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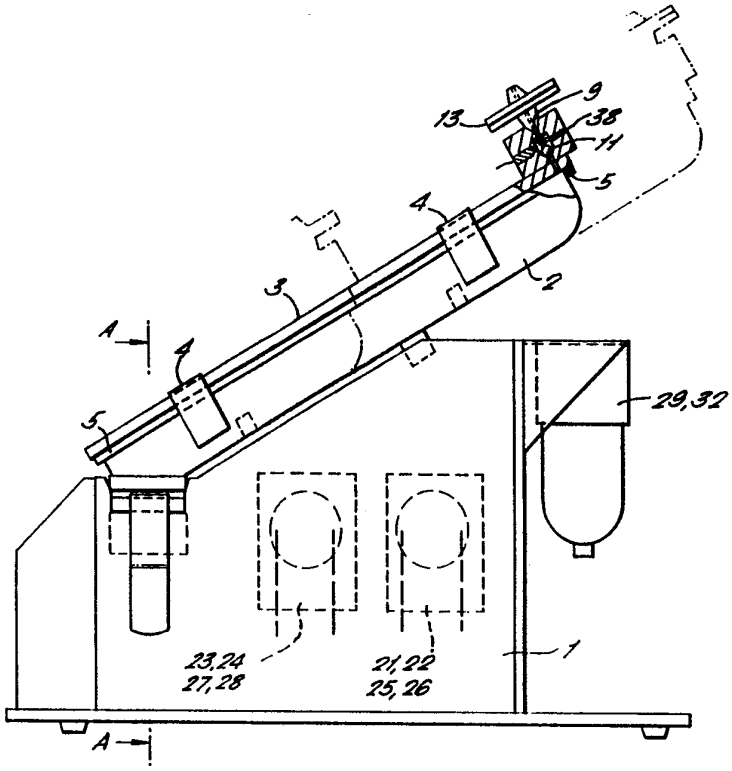

(57) Abstract

A process for sterilising surgical instruments at ambient temperature comprises the steps of firstly decontaminating the surgical instrument in a closed environment by washing it with a detergent liquid having bactericidal properties to remove any blood, body fluid and/or body tissue adhering to the instrument, and secondly washing the instrument in a strongly bactericidal liquid to sterilise the instrument. Automated apparatus for carrying out the process is also described, and also a prepacked container of concentrated liquids for use in the process and apparatus.

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STERILISING METHOD AND APPARATUS

This invention relates to a sterilising method and apparatus, and in particular to a sterilising method and apparatus for surgical instruments such as endoscopes.

The usual method of sterilising surgical instruments is by autoclaving, i.e. by enclosing the instruments in a chamber and supplying steam under high pressure and at high temperature. Steam sterilising is very effective but has several disadvantages, including that the process is relatively slow; the steam sterilising apparatus cannot be conveniently located close to the area where the surgical instruments are to be used, and also cannot be used for delicate surgical instruments which have integral optics and sensors, such as endoscopes, which are likely to be damaged by steam and heat.

For the latter type of instruments cold sterilising procedures have to be used.

Cold sterilising procedures at present employed usually involve chemicals such as formaldehyde, gluteraldehyde or hydrogen peroxide. However, there are also disadvantages in these procedures in that the chemicals are not easy to handle, being toxic, corrosive and/or inflammable and may also cause dermatitis and other harm to persons involved in the procedures. Additionally, chemical procedures usually require relatively long periods of time and consequently may restrict use of the surgical equipment; the temptation may then be present to re-use such equipment before it has been effectively re-sterilised.

Cold cleaning procedures are known for example from EP 0 038 168 in which surgical instruments such

as endoscopes are first washed with a detergent liquid and are then washed with a liquid disinfectant. However such procedures are not sterilisation procedures. Sterilisation destroys all life forms including, in particular, bacterial spores, whereas disinfection only implies the absence of pathogenic life forms. Thus procedures such as described in EP 0 038 168 do not actually sterilise surgical instruments, and a separate sterilisation procedure is necessary. Additionally they involve risks of splashing with chemicals, and with blood and body tissue and fluids from the spraying of the surgical instruments with detergents, and the latter risks cannot be ignored with the growing prevalence of AIDS.

The trend in surgical techniques, particularly microsurgical techniques, has been towards operations without general anaesthetic or even without local anaesthetic, thereby increasing the speed of surgical operations and creating a demand for re-sterilised surgical instruments to be available more quickly. On the other hand surgical instruments such as endoscopes tend to be costly and therefore it is impractical to have a large number of such instruments available for use in rotation.

