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A B O G A D O S

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2797/P.

**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES**

E. S. D.

Ref.: Expediente No. 05020331
Solicitud de Patente a nombre de
Ethicon, Inc.

SUPERINDUSTRIA Y COMERCIO

Radicacion : 05020331 00000002

Folios: 50

Fecha (AMU): 2003-03-10 14:38:50

Tramite : 002 PATENTES 0 1 REGISTRAR/ 444 RESPUESTA

Dependencia: 0020 DIVISION DE NUEVAS CREACIONES

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 10/793,455 presentada en Estados Unidos de América el día 4 de marzo de 2004, con la debida traducción de lo pertinente.

Señor Superintendente,


JIMENA ESCOBAR URIBE
C.C.39.779.452 de Usaquén
T.P. 68228
Cód. 5376

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

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

Febrero 9 de 2005

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: 10/793,455

Fecha de Presentación: Marzo 4 de 2004

Por la autoridad del
Comisionado de Patentes y Marca

(fdo) T. Lawrence
Oficial Certificador
Sello oficial de la Oficina de Patentes y Marcas de los
Estados Unidos de América

N _ VEDAD DE LA INVENCION

REIVINDICACIONES

5 1.- Un método para suministrar un esterilizante líquido a un esterilizador que comprende los pasos de: a) perforar una celda de un cartucho con una primera aguja que tiene un primer lumen, b) hacer fluir un gas hacia la celda para presurizar la celda en relación con una presión dentro del primer lumen e impulsar el esterilizante líquido hacia afuera de la celda a
10 través del primer lumen, y c) hacer fluir el esterilizante líquido del lumen a un vaporizador en el esterilizador.

 2.- El método de conformidad con la reivindicación 1, caracterizado además porque un segundo lumen a través de la primera aguja se abre hacia la celda y comprende el paso de inyectar el gas en la celda a
15 través del segundo lumen.

 3.- El método de conformidad con la reivindicación 1, caracterizado además porque comprende los pasos de perforar la celda con una segunda aguja que tiene una segunda abertura de lumen de modo que el lumen se abre hacia la celda e inyecta el gas en la celda a través del segundo
20 lumen.

 4.- El método de conformidad con la reivindicación 1, caracterizado además porque el gas está a presión atmosférica y el primer lumen está a una presión por debajo de la presión atmosférica.

5.- El método de conformidad con la reivindicación 1, caracterizado además porque el gas está a una presión mayor que la presión atmosférica.

6.- El método de conformidad con la reivindicación 1,
5 caracterizado además porque los pasos a), b) y c) se repiten con una segunda celda.

7.- El método de conformidad con la reivindicación 1, caracterizado además porque el esterilizante líquido comprende peróxido de hidrógeno.

10 8.- El método de conformidad con la reivindicación 1, caracterizado además porque en el paso a) la aguja entra a la celda lateralmente.

9.- El método de conformidad con la reivindicación 1, caracterizado además porque en el paso a) la aguja entra a la celda en una
15 porción superior de la misma y viaja hacia abajo en la misma.

10.- El método de conformidad con la reivindicación 9, caracterizado además porque comprende el paso de colocar la primera aguja de tal manera que el primer lumen se abre hacia la celda en o cerca de su punto más bajo para aumentar al máximo la extracción de esterilizante líquido
20 de la celda.

11.- El método de conformidad con la reivindicación 1, caracterizado además porque comprende el paso de colocar la primera aguja de tal manera que el primer lumen se abre hacia la celda en o cerca de su

punto más bajo para aumentar al máximo la extracción de esterilizante líquido de la celda.

12.- El método de conformidad con la reivindicación 1, caracterizado además porque comprende el paso de colocar la primera aguja
5 de tal manera que el primer lumen se abre hacia la celda en una posición vertical predeterminada y extraer el esterilizante líquido por arriba de la posición predeterminada, de tal manera que, por lo tanto, se extraiga menos de la cantidad total del esterilizante líquido en la celda.

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PA 1281626



THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

February 09, 2005

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: 10/793,455

FILING DATE: March 04, 2004

**By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS**



**T. LAWRENCE
Certifying Officer**

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UTILITY PATENT APPLICATION TRANSMITTAL Only for new nonprovisional applications under 37 CFR 1.53(b)	Attorney Docket No.	ASP-5018
	First Inventor	Alfredo M. Chaparena
	Title	METHOD OF DELIVERING LIQUID STERILANT TO A STERILIZER
	Express Mail Label No.	ER 674483267US

U.S. PTO
10/793455

APPLICATION ELEMENTS see MPEP Chapter 600 concerning utility patent application elements.	ADDRESS TO: Mail Stop Patent Application Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450
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☒ **Fee Transmittal Form (e.g., PTO/SB/17)**
(submit an original and a duplicate for fee processing)

☐ **Applicant claims small entity status.**

☒ **Specification [Total Pages 22]**
(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

☒ **Drawing(s) (35 USC 113) [Total Sheets 18]**

☒ **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)
- l. ☐ **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).

☐ **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:
 - l. ☐ CD-ROM or CD-R (2 copies); or
 - ll. ☐ 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

☐ **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

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

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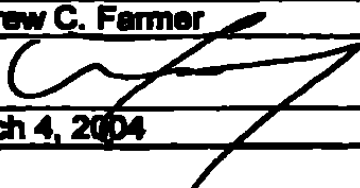
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20. TELEPHONE CONTACT

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21. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

NAME	Andrew C. Farmer	Reg. No. 35868
SIGNATURE		
DATE	March 4, 2004	

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FEE TRANSMITTAL

Complete if Known

Application Number	
Filing Date	March 4, 2004
First Named Inventor	Alfredo M. Chaperena
Group Art Unit	
Examiner Name	
Attorney Docket Number	ASP-5016

FEE CALCULATION

CLAIMS AS FILED

(1)	(2)	(3)	(4)	(5)
FOR:	NUMBER FILED	NUMBER EXTRA	RATE	BASIC FEE \$770.00
TOTAL CLAIMS	12 - 20 =	0	x 18.00	\$ 0.00
INDEPENDENT CLAIMS	1 - 3 =	0	x 88.00	\$ 0.00
MULTIPLE DEPENDENT CLAIMS	☐	N/A	\$280.00	
			TOTAL FEES	\$ 770.00

METHOD OF PAYMENT

☒ Please charge Deposit Account No. 10-0750/ASP-5016/ACF in the amount of \$770.00.
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-5016/ACF. Three copies of this sheet are enclosed.

SUBMITTED BY:		<i>Complete (if applicable)</i>	
Typed or Printed Name	Andrew C. Farmer	Reg. No. 35,888	
Signature		Date: March 4, 2004	Deposit Account No. 10-0750

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60A

DOCKET NO. ASP-5016

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Alfredo M. Choperena et al.

For : Method of Delivering Liquid Sterilant to a Sterilizer

Express Mail Certificate

"Express Mail" mailing number: ER674483267US

Date of Deposit: March 4, 2004

I hereby certify that this complete application, including specification pages, claims, informal drawings and an unexecuted Declaration and Power of Attorney, is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Laurie Phillips

(Typed or printed name of person mailing paper or fee)

Laurie Phillips

(Signature of person mailing paper or fee)

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METHOD OF DELIVERING LIQUID STERILANT TO A STERILIZER

Background of the Invention

5 This application relates to the delivery of sterilant from a cassette to an instrument sterilizer, and more particularly to the extraction of sterilant from the cassette.

10 One popular method for sterilizing instruments, such as medical devices, is to contact the devices with a vapor phase chemical sterilant, such as hydrogen peroxide. In many such sterilizers, it is preferred to deliver the sterilant in liquid form and vaporize it in the
15 sterilizer. One particularly convenient and accurate method for delivering the liquid sterilant is to put a predetermined quantity of sterilant into a cassette and deliver the cassette to the sterilizer. The sterilizer then automatically extracts the sterilant from the
20 cassette and uses it for sterilization procedure. Typically, such a cassette would entail multiple cells containing equal amounts of liquid sterilant with a sterilization procedure employing the sterilant from one or more cells. Such a system is currently available in
25 the STERRAD® sterilization system available from Advanced Sterilization Products in Irvine, California.

 U.S. Patent Nos. 4,817,800; 4,869,286; 4,899,519; 4,909,287; 4,913,196; 4,938,262; 4,941,518; 5,882,611;
30 5,887,716; and 6,412,340, each incorporated herein by reference, disclose such cassettes and a method for draining liquid sterilant from a cell within a cassette. In essence, the cassette travels horizontally with a horizontally oriented cell and one or more needles pierces

the cell from below while compressed air is applied to an upper surface of the cassette cell. The cell is made from a flexible material so that the air compresses the cell and forces the sterilant out through the needles. Such a
5 system limits the cassette design to an outer shell providing rigidity enclosing an inner cell of a flexible material. Further, the cell needs to be designed carefully to allow a complete collapse without trapping any of the liquid sterilant within a wrinkle in the cell
10 during its collapse.

