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

2837/P.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES
E. S. D.

Ref.: Expediente No. 05-051.944
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, en respuesta al oficio No. 13040 notificado por fijación en lista el día 23 de junio de 2005, atentamente me permito presentar los siguientes documentos.

1. Artes finales en tamaño 12 x 12 centímetros (por duplicado) de la figura característica.

2. Copias certificadas de la solicitud de patente números 10/856,435 presentada en Estados Unidos de América el día 28 de mayo de 2004 y 10/978,034 presentada en Estados Unidos de América el día 29 de octubre de 2004, con la debida traducción de lo pertinente.

3. Anexo (2) documentos de cesión suscritos por el inventor a favor de mi mandante.

Sobre el particular, es importante resaltar que de conformidad con las normas legales vigentes, artículo 1 de la Resolución 210 de 2001, expedida por el Superintendente de Industria y Comercio y artículo 2 de la Convención de la Haya, el documento en inglés que se pretenda aportar como parte de los trámites de propiedad industrial ante la Superintendencia de Industria y Comercio no requieren traducción. Por otro lado, la legalización consular y/o diplomática de los documentos expedidos en el extranjero no es necesaria. Por lo tanto, los

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

documentos de cesión anexos a este memorial son válidamente presentados en idioma inglés y con la correspondiente Apostilla.

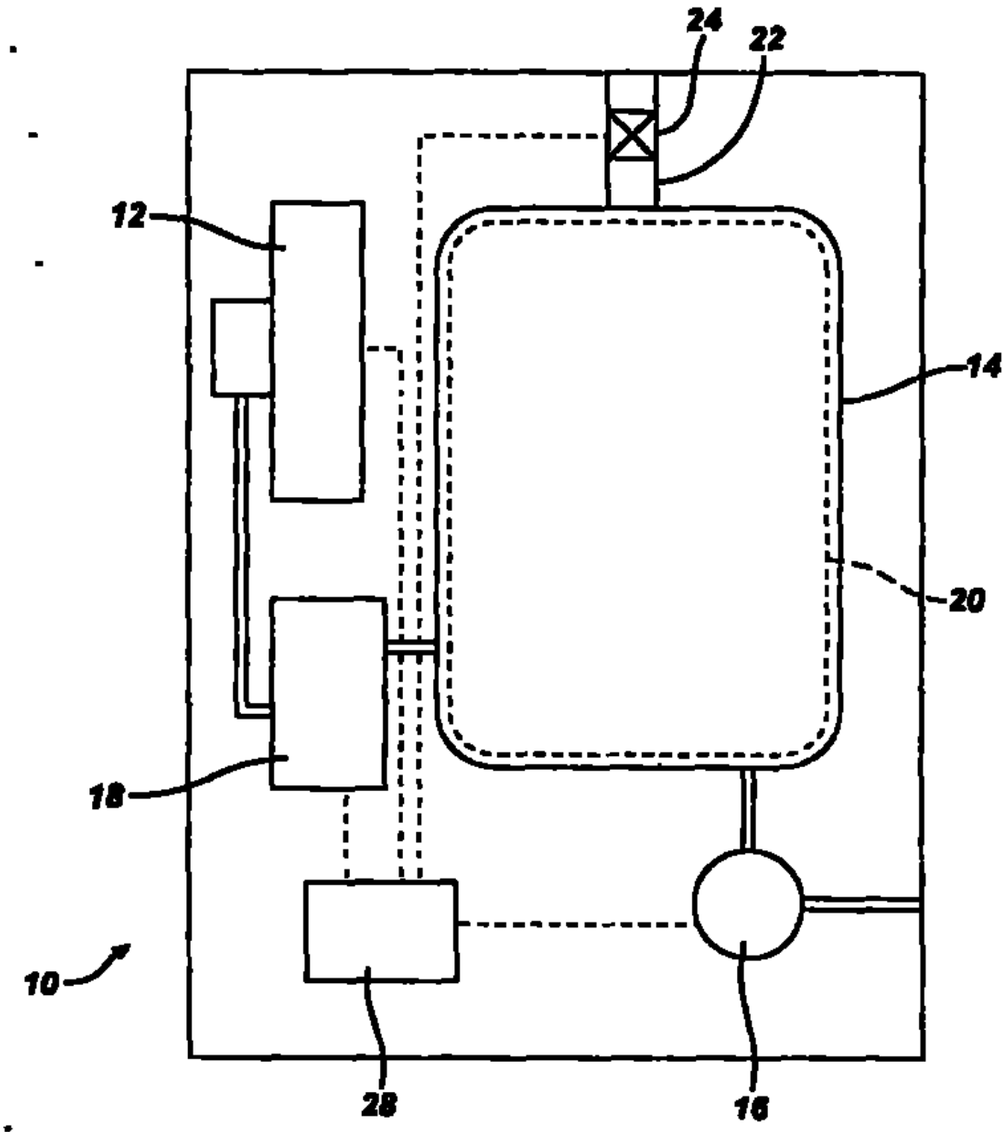
Finalmente, en relación con el requerimiento de ese despacho, de conformidad con el cual se debe presentar el extracto de la patente, me permito informar que fue adjuntado ante ese despacho mediante solicitud radicada el 27 de mayo de 2005.

Espero con esto haber dado cabal cumplimiento a lo solicitado por ese despacho y de conformidad con lo indicado en los artículos 3°, inciso 3; 35, inciso 2 y 59, inciso 2 del CCA, al analizar este memorial, atentamente ruego se traten todas las cuestiones planteadas con motivo del mismo.

Señor Superintendente,

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

FIG. 1



73
72

APOSTILLE

(CONVENTION DE LA HAYE DU 5 OCTOBRE 1961)

1. COUNTRY: UNITED STATES OF AMERICA

2. THIS PUBLIC DOCUMENT HAS BEEN SIGNED BY:
CHRISTINA A CLICKNER

3. ACTING IN THE CAPACITY OF:
NOTARY PUBLIC OF NEW JERSEY

4. BEARS THE SEAL/STAMP OF:
CHRISTINA A CLICKNER, NOTARY

CERTIFIED

5. AT TRENTON, NEW JERSEY

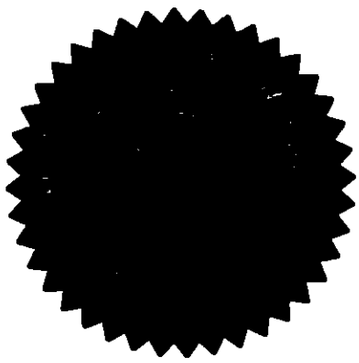
6. THE 8TH DAY OF JUNE 2005

7. BY: John E McCormac, CPA, NEW JERSEY TREASURER

8. NO. A228748

9. SEAL/STAMP:

10. SIGNATURE



ASP 5018 CO

CERTIFICATION

I hereby certify that I have compared the attached document with the original, and that such said document is a true copy of the original Assignment document as filed in the U.S. Patent Office in connection with USSN 10/978,034 filed OCTOBER 29, 2004.