There is therefore a demand for a convenient cold sterilising method and apparatus which can effectively clean a surgical instrument of blood, body fluids and/or tissue and also sterilise the instrument in a short period of time with low risk to the operator, the procedure being automated and as convenient as possible. It is also desirable that the apparatus should retain infected material so that it is not discharged to the surroundings or to the drains. As with all sterilising apparatus the surgical instruments should be kept in a sterile

environment until they are to be used.

According to the present invention there is provided a process for sterilising surgical instruments at ambient temperature which process comprises the steps of firstly decontaminating the surgical instrument in a closed environment by washing it in a detergent liquid having bactericidal properties to remove any blood, body tissue and/or fluid adhering to the instrument, and secondly washing the instrument in said closed environment in a strongly bactericidal liquid to sterilise the instrument. It is particularly preferred that the detergent liquid used is an aqueous solution of a quaternary ammonium salt, alkyltrimethyl ammonium bromides being particularly preferred, for example, cetrimide which is a mixture of C_{12}, C_{14} and C_{16} alkyltrimethyl ammonium bromides, as they are both surfactants and strong bactericides. The quaternary ammonium salt is preferably used at a concentration of the order of about 1% by weight. Also, the strongly bactericidal liquid is preferably an aqueous solution of iodine, used at a preferred concentration of the order of about 0.2% by weight. Means are preferably provided to meter the desired quantity of each agent so as to provide the required concentration of it in the treatment fluids. Although alternative liquids may be used in the two essential steps of the process, as defined above, the above-mentioned solutions are those which have been found to be particularly appropriate and efficacious, and are regarded to be particularly preferred, being particularly suited to the process from a number of aspects, and being significantly superior to other possible cleaning and sterilising agents which might be employed.

Also provided by the present invention is an

apparatus suitable for use in the above process for sterilising surgical instruments which apparatus comprises a base unit having connected thereto a closed container for surgical instruments within which the surgical instruments are to be sterilised, said container having a fluid-tight lid, holding means for holding said surgical instruments, an inlet and an outlet for the detergent and sterilising liquids, venting means, pump means for pumping the detergent and sterilising liquids into and out of the container, and sensor and control means for controlling the order and amount of pumping. Preferably filter means are provided to stop bacterial or viral passage when liquids and air are pumped into and out of the apparatus.

The water which is used in the process and apparatus of this invention, as hereinafter exemplified, is ordinary unheated tap water. The water is permitted to enter the apparatus through a bacterial filter of maximum pore size 0.2 μm. A similar filter is used to process the liquids pumped out of the apparatus. It should also be noted that liquids entering the apparatus displace air which is also passed out of the equipment through an air filter of maximum 0.2 μm pore size and air drawn into the equipment when solutions are pumped out of the equipment is also drawn through a similar filter. Thus, these filters serve to isolate the equipment bacteriologically from its surroundings.

Specific embodiments of the invention will now be described with reference to the accompanying drawings in which:

Figure 1 is a simplified side view of an apparatus in accord with the present invention showing the disposition of several of the main components of the apparatus.

Figure 2 is a view in section at line A-A of Figure 1.

Figure 3 is another view partially in section of part of the apparatus shown in Figure 1.

Figure 4 is a schematic representation of the apparatus showing the inter-connection of various parts as shown in Figures 1, 2 and 3;

Figure 5 is a perspective view of a disposable storage unit for surfactant and steriliser liquids which can be used in the apparatus; and

Figure 5A is a section through a part of Figure 5.

Referring to Figures 1 to 3 the apparatus comprises a base unit 1 having detachably connected thereto a container tray 2. The alternative end positions of the upper end of the tray, as indicated by the broken lines, show that different sizes and shapes of tray can be used with the same base unit. The tray 2 has a lid 3 which is held by clip or screw means 4 onto a rim seal 5. The base of the tray is provided with passages 6 and 7 for fluids which connect with corresponding passages in the base unit. Passage 6 is provided for inlet of liquids into the container tray and passage 7 is an outlet for liquids. At the other, upper end of the container tray are provided respectively an air inlet passage 8 and an air outlet passage 9 through the lid 3 of the container each of said passages being provided with a non-return valve 10,11 and a biological air filter 12,13.

