

March 6, 1973

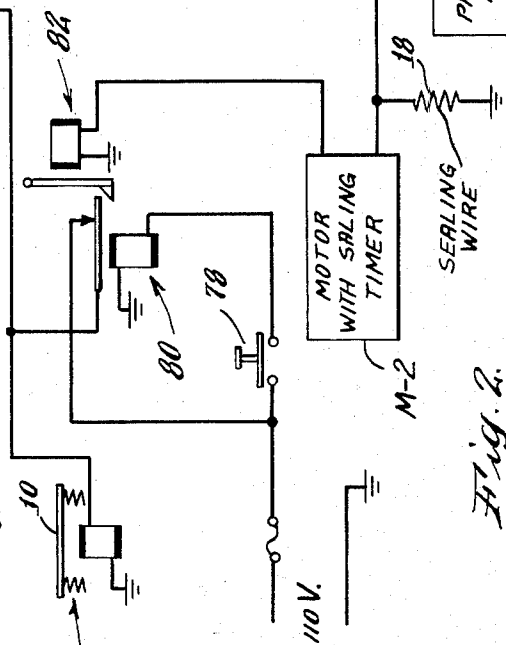
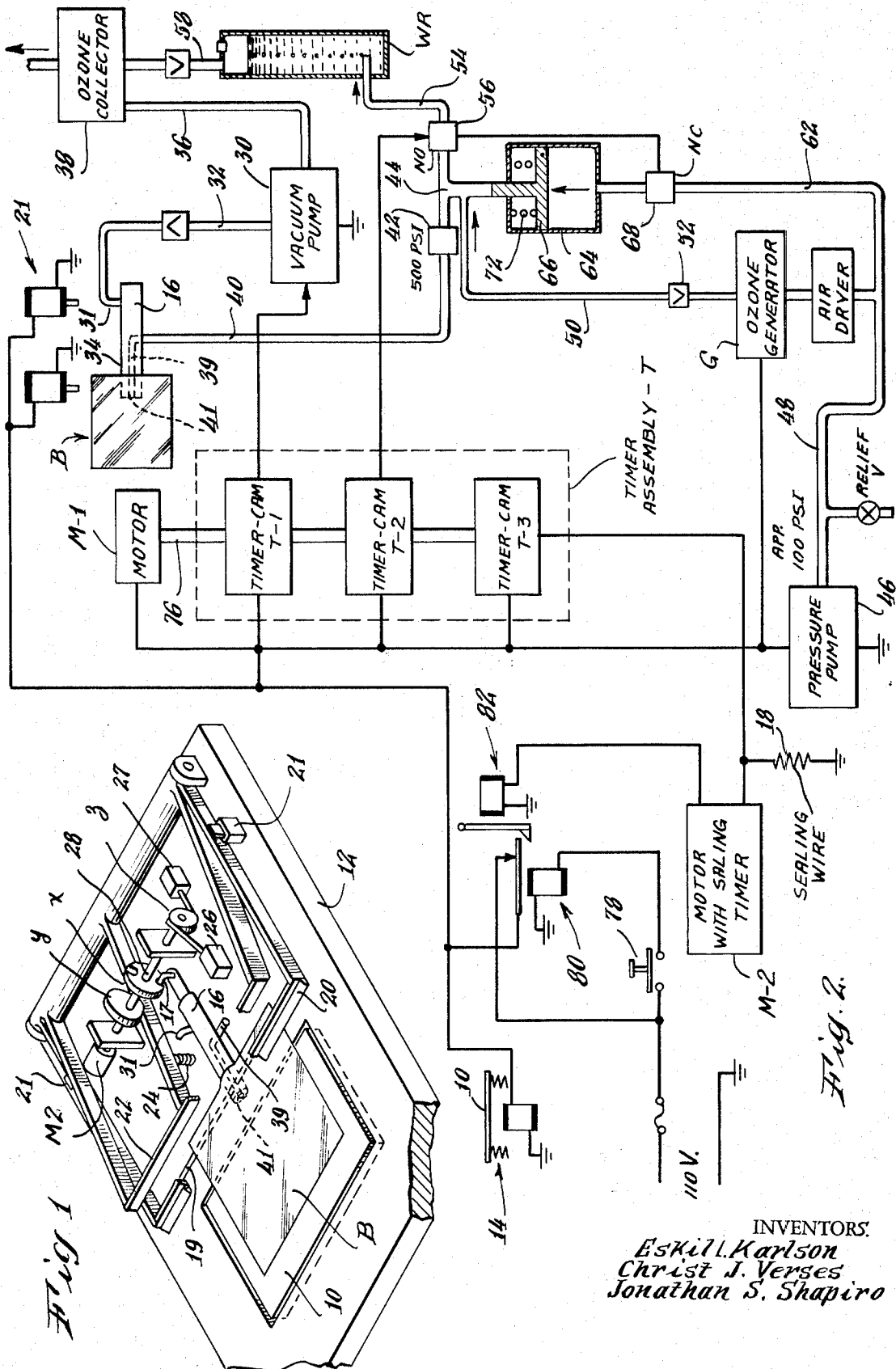
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3,719,017