Christina A. Clickner
(Notary Public of New Jersey)
My Commission Expires:
March 2, 2010

DOCKET NO. ASP-5018 CIP
Sole Inventor

A S S I G N M E N T

Serial No.
Filed October 29, 2004

WHEREAS, James P. Kohler, residing at 25221 Champlain Road, Laguna Hills, CA 92653 (hereinafter called "Assignor"), has made certain new and useful inventions or discoveries relating to

CASSETTE ASSEMBLY

for which he has on the 5th day of Nov., 2004 executed an application for Letters Patent of the United States; and

WHEREAS, Ethicon, Inc., a corporation of the State of New Jersey, (hereinafter called "Assignee"), is desirous of acquiring the entire right, title, and interest therein;

NOW, THEREFORE, BE IT KNOWN that for and in consideration of the sum of One Dollar and other valuable considerations to him moving, the receipt of which is hereby acknowledged, Assignor has sold, assigned, and transferred, and does hereby sell, assign, and transfer unto said Assignee the entire right, title, and interest in and to all said inventions and discoveries disclosed in said application whose identification above by serial number and filing date, when available is hereby authorized, and in and to said application, all substitutions, divisions, and continuations thereof, and in and to all Letters Patent, United States and foreign, that may be granted for said inventions and discoveries, and in and to all extensions, renewals, and reissues thereof, the same to be held and enjoyed by said Assignee, its successors and assigns, as fully and entirely as the same would have been held and enjoyed by Assignor if this Assignment and sale had not been made;

And Assignor hereby authorizes and requests the Commissioner of Patents of the United States to issue said Letters Patent in accordance with this Assignment;

And for the consideration aforesaid, Assignor covenants and agrees with said Assignee that he has a full and unencumbered title to the inventions and discoveries above described and hereby assigned, which title he warrants unto said Assignee, its successors and assigns;

And for the consideration aforesaid, Assignor further covenants and agrees that he will, whenever requested, but without cost to him promptly communicate to said Assignee or its representatives any facts known to him relating to said inventions and discoveries, testify in any interference or legal proceedings involving said inventions and discoveries, and execute any additional papers that may be necessary to enable said Assignee or its representatives, successors, nominees, or assigns to secure full and complete protection for the said inventions and discoveries or that may be necessary to vest in said Assignee the complete title to the said inventions and discoveries and patents hereby conveyed and to enable it to record said title.

IN TESTIMONY WHEREOF, Assignor has hereunto set his hand and seal this 5 day of Nov . 2004.

James P. Kohler (L.S.)

STATE OF) California
) ss.
COUNTY OF) Orange

BE IT REMEMBERED, That on this 5th day of November 2004, before me, a Notary Public, personally appeared James P. Kohler, who I am satisfied is the person named in and who executed the foregoing instrument in my presence, and I having first made known to him the contents thereof, he did acknowledge that he signed, sealed, and delivered the same as his voluntary act and deed for the uses and purposes therein expressed.

Notary Public

ROSETTE V. BERBERIAN
Commission # 1437836
Notary Public - California
Orange County
My Comm. Expires Sep 3, 2007

77
76

APOSTILLE

(CONVENTION DE LA HAYE DU 5 OCTOBRE 1961)

1. COUNTRY: UNITED STATES OF AMERICA

2. THIS PUBLIC DOCUMENT HAS BEEN SIGNED BY:
CHRISTINA A CLICKNER

3. ACTING IN THE CAPACITY OF:
NOTARY PUBLIC OF NEW JERSEY

4. BEARS THE SEAL/STAMP OF:
CHRISTINA A CLICKNER, NOTARY

CERTIFIED

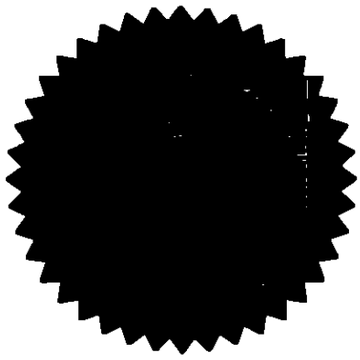
5. AT TRENTON, NEW JERSEY

6. THE 8TH DAY OF JUNE 2005

7. BY: John E McCormac, CPA, NEW JERSEY TREASURER

8. NO. A228749

9. SEAL/STAMP:



10. SIGNATURE

ASP 5018 CO

CERTIFICATION

I hereby certify that I have compared the attached document with the original, and that such said document is a true copy of the original Assignment document as filed in the U.S. Patent Office in connection with USSN 10/856,435 filed MAY 28, 2004.

Christina A. Clickner
(Notary Public of New Jersey)
My Commission Expires:
March 2, 2010

79
78

DOCKET NO. ASP-5018
Sole Inventor

A S S I G N M E N T

Serial No.
Filed May 28, 2004

WHEREAS, James P. Kohler, residing at 25221 Champlain Road, Laguna Hills, CA 92653 (hereinafter called "Assignor"), has made certain new and useful inventions or discoveries relating to

CASSETTE WITH ENCODED LUMEN CLAIM

for which he has on the 16th day of June, 2004 executed an application for Letters Patent of the United States; and

WHEREAS, Ethicon, Inc., a corporation of the State of New Jersey, (hereinafter called "Assignee"), is desirous of acquiring the entire right, title, and interest therein;

NOW, THEREFORE, BE IT KNOWN that for and in consideration of the sum of One Dollar and other valuable considerations to him moving, the receipt of which is hereby acknowledged, Assignor has sold, assigned, and transferred, and does hereby sell, assign, and transfer unto said Assignee the entire right, title, and interest in and to all said inventions and discoveries disclosed in said application whose identification above by serial number and filing date, when available is hereby authorized, and in and to said application, all substitutions, divisions, and continuations thereof, and in and to all Letters Patent, United States and foreign, that may be granted for said inventions and discoveries, and in and to all extensions, renewals, and reissues thereof, the same to be held and enjoyed by said Assignee, its successors and assigns, as fully and entirely as the same would have been held and enjoyed by Assignor if this Assignment and sale had not been made;

And Assignor hereby authorizes and requests the Commissioner of Patents of the United States to issue said Letters Patent in accordance with this Assignment;

And for the consideration aforesaid, Assignor covenants and agrees with said Assignee that he has a full and unencumbered title to the inventions and discoveries above described and hereby assigned, which title he warrants unto said Assignee, its successors and assigns;

And for the consideration aforesaid, Assignor further covenants and agrees that he will, whenever requested, but without cost to him promptly communicate to said Assignee or its representatives any facts known to him relating to said inventions and discoveries, testify in any interference or legal proceedings involving said inventions and discoveries, and execute any additional papers that may be necessary to enable said Assignee or its representatives, successors, nominees, or assigns to secure full and complete protection for the said inventions and discoveries or that may be necessary to vest in said Assignee the complete title to the said inventions and discoveries and patents hereby conveyed and to enable it to record said title.

IN TESTIMONY WHEREOF, Assignor has hereunto set his hand and seal this 16 day of June . 2004.

James P. Kohler (L.S.)

STATE OF California
) ss.
COUNTY OF Orange

BE IT REMEMBERED, That on this 16th day of June, 2004, before me, a Notary Public, personally appeared James P. Kohler, who I am satisfied is the person named in and who executed the foregoing instrument in my presence, and I having first made known to him the contents thereof, he did acknowledge that he signed, sealed, and delivered the same as his voluntary act and deed for the uses and purposes therein expressed.

Notary Public

Commission # 1457884
Notary Public - California
Orange County
My Comm. Expires Sep 8, 2007

Fig 81: EXPLAIN
FLUORESCENCE

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

Mayo 16 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: 10/856,435

Fecha de Presentación: 28 de mayo 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

NOVEDAD DE LA INVENCION

REIVINDICACIONES

1.- Un cartucho para un esterilizador, el cartucho comprende: un cuerpo; una o más celdas en el cuerpo, por lo menos una de una o más celdas contiene una cantidad de esterilizante líquido; y un código de barras asociado con el cartucho, el código de barras tiene codificado en el mismo una cláusula de lumen.

2.- El cartucho de conformidad con la reivindicación 1, caracterizado además porque el código de barras tiene codificado en el mismo un identificador para un tipo o modelo de esterilizador al cual está relacionada la cláusula de lumen.

3.- El cartucho de conformidad con la reivindicación 1, caracterizado además porque el esterilizante comprende solución de peróxido de hidrógeno.

4.- El cartucho de conformidad con la reivindicación 1, caracterizado además porque la cláusula de lumen especifica una longitud y diámetro interno de un lumen.

5.- El cartucho de conformidad con la reivindicación 4, caracterizado además porque la cláusula de lumen especifica un material del cual está construido el lumen.