The present invention overcomes these and other limitations of the prior art.

15 Summary of the Invention

A method, according to the present invention, of delivering a liquid sterilant to a sterilizer comprises the steps of: a) piercing a cell of a cassette with a
20 first needle having a first lumen, b) flowing a gas into the cell to pressurize the cell relative to a pressure within the first lumen and drive the liquid sterilant out of the cell through the first lumen, and c) flowing the liquid sterilant from the lumen to a vaporizer in the
25 sterilizer.

In one aspect of the invention, a second lumen through the first needle opens into the gas is injected into the cell through the second lumen. In another aspect
30 of the invention, the method includes the steps of piercing the cell with a second needle having a second lumen opening so that the lumen opens into the cell and injecting the gas into the cell through the second lumen.

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In one aspect of the invention, the gas is at atmospheric pressure and the first lumen is at a pressure below atmospheric pressure. In another aspect of the invention, the gas is at a pressure greater than
5 atmospheric pressure.

The method is suitable for use with cassettes having multiple cells and steps a), b) and c) can be repeated therewith.
10

Preferably, the liquid sterilant comprises hydrogen peroxide.

In one aspect of the invention, in step a) the needle
15 enters the cell laterally. In another aspect of the invention, in step a) the needle enters the cell at an upper portion thereof and travels downwardly therein. The needle can be positioned such that the first lumen opens into the cell at or near its lowest point to maximize
20 extraction of liquid sterilant from the cell, or at a predetermined vertical position to extract the liquid sterilant above the predetermined position, such that less than a total amount of liquid sterilant in the cell is thus extracted.

25

Brief Description of the Drawings

FIG. 1 is a block diagram of a sterilizer employing a cassette handling system according to the present
30 invention;

FIG. 2 is a rear perspective view of a cassette handling system according to the present invention;

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FIG. 3 is a front perspective view of the cassette handling system of FIG. 2;

FIG. 4 is a front perspective view of the cassette
5 handling system of FIG. 2 showing a spent cassette collection box;

FIG. 5 is a rear perspective view of the cassette handling system of FIG. 2 showing its carriage in the
10 insert position;

FIG. 6 is a rear perspective view of the cassette handling system of FIG. 2 showing its carriage as it moves toward the home position;

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FIG. 7 is a rear perspective view of the cassette handling system of FIG. 2 showing its carriage in position to read a bar code on the cassette;

20 FIG. 8 is a rear perspective view of the cassette handling system of FIG. 2 showing its carriage in the home position;

25 FIG. 9 is a front perspective view of the cassette handling system of FIG. 2 showing its carriage in position to tap the cassette's first cell;

FIG. 10 is a cross sectional view of the cassette showing a cell therein;

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FIG. 11 is a front perspective view of the cassette handling system of FIG. 2 showing upper and lower needles on an extractor subsystem penetrating the first cell of the cassette;

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FIG. 12 is a front perspective view of the cassette handling system of FIG. 2 showing upper and lower needles on the extractor subsystem in position to penetrate the
5 last cell of the cassette;

FIG. 13 is a front perspective view of the cassette handling system of FIG. 2 showing the cassette being ejected therefrom;

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FIG. 14 is a flow chart of the cassette handling process;

FIG. 15 is a rear perspective view of an alternative
15 embodiment of a cassette handling system of the present invention employing RFID technology;

FIG. 16 is a memory map of an RFID tag of the cassette shown in FIG. 15;

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FIG. 17 is a top plan view of an unfolded blank for forming the spent cassette collection box of FIG. 4; and

FIG. 18 is a perspective view of the blank of FIG. 17 folded to form the spent cassette collection box.

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Detailed Description

FIG. 1 shows in block diagram form a vapor phase sterilizer 10 employing a cassette handling system 12
30 according to the present invention. The sterilizer 10 comprises a vacuum chamber 14 and a vacuum pump 16 for exhausting atmosphere therefrom. A vaporizer 18 receives liquid sterilant from the cassette handling system 12 and supplies it in vapor form to the vacuum chamber 14. A

screen grid electrode 20 is provided within the vacuum chamber 14 for exciting the contents into the plasma phase during a portion of the sterilization cycle. A micro filtered vent 22 and valve 24 allow sterile air to enter the vacuum chamber 14 and break the vacuum therein. A control system 28 ties in to all of the major components, sensors and the like within the sterilizer 10 to control the sterilization cycle.

10 A typical sterilization cycle might include drawing a vacuum upon the vacuum chamber 14 and turning on power to the electrode 20 to evaporate and extract water from the vacuum chamber 14. The electrode 20 is then powered off and a low vacuum of less than 1 torr drawn on the vacuum
15 chamber 14. Sterilant, such as hydrogen peroxide solution, is vaporized by the vaporizer 18 and introduced into the vacuum chamber 14 where it diffuses into contact with the items to be sterilized and kills microorganisms thereon. Near the end of the cycle, power is again
20 applied to the electrode 20 and the sterilant is driven into the plasma phase. The electrodes 20 are powered down and filtered air is drawn in through the valve 24. This process can be repeated.

25 Turning also to FIGS. 2 to 4, the cassette handling system 12 according to the present invention is shown. It comprises in gross; a carriage 32 for holding a cassette 34, a lead screw 36 and motor 38, an extractor subsystem 40 and a scanner 42.

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The carriage 32 comprises a bottom panel 44, a side panel 46 and top panel 48 along with small vertical flanges 50 and 52 on the top and bottom and top panels 48 and 44, respectively, to capture the cassette 34. The

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bottom, side and top panels 44, 46 and 48 flare outwardly at an entrance 54 of the carriage to aid in insertion of the cassette 34. Two spring catches 56 on the flanges 50 and 52 engage irregular surfaces of the cassette 34 to
5 firmly position the cassette 34 within the carriage 32.

The carriage 32 travels along the lead screw 36 and is supported on an upper rail 58. A lead screw nut 60 attached to the bottom panel 44 and having a threaded
10 opening 62 and an unthreaded opening 63 receives the lead screw 36 and effects horizontal movement of the carriage 32 in response to rotations of the lead screw 36. Flanges 64 extend outwardly from the top panel 48 and flanges 66 extend outwardly from the side panel 46 each having
15 openings 69 for receiving the upper rail 58. The motor 38 is preferable a stepping motor and connects to the lead screw 36 to precisely control the horizontal position of the cassette 34 relative to a frame 68.

20 The extraction assembly 40 comprises an upper needle 70 and a lower needle 72, each being of a lumened configuration. The upper needle connects to an air pump 74 which can force air out through the upper needle 70. The lower needle 72 connects to a valve 76 and from there
25 is plumbed to the vaporizer 18.

The scanner 42 is oriented so as to be able to read a barcode 80 on the cassette 34 as well as a barcode 82 on a spent cassette collection box 84. Upon insertion of the
30 cassette 34 into the carriage 32 the scanner 42 reads the cassette barcode 80. The barcode 80 is preferably encoded with information regarding the contents of the cassette 34, including lot numbers and expiration dates. This information can be used to determine whether the cassette

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34 is fresh and of the correct type and whether the cassette 34 has been used in the system before and thus is at least partially empty. The code is communicated to the control system 28 which makes these determinations.

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The scanner 42 can also see the spent cassette collection box barcode 82 when the carriage 32 moves inwardly and away from the scanner 42. Each spent cassette collection box 84 preferably has two barcodes 82, one in each opposing corner so that the scanner 42 can see one of them regardless of which end of the spent cassette collection box 84 is inserted first. With the spent cassette collection box 84 filled, the spent cassettes 34 block the barcode 82 which alerts the control system 28 that there is no capacity for receiving additional spent cassettes 34. Preferably this message will be output to a user, such as on a display screen (not shown). If the cassette 34 is empty it will not be ejected and no new cycles will be run until a spent cassette collection box 84 having capacity to receive a spent cassette 34 is placed into the sterilizer 10.

A forward flag 86 and rearward flag 88 project outwardly and downwardly from the carriage side panel 46. They slide through a slot 90 in a slot sensor 92 which detects their presence within the slot 90, such as by blocking a beam of light. Travel of the front flag 86 and rear flag 88 through the slot sensor 92 provides a reference location of the carriage 32 to the control system 28.

The top panel 48 of the carriage 32 can rotate about the upper rail 58. A spring 94 between the top panel 48 and side panel 46 biases the top panel 48 downwardly to

hold the cassette 34 within the carriage 32. A disposing
cam 96 sits behind the side panel 46 and aligns with an
ejecting tab 98 which extends outwardly and downwardly
from the top panel 48 and which can project through an
5 opening 100 in the side panel 46 when the top panel 48
rotates upwardly. Such rotation of the top panel 48
releases its hold upon the cassette 34 and due to the
ejecting tab 98 projecting through the opening 100 pushes
the cassette 34 out of the carriage 32 and into the spent
10 cassette collection box.