STERILIZING AND PACKAGING DEVICE

Filed Oct. 16. 1970

2 Sheets-Sheet 1



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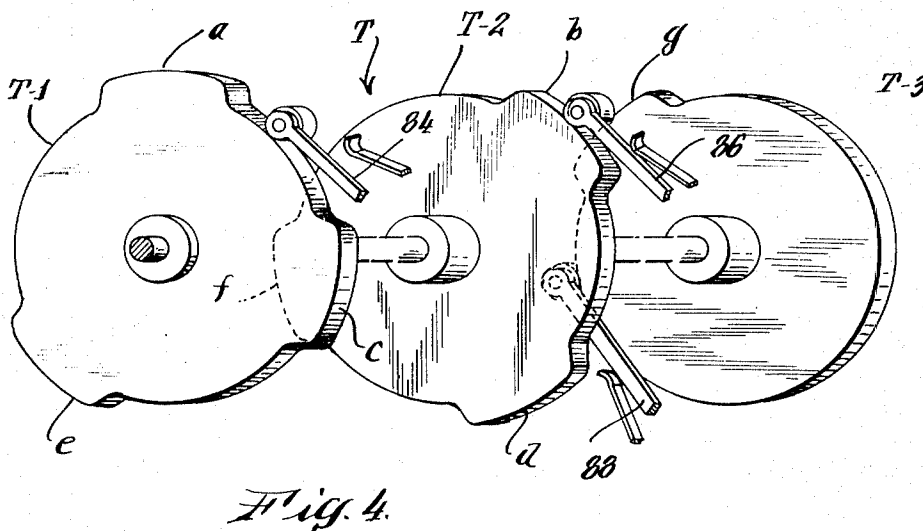
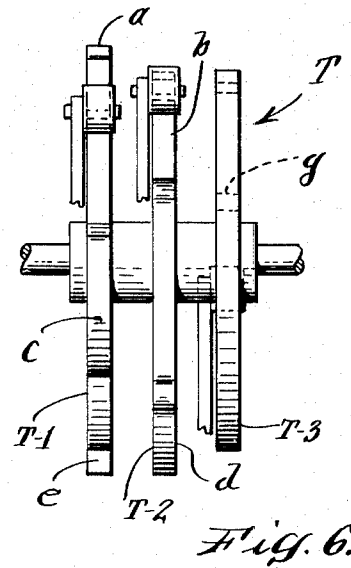
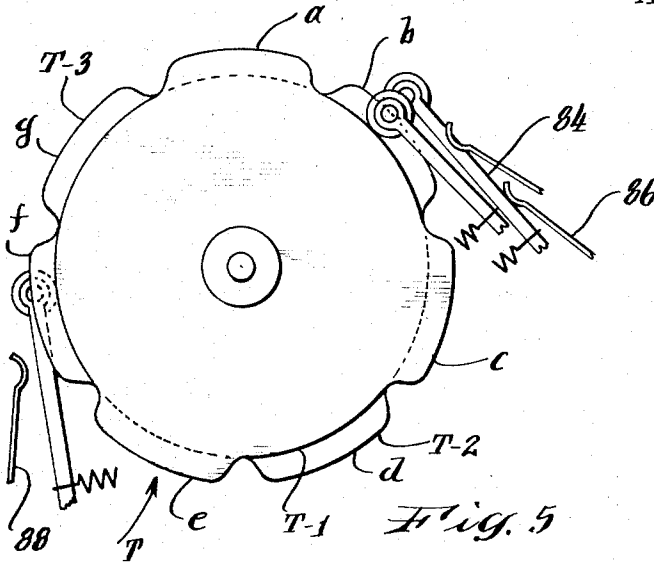
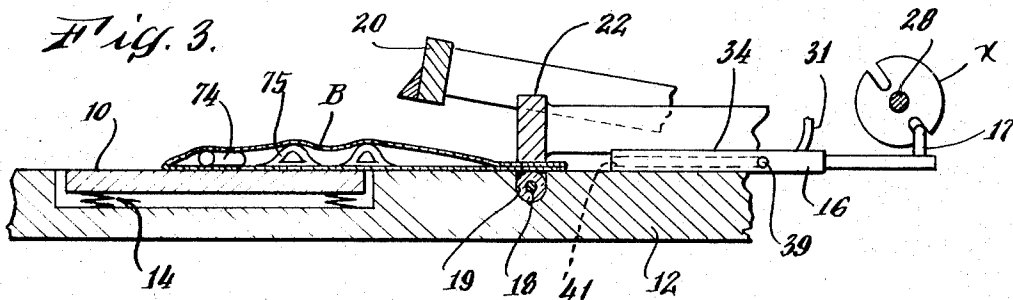
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STERILIZING AND PACKAGING DEVICE

