

Reivindicaciones 1 a 10: Un método, para la esterilización de un artículo, que comprende: colocar un vaporizador en comunicación fluida con una cámara de esterilización, a través de una restricción de difusión, que está a una presión más baja que la del vaporizador; vaporizar una solución esterilizante, que comprende un esterilizante y un solvente, en el vaporizador; comparar la presión en la cámara de esterilización con una presión predeterminada, después de vaporizar el esterilizante sustancialmente de manera completa, y, si está por encima de la presión predeterminada, aislar la cámara de esterilización del vaporizador y disminuir la presión en la cámara de esterilización hasta una presión por debajo de la predeterminada; colocar, entonces, el vaporizador en comunicación fluida abierta con la cámara de esterilización; difundir el esterilizante vaporizado en la cámara de esterilización; y, poner en contacto el artículo con éste.

Reivindicaciones 11 a 15: Un método, para la esterilización de un artículo, que comprende: proveer una solución esterilizante, que comprende, a su vez, un esterilizante y un solvente; vaporizarla en un vaporizador, colocar el vaporizador en comunicación fluida con una cámara de esterilización a través de una restricción de difusión; donde la cámara está a una presión más baja que la del vaporizador; incrementar la relación de esterilizante a solvente en el vaporizador, preferentemente a través de la extracción de una fase vapor del solvente del vaporizador a través de la restricción de difusión y la expulsión de por lo menos una porción de este solvente de la cámara y después aislar el vaporizador de la cámara y disminuir la presión en la cámara de esterilización hasta una presión por debajo de la predeterminada, seleccionada para incrementar la difusión del esterilizante vaporizado en áreas de difusión restringida del artículo; colocar, después, el vaporizador en comunicación fluida abierta con la cámara de esterilización; difundir el esterilizante vaporizado en la cámara de esterilización; y, poner en contacto el artículo con éste.

Reivindicaciones 16 a 18: Un sistema de esterilización, que comprende: una cámara de esterilización; una bomba de vacío conectada a la cámara; un vaporizador, conectado a la cámara, que tiene: un compartimento, una primera trayectoria de salida, desde el alojamiento en la cámara, que está restringida por una restricción de difusión y una primera válvula; una segunda trayectoria de salida desde el alojamiento en la cámara y una segunda válvula, con lo cual el compartimento se puede colocar en comunicación fluida con la cámara no impedida a través de la restricción de difusión; y, un controlador, para controlar un procedimiento de esterilización, que está programado para seguir el siguiente procedimiento: colocar el vaporizador en comunicación fluida con la cámara solamente a través de la restricción de difusión; vaporizar una solución esterilizante en el vaporizador y, cuando la vaporización se complete sustancialmente, cerrar la primera válvula y disminuir la presión dentro de la cámara.

El problema planteado en esta solicitud es satisfacer la necesidad de lograr una esterilización completa de ciertos artículos.

Para solucionar este problema técnico la solicitud en estudio proporciona un sistema y un método que emplea una restricción de difusión entre la bomba de vacío y la cámara de esterilización

- Clasificación Internacional de Patentes (IPC) asignada: A61L 2/20, 2/26

3. De la solicitud de Patente

3.1 Descripción (artículo 28 D. 486)

- Durante el análisis del texto de la descripción y de las ilustraciones anexadas, se observaron los siguientes defectos:
 - 1) En el título o nombre de la invención se menciona un *aparato de control de entrada* que no ha sido reclamado en el capítulo reivindicatorio, por lo que debe suprimirse tal alusión.
 - 2) En la página 1, folio 7, aparece por primera vez una expresión (*patente de E.U.A. n.º 6,365,102*) en la cual se hace mal uso de la coma. En Colombia debe emplearse la coma decimal.
 - 3) En la página 2, folio 8, aparece por primera vez una expresión relativa al *lumen*. Como, según el Diccionario de la Real Academia Española (DRAE), el significado de *lumen* (una unidad del Sistema Internacional) no concuerda con el contexto, el solicitante debe sustituir todas las expresiones en donde se encuentre este término o sus derivados.
 - 4) Las figuras 1 a 22, folios 52 a 75, contienen, todas, un encabezamiento con texto ajeno a la divulgación técnica, por lo que debe suprimirse.
 - 5) En la página 9, folio 15, aparece la expresión *0.5 torr* en la cual, en primer lugar, no se emplea la coma decimal; y, en segundo lugar, por primera vez, se emplea una unidad de presión no admitida por el Sistema Internacional. El solicitante debe hacer la conversión correspondiente.
 - 6) En la misma página 9 aparece por primera vez una expresión, en forma de sigla (HEPA), cuyo significado se desconoce. El solicitante debe dar el significado de cada sigla que utilice en la primera oportunidad en que aparezca.
 - 7) En la página 14, folio 20, el contenido del *Cuadro 1* es ininteligible.
 - 8) En la página 16, folio 22, aparece la expresión *una reducción de seis log* cuyo significado se desconoce.
 - 9) En la página 26, folio 32, aparecen las expresiones *0.0305 m/seg a 1.524 m/seg*, *0.0732 m/seg* en las cuales, en primer lugar, se omite el uso de la coma decimal; y, en segundo lugar se emplean unos símbolos de unidades que no son los admitidos por el Sistema Internacional. Las expresiones objetadas deben ser sustituidas por *0,0305 m/s a 1,524 m/s*, *0,0732 m/s*.
 - 10) En la misma página 26 aparece la expresión *0.058 metros cuadrados* que debe ser sustituida por *0,058 m²*.
 - 11) En la página 28, folio 34, aparece la expresión *Un anillo en O 282* en la cual, por una parte, el número de referencia 282 debería ir encerrado entre paréntesis para evitar confusiones; y, por otra parte, al observar lo que dicho número de referencia señala en la figura 13, folio 65, es un empaque más cuadrado que circular, por lo que la denominación *anillo en O* es engañosa.
 - 12) En la página 32, folio 38, se menciona dos veces el número de referencia 332 con relación a la figura 17, pero tal número no se encuentra en la figura 17, folio 70, ni en ninguna otra figura. Un defecto similar se encuentra en la página 33, folio 39.
 - 13) En la página 39, folio 45, aparece el *Cuadro 2* en el cual, en primer lugar, se encuentra una fila donde se encuentran los términos *Instantáneo | Corto | Largo* que no tienen correlación con alguna denominación genérica; en segundo lugar, en la segunda fila, aparecen otros términos que, también, carecen de correlación; en tercer lugar, se encuentran ciertos valores de presión en unidades que no son las del Sistema Internacional; en cuarto lugar, en la primera columna hay algunas palabras truncadas; y, en quinto lugar, se desconoce, en general, cuál es el sentido del cuadro.

14) En varias figuras se encuentran ciertos detalles que no están debidamente señalados con los números de referencia correspondientes. Es el caso de las figuras 1, 3, 3A, 4, 5, 7, 13, 20, 21 y 22; folios 52, 54, 55, 56, 57, 59, 65, 73, 74 y 75 respectivamente. Si no se va a decir nada sobre algún detalle en cierta figura, es preferible omitirlo.

