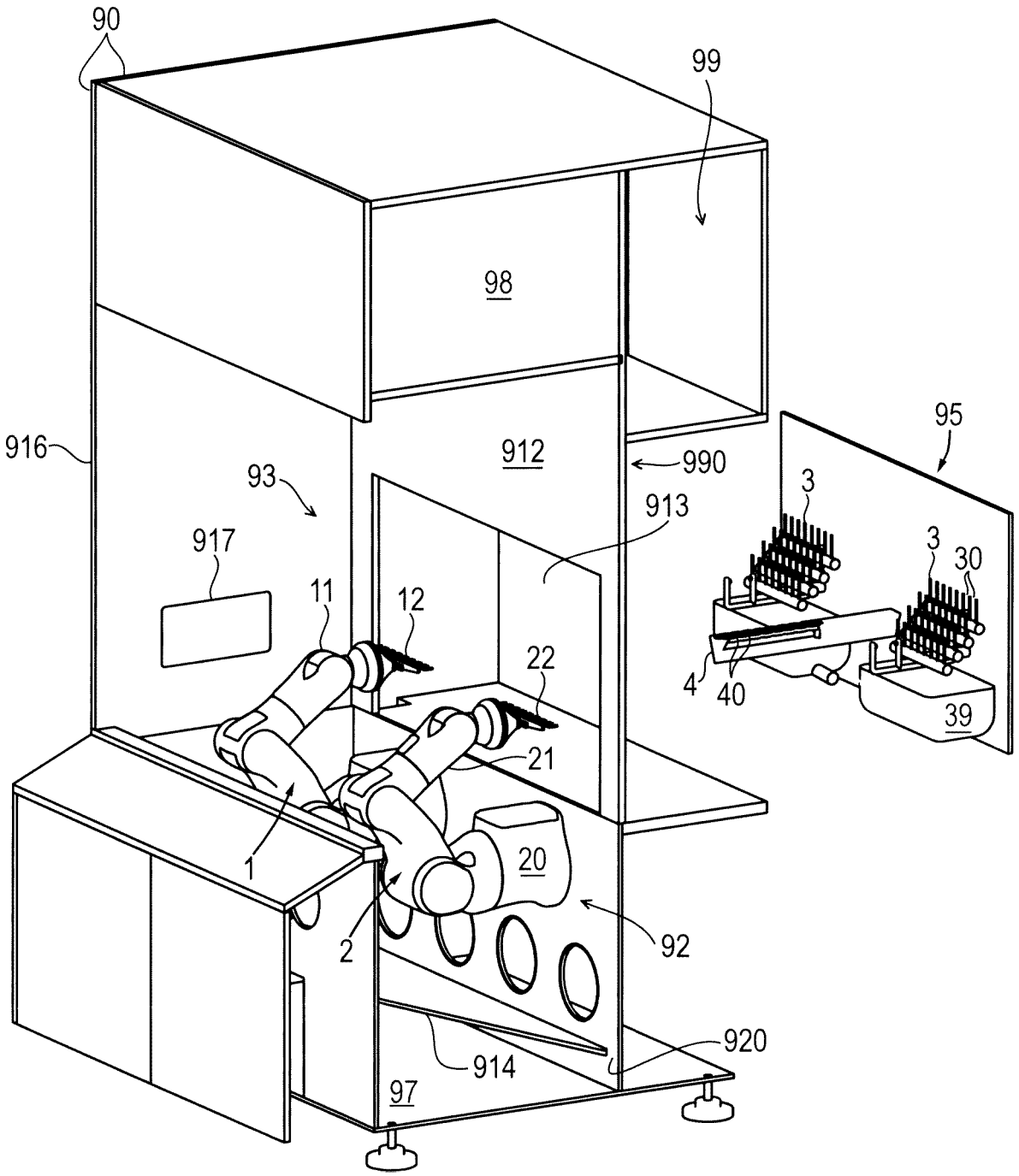

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