METHOD OF STERILIZING

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This invention relates to a method and apparatus for sterilizing all types of materials and equipment by treatment with a gas and is a division of my application Serial No. 701,065, filed December 6, 1957.

Sterilizing at high temperature is a conventional gas sterilizing treatment, but certain pieces of equipment, that are used in hospitals, are deleteriously affected, or are attacked, by steam; and consequently sterilization of these objects with steam is either not practical, or not entirely satisfactory. For example, the high heat of steam sterilization attacks, and may destroy, materials such as plastics, rubber, waxes, certain adhesives, and many drugs. Then, too, the high moisture content of steam causes tarnishing, dulling, and rusting, of surgical instruments, knives and other metallic surgical instruments. Steam, too, is not suitable for sterilizing such articles as temperature gauges that are affected by heat. In some instances, too, it is difficult to make certain goods bacteriologically safe with steam, as, for instance, tubing for intravenous work. Here the inside of the tubing may not be reached to the required degree by the steam.

For these reasons, in recent years attempts have been made to develop processes and equipment for effective sterilization through the use of non-corrosive gases that are effective at ordinary temperatures or at temperatures below the temperature at which steam is effective.

Ethylene oxide has many desirable characteristics as a sterilizing agent. For example, it is non-corrosive and does not damage the substance or equipment being sterilized. It is usable at low temperature. Moreover, it is destructive to all forms of organisms; and it has a relatively rapid action. Furthermore, after it has been used, it can be removed by aspirating the sterile material.

However, the use of ethylene oxide as a sterilizing agent is subject to several disadvantages. For example, ethylene oxide is quite flammable and explosive when mixed with air in certain proportions, and accordingly, safety precautions are required for handling the gas. Moreover, it can cause blisters if the goods being sterilized are goods such as rubber gloves, for instance, in which the gas can become pocketed, and a person wears the gloves without previously thoroughly removing all traces of the ethylene oxide gas heretofrom. Then, too, in the use of the gas, the techniques required to produce a 100% kill of bacteria of all types have frequently involved complicated and time consuming routines. In fact, because of the intricacies involved in known routines for obtaining a 100% effective sterilizing action, the application of ethylene oxide to sterilizing has been somewhat limited.

An object of the present invention is to provide a relatively simple process, based on the use of ethylene oxide as a low-temperature sterilizing agent, which will produce a 100% effective biocidal action consistently.

Another object of the invention is to provide a sterilizing process employing ethylene oxide as the sterilizing agent in a manner such that consistent and uniform biocidal action can be obtained.

Another object of the invention is to provide a sterilizing process using ethylene oxide as the sterilizing agent, that provides conditions within a sterilizing chamber that are most conducive to killing the most resistant, spore-bearing bacteria.

Still another object of the invention is to provide a sterilizing process of the character described that will properly condition the goods to be sterilized before introducing sterilizing gas into the sterilizing chamber.

A still further object of the invention is to provide a sterilizing process using ethylene oxide as the sterilizing agent, which will remove from the goods sterilized, after the sterilizing operation has been completed, all harmful trace of the sterilizing agent, so that the goods can be used without danger that the person handling or wearing the goods will be blistered by traces of the gas.

Herefore, in using ethylene oxide as a sterilizer, the gas has been used in substantially undiluted condition and/or the articles, which are to be sterilized, have been in an uncontrolled condition with respect to moisture content when subjecting them to the gas. I have discovered that if an article is dry, the dehydrated bacteria thereon exhibit a high degree of resistance to the killing action of the ethylene oxide gas.

With my process, then, a controlled humid condition is produced in the sterilizer prior to treatment of the goods with the gas so that absolute bacteria kill can be assured. It has been found that an atmosphere with a relative humidity of 20% or more is desirable. If the articles are wet, however, the efficiency of the gas is destroyed. 50% humidity in the sterilizing chamber seems to be a desirable maximum.

With my process, also, I mix the gas with carbon dioxide, Freon, or some other gas which acts not only as a propellant but as a flame deterrent.

It has been found that under proper conditions the ethylene oxide will diffuse through all types of porous substances, and through substances that are not generally considered to be porous, such as, for example, water-impermeable cellophane, wax-coated films, and polyethylene films. For this reason, ethylene oxide as used in the process of the present invention is an ideal sterilizing agent for packaged goods that must be stored in sterile condition.

One embodiment of a gas sterilizer constructed according to this invention for carrying out my process is illustrated in the accompanying drawings. In the illustrated embodiment there are: a pump for evacuating the sterilizing chamber; means for injecting water vapor into the sterilizing chamber; means for injecting a mixture of ethylene oxide and water vapor into the chamber; a heater for controlling the temperature of the sterilizing chamber; means for admitting air into the chamber; a filter and ultra-violet lamp to remove bacteria from the air that is admitted to the sterilizing chamber; and means for controlling the various operations so that the operations follow one another in the proper sequence and for the proper periods of time automatically, once the sterilizer has been placed in operation.