6.- El cartucho de conformidad con la reivindicación 1,

caracterizado además porque el código de barras tiene codificado en el mismo una longitud y un diámetro interno para la cláusula de lumen.

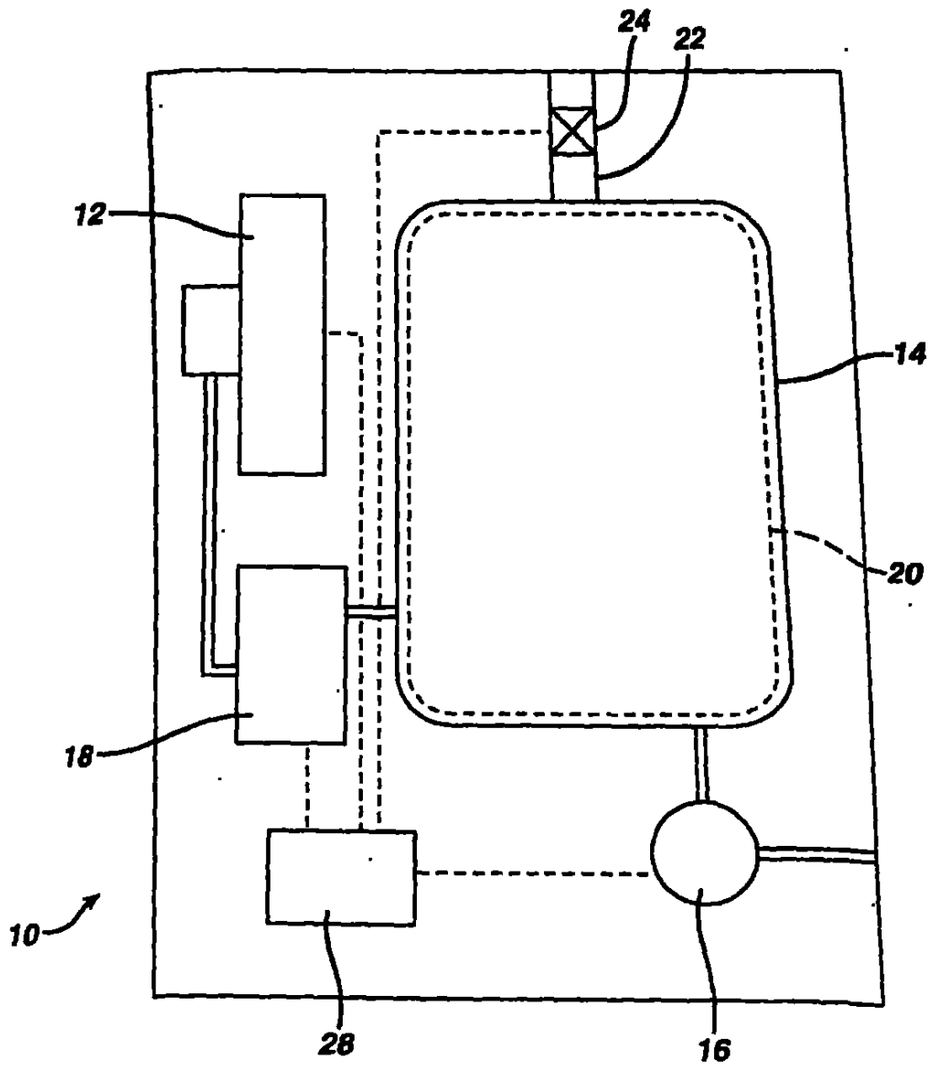
7.- El cartucho de conformidad con la reivindicación 6, caracterizado además porque el código de barras tiene codificado en el mismo un material para la cláusula de lumen.

8.- El cartucho de conformidad con la reivindicación 1, caracterizado además porque el código de barras está en una etiqueta fijada al cuerpo.

9.- El cartucho de conformidad con la reivindicación 1, caracterizado además porque el código de barras está impreso en el cuerpo.

10.- El cartucho de conformidad con la reivindicación 1, caracterizado además porque comprende una pluralidad de las celdas.

FIG. 1



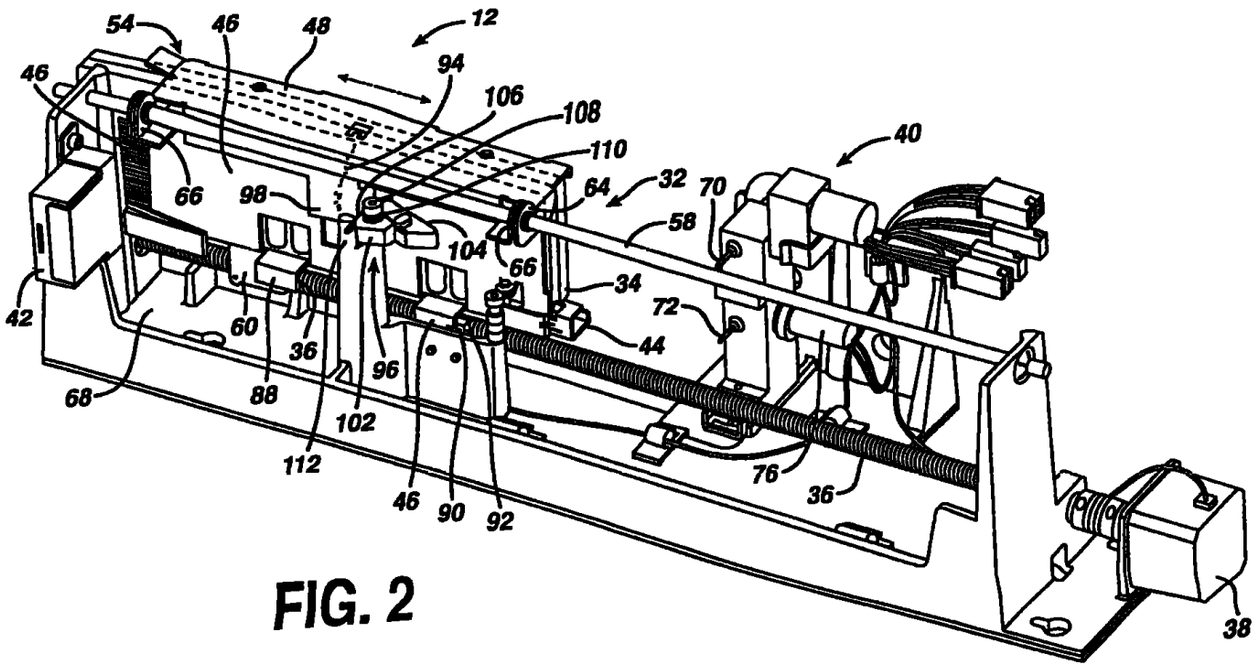

54
46
48
12
94
106
108
110
40
46
66
98
64
32
70
58
104
66
34
72
42
60
36
44
96
68
88
102
112
46
90
92
76
36
38

