

Feb. 10, 1970

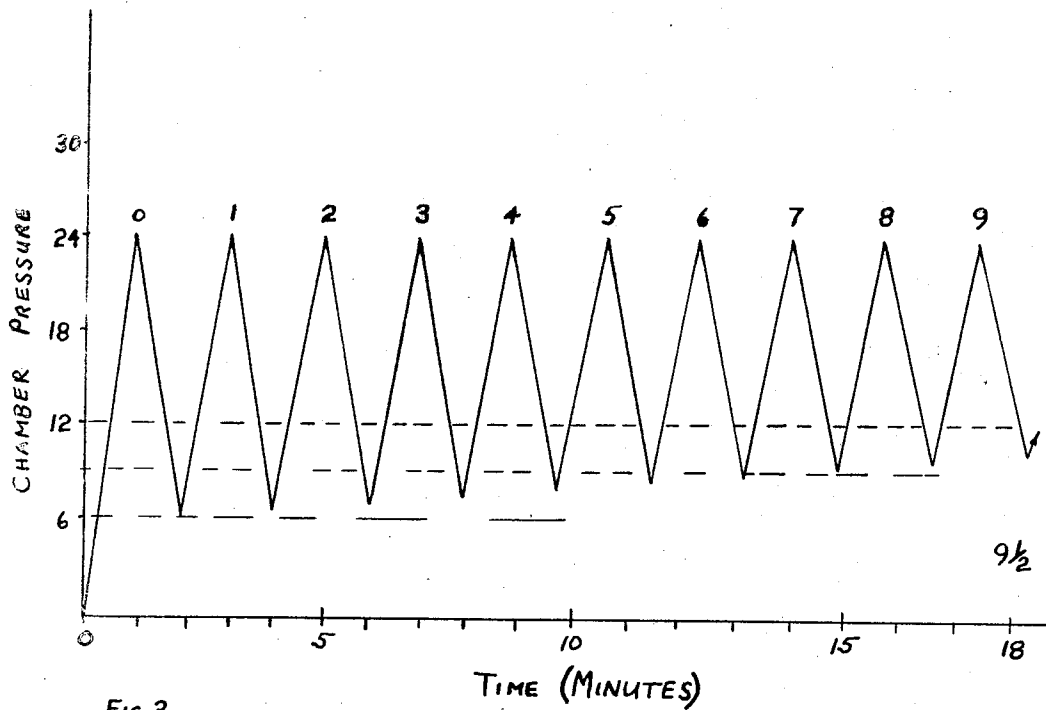
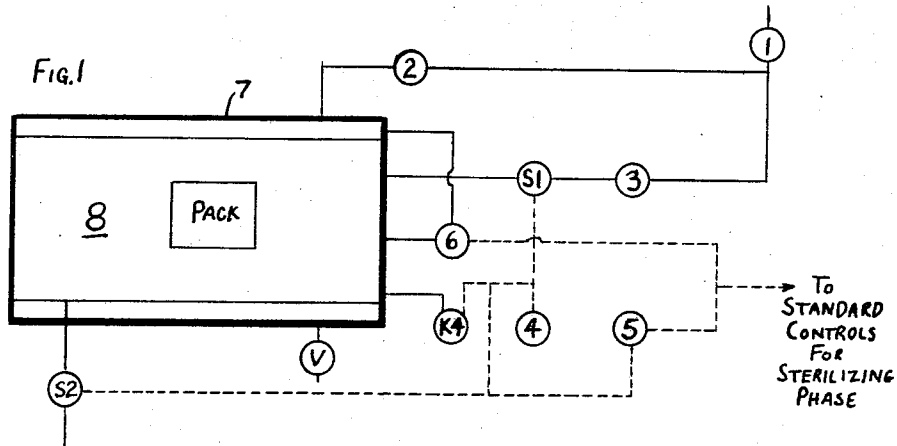
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PULSING PROCESS OF STERILIZATION