The item of surgical equipment 14 to be decontaminated and rendered sterile is held by clips in the tray 2 and the fluid inlet 6 is so arranged that fluid issuing from its end 15 is directed so as to wash the said item of surgical equipment. The inlet 6 may in fact be provided with a plurality of

ends 15 each adapted to provide a directed and appropriately sized jet of liquid onto the surgical instrument 14. After each washing or soaking step liquid is drained from the tray 2 through the passage 7.

The fluid passages 6 and 7 in the base of the tray are both provided with sealing means 16 and 17 to seal the tray when it is not connected to the base unit. Sealing means 16 is in the form of a non-return valve whereas sealing means 17 is a valve which seals the drain 7, being opened by rod 18, which is fixed to the base unit of the apparatus, as the tray 2 is brought into contact with the base unit. Clamping means 19 secure the tray 2 to the base unit 1 and O-ring seals 20 provided in the base unit give pressure-tight connection between the base unit 1 and the tray 2. The correct positioning of the tray 2 on the base unit is ascertained by means of switch means 20 which gives an electrical indication of the correct positioning.

In the base of the apparatus are provided four displacement pumps, 21, 22, 23 and 24 together with motors 25, 26, 27 and 28 to operate them and also a filter 29 for inflowing tap water from the supply 30 through the normally off solenoid valve 31, and also a filter 32 in the flow to the drain 33.

In the embodiment of the apparatus being described the pumps 21, 22, 23, and 24 are preferably of the peristaltic type having a tube held in a circular arc, the tube being closed and thereby trapping the fluid to be pumped, by means of rollers pressing against the tube and so moving along the tube relatively so as to displace the trapped fluid. Also in this embodiment the motors are preferably direct current motors. Each motor is supplied electrically and controlled by the controller 34 in

accord with predetermined programming of events with reference to the tray position sensor 20 and the pressure switch 38.

The pump 21 controls the flow of tap water from the supply 30 through the filter 29 and through the passage 6 and valve 16 into the tray so as to spray the surgical instrument. The pump 22 controls the flow of liquid from the outlet 7 of the tray through the drain filter 32 to the drain 33. The pump 23 controls the flow of sterilant liquid from the container 34 into the flow from the pump 21. Similarly the pump 24 controls the flow of surfactant liquid from the container 35 into the flow from the pump 21. The containers 34 and 35 are preferably supported by the base unit 1, and more preferably are in the form of a disposable pack 42 supported on weighing means 45 as hereinafter described with reference to Figures 5 and 5A.

The non-return valves 8 and 9 are connected to filters 12 and 13 in the lid of the tray, as explained previously, and these filters permit air to pass to and from the container tray 2.

The afore-mentioned predetermined programme of events is best understood by referring to the schematic diagram of Figure 4.

When the tray 2 is connected to the base frame 1 this causes switch 20 to operate. The solenoid valve 31 in the cold water supply 30 then opens and pump 21 driven by motor 25 causes the cold tap water to pass in a controlled manner into the tray 2 through valve 16 so as to spray the surgical instrument. Simultaneously pump 22 driven by motor 26 pumps the liquid draining through valve 17 through the filter 32 into the drain 33. The detector 36 attached to pump 21 detects the rotations of the pump and similarly detector 37 attached to pump 22 detects the

rotation of pump 22. After a prescribed number of rotations the controller 34 causes the pump 21 to stop and then after a further prescribed number of rotations of the pump 22 causes the pump 22 to stop. After a prescribed delay pump 21 together with pump 24 are started, filling the tray 2 with a prescribed mix of fluid from inlet 30 and surfactant from container 35 until all air is expelled from the container and a rise in liquid flow pressure is detected by pressure switch 38 which is integral with the non-return valves 10,11. The pressure switch 38 causes the controller 34 to stop the pumps 21 and 24. After a further prescribed delay pump 22 is then operated for a prescribed number of rotations as sensed by the detector 37 thereby emptying the tray 2. The cycle may then be repeated depending on the nature of the surgical instrument to be decontaminated.

Pump 21 is then operated together with pump 23 so as to provide a sterilising fluid which passes into the tray 2 until all air has been expelled and the pressure sensor 38 senses an increased in fluid flow pressure. The pumps 21 and 23 are then stopped. After a prescribed delay pump 22 is operated for a number of revolutions which exceeds the number of revolutions of pump 21 during its last operation by a prescribed number, this ensuring that the tray 2 is drained through the filter 12 and filled with sterile air which has passed through the filter 12. A record of the operations performed by the pumps as detected by the detector means 36, 37, 38 and 39 and the pressure switch 38 is output from the controller 34 to a recording means 40. Electrical power means are provided through the power supply 41.

