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(52) UK CL (Edition W):
A5G GAB G101

(56) Documents Cited:
US 6207119 B1 **US 5976474 A**
US 5783156 A **US 4284600 A**

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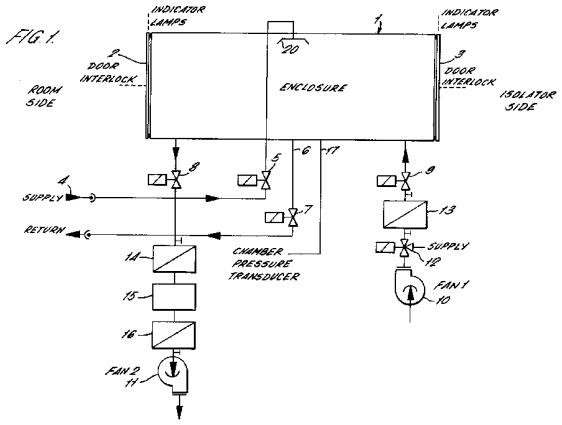
UK CL (Edition W) **A5G**
INT CL[7] **A61L**
Other: **Online: WPI, EPODOC, JAPIO**

(54) Abstract Title: **A pre-sterilisation ante-chamber for an isolated processing enclosure**

(57) An ante-chamber 1 for pre-sterilising components/materials to be supplied to a processing enclosure (e.g. an isolator enclosure, room, cabinet or the like). The ante-chamber has a closable entry 2 for receipt of components/materials and a closable exit 3 for supply of materials/components to the processing enclosure, valve controlled supply and return conduits 4-7 for sterilant vapour for sterilising the chamber and its contents, and valve controlled supply and purge gas conduits 8-9 for purging the chamber of sterilant at the end of the sterilising operation. The supply and return conduits have filters to stop particles from the air being delivered to the chamber and recovered from the chamber respectively. The valves for controlling the supply and return conduits are disposed between the filters and the enclosure, the arrangement being such that the supply and return conduits for purge gas may be arranged to receive sterilant vapour periodically to sterilise the conduits.



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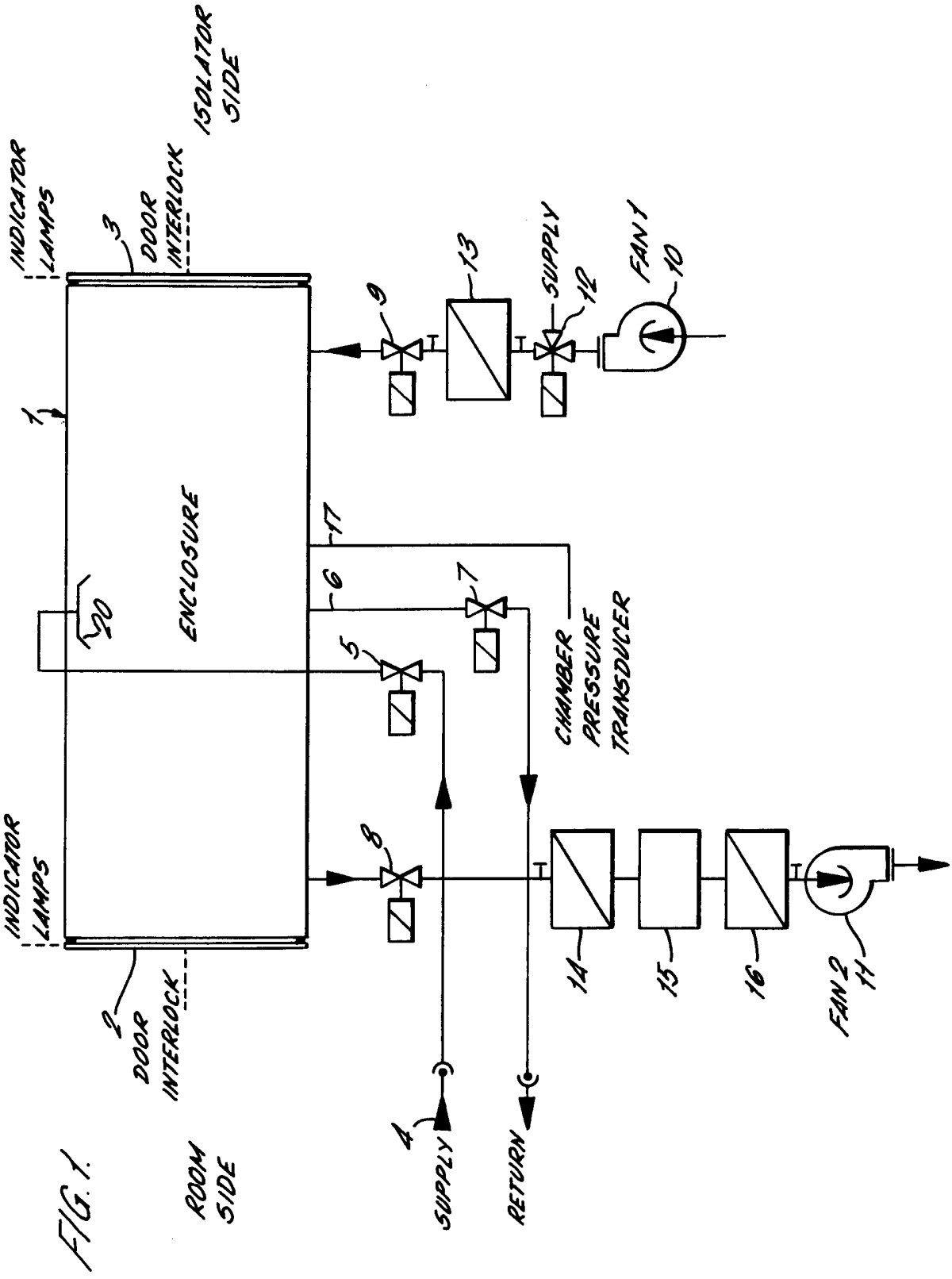
At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.