FIG. 2

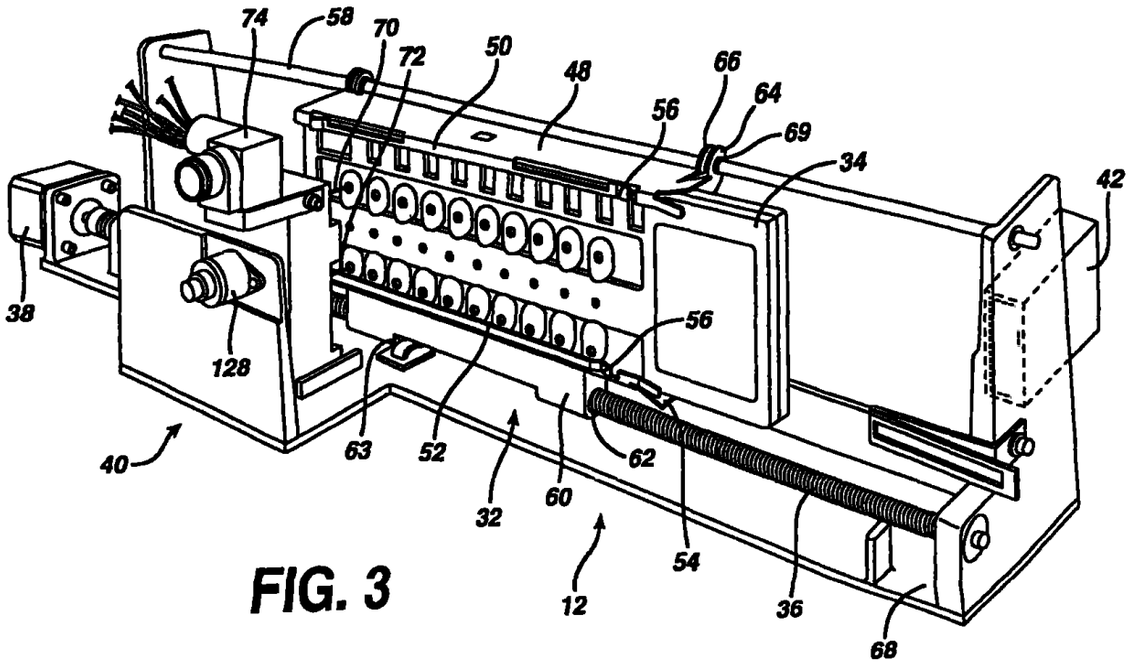

74
58
70
72
50
48
66
64
69
34
42
56
38
128
56
40
63
52
62
32
60
54
12
36
68

FIG. 3

FIG. 4

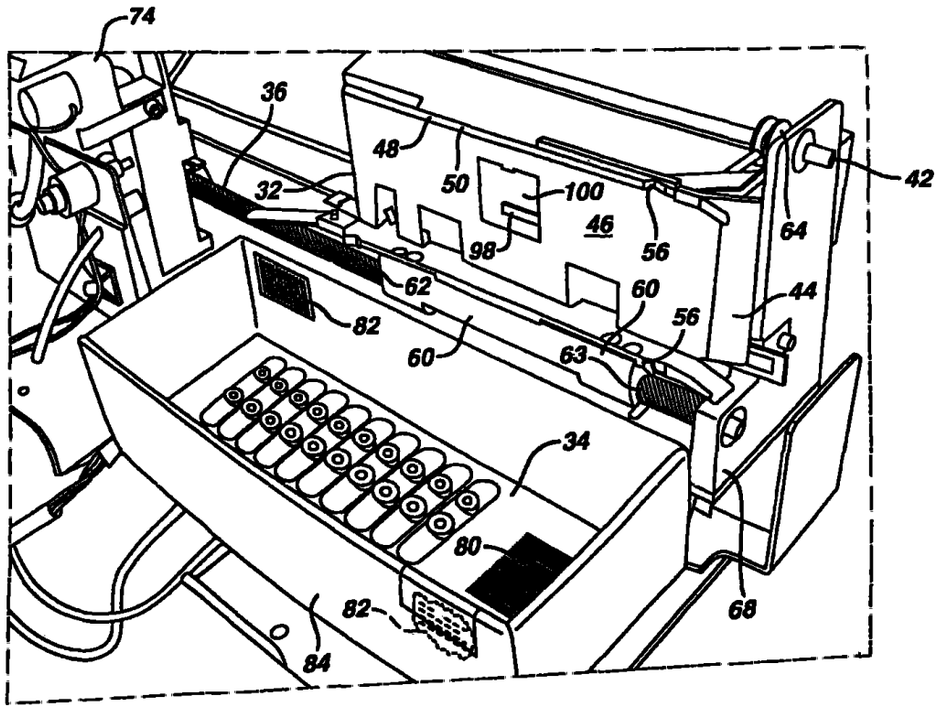