In a typical operating cycle according to the invention, after the sterilizing chamber has been loaded and sealed, the chamber is evacuated. After a predetermined vacuum has been attained, a predetermined amount of water vapor is passed into the chamber. A dwell of a few minutes permits diffusion of the water vapor throughout the chamber and into the spore-forming bacteria on the goods being treated. A predetermined amount of a mixture of ethylene oxide and an inert gas is then admitted into the chamber and is permitted to remain in the chamber for a predetermined period of time. This period of time will be determined by the concentration of the ethylene oxide used, the temperature of the chamber, the humidity, and the type of organisms to be destroyed. After this period of time has elapsed, the pump is actuated to evacuate the chamber again, to remove the eth-
ylene oxide therefrom and to discharge it into the atmosphere. When the gas has been substantially completely evacuated from the chamber, air is drawn into the chamber through the bacteria-retainive filter. This reduces to a minimum the objectionable odor of any gas remaining in the chamber, prevents harmful concentrations of gas from remaining in the goods, and brings the pressure in the chamber up to atmospheric pressure so that the door of the chamber can readily be opened. A signal indicates when the desired pressure in the chamber has been attained. The cycle is complete. The door of the chamber can then be opened, and the sterile contents may be removed.

This invention may be best understood from the following description and claims when read in conjunction with the accompanying drawings.

In the drawings:

FIG. 1 is a front elevation of a sterilizer constructed according to one embodiment of the invention;

FIG. 2 is a side elevation with the side of the sterilizing cabinet removed and with part of the sterilizing chamber or tank broken away, to show the connections between the several components of the sterilizer;

FIG. 3 is a rear view, with the rear wall of the cabinet removed again to show the structure and fittings of the sterilizer;

FIG. 4 is a side elevation, on an enlarged scale, showing the water vapor injection system used in this embodiment of the invention; and

FIG. 5 is a wiring diagram illustrating one way in which the sterilizer may be wired to accomplish its purpose.

Referring now in detail to the drawings, the sterilizer comprises a cabinet 10 in which a jacketed, generally drum-shaped sterilizing chamber 12 is mounted. A chamber 12 is closed at its front end by a hinged-mounted door 13, and has sufficiently heavy walls so that it may be evacuated. A normally-open switch 14 is mounted on the casing 10 adjacent the door, to be closed only when the door 13 is closed.

An electrical heater assembly 15 is mounted outside the chamber to permit control of the temperature in the chamber during the sterilization cycle. A plurality of thermostats 16 are mounted in the chamber to detect the temperature at various points in the chamber, and to control, in turn, the operation of the heater.

The chamber 12 is connected to a motor-driven pump 17 through a duct-work that includes a line 18 (FIG. 2) that is connected at one end to the chamber 12 and at its other end to a normally-closed solenoid-operated valve 20 (FIGS. 3 and 5), a line 21 that connects the valve 20 to a filter 22 (FIG. 3), a line 23, a check valve 24, and a line 25 that connects the check valve 24 to the pump. The pump 17 discharges through a line 26, a trap 27, a line 28, and a pipe 30 to atmosphere. A blow-off valve 29 is connected for safety reasons from the sterilization chamber to the same exhaust pipe 30, and thus to atmosphere.

A water bottle 31 (FIGS. 1 and 4) is detachably mounted by means of a fitting 32 on the front of the cabinet 10. The water bottle is suspended from the fitting 32 by a threaded nipple 35 which threads into the fitting 32. The cap 33 for the bottle is threaded onto the nipple and the bottle is suspended by its cap. A tube 34 is secured in the nipple and is disposed to extend into the bottle, terminating close to the bottom of the bottle. A pair of electrodes 39 are mounted on the tube 34, at a predetermined distance from the bottom of the bottle 31, for a purpose to be described presently.

The bore of the tube 34 is aligned with the bore of nipple 35 and is enlarged at its upper end to provide a seat 36. A ball check valve 37 is constantly pressed by a spring 38 against this seat 36, so that the bore of nipple 35 is normally closed. The fitting 32 is formed with a horizontal bore 35 that communicates with the bore of nipple 35 when the ball 37 is disengaged from its seat. The horizontal bore 35 is connected through a pipe 40 to a normally-closed solenoid-operated valve 48 (FIGS. 3 and 5) that communicates through a petcock 41 with tubing 42 (FIGS. 3 and 4). Part of the tubing 42 is mounted adjacent heater 43 so that the water passing through the tubing will be converted into vapor. The tubing 42 is connected through a cross 44 with the sterilizing chamber 12.

In the apparatus shown, the sterilizing gas is adapted to be supplied from portable, replaceable cylinders, such as denoted at 45 in FIG. 1. Each cylinder 45 is positioned for use by detachably mounting it in inverted position on the header 46 that projects from the front of the cabinet 10. The header 46 is hollow for the flow of gas therethrough. The header 46 is provided with conventional means (not shown) to open, or pierce, the top of the cylinder automatically when the cylinder is mounted on the block.

Flow of the gas to the tank 12 is controlled by a solenoid-operated valve 51 and in turn controls a pressure switch 47. The pressure switch 47 (FIGS. 2 and 5) is connected with the bore of the block 46 through a line 50, to be operated by the pressure of the gas. The valve 51 (FIGS. 2, 3 and 5) is a normally-closed solenoid-operated valve and it communicates through the tubing 52 with the header 46. The tubing 53 is connected between the valve 51 and the cross 44 for communication with the sterilizing chamber 12.

