

ESCOBAR - URIBE ASOCIADOS

A B O G A D O S

Carrera 11A No. 94 -76 - Of.305 - P.O. Box 94948, Bogotá, D.C. - Colombia

Tels: (571) 6162051 - Fax (571) 6161889

www.escobaruribe.com - info@escobaruribe.com

A2

3055/P.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO DIVISION DE NUEVAS CREACIONES

E. S. D.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



No. 07-033222- -00001-0000

Fecha: 2007-04-27 16:20:53 Dep. 2020 NUECREACIONES
Tra. 2 PATENTES Eve: 1 REGDEPOSITO
Act. 329 CTOINFORMACION Folios: 37

Ref.: Expediente No. 07-033.222
Solicitud de Patente a nombre de
Ethicon, Inc.

Yo, JIMENA ESCOBAR URIBE, identificada como aparece al pie de mi firma, domiciliada en la Carrera 11 A No. 94-76, of. 305, obrando como apoderada de la sociedad **Ethicon, Inc.**, domiciliada en Somerville, New Jersey, Estados Unidos de América, solicitante de la patente de la referencia, atentamente me permito presentar copia certificada de la solicitud de patente número 11/395,603 presentada en Estados Unidos de América el día 31 de marzo de 2006, con la debida traducción de lo pertinente.

Señor Superintendente,

JIMENA ESCOBAR URIBE

C.C.39.779.452 de Usaquén

T.P. 68228

Cód. 5376

43

ESTADOS UNIDOS DE AMERICA
A TODOS AQUELLOS A QUIENES EL PRESENTE LLEGUE:

DEPARTAMENTO DE COMERCIO DE LOS ESTADOS UNIDOS
Oficina de Patentes y Marcas de los Estados Unidos

28 de marzo de 2007

La presente es para certificar que el anexo es una copia fiel de los registros de la Oficina de Patentes y Marcas de los Estados Unidos, de los documentos de la solicitud de patente identificada más adelante, que cumplieron con los requerimientos para concederse una fecha de presentación de acuerdo con 35 USC 111.

Número de Solicitud: 11/395,603

Fecha de Presentación: 31 de marzo de 2006

EL CÓDIGO DEL PAÍS Y EL NÚMERO DE SU SOLICITUD DE PRIORIDAD, PARA SER USADA EN LA PRESENTACIÓN EXTRANJERA BAJO EL CONVENIO DE PARÍS ES US11/395,603.

Por la autoridad de
Bajo el Secretario de Comercio para la Propiedad Intelectual y el Director de la Oficina de Patentes y Marcas de los Estados Unidos de América

(fdo) M. SIAS

Oficial Certificador

Sello oficial de la Oficina de Patentes y Marcas de los Estados Unidos de América

44

PA 1592023



THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

March 28, 2007

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: 11/395,603

FILING DATE: March 31, 2006

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS US11/395,603

**By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office**



**M. SIAS
Certifying Officer**

UTILITY
PATENT APPLICATION
TRANSMITTAL

Attorney Docket No.

ASP-5045USNP

Inventor

Szu-Min Lin, Robert C. Platt, Chun-Chieh J. Tseng

Title

A DISPENSER FOR DELIVERING FOAM AND MIST

Express Mail Label No.

EL961542163US

(or for new nonprovisional applications under 37 CFR 1.53(b))

APPLICATION ELEMENTS

ADDRESS TO: Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

1. ☒ Fee Transmittal Form (e.g., PTO/SB/17)
(submit an original and a duplicate for fee processing)
2. ☐ Applicant claims small entity status.
3. ☒ Specification [Total Pages 20]
(Preferred arrangement set forth below)
- Descriptive Title of the Invention
 - Cross Reference to Related Applications
 - Statement Regarding Fed sponsored R&D
 - Reference to sequence listing, a table, or a computer program listing appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
4. ☒ Drawing(s) (35 USC 113) [Total Sheets 6]
5. Oath or Declaration [Total Pages 3]
- a. ☒ unexecuted
- b. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 18 completed)
- i. ☐ **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☐ Application Data Sheet. See 37 CFR 1.76

7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)

8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)

- a. ☐ Computer Readable Form (CRF)
- b. ☐ Specification Sequence Listing on:
- i. ☐ CD-ROM or CD-R (2 copies); or
 - ii. ☐ paper
- c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney
(when there is an assignee)
11. ☐ English Translation Document (if applicable)
12. ☐ Information Disclosure Statement
(IDS)/PTO-1449 ☐ Copies of IDS Citations
13. ☐ Preliminary Amendment
14. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
16. ☐ Request and Certifications under 35 U.S.C. 122
(b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☐ Other

18. ☐ If a CONTINUING APPLICATION, check appropriate box and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☐ Divisional ☐ Continuation-in-Part (CIP) of prior application No.: , filed

Prior application information: Examiner Group Art Unit:

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

- ☒ Customer Number or Bar Code Label 000027777 or ☐ Correspondence Address below

Name: Philip S. Johnson, Esq.
Address: Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003 USA

20. TELEPHONE CONTACT

Please direct all telephone calls or telefaxes to Andrew C. Farmer at:
Telephone: (732) 524-2825 Fax: (732) 524-2808

21. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

NAME	Andrew C. Farmer	Reg. No. 35,868
SIGNATURE	/Andrew C. Farmer/	
DATE	March 31, 2006	

A6

FEE TRANSMITTAL	<i>Complete if Known</i>	
	Application Number	
	Filing Date	March 31, 2006
	Inventor	Szu-Min Lin, Robert C. Platt, Chun-Chieh J. Tseng
	Group Art Unit	
	Examiner Name	
	Attorney Docket Number	ASP-5045USNP

FEE CALCULATION

CLAIMS AS FILED

(1)	(2)	(3)	(4)	(5)
FOR:	NUMBER FILED	NUMBER EXTRA	RATE	BASIC FEE \$300.00
TOTAL CLAIMS	14 - 20 =	0	x 50.00	\$ 000.00
INDEPENDENT CLAIMS	1 - 3 =	0	x 200.00	\$ 0.00
SEARCH FEE	NA	NA	NA	\$ 500.00
EXAMINATION FEE	NA	NA	NA	\$ 200.00
APPLICATION SIZE FEE If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 25 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).	0 - 100 =	/50	x 250.00 (If the specification and drawings exceed 100 sheets of paper, for each additional 50 sheets or fraction thereof)	\$
MULTIPLE DEPENDENT CLAIMS	☒	N/A	\$360.00	
			TOTAL FEES	\$ 1000.00

METHOD OF PAYMENT

- ☒ Please charge Deposit Account No. 10-0750/ASP-5045USNP/ACF in the amount of \$1,000.00. Three copies of this sheet are enclosed.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required in connection with the filing of this communication, or credit any overpayment, to Account No. 10-0750/ASP-5045USNP/ACF. Three copies of this sheet are enclosed.

SUBMITTED BY:		<i>Complete (if applicable)</i>
Typed or Printed Name	Andrew C. Farmer	Reg. No. 35,868
Signature	/Andrew C. Farmer/	Deposit Account No. 10-0750

A DISPENSER FOR DELIVERING FOAM AND MIST

BACKGROUND OF THE INVENTION

The present application relates to a dispenser for
5 delivering selectively either a foam or a mist and more particularly such a dispenser useful in delivering foams and mists for pretreatment of instruments prior to a washing and sterilization process.

