(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
21 October 2010 (21.10.2010)

PCT

(10) International Publication Number
WO 2010/119130 A2

(51) International Patent Classification:
B65B 3/00 (2006.01)

(21) International Application Number:
PCT/EP2010/055061

(22) International Filing Date:
16 April 2010 (16.04.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/170,209 17 April 2009 (17.04.2009) US

(72) Inventor; and
(71) Applicant : **LIEPOLD, Gerhard** [DE/US]; 10 Friar Lane, Watchung, New Jersey 07060 (US).

(74) Agents: **MCKEOWN, Yvonne Mary** et al.; Maclachlan & Donaldson, 47 Merrion Square, 2, Dublin (IE).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

WO 2010/119130 A2

(54) **Title**: AN APPARATUS FOR CONTAINED PROCESSING OF SUBSTANCE

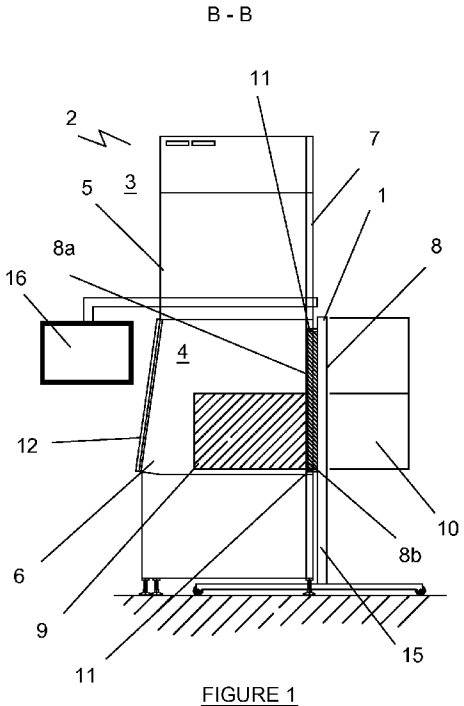

FIGURE 1

(57) **Abstract**: A mobile panel assembly (1) for sealingly coupling with an isolator apparatus (2) is provided wherein devices required to carry out a process inside the isolator are located at one side of panel (8) and equipment for actuating and driving the devices inside the isolator apparatus are located at the other side of the panel (8) in a ready to operate state. An opening matching the size and shape of the panel (8) is formed in a housing (5). An internal processing area (6) of the isolator apparatus (2) is defined inside the housing (5). In preparation for use, the panel (8) is placed in register with the opening of the housing (5) and a seal is formed between the housing (5) and the panel (8) to isolate the internal processing area (6) from the environment. The devices mounted at the interior-facing side (8a) of the panel (8) are received through the opening and accommodated within the internal processing area (6).

AN APPARATUS FOR CONTAINED PROCESSING OF SUBSTANCE

FIELD OF THE INVENTION

(0001) The invention relates to an apparatus for contained processing of substance and to corresponding method of assembly and use of the apparatus. More specifically, the invention relates to a mobile sub-assembly of an isolator apparatus.

DESCRIPTION OF THE PRIOR ART

(0002) In the pharmaceutical industry many processes, such as, for example, filling of dosage containers, including vials, ampoules, syringes and the like, with liquid or powdery substance; compounding, lyophilization, freeze drying, are typically carried out using an isolator apparatus specifically built for that process. A typical isolator apparatus includes a horizontal table on which the devices required to carry out a particular process in the contained zone are pre-arranged. Equipment for driving the devices in the contained zone of the isolator is usually arranged underneath the horizontal table top. An enclosure is then built around the table which continuously isolates the table and the remaining interior of the enclosure from the external environment. The interior of the isolator enclosure is typically arranged in communication with systems for providing and maintaining certain conditions inside the isolator, depending on the type of processing, such as for example, air filters, sterilising equipment, air-intake or compressors or temperature control equipment. The interior of the isolator is usually accessible via a sealed access device such as for example a glove access port so that an operator can manipulate within the contained zone without compromising the atmosphere of the contained zone or the exterior environment. Before the start of the process, the interior of the isolator is typically sterilised e.g. using steam, VHP (Vapour Hydrogen Peroxide), UV light etc. The driving equipment is then activated.

(0003) The above described method suffers a number of drawbacks, one of which includes lengthy and relatively complex installation, the requirement for a good deal of free space and careful handling. Installation and sterilisation are awkward due to the relatively large area of the isolator table. Post-processing problems include the time consuming and awkward disassembly of the system.

US RE38,747 E (Jagger) provides an isolator apparatus in which tooling is fixed to a vertical wall inside the isolator apparatus. It partially solves the space problem but not the problems associated with installation, sterilisation and disassembly.

SUMMARY OF THE INVENTION

(0004) It is an object of the present invention to seek to alleviate the aforementioned problems.

(0005) Accordingly, the present invention provides a panel assembly for coupling with a housing of an isolator apparatus for contained processing of substance,

the panel assembly comprising

a panel having first and second opposing outer surfaces;

a first set of implements for processing substance inside the isolator apparatus, the first set of implements comprising at least one implement; and the first set of implements being mounted on the first outer surface of the panel;

the panel being sized and shaped so as to close an opening formed in a housing of the isolator apparatus upon alignment with the opening thereby isolating from the environment an internal processing area defined by the housing of the isolator apparatus and exposed to the environment through the opening;

wherein the implements of the first set are selected of such a configuration and are mounted on the first outer surface of the panel with respect to each other so as to be received through the opening and accommodated in the internal processing area of the housing of the isolator apparatus when the panel is aligned with the opening of the housing with the first outer surface facing the internal processing area of the isolator apparatus; whereby the first set of implements remains mounted on the first outer surface of the panel upon alignment of the panel with the opening.

(0006) Preferably, the shape and size of the panel match substantially the shape and size of the opening in the housing.

(0007) It will be appreciated that in the present application, the terms “horizontal”, “vertical”, “upright”, “inclined” or similar terms describing orientation of an object are used in relation to the ground or a floor surface.

(0008) The opening in the housing of the isolator is preferably formed by removing a wall of the housing or cutting out the opening in the wall of the housing. In one arrangement, the wall or the cut out portion of the wall can be used to form the panel.

(0009) The panel is preferably sized and shaped to match the removed wall of the housing or the cut out portion in the wall and forms the wall of the housing, i.e. becomes part of the isolator apparatus, upon coupling with the housing of the isolator apparatus.

(0010) The panel ideally includes a coupling means for coupling with the housing of the isolator apparatus.

(0011) Ideally, the panel includes sealing means for forming a seal between the panel and the housing and thereby isolating the internal processing area of the isolator apparatus from the environment.

(0012) Conveniently, the first set of implements includes all the implements necessary for carrying out a required process in the interior of the isolator apparatus.