- La descripción no cumple con los requisitos de claridad y divulgación completa, lo que dificulta o impide su comprensión y ejecución de acuerdo al art. 28 de la Decisión 486

3.2 Reivindicaciones (artículo 30 D 486)

- Durante el análisis del texto de las reivindicaciones se observaron los siguientes defectos:
 - 1) En la reivindicación 1, folio 47, aparece por primera vez en el capítulo reivindicatorio la expresión *un vaporizador en comunicación fluida con una cámara de esterilización a través de una restricción de difusión* (subrayado por el examinador), condición que no está soportada por la descripción. De hecho, en la figura 1, folio 52, se señala con el número de referencia 20 tal restricción, y, en la página 9, folio 15, se alude a ella como *una placa con orificio 20* y se dice, además, *Entre la bomba de vacío 16 y la cámara 12, (...) se localiza (...) y, opcionalmente, una placa con orificio 20*. También se menciona en la página 16, folio 22, y en la página 17, donde se aclara: *el orificio 36 en la placa 20*. En la figura 3, folio 54, se encuentra la *placa con orificio 20a* como se dice en la página 17, folio 23. En cualquier caso, esta restricción se encuentra siempre entre la bomba de vacío (16, 16a) y la cámara de esterilización (12, 12a) no entre el vaporizador y la cámara. Una expresión similar a la objetada se encuentra en las reivindicaciones 7, 11, 14 y 16 a 18, folios 48, 49, 50 y 51. Por tanto, las reivindicaciones mencionadas carecen de soporte por la descripción. Además, en la descripción se especifica esta característica como opcional, no como esencial para la invención.
 - 2) En las reivindicaciones 1 y 11, folios 47 y 49, respectivamente, se encuentra la expresión *y poner en contacto el artículo* como última etapa del método reclamado en estas reivindicaciones, pero no está claro con qué se pone en contacto el artículo.
- Las reivindicaciones no cumplen con los requisitos de definición, claridad, concisión o sustento por la descripción de acuerdo al art. 30 de la Decisión 486. Debe entenderse que las reivindicaciones dependientes de las reivindicaciones objetadas son, asimismo, objetadas, por razones análogas.

Se deben presentar, entonces, nuevos capítulos descriptivo y reivindicatorio, ambos completos, junto con un nuevo juego de dibujos, donde se hayan corregido todas las objeciones que se han hecho arriba. Esto con el fin de evitar -cuando solo se presentan algunas páginas sueltas corregidas- que el lector tenga que desplazarse desde un sitio a otro de la solicitud y luego regresar a donde estaba antes sin perder la ilación de la lectura, porque esto produce confusión y afecta negativamente la claridad de dichos capítulos.

4. Determinación del Estado de la Técnica

- La fecha que se ha tenido en cuenta para determinar el Estado de la Técnica es la

Fecha de presentación de la solicitud prioritaria 2004-10-12

- Se realizó la búsqueda en el estado de la técnica de documentos relacionados con la solicitud teniendo en cuenta la fecha indicada; y durante la búsqueda de anterioridades se encontraron los siguientes documentos, que forman parte de la familia de patentes de la presente solicitud: Publicación US 2006/0078459 A1 del 06-04-13; Patente US 7 252 800 del 07-08-07; publicación EP 1 647 285 A1 del 06-04-19. Se anexa la copia de las primeras páginas de estos documentos junto con la copia del Informe de Búsqueda Europeo y la copia del capítulo reivindicatorio admitido por la USPTO. También se encontraron los siguientes documentos que forman parte del estado de la técnica más cercano al objeto de la solicitud:

n.º	Documento	Título	Fecha de publicación
D1	Patente US 6 238 205 B1, cuyo inventor es Joel Svedlund, quien le cedió sus derechos a la Optimus International AB	«Burner assembly»(Un montaje de quemador)	2001-05-29
D2 (*)	Patente US 6 325 972 B1, cuyos inventores son Paul Jacobs, Suz-Min Lin y Jenn-Hann Wang, quienes le cedieron sus derechos a la Ethicon, Inc.	«Apparatus and process for concentrating a liquid sterilant and sterilizing articles therewith»(Un aparato y un procedimiento para concentrar un esterilizante líquido y para esterilizar artículos con él)	2001-12-04
D3 (**)	Publicación US 2003/0235511 A1, cuyos inventores son Paul T. Jacobs, Szu-Min Lin, Jenn-Hann Wang, James P. Kohler, Richard Jed Kendall y Anahid Gamsarian	«Sterilization system and method and inlet control apparatus therefor»(Un método y un sistema de esterilización y un aparato para el control de entrada para los mismos)	2003-12-25

(*) Documento citado por el solicitante, ver página 1, folio 7.

(**) Documento citado por el solicitante, ver página 2, folio 8.

Se anexa la copia de las páginas pertinentes de estos documentos

NOTAS: No se realizaron las evaluaciones de los demás requisitos de patentabilidad, porque se hicieron algunas objeciones respecto a la definición, la claridad, la concisión y el sustento por la descripción de las reivindicaciones.

A pesar de lo anterior, con base en el Informe de Búsqueda Europeo y en las enseñanzas de los documentos encontrados hasta ahora, se prevén objeciones respecto a la novedad, o respecto al nivel inventivo del objeto de la solicitud, porque no habría un efecto sorprendente o inesperado en lo que se divulga en la solicitud.



(12) **United States Patent**
Jacobs et al.

(10) **Patent No.: US 7,252,800 B2**
(45) **Date of Patent: *Aug. 7, 2007**

(54) **STERILIZATION SYSTEM AND METHOD
AND INLET CONTROL APPARATUS
THEREFOR**

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Gamsarian, Fullerton, CA (US)

(73) **Assignee:** Ethicon, Inc., Somerville, NJ (US)

(*) **Notice:** Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 630 days.

This patent is subject to a terminal dis-
claimer.

(21) **Appl. No.:** 10/403,140

(22) **Filed:** Mar. 31, 2003

(65) **Prior Publication Data**
US 2003/0235511 A1 Dec. 25, 2003

Related U.S. Application Data
(63) Continuation-in-part of application No. 09/975,714,
filed on Oct. 11, 2001, now abandoned, which is a
continuation of application No. 09/223,479, filed on
Dec. 30, 1998, now Pat. No. 6,325,972, which is a
continuation-in-part of application No. 10/186,019,
filed on Jun. 28, 2002, now Pat. No. 6,852,279.

(51) **Int. Cl.**
A61L 2/20 (2006.01)

(52) **U.S. Cl.** 422/33; 422/292; 422/305

(58) **Field of Classification Search** 422/33,
422/292, 305, 27
See application file for complete search history.

(56) **References Cited**

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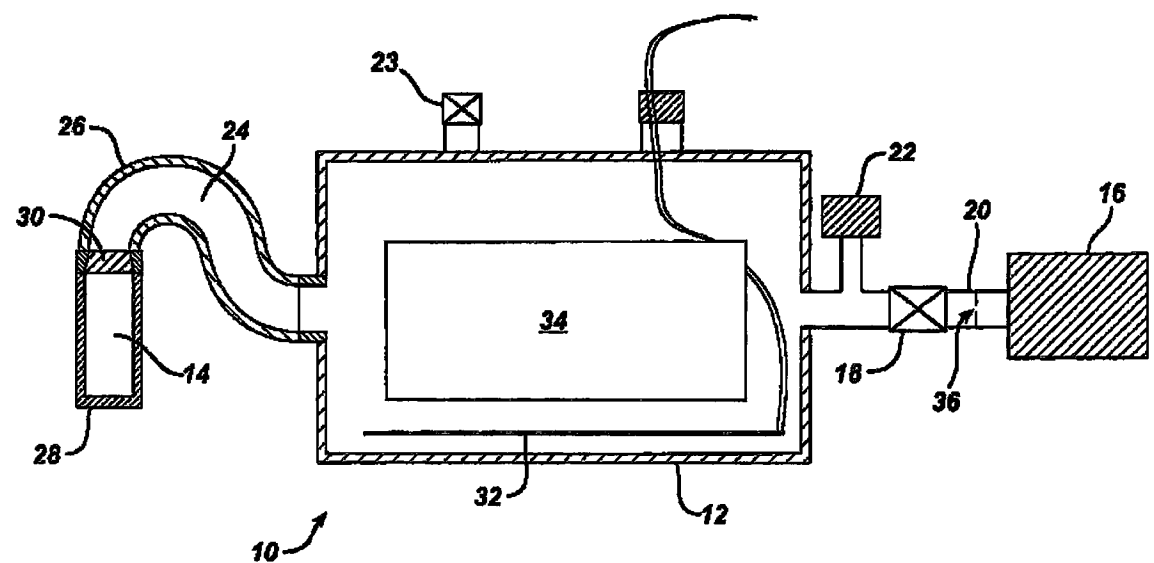
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Primary Examiner—E. Leigh McKane

(57) **ABSTRACT**

A chemical vapor sterilization process is enhanced by con-
centrating a germicide via exploitation of the difference
between the vapor pressures of the germicide and its solvent.
A diffusion restriction can be placed into the diffusion path
to assist this process and the path then opened to provide
rapid diffusion of the thus concentrated germicide.