INDICATOR LAMPS
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DOOR INTERLOCK
ISOLATOR SIDE
1
ENCLOSURE
20
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SUPPLY
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FAN 1
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CHAMBER PRESSURE TRANSDUCER
INDICATOR LAMPS
8
14
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FAN 2
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DOOR INTERLOCK
ROOM SIDE
4
SUPPLY
RETURN

FIG. 1.

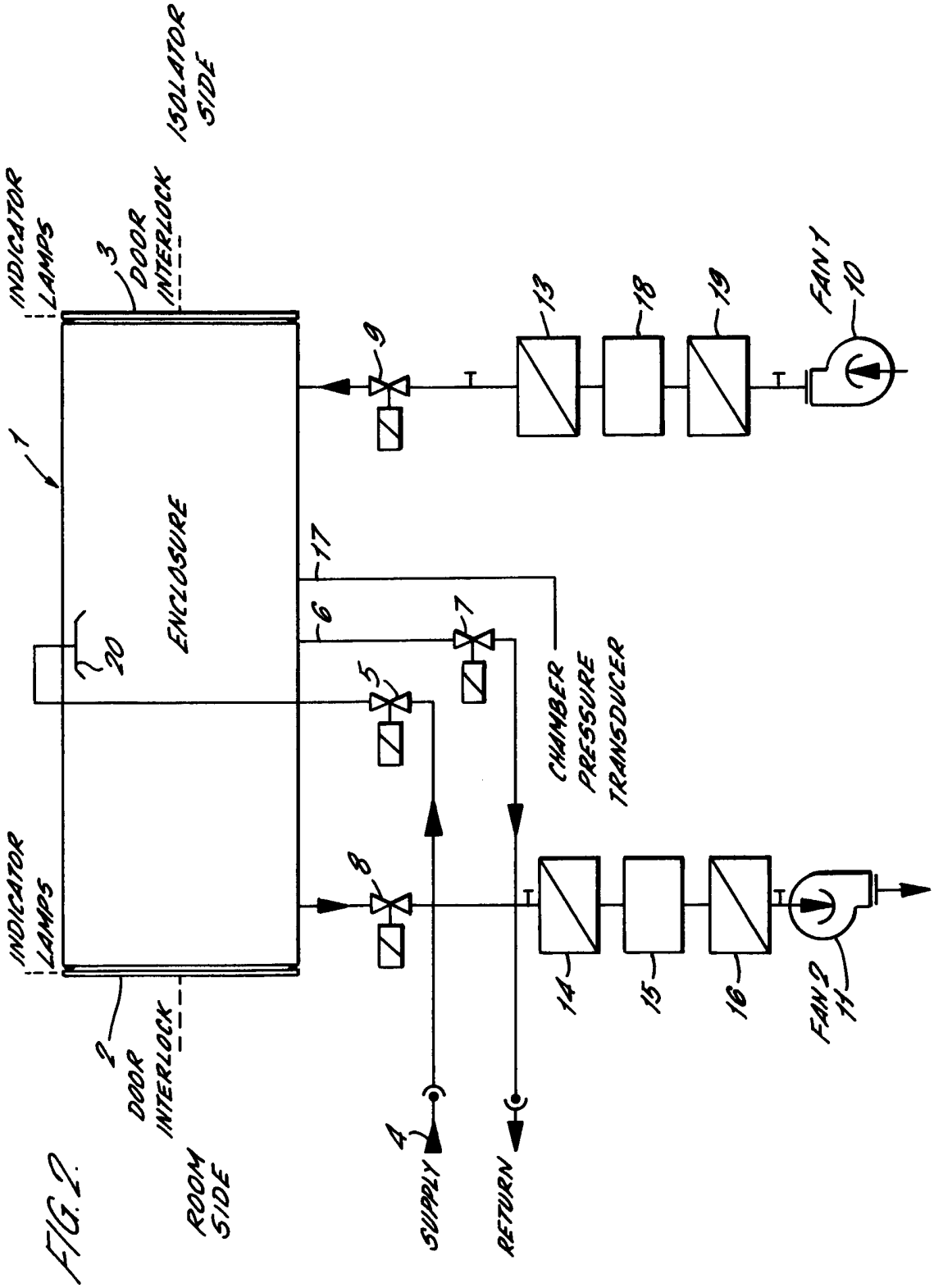
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FIG. 2.