(0013) The panel assembly preferably includes a second set of implements, the second set of implements comprising at least one implement; and the second set of implements being mounted at the second outer surface of the panel. The second set of implements preferably includes a drive means arranged in communication with the first set of implements for driving the implements of the first set.

(0014) As is apparent from the foregoing, the first outer surface faces the interior of the isolator apparatus when the panel is coupled with the housing of the isolator apparatus, and the second surface faces the external environment.

(0015) The first set of implements is mounted on the first outer surface in a ready to operate state so that no further preparatory steps are required to be performed with respect to the first set of implements when the panel assembly is coupled with the housing of the isolator apparatus. Also, the implements of the first set are mounted spaced apart from each other on the first outer surface in such a manner that when the panel is in a substantially upright orientation (i.e. when the first and second outer surfaces are substantially perpendicular to the ground, or at an angle to the ground), the implements are spaced apart from each other in both horizontal and vertical direction in relation to the ground, thereby saving space and providing for an easy access to the implements by an operator.

(0016) The implements of the first and the second sets are preferably connected through passageways formed for this purpose in the panel via a connecting means having an exterior and an interior, the connecting means being sealingly coupled with the panel about the passageways so that no communication is possible between the opposing surfaces of the panel through the passageways outside the interior of the connecting means.

(0017) Conveniently, the connecting means includes one or more manifolds for transfer of substance from a location at or adjacent the second outer surface of the panel to a location at or adjacent the first outer surface thereof. In one modification, the passageways include a coupling means for sealingly coupling with the manifold thereby establishing communication between the first and second surfaces of the panel. It is however envisaged that the substance to be processed can be located at the first outer surface before the panel is coupled with the housing of the isolator apparatus so that there is no need to transfer the substance from outside the isolator apparatus into the internal processing area during the contained processing. The panel assembly includes one or more suitable vessels for holding the substance to be processed, the vessel being mounted at the relevant desired side of the panel assembly.

(0018) Preferably, during manufacturing of the panel assembly, internal surfaces of the panel assembly such as internal surfaces of passageways, manifolds and vessels of the panel assembly are sterilised and subsequently isolated from the environment so that there is no need to re-sterilise the internal surfaces of the panel assembly when it is coupled with the housing of the isolator apparatus.

(0019) Ideally, the implements of the second set include a further drive means, e.g. a pump, for driving substance along the internal passageways of the panel assembly.

(0020) Materials of the components of the panel assembly may include metal (e.g. stainless steel), polymers (e.g. a plastics material or a silicone) or a combination of the above materials.

(0021) The sealing means is preferably operable between a sealing mode and an open mode. Furthermore, the sealing means is arranged in cooperation with a seal actuating means, the actuating means being configured to operate the sealing means between the

sealing mode and the open mode. The seal actuating means is preferably provided at the second outer surface of the panel. Various types of sealing means are envisaged within the scope of the present invention as would be apparent to a person skilled in the art. For example, an expandable (and contractible) seal is considered suitable. The sealing means may be configured to function as the coupling means.

(0022) In one of the convenient arrangements, the panel is configured in such a manner that when the panel is coupled with the housing it is oriented in a generally upright rather than horizontal orientation so as to save space and provide for easy access to the implements of the first and second sets by an operator both when the panel assembly is coupled with an isolator and/or when the panel assembly is free standing.

(0023) The isolator housing preferably includes front and back walls. In one modification, the opening is formed in the back wall of the isolator housing. A contained access port, such as, for example, a glove access port can be provided in the front wall of the housing, to enable an operator manipulate in the internal processing area of the isolator apparatus when the panel assembly is coupled with the housing.

(0024) In a preferred embodiment, the panel assembly is mounted on a transport means. The transport means can be in the form of, for example, castors, chassis, a cart, a trolley, a rail, a conveyor, an overhead support, or other transport arrangements apparent to a person skilled in the art.

(0025) In a convenient arrangement, the panel assembly is mounted on the transport means in the same orientation in which it is brought into alignment with the opening in the housing of the isolator apparatus, so that the panel can be aligned with the opening in the housing of the isolator apparatus by moving the panel assembly in the relevant orientation on the transport means into alignment with the opening of the housing.

(0026) The implements of the first and second set are removably mounted on the panel so that all or some of the implements can be removed and/or replaced with other implements suitable for another process. In this manner, the same isolator apparatus and/or the same panel can be used for different processes.

(0027) Preferably, the implements of the first set are treatable inside the isolator, for example by sterilisation, such as for example, VHP, steam, UV light or other sterilisation methods known to a person skilled in the art.

(0028) Also, several panel assemblies may be provided each having different sets of implements, each set of implements being designed for a specific process, and each panel assembly being suitable for use with the same isolator apparatus so that the same isolator apparatus can be used for different processes.

(0029) The panel assembly of the present invention provides the advantages that smaller area is occupied by the isolator apparatus coupled with the panel assembly compared with prior art isolator apparatus; high level of interchangeability is achieved; costs and time are saved; processing e.g. filling can all be done automatically without the need for an operator to manipulate in the internal processing area during the contained processing; and due to the reduced area, sterilisation becomes more reliable, more simple and more efficient.

(0030) In a preferred arrangement, the panel assembly is controlled by an electronic, preferably programmable, control system, and is interconnected with the electronic control system via a Human Machine Interface.

(0031) In a further aspect, the invention provides a panel assembly as herein described, wherein the panel assembly is coupled with an isolator housing as herein described in a manner herein described.

(0032) In yet a further aspect, the invention provides an isolator apparatus comprising a housing that defines an internal processing area of the isolator apparatus, there being an opening formed in the housing exposing the internal processing area to the environment; the opening being sized and shaped so as to be closed by a panel of a panel assembly as herein described and to receive and accommodate in the internal processing area the implements of the first set of the panel assembly when the panel assembly is aligned with the opening of the housing

(0033) In still a further aspect, the invention provides a system for contained processing of substance comprising a panel assembly as herein described and an isolator apparatus as

herein described, wherein the panel assembly is coupled with the housing of the isolator apparatus or wherein the panel assembly is decoupled from the housing of the isolator apparatus.

(0034) The system of the present invention is particularly suited for use in the pharmaceutical industry for such contained processes as filling of dosage containers, such as vials, syringes, ampoules or other containers; compounding; freeze drying, lyophilization. It will be appreciated however that the use of the system is possible for other contained processes in the pharmaceutical or other industry, as well as in experimental applications, such as industrial, medical and research laboratories. The system is ideally suited to any small to medium scale operations where either the material being handled needs to be isolated from the external environment and/or where the external atmosphere must be protected from contamination with the material being handled.

(0035) The panel assembly and the isolator apparatus of the present invention are most suitable for use on a clinical trial scale, for example, for filling dosage containers in a closed type of isolator apparatus in quantities of approximately 4000 dosage containers per batch. It will be appreciated that the use on a laboratory scale or on a production scale is also envisaged.