FIG. 5

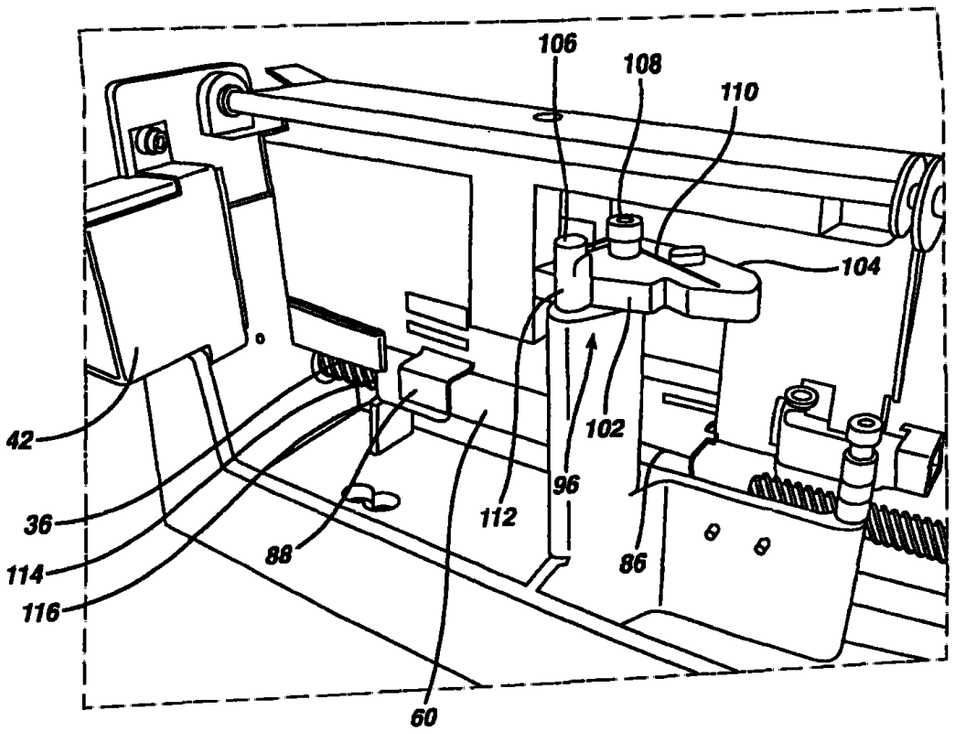


FIG. 6

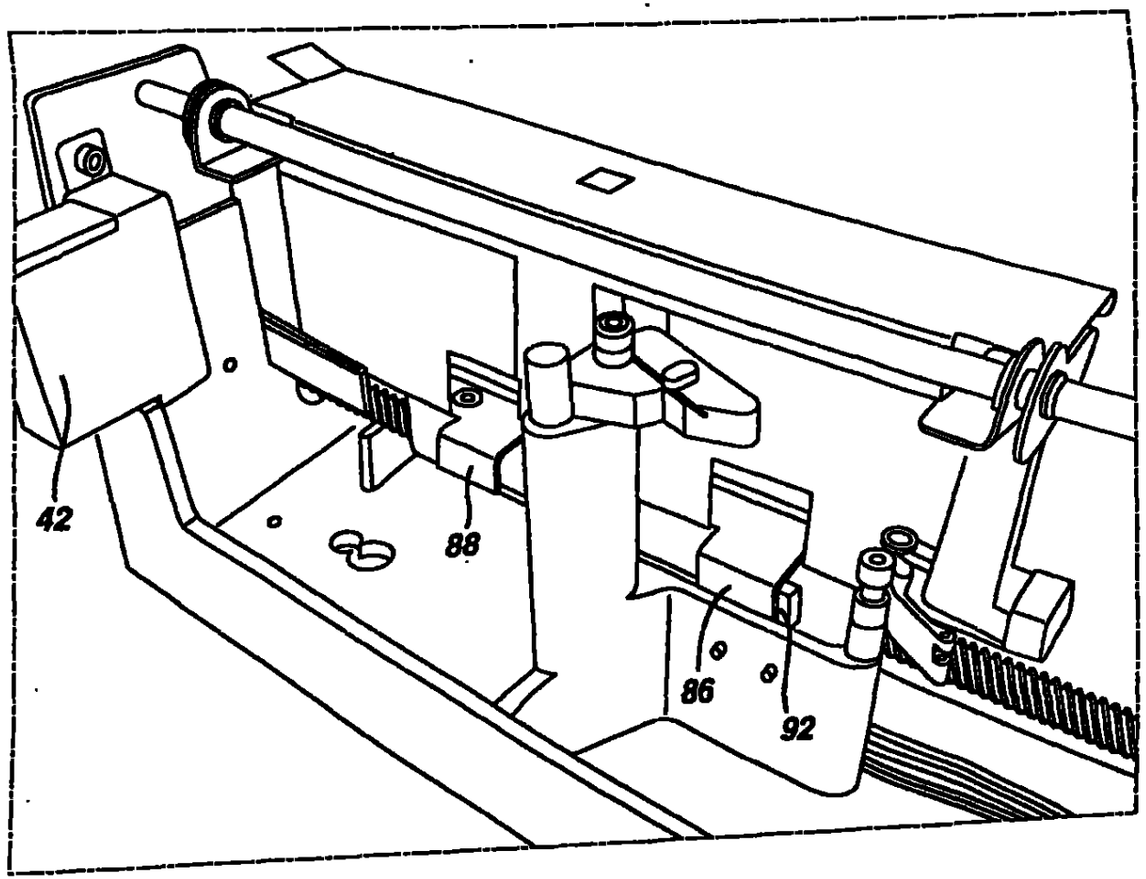


FIG. 7

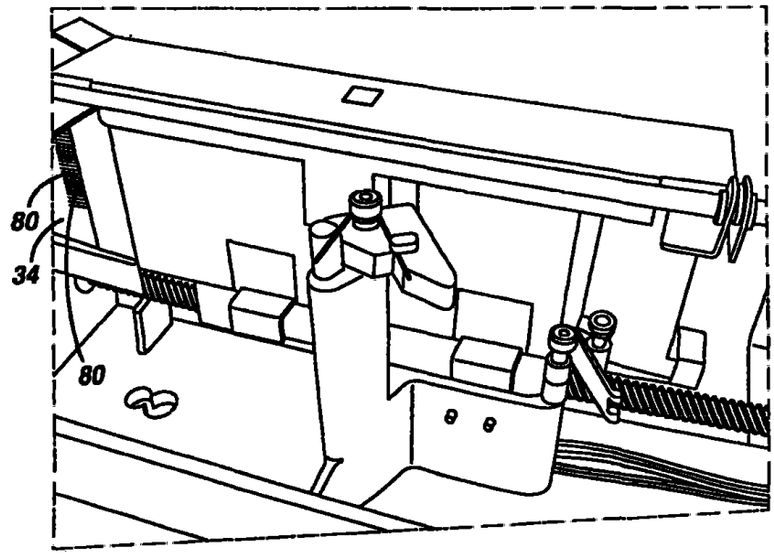
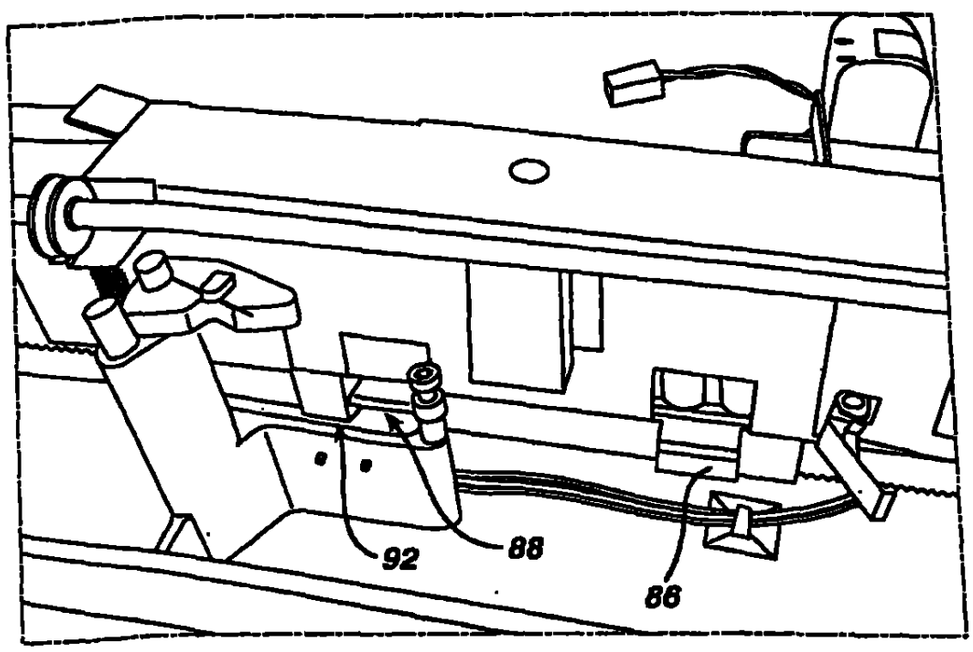