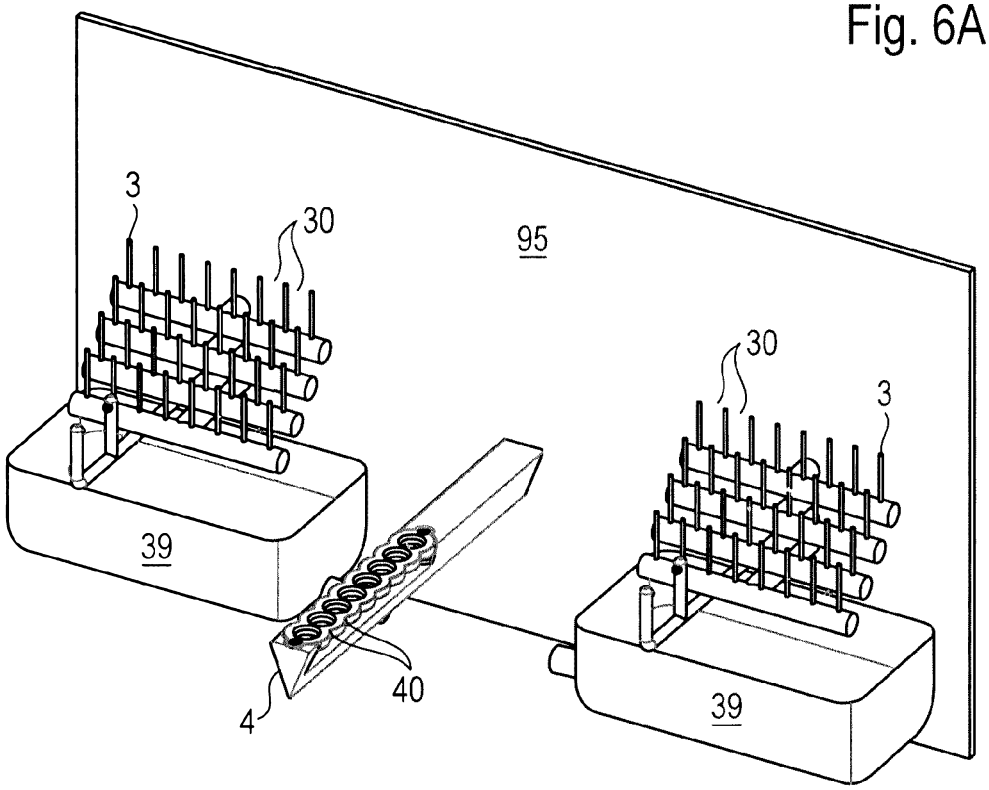
Fig. 5