It will be appreciated that the number and

sequence of washing, decontamination, and sterilising steps can be varied to suit particular requirements and the apparatus programmed accordingly. The above procedure is just an example of a sequence which may be employed. Thus, in one preferred procedure the tray is first filled with cold tap water, then drained, and then filled with a 1% aqueous solution of cetrimide (alkyltrimethyl ammonium bromides) by pumping an appropriate amount of stock solution and diluting it with the cold tap water supply and thereafter pumping out the tray without further delay. The tray is then refilled with a similar solution of the cetrimide which is then allowed to stand for 10 minutes. The solution of the cetrimide is then pumped out and this is followed by two rinses of the equipment with water. Thereafter a solution of iodine is sprayed into the tray, having been formed from a concentrated iodine solution and suitable dilution with the cold water supply to give a final concentration of .2%. This is again allowed to stand for 10 minutes at ambient temperature and then pumped out. Finally, the equipment is given a single rinse with water and the surgical instrument(s) is then ready for use but kept in the tray, under sterile conditions, until required. It will be appreciated that the exact sequence, timings, can be varied to suit the particular circumstances.

As mentioned hereinbefore a preferred feature of the present invention is the use of prepackaged surfactant and sterilant liquids as this greatly simplifies the use of the sterilising equipment in accord with the invention. Thus, with prepackaged liquids of preset concentration no adjustment in the programming of the procedure need be made and the prepackaging also ensures that the materials used are as specified and have not been tampered with.

In a preferred embodiment as shown in Figures 5 and 5A the two liquids are provided in a disposable box 42 containing a total of some 5 litres of the materials in the correct proportions for use in the sterilising process in two flexible bags 43 that collapse as the liquids are pumped out.

Each bag is fitted with a different and specific taper of bayonet connector 44a,44b to enable it to be correctly connected to the sterilising machine. Each connector is fitted with a sprung non-return valve 46 (as shown in Figure 5A) to stop any attempt to refill the flexible bags either during or after use in the machine.

To ensure there has been no tampering, or a leak, the storage unit may be filled to an accurately controlled weight, the box being situated on a weighing platform 45 situated on the base 1 of the steriliser.

It is essential that any sterilising process is monitored and records maintained of the correct functioning of the apparatus and the correct usage of sterilant and surfactant. The apparatus of the invention as exemplified is therefore provided with peristaltic pumps to transfer water and the surfactant/sterilant into the sterilising tray which may vary considerably in size, it being envisaged that different types and sizes of tray can be interchangeably used in the apparatus of the invention.

By the provision of a simple electronic weigh platform 45 - preferably using a shear transducer - connected to the controller 34 it is possible to first check the weight of the full unused surfactant/sterilant storage unit and then monitor the use of the chemicals during each phase of the sterilising process and finally provide a warning of the need to

replace it. If the storage unit is the wrong weight a suitable alarm can be given.

It will be appreciated that the process and apparatus as specifically described above enables surgical equipment to be rapidly sterilised and therefore to be quickly reusable. Furthermore the process and apparatus operates at ambient temperature with chemicals that are not dangerous. The operator of the process does not have to handle either the sterilant or the contaminated surgical equipment. Furthermore, the apparatus is particularly adapted to handle fragile equipment.

CLAIMS:

1. A process for sterilising surgical instruments at ambient temperature which process comprises the steps of firstly decontaminating the surgical instrument in a closed environment by washing it with a detergent liquid having bactericidal properties to remove any blood, body fluid and/or body tissue adhering to the instrument, and secondly washing the instrument in said closed environment in a strongly bactericidal liquid to sterilise the instrument.

2. A process as claimed in claim 1 wherein the detergent liquid is an aqueous solution of a quaternary ammonium salt.

3. A process as claimed in claim 2 wherein the quaternary ammonium salt is one or more alkyltrimethyl ammonium bromides.

4. A process as claimed in claim 3 wherein the alkyltrimethyl ammonium bromides are used in a concentration of the order of about 1% by weight.

5. A process as claimed in any one of the preceding claims wherein the strongly bactericidal liquid is an aqueous solution of iodine.