Filed June 20, 1968

2 Sheets-Sheet 1



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FIG. 2

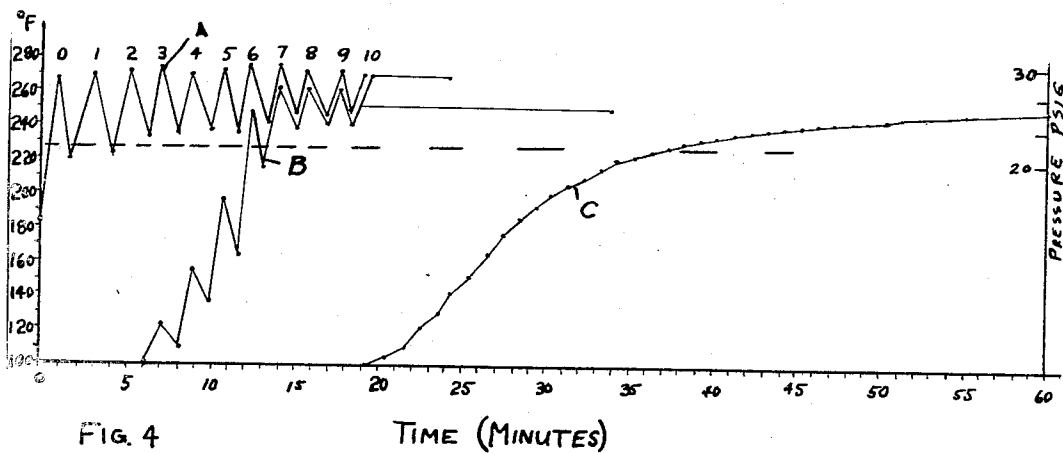
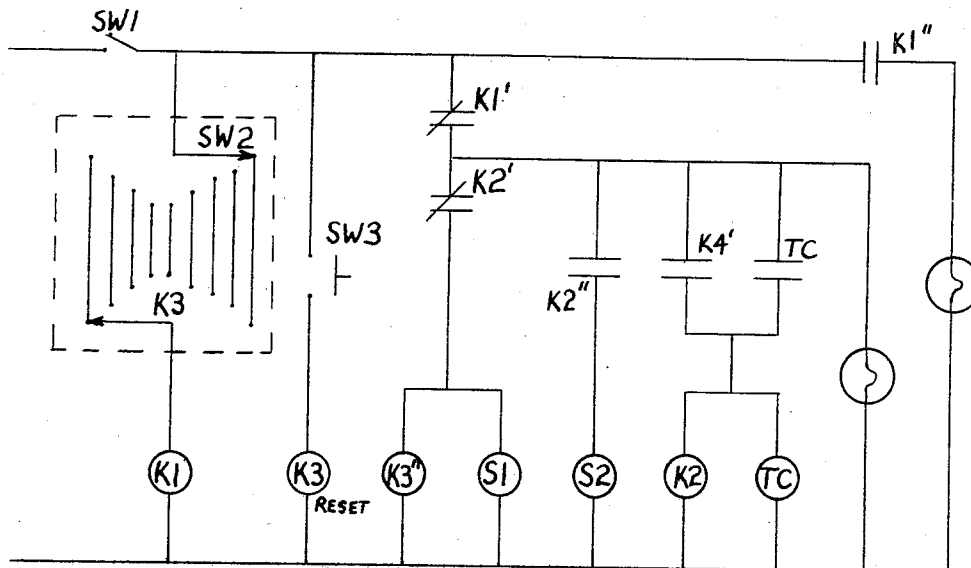


FIG. 4

TIME (MINUTES)

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PULSING PROCESS OF STERILIZATION
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 Continuation-in-part of application Ser. No. 677,479, Oct. 23, 1967. This application June 20, 1968, Ser. No. 745,651

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7 Claims

ABSTRACT OF THE DISCLOSURE

System of sterilization in which the chamber is flushed with steam by means of pulsing, which consists of raising the pressure in the sterilization cabinet to a predetermined level, exhausting the chamber to atmospheric pressure by opening the exhaust valve for a predetermined time and then raising the pressure to said predetermined level and repeating the steps of venting and pressurizing for a predetermined number of times automatically to achieve substantial saturation with steam or other vapor and then sterilizing for a specified period of time.

This application is a continuation-in-part application of application, Ser. No. 677,479, filed Oct. 23, 1967, now abandoned.

This invention relates to sterilizing systems and, more particularly, to a steam pressure sterilizer utilizing a pulsing or cycling of the steam pressure in the chamber.

Two general classifications of sterilizing methods are:

- (1) Pre-vacuum method; and
- (2) Downward displacement method.

The basic difference between the pre-vacuum steam sterilization system and all others is the absolute dependence of the pre-vacuum sterilization system on a pumping system to remove residual air from the load to be sterilized. The removal of air from the sterilizer and load has been cited as the first essential in the sterilization of textiles and other porous materials.