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2 Sheets-Sheet 2



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STERILIZING AND PACKAGING DEVICE

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9 Claims

ABSTRACT OF THE DISCLOSURE

An article to be sterilized is placed in a container from which air is withdrawn and replaced with a sterilizing medium, preferably ozone mist, to which all surfaces of the article are exposed, and the container is sealed leaving the article in the sterilizing medium. The exhausting and refilling and sealing are performed automatically, in timed relation, and the exhausting and refilling steps may be repeated one or more times before the sealing step.

FIELD OF THE INVENTION

This invention relates to the method of sterilizing an article by enclosing it in a container in the presence of a sterilizing medium and agitating the container to expose all surfaces of the article therein to the medium, and also relates to preferred apparatus for evacuating air from a container, and replacing the air with a sterilizing medium and sealing it, while vibrating the container to bounce the article therein and thus expose all its surfaces to the sterilization medium.

The term "air" is used herein broadly. The invention particularly contemplates the use of a mixture of ozone gas and a very fine water mist, hereinafter referred to as "ozone mist," as the sterilizing medium.

The container is preferably one which can be readily and effectively sealed, such as a plastic bag, and it is desirable that the container be transparent so that means for indicating the attainment of a sterile condition within the container by color change occurring within a predetermined period after sealing, such as are disclosed in our copending U.S. patent application, Ser. No. 81,256, filed Oct. 16, 1970, can be observed through the wall of the container.

It will be noted that the method disclosed herein can be performed by hand or by various forms of apparatus of which the apparatus disclosed herein is preferred.

An object of the invention is to enclose an article in a sealed container in the presence of a sterilizing medium.

Another object of the invention is to provide apparatus by which a sealed container such as a plastic bag, with a sterilizing medium enclosed therein, may be provided automatically, in a series of timed steps performed in a predetermined sequence.