The disposing cam 96 controls rotation of the top
panel 48. It comprises a generally triangular shape,
having an outwardly facing side 102, forwardly facing side
15 104 and rearwardly facing side 106. Turning also now to
FIG. 5, it mounts for rotation upon an upwardly extending
spindle 108. A spring 110 biases the disposing cam 96
counterclockwise, urging the outwardly facing side 102
into contact with an abutment 112. Inward movements of
20 the carriage 32 allow the ejecting tab 98 to cam over the
rearwardly facing side 106 of the disposing cam 96, thus
allowing the disposing cam 96 to rotate clockwise and
allow the ejecting tab 98 to pass thereby without
effecting rotation of the top panel 48. However, outward
25 movement of the carriage 32 causes the ejecting tab 98 to
cam over the forwardly facing side 104 of the disposing
cam 96. During such motion contact between the outwardly
facing side 102 of the disposing cam 96 and the abutment
112 prevents rotation of the disposing cam 96. The
30 camming of the ejecting tab 98 thus causes it to move
laterally toward the side panel 46 thereby rotating the
top panel 48 upwardly and releasing the cassette 34 from
the carriage 32.

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Prior to inserting the cassette 34 the carriage 32 is fully retracted to its outward position (to the left as shown in FIG. 5). In this position also, a forward end 114 on the lead screw nut 60 engages a stop 116 thus positively locating the position of the carriage 32. Turning also now to FIG. 6, manual insertion of the cassette 34 causes the carriage 32 to move inwardly (to the right as shown in FIG. 6) and moves the front flag 86 into the slot sensor 92. This movement is preferably caused by the physical force from inserting the cassette 34, however, a torque or other sensor could be applied to allow the stepping motor 38 to take over this movement upon feeling the force of the cassette 34 being inserted into the carriage 32. Allowing this movement to come from the force of the insertion of the cassette 34 ensures that the cassette 34 is fully seated within the carriage 32 before the movement begins.

Once the front flag 86 is read by the slot sensor 92 the stepper motor 38 takes over and starts to move the carriage 32 inwardly. Turning also now to FIG. 7, during this stage, the scanner 42 scans the barcode 80 on the cassette 34. The control system 28 interprets the information coming from the barcode 80 and determines whether the cassette 34 has been used in the sterilizer 10 before, whether the cassette contains fresh sterilant, and other data as appropriate. Preferably, the information in the barcode 80 is encrypted to prevent unauthorized parties from creating cassettes which may not meet the quality standards necessary for proper sterilization.

If the control system 28 rejects the cassette 34 a carriage 32 is moved sufficiently inwardly so as to pass the ejecting tab 98 past the disposing cam 96 and is then

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5 moved back to the insertion position shown in FIG. 5 to eject the rejected cassette 34. If the cassette 34 is accepted, the carriage 32 continues inward movement to the home position as shown in FIG. 8 in which the rear flag 88 has just passed out of the slot sensor 92.

10 Turning also now to FIGS. 9 and 10, the cassette 34 comprises a plurality of cells 118 containing liquid sterilant 120. Various structures of a cassette may be employed. The cassette 34 shown comprises a hard outer shell 122, preferably formed of an injection molded polymer, such as high impact polystyrene, high density polyethylene or high density polypropylene, which encloses the individual cells 118, the cells 118 being formed of a
15 blow molded polymer such as low density polyethylene. However, a more rigid material can be used to form the cassette cells 118 in which case the outer shell 122 could be omitted. In the cassette 34 shown, an upper aperture 124 and lower aperture 126 through the shell 122 allows
20 the upper and lower needles 70 and 72 to penetrate the shell. The cell 118 is formed of a material easily penetrated by the needles. If the cell 118 is formed of a more substantial material, a thinning of the material could be provided at the locations to be penetrated by the
25 needles 70 and 72.

30 The control system 28 uses the home position of FIG. 8 as a reference position for positioning the various cells 118 in front of the extractor subsystem 40. By moving the carriage 32 a predetermined amount from the home position a given cell 118 can be brought to face the extractor system 40. In FIG. 9, cell one has been placed in front of the extractor system 40. Turning also now to FIG. 11, an actuator 128 drives the extractor subsystem 40

toward the cassette 34 causing the upper and lower needles 70 and 72 to penetrate the upper and lower apertures 124 and 126 and enter the cell 118. After the needles have fully extended, the air pump 74 drives air into the cell 118 through the upper needle 70. The system waits a couple of seconds before starting the air pump 74 and opening the valve 76 to ensure proper placement and settling of the needles within the cell 118. The sterilant 120 flows out through the lower needle 72 and is piped off to the vaporizer 18. After a sufficient time to extract the sterilant 120, the air pump 74 switches off and the actuator retracts the extractor subsystem 40 from the cassette 34.

15 The vaporizer 18 connects to the vacuum chamber 14 which allows the lower needle 72 to easily be placed at a pressure below atmospheric. Thus, the pump 74 can optionally be replaced by a valve (not shown) open to atmosphere, in which case the incoming atmospheric
20 pressure air will provide the driving force to empty the cell 118.

25 Rather than employ upper and lower needles 70 and 72, one needle having two lumens therethrough would suffice. One of the lumens would provide pressurizing gas and one would extract liquid sterilant. A further alternative arrangement would be to pierce the cell 118 vertically, or substantially so, from an upper part of the cell 118, preferably with such a double lumen needle. This would
30 minimize leakage around the hole created by the needle entering the cell 118. Such entry would also allow the tip of the needle to come closer to the lowest point of the cell 118 for maximum extraction efficiency. If one desired to extract less than all of the contents of the

cell 118, one method would be to position the needle extracting the sterilant, such as the lower needle 72 or the just mentioned double lumen needle, at the level in the cell 118 down to which extraction is desired. Liquid
5 sterilant above the position would be extracted and sterilant below would remain. This would be particularly convenient with the just mentioned vertically traveling needle.

10 Turning also to FIG. 12, each time the control system 28 determines that a new dose of sterilant 120 is required, the stepper motor 38 moves the cassette to position the next cell 118 in front of the extractor
15 subsystem 40 and a new extraction takes place. Multiple extractions may be employed for a given sterilization cycle. When the cassette 34 has been depleted, the carriage 32 moves towards the insert position thus causing the ejecting tab 98 to cam over the disposing cam 96 to
20 rotate the top panel 48 upwardly and project the ejecting tab 98 through the opening 100 to drive the cassette 34 out of the carriage 32 as described above and as shown in FIG. 13. The cassette 34 falls into the spent cassette collection box 84 and the carriage 32 returns to the
insertion position as shown in FIG. 5.

25 The foregoing discussion described the operation of the cassette handling system in some detail. FIG. 14 shows, in block diagram form, the basic operation of the cassette handling system 12.

30 The system of reading barcodes on the cassette 34 and spent cassette box 84 can be replaced with radio frequency identification tags, commonly known as RFID tags. An RFID system 130 is shown in FIG. 15. It comprises a controller

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132 connected via an SPDT reed relay 134 to a cassette
insertion antenna 136 located on the carriage 32 and a
cassette disposal antenna 138 located beneath the spent
cassette box 84. Each cassette 34 carries a cassette RFID
5 tag 140. Similarly, each spent cassette collection box 84
carries a collection box RFID tag 142. Preferably, the
controller 132 comprises a Texas Instruments multifunction
reader module S4100 and the RFID tags 140 and 42 comprise
Texas Instruments RFID tag RI-101-112A each of which are
10 available from Texas Instruments, Dallas, Texas.

The control system 28 (FIG. 1) selects one of the
antennas, as for instance the cassette insertion antenna
136 and sends a signal to the relay 134 to engage this
15 antenna with the RFID controller 132. The antenna reads
the information stored on the cassette insertion RFID tag
140 which identifies the cassette 34 and its contents.
The information read is similar to the information read
using the barcode, however preferably, the RFID tag 140
20 has the ability to update the information stored thereon.
Accordingly, additional data such as the filling status of
individual cells 118 within the cassette 34 can be stored
in the RFID tag. Thus, if the cassette 34 is removed and
then reinserted into the sterilizer 10, or even into
25 different sterilizer 10, the control system 28 can be
apprised of the status of each of the individual cells 118
within the cassette 34. This allows the reuse of a
partially used cassette 34. Also, since the RFID tag 140
can hold more data than the barcode 80, more data about
30 the cassette 34, its contents and manufacturing can be
included thereon.

The spent collection box antenna 138 reads the spent
collection box RFID tag 142 to determine the presence or

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absence of the spent cassette collection box 84. Other data such as a unique identifier for the box 84, the capacity of the box 84, how many cassettes 34 are currently in the box 84 and how many of the cells 118
5 therein are not empty can be included on the RFID tag 142. The control system 28 can track how many cassettes 34 have been ejected into the box to determine whether it has room for more spent cassettes 34. The antenna 138 can also read the cassette RFID tags 140 and count the number of
10 cassettes 34 within the box 84. When the box 84 is full the control system 28 alerts the operator, as by a message on a screen. This message can also include information regarding the cassettes 34 within the box 84. For instance if not all of the cassettes 34 have been
15 completely drained the operator can be informed of this to decide if more careful disposal may be indicated.