In pre-vacuum steam sterilization systems, air is removed from the sterilizer by a powerful pump which reduces the absolute pressure to a few millimeters of mercury before steam is admitted. This has been said to be the only method which can overcome the effects of bad packing or overloading of sterilizers.

In the downward displacement method, air is removed from the load by gravity, the difference in density between cool air and steam. This method is effective only if the sterilizer is carefully packed.

In sterilizing of supplies in hospitals and the like, it is desirable to have a very short load lag in the sterilizing process since this reduces the entire sterilizing cycle. Load lag is the time elapsed between the instant a given acceptable steam sterilization temperature of a given chamber is reached; for example, 250° F., and the time the load reaches the same temperature throughout.

Pre-vacuum sterilization systems have advantages over other sterilization systems due to the short load lag. When an almost perfect vacuum is drawn, steam permeates the load almost instantaneously. With a minimal penetration time, a high sterilization temperature may be employed with a consequent reduction in holding time and safety period. Consequently, the complete sterilization cycle time can be reduced.

Both the pre-vacuum method and the downward displacement method have disadvantages. A pre-vacuum sys-

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tem requires for proper operation a vacuum tight system with an air leakage rate no greater than one torr (millimeter mercury absolute) per minute. Leaks greater than this make the system unreliable for effective sterilization. The controls for the pre-vacuum method are complex and frequently subject to malfunction. The vacuum pumping system is costly and, in many cases, difficult to maintain. Gravity discharge or downward displacement sterilization requires painstaking supervision of operator technique. Poor loading can jeopardize or nullify the effectiveness of the method. In order to assure sterility of large loads, extended times at high temperature are necessary; however, at these high temperatures, fabric life is shortened due to high temperature oxidation. This results in costly replacement of hospital materials and further adds to today's already increasing hospital expenses.

The present invention relates to a pulsing method of sterilization. The pulsing method of sterilization disclosed herein is a reliable and effective compromise between the expensive and complex pre-vacuum method and the slow, proper loading dependent, fabric destroying downward displacement method. A pulsing sterilizer can reduce load come-up time (time for the load to reach the desired sterilizing temperature) to one-third the time necessary with a downward displacement system.

The pulsing method of sterilization as outlined herein has been experimentally designed to be independent of operator loading technique and will insure sterility in improperly loaded sterilizers. One pulsing sterilizer could replace two equivalent size downward displacement sterilizers at a cost little more than the price of one of the replaced sterilizers. Fabric life will be extended due to shorter exposure time at high temperature. The controls for the pulsing method are simple, reliable, and readily available. Maintenance and service costs are reduced accordingly.

It is, accordingly, an object of the present invention to provide an improved sterilizing method.

Another object of the invention is to provide an improved steam sterilizing system.

Still another object of the invention is to provide a steam sterilizing system wherein steam under pressure is alternately admitted to and exhausted from a sterilizing chamber for a plurality of predetermined cycles prior to the admission of the steam for sterilization.

A further object of the invention is to provide a gas sterilizing system wherein gas under pressure is alternately admitted to and exhausted from a sterilizing chamber for a plurality of predetermined cycles prior to the admission of the gas for sterilization.

Still a further object of this invention is to provide a vapor sterilizing system wherein vapor under pressure is alternately admitted to and exhausted from a sterilizing chamber for a plurality of predetermined cycles prior to the admission of the vapor for sterilization.

These and other objects of the invention will be apparent from the ensuing description and the appended claims.

Certain forms of the invention are illustrated by way of example in the accompanying drawings in which:

FIG. 1 is a schematic view of an apparatus to carry out the invention;

FIG. 2 is a schematic diagram of an electrical pulsing control circuit;

The symbols FIGURES 1 and 2 indicate parts of the apparatus as follows:

S1—Solenoid operated pulsing steam input valve

S2—Solenoid operated pulsing steam exhaust valve

SW1—Main power switch
 SW2—Selector switch—Pulse number
 SW3—Reset switch
 K1—Spot relay
 K2—Spot relay
 K3—Stepping relay
 K4—Pressure actuated switch
 TC—Time clock
 1—Main steam supply pressure regulator
 2—Jacket pressure regulator
 3—Pulsing steam pressure regulator
 4—Pulsing steam exhaust time switch
 5—Pulse number control selector
 6—Sterilize phase control valve
 7—Sterilizer steam jacket
 8—Sterilizer chamber

FIG. 3 is a diagram of the pressure time relationship inside the steam sterilizer in a cycle according to the invention; and

FIG. 4 is a diagram showing the relationship of the chamber drain temperature and the load center temperature of the cycle disclosed herein compared with a cycle used in the art.