FIG. 8



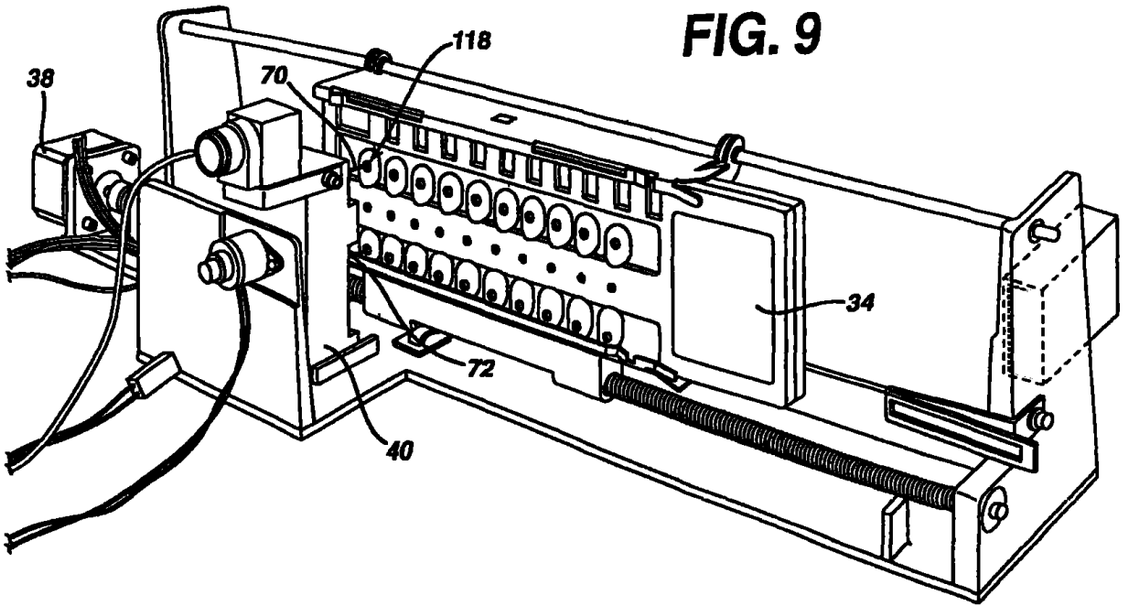


FIG. 9

FIG. 10

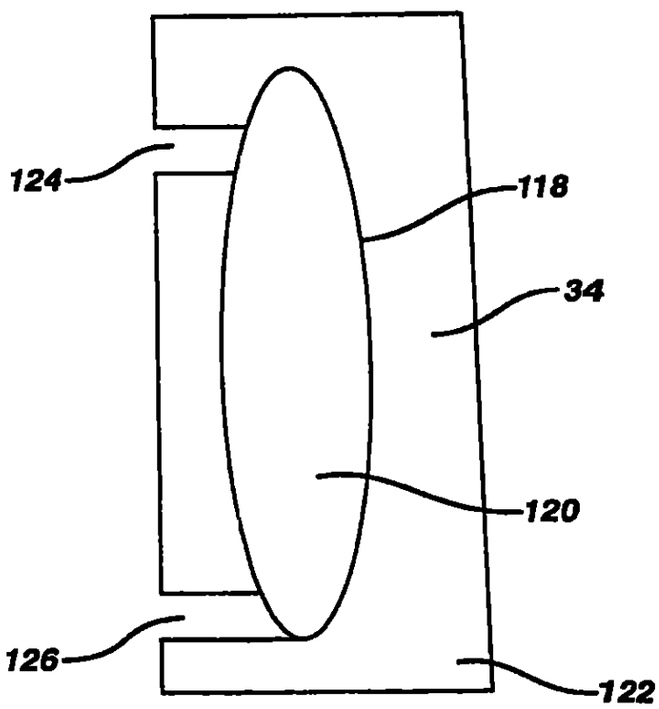


FIG. 11

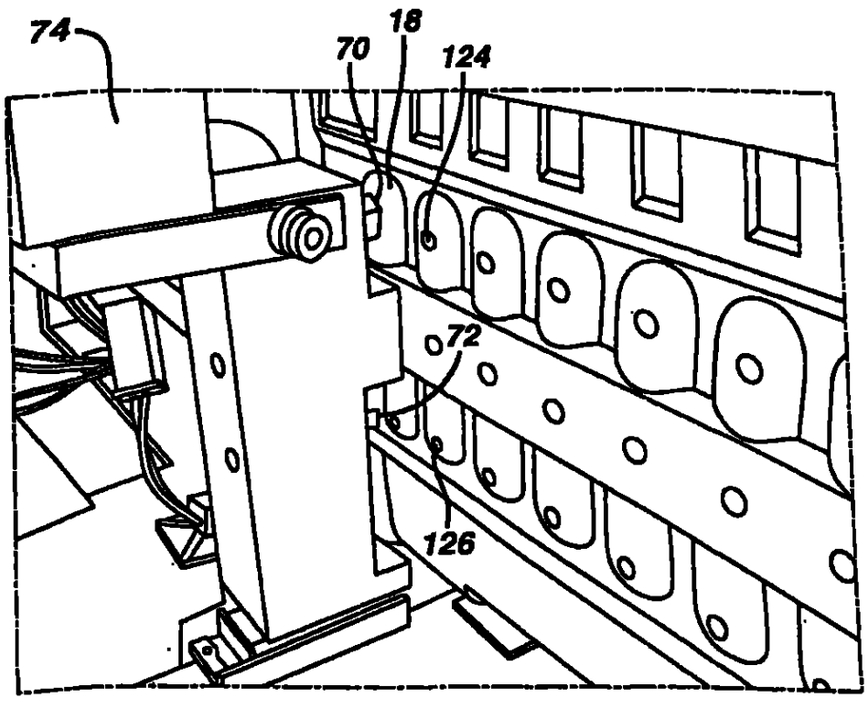


FIG. 12

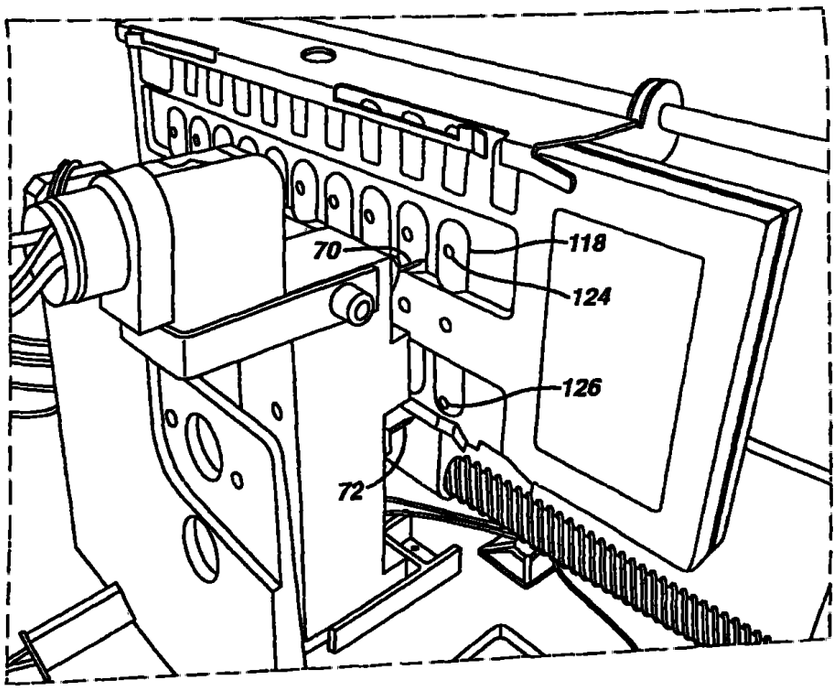


FIG. 13

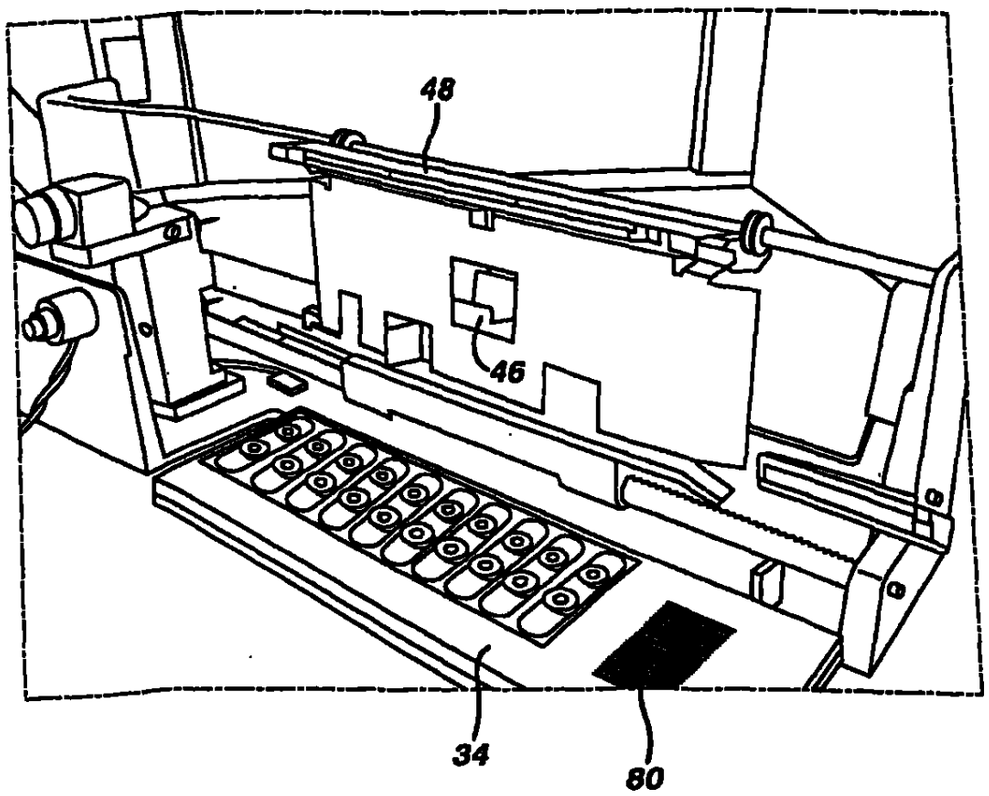


FIG. 14

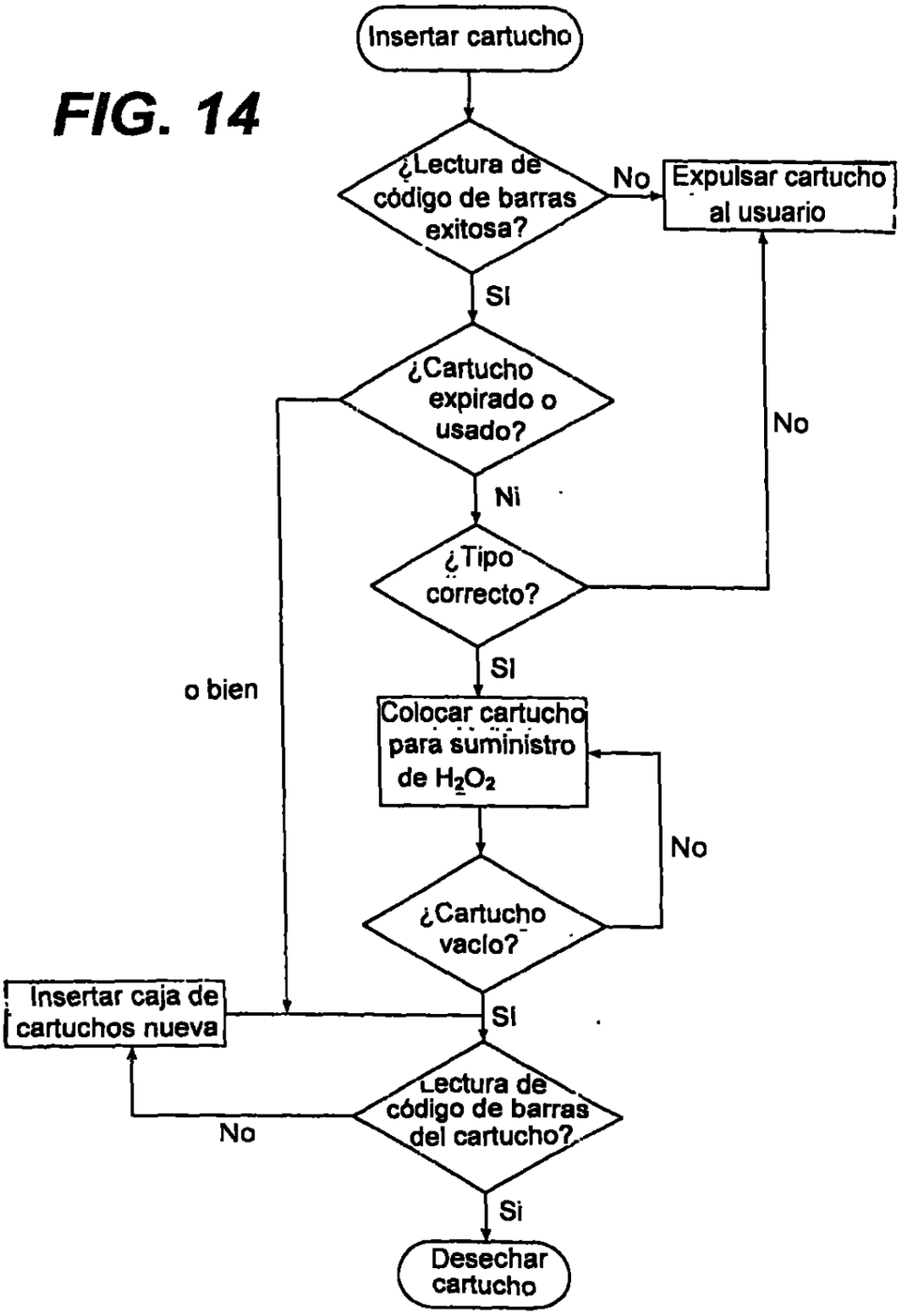

Insertar cartucho
¿Lectura de código de barras exitosa?
No
Expulsar cartucho al usuario
Sí
¿Cartucho expirado o usado?