14 Claims, 21 Drawing Sheets



What is claimed is:

1. A sterilization system comprising:

a sterilization chamber;

a vacuum pump connected to the sterilization chamber; and

a vaporizer connected to the sterilization chamber, the vaporizer comprising:

an enclosure;

a first outlet path from the enclosure into the chamber, the first outlet path being restricted by a diffusion restriction; and

a second outlet path from the enclosure into the chamber and a valve in the second outlet path, whereby the enclosure can be placed into fluid communication with the sterilization chamber unimpeded by the diffusion restriction; and

wherein the diffusion restriction has the equivalent diffusion restriction of an orifice of between 1 mm to 3 mm in diameter.

2. A sterilization system according to claim 1 wherein the first outlet path and second outlet path are separate from each other.

3. A sterilization system according to claim 1 wherein the valve is a plug valve.

4. A sterilization system according to claim 1 wherein the diffusion restriction comprises an orifice plate having an orifice therethrough.

5. A sterilization system according to claim 1 wherein the orifice is about 2 mm in diameter.

6. A sterilization system comprising:

a sterilization chamber;

a vacuum pump connected to the sterilization chamber; and

a vaporizer connected to the sterilization chamber, the vaporizer comprising:

an enclosure;

a first outlet path from the enclosure into the chamber, the first outlet path being restricted by a diffusion restriction; and

a second outlet path from the enclosure into the chamber and a valve in the second outlet path, whereby the enclosure can be placed into fluid communication with the sterilization chamber unimpeded by the diffusion restriction; and

a third outlet path from the enclosure into the sterilization chamber, the third outlet path being obstructed by a pressure relief mechanism wherein the pressure relief mechanism comprises a rupture disc.

7. A sterilization system comprising:

a sterilization chamber;

a vacuum pump connected to the sterilization chamber; and

a vaporizer connected to the sterilization chamber, the vaporizer comprising:

an enclosure;

a first outlet path from the enclosure into the chamber, the first outlet path being restricted by a diffusion restriction; and

a second outlet path from the enclosure into the chamber and a valve in the second outlet path, whereby the enclosure can be placed into fluid communication with the sterilization chamber unimpeded by the diffusion restriction; and

a temperature controllable condensing surface in the first outlet path upstream of the diffusion restriction.

8. A method of sterilizing an article comprising the steps of:

providing a sterilant solution which comprises a sterilant and a solvent;

vaporizing the sterilant solution in a vaporizer;

placing the vaporizer into fluid communication with a sterilization chamber through a diffusion restriction, the sterilization chamber being at a lower pressure than the vaporizer;

increasing the ratio of sterilant to solvent in the vaporizer by preferentially drawing a vapor phase of the solvent out of the vaporizer through the diffusion restriction and exhausting at least a portion of this solvent out of the sterilization chamber;

placing the vaporizer into open fluid communication with the sterilization chamber and diffusing vaporized sterilant into the sterilization chamber and into contact the article.

9. A method according to claim 8 wherein the sterilant is hydrogen peroxide and the solvent is water.

10. A method according to claim 8 wherein the step of placing the vaporizer into open fluid communication with the sterilization chamber comprises opening a valve between the vaporizer and the sterilization chamber.

11. A method according to claim 8 wherein the step of placing the vaporizer into fluid communication with the sterilization chamber through a diffusion restriction comprises interposing an orifice between the vaporizer and the sterilization chamber.

12. A method according to claim 8 and further comprising placing a pressure relief mechanism between the vaporizer and the sterilization chamber.

13. A method according to claim 12 wherein the pressure relief mechanism comprises a rupture disc.

14. A method according to claim 8 and further comprising the step of condensing at least a portion of the sterilant upstream of the diffusion restriction.

* * * * *

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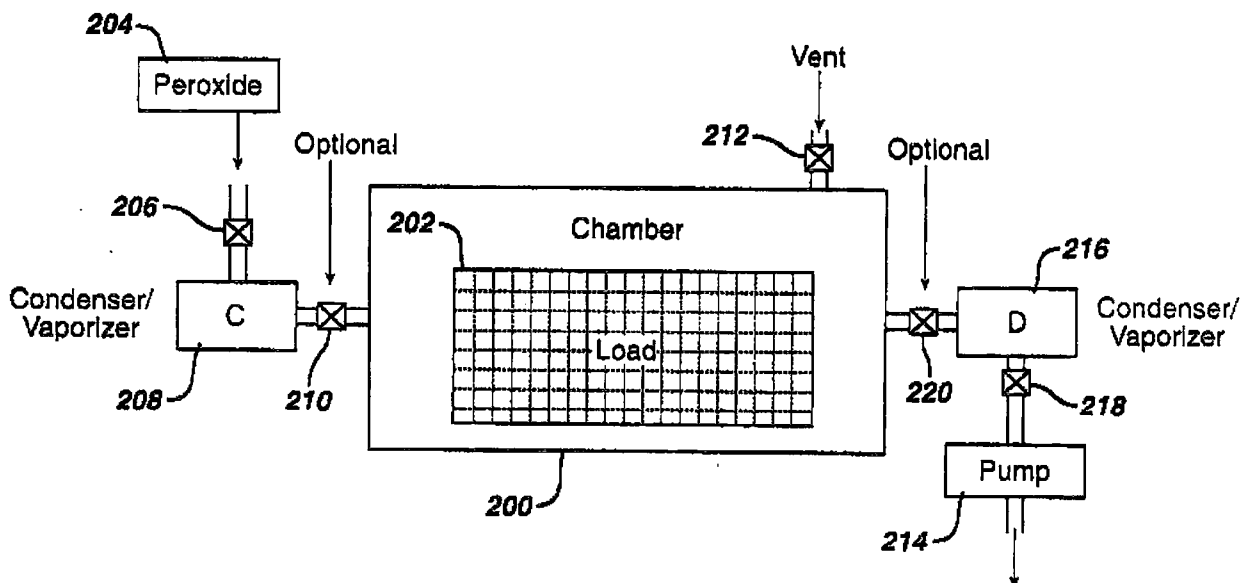
(84) Designated Contracting States: AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI SK TR Designated Extension States: AL BA HR MK YU	(72) Inventors: - Kohler, James P. Laguna Hills, CA 92653 (US) - Lin, Szu-Min Irvine, CA 92620 (US) - Kendall, Richard Jed San Clemente, CA 92672 (US)
(30) Priority: 12.10.2004 US 962962	(74) Representative: Fisher, Adrian John et al CARPMAELS & RANSFORD 43-45 Bloomsbury Square London WC1A 2RA (GB)
(71) Applicant: ETHICON, INC. Somerville, New Jersey 08876 (US)	

(54) Sterilization system and method

(57) A chemical vapor sterilization process is enhanced by concentrating a germicide via exploitation of the difference between the vapor pressures of the germicide and its solvent. A diffusion restriction can be placed into the diffusion path to assist this process and

the path then opened to provide rapid diffusion of the thus concentrated germicide. The path through the diffusion restriction can be closed to allow the pressure in a sterilization chamber to be lowered prior to receiving the concentrated germicide.