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A Pre-Sterilisation Ante-chamber for a processing Enclosure

This invention relates to pre-sterilisation ante-chamber for processing enclosures such as isolator enclosures, rooms, cabinets or the like in which processing operations are conducted under sterile conditions.

The present invention is a method for the rapid surface gaseous sterilisations of components and material within a chamber so that the surfaces of the said components and materials may be rendered sterile. The said components and materials may then be transferred from the chamber into a sterile processing area without the risk of causing contamination within the processing area.

Typically when small numbers of aseptic drug preparations are required they are dispensed either in a hospital pharmacy or a pharmacy facility that serves a hospital. Normally the components and material required for the dispensing are placed in an isolator for aseptic processing. The surfaces inside the isolator are bio-decontaminated, generally by using a gaseous process; the drugs are then dispensed and removed from the isolator. The problem with this technique is that because the sterilising cycle is long it is necessary to place sufficient components and material inside the isolator for one whole day's work. The workload must therefore be planned the previous day making it difficult to respond to emergencies and changes in requirements, making the process very inflexible. Large banks of pre-sterilised material are often therefore used to improve the flexibility of response, but this approach is space consuming and expensive.

The main reason that the decontamination process is long is the absorption of the sterilizing gas into the surface of the components and material forming the load and also the surfaces of the chamber including the HEPA filters used to provide a stream of sterile air to the chamber. If the size of the load can be reduced and HEPA filters not exposed to the gas much shorter cycles times would result, thus giving the required flexibility to bio-decontaminate components and material on demand. Removing the HEPA filters from the space that is bio-decontaminated with the components and material creates a further problem, in that all surfaces that come into contact with the air entering or leaving the chamber must be sterile, or these surfaces will be a source of bio-contamination that may enter the chamber and hence contaminate the product.

A greater degree of flexibility may be achieved by using a relatively small chamber on the side of the dispensing isolator, and devising a rapid surface sterilization process

for the product and components inside the chamber. By reducing the sterilization time to less than 20 minutes it becomes possible to generate a flow of material through the small chamber into the working isolator and thus give a greater degree of flexibility to the operations. To achieve such a short cycle time it is essential to arrange that surface decontamination is achieved in about 6 minutes and that aeration, the removal of the sterilant gas is achieved in 14 minutes.

Surface sterilization will only be achieved in such a short period if the gas injection rate is high and the gas distribution within the chamber is carefully managed to achieve even gas distribution at even gas temperatures.

To achieve rapid aeration, high purge air rates are required but of equal importance is to ensure that there are no absorbent surfaces, such as HEPA filters, in contact with the gas, during the load sterilisation.

The operation of such a chamber may best be described by reference to Fig 1.