(0036) The use of the system is preferred with a closed type of an isolator apparatus, in which the processing is carried out in batches and the processed batch has to be retrieved from the isolator apparatus and relocated to a downstream processing location. For example, in a vial filling isolator apparatus, filled vials are accumulated in an accumulation container at one end of the processing area. When all the vials of the batch have been filled, the isolator apparatus is opened to the environment and the accumulation container is removed. However, the panel assembly of the invention can be readily adapted for use with an isolator apparatus of an open type, in which ports are provided, arranged in communication with other stations in a continuous production line. The ports are opened when required to receive or discharge a batch of units for processing and closed to re-isolate the interior of the isolator from the remaining parts of the production line.

(0037) In a panel assembly designed for filling, the implements of the first set may include among other equipment, tubing, dispensing appliance(s), conveyor(s), accumulation tray(s). In a panel assembly designed for compounding, the implements of the first set may include among other equipment, dispensing appliance(s), mixing implement(s), conveyor(s), accumulation tray(s).

(0038) Unlike known systems, the panel assembly of the present invention can be manufactured and assembled away from the location where contained processing is to be carried out and the panel can be delivered in an assembled state to the relevant location.

(0039) At the relevant location, the panel assembly is coupled about the opening in the housing of the isolator apparatus with the first outer surface of the panel facing the interior of the isolator apparatus to close off the opening and isolate the interior of the isolator apparatus from the environment. At the same time, the implements of the first set are received through the opening and accommodated within the internal processing area of the isolator apparatus while still remaining mounted on the first surface of the panel. No further adjustment or installation is required to be carried out inside the isolator once the panel assembly has been coupled with the housing of the isolator apparatus.

(0040) The internal processing area of the isolator apparatus is then sterilised (or otherwise treated, as the case may be) using a suitable sterilisation method, such as, for example, VHP, steam or UV light sterilisation.

(0041) Next, the drive means at the second surface of the panel is activated thereby actuating the implements of the first set and the internal passageways of the panel and the vessels are opened to be in communication with the internal processing area.

(0042) Thus, the invention provides a method of assembling an isolator apparatus and a panel assembly as herein described comprising the steps of:

(a) providing a panel assembly as herein described

(b) providing an isolator apparatus as herein described; and

(c) aligning the panel assembly with the opening in the housing of the isolator apparatus with the first surface of the panel facing the interior of the isolator apparatus so as to close the opening whereby the implements of the first set are received through the

opening and accommodated in the internal processing area of the isolator apparatus while still remaining mounted on the first surface of the panel.

(0043) Preferably, the method of assembly further includes the steps of

(d) prior to step (b), providing a transport means as herein described;

(e) mounting the panel on the transport means in the same orientation in which it is to be brought into alignment with the opening in the housing of the isolator apparatus;

(f) during step (c) moving the panel assembly in the relevant orientation on the transport means into alignment with the opening of the housing; and (g) sealingly coupling the panel with the housing of the isolator apparatus thereby isolating the internal processing area of the isolator apparatus from the environment.

(0044) In another aspect, the invention provides a method of contained processing of substance comprising the steps of:

(a) providing the panel assembly and an isolator apparatus as herein described;

(b) assembling the panel and the isolator apparatus according to the method as herein described;

(c) treating the internal processing area of the isolator apparatus; and

(d) activating the relevant implements of the second set of implements at the second surface of the panel, thereby actuating the relevant implements of the first set at the first surface of the panel and opening the internal passageways of the panel and the vessels thereby establishing communication of the vessels and passageways with the internal processing area and the implements of the first set.

(0045) A further step of the method of contained processing of substance includes the steps of

(e) cleaning the internal processing area of the isolator apparatus and the portion of the panel assembly that faces the internal processing area; and

(f) disconnecting the panel assembly from the isolator apparatus so that another panel assembly can be coupled with the isolator apparatus or so that the first panel assembly can be re-fitted with different implements for another specific process and subsequently used again with the same isolator apparatus.

(0046) The system of the present invention is particularly suitable for sterile transfer of substance (e.g. fluid, powder) from a first sterile location (e.g. vessel mounted on or

connected via a contained manifold to the panel assembly) to a second sterile location (a vessel inside the isolator, e.g. vial, syringe, or other container).

(0047) It will be appreciated that the system is not limited to the use only for transfer between two sterile locations, but can be used in an application where substance needs to be transferred between two locations having the same level of cleanness by non direct means. It will also be appreciated that the substance itself needs not necessarily be sterile. The system of the invention is suitable for the transfer or handling of non-sterile, toxic or hazardous materials, including bio-hazardous material. Furthermore, it will be appreciated that the invention is not limited to use in the pharmaceutical industry, but can be utilised in any application where a substance needs to be processed in a contained manner.

(0048) It will be appreciated that the system is also suitable for transferring substance between first and second locations having the same level of cleanness which is different from the level of cleanness of the environment.

(0049) Because the vessels and internal passageways of the panel assembly of the present invention are already sterilised and isolated at the time the panel assembly is supplied to the location of the contained processing, the present system enables the process of *in situ* treatment, such as sterilisation of the components of the panel assembly which come into contact with the substance being processed, to be shortened considerably compared with known systems. *In situ* treatment, such as sterilisation, is only required for the external surfaces of the components of the panel assembly exposed to the isolator interior upon coupling of the panel assembly with the isolator apparatus. Thereby the risk of cross-contamination is reduced compared with known systems thereby providing a high level of product security.

(0050) In one embodiment, the system is provided with a means for re-isolating the vessels and internal passageways of the panel assembly after the contained processing has been completed in order to prevent any matter present within the panel assembly, which may include for example hazardous and/or toxic materials, contaminating the outside environment during disassembly. Therefore, post-transfer sanitation is required only for the parts of the isolator interior and the components of the panel assembly

exposed of the interior of the isolator. For this purpose, the isolator is connected to an appropriate sanitation system.

(0051) As is apparent from the foregoing, with the use of the panel assembly and the isolator apparatus of the present invention contained processing of substance is substantially simplified. In particular, fewer assembly steps are required to assemble the isolator apparatus and the step of sterilisation becomes significantly less complicated.

(0052) The panel assembly of the present invention eliminates the need for arranging individual devices on a horizontal support surface of an isolator at the location of the contained processing and then building an isolator enclosure around the horizontal support surface.

BRIEF DESCRIPTION OF THE DRAWINGS

(0053) The invention will now be described with reference to the accompanying drawings which show, by way of example only, embodiments of a panel assembly and an isolator apparatus of the present invention. In the drawings:

(0054) Figure 1 is a schematic cross-sectional side elevation (along the line B-B in Figure 3) of an isolator apparatus coupled with a panel assembly according to the invention;

(0055) Figure 2 is a schematic side elevation of the isolator apparatus of Figure 1 without the panel assembly of the invention;

(0056) Figure 3 is a schematic front elevation of the isolator apparatus of Figure 1;

(0057) Figure 4 is a schematic top view of the isolator apparatus of Figure 3;

(0058) Figure 5 is a schematic side elevation of a panel assembly according to the invention;

(0059) Figure 6 is a schematic front elevation of the panel assembly of Figure 5; and

(0060) Figure 7 is a cross-sectional elevation of the panel assembly of Figure 6 taken along the line A-A in Figure 6.