SUMMARY OF THE INVENTION

An article to be sterilized and maintained in a sterile condition, such as a surgical instrument, is placed in a container, preferably a transparent, readily sealable bag; the air in the container is exhausted and replaced by a sterilizing medium; and the container is sealed, the container being agitated to cause the article therein to bounce and move relative to the container, within the medium introduced within the container, to expose all surfaces of the article to the sterilizing medium.

The steps of positioning a container with a nozzle extending into the mouth of the container, clamping the container on the nozzle, vibrating the support while exhausting air from the container and while filling the container with a sterilizing medium, preferably ozone mist,

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unclamping the container and separating the nozzle from the container, and sealing the container, are performed in timed sequence. A vacuum pump, pressure pump, ozone generator, water reservoir, pressure amplifying chamber and mixing chamber are connected by conduits and in an electric control circuit with known means for evacuating and sealing bags, the control circuit including timing cam means by which the bag evacuating, refilling and sealing operations are performed in predetermined sequence and for predetermined periods of time.

If desired the operations of exhausting air from a container and refilling it with a sterilizing medium, such as ozone mist, may be repeated one or more time to more completely expel air from the container and surround the article therein with the sterilizing medium.

The invention will be best understood by reading the accompanying description in connection with the drawings in which:

FIG. 1 is a perspective view of means for positioning a bag in operative relation to nozzle means while air is exhausted from the bag and replaced by a sterilization means such as ozone mist, and the bag is sealed,

FIG. 2 is a schematic view of an electric control circuit and the means by which the air is exhausted from the bag and replaced with ozone mist,

FIG. 3 is a cross section taken on the lines 3—3 of FIG. 1,

FIG. 4 is a perspective view of a timing cam assembly, FIG. 5 is an end view of the assembly shown in FIG. 4, and

FIG. 6 is a front elevation of the cam assembly shown in FIGS. 4 and 5.

DESCRIPTION OF THE ILLUSTRATED EMBODIMENT OF THE INVENTION

In the embodiment of the invention illustrated in the drawings a bag supporting plate 10 is provided on a base 12, which is recessed to receive it so that the top of the plate will be flush with the top of the base, above vibrating means 14, and in front of a nozzle 16 which is moveable toward and away from plate 10, and is reciprocated by cam means on the shaft 28 of motor M-1 as will be described. A heating wire 18, preferably enclosed in an electrically insulating and heat transmitting sheath such as glass fiber, is disposed just in front of support plate 10, on base 12 which is preferably recessed to receive it so that its upper surface will be flush with the surface of the base. The U-shaped clamping bar 20 is mounted by its free ends on base 12 for swinging movement toward and away from the open end of a bag B positioned on plate 10 with its mouth extending around the forward end of nozzle 16. As shown in FIG. 1 nozzle 16 has been advanced toward plate 10, by means to be described, so that its front end extends over the wire 18 and is surrounded by the mouth of the bag B. The bag clamping and unclamping movements of bar 20 are controlled by solenoid means 21, forming part of the control circuit shown in FIG. 2. Bar 20 is swung down near the beginning of a cycle to clamp down the upper wall of a bag on the end of the nozzle, and is lifted and returned to inoperative position after the bag has been filled with a sterilizing medium and substantially simultaneously with the withdrawal of the nozzle to permit sealing of the mouth of the bag.

The sealing of the bag is accomplished by cooperation of a U-shaped bar 22 with the heating wire 18. Sealer bar 22 is mounted by its free ends on base 12 for swinging movement toward and away from a position in which it presses the bag, adjacent its open end, against the heating wire 18. It is not swung down onto the bag until after the nozzle 16 has been withdrawn from the bag. Wire 18 is

heated, as will be described, in timed sequence with the withdrawal of nozzle 16 and the swinging down of bar 22.

Nozzle 16 is a short rigid member having two nipples 31 and 39, to which the forward ends of flexible conduits 32 and 40 are respectively connected. Nipple 39 continues through the side wall of nozzle 16 to the front end of nozzle 16 as a small tube having the discharge orifice 41 and surrounded by annular space 34 with which conduit 32 communicates. Also projecting from nozzle 16 is a pin or cam follower 17.