FIG. 9



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soaking, flow through, aerosol spray, condensation of a vapor. Any other methods involving physically contacting the articles to be sterilized with sterilant would be considered direct contacting. Indirect contacting includes those methods in which sterilant is introduced into the chamber, but not directly on or in the articles to be sterilized.

At the end of the process, deep vacuum can be used to remove residual sterilant. A plasma can also be used to both enhance sterilization efficacy and to remove residual sterilant.

The pumps shown schematically in the figures can be any commercially available pump. Two preferred pumps are from Leybold Vacuum Products, Inc. (Export, Pa.) (Model D16A, pump rate =400 liters/min) and KNF Neuberger, Inc. (Trenton, N.J., Model N740, pump rate =45 liters/min). The Leybold pump can reach a pressure of less than 0.1 torr and the KNF pump can reach a pressure of less than 10 torr.

For certain substrates being sterilized, such as nylon or polyurethane, excess hydrogen peroxide in the system may leave a residual which is difficult to remove. In order to avoid an excess residual, the vapor concentration of hydrogen peroxide is preferably kept below 30 ml/l, more preferably less than 20 mg/l, and more preferably still less than 15 mg/l. If higher vapor concentrations of hydrogen peroxide are desired, excess residual can be removed using a gas plasma. When using substrates such as stainless steel, polyethylene or polypropylene, which do not retain a residual, there is no reason to limit to the amount of peroxide which can be present in the vapor phase in the system during sterilization.

To further reduce water within the system, the chamber 2 may be dried prior to the introduction of hydrogen peroxide. Many means may be employed to drive water out of the chamber. Primarily, this is accomplished by vaporizing the water and pumping it out of the chamber. The vaporization can be accomplished with heat, plasma induction, vacuum or the like either alone or in combination. Merely drawing a vacuum prior to introducing the hydrogen peroxide accomplishes a beneficial drying of the chamber 2. If the chamber 2 is heated during this process and if a high energy electromagnetic field is applied to urge the water into the plasma stage the drying is enhanced. U.S. Pat. No. 5,656,238 issued on Aug. 12, 1997 to Spencer et al. and incorporated herein by reference teaches such techniques in more detail.

Vaporization of the hydrogen peroxide can be achieved using well known methods as described above; FIGS. 6 to 8 show several new preferred methods. In FIG. 6, a chamber 30 is evacuated by a pump 32 separated from the chamber 30 by a throttle valve 34. A vaporizer 36 comprises a housing

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preferably in a controlled fashion from the cup 42 by controlling the temperature of the cup 42 and the pressure in the chamber 30. Temperature control of the cup 42 can be as simple as thermally isolating it from the chamber 30, or a more active control system can be employed such a cooling coil or the like to maintain the cup 42 at a desired low temperature. Preferably, the entire vaporizer 36 is thermally isolated from the chamber 30 or temperature controlled in some fashion. Lower temperatures of vaporization enhance the preferential vaporization of water by exploiting the larger difference between the vapor pressures of water and hydrogen peroxide at lower temperatures. Creating a diffusion restriction 44 between the vaporizer 36 and chamber 30 enhances the preferential extraction of water vapor from the chamber as water vapor will more easily traverse the diffusion restriction and be pumped out of the chamber during the vaporization process. The diffusion restriction 44 may be simply reducing the clearance between the cup 42 and housing 38 through with the vapor must travel to reach the chamber 30.

FIG. 7 shows a similar chamber 50, pump 52 and valve 54 with modified vaporizer 56. The vaporizer 56 comprises a chamber 58 separated from the chamber 50 by a diffusion restriction 60, such as a permeable membrane. Liquid hydrogen peroxide solution enters the chamber 58 through a valve 62. FIG. 8 illustrates a similar arrangement with a chamber 70, pump 72, valve 74, and vaporizer 76 with a chamber 78 and valved hydrogen peroxide solution inlet 80. Restriction of the diffusion between the vaporizer chamber 78 and main chamber 70 is variable. During initial vaporization when primarily water is vaporizing the vapors pass through a tight diffusion restriction 82. After the concentration of the hydrogen peroxide solution reaches a given level a valve 84 may be opened to speed the vaporization and diffusion of the concentrated hydrogen peroxide solution.

Preferably, the temperature in the chamber is no less than 5° C. nor more than 150° C. with the range of 50 to 65° C. being preferred, and the pressure should be no less than 0.01 torr, nor typically greater than atmosphere during the process, with the lowest vacuum being typically 0.4 torr and the diffusion pressure preferably being between 2 and 10 torr, although other conditions within the spirit of the invention will be apparent to those of skill in the art. During the concentration stage, the pressure should not fall below 0.5 torr. Shorter overall cycles are preferred for convenience, with 5 minutes being a desirable goal, but longer times upwards of 6 hours or more may be warranted in some circumstances.

TABLE 1-continued

Test conditions					
Normal process		New process			
Step	Test A	Test B	Test C	Test D	Test E
3	Close valve	Vaporization & diffusion	Inject H ₂ O ₂ at 30 torr	Inject H ₂ O ₂ at 0.3 torr	Close valve
4	Inject H ₂ O ₂ at 0.3 torr	Vacuum to about 2 torr	Vaporization & diffusion	Vaporization & diffusion	Inject H ₂ O ₂ at 0.3 torr
5	Vaporization & diffusion	Close valve	Vacuum to about 2 torr	Vacuum to about 2 torr	Vaporization & diffusion
6	Vent to 1 atm	Vaporization & diffusion	Close valve	Close valve	Open valve
7		Vent to 1 atm	Vaporization & diffusion	Vaporization & diffusion	Vacuum to about 2 torr
8			Vent to 1 atm	Vent to 1 atm	Close valve
9					Vaporization & diffusion Vent to 1 atm

TABLE 2

Sterility test results (positives/samples)					
Normal process		New process			
Lumen size	Test A	Test B	Test C	Test D	Test E
1 × 400 mm	2/2	0/2	0/2	0/2	0/2
1 × 350 mm	2/2	0/2	0/2	0/2	0/2
1 × 300 mm	2/2	0/2	0/2	0/2	0/2
1 × 250 mm	2/2	0/2	0/2	0/2	0/2

Monitoring of the temperature, pressure and hydrogen peroxide conditions within the chamber 30 (FIG. 6) allows the process to be controlled more precisely. Preferably, an automated control system, preferably employing a computer processor, receives inputs of the temperature, pressure and perhaps also the hydrogen peroxide concentration and calculates the optimal pressure at which to maintain the chamber to remove the water from the hydrogen peroxide solution and from the chamber 30. It can also determine when the solution is sufficiently concentrated. For instance, it may be desired to only concentrate the solution to a certain degree so as to minimize the loss of hydrogen peroxide from the chamber, thereby minimizing hydrogen peroxide emissions from the chamber. While preferentially vaporizing the water from the solution, some hydrogen peroxide will also vaporize. Accordingly, one may wish to balance the efficient use of the quantity of hydrogen peroxide within the solution against the goal of eliminating all water from the solution and the chamber. By monitoring the ratio of water and peroxide the vapor phase, the valve 34 can be controlled to remove the vapor until the desired ratio is achieved. The ratio can be determined using a hydrogen peroxide monitor and a moisture monitor, or by using a hydrogen peroxide monitor and a pressure sensor and then calculating the water using the PVRT equation and making the assumption that water and peroxide are essentially the only gases within the chamber 34.