RFID technology is disclosed in the following U.S. Patents, each of which is incorporated herein by
20 reference: U.S. Patent Nos. 6,600,420; 6,600,418; 5,378,880; 5,565,846; 5,347,280; 5,541,604; 4,442,507; 4,796,074; 5,095,362; 5,296,722; 5,407,851; 5,528,222; 5,550,547; 5,521,601; 5,682,143 and 5,625,341.

25 RFID tags typically comprise an antenna and an integrated circuit produced in a thin form factor so they can be inconspicuously placed upon an object such as the cassette 34. Radio frequency energy sent by the antennas 136 and 138 induce sufficient current within the antenna
30 inside the RFID tags 140 and 142 to power the integrated circuit therein. Some types of RFID tags carry their own power source and have longer detection ranges, but that adds additional expense and is probably not justified for the present use.

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FIG. 16 shows the memory map for the memory within the RFID tags 140 and 142. A 64-bit unique ID (UID) is set at the factory and cannot be changed. Each RFID tag has its own unique number here. Sixty-four 32-bit blocks can be programmed by the user. These can be populated with information such as the manufacture date, expiration date, product ID, serial number, lot numbers, manufacturing location, filling status of the cells, strength and type of sterilant, time spent within the sterilizer 10 and the like.

Some sterilants are affected by heat. The RFID tag 140 can optionally include temperature collection instrumentation and update that information on the tag. If design temperature profiles are exceeded, such as a maximum temperature or excessive temperature over a time period, then the cassette 34 can be rejected by the control system 28. Temperature measuring RFID tags are available from KSW-Microtec, Dresden, Germany and from Identec Solutions, Inc., Kelowna, British Columbia, Canada. The interior of the sterilizer 10 where the cassette 34 sits may be higher than ambient temperature. Thus, it may be beneficial to put a maximum residence time (on board shelf life) on the tag 140 or even to update on the tag 140 this time the cassette has already spent inside of the sterilizer.

To test sterilant measuring equipment in the sterilizer 10, it may be beneficial to provide cassettes 34 having water or other fluids within one or more cells 118. Information regarding the special nature of the cassette 34 and its contents could be written onto the RFID tag.

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During a cycle the sterilizer may only require part of the contents of a cell 118. For instance, a particular cycle may call for the contents of one and a half cells.

5 The half filled nature of the cell 118 can be stored and then for the next cycle that cell 118 can be drained.

Preferably, communications between the tag 140 and 142 and the controller 132 are encrypted. For instance,
10 the UID can be XORED with an eight-bit master key to form a diversified key for encrypting the data. Encryption algorithms such as the data encryption standard (DES) triple DES, asymmetrical encryption standard (AES) or RSA security can be used for the encryption. The RFID
15 controller 132 reads the data and the algorithm in the control system 28 decrypts the data to reveal the stored information.

Other methods could be used to communicate between
20 the cassette 34 and the sterilizer 10. For instance information could be stored magnetically on the cassette 34, such as with a magnetic encoded strip, and be read by a magnetic reader on the sterilizer. Wireless technology is becoming cheaper every day and it is envisioned that
25 the cassette 34 could include an active transmitter and a power source (i.e. a battery) such as powered RFID tags or Bluetooth, 802.11b or other communication standard.

Further, the sterilizer 10 can be set up to
30 communicate back to a central source, such as the manufacturer or distributor thereof, and provide information regarding its performance and the performance of the cassettes 34. Poorly performing cassettes 34 could be identified, as for instance sterilant monitors in the

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sterilizer not detecting sterilant during a cycle thus indicating some failure such as an empty cassette or bad sterilant therein. An improperly manufactured batch of cassettes 34 could then be quickly identified and recalled. Such communication could occur over telephone, pager or wireless telephone networks or over the Internet.

Turning now also to FIGS. 17 and 18, the spent cassette collection box 84 is preferably folded from a single sheet of printed cardboard or other stock. FIG. 17 shows an unfolded blank 150 and FIG. 18 shows the blank 150 folded to form the spent cassette collection box 84.

The blank 150 is divided by a series of fold lines (shown dashed) and cut lines into a bottom panel 152, side panels 154, end panels 156 and top flaps 158. Folding tabs 160 extend laterally from the side panels 154. Additional folding tabs 162 extend laterally from the end panels 156. Barcodes 82 are printed on the side panels 154 in a position to be visible in an upper interior corner of the spent cassette collection box 84 when it is folded into the configuration shown in FIG. 18. A pair of top flap locking tabs 164 extend from the top flaps 158 and fit into slots 166 in the opposing top flap 158 when the box 84 is closed and into slots 168 at the intersection of the bottom panel 152 and side panel 154 when the box 84 is opened.

To fold the box, the folding tabs 160 on the side panels 154 are folded upwardly and then the side panels 154 are folded upwardly, thereby aligning the folding tabs 160 with the intersection between the bottom panel 152 and the end panels 156. The end panels 156 are then folded upwardly and the end panel folding tabs 162 are folded

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downwardly over the folding tabs 160. Locking tabs 170 on the end panel folding tabs 162 fit into slots 172 at the intersection between the bottom panel 152 and end panels 156.

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To place the box 84 into the open position as shown in FIG. 18, the top flaps 158 are folded downwardly to the outside and the locking tabs 164 fitted into the slots 168. Once the box 84 is filled with spent cassettes, the top flaps 158 are folded upwardly over the top and the locking tabs 164 can then be fitted into the slots 166 on the opposing top flaps 158. This unique folding arrangement allows spent cassettes 34 to fall into the open box 84 easily without the top flaps 158 getting in the way and also allows easy closure of the box 84 once it has become filled.

While the invention has been particularly described in connection with specific embodiments thereof, it is to be understood that this is by way of illustration and not of limitation, and that the scope of the appended claims should be construed as broadly as the prior art will permit.

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WHAT IS CLAIMED IS:

1. A method of delivering a liquid sterilant to a sterilizer comprising the steps of:

5 a) piercing a cell of a cassette with a first needle having a first lumen;

b) flowing a gas into the cell to pressurize the cell relative to a pressure within the first lumen and drive the liquid sterilant out of the cell through the
10 first lumen; and

c) flowing the liquid sterilant from the lumen to a vaporizer in the sterilizer.

2. A method according to claim 1 wherein a second
15 lumen through the first needle opens into the cell and further comprising the step of injecting the gas into the cell through the second lumen.

3. A method according to claim 1 and further
20 comprising the steps of piercing the cell with a second needle having a second lumen opening so that the lumen opens into the cell and injecting the gas into the cell through the second lumen.

25 4. A method according to claim 1 wherein the gas is at atmospheric pressure and the first lumen is at a pressure below atmospheric pressure.

5. A method according to claim 1 wherein the gas is
30 at a pressure greater than atmospheric pressure.

6. A method according to claim 1 wherein steps a), b) and c) are repeated with a second cell.

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7. A method according to claim 1 wherein the liquid sterilant comprises hydrogen peroxide.

5 8.. A method according to claim 1 wherein in step a) the needle enters the cell laterally.

9. A method according to claim 1 wherein in step a) the needle enters the cell at an upper portion thereof and travels downwardly therein.

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10. A method according to claim 9 and further comprising the step of positioning the first needle so that the first lumen opens into the cell at or near its lowest point whereby to maximize extraction of liquid
15 sterilant from the cell.

11. A method according to claim 1 and further comprising the step of positioning the first needle so that the first lumen opens into the cell at or near its
20 lowest point whereby to maximize extraction of liquid sterilant from the cell.

12. A method according to claim 1 and further comprising the step of positioning the first needle so
25 that the first lumen opens into the cell at a predetermined vertical position and extracting the liquid sterilant above the predetermined position, such that less than a total amount of liquid sterilant in the cell is thus extracted.

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ABSTRACT

A method of delivering a liquid sterilant to a sterilizer involves piercing a cell of a cassette with a first needle having a first lumen, flowing a gas into the cell to pressurize the cell relative to a pressure within the first lumen and drive the liquid sterilant out of the cell through the first lumen. The liquid sterilant travels from the lumen to a vaporizer in the sterilizer.

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PTO/SB/01 (10-03)
Approved for use through 10/31/2002 OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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DECLARATION AND POWER OF ATTORNEY FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63) ☒ Declaration Submitted with Initial Filing (unexecuted) OR ☐ Declaration Submitted after Initial Filing (Surcharge (37 CFR 1.16(e)) required)	Attorney Docket Number	ASP-5016
	First Named Inventor	Alfredo M. Choperena
	COMPLETE IF KNOWN	
	Application Number	
	Filing Date	March 4, 2004
	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:

METHOD OF DELIVERING LIQUID STERILANT TO A STERILIZER
(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 385(b) of any foreign application(s) for patent or inventor's certificate, or 385(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/SB02B 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, §1.58(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
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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.		
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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.