6. A process as claimed in claim 5 wherein the concentration of iodine is of the order of about 0.2% by weight.

7. A process as claimed in any one of the preceding claims wherein the decontamination and sterilising steps are carried out in a closed

container the inflow and outflow of liquid and air to and from the container being through bacteriological filters.

8. A process as claimed in any one of the preceding claims wherein concentrated detergent liquid and concentrated strongly bactericidal liquid are contained within a single prepacked container and are separately drawn from the container and diluted in controlled manner with water to provide the said detergent liquid and strongly bactericidal liquid.

9. A process as claimed in claim 7 or claim 8 wherein the said container is weighed continuously or intermittently in order to monitor the usage of the said concentrated liquids and the operation of the process.

10. A process as claimed in claim 1 substantially as hereinbefore described with reference to and as illustrated in the accompanying drawings.

11. An apparatus suitable for use in the process for sterilising surgical instruments as claimed in claim 1 which apparatus comprises a base unit having connected thereto a closed container for surgical instruments within which the surgical instruments are to be sterilised, said container having a fluid tight lid, holding means for holding said surgical instruments, an inlet and an outlet for the detergent and sterilising liquids, venting means, pump means for pumping the detergent and sterilising liquids into and out of the container, and sensor and control means for controlling the order and amount of pumping.

12. An apparatus as claimed in claim 11 further comprising filter means to bacterial or viral passage when liquids and air are pumped into and out of the apparatus.

13. An apparatus as claimed in claim 11 or claim 12 wherein the container for surgical instruments is detachably connected to the base unit means being provided to seal the container when it is detached from the base unit.

14. An apparatus as claimed in any one of claims 11 to 13 wherein means are provided to detect the correct positioning of the container on the base unit.

15. Apparatus as claimed in any one of claims 11 to 14 wherein means are provided to supply and exhaust in sequence a detergent liquid and a strongly bactericidal liquid.

16. Apparatus as claimed in any one of claims 11 to 15 wherein stock detergent liquid and bactericidal liquid are provided in a prepacked container having liquid supply connectors which are adapted to connect with corresponding connectors in the apparatus.

17. Apparatus as claimed in claim 16 further comprising weighing means for said prepacked container.

18. Apparatus as claimed in claim 17 comprising means for monitoring usage of each liquid during each phase of this sterilising process.

19. Apparatus as claimed in claim 17 or claim 18 comprising means for monitoring said weighing means to provide warning of exhaustion of supply of said liquids.

20. Apparatus as claimed in any one of claims 17 to 19 comprising means for monitoring said weighing means to provide warning of incorrect weight of said container.

21. An apparatus as claimed in any one of claims 11 to 20 wherein means are provided to record the operations carried out by the pumps.

22. An apparatus as claimed in any one of claims 11 to 21 substantially as hereinbefore described with reference to and as illustrated in the accompanying drawings.

23. A container of detergent and bactericidal liquids suitable for use in the apparatus as claimed in claim 11 which container comprises a substantially rigid box containing a plurality of flexible bags, of which one bag contains a concentrated detergent solution and a second bag containing a concentrated bactericidal solution, each bag being provided with an outlet tube having a connector containing a non-return valve for connecting to the said apparatus, the connectors being of different size or shape to prevent erroneous connection to the said apparatus.

24. A container as claimed in claim 23 substantially as hereinbefore described with reference to Figures 5 and 5A of the accompanying drawings.