Fig. 6A



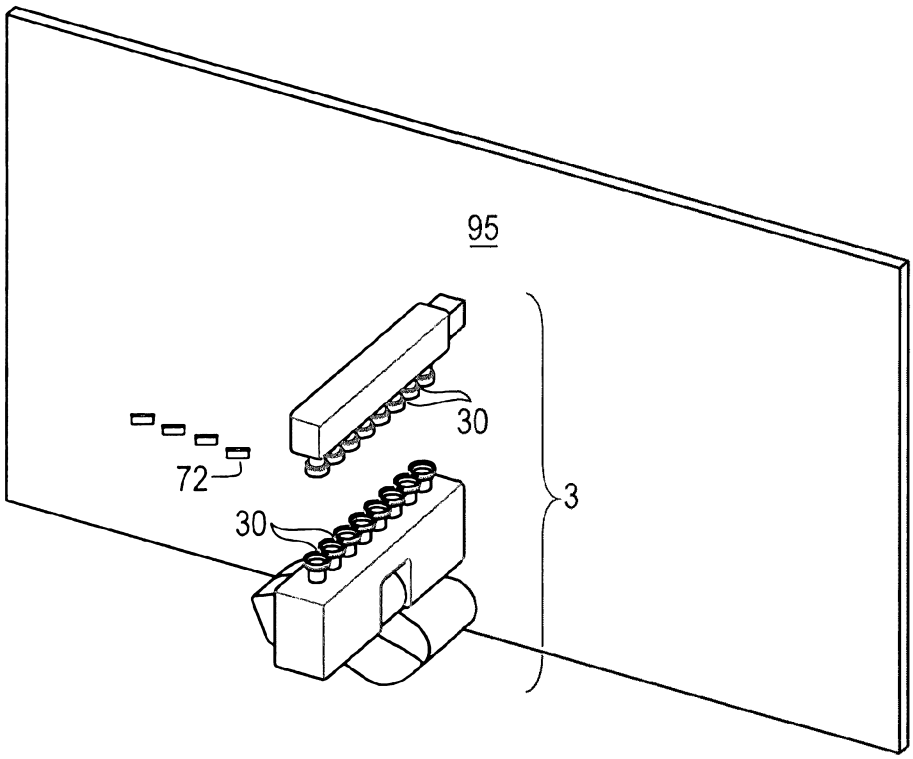


Fig. 6B

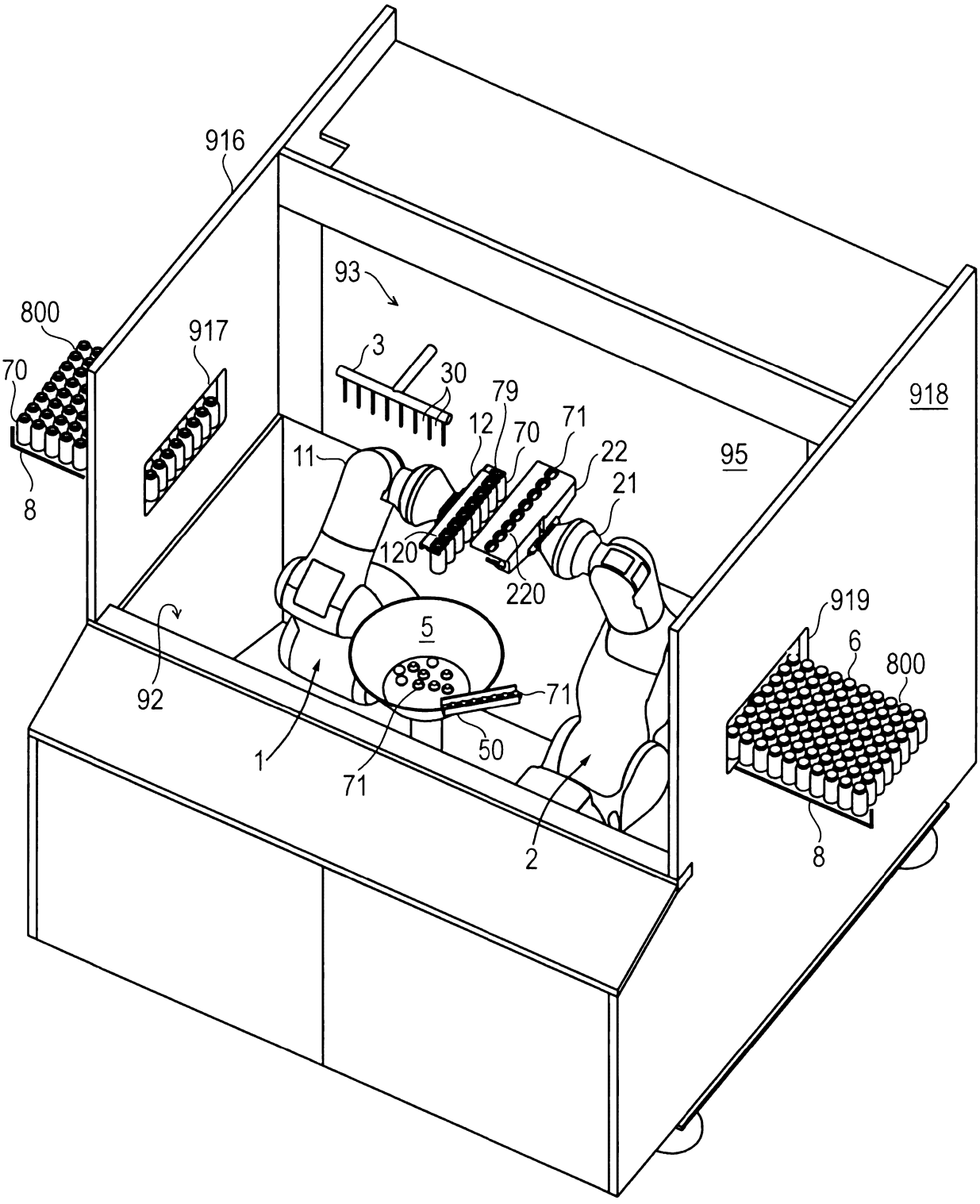

