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(54) Title: HYDROGEN PEROXIDE STERILIZATION PROCESS AND DEVICE

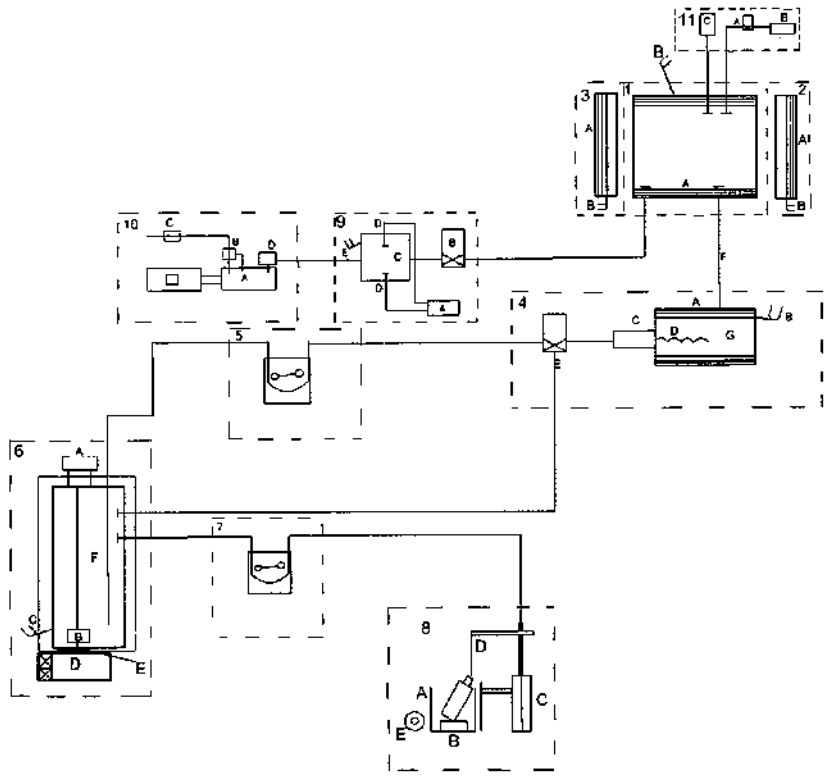

FIG. 1

(57) Abstract: This invention concerns a hydrogen peroxide sterilization device, with injection of hydrogen peroxide vapour, provided with a vaporizer that feeds a sterilization chamber, with a dose that varies in function of the control performed by a computer or control unit. The vaporizer works with a pressure inferior to the atmospheric one and is heated by an electrical resistance heater. All the vaporization process is made in vacuum. The filling of the sterilant agent is made drop-by-drop by a capillary tube which transforms the liquid into a pulverized gas. The computer controls the electrical valve following the dosing pump from the pressure and/or temperature information that comes from various pressure and/or temperature sensors. The pressure inside the chamber is maintained during the sterilization process in a constant predefined value. The invention also refers to the hydrogen peroxide sterilization process that uses the referred device.

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DESCRIPTION

HYDROGEN PEROXIDE STERILIZATION PROCESS AND DEVICE

The invention refers to a process and device for the hydrogen peroxide sterilization and it is based on the hydrogen peroxide vapour injection into a sterilization chamber with a temperature between 20°C and 70°C. The process takes place in a chamber with two doors (with sanitary barrier) warmed between 20°C and 70°C.

PREVIOUS INVENTIONS

Document WO 03072150 discloses a vapour generation unit which receives an aqueous hydrogen peroxide solution and includes a desiccant cartridge product.

Document EP1764115 describes a sterilization system which includes a hydrogen peroxide generator. It has a space for the introduction of the hydrogen peroxide in a treatment space and dehumidifier. It is important to note that there is a dehumidified air passage between the dehumidifier and the treatment space.