DETAILED DESCRIPTION OF THE INVENTION

(0061) One preferred embodiment of an isolator apparatus and a panel assembly according to the invention is shown schematically in Figures 1 to 7. The panel assembly

is indicated generally by reference numeral 1 and the isolator apparatus is indicated generally by reference numeral 2.

(0062) The isolator apparatus 2 is located in a first environment 3. Contained processing of substance is carried out in a second environment 4 within the isolator apparatus 2.

(0063) The isolator apparatus 2 includes a housing 5 comprising walls which define an internal processing area 6 interior of the isolator apparatus 2. An opening (not indicated by a numeral) is formed in one wall (which in use is a back wall 7) of the isolator apparatus 2.

(0064) The panel assembly 1 includes a panel 8 having first and second opposing outer surfaces 8a, 8b, respectively. In use, the first surface 8a faces the interior of the isolator apparatus 2 and the second surface 8b faces the first environment 3. The panel 8 is sized and shaped so as to close the opening in the housing 5 upon alignment with the opening thereby isolating the internal processing area 6 from the first environment 3.

(0065) With reference to Figure 1, a first set 9 of implements for processing substance inside the isolator apparatus 2, is mounted on the first outer surface 8a of the panel 8. The implements of the first set 9 are selected of such a configuration and are mounted on the first outer surface 8a of the panel 8 with respect to each other so as to be received through the opening and accommodated in the internal processing area 6 of the housing 5 of the isolator apparatus 2 when the panel 8 is aligned with the opening of the housing 5 with the first outer surface 8a facing the internal processing area 6 of the isolator apparatus 2. When the panel 8 is aligned with the opening in the above described manner, the first set 9 of implements remains mounted on the first outer surface 8a of the panel 8. The first set 9 of implements includes all the implements necessary for carrying out a required process in the interior of the isolator apparatus 2.

(0066) The panel assembly 1 preferably includes a second set 10 of implements mounted on or adjacent the second outer surface 8b of the panel 8. The second set 10 of implements drive means (not shown) arranged in communication with the first set 9 of implements for actuating and driving the implements of the first set 9.

(0067) In the presently described embodiment, the shape and size of the panel 8 match substantially the shape and size of the opening in the housing 5.

(0068) The opening in the housing 5 of the isolator may be formed by removing a wall of the housing 5 or cutting out the opening in the wall of the housing 5.

(0069) The panel 8 is preferably sized and shaped to match the wall of the housing or the cut out portion in the wall and forms the wall of the housing 5, i.e. becomes part of the isolator apparatus 2 upon coupling with the housing 5.

(0070) The panel 8 includes an expandable (and contractible) seal 11 for sealing between the panel 8 and the housing 5 and thereby isolating the internal processing area 6 of the isolator apparatus 2 from the first environment 3. Other types of seal are envisaged however within the scope of the invention.

(0071) The first set 9 of implements is mounted on the first outer surface 8a in a ready to operate state so that no further preparatory steps are required to be performed with respect to the first set 9 of implements when the panel assembly 1 is coupled with the housing 5.

(0072) The implements of the first set 9 are mounted spaced apart from each other on the first outer surface 8a so that when the panel 8 is in a substantially upright orientation, the implements are spaced apart from each other in both horizontal and vertical direction in relation to the ground, thereby saving space and providing for an easy access to the implements by an operator.

(0073) The implements of the first and the second sets 9, 10 are preferably interconnected through passageways (not shown) formed for this purpose in the panel 8 via a connecting means (not shown), such as tubing or pipes (not shown). The connecting means is sealingly fed through the panel 8 so that no communication is possible between the opposing surfaces 8a, 8b of the panel 8 through the passageways outside the interior of the connecting means.

(0074) The connecting means includes one or more manifolds (not shown) for transfer of substance between first and second outer surfaces 8a, 8b of the panel 8.

(0075) The panel assembly 1 also includes one or more suitable vessels (not shown) for holding the substance to be processed. Such vessel or vessels are mounted at the first or second surface 8s, 8b of the panel assembly 1.

(0076) During manufacturing of the panel assembly 1, internal surfaces of the panel assembly such as those of passageways, manifolds and vessels of the panel assembly 1 are sterilised and subsequently isolated from the first environment 3 so that there is no need to re-sterilise the internal surfaces of the panel assembly 1 when it is coupled with the housing 5.

(0077) The implements of the second set 10 also include one or more pumps (not shown), for driving the substance along the internal passageways of the panel assembly 1.

(0078) The seal 11 operates between a sealing mode and an open mode and is arranged in cooperation with a seal actuating means (not shown) provided at the second outer surface 8b of the panel 8 for operating the seal 11 between the sealing mode and the open mode. In the present embodiment, the seal 11 functions as the coupling means to couple the panel 8 with the housing 5. Separate coupling means however can be provided.

(0079) When the panel 8 is coupled with the housing 5, it is oriented in a generally upright rather than horizontal orientation so as to save space and provide for easy access to the implements of the first and second sets 9, 10 by an operator both when the panel assembly 1 is coupled with the housing 5 and when the panel assembly 1 is free standing.

(0080) The isolator housing 5 includes front and back walls 12, 7 respectively. The opening is formed in the back wall 7 of the isolator housing 5. A plurality of contained access ports, in the form of glove access ports 14 are provided in the front wall 12 of the housing, to enable an operator manipulate in the internal processing area 6 of the isolator apparatus 2 when the panel assembly 1 is coupled with the housing 5.

(0081) The panel assembly 1 is mounted on a transport means in the form of a chassis 15. The panel assembly is mounted on the chassis 15 in the same orientation in which it

is brought into alignment with the opening in the housing 5. Therefore, the panel 8 aligns with the opening in the housing 5 as the panel assembly 1 is moved on the chassis 15 towards the opening of the housing 5.

(0082) The implements of the first and second set 9, 10 are removably mounted on the panel 8 so that all or some of the implements can be removed and/or replaced with other implements suitable for another process. In this manner, the same isolator apparatus and the same panel can be used for different processes.

(0083) The implements of the first set 9 are treatable inside the isolator, for example by sterilisation, such as for example, VHP, steam, UV light or other sterilisation methods known to a person skilled in the art.

(0084) The panel assembly 1 is controlled by an electronic, preferably programmable, control system (not shown), and is interconnected with the electronic control system via a Human Machine Interface 16.