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Fig. 7A

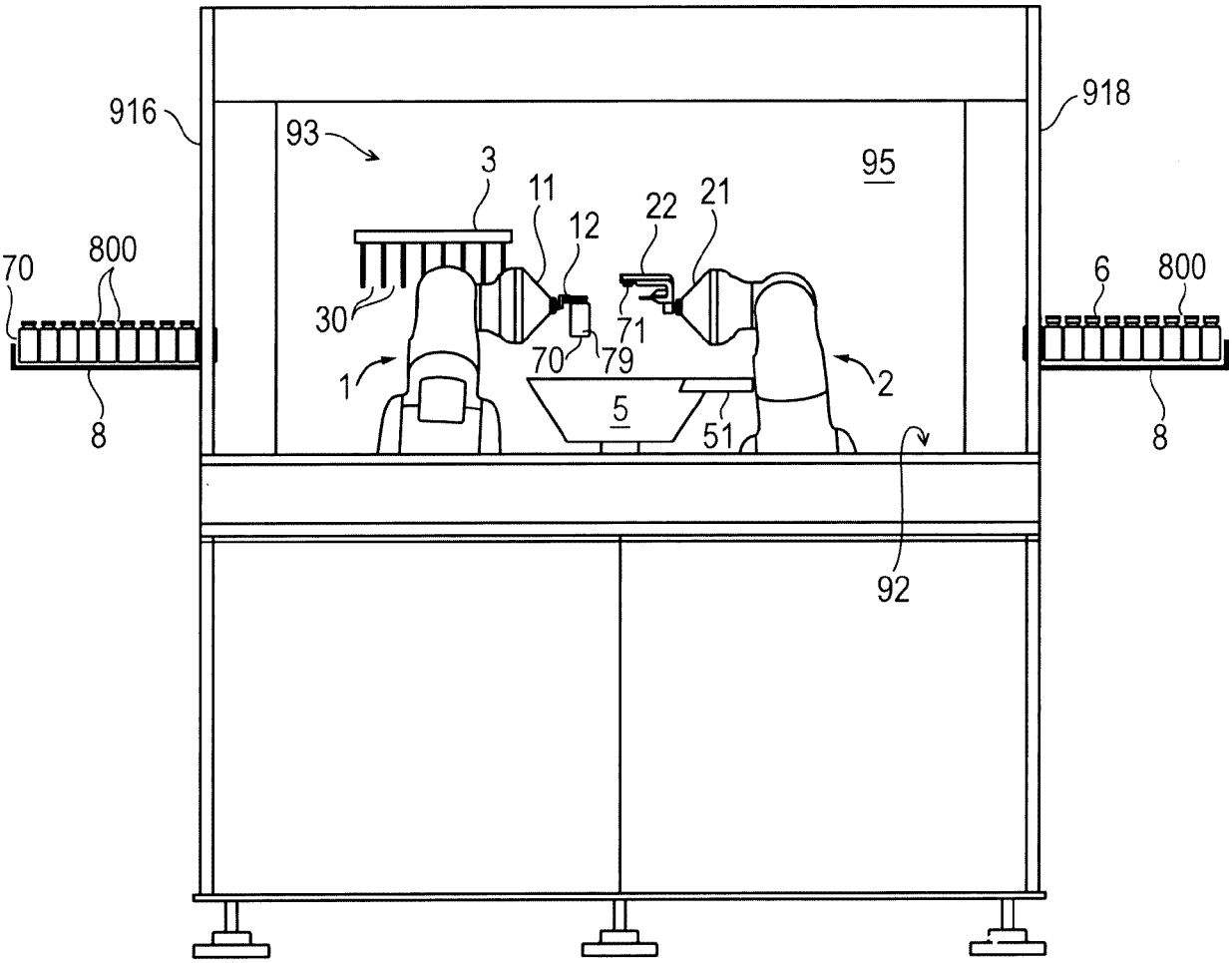

Fig. 7B