It is known that certain spectra of light passing through the chamber can be measured to determine the hydrogen peroxide concentration. One particular method is disclosed in co-pending U.S. application Ser. No. 08/970,925 filed Nov. 14, 1997, incorporated herein by reference.

Table 3 illustrates the effects of the ratio of hydrogen peroxide vapor to water vapor in the chamber 30 on the ability to sterilize long narrow lumens or other diffusion restricted environments. Water vapor was first introduced into the system and then essentially pure hydrogen peroxide vapor was introduced by liberation from a solid form. The lower concentrations of water show no failures, whereas with the higher ratio in the last column the efficacy decreased and in one test 3 out of 3 samples failed. Table 4 shows similar results by comparing a sterilization process in which the concentration of hydrogen peroxide is not increased according to the present invention with a process in which it is increased. Table 5 shows the degree of concentration achieved according to the present invention. By monitoring the concentration (i.e. the ratio of hydrogen peroxide to water) during the sterilization cycle it should be possible to achieve the long sought goal of parametric release. One could be assured that if the proper concentration was maintained for a sufficient period of time that a particular load of instruments placed within the chamber 30 and sterilized according to the present invention then the process would be sufficiently predictable so as to allow the load to be released for use without further checking with a biological indicator. Typically, such processes always employ a biological indicator in the load, such as with a test load of microorganisms, which is then checked to ensure that sufficient sterilization has been achieved to kill all of the test microorganisms. With parametric release the time consuming process of biological indicators can be skipped.

TABLE 3

(A) Effect of water to peroxide ratio on efficacy Efficacy with <i>Bacillus subtilis</i> var. <i>niger</i> on SS blade in 3 mm × 500 mm SS LTU in 173L chamber				
Sterility results (positives/samples)				
Diffusion time (minutes)	0.653 mg/L H ₂ O 6 mg/L H ₂ O ₂	3.266 mg/L H ₂ O 6 mg/L H ₂ O ₂	6.532 mg/L H ₂ O 6 mg/L H ₂ O ₂	
5	0/3	0/3	3/3	
10	0/3	0/3	2/3	
15	0/3	0/3	0/3	
30	0/3	0/3	0/3	

TABLE 5

(A) Concentrating the 59% peroxide solution			
	Ratio of peroxide to water		
	Before concentrating	Right after concentrating	After all peroxide vaporized
Solution in vaporizer	1.4:1	19:1	none
Vapor in chamber	<1.4:1	0.85:1	4.9:1

TABLE 4

(A) Effect of water to peroxide ratio on efficacy			
Lumen Dimension (Diameter) × (length)	Sterility results (positives/samples)		
	Without concentrating process 8.43 mg/L H ₂ O 12 mg/L H ₂ O ₂	With concentrating process 1.49 mg/L H ₂ O 7.3 mg/L H ₂ O ₂	
1 × 400 mm	2/2	0/2	
1 × 350 mm	2/2	0/2	
1 × 300 mm	2/2	0/2	
1 × 250 mm	2/2	0/2	

The process may be further enhanced by admitting sufficient hydrogen peroxide into the system so as to force some of the vaporized solution to condense upon the instruments being sterilized within the system. As described above, the solution can be vaporized by admitting it into the system at any pressure above the vapor pressures of water and hydrogen peroxide in the solution and then vaporized by reducing the pressure, or by admitting the solution at a pressure substantially below these vapor pressures whereupon it will start to vaporize thus releasing gas and increasing the pressure. In the second scenario if the pressure is then further reduced by pumping the concentration of the hydrogen peroxide in the system can be increased. This is especially true if the pressure rises to a level at least above the vapor pressure of hydrogen peroxide thereby limiting further vaporization of hydrogen peroxide from solution and perhaps encouraging some of the hydrogen peroxide to condense upon objects such as instruments within the system. Some of the water vapor would likely also condense in such event. By controlling the pressure excess water vapor would be exhausted from the system and then the condensed solution would re-vaporize. To the extent that such solution had condensed within diffusion restricted areas the re-vaporization therein would further increase the concentration in the those areas to enhance the sterilization efficacy therein. The quantity of solution admitted will primarily determine the pressure rise to initiate such condensation. The process is described in more detail in our co-pending application entitled "Sterilization of Diffusion-Restricted Area by Re-Vaporizing the Condensed Vapor" filed contemporaneously herewith.

A typical cycle might comprise placing a load of instruments (not shown) within a CSR wrapped tray within the chamber 30 and then drawing a vacuum on the chamber 30 with the pump 32 down to below 1 torr or about 0.4 torr. An electromagnetic field applied to the chamber 30 at such time tends to drive any remaining water into the vapor or plasma stage so that it can be removed by the pump 32. The pump 32 can be cycled or merely run continuously with the valve 34 controlling the vacuum process. Fresh dry air may be

admitted to the chamber 30 including raising of the pressure back to atmosphere. Preferably the hydrogen peroxide solution, preferably a 59% hydrogen peroxide solution, is admitted to the vaporizer 36 at atmospheric pressure and then the pump 32 exhausts the chamber 30 to a level at which the solution begins to vaporize. A monitor 100 for hydrogen peroxide vapor and monitor 102 (see FIG. 6) for water vapor in connection with an automated control system 104 can be employed to optimize the pressure conditions to enhance the initial vaporization and exhaust of water vapor. After the solution is sufficiently concentrated the pressure in the chamber 30 can be further lowered to vaporize the remaining solution. The valve 32 is closed to isolate the chamber 30 and the vaporized hydrogen peroxide solution is allowed to diffuse throughout the chamber to contact the instruments. Additional dry air or other gas can be admitted at this time to help push the sterilizing vapors into diffusion restricted areas, with the chamber 30 then further exhausted to resume a vacuum in the range of 2 to 10 torr. Additional admissions of air and vacuum can be employed, especially in connection with additional admission and concentration of hydrogen peroxide solutions. After the hydrogen peroxide vapors have diffused throughout the chamber for a sufficient time an electromagnetic field may be applied to drive the vapor into the plasma stage and effect further sterilization. When the field is removed the ions formed from the hydrogen peroxide recombine as water and oxygen, leaving little residual hydrogen peroxide. The chamber can be raised to atmospheric pressure and the load removed.

It should be noted that the present invention is not limited to only those embodiments described in the Detailed Description. Any embodiment which retains the spirit of the present invention should be considered to be within its scope. However, the invention is only limited by the scope of the following claims.

What is claimed is:

1. A method of furnishing concentrated hydrogen peroxide vapor to an article comprising the steps of:
 - placing the article into a chamber containing an inner atmosphere;
 - placing a solution comprising hydrogen peroxide and water into fluid communication with the chamber, said solution having a ratio of hydrogen peroxide to water;
 - vaporizing the solution in the inner atmosphere to form water vapor and hydrogen peroxide vapor;
 - selectively drawing water vapor from the chamber to increase a ratio of hydrogen peroxide to water in the chamber;
 - contacting the article with the hydrogen peroxide vapor; and
 - wherein the step of contacting the article with the hydrogen peroxide vapor is limited to less than one hour and achieves a level of sterilization such that in a straight round lumen having two open ends, a diameter of 1 mm and a length of 250 mm with 10⁶ viable spores of *B. Stearothermophilus* located within the lumen at a midpoint thereof, all of the spores would be killed.
2. A method according to claim 1 wherein the ratio of hydrogen peroxide vapor to water vapor after the step of selectively drawing water vapor from the chamber exceeds the ratio of hydrogen peroxide to water in said solution.
3. A method according to claim 1 wherein the ratio of hydrogen peroxide to water, by weight, after the step of selectively drawing water vapor from the chamber exceeds 3 to 1.