Like the reciprocation of the nozzle the descent of sealer bar 22 and the heating of wire 18 are controlled by cam means on the shaft 28 of motor M-2.

Motor M-2 is shown mounted on base 12. As shown in FIG. 2 motor M-2 is actuated by the operation of timing cam T-3, forming part of the timing cam assembly T, see FIGS. 4-6. On the shaft 28 of motor M-2 are mounted three cams—x, y and z. Cam x on the motor shaft 28 cooperates with the cam follower 17 shown disposed on a rearward extension of the nozzle 16, causing the nozzle to be moved rearwardly after air has been exhausted from a bag and replaced by a sterilizing medium, in order to be out of the way when the sealer bar 22 descends. Cam x is shaped so that as the last act in each cycle, after a bag has been sealed and removed from support plate 10, the nozzle is again advanced in preparation for the next cycle to a position where the mouth of the next bag, as it is positioned on support 10 with its open end extending over the sealing wire 18, can be placed in communication with the nozzle.

Cam y on the motor shaft 28 bears on the sealer bar 22 and its high point pushes the sealer bar down into sealing position, against the action of a spring 24 by which the sealer bar is again elevated immediately after the high point on the cam has passed.

Cam z is a timing cam which at the correct time in an operating cycle, preferably just subsequent to the lifting of the clamping bar 20 and the retraction of nozzle 16, closes a switch 26 which connects wire 18 in the electric circuit, as shown in FIG. 2, thereby heating wire 18 before the bag is pressed down on the wire by sealer bar 22. Cam z also controls switch 27 which when closed actuates the latching release relay 82.

Conduit 32 leads from the nipple 31 of nozzle 16 to a vacuum pump 30. When the vacuum pump is actuated, by closing the start switch 78 of the electric control circuit and starting rotation of a timing cam assembly T to be described, the fluid contents of bag B is drawn into and through vacuum pump 30, and is discharged into chamber 38.

Conduit 40 leads from the nipple 39 which extends through the wall of nozzle 16, to a chamber 42 in which ozone gas from the generator G and water from the water reservoir WR, are mixed. The air intake side of ozone generator G is connected to a pressure pump 46 by conduit 48, and the outlet side of ozone generator G is connected to mixing chamber 44 by conduit 50 in which is the one-way valve 52.

The water reservoir WR is disposed to feed water by gravity to mixing chamber 44 through conduit 54 and the normally open valve 56 therein. Any ozone gas bubbling up through conduit 54 and water reservoir WR is lead through conduit 58 into ozone collector 60 which contains a substance, such for example as activated carbon, adapted to convert the ozone gas into oxygen and carbon dioxide before discharge into the atmosphere.

Pressure pump 46 is also connected, by conduits 48 and 62 to the pressure amplifying cylinder 64 beneath the piston 66 therein. In conduit 62 is the normally closed valve 68. When valve 68 is opened, which is done simultaneously with the closing of valve 56 by action of the rotating timing cam assembly T, the pressure from pump 46 causes piston 66 to rise in cylinder 64, against the force of spring 72, thereby substantially increasing the pressure

of the mixture of ozone gas and water in mixing chamber 44, from say 100 p.s.i. to a pressure of from 500 to 1000 p.s.i. Since valve 42 in tube 40 is set to open at 500 p.s.i. the increased pressure in mixing chamber 44 forces the water and ozone gas contents of chamber 44 past valve 42 and through tube 40 into the bag B from which air has just been evacuated. Upon encountering the low pressure within bag B the water particles in the mixture of water particles and ozone gas from the mixing chamber explode forming a very fine mist intimately mixed with ozone gas forming what is referred to herein as ozone mist which is stable and slow to separate and effective in sterilizing the inner surface of the bag and the article or articles enclosed therein.

