APPARATUS FOR PORTABLE, HIGH CONCENTRATION GAS STERILIZATION
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Abstract of the disclosure
A portable, self-contained apparatus for improved rapid gaseous sterilization. Ethylene oxide is automatically introduced, from cartridges, into an evacuated chamber containing the items to be sterilized. The items can be automatically sterilized in about forty-five minutes. High concentrations of ethylene oxide can be utilized without danger of explosion.

This invention relates to an improved portable gaseous sterilization apparatus of the disposable cartridge type. It also relates to an improved method of gaseous sterilization.

It has heretofore been proposed to provide disposable cartridge, or ampule, portable gas sterilizers of the manually operated, adjustable chamber volume type as in U.S. Patent 2,965,936 to Kaye of Dec. 27, 1960 or of the flexible walled chamber type as in U.S. Patent 3,114,599 to Fanning of Dec. 17, 1963. It has also been proposed to use only relatively low concentrations of ethylene oxide in the cartridges of such devices, such as 15 to 30%, because of the flammability and explosiveness of ethylene oxide, the mixture usually containing carbon dioxide, or other diluents, as in the above patents and as in U.S. Patent 2,891,838 to Kaye of June 23, 1959 and in his patent application Ser. No. 791,114 filed Feb. 4, 1959 entitled "Sterilant" now U.S. Patent 3,238,096.

In the apparatus and method of this invention, the concept runs counter to formerly accepted theories in that the gaseous sterilant mixture in the cartridge is a relatively high concentration of ethylene oxide, namely about 85% and about 15% of inert gases such as carbon dioxide. While the prior art has shown that high concentrations of ethylene oxide are dangerous, inflammable and explosive and must be avoided by diluting the mixture, the apparatus and method of this invention successfully handles the same without danger. In general the invention contemplates the use of an enclosure with a rigid walled, fixed-volume sterilization chamber having a resiliently gasketed and resiliently hinged door. Power pump means, control means, electric circuitry and gas supply means are all mounted outside the chamber but within the enclosure, thereby providing automatic control cycling while avoiding any possibility of sparks or arcs reaching the ethylene oxide in the system. The gasketed door is held tightly in sealing engagement when the chamber is evacuated by atmospheric pressure but the spring hinges are yieldable outwardly if explosive pressures from the chamber should overcome such atmospheric pressure.

The principal object of the invention is to provide gaseous sterilization apparatus which is automatic in operation, capable of handling high concentrations of ethylene oxide and which is substantially flame proof and explosion proof.

Another object of the invention is to provide a relatively low cost, rugged, efficient portable gas sterilizer having a cold cycle of about three hours and a hot cycle of about forty-five minutes, either cycle being automatic upon the introduction of a high concentration cartridge into the cartridge receptacle.

A further object of the invention is to provide a gaseous sterilization apparatus, utilizing a disposable cartridge containing at least 85% ethylene oxide and having resilient gaskets, seals and hinges for yieldably sealing the gas flow system.

Other objects and advantages of the invention will be apparent from the drawings and from the drawings in which:
FIGURE 1 is a perspective view from the front of the apparatus of the invention;
FIGURE 2 is a side elevation thereof;
FIGURE 3 is an enlarged, diagrammatic, rear elevation thereof;
FIGURE 4 is a still further enlarged, fragmentary side elevation, in section, showing the yieldable hinges, spring latch and gaskets of the cold cycle mechanism,
FIGURE 5 is an enlarged, fragmentary side elevation of the cartridge and cartridge receptacle;
FIGURE 6 is a diagram of the steps of the hot cycle method;
FIGURE 7 is a diagram of the steps of the cold cycle method, and
FIGURE 8 is a circuit diagram.

As shown in FIGURES 1 and 2, the gaseous sterilization apparatus 20 of this invention includes an enclosure 21, having a front wall 22 and a removable back wall 23. A fixed volume, rigid walled gas sterilization chamber 24 is mounted within enclosure 21, to provide therearound an upper compartment 25 and rear compartment 26 to house the various actuating mechanisms.

The gas sterilization chamber 24 has imperforate, rigid side, bottom and rear walls, with a single gas port 27 preferably centrally of the rear wall 28 and with a relatively large access opening 29 in the front wall 30. (FIG. 4.) One or more shelves such as 31 are provided within chamber 24 for supporting articles 32 to be sterilized which have been passed through opening 29.