As previously described, after the sterilization has been completed air is drawn into the tank 12 to remove any traces of the gas and to bring the sterilizing chamber up to atmospheric pressure. The air enters the evacuated chamber through an opening 55 (FIG. 1) in the front of the cabinet by the opening of solenoid valve 61. To prevent the sterilized goods from being contaminated by this atmospheric air, a plurality of bacteria-retainive filter elements 54 are mounted within the inlet duct 56. Inlet port 55 communicates with an air inlet duct 56. Downstream of the filter elements 54, the duct 56, an ultra-violet lamp 57 is mounted to extend axially of the air inlet duct. The duct 56 is connected through a check valve 58 with a line 60. This line is connected by a normally-open solenoid valve 61 with a line 62 that in turn is connected by the fitting 44 with the sterilizing chamber 12.

One way in which the apparatus can be wired to accomplish its purpose is shown in the accompanying FIG. 5. 63 denotes one main line supplying current to the apparatus; and 64 designates the other main or ground line. A master switch 65 is mounted in the line 63. The master switch is series-connected through a line 66, a conventional thermal switch 67, a line 68, the heater assembly 15 (FIG. 2), that is mounted in the sterilizing chamber 12, and a line 19, with the ground wire 64. The thermal switch 67 is a normally-closed thermally-controlled switch that is adjusted to open when the temperature of the chamber, as detected on the thermostats 16, is too high.

The line 63 is also series-connected through the master switch 65, line 66, line 71, a “gas low” lamp 72, and a line 73, with the pressure switch 47. The pressure switch 47 is a two-way switch. It has three terminals, and is adjustable so that above a predetermined pressure, a selected two of its three terminals are connected, while below the predetermined pressure, is a selected different two of the three terminals are connected. In the present device, the three terminals of switch 47 are connected, respectively, with the lines 73, 75, 77. The pressure switch 47 is so adjusted that at pressures below sixty p.s.i., the line 73 is connected through the switch with the line 75, while at pressures above sixty p.s.i., the line 75 is connected with the line 77. The connection of line 77 will be described later.

The line 75 is series-connected with the solenoid of the air inlet valve 61 (FIG. 3), and, in turn, is connected by the line 76 to the ground wire 64. The pressure switch 47
is connected as shown in FIGS. 2 and 3 through the conduit 46 with the source of gas supply, the cylinder 45. The solenoid of the valve 41 has a very high resistance relative to the resistance of the “gas low” lamp 72 (FIGS. 1 and 5). Thus, if there is no gas cylinder 45 in place, or if the pressure in the cylinder is less than the minimum pre-determined pressure that indicates a properly filled supply cylinder, switch 47 will connect lines 73 and 75, and the lamp 72 will light up, but the solenoid will not be actuated.

The line 75 is also connected to a line 78 that is connected to one contact arm 79 of the relay 80. The relay 80 is set so that the contact arm 79 normally is in electrical contact with the relay terminal 79'. The terminal 79' is connected through a line 81 with one terminal 81' of a relay 82.

The main line 63 is also serially connected through the master switch 65 with a line 83 that is connected to one contact arm 83' of a relay 84. The relay 84 is set so that the line 83 is normally connected through the relay with the relay terminal 85' and the line 85. The line 85 is connected through a line 86, the primary coil 87 of a transformer 88, and through the line 90 with the ground wire 64. The line 85 is also connected with a line 91, a warning lamp 92, and a line 93 that is connected to one terminal 93' of the relay 82.

The secondary coil 94 of the transformer 88 is connected through a line 95 with the coil 96 of the relay 82, and a line 97 that is connected to one of the electrodes 39 (FIG. 4) that is mounted on the tube 34 at a predetermined distance from the bottom of the water bottle 31. The other electrode 39 is connected through a line 98 to the secondary coil 94 of the transformer 88. The electrodes 39 are designed to conduct only when immersed in water. If the operator has neglected to put a water bottle 31 in the apparatus, or if the level of water in the bottle is low, then, signal lamp 92 will be lighted to give warning of the condition.

A line 63 is also connected through the master switch 65 and the lines 66 and 101, with an adjustable timer 102. The timer 102 operates a two-way switch that has three terminals, one of which is connected to the line 101, a second of which is connected to the line 103, and the third of which is connected to a line 104. When the timer is set at its zero setting, the line 101 is connected through the timer switch with the line 103. When the timer is manually adjusted to any time setting, the lines 101 and 103 are disconnected and the line 101 is connected through the timer switch to the line 104.

The line 103 is connected to one contact arm 103' of the relay 84, that is normally connected to the relay terminal 109. The terminal 109 is connected through the line 110, and a line 111, with a two-way vacuum switch 112. The vacuum switch 112 has three terminals, and the line 111 is connected to one terminal. The other terminals are connected, respectively, to the lines 113 and 114. The switch 112 is so adjusted that a slight vacuum of about three or more inches of mercury, the line 111 is connected through the switch to the line 113; and when the vacuum in the sterilizing chamber is greater than three inches of mercury, the line 111 is thus connected in series through an “air-in” lamp 115 (FIGS. 1 and 5), and the line 116, to the ground wire 64. The line 114 is series-connected through a “load” lamp 117 and a line 118 with the ground wire 64.