10 Medical instruments after use are typically contaminated with blood and other body matter as well as potentially contaminated with infectious microorganisms. Before being reused in a future medical procedure these instruments must be washed and sterilized. The process of
15 washing and sterilization becomes complicated when blood and other matter are allowed to dry onto the instruments. Blood in particular becomes much more difficult to remove once it has dried.

20 It has been suggested that after use instruments be placed into a liquid filled container to maintain moisture and prevent foreign matter thereon from drying and becoming more difficult to remove. However, such containers can be quite heavy and difficult to move and
25 the liquid therein can become contaminated and it is not desirable to spill this liquid. One solution that has been proposed is an enzymatic foam which is sprayed onto instruments after use and prior to eventual sterilization. The foam weighs less than a liquid and purports to enhance
30 cleaning by initiating some degree of cleaning at the early stage when the foam is placed upon the instrument. Such foams provide little or no antimicrobial activity.

SUMMARY OF THE INVENTION

A dispenser, according to the present invention,
5 provides for dispensing a mist or a foam. It comprises a solution in the dispenser, a foaming nozzle on the dispenser for dispensing the foam from the solution and a misting nozzle on the dispenser for dispensing the mist from the solution.

10

Preferably, the solution comprises hydrogen peroxide, preferably in a range of from 0.1% to 15% by weight, more preferably 2% to 10% by weight and most preferably 3% to 8% by weight. It can also comprise peracetic acid.

15

Preferably, instructions are including instructing a user to foam the solution onto a contaminated surface of a medical instrument prior to cleaning of the instrument and to maintain the foam in contact with the surface until
20 such time as the instrument is cleaned. Further preferable instructions include instructions to apply the mist into a lumen of the instrument prior to cleaning of the instrument.

25

In one aspect of the invention, the dispenser includes a propellant therein for dispensing the foam and mist under pressure of the propellant. This includes typical aerosol propellants such as chlorofluorocarbons (CFCs) and more preferably more environmentally acceptable
30 propellants such as volatile hydrocarbons (i.e. propane, n-butane and isobutane, dimethyl ether, methylethyl ether, nitrous oxide and hydrofluoroalkanes (HFA).

In one aspect of the invention, each of the foaming nozzle and misting nozzle are of a manually pumping type.

5 The solution further preferably comprises a surfactant, a foam booster, a thickening agent and a pH adjustor.

10 An accessory spray tube is preferably provided which is adapted to the nozzle for spraying mist into smaller opening or area.

BRIEF DESCRIPTION OF THE DRAWINGS

15

FIG. 1 is a block diagram of a system according to the present invention;

20

FIG. 2 is a block diagram of an enhanced system of FIG. 1;

FIG. 3 is a front elevation view of a foam dispenser for use in the system of FIG. 1;

25

FIG. 4 is a front elevation view of an alternative foam dispenser for use in the system of FIG. 1;

30

FIG. 5 is a front elevation view in cross-section of a container for use in the system of FIG. 1;

FIG. 6 is a front elevation view in cross-section of an alternative container for use in the system of FIG. 1; and

SD

FIG. 7 is a front elevation view in cross-section of a further alternative container for use in the system of FIG. 1.

5

DETAILED DESCRIPTION

During a medical procedure, one or more medical instruments may be employed. These instruments become contaminated with blood, tissue and potentially
10 contaminating microorganisms. Typically the instruments are set aside after use to await washing and sterilization. This waiting period can be several hours or much longer. During this waiting period blood and
15 other matter which dries upon the instrument becomes much more difficult to remove during the subsequent cleaning procedure. This can be a particular problem when a procedure lasts many hours and uses many different instruments or when due to limited personnel time, it is
20 difficult to process the instruments in a timely fashion.

Turning to the drawings, and in particular to FIG. 1, according to the present invention, after use and prior to a complete washing and sterilization procedure the
25 instruments 10 are placed into a container 12 and covered with a foam 14. The foam comprises hydrogen peroxide. The hydrogen peroxide foam 14 acts to dissolve blood, even dried on blood, and to initiate antimicrobial activity against microorganisms on the instrument. The foam 14
30 encapsulates the instruments 10 and maintains a moist state thereon to inhibit drying of blood and other matter on the instrument. Keeping the blood and other matter from drying promotes superior washing in a subsequent washing and sterilization process.

One method of dispensing the hydrogen peroxide foam 14 would be to spray the foam 14 from a foaming aerosol spray can 16. Such cans employing a propellant are well known to those of skill in the art. Also, the container 12 preferably includes an insert or tray 18 having a plurality of apertures therethrough to allow easy rinsing of the instruments 10 and for efficient diffusion of vapor sterilants into contact with the instruments 10 when the container 12 is used in a sterilization procedure. A lid 20 is also preferably provided.

Instruments 10 are placed into the container 12 as they are finished being used in a procedure. A quantity of foam 14 is sprayed over the instruments 10 to keep them moist and inhibit drying of blood thereon, to start dissolving the blood thereon and to disinfect the instruments. The foam 14 preferably contains between 1 to 15 percent hydrogen peroxide by weight and more preferably between about 3 to 8 percent. Such concentration may not achieve a level of sterilization sufficient for immediate reuse on a patient, but will substantially reduce the load of microorganisms on the instrument surfaces so as to minimize the chances that personal handling the instruments, especially during cleaning, will get infected from them. The lid 20 is preferably placed on the container 12 prior to transporting the instruments from the location of the procedure, such as an operating room, to the location of the washing. When the instruments 10 are ready for washing, the insert 18 can be lifted out and the foam 14 rinsed off while the instruments 10 are still in the insert 18. Normal washing and sterilization may then occur. Washing may comprise treatment with enzymatic cleansers, detergents or other cleaning agents, preferably

4
52

in combination with mechanical scrubbing or agitation, including optionally treatment with water jets, ultrasonic vibration or the like. Following washing the instrument should be sterilized, preferably in the container 12, such as by chemical vapor or steam autoclaving.

It is particularly convenient if the container 12 with the insert 18 is adapted for use in the terminal sterilization such as a STERRAD[®] hydrogen peroxide / gas plasma system or a steam system. Suitable materials, such as liquid crystal polymers, and construction details for such containers, especially containers adaptable to either steam or hydrogen peroxide, are shown in US Patent Nos. 6,379,631 and 6,692,693 to Wu incorporated herein by reference. Such containers are typically wrapped with CSR wrap or incorporate semi-permeable membrane filters to allow sterilization of instruments therein with vapor sterilants while protecting the against ingress of potentially contaminating microorganisms after sterilization.

Turning also now to FIG. 2, in addition to covering an exterior surface of the instrument 10 with the hydrogen peroxide foam 14, if the instrument 10 has a lumen 22, a liquid or mist 24 comprising hydrogen peroxide is preferably sprayed into the lumen 22 prior to placing the instrument 10 into the container 12 and covering the instrument 10 with foam 14. The mist is also preferably dispensed from a pressurized container 26 employing a propellant as is known in the art.