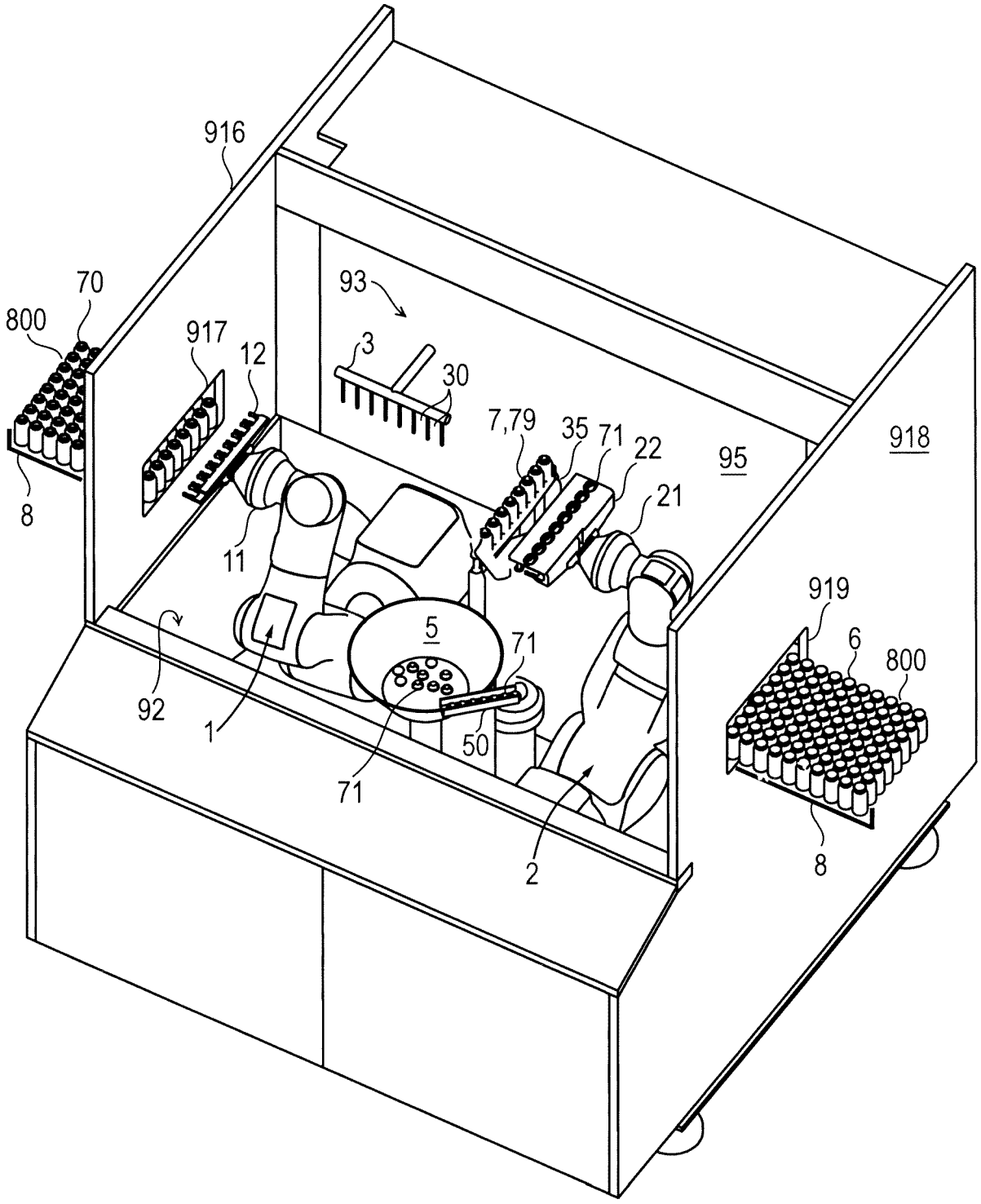
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Fig. 7C