In carrying out the invention, a sterilizer autoclave 8 will be provided with a suitable steam jacket 7 as shown. The system may be applied to any typical sterilizer autoclave. For any given sterilizer the alternate pressurizing and exhausting will enable one to achieve sterilization temperature in a shorter time than with the downward displacement method without the necessity of providing vacuum equipment. A steam line supply at, for example, 60 p.s.i.g., is directed into the sterilizer through the arrangement of valves and piping shown in FIG. 1. The steam in the jacket and chamber of the sterilizer may be regulated by regulators 1, 2, and 3 to achieve the desired sterilizing temperature. The circuit includes a pulsing steam exhaust or vent time switch 4, a pulse number control selector 5, and a sterilize phase control valve 6.

To verify the advantages of the system disclosed herein, tests were made on a standard 48 inch autoclave on test packs which consisted of:
 5 muslin sheets (130 threads/inch).

Each sheet folded double six times to give sixty-four layers per sheet.

Overwrapper consisting of double muslin.

Dimensions of pack approximately 5" x 10" x 14".

Weight approximately 8.2 pounds.

These packs had a density of 20.6 pounds per cubic foot. The above test pack was chosen as a challenge load upon which to perfect the pulsing method of sterilization since it was easy to duplicate, economical, and very difficult to sterilize in a short cycle.

Packs such as used in the tests herein would be difficult or impossible to sterilize by the downward displacement processes in the normally acceptable time. Recommended practice for routine downward displacement sterilization is to have packs no larger in dimension than 12" x 12" x 20" and weighing ten to eleven pounds to give a pack density in the range of 6.0 to 6.6 lb./ft.³.

In addition to dense test packs, the test loads were set up to simulate improper loading techniques in the sterilizer chamber such that the pulsing method would be designed to insure sterility under the worst possible conditions.

The number of pulses, pulsing steam supply pressure, and pulsing control points have all been determined for the worst possible load conditions and the determined values are the best possible comprise to satisfy sterilizing requirements under all expected conditions. It is to be understood that a particular load can have a particular set of pulsing conditions adapted to it for the shortest sterilizing cycle. The conditions as outlined herein, however, will insure that all fabric and porous materials will be sterilized in the shortest possible cycle for a wide range of loads and poor operator technique and be one-third of the equivalent load come-up time for a downward displacement system.

TEST DATA SHOWING: COMPARISON TIMES FOR LOAD COME-UP, GRAVITY DISCHARGE VERSUS PULSING

Pulsing steam supply pressure, p.s.i.g.	Number of pulses before start of sterilize phase	Number of dense packs in test load	Average time to reach 250° F. throughout load, min.:sec.	Average time to reach 270° F. throughout load, min.:sec.	Method of sterilization	Jacket pressure, p.s.i.g.
60	9½	20	61:00	-----	Gravity discharge.....	18
60	9½	20	20:00	-----	Pulsing charge to 24 p.s.i.g. Exhaust for 60 seconds.	18
60	9½	20	27:30	-----	Pulsing charge to 24 p.s.i.g. Exhaust for 40 seconds.	18
40	9½	20	38:00	-----	Pulsing charge to 22 p.s.i.g. Exhaust for 30 seconds.	18
60	9½	20	17:47	20:07	Pulsing charge to 24 p.s.i.g. Exhaust for 60 seconds.	34
60	9½	1	20:00	-----	Gravity discharge.....	18
60	9½	1	10:30	-----	Pulsing charge to 24 p.s.i.g. Exhaust for 40 seconds.	18
60	9½	1	12:55	-----	Pulsing charge to 24 p.s.i.g. Exhaust for 30 seconds.	18
60	9½	1	9:36	9:50	Pulsing charge to 24 p.s.i.g. Exhaust for 40 seconds.	18
40	9½	1	14:00	-----	Pulsing charge to 24 p.s.i.g. Exhaust for 30 seconds.	18

NOTE.—Any steam supply line pressure above 25 p.s.i.g. may be utilized but higher supply pressures of pulsing and/or sterilizing steam will decrease the sterilizing cycle time.

A pulse as used herein is defined as the venting of a chamber in which pressure has reached a selected value by opening valve for a predetermined time while closing the input valve for said same predetermined time and then pressurizing the chamber again by closing the valve and opening the input valve until the said pressure is achieved.