The components and material, known as the load, to be bio-decontaminated are placed inside the chamber (1) through the chamber door (2). At the other end of the chamber (1) is a second door (3) connected to the dispensing isolator (not shown) or processing enclosure. It would be good practice to provide the door (2) and the second door (3) with interlocks such that only one door may be opened at a time and also that either the door (2) or the second door (3) may only be opened when the atmosphere inside the chamber (1) is safe.

Once the load is placed inside the chamber (1) and the door (2) and second door (3) are closed and sealed sterilizing gas may be introduced into the chamber (1) through the port (4) which connects to the chamber. At this time the valve (5) must be opened to allow the gas to enter the chamber (1). The sterilizing gas is removed from the chamber (1) through the port (6) and the valve (7). The most commonly used sterilizing gas is hydrogen peroxide, and generally the commercially available hydrogen peroxide gas generators operate as a close of loop system with the gas returning to the generator. During the circulation of the sterilizing gas the valves (8) and (9) which are connected to the chamber (1) remain closed.

Once the gaseous sterilization phase has been completed and it is required to remove the gas from the chamber the valves (8) and (9) are opened and the Fan 1 (10) and Fan 2 (11) are switched on. At this point the 3-way valve (12) must be set to connect

the air from the Fan 1 (10) to the valve (9).

The fan 1 (10) takes air from the surrounding environment passing it through the 3-way valve (12) and the HEPA filter (13) and valve (9) into the chamber (1). This fresh air will reduce the gas concentration in the chamber (1) by dilution. An equal quantity of air must be removed from the chamber (1) through the valve (8) the HEPA filter (14) the catalytic filter (15) and the HEPA filter (16) by the fan 2 (11). It is important that the air fed into the chamber (1) by the Fan 1 (10) is filtered through the HEPA filter (13) to ensure that the chamber (1) and the load inside the chamber (1) remains sterile after gassing. Also on the exhaust side the air removed from the chamber (1) must pass firstly through a HEPA filter (14) to stop any particles escaping back into the chamber and rendering it non-sterile. The catalytic filter (15) is used to render the exhaust gas safe before it is passed through the HEPA filter (16) to remove any dust particles and then back into the surrounding environment.

A further connection (17) to the chamber (1) is required to monitor the pressure inside the chamber (1). A small HEPA filter to avoid any contamination of the chamber (1) must also protect the connection (17). The pressure as measured at the connection (17) is used to control the Fan 1 (10) and Fan 2 (11) to achieve the required pressure in the chamber (1). The Fan 1 (10) and Fan 2 (11) must also be adjusted to achieve airflow through the chamber at sufficiently high flow to remove the sterilizing gas in about 15 minutes. Experiment has shown that this will require an air change rate of about 2000 per hour.

Because of the need to ensure that the hydrogen peroxide gas does not come into contact with the HEPA Filters (13) and (14) there is a space between the filter (14) and valve (8), and also a space between the filter (13) and valve (9) that is not sterilized. This space forms part of the air path during the aeration of the cycle. Any contamination in these spaces may therefore be transferred to the chamber (1) and hence may contaminate the load within the chamber.

Two possible techniques are available to ensure that these spaces are bio-decontaminated and hence do not pose a risk to the load. The first may be described by reference to Fig 1. The hydrogen peroxide gas supply is connected to the 3-way valve (12) such that the gas flows into the valve (12) and then to the chamber (1) via the HEPA filter (13) and the valve (9), which must be open. The valves (7) and (5) must be closed and the valve (8) opened to allow the gas to pass out through the HEPA Filter (14) and then the carbon filter/catalyst (15) which renders the gas safe

and then through the HEPA Filter (16) and finally exhausting through the Fan 2 (11). The passage of gas from the 3 way valve (12) through the chamber (1) and out through the Fan 2 (11) is allowed to continue for sufficient length of time to ensure decontamination of all of the components in this flow path.

At the end of the period the system is put back into aeration, as before, to remove the hydrogen peroxide vapour. Because this air path is protected by HEPA filtration it will require bio-decontamination at infrequent intervals, probably once every two weeks, depending on the usage of the chamber.

The second technique may be described with reference to Fig 2.