The line 104 is connected through the lines 123 and 124 with one terminal of a conventional two-way vacuum switch 125. The switch 125 has three terminals, one of which is connected to the line 123, the second of which is connected to a line 126, and the third to a line 127. The switch 125 is adjusted so that when there is a vacuum in the sterilizing chamber of more than twenty-seven inches of mercury inclusive, the line 124 is connected to the line 127, and when the vacuum is less than twenty-seven inches of mercury, the line 126 is connected to the line 127.

The line 127 is connected through a line 134 to one terminal of a conventional pressure switch 135. The pressure switch 135 is a two-way switch and has three terminals, one of which is connected to the line 134, a second of which is connected to the line 136, and one of which is not connected to any exterior circuit. The pressure switch 135 is so adjusted that when the pressure in the sterilizer chamber 12 is above five p.s.i., the line 134 is connected to line 136 through the switch, and when the pressure in the sterilizer chamber is below five p.s.i., the line 134 is disconnected from the line 136, so that the switch is open. The line 136 is connected to the line 123, the line 104, and with one terminal of the timer 102.

The time delay device 133 has a motor 137 that controls the position of the armature 132. The armature 132 is mounted to move between two terminals 138 and 139, that are connected, respectively, to the lines 140 and 141. The line 141 is series-connected through a line 144, the “humidity” lamp 145 (FIGS. 1 and 5), and a line 146, with the ground wire 64. The lamp 145, when illuminated, indicates that water vapor is being permitted to enter the chamber 12 in an amount to produce proper relative humidity.

The “gas out” lamp 167 (FIGS. 1 and 5) can be energized, in a manner to be described presently, to indicate that the bicidal gas is being evacuated from the chamber. The “gas in” lamp 171 (FIGS. 1 and 5) can be energized, in a manner also to be described presently, to indicate that the sterilizing gas is in the chamber.

The line 75 is also connected through lines 172 and 175, the “cycle on” lamp 176, and line 177, to the ground wire 64. The “cycle on” lamp denotes that the apparatus is in operation, effecting the sterilization process.

**OPERATION OF THE STERILIZER**

The operation of the apparatus in a typical sterilization cycle will now be described.

To place the apparatus in operation, the master switch 65 is closed to establish an electrical connection between the lines 63 and 66. This completes an electrical circuit from the line 66, through the thermal switch 67, line 68, the jacket heater 15, and the line 19, to the ground wire 64. Through suitable adjustment of the thermal switch 67, the heater assembly is set to raise and hold the temperature in the sterilizing chamber 12 to a predetermined value. This heater circuit is energized as long as the master switch 65 and the thermal switch 67 are closed.

If a gas cylinder 45 (FIG. 1) has not been installed, or if the pressure in the cylinder is below the optimum working minimum, a circuit is also established from the line 66, through the thermocouple 71, the “gas low” signal lamp 72, the line 73, the pressure switch 47, the line 75, the solenoid of the “air-in” valve 61, and the line 76, to the ground wire 64. As previously pointed out, the solenoid of the “air-in” valve 61 is set so the valve is normally open, and its high resistance prevents it from being energized at this time. The “gas low” lamp 72 will, therefore, be illuminated to indicate to the operator that a fresh gas cylinder 45 should be installed. If the gas cylinder 45 has been installed and the gas therein has the proper pressure, switch 47 will connect lines 73 and 77, and signal lamp 72 will not be illuminated.

At the time that master switch 65 is thrown in, a circuit is also made from the line 66 through the line 101, the timer 102, and the line 103 to the contact arm 103' of the relay 84, and through the contact arm 103', the terminal 109 of the relay, lines 110 and 111, through the switch 112, the line 114, the “load” lamp 117, and the line 118, to the ground wire 64. The pressure in the sterilizing chamber being at this time atmospheric and switch 112 at this time, therefore, connecting lines 111 and 114. At this time, also, a circuit is made through the line 110, the line 120, the ultra-violet lamp 57, and the line 121 to the
ground wire 64. The "load" lamp 117 indicates to the operator that the device is ready to be loaded, and that the door 13 of the sterilizer chamber 12 can be opened without fear that the chamber is under higher than atmospheric pressure or under vacuum, as would possibly result from incomplete or faulty cycle.

A circuit is also made from the line 66 through the line 83, the contact arm 83' of the relay 64, the relay terminal 85', the line 88, the line 86, the primary coil 87 of the transformer 88, and the line 90, to the ground wire 64; and, if the water in the bottle 31 is low, through the line 85, the line 91, the "fill water" lamp 92, the line 93, the relay terminal 93', the relay contact arm 174, the line 173, the line 154, the line 155, the motor of the vacuum pump 17, and the line 156 to the ground wire 64. At the same time, a circuit is made from the line 154 through the line 157, the solenoid of the valve 20, and the line 158 to the ground wire 64.

If through oversight the bottle 31 is not filled with water, the lamp 92 will light up to signal the operator to replenish the water and replenish the resistance of the motor of the vacuum pump 17 and of the solenoid of the vacuum valve 20 are so high relative to that of the lamp 92 that although the lamp 92 lights up with this circuit, neither the solenoid nor the motor are energized. When the bottle 31 is filled with water to a predetermined level, the resistances 39 will be submerged when the bottle is mounted on the fitting 32; and when the electrodes 39 are submerged in water, a circuit is completed between the two electrodes, through the line 98, the transformer secondary 94, the line 95, the relay coil 96, and the line 97. The relay coil 96 is thus energized to shift the relay contact arm 174 to engage the relay terminal 81', so that no circuit is made to lamp 92.