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☐ A petition has been filed for this unsigned inventor

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(first and middle (if any)) Chopera

Family Name
or Surname Alfredo M.

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Date

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State CA

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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.

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☐ A petition has been filed for this unsigned inventor

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Family Name
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Inventor's
Signature

Date

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Citizenship USA

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Country USA

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NAME OF THIRD INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name
(first and middle (if any))

Family Name
or Surname

Inventor's
Signature

Date

Residence: City

State

Country

Citizenship

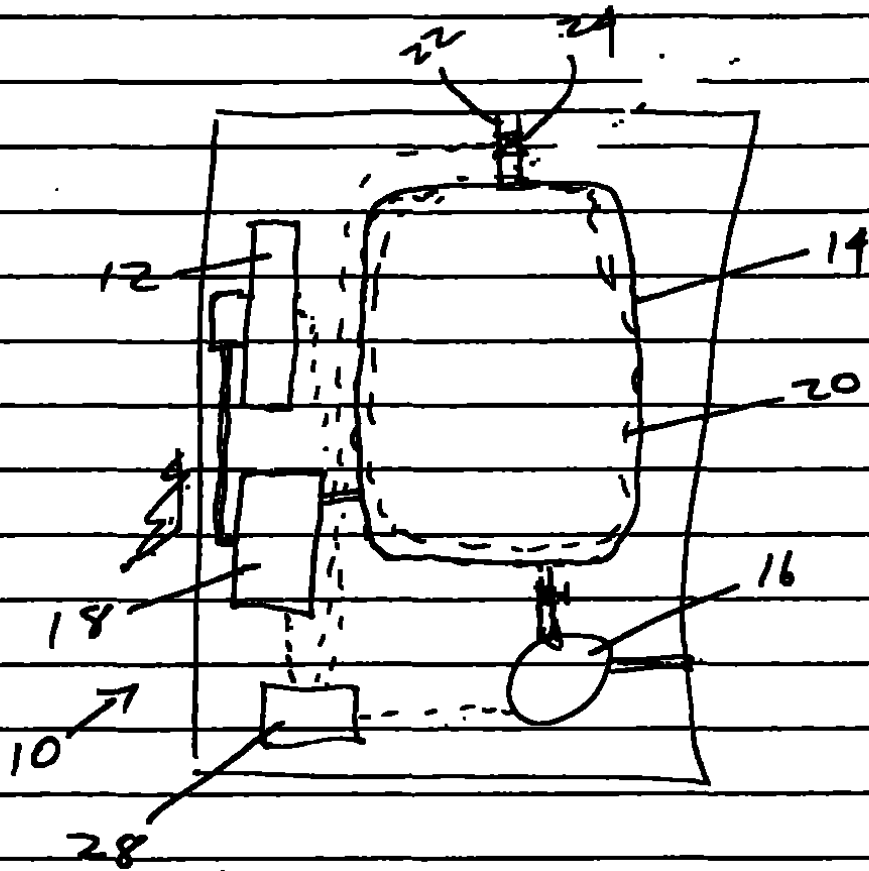
Mailing Address

City

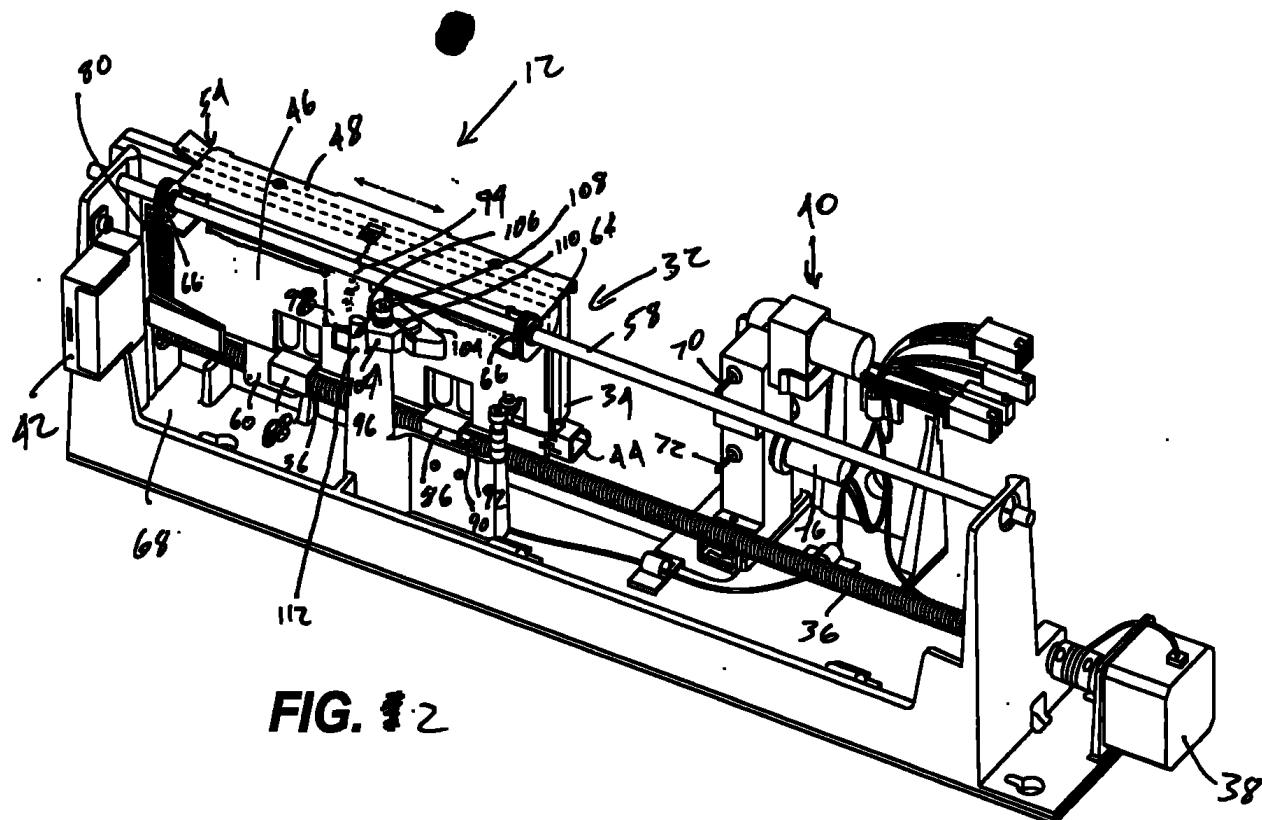
State

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Country



F 16. 1



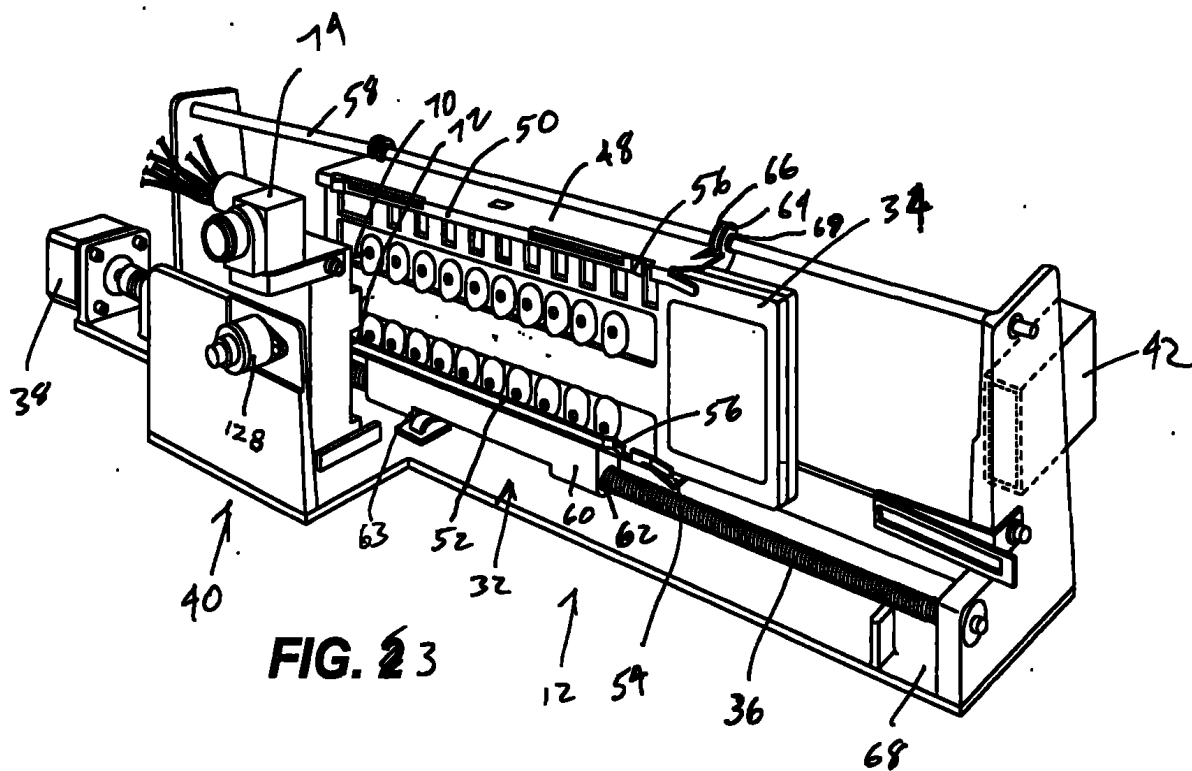
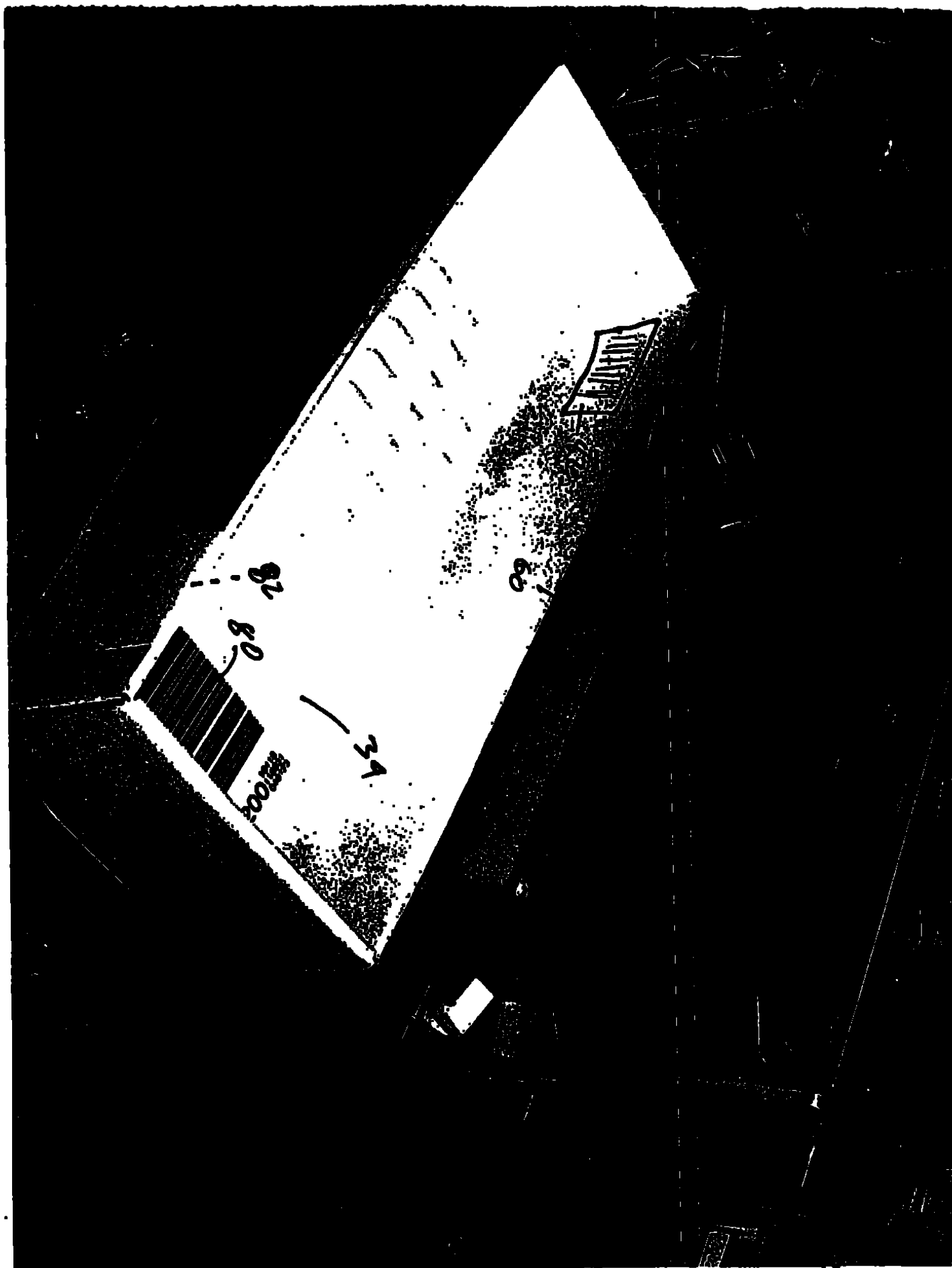
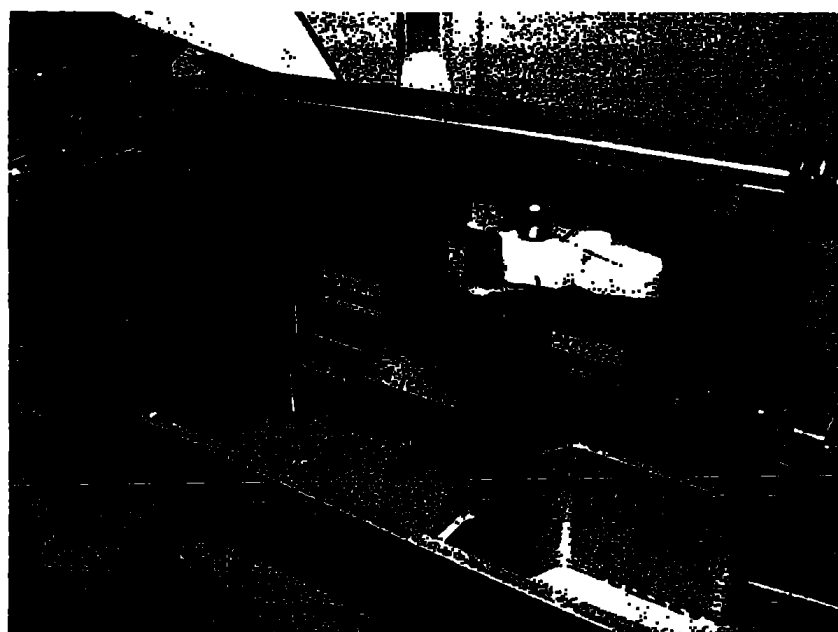


FIG. 23

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Insert Position: detail of slide 1



Nut on lead screw
touches a hard stop.

F165

Barcode start



- Inserted cassette (not shown) pushes flag 1 of carriage to block beam of slot sensor, triggering stepper motor to move the carriage in while scan engine reads barcode on cassette.

FIG. 6

Barcode reading

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- Cassette is being moved in while scan engine (not shown) reads barcode.
- Side clamp holds cassette fixed to carriage.

FIG 7

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Home position

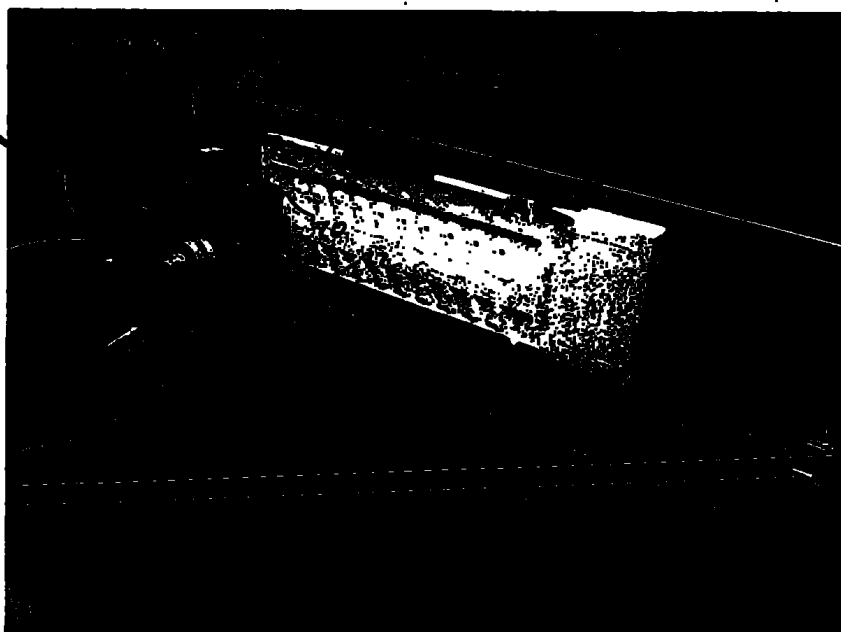


• Trailing edge of
flag 2 just passes
slot sensor.