A door 33 covers the opening 29 and is provided with a rectangular groove 34 containing a resilient, yieldable gasket 35 of neoprene, fluorocarbon polymer, or other suitable material, the gasket mating with a rectangular flange 36 projecting from the front wall 30 around the opening 29. When the door 33 is pressed tightly against the front wall 30, by the evacuation of the chamber, the flange 36 becomes embedded in the gasket to tightly seal the chamber.

Door 33 is provided with a closure latch 37, including the hooked lever 38 pivoted at 39 to the enclosure and having a coil spring 40 for spring loading the hook 41 downwardly. A knob 43 includes a rod 44 slidably in the door 33, the coil spring 45 urging the knob outwardly and the polygonal hollow nut 46 on the terminal end of the rod 44 serving as a cam face to lift the hook 41 when the knob is pressed inwardly (FIG. 4). An undercut handle 47 is also provided on door 33 for convenience, and the door includes a window 48 for viewing the sterilization operation. A pair of pivot door braces 49 serve also as door stops.

The lower edge 51 of door 33 is provided with hinges 52, spring loaded to yield outwardly in the event that internal pressure in the chamber overcomes atmospheric pressure urging the door into tight seal condition. As shown, each hinge 52 is pivotable in a recess 53, on a pivot pin 54 and is integral with a rod 55. Each rod 55 is slidable in the front wall 30 and provided with a head 56 and coil spring 57 operable on the head. Thus spring 57 can yield to permit the door to yield outwardly at its lower edge, while normally holding the lower edge tightly against the front wall of the chamber.

The upper sloping portion of front wall 22 includes a
vacuum gauge 60 of well known type, the time exposure panel 61 and the outer end of the cartridge receptacle 62, the latter having the threaded cap 63 connected to the enclosure by a chain 64.

As best shown in FIGURE 5, the sterilant gas supply means 66 includes the cartridge receptacle 62 which is a hollow cylinder having the threaded outer end 67, fixed by flange 68, and the end casing 69, formed therewith normal to the sloping portion of front wall 22. Receptacle 62 receives the disposable, pressurized, cylindrical cartridge 69, which contains the mixture 71 of 85% ethylene oxide and 15% inert gases, the tightening of threaded cap 63 on the end 67 not only sealing the receptacle but also advancing the cartridge with mechanical advantage.

A gas tube 72, leading to the port 27, has its sharp rim 73 fixed centrally of the inner end 74 of receptacle 62, the rim preferably being tapered at the 60° angle shown to clearly puncture the adjacent end 75 of the cartridge when the cartridge has been advanced thereover.

The end 75 of cartridge 69 includes the projecting portion 76 with the recessed central portion 77 so that as portion 77 is engaged by the puncturing rim 73, portion 76 engages the annular disc 78 slidable on the tube 72. A safety element 79, of resiliently made, is fixed around tube 72 to seal the opening formed in the portion 77 while the advancing cartridge advances the disc 78 to advance the actuating rod 81. Advance of rod 81 actuates the armature 82 of a switch 83. A coil spring 84 retracts rod 81 and coil springs 85 and 86 retracts disc 78.

As best shown in FIGURE 3 the gas sterilant supply system includes the tube 72 which leads from the cartridge receptacle 62 through the solenoid valve 88 and the diffuser 89 to the manifold block 90 and the gas port 27. A gas outlet tube 91 leads from gas port 27 through solenoid valve 92 and filter 93 to the atmosphere outlet 94. The evacuation and purging system also includes power driven pump 95, preferably in the form of the electric motor 96 and pump 97, the pump being connected by tube 98 to the atmosphere at 99 and by tube 101 to the gas port 27. A muller 102 is provided on tube 98 and a tube 103 leads to the vacuum gauge 60.

The automatic cycle control means 105 includes a cycle, or program, timer 106 of suitable type, for example, a plurality of rotating disc-like cams on a driven shaft, each cam having circumferential slots to actuate switch arm cam followers to energize the desired circuits in the desired sequence. The cycle is driven by an electric motor 107, having a constant r.p.m. and the cam system 108 is arranged to provide about a two minute evacuation period, a three hour exposure period and a two minute purging period on the cold cycle or to provide a heating period of seven minutes, a two minute evacuation period, a forty-five minute exposure period and a two minute purging period on the hot cycle.