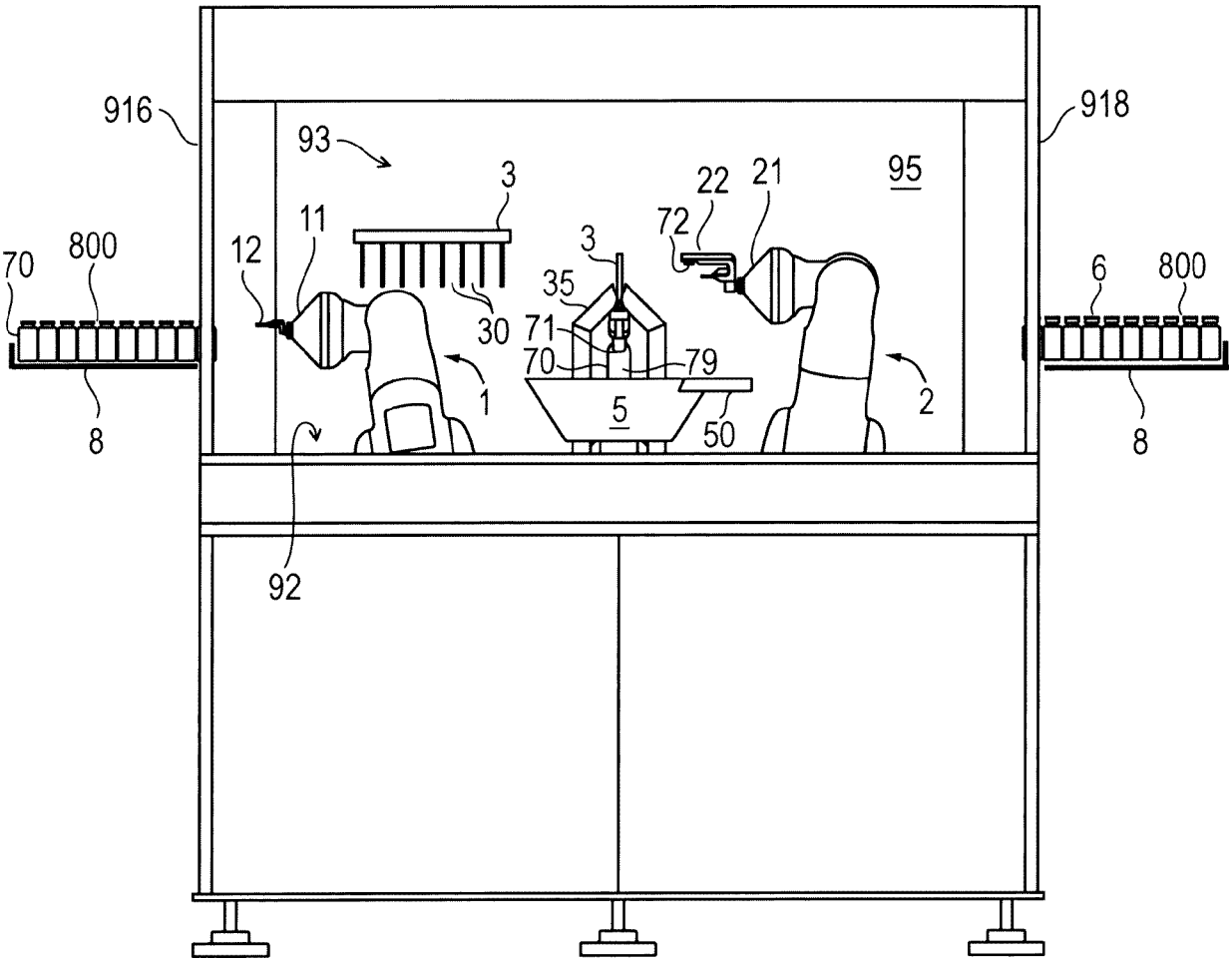
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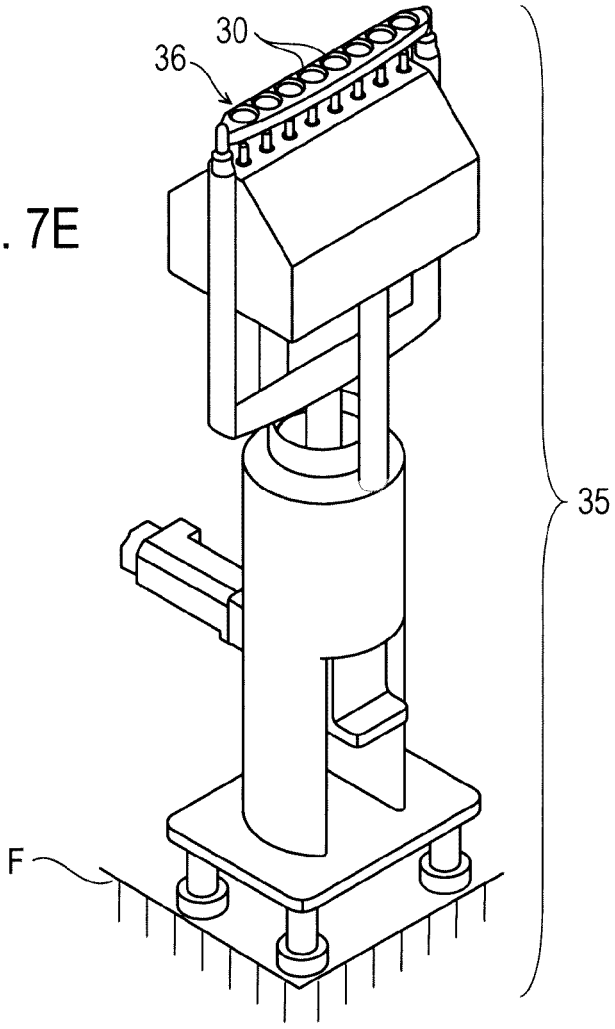
Fig. 7D