Document CA2519664 describes a sterilization process where the hydrogen peroxide solution is dripped from an injector into an evaporator during 3 minutes with a flow of 5g/minute. The working chamber is filled with hydrogen

peroxide after the reduction of the inside humidity from 1 to 10%. The sterilization occurs thanks to the hydrogen peroxide saturation inside the working chamber.

It is necessary to mention the technical documents in EP 06398011 application filed by the present applicant referring to a hydrogen peroxide sterilization device. According to that patent application, the extracted hydrogen peroxide from the chamber is burned thanks to a high tension inside a burner.

The present patent application results from an improvement and development of the invention described in patent application EP 06398011.

Advantages of the device of the present invention:

- The drop-by-drop vaporization device has advantages compared to the existing ones, as the precision obtained with the sterilant agent dripping, using a capillary tube in the vaporizer and the doses variability applied through a computerized control system, which monitors the functioning of the device through various pressure and temperature probes. The dosing system is not made by only one dose system as it happens in other sterilizers.

- The vaporizer vaporizes in 30 seconds a total of 2,5 ml of hydrogen peroxide. It does not work necessarily in

the saturation.

- Concerning the injection, the injection device does not have a syringe injector but a capillary tube inside the vaporizer, which transforms the liquid into pulverized gas;

- The invention sterilization process occurs after the pressure within the vaporizer reaches 1 mbar and all the sterilization process is performed in vacuum;

- The invention vaporizer is physically opened to the chamber, and there is no valve between the vaporizer and the chamber;

- In the invention device, the vaporizer is part of the chamber;

- The control system is not based on the relative humidity, but it is based on the chamber pressure.

DRAWINGS DESCRIPTION:

The invention is now described as a non limitative example with reference to the attached drawings:

Figure 1 shows a device scheme drawing which allows

accomplishing the sterilization process according to the invention.

Figure 2 is a graphic depicting the device functioning with the pressure evolution in the vaporizer depending on the time.

DETAILED DESCRIPTION:

Referring to Figure 1, the perforating unit (8) is composed by a drawer (8A), a recognition sensor (8B), a perforating cylinder (8C) and a closing drawer cylinder (8E). The drawer where the sterilant agent recharge is placed works with an electric and/or pneumatic cylinder mechanism.

The sensor (8B) reads and accepts the sterilant agent recharge, and the recharge is used according to the manufacturer instructions.

After the recharge has been recognized, the drawer (8A) is closed and the needle (8D) perforates the recharge. This needle works thanks to a mechanical and/or electrical system. After the perforation, the sterilant agent is pumped by the pump (7) and placed into the tank (6F).

The sterilant agent is removed from the tank (6F); thanks to a dosing pump (5) the liquid passes through a

vaporization valve(4E) which introduces the hydrogen peroxide into the vaporizer capillary tube (4D). The sterilant agent tank (6F) has a float (6B). The level of sterilant agent is controlled by a level sensor (6A).

The sterilant agent vaporization is dripped and is obtained by a new device which includes vaporizer (4G), within which there is a capillary tube (4D) heated by an electrical resistance heater (4A), is fed by a dosing pump (5).

As the vaporization is dripped, it is possible to dosing small vapour quantities from the vaporizer chamber (4G) to the sterilization chamber (1A).

The process is developed inside a sterilization chamber (1A) with two doors (with sanitary barrier) heated between 20°C and 70°C in order to achieve a biological kill inside a "PCD" with 10 meters length.

This vaporizer (4) is essentially based on a chamber (4G) - provided with an electrical resistance heater (4A) - needs to have a programming command, in order to control the opening/closing of the vaporizer valve (4E), after the continuous pressure calculation. Between the product entry valve (4E) and the vaporizer (4G) there is a device designed for the drop-by-drop vaporization. The dosing is ensured by an electrical valve (4E) at the entry of the

vaporizer, commanded by a computer or control unit.

After being heated by the vaporizer (4G) the capillary tube (4D) is able to vaporize drop-by-drop with a programmed command by the computer.