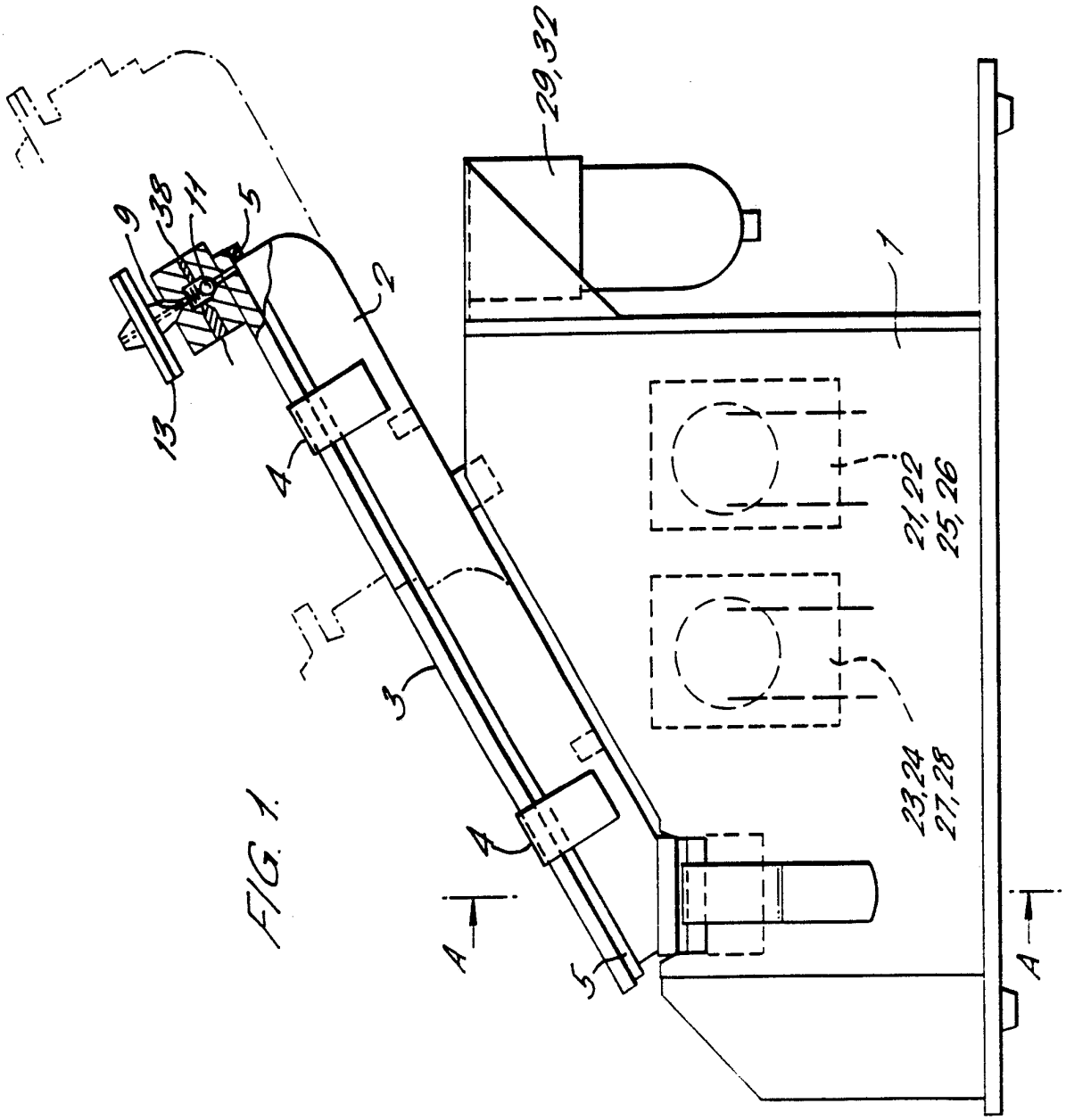


FIG. 1.

FIG. 2.