Electric resistance elements 110 are provided within the enclosure 20, extending around the outer walls of chamber 24 for heating the interior of the chamber if a hot cycle is desired. All of the automatic mechanism of the device is contained within the compartments such as 25, 26 of enclosure 21 and is readily accessible by the removal of the detachable rear wall 23. In the optional preliminary heating step the chamber is heated to about 100°F, and in both the hot and cold cycles, the chamber is evacuated to about 2000 Hg, the evacuation assisting the gas sterilant to penetrate into the articles being sterilized. It should be noted that the method and apparatus of the invention does not involve exposure of the contents to pressure, other than that of the incoming gas and does not involve the injection of moisture. The timer is driven by a spring-closed solenoid valve 92 to control in this invention because the high concentration of ethylene oxide eliminates the need for the addition of moisture.

Control means 105 includes a suitable electric circuit, for energizing the digital time lapse indicator 61, motor 107, pilot lights and the like, such circuits being well known. The primary circuits 111, and secondary circuit 115, are shown diagrammatically in FIGURE 8. The switch 83 closes a circuit through a source of current 112 and conductors 113 and 114 to the cycle timer 106 thereby placing the device under the control of the timer.

For convenience, the vacuum gauge 60 is turnable to indicate a hot cycle or a cold cycle, there being a suitable electric switch 116 on the turn shaft of the gauge, within the enclosure 21, and extending downward therefrom, the switch comprising a secondary circuit 115 including the switch 116, the source of current 117 and the conductors 118 and 119. Thus if the vacuum gauge is turned to the hot cycle, the cycle timer 106 programs accordingly, and if the gauge is turned to the cold cycle the cycle timer also programs accordingly.

In the hot cycle the time 106 first energizes the circuit 121 to the resistance elements 110 for a predetermined period sufficient to raise the temperature of the chamber 24 to 140°F, then energizes the circuit 122 to pump means 95 to evacuate the chamber 24 to 26 Hg, the evacuation period being about two minutes. Timer 106 then de-energizes circuit 122 and energizes circuit 123 to the normally closed solenoid valve 88, thereby passing sterilant into the diffuser and thence through gas port 27 into the evacuated chamber 24. Upon a time lapse of forty-five minutes, on the hot cycle, timer 106 energizes a circuit 124 to close circuit such as motor 107 to connect the port 27 with the outlet 94 and energizes a circuit 125 to pump means 95 to pump atmospheric air into chamber 24 to purge the gas system and chamber of the sterilant gas.

On the cold cycle, the timer 106 first energizes circuit 122 to pump means 95 to evacuate chamber 24 to about 26 Hg in a period of about two minutes. It then energizes the circuit 123 to normally closed solenoid valve 88 to introduce sterilant into the chamber 24, and after a period of about three hours, then energizes circuits 124 and 125 to purge the chamber.

It will be seen that in operation the apparatus of the invention is a completely automatic portable gas sterilizer, self contained within an enclosure and capable of utilizing a high concentration of ethylene oxide, the actual concentration within chamber 24 being at least 1000 milligrams per liter.

While such a concentration of ethylene oxide has heretofore been considered dangerous, the following is the result of tests made of the apparatus and method of the invention which indicate its safety.

Test equipment

A portable gas sterilizer identical with that shown and described herein was used, the only modification being that a 3/4-24 tapped hole was made in the end of the manifold block 90.

A small spark plug was inserted in this hole and connected to a Ford coil and a six volt battery whereby a spark could be made across the gap of the spark plug. A mirror was set up so that the spark plug could be seen through the window 48 of door 33.

Procedure

A 30 gram cartridge 69 containing 85% liquid ethylene oxide and 15% inert liquid ingredients, namely carbon dioxide, was inserted in receptacle 62, the cap 63 tightened and the cold cycle started as described herein; the vacuum pump 95 drew down 23 inches of vacuum and shut off. The ethylene oxide liquid went into the diffuser 89 and the gas therefrom went into the chamber 24.