The vaporizer (4G) is heated by an electrical resistance heater (4A) at a temperature between 80°C and 200°C. The vaporizer (4A) has a pressure and/or temperature probe (4B) which sends the information to the control computer. The hydrogen peroxide is injected drop-by-drop into the vaporizer (4G), which is mechanically connected to the sterilization chamber (1A) by a clamp system with a Teflon tube (4F) which conveys the hydrogen peroxide and allows the entry of the vapour inside the chamber (1A) in the best conditions.

Between the dosing pump (5) and the vaporizer valve (4E) there is a return line of the sterilant agent.

Near the vaporizer entry valve (4E), there is an air removing system thanks to a vacuum pump (10A), which removes the air before starting the drop-by-drop injection. The gas passes through a burner (9C) with high-tension electrodes (9D).

The sterilization chamber (1A) has a pressure and/or temperature probe (11C e 1B) which informs the computer

that controls the process.

According to the drawing 1, in order to achieve a drop-by-drop injection, the capillary tube (4D) has a length between 50mm and 2500mm with a hole from 1µmm to 0,1 mm, which allows the drop-by-drop vaporization. The entry valve (4E) is controlled based in the value vaporized in each opening. There will be successive openings of the valve until reaching the established value for a pressure between 5mbar and 155mbar.

The dosing system has no air, which means that if there is less material inside the chamber for the same value of pressure, it will be necessary to inject more hydrogen peroxide. On the other hand, if there is more material inside the chamber for the same pressure value, it will be necessary to inject less hydrogen peroxide.

The sterilization is reached in lumen with 10 meters of length and 1mm diameter with biological indicators Stearothermophilus inside a container inserted inside the lumen in a population of $1.2x10^5$ during the sterilization period between 80 and 2200 seconds (diffusion phase).

The dripping dosing system is ensured by a peristaltic pump (5) that starts the pumping between 10 and 80 seconds before the injection, in order to remove all the air in the tubes. After this pumping period, and air removal from the

tubes, the vaporizer valves (4E) open with intermittent opening controlled by the pressure read in the sterilization chamber (1A).

With this process, there is a curve of vaporization with an entry similar with that shown on the drawing 2. The diffusion period occurs between 80 and 2200 seconds with a pressure between 5 and 155mbar.

Modifications can be made to the disclosed sterilization device, maintaining the functioning principle in the attached claims, for example modifications with equivalent element, which fall in the scope of this invention.

CLAIMS

1 - Hydrogen peroxide sterilization device with hydrogen peroxide vapour injection, provided with a vaporizer that feeds a sterilization chamber, characterized in that the feeding is made with a dose varying with the control function performed by a computer or control unity; the vaporizer works with a pressure inferior to the atmospheric one and it is heated by an electrical resistance heater, all the vaporization process being made in vacuum, the filling of the sterilant agent being made drop-by-drop by a capillary tube which transforms the liquid into a pulverized gas, the computer controls the electrical valve following the dosing pump taking into account the information concerning the pressure and/or temperature coming from various pressure and/or temperature sensors, and the pressure inside the chamber is maintained during the sterilization process at a constant predefined value.

2 - Device according to Claim 1, characterized by a chamber pressure of approximately 1mbar.

3 - Device according to Claim 1, characterized by a vaporizer that is able to vaporize a total of 2,5 - 6ml of hydrogen peroxide for a period of 30-100 seconds.

4 - Device according to Claim 1, characterized in that the pressure inside the sterilization chamber is about 5 to

55mbar during the sterilization phase.

5 - Device according to the previous claims, characterized by having various pressure and/or temperature sensors, namely in the vaporizer, in the sterilant agent tank and in the sterilization chamber.

6 - Device according to Claim 1, characterized in that the hydrogen peroxide vapour injection in the sterilization chamber occurs in a temperature value between 20°C and 70°C.

7 - Device according to the previous claims, characterized by a vaporizer that is heated by an electrical resistance heater to a temperature between 80°C and 200°C.