The timer 102 is set manually, to the desired exposure time. This shifts the contact of the timer to disconnect line 101 from line 103 and connect line 101 with line 104. When the sterilizer chamber has been loaded with the goods to be sterilized, the door 13 is closed, to close the door switch 14. Thus, an electrical circuit is made through the line 104, the line 122, the now-closed door switch 14, the line 77, the pressure switch 47, the line 75, the solenoid of the "air-in" valve 61, and the line 76, to the ground line 64; and from the line 75, through the line 176, the "cycle on" lamp 176, and the line 177 to the ground line 64. The solenoid of the solenoid of the fully opened "air-in" valve 61 is thus energized to close the valve to prevent the entry of air into the sterilizing chamber 12. The energized "cycle on" lamp 176 stays on during the entire cycle, to signal the operator that a cycle is in progress.

A circuit is also closed from line 75 through the line 78, the relay contact arm 79, the relay terminal 79', the line 81, the terminal 81' of the relay 82, the relay contact arm 174, which is now in its upper position because there is water in the bottle 31, the line 173, the line 154, the line 155, the motor of the vacuum pump 17, and the line 156 to the ground wire 64; and from the line 154 through the line 157, the solenoid of the valve 20 to energize the solenoid to open that valve, and the line 158 to the ground wire 64; and from the line 154 through the line 153, the contact arm 152 of the relay 80, the relay terminal 160, the line 161, the "air out" lamp 162, and the line 163 to the ground wire 64.

Thus, the vacuum or "gas out" valve 20 is opened, and the vacuum pump 17 is actuated to remove air from the sterilizing chamber 12 through the line 18 (FIGS. 2 and 3), the valve 20, the line 21, the filter 22, the line 23, the check valve 24, and the line 25, and to discharge the evacuated air through the line 26, the pipe 27, the bottle 28, and the air discharge line 30. The "air out" lamp 162 indicates that the pump 17 is evacuating the sterilizer chamber 12.

When a vacuum of 27 inches of mercury absolute has been reached in the sterilizing chamber 12, the vacuum switch 125 operates to connect the line 124 with the line 127. This establishes several circuits: a circuit from the line 104, the line 123, the line 127, the line 128, the line 146 to the relay device 133, the line 139, the line 141, the line 147, the solenoid of the moisture inlet valve 48, and the line 148, to the ground wire 64; a circuit from the line 141 through the line 144, the humidity indicating lamp 145, and the line 146 to the ground wire 64; another circuit from the delay device terminal 139 through the line 142, the delay device timer motor 137, and the line 143 to the ground wire 64; and another circuit from the line 127, through the line 128, and the two parallel-connected relay coils 150 and 151 of the relays 80 and 84, respectively, and the line 106, to the ground wire 64.

Energization of the solenoid of valve 48 causes this valve to be opened. The differential in pressure between the water bottle 31 and the sterilizing chamber 12 then opens ball check valve 37 (FIG. 4) against the resistance of spring 38, causing flow of water from the bottle 31 through the pipe 40, the valve 48, the tubing 42 past the heater 43, and through the fitting 44 into the sterilizer chamber 12. As the water passes the heater 43 it is vaporized and passes through the T 44 and into the sterilizing chamber 12 in vapor form. The lamp 145 indicates at this time that the water is being vaporized and passed into the sterilizing chamber 12.

When the relay coils 150 and 151 of the relays 80 and 84, respectively, are energized, the four respective relay contact arms 79', 152, and 83', 103' are shifted, thus interrupting the circuit to the lines 173 and 154, and turning off the motor of the vacuum pump 17, de-energizing the solenoid of the vacuum valve 20 to close that valve, and turning off the "air out" lamp 162.

Also a circuit is established from the timer 102, line 104, line 123, switch 125, and line 127, through the line 128, line 130, the relay terminal 130', the relay contact 79, the line 75, and the line 78, the solenoid of the "air in" valve 61 and the line 76, to the ground wire 64. In this way the valve 61 is held closed to prevent entry of air in the chamber 12 during and after evacuation of the chamber.

The amount of water in the bottle 31 is predetermined so that the amount of water vapor that passes into the sterilizing chamber 12 is controlled, to introduce the proper amount of water vapor. The delay device motor 137 is adjusted to provide a dwell period of approximately 10 minutes, during which the contents of the chamber are exposed to the water vapor; the motor could be adjusted for any other desired dwell period, to permit proper diffusion of moisture into the particular material that is being sterilized. The action of the water vapor on the various micro-organisms in the goods causes the organisms to reach a state in which they will be most susceptible to ultimate kill upon exposure to the sterilizing gas.

At the end of the dwell period, the armature 132 of the delay device is moved by the motor 137 out of contact with terminal 139 into contact with the terminal 138. A circuit is then established from the timer 102, the line 104, through the line 123, the line 124, the vacuum switch 125, line 127, the line 131, the armature 132, the delay device terminal 138, the line 140, the line 107, the solenoid of the gas inlet valve 151, and the line 108 to the ground wire 64. Another circuit is simultaneously established through the line 140, the line 107, the timer coil 105, and the line 106 to the ground wire 64. Still another circuit is simultaneously established from the line 140, through the line 107, the line 172, the line 146 through the line 170, the line 165, the relay terminal 164, the relay contact arm 162, the lines 153, 154, and 155, the motor of the vacuum pump 17, and the line 156, and also through the line 157, the solenoid of the vacuum valve 20, and the line 158, to the ground wire 64. The solenoid of the vacuum valve
20 and the motor of the vacuum pump 17 are not energized in this circuit, but there is sufficient energy to illuminate light 171, signifying that gas is flowing into chamber 12.