With this technique hydrogen peroxide gas is supplied from the generator through valve (5) into the chamber (1). The valve (7) remains closed and valves (8) and (9) are opened, allowing the gas to flow from the chamber (1) through two pathways. The gas leaves the chamber (1) either through valve (8) or valve (9). The gas leaving through valve (9) passes through the HEPA filter (13) and the CAT2 (18) where the gas is rendered safe. The exhaust gas then passes through HEPA 4 (19) and finally exits the system through Fan 9 (10). The other stream of gas leaving through valve (8) passes through HEPA filter (14), CAT1 (15) and HEPA 3 (16). By passing through CAT1 (15) the gas is rendered safe before returning to the room through the fan2 (11). This gas flow is maintained for a sufficient period of time to ensure that the whole of the flow path is bio-decontaminated. Once sufficient time has elapsed then the system may be returned to aeration mode to remove the hydrogen peroxide gas.

Because gas distribution within the chamber (1) and around the load is very important it is sensible to use some device to give the gas some kinetic energy when entering the chamber. This may be achieved by using a rotating nozzle (20), which not only ensures that the gas enters the chamber at high velocity but also changes the direction of the jet. Alternatively the rotating nozzle (20) may be replaced with either a fixed nozzle or a number of fixed nozzles that ensure good gas distribution.

A loading system will be required to place the load into and remove it from the chamber (1). A suitable system would be a trolley/rack that can be partially withdrawn from the chamber through the outer door (2) to assist with loading the chamber (1). After sterilisation the trolley/rack system can then withdrawn into the processing enclosure through the inner door (3) where it may be unloaded.

The chamber (1) and all of the associated components should form one integrated self-contained unit that may be constructed as a mobile device capable of being moved to interface with various process enclosures.

CLAIMS

1. An ante-chamber for pre-sterilising components/materials to be supplied to a processing enclosure (e.g. an isolator enclosure, room, cabinet or the like) the ante-chamber having a closable entry for receipt of components/materials and a closable exit for supply of materials/components to the isolator enclosure, valve control and supply and return conduits for sterilant vapour for sterilising the chamber and its contents and valve controlled supply and purge gas conduits for purging the chamber of sterilant at the end of the sterilising operation, the supply and return conduits having filters to filter out particles from the air being delivered to the chamber and recovered from the chamber respectively and the valves for controlling the supply and return conduits being disposed between the filters and enclosure, the arrangement being such that the supply and return conduits for purge gas may be arranged to receive sterilant vapour periodically to sterilise the conduits.

2. An ante-chamber as claimed in claim 1, wherein a valve controlled supply of sterilant is provided for the purge gas supply conduit for supplying sterilant vapour through the conduit and to the return conduit via the ante-chamber to sterilise the purge gas supply and return conduit.

3. An ante-chamber as claimed in claim 2, wherein the valve for controlling the supply of sterilant to the purge gas supply conduit is located upstream of the filter in the conduit.

4. An ante-chamber as claimed in claim 2 or claim 3, wherein the return conduit for purge gas from the chamber has a catalyst downstream of the filter for converting the sterilant into products which may be discharged to atmosphere.

5. An ante-chamber as claimed in claim 4, wherein a further filter is located in the return conduit downstream of the catalyst to remove any particle in the purge gas received from the catalyst.

6. An ante-chamber as claimed in any of the preceding claims, wherein the sterilant gas supply conduit chamber has a fan for delivering air to the ante-chamber via the filter and valve to purge sterilant gas from the chamber.

7. An ante-chamber as claimed in any of the claims 1 to 6, wherein the return conduit for purge gas has a fan for extracting purge gas from the chamber disposed downstream of the valve control and filter.

8. An ante-chamber as claimed in any of the claims 1 to 6, wherein the supply and return conduits for purge gas both contain a pair of filters and a catalyst for converting sterilant to harmless products disposed between the filters and the valves are arranged to open both return and supply conduits to atmosphere for delivery of sterilant gas from the ante-chamber to sterilise the supply and return conduits.

9. An ante-chamber for pre-sterilising components/materials to be deployed in an isolator enclosure substantially as described, with reference to and as illustrated in Figure 1 or Figure 2 of the accompanying drawings.

Application No: GB 0222154.7 **Examiner:** Nicola Keeley
Claims searched: 1-8 **Date of search:** 14 January 2004

Patents Act 1977 : Search Report under Section 17

Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance	
X	1	US 5976474 A	(BARNSTEAD) See especially figure 1
X	1	US 4284600 A	(GILLIS) See especially figures
A		US 6207119 B1	(DICCIANNI) See whole document
A		US 5783156 A	(RENZI) See whole document

Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.

Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC[W]:

A5G

Worldwide search of patent documents classified in the following areas of the IPC[7]:

A61L

The following online and other databases have been used in the preparation of this search report:

WPI, EPODOC, JAPIO