8 - Device according to the previous claims, characterized by a vaporizer that has a pressure and/or temperature probe that sends the information to the control computer.

9 - Device according to the previous claims, characterized in that the hydrogen peroxide is injected drop-by-drop into the vaporizer, which is mechanically connected to the sterilization chamber by a clamp system and a Teflon tube which leads the hydrogen peroxide in a gaseous state to the sterilization chamber.

10 - Device according to the previous claims, characterized

by a return line of the sterilant liquid between the dosing pump and the vaporizer valve.

11 - Device according to the previous claims, characterized by having near this entry valve in the vaporizer, an air removing system thanks to a vacuum pump which removes the air before the start of the drop-by-drop injection in the sterilization chamber.

12 - Device according to the previous claim characterized in that the air passes through a burner at high temperature with high tension electrodes.

13 - Device according to Claim 1, characterized by having a capillary tube between 50 mm and 250 mm of length with a hole of de 2µmm a 0,1mm.

14 - Device according to the previous claims, characterized by having an entry valve in the vaporizer that is controlled based on the value vaporized in each opening.

15 - Device according to the previous claims, characterized by having successive openings of the valve until the vaporization established value is reached in order to obtain a pressure between 5mbar and 155mbar.

16 - Device according to the previous claims, characterized in that the sterilant agent pumping is made by a

peristaltic pump between 10 and 80 seconds before the injection, in order to remove all the air in the tubes.

17 - Device according to the previous claim, characterized in that the valve opening occurs after said pumping period and after the removal of the air from the tubes, with intermittent opening controlled by the pressure read in the sterilization chamber.

18 - Hydrogen peroxide Sterilization and/or Disinfection Process, characterized by using a device according to Claims 1 to 17.