When the solenoid of the "gas in" valve 51 is energized, the normally closed valve 51 is opened, and the sterilizing gas from the gas cylinder 45 enters the chamber 12. The gas in the cylinder 45 is at an elevated pressure, and flows through the header 46 of the relay 153, the line 157, the valve 51, and the line 53, into the chamber 12. Gas continues to flow from the cylinder 45 until the pressure in the chamber 12 and in the gas cylinder 45 are equal. This should occur when the chamber pressure is approximately ten to thirty p.s.i. for proper sterilizer operation. The amount of gas in the cylinder 45 is preferably predetermined to provide the correct concentration and pressure in the chamber 12 required to kill all life forms present.

As soon as the gas pressure in the sterilizing chamber 12 exceeds five p.s.i. the pressure switch 135 is shifted to connect the line 136 with the line 134. Thus, a circuit is completed from the timer 102, through the lines 104, 123, and 136, the pressure switch 135, the lines 134, 131 and 128, respectively, to hold the circuits previously described.

The sterilizing gas remains in the chamber during the period set on the timer 102. During this entire period, the jacket heater 15 and the thermal switch 67 operate to maintain a selected temperature in the sterilizing chamber 12. The "cycle on" lamp 176 (FIGS. 1 and 5) remains illuminated, to indicate to the operator that a cycle is in progress. Also, the "gas in" light 171 (FIGS. 1 and 5) is lighted to indicate to the operator that the sterilizing chamber is charged with gas under pressure.

In case of power failure during the sterilizing period, the normally closed "gas out" solenoid valve 20, and the normally closed "gas in" solenoid valve 51 close. The normally open "air in" solenoid valve 61 opens, but the check valve 57 closes to prevent the escape of any of the sterilizing gas from the chamber 12 to the atmosphere. The pressure of the sterilizing gas in the chamber 12 holds the pressure switch 135 in the position in which the lines 136 and 134 are electrically connected. Thus, when the power is restored, the cycle will be resumed. Since the timer motor is electrical, it would be inoperative during the period of power interruption. This off period would add to the exposure time and would merely make more certain the probability of obtaining a one hundred percent kill.

As the pressure in the sterilizing chamber builds up, the vacuum switch 125 is shifted to connect the lines 120 and 127. This establishes a circuit from the master switch 65 through the line 83, the contact arm 83' of the relay 84, the relay terminal 129, the line 126, the vacuum switch 125, the line 127, and through two lines, respectively, 131 and 128, to complete circuits previously described. The circuit made through the line 128 becomes an alternate circuit to hold the two relay coils 150 and 151, respectively. Since this circuit is made through the line 83, this circuit 65, through lines 66 and 127 is not disturbed by the shift of the timer 102 at the expiration of the gas exposure period.

When the sterilizing period expires, the timer 102 shifts to disconnect the lines 101 and 104, and to connect the lines 101 and 103. A circuit is then established from the master switch 65, through the line 102, the line 103, the contact arm 103' of the relay 84, the relay terminal 172' the line 173, the line 154, the line 155, the motor of the vacuum pump 17, and the line 156, to the ground wire 64. This starts the pump 17. At the same time a circuit is completed from the line 84, through the line 83, the vacuum valve 20, and the line 158, to the ground wire 64. This opens the valve 20. At the same time a circuit is established from the line 154, through the line 153,
gered by timing within that particular step. It is seen, therefore, that if the apparatus is once set for a certain cycle of operation, and left at that setting, the apparatus will repeat this cycle time and again, regardless of the skill or lack of skill of the particular operator assigned to the apparatus. Thus, the sterilizer can be adjusted by a supervisor and uniform results are assured regardless of the skill of help employed to load and unload the sterilizer.

For sterilizers of small capacity, as in the apparatus whose operation was described above, a fresh cylinder of sterilizing gas must be used for every cycle. In this way, small, convenient, preloaded cylinders of sterilizing gas can be provided that will insure exactly the proper amount of gas for kill, and the correct proportion of carbon dioxide or other inert gas to render the mixture non-combustible. However, for larger units, a large tank or reservoir of the sterilizing gas may be employed.

If this is done, the pressure switch 47 must be carefully adjusted, initially, so that the sterilizer will not begin its cycle unless the large cylinder or reservoir contains a sufficient amount of sterilizing gas to complete a cycle. Similarly, in some installations, it may be convenient to use steam from an existing service line instead of water from the sterilizer. In this day, to produce the required relative humidity in the sterilizing chamber. In such a case, it may be convenient to use a humidity gauge that is mounted in the sterilizing chamber to detect the relative humidity and to control the flow of steam.

It will be noted that in the illustrated embodiment of the invention, the unit is self-contained except for the source of electricity. No steam, water, or waste lines are required. It is merely necessary to provide a source of electricity, such as a conventional 110 volt, 60 cycle A.C. 20 amp. outlet to operate the device. Preferably, the spent ethylene oxide mixture from the sterilizing chamber is exhausted to the atmosphere for the prompt dissipation of the ethylene oxide.