(0085) The isolator apparatus 2 is preferably of a closed type. In such an isolator apparatus, processing is carried out in batches and the processed batch has to be retrieved from the isolator apparatus and relocated to a downstream processing location. For example, in a vial filling isolator apparatus, filled vials are accumulated in an accumulation container at one end of the processing area. When all the vials of the batch have been filled, the isolator apparatus is opened to the environment and the accumulation container is removed. It will be appreciated that, the panel assembly 1 can be readily adapted for use with an isolator apparatus of an open type, in which ports are provided, arranged in communication with other stations in a continuous production line. The ports are opened when required to receive or discharge a batch of units for processing and closed to re-isolate the interior of the isolator from the remaining parts of the production line.

(0086) Although not shown in the drawings, if the panel assembly 1 is intended to be used for filling, the implements of the first 9 set may include among other equipment, tubing, dispensing appliance(s), conveyor(s), accumulation tray(s). If the panel assembly 1 is intended to be used for compounding, the implements of the first set 9 may include among other equipment, dispensing appliance(s), mixing implement(s), conveyor(s), accumulation tray(s).

(0087) The advantage of the panel assembly 1 of the present invention is that it can be manufactured and assembled away from the location of the isolator apparatus 2 and the panel assembly 1 can be delivered in an assembled state to the relevant location.

(0088) At the location of the isolator apparatus 2, the panel assembly 1 is coupled about the opening in the housing 5 with the first outer surface 8a facing the interior of the isolator apparatus 2 and the seal 11 is actuated so as to close off the opening and isolate the internal processing area 6 of the isolator apparatus 2 from the environment 3. At the same time, the implements of the first set 9 are received through the opening and accommodated within the internal processing area 6 while still remaining mounted on the first surface 8a of the panel 8. No further adjustment or installation is required to be carried out inside the isolator apparatus 2 once the panel assembly 1 has been coupled with the housing 5.

(0089) The internal processing area 6 is then sterilised (or otherwise treated, as the case may be) using a suitable sterilisation method, such as, for example, VHP, steam or UV light sterilisation.

(0090) Next, the drives at the second surface 10 of the panel are activated thereby actuating the implements of the first set 9 and the internal passageways of the panel 8 and the vessels are opened to be in communication with the internal processing area 6.

(0091) After the substance has been processed, the interior of the isolator apparatus 2 including the portion of the panel 8 that faces the interior together with the implements of the first set 9 are cleaned. The panel assembly 1 is then disconnected from the isolator apparatus 2 together with the implements of the first set 9 and the processed substance (e.g. filled batch of vials, syringes; mixed compound; etc). Another panel assembly can then be coupled with the isolator apparatus 2. Alternatively, the first panel assembly 1 can be re-fitted with different implements for another specific process and subsequently used again with the same isolator apparatus 2.

(0092) It is thought that the present invention and its advantages will be understood from the foregoing description and it will be apparent that various changes may be made thereto without departing from the scope of the invention as defined by the appended claims the forms hereinbefore described being merely preferred or exemplary embodiments thereof.

CLAIMS:

1. A panel assembly for coupling with a housing of an isolator apparatus for contained processing of substance, the panel assembly comprising

a panel having first and second opposing outer surfaces;

a first set of implements for processing substance inside an isolator apparatus, the first set of implements comprising at least one implement; and the first set of implements being mounted on the first outer surface of the panel;

the panel being sized and shaped so as to close an opening formed in a housing of the isolator apparatus upon alignment with the opening thereby isolating from the environment an internal processing area defined by the housing of the isolator apparatus and exposed to the environment through the opening;

wherein the implements of the first set are selected of such a configuration and are mounted on the first outer surface of the panel with respect to each other so as to be received through the opening and accommodated in the internal processing area of the housing of the isolator apparatus when the panel is aligned with the opening of the housing with the first outer surface facing the internal processing area of the isolator apparatus; whereby the first set of implements remains mounted on the first outer surface of the panel upon alignment of the panel with the opening.

2. A panel assembly as claimed in Claim 1, wherein the shape and size of the panel match substantially the shape and size of the opening in the housing.

3. A panel assembly as claimed in Claim 1, wherein the panel is formed by a portion of the wall of the housing cut out and removed from the wall so as to form the opening in the housing.

4. A panel assembly as claimed in Claim 1, wherein the panel is sized and shaped to match a removed wall or a cut out and removed portion of the wall of the housing so as to form the opening in the housing and wherein the panel forms the wall of the housing, i.e. becomes part of the isolator apparatus, upon coupling with the housing of the isolator apparatus.

5. A panel assembly as claimed in Claim 1, wherein the panel includes a coupling means for coupling with the housing of the isolator apparatus.

6. A panel assembly as claimed in Claim 1, wherein the panel includes sealing means for forming a seal between the panel and the housing and thereby isolating the internal processing area of the isolator apparatus from the environment or the environment from the internal processing area of the isolator apparatus.

7. A panel assembly as claimed in Claim 1, wherein the first set of implements includes all the implements necessary for carrying out a required process in the interior of the isolator apparatus.

8. A panel assembly as claimed in Claim 1, wherein the panel assembly includes a second set of implements, the second set of implements comprising at least one implement; and the second set of implements being mounted at the second outer surface of the panel.

9. A panel assembly as claimed in Claim 8, wherein the second set of implements includes a drive means arranged in communication with the first set of implements for driving the implements of the first set.

10. A panel assembly as claimed in Claim 1, wherein the first outer surface faces the interior of the isolator apparatus when the panel is coupled with the housing of the isolator apparatus, and the second surface faces the external environment.

11. A panel assembly as claimed in Claim 1, wherein the first set of implements is mounted on the first outer surface in a ready to operate state so that no further preparatory steps are required to be performed with respect to the first set of implements when the panel assembly is coupled with the housing of the isolator apparatus.

12. A panel assembly as claimed in Claim 1, wherein the implements of the first set are mounted spaced apart from each other on the first outer surface in such a manner that when the panel is in a substantially upright orientation, the implements are spaced apart from each other in both horizontal and vertical direction in relation to the ground, thereby saving space and providing for an easy access to the implements by an operator.

13. A panel assembly as claimed in Claim 8, wherein the implements of the first and the second sets are preferably connected through passageways formed for this purpose in the panel via a connecting means having an exterior and an interior, the connecting means being sealingly coupled with the panel about the passageways so that no communication is possible between the opposing surfaces of the panel through the passageways outside the interior of the connecting means.

14. A panel assembly as claimed in Claim 13, wherein the connecting means includes one or more manifolds for transfer of substance from a location at or adjacent the second outer surface of the panel to a location at or adjacent the first outer surface thereof.

15. A panel assembly as claimed in Claim 14, wherein, the passageways include a coupling means for sealingly coupling with the manifold thereby establishing communication between the first and second surfaces of the panel.

16. A panel assembly as claimed in Claim 1, wherein the substance to be processed is located at the first outer surface before the panel is coupled with the housing of the isolator apparatus so that there is no need to transfer the substance from outside the isolator apparatus into the internal processing area during the contained processing.