We have found that good results are obtained when the water and ozone gas are mixed in preparations to provide within the container a minimum ozone concentration of one thousand parts per million and moisture content of 80% or more. Desirably water absorbing means, such for example as cotton compact 74, is initially placed in bags B along with the article or articles 76 to be sterilized, and particularly when the bag is evacuated after being filled with ozone mist since some water particles may be left in the bag.

Ozone generator G may desirably be of the kind disclosed in copending patent applications Ser. No. 790,775 filed Jan. 13, 1969, and Ser. No. 839,342 filed July 7, 1969.

OPERATION

The operation of the illustrated embodiment of the invention depends largely upon the timer assembly comprising timing cams T-1, T-2 and T-3 which as shown in FIG. 3 are mounted for rotation together on shaft 76. Shaft 76 is driven by motor M-1 which is actuated as soon as the circuit start button switch 78 is closed and latching relay 80 is energized and continues to operate until the circuit is broken at the end of a cycle by the actuation of the latching release relay 82 by timing cam z on the shaft 28 of motor M-2 following the actuation of motor M-2 by timer cam T-3. Closing of start switch 78 starts rotation of timing cam assembly T by actuating motor M-1 and thus bring timing cam members T-1, T-2 and T-3 into action in the sequence described below and simultaneously actuates the vibrator means 14, the solenoid means for raising and lowering clamping bar 20, the pressure pump 46, and ozone generator G. Consequently, each time a bag is placed on support plate 10 with its mouth around the forward end of nozzle 16 an operating cycle is begun by closing starting switch 78, and thereupon the vibrator plate 10 is set in motion, the clamping bar 20 is lowered to clamp bag B on the nozzle 16. Air is caused to flow through the Air Dryer into the ozone generator G. Water and ozone gas are supplied into the mixing chamber 44 and a situation is established ready to be utilized by the operation of timing cam assembly T. The three timing cams T-1, T-2, and T-3 control operation of the system until timing cam T-3 starts motor M-2 when the cams x, y and z on the shaft 28 of motor M-2 take over and control the remaining operations of the cycle as has been described above.

Timer T-1 has on its periphery one or more raised cam surfaces, the number of which depends upon how many times it is desired to repeat the operation of evacuating a container and filling it with ozone mist. As illustrated timer T-1 has three such cam surfaces, a, c and e, disposed at measured distances around its periphery showing that it is intended to evacuate the bag and replace the air therein with ozone mist three times. The three cams a, c and e each acts in the same way to close a switch by raising a spring pressed self-opening switch arm 84 and starting vacuum pump 30 and thereby evacuating air from a bag B placed on plate 10 with its open end in communication with nozzle 16, for a period of 1 or 2 seconds.

Timer T-2 is similarly provided with three cam surfaces, b, d and f, which are disposed so that they will op-

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erate immediately after cam surfaces *a*, *c* and *e* respectively have operated. Each of the cam surfaces *b*, *d* and *f* serves in the same way to close a switch by raising a spring pressed self-opening switch arm 86 and simultaneously closing normally open valve 56 and opening normally closed valve 68 thus closing communication between the mixing chamber 44 and the water reservoir WR and causing the mixture of ozone gas and water to be expelled from mixing chamber 44 into bag B.

After about 2 minutes, during which the bag has been vibrated so that any article in it will have all surfaces exposed to the ozone mist, timer T-2 causes valve 68 to close and valve 56 to reopen, thus reducing the pressure in space 44 and allowing check valve 42 to close.

Timer T-3 is provided with only one cam surface *g*, which is disposed to act, only after the cam surfaces *a*, *b*, *c*, *d*, *e*, and *f* have operated in sequence, to close a switch by raising the spring pressed self-opening switch arm 88 and activating motor M-2 which drives shaft 28 on which cams *x*, *y* and *z* are mounted and by which the operating cycle is completed as has been described.