As will be readily understood, also, existing sterilizer units may be converted to use the sterilizing method described above.

The preferred sterilizing gas is a mixture of ethylene oxide and an inert diluent gas, such as, for example, carbon dioxide, or one or more of the Freon gases. The preferred mixture is 20% by weight of ethylene oxide to 80% by weight of carbon dioxide, but other mixtures may be used. For example, a mixture of 10% by weight of ethylene oxide, with the balance carbon dioxide, is satisfactory. The inert gas renders the mixture non-combustible. Moreover, the use of the inert diluent permits use of a higher total pressure during the sterilizing operation, which enhances the biocidal effect of the ethylene oxide by bringing the ethylene oxide into more intimate contact with the micro-organisms.

For some purposes, a refinement in the cycle may be desirable, in which the sterilizing chamber is flushed with nitrogen, or other inert gas, after the sterilizing step, before the filtered air is admitted to the chamber. This step may be repeated several times, if desired, depending upon the results sought. This variation in the cycle may be advantageous, for example, where even minute traces of residual ethylene oxide must be removed from the sterilized goods. Maximum limits of residual ethylene oxide, for example, are specified by Federal legislation on certain powdered drug preparations.

Gas sterilization is particularly useful for the sterilization of hospital equipment containing optical systems, and for gauges affected by high heat. Limitation of the humidity to 20% to 40% makes sterilization possible for powdered goods, and for plastic compositions such as, for example, those employed in the production of plastic castings. The vacuum process, followed by pressure differential of applied gas, makes sterilization possible within intricate tubing assemblies, and into porous substances such as plastic sponges, and even seemingly inaccessible areas such as internal pages of books, the contents of which are not accessible to heat sterilization,

The biocidal effectiveness of the sterilizing gas varies indirectly as its concentration. Thus, a concentration of 1000 milligrams of ethylene oxide per liter of sterilizing gas produces a 100% kill twice as rapidly as will a concentration of 760 milligrams of ethylene oxide per liter of sterilizing gas. Generally, it appears that for every rise of 30°F. in the temperature of the sterilizing chamber, the exposure time can be cut in half. Thus, good results are obtained at 150°F., but the exposure time is required to be twice as long, when the other conditions are the same, to obtain the same effectiveness as is obtained at 130°F. Ordinarily, the sterilizer would be operated at 130°F.

The proper moisture content is essential for biocidal effectiveness. Thus, it has been found that where no water is injected into the chamber after initial evacuation, an exposure time of twenty-eight hours is ineffective to produce a 100% kill of bacteria, under the same conditions existing when a 100% kill is obtained after an exposure time of only four hours at the proper moisture content. A 20% to 50% relative humidity in the chamber is preferred for best operating conditions.

Examples of several operating cycles, at different concentrations of ethylene oxide and different temperatures, are provided below. Each of these cycles is controlled to provide 100% biocidal effectiveness. These cycles are adaptable to presently available sterilizing chambers of different sizes and different pressure ratings, and demonstrate the inter-relationship between the factors of gas pressure, gas concentration, chamber temperature, relative humidity, and exposure time.

**Example 1**

**Sequence of Operation**

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Unit</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Load Sterilizer and Set Temperature: Chamber Temperature</td>
<td>°F</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Set Timer: Length of Exposure</td>
<td>Hrs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Evacuate chamber</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Humidity to 2 Relative Humidity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Adjust the Sterilizing Gas: Chamber Pressure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Evacuate chamber</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Sterile air admitted</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Total Cycle Time</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Sterilizer Sizes**

<table>
<thead>
<tr>
<th>Volume (cu. ft.)</th>
<th>Lbs. of the Sterilizing Gas Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>20-36-48 (inches)</td>
<td>12</td>
</tr>
<tr>
<td>30-48-48 (inches)</td>
<td>12</td>
</tr>
<tr>
<td>40-54-60 (inches)</td>
<td>12</td>
</tr>
<tr>
<td>50-60-66 (inches)</td>
<td>12</td>
</tr>
</tbody>
</table>
The cycles are effective in destroying such organisms, for example, as B. globigii, Cl. sporogenes, E. coli Staph. aureus, and Sarcina lutea, as well as tubercle bacilli, hemolytic Streptococcus, Oidium fungus, and other life forms that are difficult to destroy. In particular, these cycles are effective against aerobic and anaerobic spore bearing bacteria, and against their spores, whereas conventional sterilization techniques are frequently ineffective against these micro-organisms. These cycles destroy, rather than merely inhibit, so that no later growth can be observed in sterilized materials. It is believed that the absolute kill obtained is dependent upon the critical interrelation of relative humidity, gas concentration and pressure, exposure time, and temperature, observed in these examples.

While the invention has been described in connection with a specific embodiment thereof, it will be understood that it is capable of further modification, and this application is intended to cover any variations, uses, or adaptations of the invention following, in general, the principles of the invention and including the support of departures from the present disclosure as come within known or customary practice in the art to which the invention pertains and as may be applied to the essential features hereinbefore set forth, and as fall within the scope of the invention or the limits of the appended claims.