17. A panel assembly as claimed in Claim 1, wherein the panel assembly includes one or more suitable vessels for holding the substance to be processed, the vessel being mounted at the relevant desired side of the panel assembly.

18. A panel assembly as claimed in Claim 1, wherein internal surfaces of the panel assembly such as internal surfaces of passageways, manifolds and vessels of the panel assembly are sterilised and subsequently isolated from the environment so that there is no need to re-sterilise the internal surfaces of the panel assembly when it is coupled with the housing of the isolator apparatus.

19. A panel assembly as claimed in Claim 8, wherein the implements of the second set include a further drive means for driving substance along the internal passageways of the panel assembly.

20. A panel assembly as claimed in Claim 6, wherein the sealing means is operable between a sealing mode and an open mode.

21. A panel assembly as claimed in Claim 20, wherein the sealing means is arranged in cooperation with a seal actuating means, the actuating means being configured to operate the sealing means between the sealing mode and the open mode.

22. A panel assembly as claimed in Claim 21, wherein the seal actuating means is provided at the second outer surface of the panel.

23. A panel assembly as claimed in Claim 6, wherein the sealing means includes an expandable and contractible seal.

24. A panel assembly as claimed in Claim 6, wherein the sealing means is configured to function as a coupling means for coupling the panel to the housing of an isolator apparatus.

25. A panel assembly as claimed in Claim 1, wherein the panel is configured in such a manner that when the panel is coupled with the housing it is oriented in a generally upright orientation.

26. A panel assembly as claimed in Claim 1, wherein the panel assembly is mounted on a transport means.

27. A panel assembly as claimed in Claim 1, wherein the transport means is selected from castors, chassis, a cart, a trolley, a rail, a conveyor or an overhead support.

28. A panel assembly as claimed in Claim 27, wherein the panel assembly is mounted on the transport means in the same orientation in which it is brought into alignment with the opening in the housing of the isolator apparatus, so that the panel is aligned with the opening in the housing of the isolator apparatus by moving the panel assembly in the relevant orientation on the transport means into alignment with the opening of the housing.

29. A panel assembly as claimed in Claim 8, wherein the implements of the first and second set are removably mounted on the panel so that all or some of the implements can be removed and/or replaced with other implements suitable for another process.

30. A panel assembly as claimed in Claim 8, wherein several panel assemblies are provided each having different sets of implements, each set of implements being designed for a specific process, and each panel assembly being suitable for use with the same isolator apparatus so that the same isolator apparatus can be used for different processes.

31. A panel assembly as claimed in Claim 1, wherein the panel assembly is controlled by an electronic control system and is interconnected with the electronic control system via a Human Machine Interface.

32. A panel assembly as claimed in Claim 1, wherein the panel assembly is coupled with the housing of an isolator apparatus.

33. An isolator apparatus comprising a housing that defines an internal processing area of the isolator apparatus, there being an opening formed in the housing exposing the internal processing area to the environment; the opening being sized and shaped so as to be closed by a panel of a panel assembly of Claim 8 and to receive and accommodate in the internal processing area the implements of the first set of the panel assembly when the panel assembly is aligned with the opening of the housing.

34. A system for contained processing of substance comprising a panel assembly of Claim 8 and an isolator apparatus of Claim 33, wherein the panel assembly is coupled with the housing of the isolator apparatus or wherein the panel assembly is decoupled from the housing of the isolator apparatus.

35. A method of assembling an isolator apparatus comprising the steps of:

(a) providing a panel assembly as claimed in Claim 8

(b) providing an isolator apparatus as claimed in Claim 33; and

(c) aligning the panel assembly with the opening in the housing of the isolator apparatus with the first surface of the panel facing the interior of the isolator apparatus so as to close the opening whereby the implements of the first set are received through the

opening and accommodated in the internal processing area of the isolator apparatus while still remaining mounted on the first surface of the panel.

36. A method of assembling an isolator apparatus as claimed in Claim 35, wherein the method of assembly further includes the steps of

(d) prior to step (b), providing a transport means as claimed in Claim 26;

(e) mounting the panel on the transport means in the same orientation in which it is to be brought into alignment with the opening in the housing of the isolator apparatus;

(f) during step (c) moving the panel assembly in the relevant orientation on the transport means into alignment with the opening of the housing; and (g) sealingly coupling the panel with the housing of the isolator apparatus thereby isolating the internal processing area of the isolator apparatus from the environment.

37. A method of contained processing of substance comprising the steps of:

(a) providing the panel assembly as claimed in Claim 8 and an isolator apparatus as claimed in Claim 33;

(b) assembling the panel and the isolator apparatus according to the method as claimed in Claim 35 or Claim 36 ;

(c) treating the internal processing area of the isolator apparatus; and

(d) activating the relevant implements of the second set of implements at the second surface of the panel, thereby actuating the relevant implements of the first set at the first surface of the panel and opening the internal passageways of the panel and the vessels thereby establishing communication of the vessels and passageways with the internal processing area and the implements of the first set.

38. A method of contained processing of substance as claimed in Claim 37, the method further comprising the steps of:

(e) cleaning the internal processing area of the isolator apparatus and the portion of the panel assembly that faces the internal processing area; and

(f) disconnecting the panel assembly from the isolator apparatus so that another panel assembly can be coupled with the isolator apparatus or so that the first panel assembly can be re-fitted with different implements for another specific process and subsequently used again with the same isolator apparatus.