What we claim is:

1. The method of packaging an article in a sterilizing medium and maintaining the article sterile until used, which comprises, placing an article in a container, exhausting the fluid contents of the container, filling the container with a sterilizing medium, agitating the bag to cause all surfaces of the article therein to be exposed to the sterilizing medium, and sealing the container with the article and the sterilizing medium therein including placing the container on a support member and vibrating the support member while exhausting the fluid contents of the container and injecting a sterilizing medium into the container and sealing the container.

2. The method of packaging an article in a sterilizing medium and maintaining the article sterile until used, which comprises, placing an article in a container, exhausting the fluid contents of the container, filling the container with a sterilizing medium, agitating the bag to cause all surfaces of the article therein to be exposed to the sterilizing medium, and sealing the container with the article and the sterilizing medium therein including the steps of mixing water and ozone gas in a mixing chamber to form the sterilizing medium, increasing the pressure of the mixture in the mixing chamber, and injecting the mixture into the container under pressure sufficient to cause the water particles to explode within the container and form a fine mist in which the ozone gas is mixed.

3. Apparatus for supplying a sealed container having a sterilizing medium therein which comprises, a container, means for exhausting air from the container, means for filling the emptied container with a sterilizing medium, means for sealing the container after it has been filled with the sterilizing medium, and control means for operating the above mentioned means in timed relation for predetermined periods of time and means for supporting the container while its gaseous content is exhausted and replaced with a sterilizing fluid medium, and means for vibrating the support means operative after the sterilizing fluid medium has been introduced into the container.

4. Apparatus for supplying a sealed container having a sterilizing medium therein which comprises, a container, means for exhausting air from the container, means for

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filling the emptied container with a sterilizing medium, means for sealing the container after it has been filled with the sterilizing medium, and control means for operating the above mentioned means in timed relation for predetermined periods of time, the means for filling the container with a sterilizing medium comprising a mixing chamber, means for supplying water and ozone gas into said mixing chamber, and means for raising the pressure within the mixing chamber and thereafter injecting the contents of the mixing chamber into the container.

5. The apparatus claimed in claim 4 including an ozone collection chamber having therein means adapted to convert ozone into non-poisonous form, and means for leading to the collection chamber ozone gas escaping from the mixing chamber and ozone gas exhausted from the container.

6. The method claimed in claim 2 in which the water and azone gas are mixed in proportions to provide within the container minimum ozone concentration of one thousand parts per million and eighty percent humidity.

7. The method of providing a sealed container filled with a sterilizing medium which comprises, positioning a plastic bag with nozzle means inserted in its open end, exhausting air from the bag through the nozzle means, mixing ozone gas and water and injecting it into the emptied bag under sufficient pressure to form a fine mist of ozone gas and water vapor therein, vibrating the bag to cause all surfaces of an article within the bag to be wetted by the ozone mist, withdrawing the nozzle means from within the mouth of the bag, and sealing the bag.

8. Apparatus for exhausting air from a flexible bag container, refilling it with ozone mist, and sealing the container with the ozone mist in it, which comprises, a nozzle, a support for positioning a bag with the nozzle extending into the mouth of the bag, means for clamping the upper side of the bag on top of the nozzle, means for vibrating the support, means for exhausting air from the bag through said nozzle, means for mixing ozone gas and water and supplying it into the bag under pressure through the nozzle means for withdrawing the nozzle from the mouth of the bag, means for sealing the bag, and an electric control circuit including switches and a timing cam switch operating assembly for actuating said means in a predetermined sequence and for predetermined periods of time.

9. The apparatus claimed in claim 8 in which the control circuit includes switch means and timing cam switch actuating surfaces for exhausting the bag at least once after it has been filled with ozone mist, and for thereafter refilling the bag with ozone mist.

References Cited

UNITED STATES PATENTS

3,516,223 6/1970 Andersen et al. 53—112 B
3,477,807 11/1969 Ernst 21—58

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U.S. Cl. X.R.

21—58; 53—22 B, 111 RC, 112 B