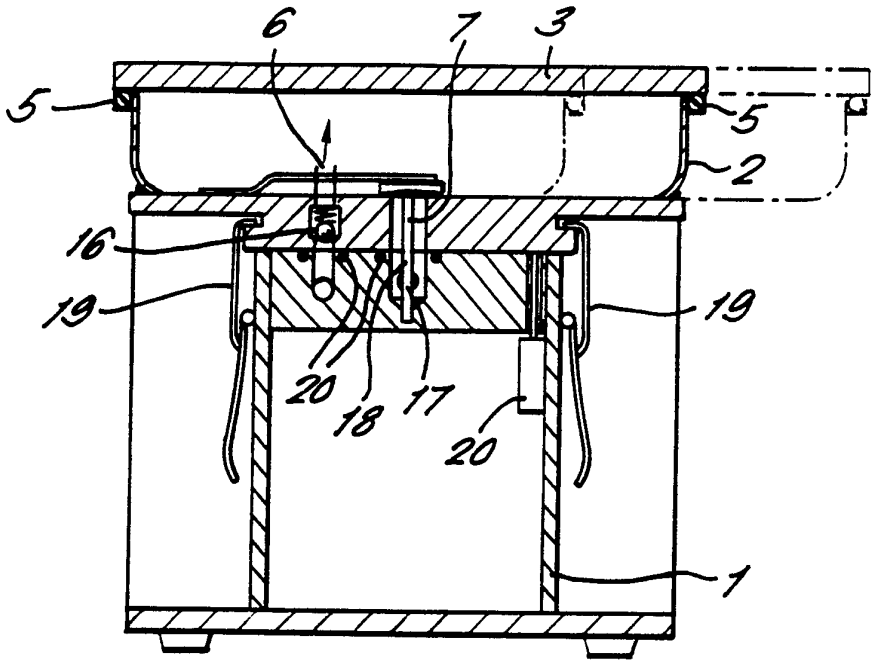
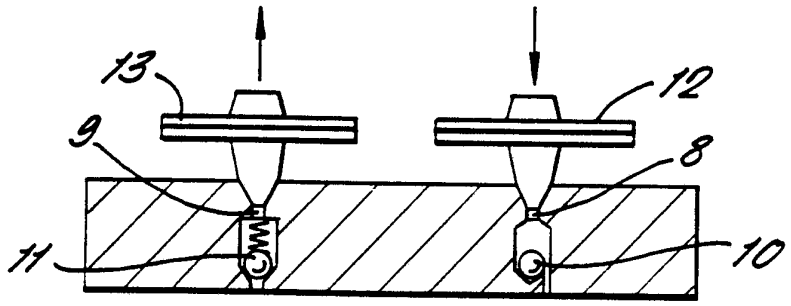


FIG. 3.