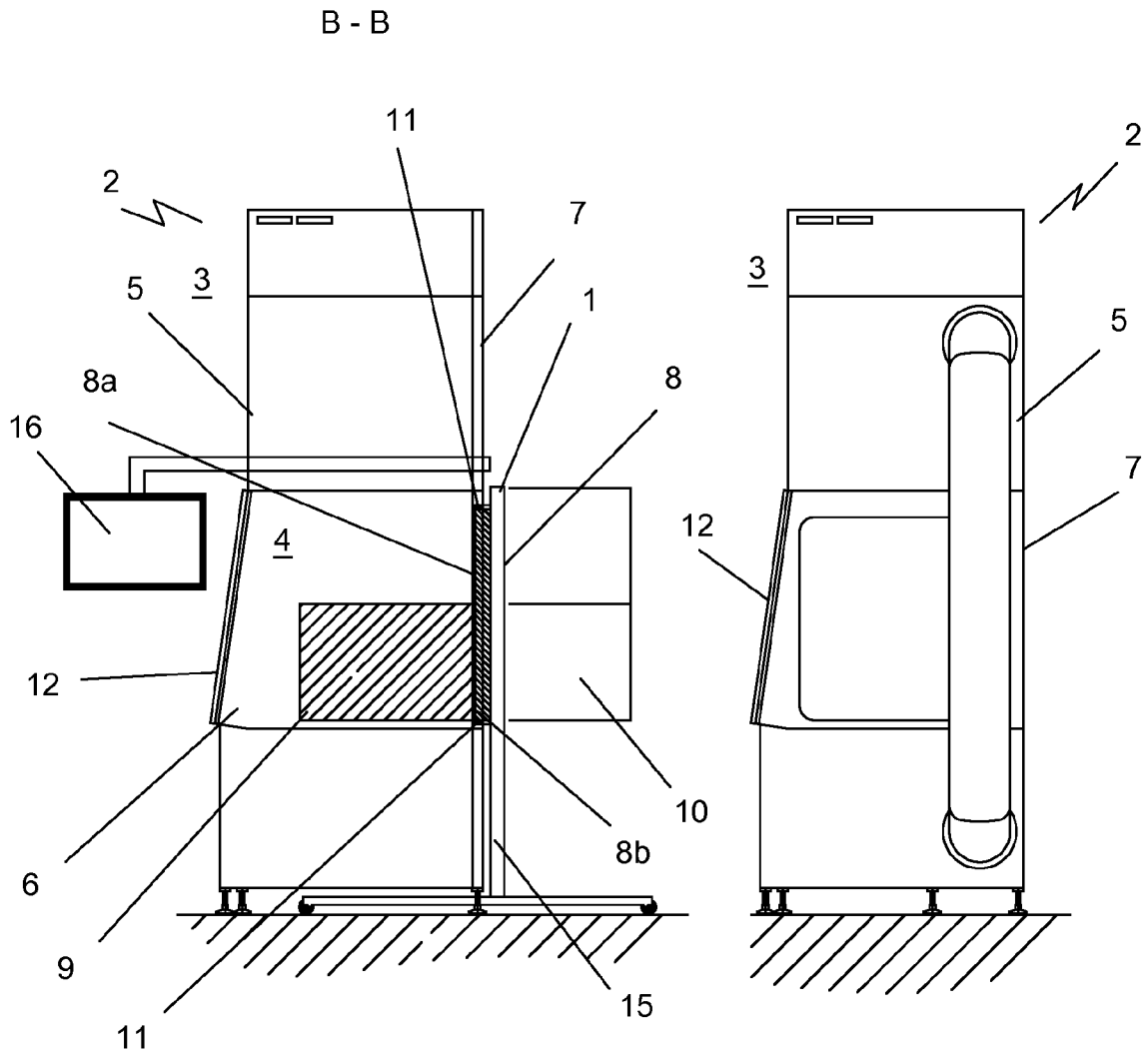

FIGURE 1

FIGURE 2

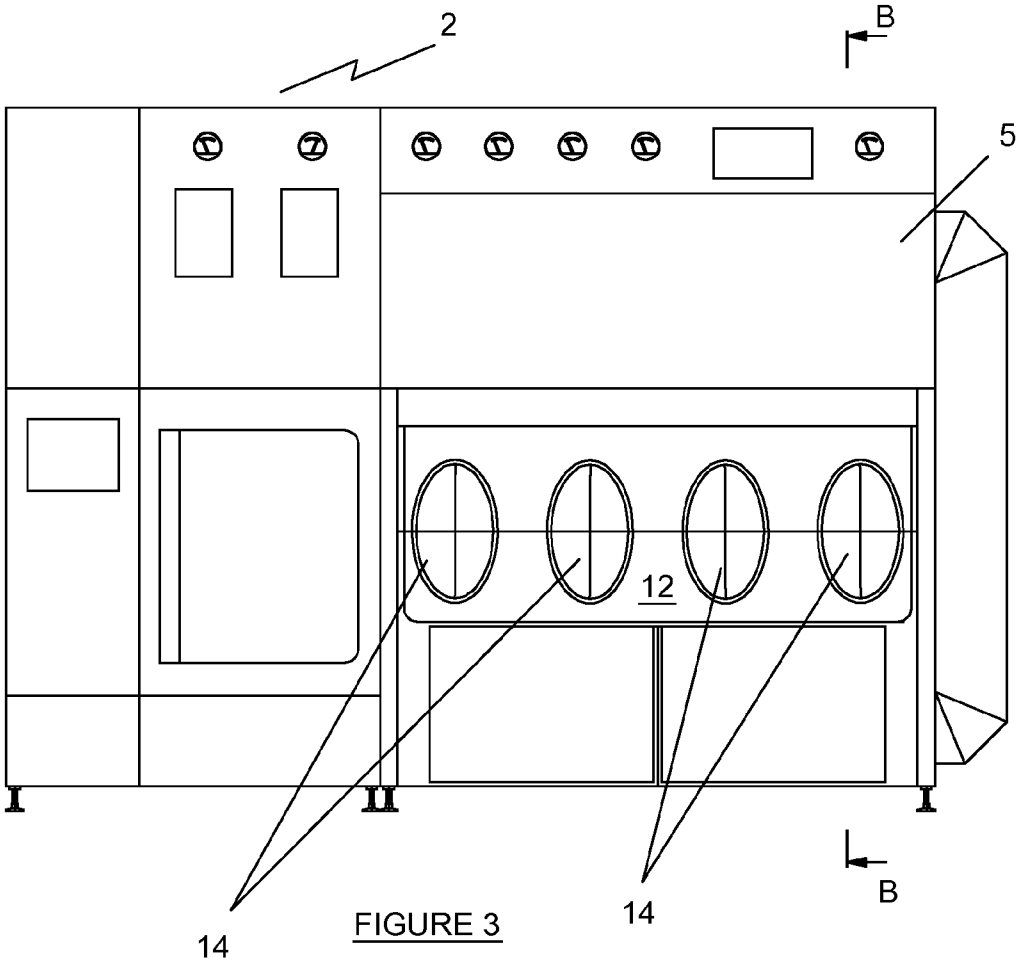

FIGURE 3

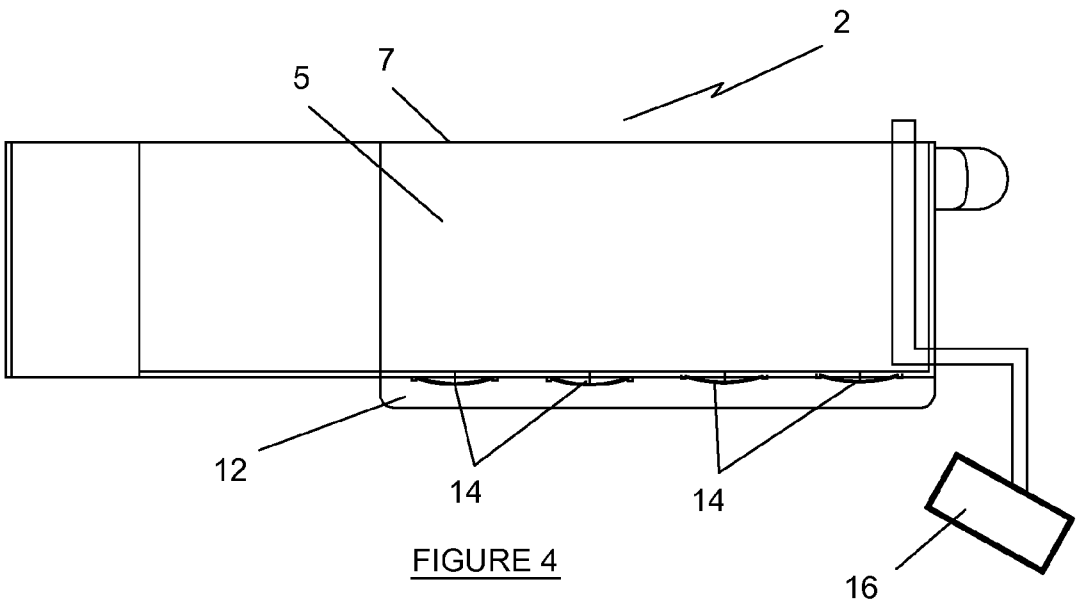