FIG 2

Cell 1

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• Stepper motor
moves cassette in
5.55 mm from
home to arrive at
cell 1

FIG. 9

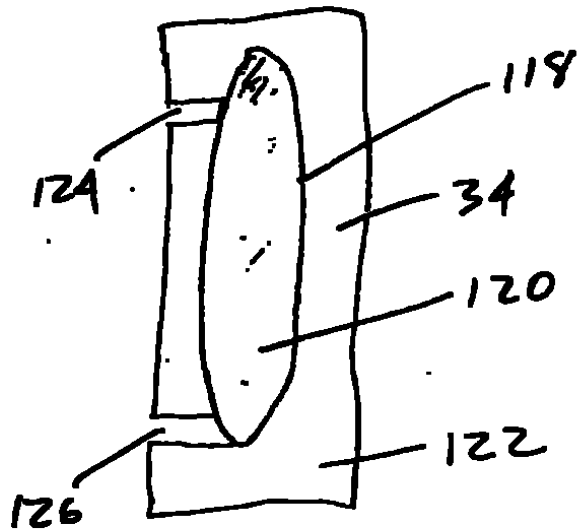
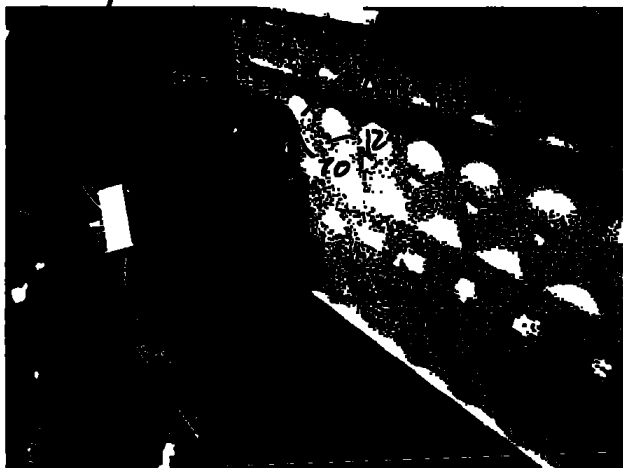


FIG. 10

Cell 1: Injection



- Needles are inside cell 1
- Air pump pressurizes cell through top needle, forcing H_2O_2 out through the bottom needle and valve (not shown), and through tubing connected to vaporizer.
- Injection sequence as follows:
 - T=0 sec: needles fully extend
 - T=2 sec: Turn on air pump and open valve.
 - T=13 sec: turn off air pump
 - T=15 sec: close valve and start to retract needles.

FIG. 11

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Cell 10

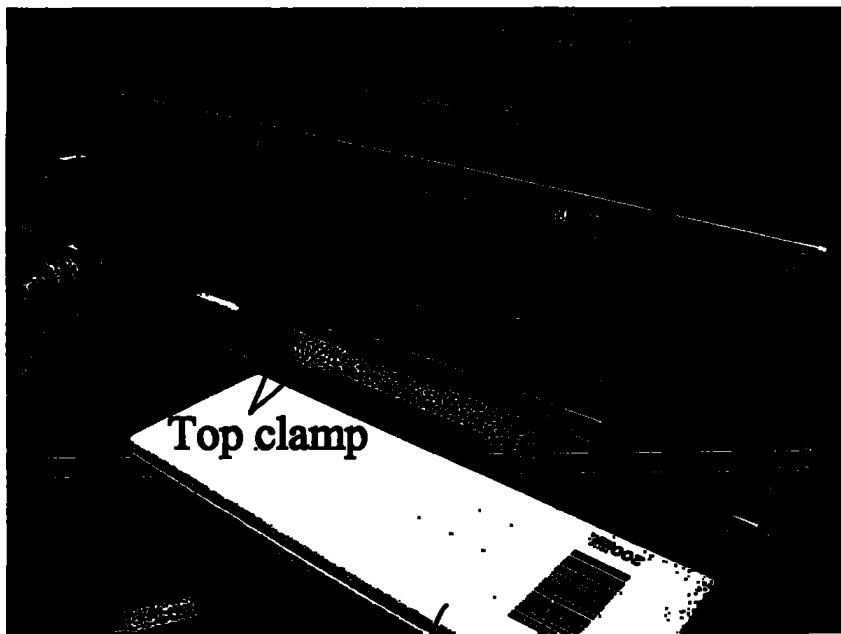


- Stepper motor moves cassette in 15 mm to arrive at the next cell.
- Once at a cell position, injection (described in page 11) takes place.
- The indexing and injection process repeat for all 10 cells.

FIG. 12

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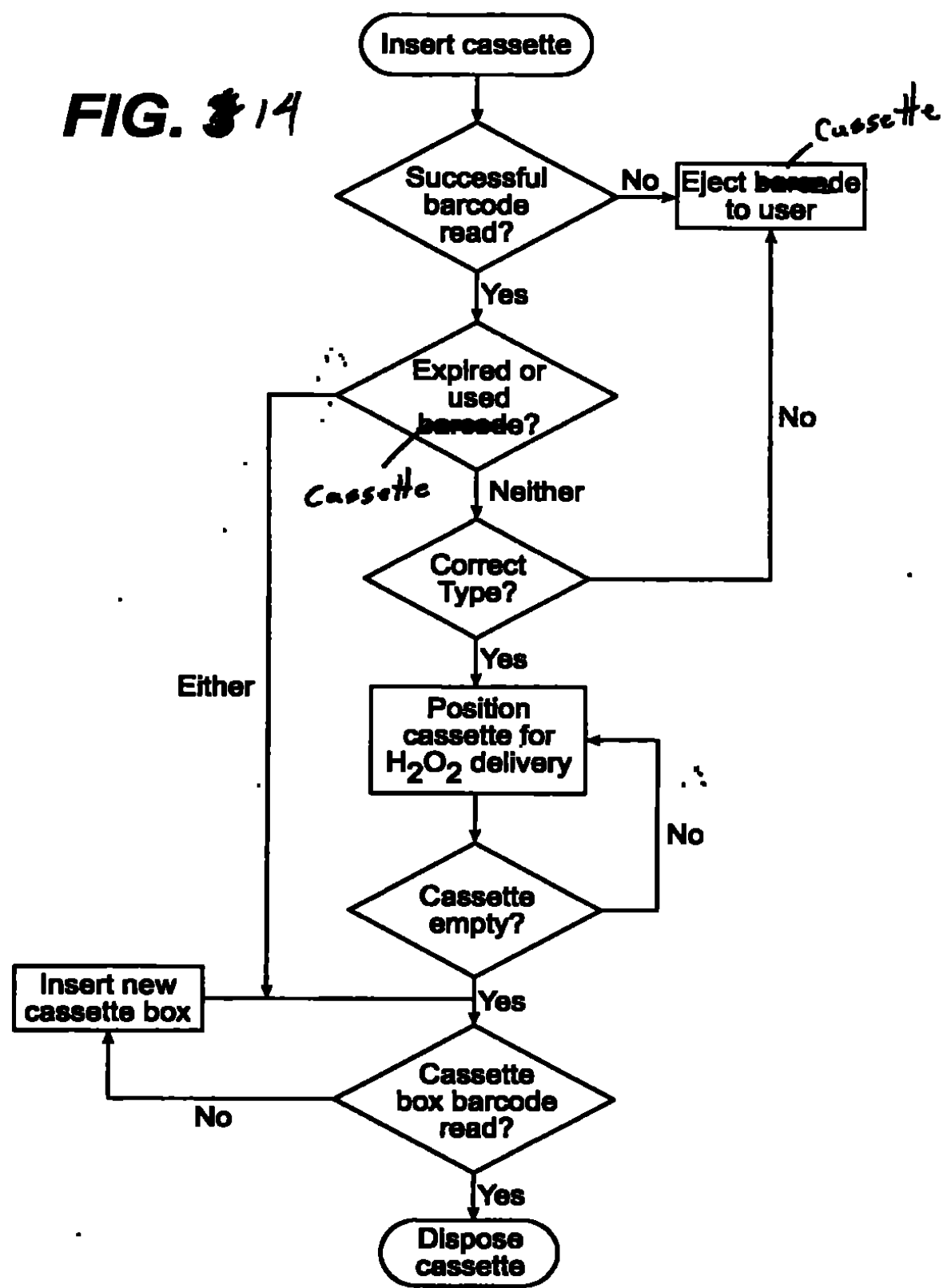
Cassette disposed



- As stepper motor moves carriage out, disposing cam (page1) causes top clamp to rotate and pushes cassette away from carriage.
- Cassette falls into cassette collector box (not shown)

FIG. 13

FIG. 14



Insert Consumable

- Consumable embedded with RFID tag is inserted into STERRAD NX delivery assembly