No
Ni
¿Tipo correcto?
Sí
o bien
Colocar cartucho para suministro de H_2O_2
No
¿Cartucho vacío?
Insertar caja de cartuchos nueva
Sí
Lectura de código de barras del cartucho?
No
Si
Desechar cartucho

FIG. 15

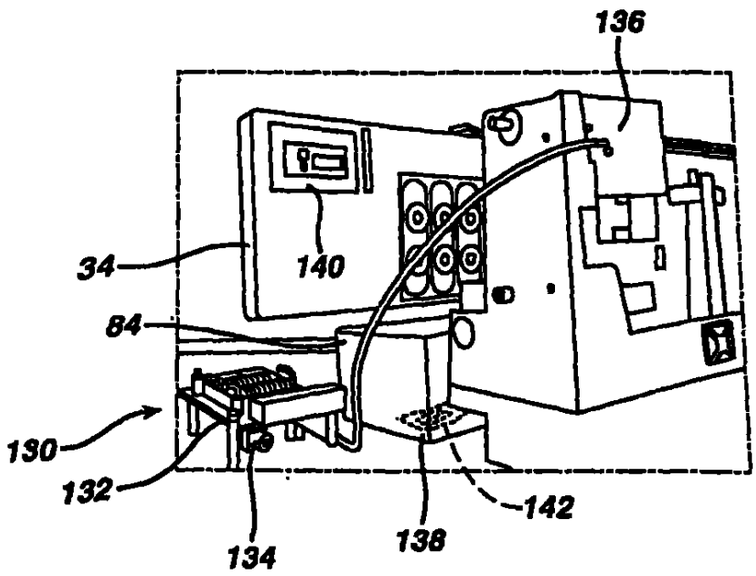


FIG. 16

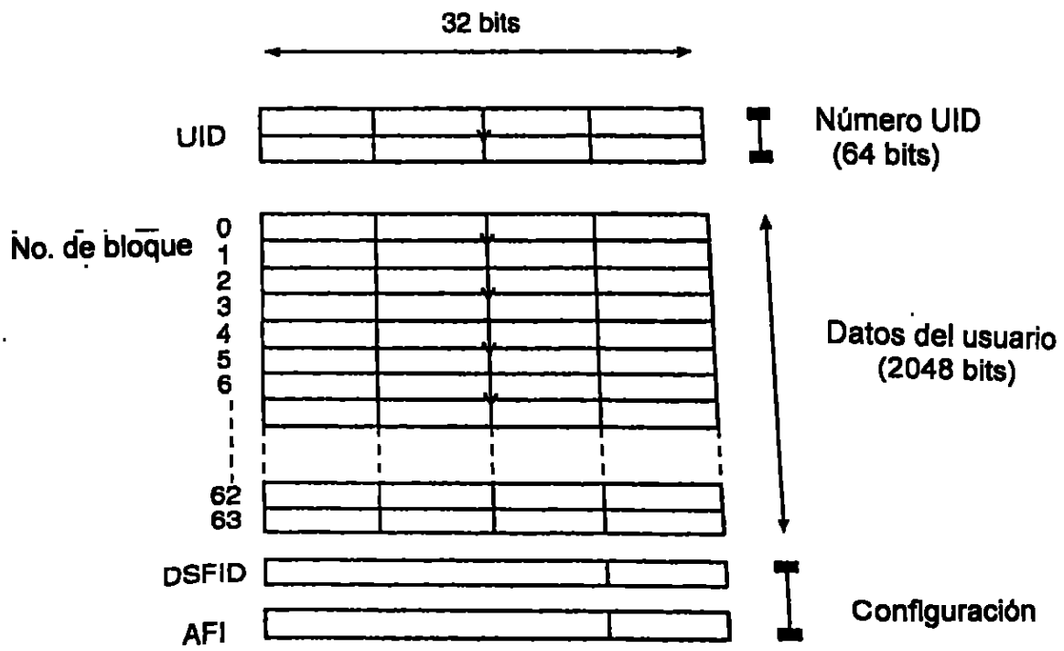

32 bits
UID
Número UID
(64 bits)
No. de bloque
0
1
2
3
4
5
6
62
63
Datos del usuario
(2048 bits)
DSFID
AFI
Configuración