Turning also now to FIG. 3, to enhance convenience, a dispenser 28 can be provided with a foaming nozzle 30 and misting nozzle 32. A foamable hydrogen peroxide solution

12

E3

and a propellant are in the dispenser 28 and when distributed through the misting nozzle 32 the solution comes out as a mist 34 appropriate for squirting into a lumen and when dispensed through the foaming nozzle 30 the solution comes out as a foam 36 appropriate for covering exterior surfaces of an instrument.

Turning also now to FIG. 4, rather than employ a propellant, a dispenser 38 having a foamable solution of hydrogen peroxide therein may employ manually operated misting nozzle 40 and foaming nozzle 42. A particularly useful foaming nozzle 42 is the Airspray F2-L11 available from Airspray NV, Alkamar, The Netherlands.

Turning also now to FIG. 5, a container 44 is illustrated having a mesh insert 46 and lid 48. A lower portion of the container has a well 50 into which a quantity of foamable hydrogen peroxide solution 52 may be placed. A port 54 and valve 56 connect to the well 50 through an air bubbler or hydrophobic membrane 58. A supply of compressed air or other gas attached to the port 54 percolates through the bubbler 58 to foam the hydrogen peroxide solution 52 and fill the container 44 with the hydrogen peroxide foam. Preferably, the lid 48 contains a viewing window 60 to view the progress of foam filling the container 44 and one or more vents 62 to allow gases in the container 44 to escape and allow the foam to fill the container 44. The vent 62 may be a simple opening, or be covered with a semi-permeable membrane or employ a one-way valve.

Turning also to FIG. 6, an alternative container 64 as structured similarly to the container 44 with an insert 66 well 68 with a hydrophobic membrane 70 and a lid 72

34

with a window 74 rather than a port for compressed air or gas, a port 76 is provided on an upper location of the container 64 and has a valve 78 and an additional hydrophobic membrane 79. By attaching the port 76 to a source of vacuum and drawing gases out of the container 64, air will percolate into the container through the hydrophobic membrane 70 providing a foaming action to hydrogen peroxide solution 52 in the well 68. In either this container 64 or the previous container 44, if the foam dissipates, it can be refoamed by employing the vacuum or compressed gas as the case may be.

Turning also now to FIG. 7, a container 80 having an insert 82 and lid 84 with a window 86 has a well 88. An agitator 90 sits within the well 88 and is attached to a motor 92 and power source, such as a battery 94, which is controlled via a switch 96. Engaging the agitator 90 foams a hydrogen peroxide solution 52 in the well 88 to fill the container 80.

Examples

Formulation 1

<u>Type of foam</u>	<u>Mousse-Like Thick Foams</u>
Application	Spray
Ingredients	Wt (g)
Deionized Water	60.0
Carbopol Aqua SF-1 Polymer	3.4
Tween 80	2.0
Glycerol	2.0
NaOH (1.0N)	As needed

H ₂ O ₂	As needed
Preservative(s)	As needed

Formulation 2

<u>Type of foam</u>	<u>Mousse-Like Thick Foams</u>
Application	Spray
Ingredients	Wt (g)
Deionized Water	120.0
Carbopol Aqua SF-1 Polymer	6.8
Tween 80	4.0
Glycerol	1.0
NaOH (1.0N)	As needed
H ₂ O ₂	As needed
Preservative(s)	As needed

5

Formulation 3

<u>Type of foam</u>	<u>High Foaming</u>
Application	Aeration/Vacuum/Spray
Ingredients	Wt (g)
Deionized Water	78.0
Fixate G-100 Polymer	6.0
Tween 80	1.0
SilSense Copolyol-1 Silicone	1.0
Glycerin	4.0
H ₂ O ₂	As needed
Preservative(s)	As needed

Formulation 4

<u>Type of foam</u>	<u>High Foaming</u>
Application	Aeration/Vacuum/Spray
Ingredients	Wt (g)
Deionized Water	85.0
SilSense Q-Plus Silicone	1.0
Tween 80	2.0
Glycerol	3.0
59% H ₂ O ₂	5.0
Preservative(s)	As needed

5

Formulation 5

<u>Type of foam</u>	<u>High Foaming</u>
Application	Aeration/Vacuum/Spray
Ingredients	Wt (g)
Deionized Water	91.0
Fixate G-100 Polymer	6.0
Tween 80	1.0
SilSense Q-Plus Silicone	1.0
59% H ₂ O ₂	5.0
Preservative(s)	As needed

Formulation 6 (for ~ 6% peroxide)

<u>Type of foam</u>	<u>High Foaming</u>
Application	Aeration/Vacuum/Spray
Ingredients	Wt (g)
Deionized Water	150.0
Tween 80	8.0
SilSense Copolyol-1 Silicone	2.0
59% H ₂ O ₂	18.0

5 Formulation 7 (for ~ 3% peroxide)

<u>Type of foam</u>	<u>High Foaming</u>
Application	Aeration/Vacuum/Spray
Ingredients	Wt (g)
Deionized Water	150.0
Tween 80	8.0
SilSense Copolyol-1 Silicone	2.0
59% H ₂ O ₂	9.0

10 Formulation 8 (Defoaming and neutralizing solution)

De-foaming agent (Rug Doctor water-based silicone emulsion)	<u>1%</u>
Catalase	~1000 units/ml
Water	Remainder

Formulation 9 (Foaming Mousse (3% H₂O₂))

Ingredient	Amount (g)	Weight %	Function	Material Type
Deionized Water	120	83.3	Solvent	Aqueous Phase
Carbopol AQUA SF-1 (35%)	10	6.9	Thickener	Acrylic Polymer
Tween 80	4	2.8	Foaming Agent	Surfactant
SilSense Q-Plus Silicone	1	0.7	Foam Booster Tack Reducer	Modified Silicone Liquid
Hydrogen Peroxide (59%)	9	6.3	Disinfecting agent Decontaminating agent	Oxidizer
Sodium Hydroxide (0.1N)	As needed	< 1.0	pH Modifier	Basic solution
Citric Acid (50%)	As needed	< 1.0	pH Modifier	Acidic solution

Final pH= 6.1

5 Modified formulation 7 (with pH adjustor)

High-Foaming (3% H₂O₂)

Ingredient	Amount (g)	Weight %	Function	Material Type
Deionized Water	150	88.8	Solvent	Aqueous Phase
Tween 80	8	4.7	Foaming Agent	Surfactant
SilSense Copolyol-1 Silicone	2	1.2	Foam Booster Tack Reducer	Modified Silicone Liquid
Hydrogen Peroxide (59%)	9	5.3	Disinfecting agent Decontaminating agent	Oxidizer
Sodium Hydroxide (0.1N)	As needed	< 1.0	pH Modifier	Basic solution
Citric Acid (50%)	As needed	< 1.0	pH Modifier	Acidic solution

Final pH= 6.0

Modified formulation 6 (with pH adjustor)

Hi-Foaming (6% H₂O₂)