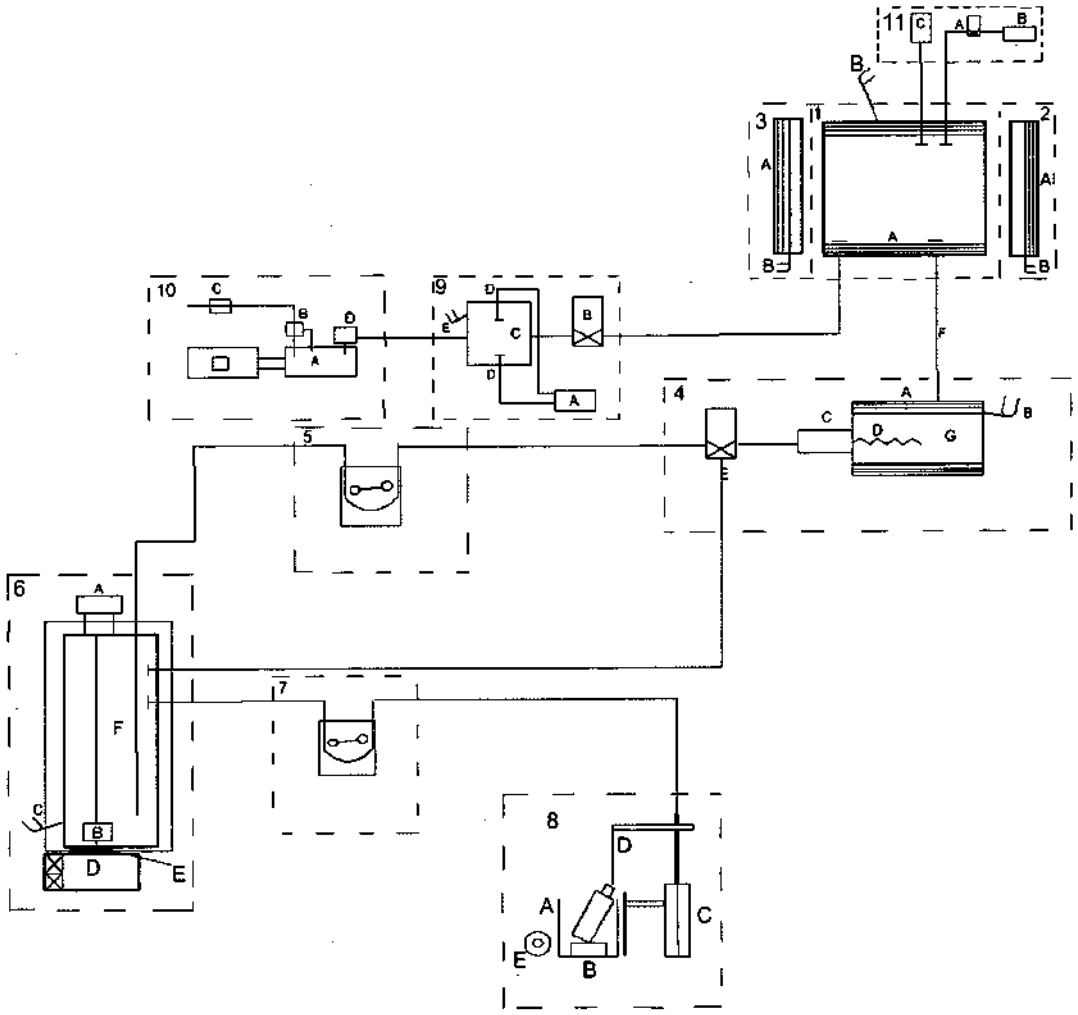
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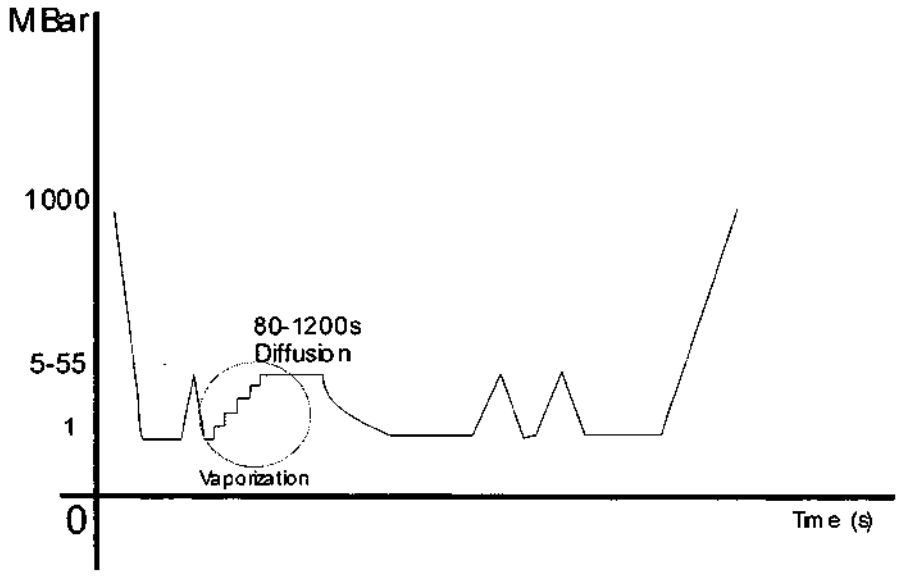
FIG. 1



CYCLE TYPE CURVES

FIG. 2

INTERNATIONAL SEARCH REPORT

International application No
PCT/PT2007/000029

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61L2/20 A61L2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2005/147527 A1 (BROWN I [US] ET AL) 7 July 2005 (2005-07-07) paragraphs [0009], [0011], [0012], [0015] - [0018], [0037] - [0039]; figures	1-18
A	US 2003/235511 A1 (JACOBS PAUL T [US] ET AL) 25 December 2003 (2003-12-25) paragraphs [0036] - [0038], [0041]; figures	1-18
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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 September 2007	28/09/2007

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Nissen, Vagn

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International application No
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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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