1. A method of sterilizing an article in an enclosed chamber comprising the steps of,
   (a) evacuating said chamber to a selected level,
   (b) introducing water vapor to humidify the chamber to a selected level,
   (c) maintaining substantially selected humidity level for a dwell period sufficient to permit proper diffusion of moisture into the article being sterilized,
   (d) introducing ethylene oxide gas into said humidified chamber,
   (e) maintaining said gas in said chamber for a dwell period sufficient to effect sterilization of the article, and
   (f) heating said chamber to a selected temperature level within a range of about 100° to 130° F. during sterilization.

2. A method of sterilizing an article in an enclosed chamber comprising the steps of,
   (a) evacuating said chamber to a selected level,
   (b) introducing water vapor to humidify the chamber to a selected level,
   (c) maintaining substantially said selected humidity level for a dwell period sufficient to permit proper diffusion of moisture into the article being sterilized,
   (d) introducing ethylene oxide gas into said humidified chamber,
   (e) maintaining said gas in said chamber for a dwell period sufficient to effect sterilization of the article, and
   (f) heating said chamber to a selected temperature level within a range of about 100° to 130° F. during sterilization.

3. A method of sterilizing an article in an enclosed chamber comprising the steps of,
   (a) evacuating said chamber to a selected level,
   (b) introducing water vapor to humidify the chamber to a selected level within a range of about 20% to 50% relative humidity,
   (c) Maintaining substantially said selected humidity level for a dwell period sufficient to permit proper diffusion of moisture into the article being sterilized,
   (d) introducing ethylene oxide gas into said humidified chamber,
   (e) maintaining said gas in said chamber for a dwell period sufficient to effect sterilization of the article, and
   (f) heating said chamber to a selected temperature level within a range of about 100° to 130° F. during sterilization.

4. A method of sterilizing an article in an enclosed chamber comprising the steps of,
   (a) evacuating said chamber to a selected level,
   (b) introducing water vapor to humidify the chamber to a selected level within a range of about 20% to 50% relative humidity,
   (c) maintaining substantially said selected humidity level for a dwell period sufficient to permit proper diffusion of moisture into the article being sterilized,
   (d) introducing ethylene oxide gas into said humidified chamber,
   (e) maintaining said gas in said chamber for a dwell period sufficient to effect sterilization of the article, and
   (f) heating said chamber to a selected level after sterilization.

5. A method in accordance with claim 4 including a final step of,
   (g) introducing said chamber air from which airborne micro-organisms have been removed.

6. A method of sterilizing an article in an enclosed chamber comprising the steps of,
   (a) evacuating said chamber to a selected level,
   (b) introducing water vapor to humidify the chamber to a selected level within a range of about 20% to 50% relative humidity,
   (c) maintaining substantially said selected humidity level for a dwell period sufficient to permit proper diffusion of moisture into the article being sterilized,
   (d) introducing ethylene oxide gas into said humidified chamber,
   (e) maintaining said gas in said chamber for a dwell period sufficient to effect sterilization of the article, and
   (f) heating said chamber to a selected temperature level during sterilization.

7. A method of sterilizing an article in an enclosed chamber comprising the steps of,
   (a) evacuating said chamber to a selected level,
   (b) introducing water vapor to humidify the chamber to a selected level within a range of about 20% to 50% relative humidity,
   (c) maintaining substantially said selected humidity level for a dwell period sufficient to permit proper diffusion of moisture into the article being sterilized,
   (d) introducing ethylene oxide gas into said humidified chamber,
   (e) maintaining said gas in said chamber for a dwell period sufficient to effect sterilization of the article, and
   (f) heating said chamber to a selected temperature level during sterilization.
8. A method of sterilizing a porous article in an enclosed chamber comprising the steps of,
(a) evacuating said chamber to a selected level,
(b) introducing water vapor to humidify the chamber to a selected level within a range of about 20% to 50% relative humidity,
(c) maintaining substantially said selected humidity level for a dwell period sufficient to permit diffusion of the water vapor into spore-forming bacteria on the article being sterilized,
(d) introducing ethylene oxide gas into said humidified chamber, and
(e) maintaining said gas in said chamber for a dwell period sufficient to effect sterilization of the article.

9. A method of sterilizing a porous article in an enclosed chamber comprising the steps of,
(a) evacuating said chamber to a selected level,
(b) introducing water vapor to humidify the chamber to a selected level within a range of about 20% to 50% relative humidity,
(c) maintaining substantially said selected humidity level for a dwell period sufficient to permit diffusion of the water vapor into spore-forming bacteria on the article being sterilized,
(d) introducing ethylene oxide gas into said humidified chamber,
(e) maintaining said gas in said chamber for a dwell period sufficient to effect sterilization of the article, and
(f) heating said chamber to a selected temperature level during sterilization.

10. A method of sterilizing a porous article in an enclosed chamber comprising the steps of,
(a) evacuating said chamber to a selected level,
(b) introducing water vapor to humidify the chamber to a selected level within a range of about 20% to 50% relative humidity,
(c) maintaining substantially said selected humidity level for a dwell period sufficient to permit diffusion of the water vapor into spore-forming bacteria on the article being sterilized,
(d) introducing ethylene oxide gas into said humidified chamber,
(c) maintaining said gas in said chamber for a dwell period sufficient to effect sterilization of the article, and
(f) heating said chamber to a selected temperature level within a range of about 100° to 130° F. during sterilization.

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