Ingredient	Amount (g)	Weight %	Function	Material Type
Deionized Water	150	84.3	Solvent	Aqueous Phase
Tween 80	8	4.5	Foaming Agent	Surfactant
SilSense Copolyol-1 Silicone	2	1.1	Foam Booster Tack Reducer	Modified Silicone Liquid
Hydrogen Peroxide (59%)	18	10.1	Disinfecting agent Decontaminating agent	Oxidizer
Sodium Hydroxide (0.1N)	As needed	< 1.0	pH Modifier	Basic solution
Citric Acid (50%)	As needed	< 1.0	pH Modifier	Acidic solution

Final pH= 5.6

5

Preferred formulation

	Preferred	More preferred	Most Preferred
Hydrogen peroxide	0.1 - 15%	2 - 10%	3 - 8%
Surfactant	0.5 - 20%	1 - 10%	2 - 6%
Foam booster (Modified silicone)	0.1 - 10%	0.3 - 5%	0.5 - 3%
Thickening agent (Acrylic polymer)	0.5 - 20%	1 - 10%	1.5 - 5%
pH	4.5 - 7.5	5 - 7	5.5 - 6.5

10

19
59

Tests

(A) Test with fresh blood

A drop of fresh blood, approximately four millimeters in diameter was applied to a Petri dish. One was left untreated and the other treated with a peroxide foam of formulation 7 generated with Airspray F2-L11 Finger Pump Foamer. Within ten minutes the untreated blood had dried whereas the treated blood had reacted and dissolved in the peroxide foam.

10

(B) Tests with dried blood

A drop of dried blood was treated with room temperature tap water for ten minutes and another drop of dried blood was treated with a 3% hydrogen peroxide foam of formulation 7 generated with Airspray F2-L11 Finger Pump Foamer. The drop of dried blood treated with tap water remained after ten minutes. After ten minutes, the drop of dried blood treated with the hydrogen peroxide foam had dissolved.

20

An additional test was conducted comparing a commercially available enzyme foam, Prepzyme XF enzyme foam, available from Ruhof Corporation of Mineola, NY. A drop of dried blood was treated with the Prepzyme XF and another drop of dried blood was treated with a 6% hydrogen peroxide foam of formulation 6. After ten minutes the blood treated with the Prepzyme XF remained whereas the blood treated with the hydrogen peroxide foam was dissolved within five minutes.

30

(C) Foam stability test

A foam prepared according to formulation 9 was placed into a Petri dish of dimensions 150 mm diameter and 15 mm deep. Prepzyme XF was placed into a similar Petri dish. The

20
60

foams were allowed to rest for one hour whereupon they were inspected. The foam of formulation 9 maintained substantially all of its volume over the period of one hour. The Prepzyme foam had fallen to the extent that a portion of the lower surface of the Petri dish was no longer covered by foam. After four hours the foam of formulation 9 still covered the bottom surface of the Petri dish.

10 (D) Tests against microorganisms

Tests of efficacy in killing microorganisms were conducted comparing both a 3% hydrogen peroxide foam prepared according to formulation 7 and 6% hydrogen peroxide foam prepared according to formulation 6 against the Prepzyme XF enzymatic foam using the following test procedure:

Step 1: Place microorganism suspension onto sterile filter

Step 2: Allow the suspension to dry

20 Step 3: Add either peroxide foam or enzyme foam to cover filter

Step 4: Allow foam to set on microorganism for pre-determined time

25 Step 5: Rinse filter with 10 mL sterile neutralizing/defoaming solution (formulation 8)

Step 6: Rinse filter with three times of 100 mL sterile water

Step 7: Place filter on TSA agar and incubate @ 32C for 48hours

30 Step 8: Determine the number of survivors (TNTC = Too Numerous to Count)

Efficacy results with duplicated samples:

Control	Staphylococcus Aureus	Pseudomonas aeruginosa
	TNTC & TNTC (Average: 1.64×10^5)	TNTC & TNTC (Average: 2.49×10^5)

Exposure Time (Minutes)	Foam	Staphylococcus aureus	Pseudomonas aeruginosa
5	No foam with catalase/de- foaming agent (Control)	TNTC & TNTC	TNTC & TNTC
	Enzyme foam (Ruhof Prepzyme XF)	TNTC & TNTC	TNTC & TNTC
	3% hydrogen peroxide foam	TNTC & TNTC	16 & 37
	6% hydrogen peroxide foam	~500 & ~500	0 & 0

10	Enzyme foam (Ruhof Prepzyme XF)	TNTC & TNTC	TNTC & TNTC
	3% hydrogen peroxide foam	~1000 & ~1000	0 & 1
	6% hydrogen peroxide foam	46 & 22	0 & 0

The invention has been described with reference to the preferred embodiments. Obviously, modifications and alterations will occur to others upon reading and understanding the preceding detailed description. It is intended that the invention be construed as including all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

NOVEDAD DE LA INVENCION

REIVINDICACIONES

- 5 1.- Un despachador para despachar una niebla o una espuma que comprende: una solución en el despachador; una boquilla para espuma en el despachador para suministrar la espuma desde la solución; y una boquilla para niebla en el despachador para suministrar la niebla desde la solución.
- 10 2.- El despachador de conformidad con la reivindicación 1, caracterizado además porque la solución comprende peróxido de hidrógeno.
- 3.- El despachador de conformidad con la reivindicación 1, caracterizado además porque incluye instrucciones para espumar la solución sobre una superficie contaminada de un instrumento médico antes de limpiar
- 15 el instrumento y mantener la espuma en contacto con la superficie hasta el tiempo en que el instrumento está limpio.
- 4.- El despachador de conformidad con la reivindicación 3, caracterizado además porque comprende instrucciones para aplicar la niebla en un lumen del instrumento antes de limpiar el instrumento.
- 20 5.- El despachador de conformidad con la reivindicación 1, caracterizado además porque comprende un propelente en el mismo.
- 6.- El despachador de conformidad con la reivindicación 1, caracterizado además porque cada una de la boquilla para espuma y la

64

boquilla para niebla son de un tipo de bombeo manual.

6.- El despachador de conformidad con la reivindicación 1, caracterizado además porque la solución comprende peróxido de hidrógeno en un intervalo de 0.1% a 15% en peso.

5 7.- El despachador de conformidad con la reivindicación 6, caracterizado además porque el porcentaje de peróxido de hidrógeno en la solución es de 2% a 10% en peso.

8.- El despachador de conformidad con la reivindicación 7, caracterizado además porque el porcentaje de peróxido de hidrógeno en la
10 solución es de 3% a 8% en peso.

9.- El despachador de conformidad con la reivindicación 2, caracterizado además porque la solución comprende además ácido peracético.

10.- El despachador de conformidad con la reivindicación 2,
15 caracterizado además porque la solución comprende además un agente tensioactivo. *cul*

11.- El despachador de conformidad con la reivindicación 2, caracterizado además porque la solución comprende además un incrementador de espuma. *cul?*

20 12.- El despachador de conformidad con la reivindicación 2, caracterizado además porque la solución comprende además un agente espesante de espuma. *cul?*

13.- El despachador de conformidad con la reivindicación 2,

caracterizado además porque la solución comprende además un ajustador de pH. ⁶⁵ cual?

14.- El despachador de conformidad con la reivindicación 1, caracterizado además porque comprende un tubo de tal manera que el tubo
5 pueda ser adaptado a la boquilla para rociar niebla hacia una abertura o área más pequeña.