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(54) **STERILIZATION SYSTEM AND METHOD
AND INLET CONTROL APPARATUS
THEREFOR**

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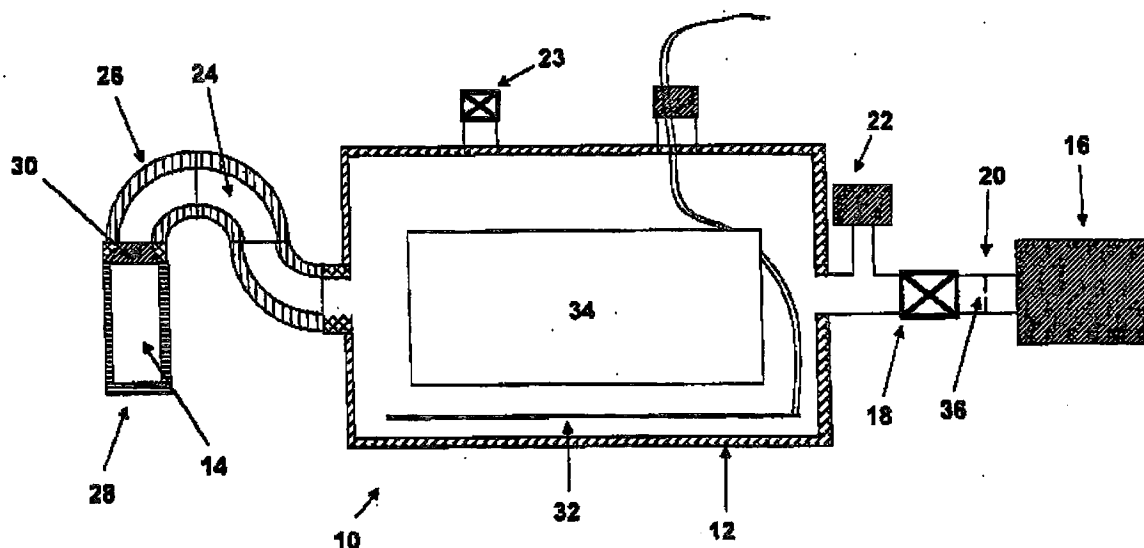
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(57) **ABSTRACT**

A chemical vapor sterilization process is enhanced by con-
centrating a germicide via exploitation of the difference
between the vapor pressures of the germicide and its solvent.
A diffusion restriction can be placed into the diffusion path
to assist this process and the path then opened to provide
rapid diffusion of the thus concentrated germicide.



tive medical devices and test lumens in a 20-liter aluminum chamber (4.4"x12"x22"). A one-inch stainless steel wire inoculated with at least 1x10⁶ *Bacillus stearothermophilus* spores was placed in the center of each of the test lumens. The effects with and without temperature control of the diffusion path were investigated with both a TEFLON, poly(tetrafluoroethylene)lumen having an internal diameter of 1 mm and a length of 700 mm, and a stainless steel lumen having an internal diameter of 1 mm, and a length of 500 mm. All lumens were open at both ends. Each of the samples were subjected to a sterilization cycle in a 20 liter vacuum chamber, which was held at 40° C. and 3 torr for 5 minutes. 1.44 ml of a 59% solution of hydrogen peroxide in water was injected at atmospheric pressure into the vaporizer which was held at 60° C. The 5 minute clock then started and the chamber was pumped down to 3 torr, which took less than one minute. In one case the diffusion path 24 had an initial temperature of 30° C. for the first minute while the chamber was evacuated to 3 torr and was then heated to 50° C. to release the condensed peroxide from the diffusion path into the chamber for the remainder of the cycle while pressure was maintained at 3 torr. In the other case, the diffusion path was held at 50° C. throughout the cycle. By maintaining the diffusion path at 50° C., no or little peroxide was retained in the diffusion path. Sterilization effectiveness was measured by incubating the test samples in growth media at 55° C. and checking for growth of the test organism. Table 1 shows the results of these tests.

TABLE 1

Lumen Type	ID & Length	50° C. Diffusion Path Throughout Process	30° C. Diffusion Path For One Minute Then increased to 50° C.
Teflon	1 x 700	2/2	0/3
Stainless Steel	1 x 500	1/2	0/3

[0045] When the diffusion path temperature was maintained at high temperature throughout the process, all of the samples in the TEFLON lumen tested positive for bacteria growth, indicating failure of sterilization, and one of two samples in the stainless steel lumen tested positive. Under the same conditions, but with an initially lower temperature diffusion path which was heated starting one minute after the diffusion began, none of the samples tested positive. Condensing the peroxide in the diffusion path during the initial vaporization stage and then re-vaporizing the condensed peroxide from the diffusion path into the chamber greatly enhance the efficacy.

[0046] Additional efficiencies can be achieved by alternating cool and warm regions in the diffusion path 24 as primarily illustrated in FIG. 2. The temperature control elements 26, in simple form heating elements, are spaced apart from one another. Also, preferably, the diffusion path 24 is vertical in this respect. As the hydrogen peroxide solution vaporizes and passes through the diffusion path 24, it is thought that it may alternately condense and re-vaporize as it passes over the heated and unheated sections of the diffusion path 24. The diffusion path could alternatively comprise alternating heating and cooling elements.

[0047] The heater 32 within the chamber 12 acts similarly to the heating of the diffusion path 24. By controlling the heater 32 temperature, the peroxide can be first condensed on the heater 32 and then re-vaporized into the chamber 12 to concentrate the peroxide.

[0048] A preferred cycle would be a modification of a cycle described in the Wu et al. U.S. Pat. No. 6,365,102, incorporated herein by reference. A series of pre-plasma energy additions with venting in-between dries moisture from the chamber 12. A vacuum is then drawn upon the chamber 12 and the hydrogen peroxide solution injected into the vaporizer 14. Alternatively, the peroxide solution can also be injected at atmospheric pressure. Some of the vaporizing solution condenses upon the cool diffusion path 24. After a time sufficient for most or all of the hydrogen peroxide solution to vaporize from the vaporizer 14, the diffusion path 24 is warmed by the temperature control elements 26 and the condensed hydrogen peroxide solution re-vaporizes. At about this time, the throttle valve 18 is closed and the pump 16 turned off to seal the chamber 12. Much of the water fraction of the hydrogen peroxide solution has thus been drawn out of the chamber 12 by the vacuum pump 16 and the remaining hydrogen peroxide solution which re-vaporizes from the diffusion path 24, or from the heater 32 in the chamber 12 if present, is of a higher hydrogen peroxide concentration than the starting solution. Preferably, a computer based control system (not shown) controls the functions of the process for ease and repeatability.

[0049] The hydrogen peroxide vapor thus produced contacts an article 34 or articles 34 in the chamber 12 and effects sterilization thereof. If those articles 34 have diffusion restricted areas, such as long, narrow lumens, it may be preferable to then vent the chamber 12 and allow clean sterile air therein to drive the hydrogen peroxide vapor deeper into the diffusion restricted areas. Then the chamber 12 is again subjected to vacuum and an additional injection of hydrogen peroxide, preferably with the heating sequence on the diffusion path, is repeated. After a time period sufficient to effect sterilization of the article 34, preferably with a six-log reduction in challenge organisms such as *Bacillus stearothermophilus*, a plasma is lit within the chamber 12, thereby enhancing the sterilization and breaking down the hydrogen peroxide into water and oxygen.