Fig. 7E



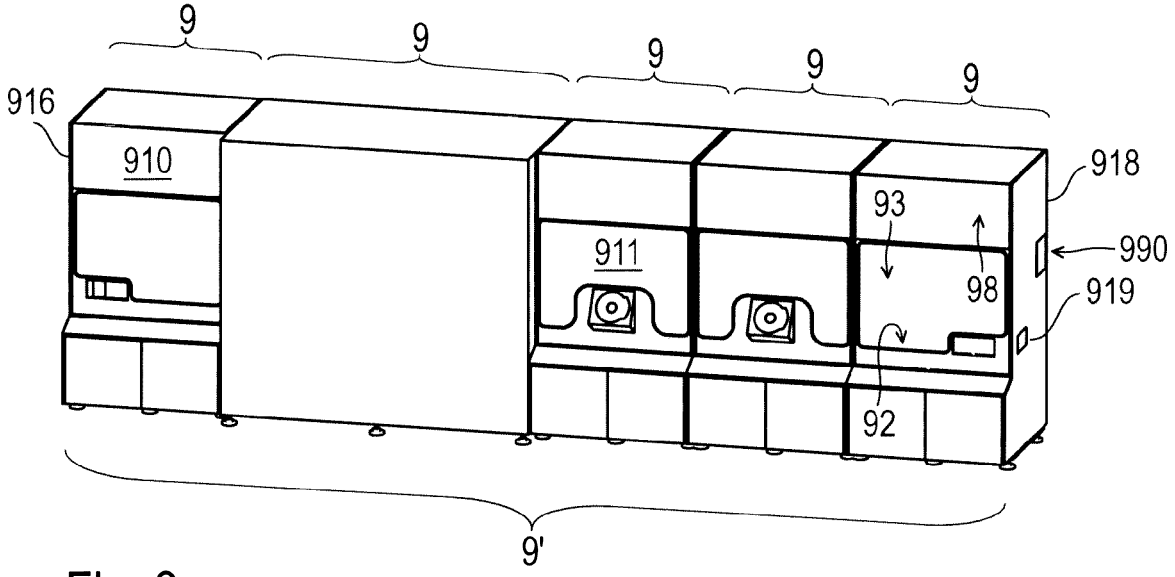


Fig. 8