WHAT IS CLAIMED IS:

1. A dispenser for dispensing a mist or a foam comprising:

- 5 a solution in the dispenser;
a foaming nozzle on the dispenser for dispensing the foam from the solution; and
a misting nozzle on the dispenser for dispensing the mist from the solution.

10

2. A dispenser according to claim 1 wherein the solution comprises hydrogen peroxide.

3. A dispenser according to claim 1 which includes
15 instructions to foam the solution onto a contaminated surface of a medical instrument prior to cleaning of the instrument and to maintain the foam in contact with the surface until such time as the instrument is cleaned.

20 4. A dispenser according to claim 3 and further comprising instructions to apply the mist into a lumen of the instrument prior to cleaning of the instrument.

25 5. A dispenser according to claim 1 and further comprising a propellant therein.

6 A dispenser according to claim 1 wherein each of the foaming nozzle and misting nozzle are of a manually pumping type.

30

6 A dispenser according to claim 1 wherein the solution comprises hydrogen peroxide in a range of from 0.1% to 15% by weight.

27

67

7. A dispenser according to claim 6 wherein the percentage of hydrogen peroxide in the solution is from 2% to 10% by weight.

5 8. A dispenser according to claim 7 wherein the percentage of hydrogen peroxide in the solution is from 3% to 8% by weight.

9. A dispenser according to claim 2 wherein the
10 solution further comprising peracetic acid

10. A dispenser according to claim 2 wherein the solution further comprising a surfactant.

15 11. A dispenser according to claim 2 wherein the solution further comprising a foam booster.

12. A dispenser according to claim 2 wherein the solution further comprising a foam thickening agent
20

13. A dispenser according to claim 2 wherein the solution further comprising a pH adjustor.

14. A dispenser according to claim 1 and further
25 comprising a tube such that the tube can be adapted to the nozzle for spraying mist into smaller opening or area.

68

ABSTRACT

A dispenser for dispensing a mist or a foam includes
5 a solution in the dispenser, a foaming nozzle on the
dispenser for dispensing the foam from the solution and a
misting nozzle on the dispenser for dispensing the mist
from the solution. The solution can include hydrogen
peroxide. Preferably, instructions are provided to foam
10 the solution onto a contaminated surface of a medical
instrument prior to cleaning of the instrument and to
maintain the foam in contact with the surface until such
time as the instrument is cleaned, and to apply the mist
of the hydrogen peroxide solution into a lumen of the
15 instrument prior to cleaning of the instrument.

29
69

ASP-5045USNP

Please type a plus sign (+) inside this box ☐

PTO/SB/01 (10-00)

Approved for use through 10/31/2002. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION AND POWER OF ATTORNEY FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63) ☒ Declaration Submitted with Initial Filing ☐ Declaration Submitted after OR Initial Filing (Surcharge (37 CFR 1.16(e)) required)	Attorney Docket Number	ASP-5045USNP	
	First Named Inventor	Szu-Min Lin	
	COMPLETE IF KNOWN		
	Application Number		
	Filing Date	March 31, 2006	
	Group Art Unit		
	Examiner Name		

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.
 I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

A DISPENSER FOR DELIVERING FOAM AND MIST
(Title of the Invention)

the specification of which

☒ is attached hereto

OR

☐ was filed on (MM/DD/YYYY) as United States Application Number or PCT International Application Number
 and was amended on (MM/DD/YYYY)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES NO
			☐ ☐ ☐ ☐	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

DECLARATION - Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	
		☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status
		Patented Patented Patented

I hereby appoint:

☒ Practitioners at Customer Number **000027777** --

Place Customer
Number Bar Code
Label Here

AND

☐ Practitioner(s) named below:
Name Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Address all telephone calls to Andrew C. Farmer at telephone number (732) 524-2825.

Direct all correspondence to: ☒ Customer Number **000027777** OR ☐ Correspondence address below

Name:

Address:

Address:

City:

State:

ZIP

Country

Telephone:

Fax:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:		☐ A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any]) Szu-Min		Family Name or Surname Lin	
Inventor's Signature		Date	
Residence: City Irvine	State CA	Country USA	Citizenship USA
Mailing Address 26 Trailing Ivy			
City Irvine	State CA	ZIP 92620	Country USA

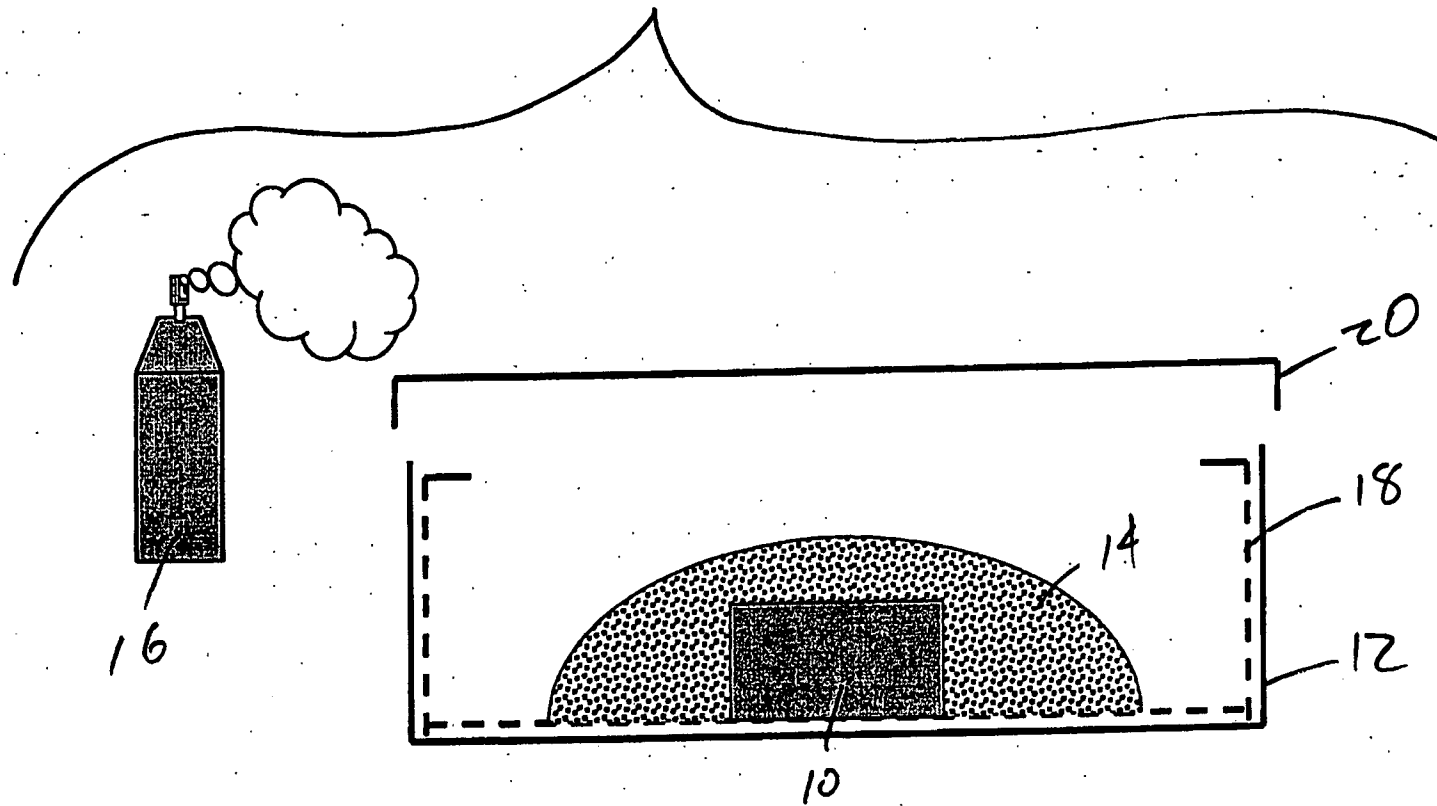
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SECOND INVENTOR:		☐ A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any]) Robert C.		Family Name or Surname Platt	
Inventor's Signature		Date	
Residence: City Laguna Niguel	State CA	Country USA	Citizenship USA
Mailing Address 5 Saint Croix			
City Laguna Niguel	State CA	ZIP 92677	Country USA