[0050] The orifice plate 20 can enhance the effect of concentrating the hydrogen peroxide during its vaporization. As described in the Lin et al. U.S. Pat. No. 5,851,485, incorporated herein by reference, a controlled or slow pump-down of the chamber 12 initially draws off more water than hydrogen peroxide from solution as the water has a higher vapor pressure, thereby leaving a higher concentration hydrogen peroxide behind. Controlling the pump-down can be difficult as vacuum pumps generally do not throttle back well and throttle valves in such service are difficult to control and expensive. By placing the orifice plate 20 in the flow path to the pump 16, the amount of atmosphere from the chamber 12 exhausted by the pump 16 is limited, and by selecting a proper size orifice 36 in the plate 20 can be controlled to a rate which effectively concentrates hydrogen peroxide in the chamber 12.

[0051] Turning also to FIG. 3, a system 10a, similar in most respects to the system 10 of FIGS. 1 and 2, with like

part numbers denoted with an "a" appended thereto, also incorporates an orifice plate 20a. However, to allow a quick pump-down of the chamber 12a, yet retain the controlled pump-down benefits of the orifice plate 20a, it incorporates two path ways from the pump 16a to the chamber 12a. A first pathway 40 contains a throttle valve 42 and a second pathway 44 contains a throttle valve 46 and the orifice plate 20a. Thus, during initial pump-down the first throttle valve 42 is open leaving the pump 16a freely connected to the chamber 12a. As the chamber 12a approaches the vapor pressure of water, the first throttle valve 42 is closed thereby forcing the pump 16a to evacuate through the orifice plate 20a and thus draw out of the chamber 12a at a slower, controlled rate more conducive to preferentially drawing water out of the hydrogen peroxide solution and out of the chamber 12a.

[0052] Turning also to FIGS. 3A and 3B, a system 110 similar to that of FIG. 1 is shown. Here, rather than use two paths as in the system 10a of FIG. 3, a valve 112 comprises a valve body 114, a valve seat 116 and a valve element 118, such as a butterfly disc, plug or the like. An orifice 120 is provided through the valve element. Thus, when the valve 112 is open evacuation can occur quickly, and when the valve 112 is closed it can occur more slowly. Such a valve could also be employed between the vaporizer 14 and the chamber 12 to further control the preferential vaporization and removal of the water from the germicide solution.

[0053] Turning now to FIG. 4, while highly concentration of the sterilizing vapor is helpful in achieving sterilization efficiency and efficacy, getting the vapor into contact with the items to be sterilized is also a concern. Typically, the low pressures (0.5 torr to 10.0 torr) inside of a chamber 12 promotes quick diffusion of the sterilant vapor to all areas therein.

[0054] FIG. 4 illustrates a sterilization system 60 comprising a chamber 62 having a vaporizer 64, vacuum pump 66 and vent 68 connected thereto. Preferably, an elongated, temperature controlled diffusion path 70 as previously described connects the vaporizer 64 to the chamber 62. A throttle valve 72 and pressure gauge 74 are provided at the pump 66.

[0055] Articles 76 to be sterilized are placed into trays or containers 78. Two types of packaging are commonly used in preparing articles 76 for sterilization. In one, the articles 76 are placed into a tray having a plurality of openings therein, and the tray is then wrapped with a material such as CSR wrap which passes sterilizing gases and blocks contaminating microorganisms. Such a tray is described in the Wu, U.S. Pat. No. 6,379,631, incorporated herein by reference. An alternative package comprises a sealable container with several ports, preferably on top and bottom surfaces thereof, with each of the ports covered by a semi-permeable membrane which passes sterilizing gases and blocks admission of contaminating microorganisms. Such a container is described in Nichols U.S. Pat. No. 4,704,254, incorporated herein by reference. The first type of packaging is typically called a "tray" and the second a "container." However, the term "container" as used herein is meant to refer to any container, packaging or enclosure suitable for containing articles to be sterilized in a chemical vapor environment.

[0056] The pump 66 connects to the chamber 62 via an exhaust manifold 80. The manifold 80 comprises one or

more shelves 82 for supporting and receiving one or more containers 78 and which connect fluidly through the throttle valve 72 to the pump 66. An opening, or preferably a plurality of openings 84 on the upper surfaces of the shelves 82 allow the pump 66 to draw atmosphere within the chamber 62 through the openings 84, through the manifold 80 and out through the pump 66.

[0057] The containers 78 preferably have openings 86 on a lower surface 88 thereon and additional openings 90 on at least one other surface. When the containers 78 are placed on the shelves 82 atmosphere being exhausted by the pump 66 is drawn in part through the openings 90 into the container 78, through the container into contact with the article or articles 76 therein and then out through the openings 86 into the manifold 80 through the openings 84 therein. When the atmosphere being so exhausted contains a sterilizing gas it enhances its penetration into the containers 78 and into contact with the articles 76 therein.

[0058] Sterilizing gases are so exhausted during the previously described cycle as the sterilant solution is vaporizing and immediately before the second admission of hydrogen peroxide. Such a cycle can also further provide a pump-down after some period of diffusion. After admitting the sterilant vapor the chamber 62 pressure rises slightly due to the presence of additional gas therein, typically from about 0.5 torr to about 10 torr. Higher pressures are as efficient with higher load and chamber temperatures.

[0059] Turning also to FIGS. 5 and 6, an alternative design (in which like part numbers to those of the design of FIG. 4 are designated with a "b" appended thereto) replaces the manifold 80 of the design of FIG. 4 with a simple port 92. The port 92 is covered by a support 94 for the container 78, the support 94 having a plurality of openings 96 there-through so that the chamber 62b is in fluid communication with the pump 66b through the container 78, the support 94 and the port 92. The support 94 can be removable.

[0060] Turning also to FIGS. 7 and 8 (in which like part numbers to those of the designs of FIGS. 4 to 6 are designated with a "c" appended thereto) shows a support 100 resting on a surface 102 in the chamber 62c through which penetrates the port 92c. The support 100 surrounds the port 92c. Thus, most or all of the atmosphere being exhausted by the pump 66c passes through the container 78 into a space 104 formed between the container 78, the support 100 and the surface 102 and then onto the pump 66c through the port 92c.

[0061] FIG. 9 discloses an alternative system in which, similar to the system of FIG. 1, a portion of the vaporized germicide solution can be condensed and the solvent, typically water, which has not condensed as quickly is removed from the atmosphere to further concentrate the germicide. The germicide is then revaporized to produce a more concentrated germicidal vapor for more efficient sterilization. The system comprises a sterilization chamber 200 containing a load 202 of items to be sterilized. A source 204 of liquid germicide solution provides the solution through a valve 206 to a first vaporizer/condenser 208 where it is vaporized and then supplied to the chamber 200. A valve 210 can be provided to isolate the vaporizer/condenser 208 from the chamber 200. The chamber 200 is also provided with a valved vent 212.

[0062] A vacuum pump 214 provides for lowering the chamber pressure as described in reference to the previous

[0072] The orifice 308 offers the advantage of a more concentrated solution by restricting the flow from the condensing/revaporization section 254 to provide a more controlled vaporization. Variations in pressure in the condensing/revaporization section 254 and in the vaporizer due to vacuum pump pressure fluctuations are dampened out by the orifice 308 to prevent surges of water vapor from carrying hydrogen peroxide droplets from the condensing/revaporization section 254. Another advantage of flow restriction by the orifice 308 is achieving a low pressure (less than 1 torr) in the sterilization chamber 200 to improve the diffusion coefficient in lumens while maintaining a greater pressure in the vaporizer/condenser 250 to operate at a greater temperature in the condensing/revaporization section 254. Without an orifice 308, sterilization chamber 200 and vaporizer/condenser 250 pressures must both be reduced to the same low pressure together, and the condenser must be operated at a very low temperature to maintain equilibrium of the solution. A lower condenser temperature is more difficult to control and may produce ice or condensate, which requires a more expensive design to protect electrical equipment.