With each admission of steam during each pulse, the residual pressure of the chamber increases since the proportion of steam to air increases as the air is vented from the chamber with the admitted steam and fresh steam is admitted, as shown in the diagram in FIG. 3.

In a typical test, as shown in FIG. 3, a standard 24" x 36" x 48" sterilizing chamber is pressurized for ex-

ample to 24 p.s.i.g. and then alternately exhausted for 40 seconds and pressurized to 24 p.s.i.g.

Pulse:	Pressure after exhaustion, p.s.i.g.
1 -----	16.5
2 -----	16.8
3 -----	17.1
4 -----	17.5
5 -----	17.9
6 -----	18.5
7 -----	19.1
8 -----	19.9
9 -----	21.2

This system has been tested keeping the pressure at the top of the pulses to as high as 80 p.s.i.g. It has been tested bringing the top pressure of the pulses to as low as 20 p.s.i.g. The number of pulses have been varied from 1 to 27. The load has been varied from 6 to 20 test packs. The jacket pressure has been varied from 18 to 34 p.s.i.g. The rate of exhaust has been varied and various sizes of machines have been used. The cycle functioned satisfactorily over these ranges of variables.

FIG. 4 shows a curve A of the variation of chamber temperature with time using the pulsing cycle disclosed herein. Curve B shows a curve of load temperature with time using the pulsing cycle disclosed herein. Curve C shows a curve of load center and temperature of a 20 standard pack load with time when no pulsing was used. It will be noted that the center of the load did not change temperature until the end of 19 minutes.

At the conclusion of the sterilizing cycle, switch SW1 is opened and the circuit is now ready for another pulsing-sterilizing cycle.

Specific examples of the steps of the method disclosed are:

EXAMPLE I

(a) Admit steam at 60 p.s.i.g. to the chamber until the chamber pressure is substantially 24 p.s.i.g.

(b) Shut off the steam supply to the chamber and energize the exhaust valve for sixty seconds to reduce the chamber pressure to about 22.

(c) Repeat the pulsing steps of (a) and (b) until the desired number of pulses is achieved. At this time, the pulsing phase is terminated.

(d) Admit steam at 250° F. for a predetermined sterilization time; for example, fifteen minutes.

EXAMPLE II

(a) Admit steam at 60 p.s.i.g. to the chamber until the chamber pressure is substantially 24 p.s.i.g.

(b) Shut off the steam supply to the chamber and energize the exhaust valve for sixty seconds, reducing the pressure to about 15.

(c) Repeat the pulsing steps of (a) and (b) until the desired number of pulses is achieved. At this time, the pulsing phase is terminated.

(d) Admit steam at 270° F. for a predetermined sterilization time; for example, four minutes.

EXAMPLE III

(a) Admit steam at 60 p.s.i.g. to the chamber until the chamber pressure is substantially 20 p.s.i.g.

(b) Shut off the steam supply to the chamber and energize the exhaust valve for sixty seconds, reducing the pressure to about 15.

(c) Repeat the pulsing steps of (a) and (b) until the desired number of pulses is achieved. At this time, the pulsing phase is terminated.

(d) Admit steam at 270° F. for a predetermined sterilization time; for example, four minutes.

EXAMPLE IV

(a) Admit steam at 60 p.s.i.g. to the chamber until the chamber pressure is substantially 30 p.s.i.g.

(b) Shut off the steam supply to the chamber and energize the exhaust valve for sixty seconds, reducing the pressure to about 15.

(c) Repeat the pulsing steps of (a) and (b) until the desired number of pulses is achieved. At this time, the pulsing phase is terminated.

(d) Admit steam at 270° F. for a predetermined sterilization time; for example, four minutes.

The sterilizing temperatures could be as low as 230° F. and could be 280° F. or more.

Example of operation of the pulsing system

FIGS. 1 and 2 show an example of the many apparatus which may be used to carry out the invention herein involving the pulsing method of sterilizing.

To start the pulsing sequence, switch SW1 is closed and switch SW3 is momentarily pressed to reset the K3 and K3' contacts of stepping relay K3' which deenergizes relay K1. Current flows through the main power pulsing pilot light and through the normally closed contacts K1' and K2' of the SPDT relays K1 and K2 to energize the pulsing steam input solenoid valve S1 and stepping relay K3'. Stepping relay K3' steps K3 and K3' contacts one position and steam flows into the sterilizer chamber through solenoid valve S1.