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF THIRD INVENTOR:		☐ A petition has been filed for this unsigned inventor	
Given Name (first and middle [if any]) Chun-Chieh J.		Family Name or Surname Tseng	
Inventor's Signature		Date	
Residence: City Irvine	State CA	Country USA	Citizenship USA
Mailing Address 27 Wildland			
City Irvine	State CA	ZIP 92603	Country USA

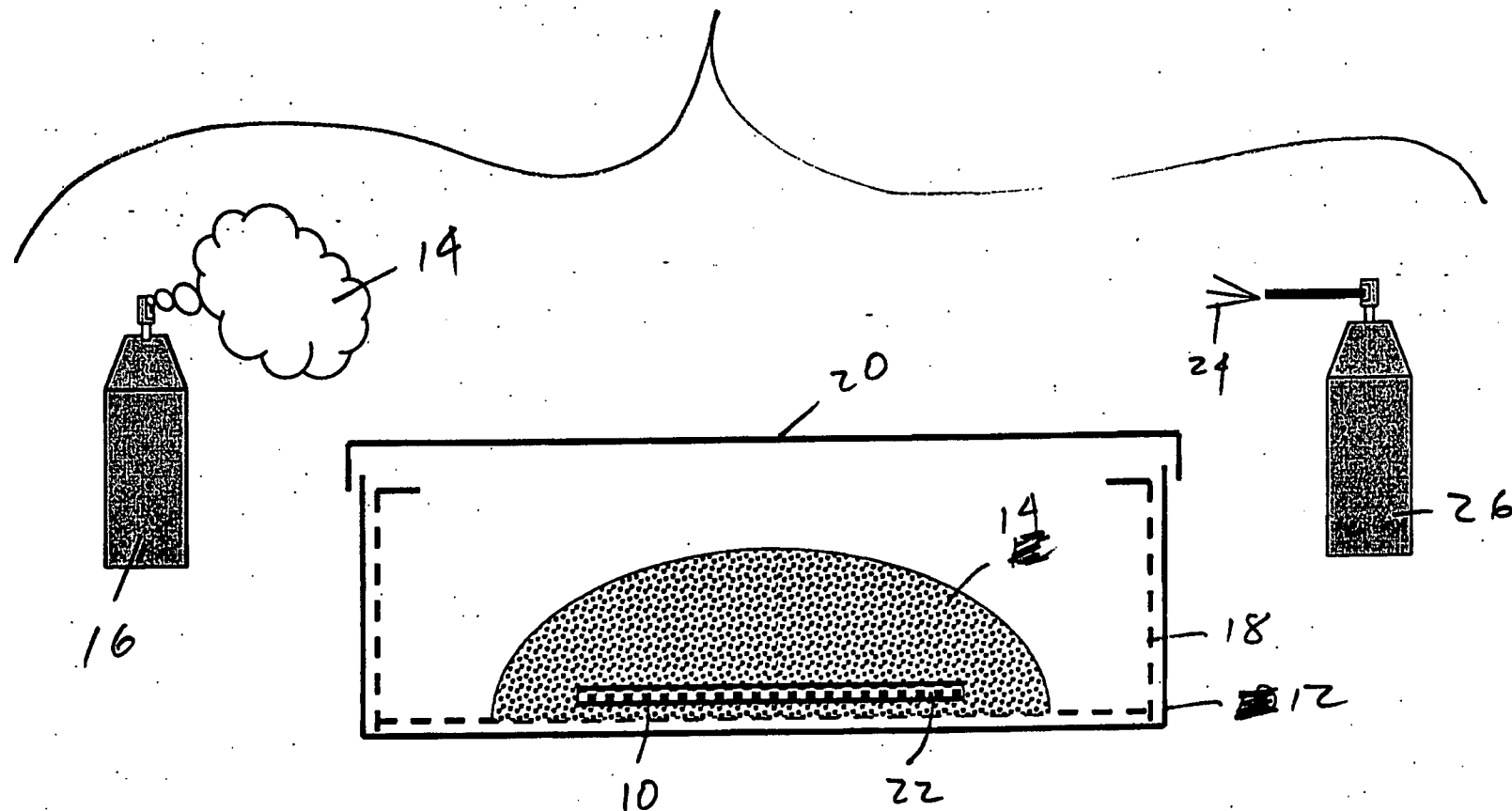
Figure 1



Soaking/covering with peroxide foam

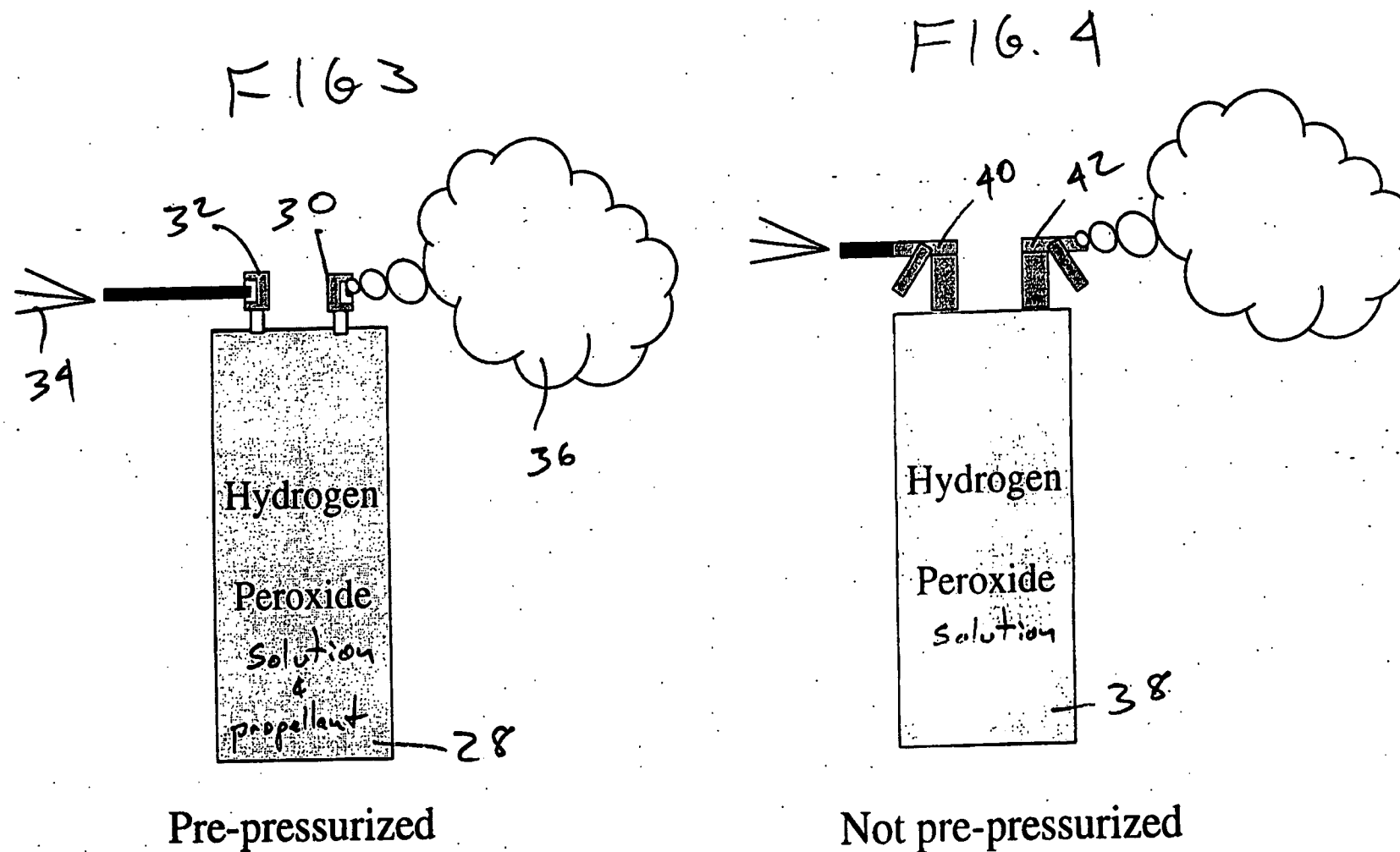
22

Figure 2



Spraying interior with peroxide spray/mist
and treating exterior with peroxide foam

~~Figure 4~~



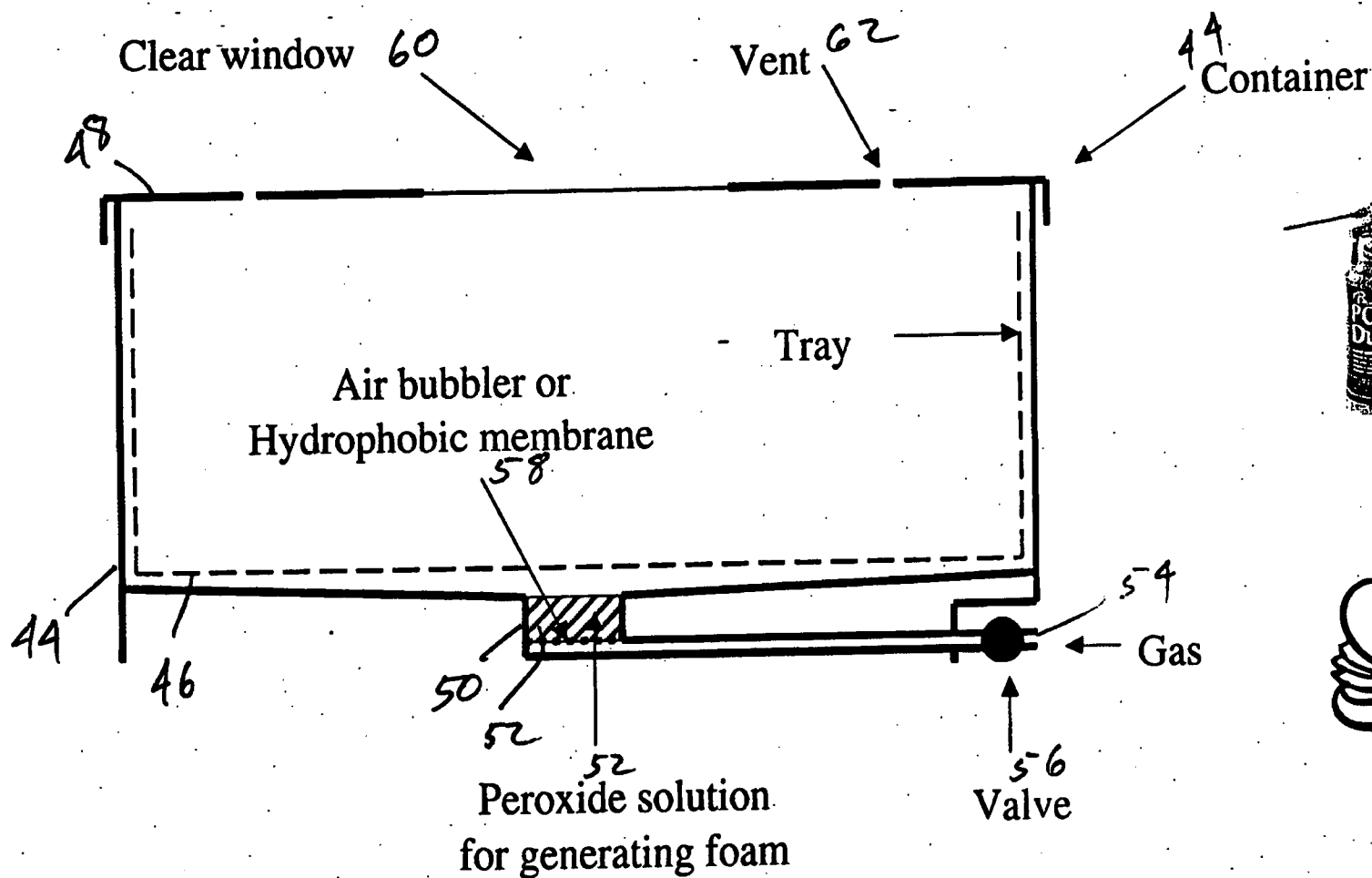
A device which can deliver liquid spray/mist and foam