FIGURE 4

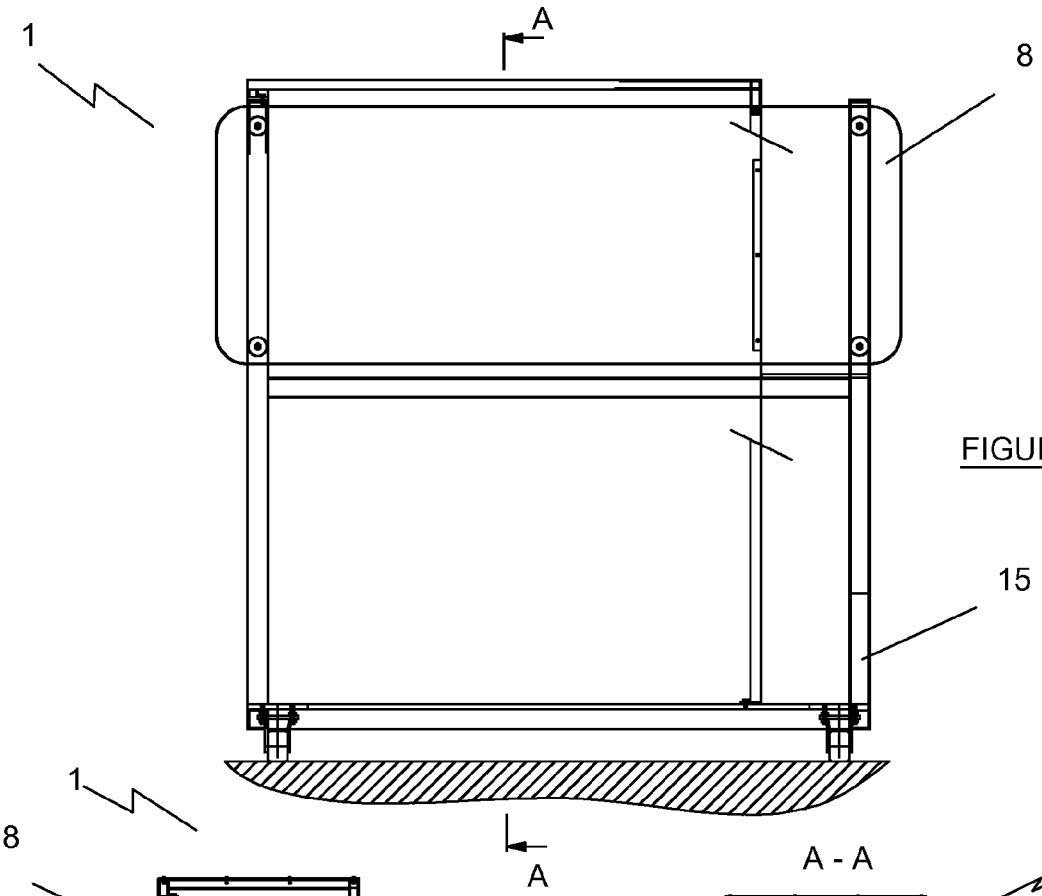

FIGURE 6

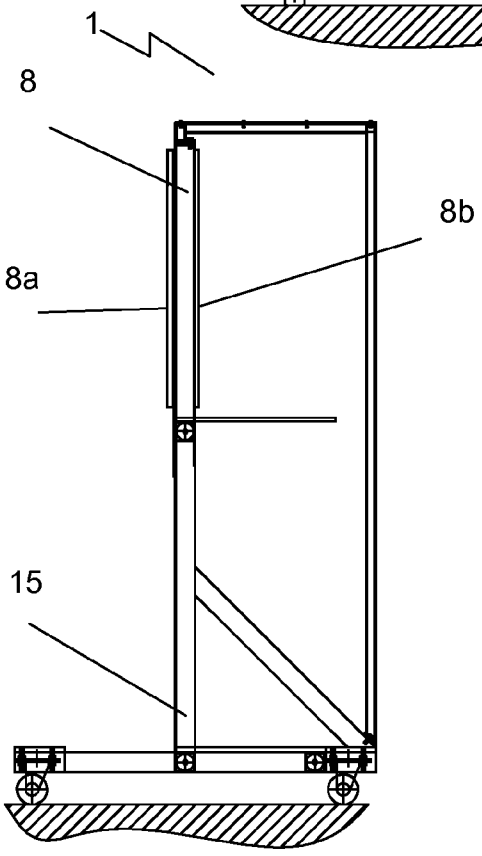

FIGURE 5

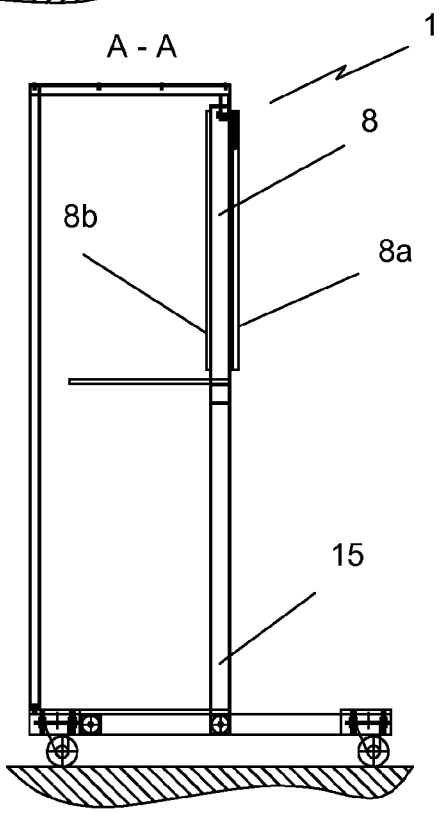

FIGURE 7