When the chamber has been charged with steam to the desired control point, for instance, 24 p.s.i.g., pressure switch K4' contacts close and allow current to flow from the normally closed K1' contacts through K4' contacts to energize the SPDT relay K2 and the time clock TC. With the relay K2 energized, the normally closed contacts K2' open and deenergize the steam input solenoid valve S1 and the stepping relay K3'. With the solenoid valve S1 closed, steam ceases flowing into the chamber.

At the same time, the normally open contacts K2'' of relay K2 close, energizing the exhaust solenoid valve S2 which exhausts or vents the chamber to a suitable drain or open receptacle through the line from the exhaust valve shown in FIG. 1. The time clock TC which was previously energized closes contacts Tc for a specified amount of exhaust time; for instance, sixty seconds, while, at the same time, the chamber is losing pressure through the exhaust steam solenoid S2. This loss of pressure resets the pressure switch K4 and opens contacts K4'. At the end of the desired exhaust period (sixty seconds), the Tc contacts of the time clock TC open, deenergizing the time clock TC and the relay K2. The normally open and the normally closed contacts K2' of relay K2 revert to their normal position, causing exhaust solenoid S2 to deenergize, steam input solenoid S1 to energize, relay K3' to step once again, and the chamber is again pressurized.

This sequence of events will continue and the chamber will be pulsed with steam in a pressure time pattern; for example, as shown in FIGURE 3, until the contacts of stepping relay K3' are electrically connected to the selected pulse number contacts of the selector switch SW2. At this time, current flows through SW2 and K3' contacts to energize SPDT relay K1. The normally closed contacts K1' of relay K1 open and deenergize the pulsing circuitry and the normally open contacts K1'' of relay K1 close and energize the sterilize phase circuitry of the sterilizer.

With the foregoing process, it has been discovered that the time to achieve complete sterilization can be reduced to at least one-third of the time required utilizing a gravity discharge system.

This system has been tested over ranges of pulsing steam pressure as low as 20 p.s.i.g. to as high as 80 p.s.i.g. The number of pulses has been varied from one to twenty-seven; the loads have been varied from one dense test pack to twenty dense test packs and other packs of various kinds; the jacket pressure has been varied from 18 to 34 p.s.i.g.; and the control points have been varied as to pressure, time, temperature, and the speed of exhaust of

the chamber in various sizes of machines. It is clear that the cycle would function satisfactorily over even broader ranges of variations than those tested.

The foregoing detailed description has been given for clearance of understanding only and no unnecessary limitations should be understood therefrom.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A method of sterilizing comprising the steps of:

- (1) providing a chamber,
- (2) placing a load of materials to be sterilized in said chamber,
- (3) introducing steam into said chamber to raise the pressure in said chamber to a predetermined pressure not less than 20 p.s.i.g., said steam raising the temperature of said chamber at a faster rate than the temperature of said load,
- (4) terminating the introduction of steam while substantially simultaneously venting the steam with commingled air from the chamber to atmospheric pressure solely by means of said chamber pressure for a predetermined time to decrease said chamber pressure to a lower positive pressure,
- (5) terminating said venting step while substantially simultaneously repeating step (3), steps (4) and (5) constituting a pulse,
- (6) repeating said pulse a predetermined number of times until the load temperature throughout substantially reaches a predetermined steam sterilizing temperature,
- (7) and then introducing steam at substantially said predetermined steam sterilizing temperature not less than 230° F. to raise the pressure in said chamber to said predetermined pressure for sterilization.

2. The method of sterilizing as claimed in claim 1, wherein said pulse is repeated approximately nine and one-half times.

3. The method of sterilizing as claimed in claim 1, wherein the steam introduced into the chamber in step (3) is introduced at a steam supply pressure of at least

twenty-five p.s.i.g., said predetermined pressure is approximately twenty-four p.s.i.g., said lower positive pressure is at least twenty-two p.s.i.g., and said pulse is repeated at least seven times.

4. The method of sterilizing as claimed in claim 3, wherein said predetermined steam sterilizing temperature is between approximately 230° F. and 280° F.

5. The method of sterilizing as claimed in claim 1, wherein the steam introduced into the chamber in step (3) is introduced at a steam supply pressure of approximately sixty p.s.i.g.

6. The method of sterilizing as claimed in claim 5, wherein said predetermined pressure is twenty-four p.s.i.g. and said steam is introduced in step (7) at approximately sixty p.s.i.g.

7. The method of sterilizing as claimed in claim 5, wherein said predetermined steam sterilizing temperature is 270° F.

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