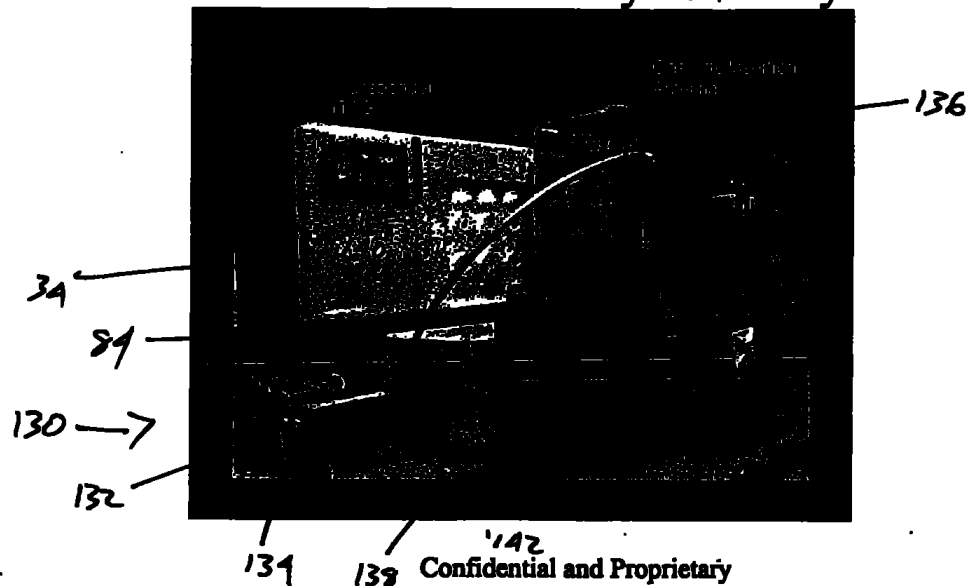


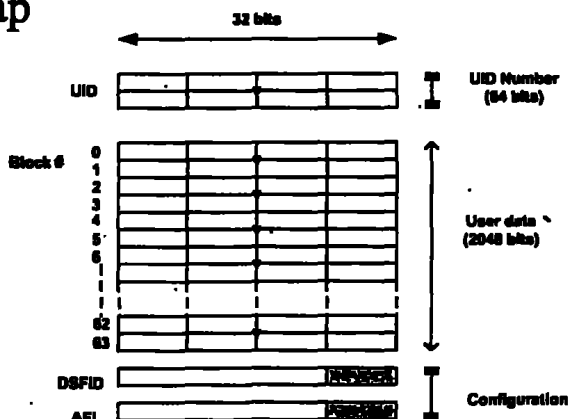
FIG. 15

Confidential and Proprietary
Information of ASP

103

RFID Transponder (Tag)

- RFID Tag RI-103-112A is embedded on polymer film during consumable manufacturing and peroxide filling process.
- Supports ISO 15693-2, -3 standard
- Transponder memory map
 - 64 bit UID factory locked
 - 2048 bit user data memory



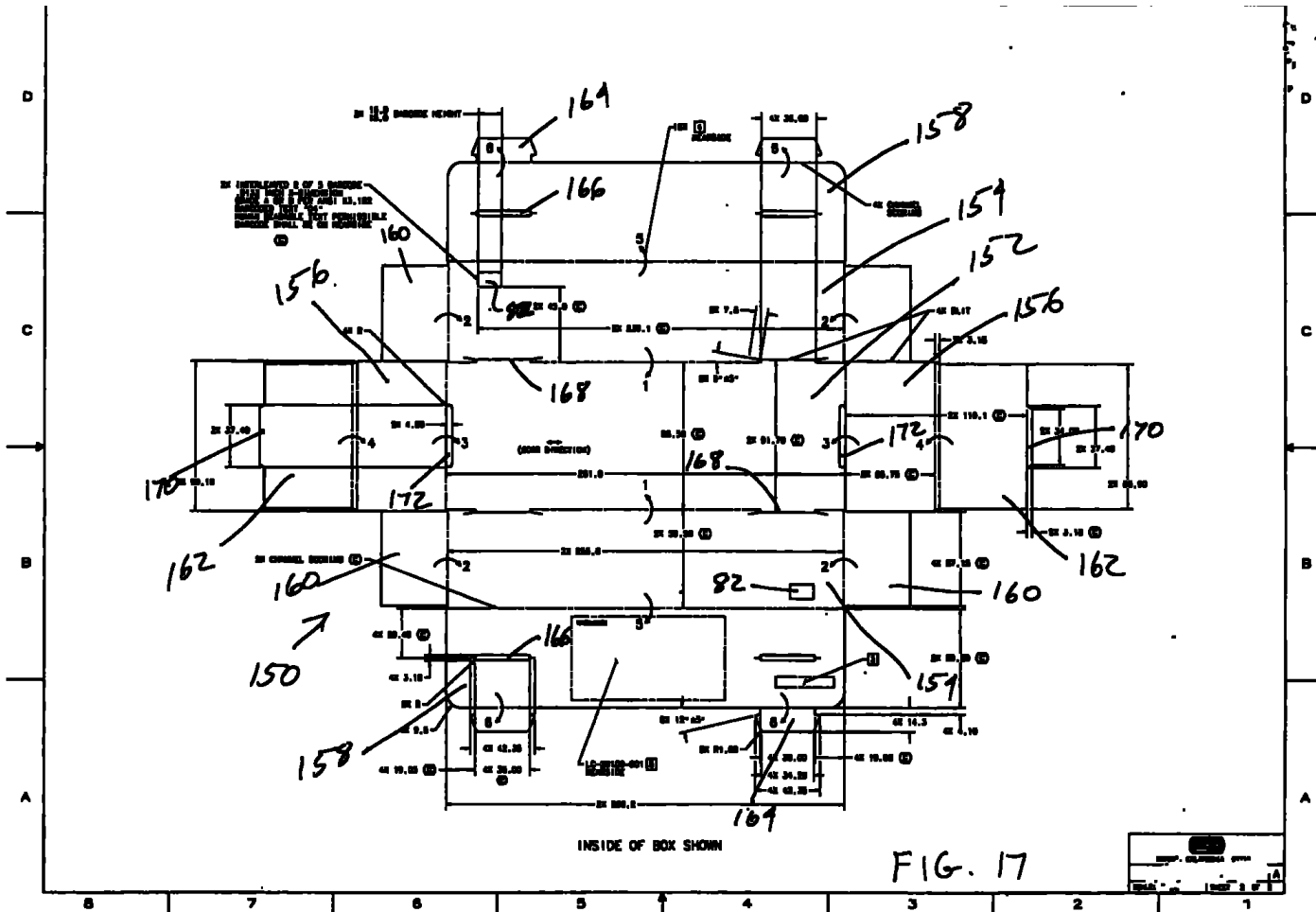
Confidential and Proprietary
Information of ASP

Fig. 16

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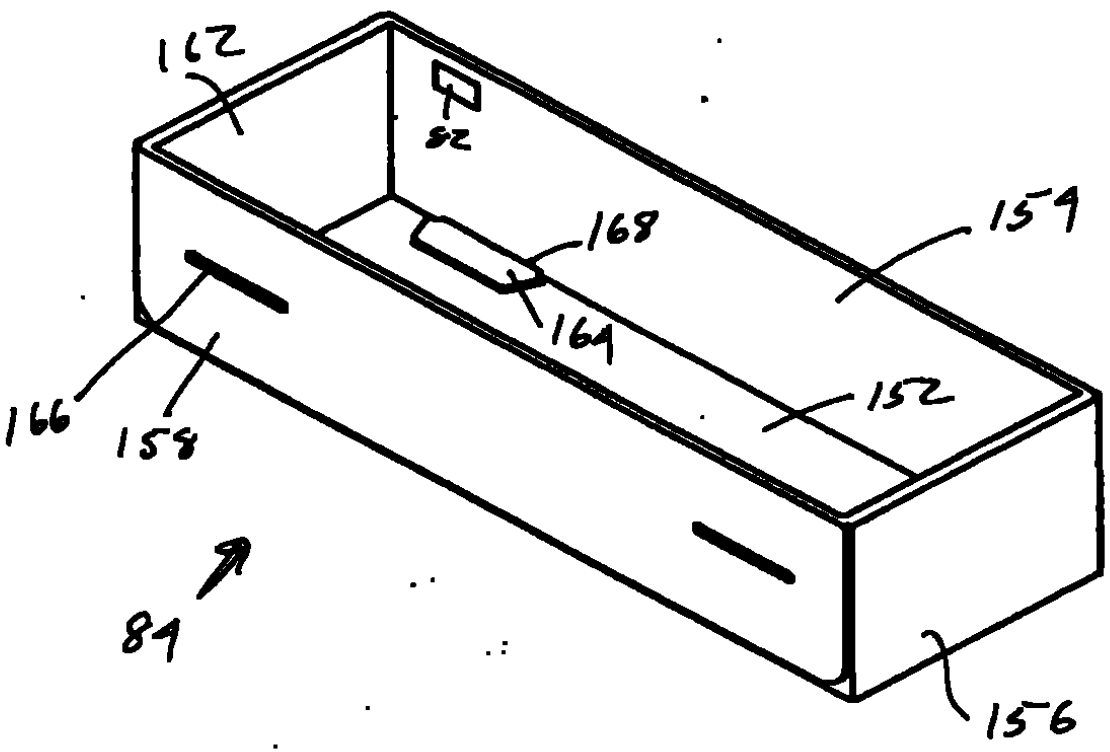


FIG. 18