[0073] An O-ring 282 seals the plates 276 on the thermo-electric devices 270 and 272 against the housing 264. An aperture 284 through the housing 264 aligns with an aperture 286 through the insulator 262 to place a chamber 288 defined by the housing 264 into fluid communication with the inlet manifold 252. An outlet passage 290 in the housing 264 connects to an upper portion of the chamber 288 and to a second aperture 292 through the insulator 262 which in turn aligns with the outlet manifold 256 to place the chamber 288 in fluid communication with the outlet manifold 256. A safety thermostat 294 atop the housing 264 is wired outside of the control system to shut down heating of the vaporizer/condenser 250 above a predetermined temperature. Temperature sensors 295 and 297 measure temperature in the inlet manifold 252 and condensing/revaporization section 254 respectively. A pressure sensor 296 interfaces with the outlet manifold 256. Heat sinks 298 having fan housings attach to each of the thermoelectric devices 270 and 272.

[0074] The outlet manifold connects to a valve manifold 300 which provides three possible flow paths between the vaporizer/condenser 250 outlet manifold 256 and a valve manifold outlet 302 from the valve manifold 300. The valve manifold outlet 302 communicates with the main chamber 200. A main flow passage 304 is controlled by a valve 306 which can open to allow flow through the main passage 304 to the valve manifold outlet 302 or close to block such flow. The second passage is through an orifice 308 in an orifice plate 310 which provides a flow restriction to enhance the ability to preferentially draw water vapor from the vaporizer/condenser 250. A third potential passage is through a rupture disk 312 which is designed to rupture in case of a catastrophic overpressure within the housing chamber 288, such as in the unlikely event that an oxidizable sterilant such as hydrogen peroxide combusts therein. The orifice 308 could be moved to a position within the shut-off valve 306, similar to that described in reference to the valve element 118 in FIGS. 3A and 3B.

[0075] In operation, the main chamber is first evacuated to a low pressure sufficient to induce vaporization, such as 0.4 torr and the valve 306 is closed placing the vaporizer/condenser 250 into fluid communication with the chamber 200 solely through the orifice 308. The inlet manifold 252 is

heated with the heater 260 and a quantity of sterilant solution such as a 59% hydrogen peroxide/water solution is injected into the inlet manifold 252 where it vaporizes and diffuses into the housing 264 through the apertures 286 and 284. The thermo-electric devices 270 and 272 at this time are drawing energy out of the rods 278 and dissipating it through the heat sinks 298 thus allowing the vaporized sterilant to recondense on the rods 278.

[0076] The temperature of the inlet manifold 252 can be controlled to slowly vaporize the sterilant thus allowing the water to more quickly vaporize and flow through the vaporizer 250 and out through the orifice 308 to concentrate the remaining sterilant. The condenser/revaporization section 254 quite effectively concentrates the sterilant such that to speed up the process a fast vaporization in the inlet manifold can be employed while still achieving a high degree of concentration.

[0077] The condensate on the rods 278 tends to be more highly concentrated in the sterilant. After a time, when the initial charge of sterilant solution has been vaporized and a portion thereof condensed on to the rods 278, the thermo-electric devices 270 and 272 are reversed to apply heat to the rods 278 and revaporize the sterilant. At this time, the heat sink 298 will still contain heat which had been extracted during the prior step and that heat can be used by the thermo-electric devices 270 and 272 to very efficiently heat the rods 278 and revaporize the sterilant. This added efficiency improves the energy efficiency of the device and allows a smaller and more compact vaporize condenser 250 to provide adequate heating and cooling. After the sterilant has been revaporized, the valve 306 is opened to allow efficient diffusion of the sterilant vapor into the main chamber 200.

[0078] If a second vaporizer/condenser 216 is employed, its structure preferably mimics that of the vaporizer/condenser 250 without the inlet manifold 252. In such a system, after initial diffusion into the main chamber 200, rods within the second condenser 216 would be chilled and the pump 214 turned on to preferably extract water vapor from the condensing sterilant. After a period of time when sterilant has condensed, the rods would be heated to revaporize the sterilant and the pump 214 turned off. This revaporized sterilant would have somewhat higher concentration and would then re-diffuse into the chamber 200 to further enhance the sterilization process.

[0079] Other system arrangements are possible. FIG. 16 illustrates an alternative embodiment which can enhance efficiency in conserving and concentrating the germicide solution. In this system, a chamber 314 containing a load 316 has a first condenser/vaporizer 318 connected to a source 320 of germicide solution and a second condenser/vaporizer 322. The first condenser/vaporizer 318 is isolated from the source 320 by a valve 323 and from the chamber 314 by a valve 324. It also connects to an exhaust pump 325 and is isolated therefrom via a valve 326. The second condenser/vaporizer 322 is isolated from the chamber 314 by a valve 327 and connects to the pump 325 and is isolated therefrom via a valve 328. A vent 329 is also provided.

[0080] FIG. 17 illustrates a similar system 330 employing a single condenser/vaporizer 332 (of structure similar to the condenser/vaporizer 250 with an additional outlet) connected to a sterilization chamber 334 adapted to receive a

REPUBLICA DE COLOMBIA

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

RESOLUCION Nº 2 2 1 0 9

Por la cual se niega una patente de invención

Rad. Nº 05-103740

EL SUPERINTENDENTE DE INDUSTRIA Y COMERCIO

en ejercicio de sus facultades legales, en especial de las que se confirieron en el artículo 4, numeral 5 del decreto 2153 de 1992, y

CONSIDERANDO:

PRIMERO: Que mediante escrito radicado en esta Superintendencia el 11 de octubre del 2005, bajo el número 05103740 se presentó la solicitud de patente para la invención denominada: "SISTEMA Y METODO DE ESTERILIZACION Y APARATO DE CONTROL DE ENTRADA DE ORIFICIO PARA LA MISMA", contenida en el expediente de la referencia.

SEGUNDO: Que efectuado el examen de forma en cuanto a los requisitos que debe llenar la solicitud y cumplidas las exigencias legales, se ordenó publicar el extracto sin que se hubieran presentado oposiciones por parte de terceros.

TERCERO: Que el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina establece que: *"Si la oficina nacional competente encontrara que la invención no es patentable o que no cumple con alguno de los requisitos establecidos en esta Decisión para la concesión de la patente, lo notificará al solicitante. Este deberá responder a la notificación dentro del plazo de sesenta días contados a partir de la fecha de la notificación. Este plazo podrá ser prorrogado por una sola vez por un período de treinta días adicionales.(...) Si el solicitante no respondiera a la notificación dentro del plazo señalado, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, la oficina nacional competente denegará la patente"*.

CUARTO: Que realizado el examen de fondo, se requirió al solicitante en los términos del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, para que presentara respuesta a las observaciones de carácter técnico visibles a folios 183 a 207 del cuaderno administrativo, relacionadas con la patentabilidad o cumplimiento de los requisitos establecidos por esta Decisión para la concesión de la patente. Frente a dicho requerimiento no hubo pronunciamiento alguno por parte del mismo, por lo cual es procedente negar el privilegio de patente solicitado con fundamento en lo dispuesto en el artículo 45 de la Decisión 486.