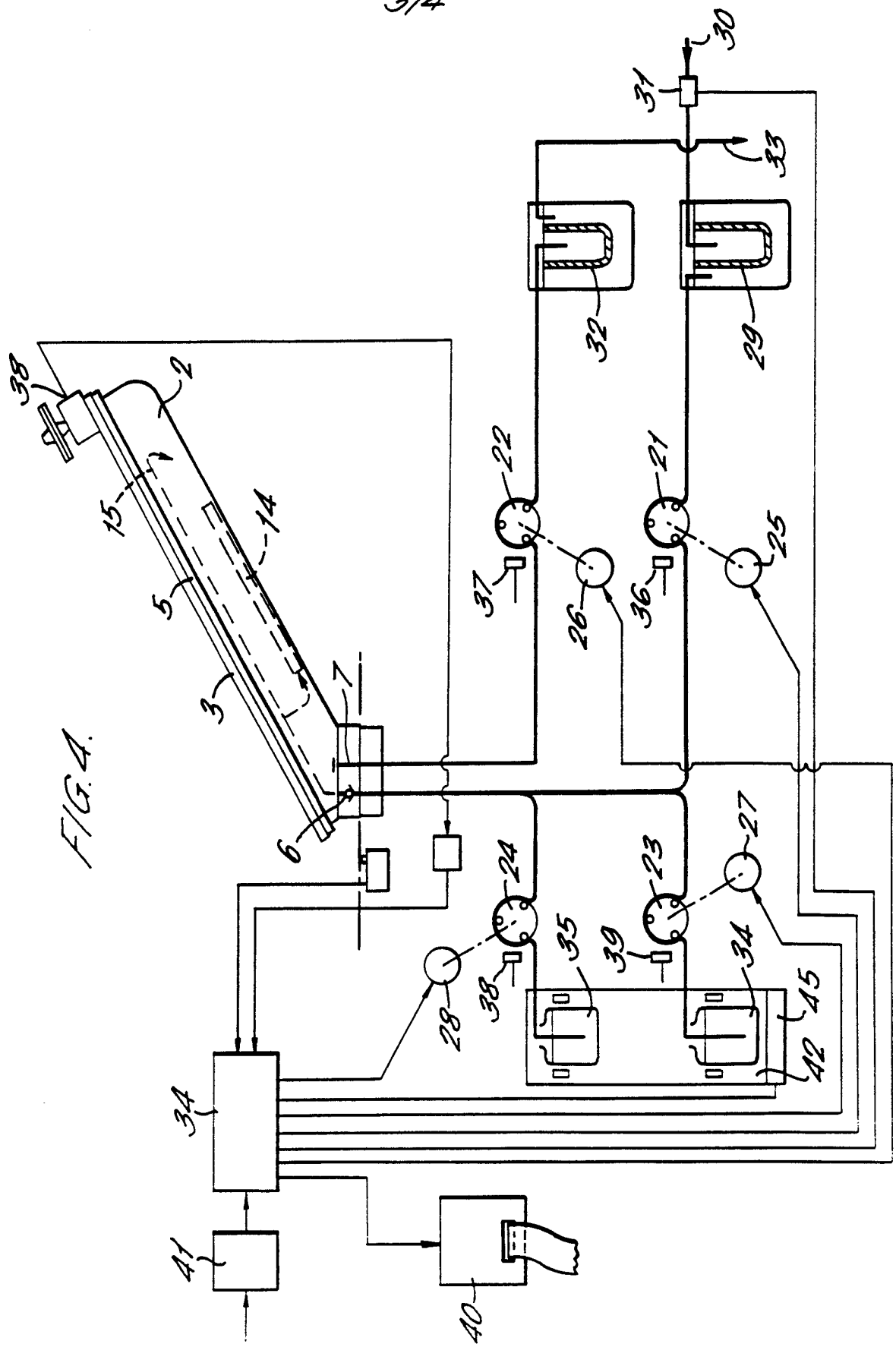

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FIG. 4.

FIG. 5.

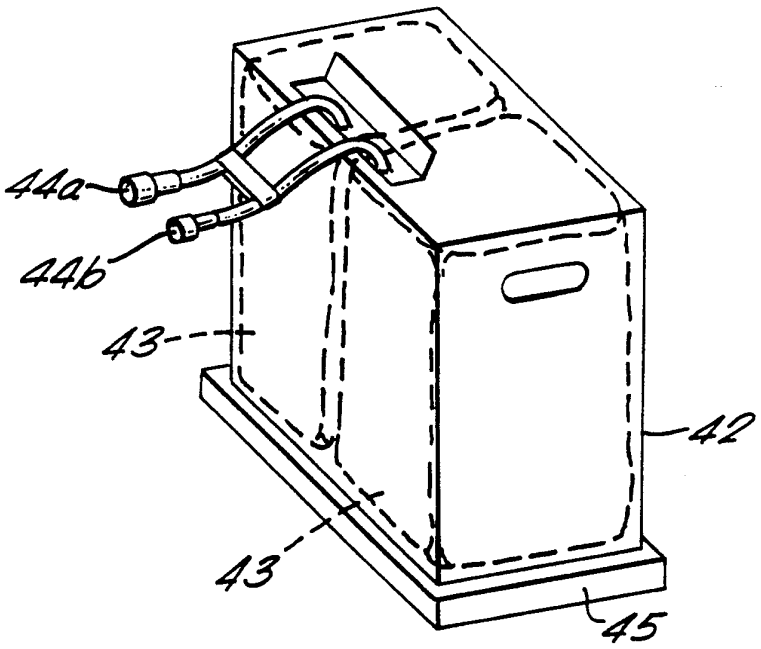
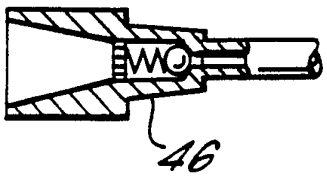


FIG. 5A.



INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 92/00025

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl.5 A 61 L 2/18 A 61 B 1/12

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl.5	A 61 L A 61 B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
X	DE,A,3327466 (SURGIKOS) 14 February 1985, see claims 1,10; page 4, lines 9-15	1
X	Microbiology Abstracts A, vol. 13, no. 12, December 1978, Information Retrieval (London, GB), A. GARCIA de CABO et al.: "A new method of disinfection of the flexible fibrebronchoscope", page 135, abstract no. 9230 A13, & THORAX, 33(2), 270-272, see the whole abstract	1
A	EP,A,0401594 (RIWOPLAN) 12 December 1990	11
A	EP,A,0268227 (HENKEL) 25 May 1988	11
A	EP,A,0072257 (KEYMED) 16 February 1983	

° Special categories of cited documents :[10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
16-04-1992	07. 05. 92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	Nicole De Bie

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 9200025 SA 54994

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 28/04/92
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE-A- 3327466	14-02-85	None	
EP-A- 0401594	12-12-90	DE-A- 3918432	13-12-90
EP-A- 0268227	25-05-88	DE-A- 3639322	26-05-88
		AU-A- 6556790	31-01-91
		AU-B- 601515	13-09-90
		AU-A- 8123587	19-05-88
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		US-A- 4994200	19-02-91
		ZA-A- 8708576	17-05-88
EP-A- 0072257	16-02-83	None	