After the gas was in the chamber the spark plug was energized with negative results since no explosion occurred. Throughout the gas exposure period, the spark plug was repeatedly energized to create sparks visible through the window 48 still with no explosion.

The spark plug was not only ignited with maximum gas concentration, but it was kept ignited as the gas-air mixture went from a high concentration of gas to a-
complete concentration of air and at no time was there any explosion.  
When the chamber 24 was being purged into the outside air, a match was held in the stream of gas emitted from the outlet 94. The stream ignited from a point approximately two inches from the end of the outlet to a point approximately fourteen inches from the outlet 94. When the match was removed from the stream, the flame would blow itself out and did not continue burning. 

1. Gaseous sterilization apparatus comprising:  
a portable enclosure having a scalable sterilization chamber therein, said chamber having a gas port in one wall thereof and an opening in one wall thereof, covered by a door, for receiving articles to be sterilized;  
power driven pump means within said enclosure and connected to said gas port for evacuating and purging said chamber;  
sterilant gas supply means, within said enclosure, said means including a disposable, pressurized cartridge of fluid sterilant and cartridge discharge mechanism connected to said gas port for introducing gas from said cartridge into said chamber; and  
automatic cycle control means within said enclosure including a cycle timer responsive to said cartridge discharge mechanism to actuate said pump means for evacuating said chamber, to introduce said gas sterilant into said chamber and then, after a pre-selected exposure time, to actuate said pump means for purging said chamber.  

2. Apparatus as specified in claim 1 wherein:  
said door is hingedly mounted on said enclosure along one edge thereof by hinges, spring loaded inwardly toward the interior of said chamber;  
whereby said door edge may yield slightly outwardly under predetermined pressure from the interior of said chamber.  

3. Apparatus as specified in claim 1 wherein:  
said cartridge contains a mixture of 85% ethylene oxide and 15% inert ingredients.  

4. Apparatus as specified in claim 1 wherein:  
said cartridge discharge mechanism includes a cartridge receptacle having a threadedly mounted end cap at the outer end and a sharp, rimmed tube, connected with said gas port, at the inner end, the tightening of said cap, advancing said cartridge until it is punctured by the sharp rim of said tube.  

5. Apparatus as specified in claim 4 wherein said receptacle includes an annular disc encircling said sharp rimmed tube and in the path of said cartridge when advanced by said cap, said control means comprises an electric circuit including an electric motor driving said pump means, said cycle timer, and a switch having an armature in the path of said disc whereby the advance and puncturing of said cartridge actuates said switch and energizes said control circuit.  

6. Apparatus as specified in claim 4 wherein said cartridge discharge mechanism includes a resilient, yieldable gasket encircling the sharp rim of said tube within said receptacle and in the path of said cartridge for sealing said cartridge to said tube.  

7. Gaseous sterilization apparatus comprising:  
a portable enclosure having a fixed volume sterilization chamber therein, said chamber having a gas port in one wall thereof and a resiliently gasketed hinged door in one wall thereof;  
electric motor pump means within said enclosure and connected to said port for evacuating and purging said chamber;  
a cartridge receptacle connected to said port, said receptacle having a threadrad cap at the outer end, a sharp rimmed tube in the inner end connected to said port and an electric switch connected to said cartridge receptacle and responsive to the introduction of a cartridge into the cartridge receptacle;  
a disposable pressurized gas sterilant cartridge containing at least about 85% ethylene oxide, in said receptacle, said cartridge discharging said ethylene oxide into said tube when pressure of said cap thereon causes said sharp rimmed tube to puncture the cartridge, and  
a primary electric circuit connected to said electric switch for activating a sterilization cycle, said circuit including said switch, said electric motor, a cycle timer and a source of current.  

8. Apparatus as specified in claim 7 plus springs on the hinges of said door urging said door inwardly toward the interior of said chamber while permitting said door to yield outwardly under intense pressure.  

9. Apparatus as specified in claim 7 plus electric resistance heating elements within said enclosure on the outside of said chamber, a switch on the outside of said enclosure for selecting either a hot or cold sterilization cycle and a secondary circuit for activating the hot sterilization cycle, said circuit including said switch, said heating elements and all of the components in said primary circuit, whereby said chamber may be selectively heated to reduce exposure time.  

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