7/29
34

F16.5

~~Figure 8~~

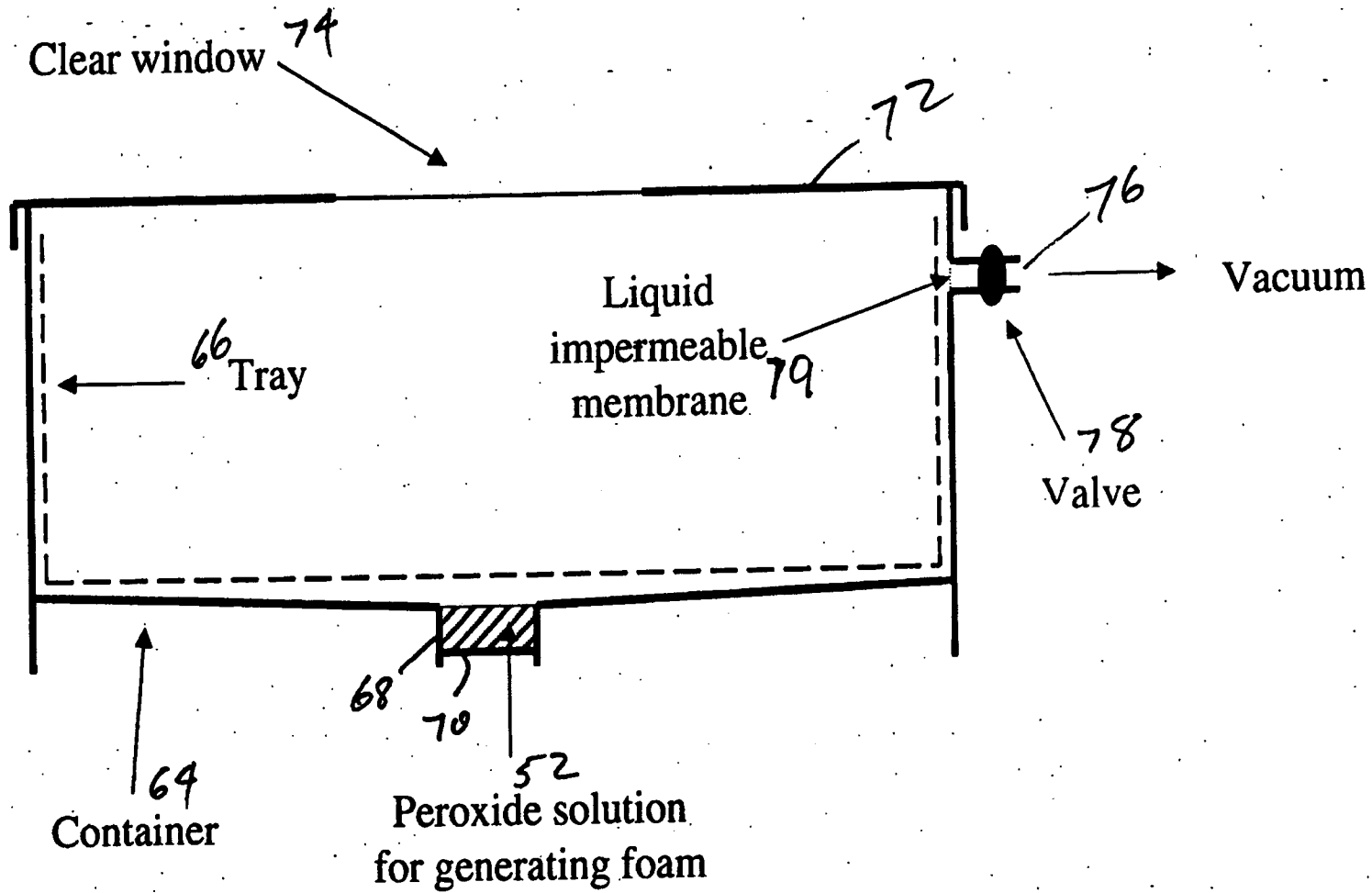
Generating (re-generating) peroxide foam with aeration



Handwritten initials and marks.

FIG 6
~~Figure 9~~

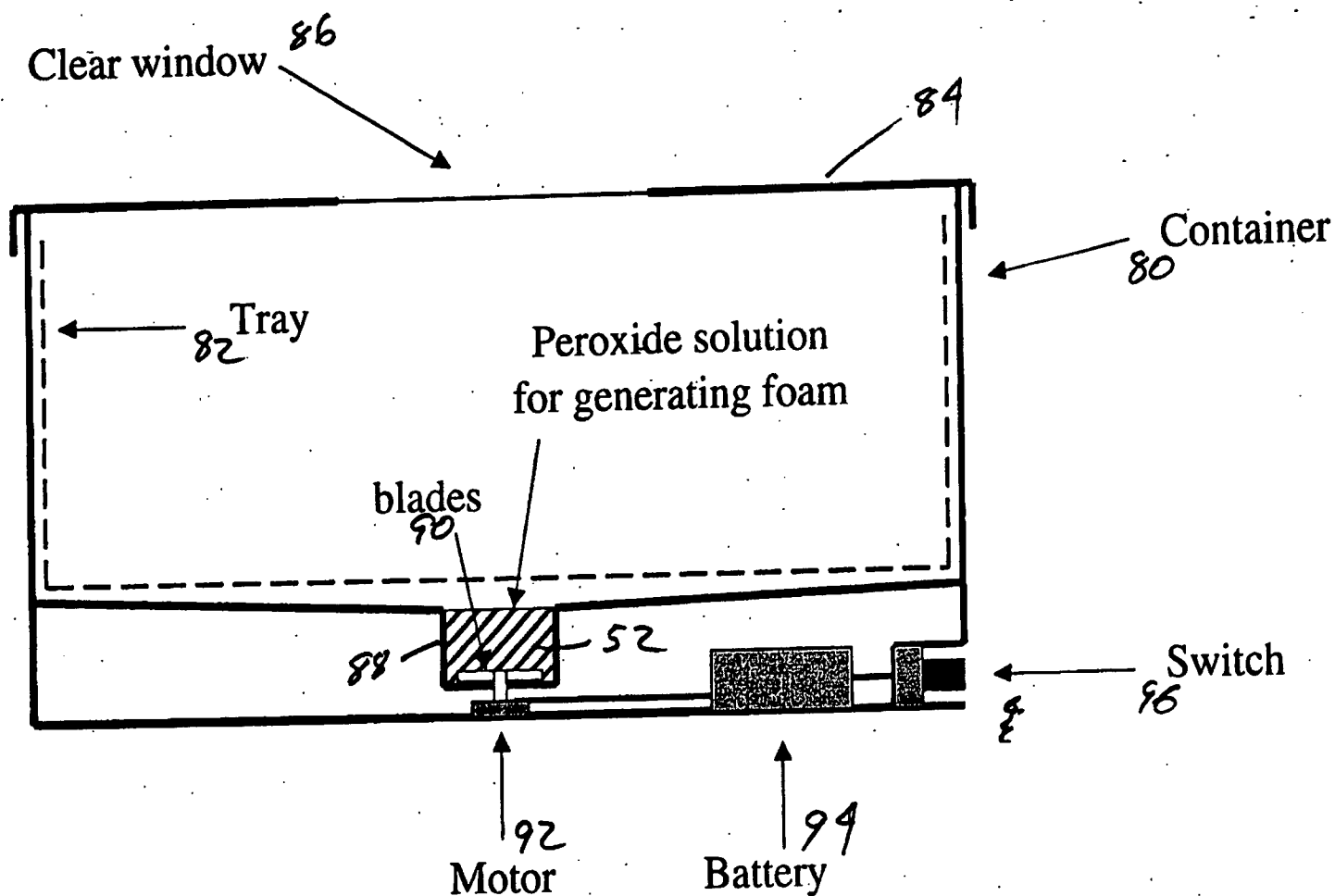
Generating (re-generating)
peroxide foam with reduced pressure



Handwritten marks: a large 'X' and the number '22'.

Figure ~~1038~~ 7

Generating (re-generating) peroxide foam with agitation



Handwritten marks and signatures at the bottom right of the page.