FIG. 17

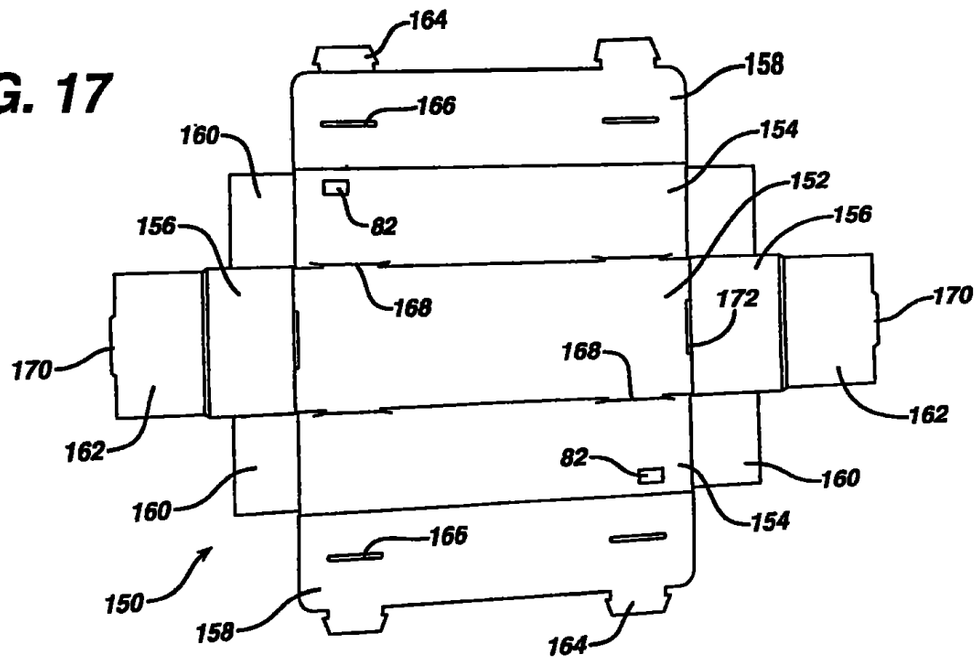
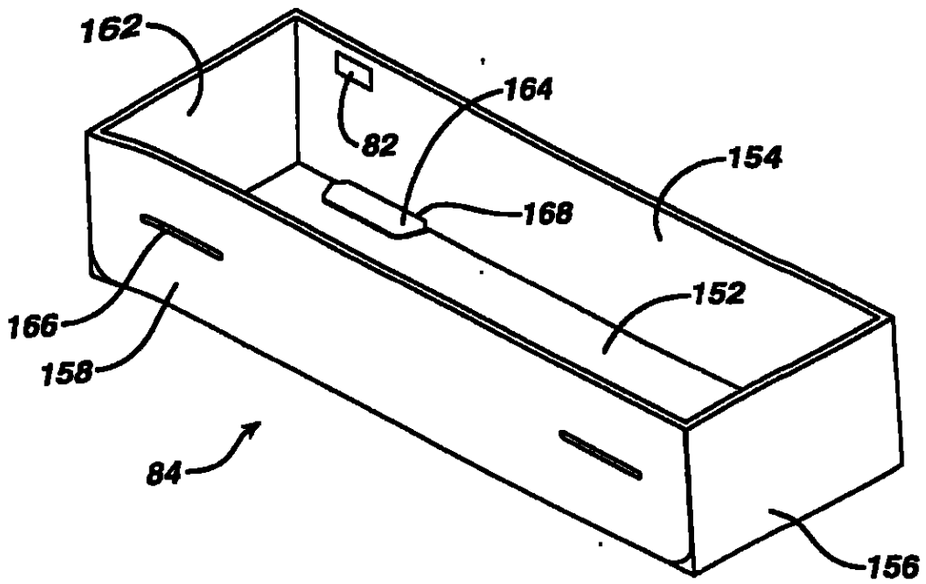
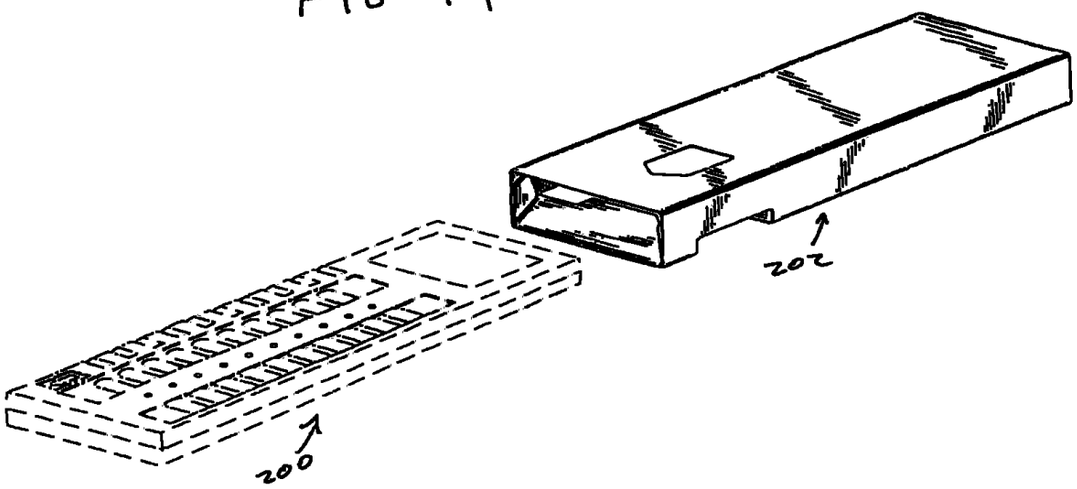

164
158
166
160
154
152
82
156
156
168
172
170
170
168
162
162
82
160
160
154
166
150
158
164

FIG. 18



101

FIG 19



181

FIG. 20

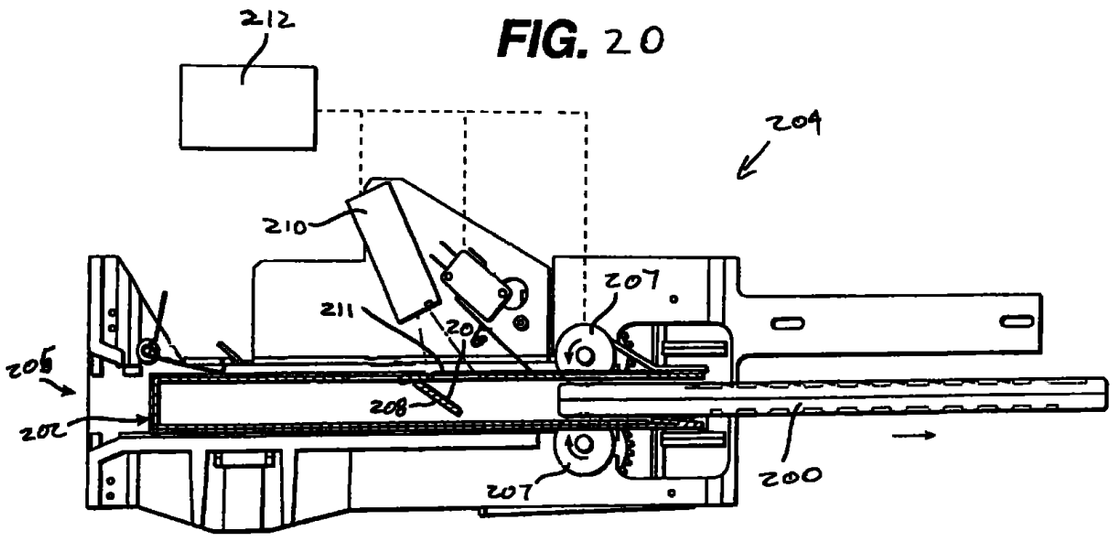


FIG 21

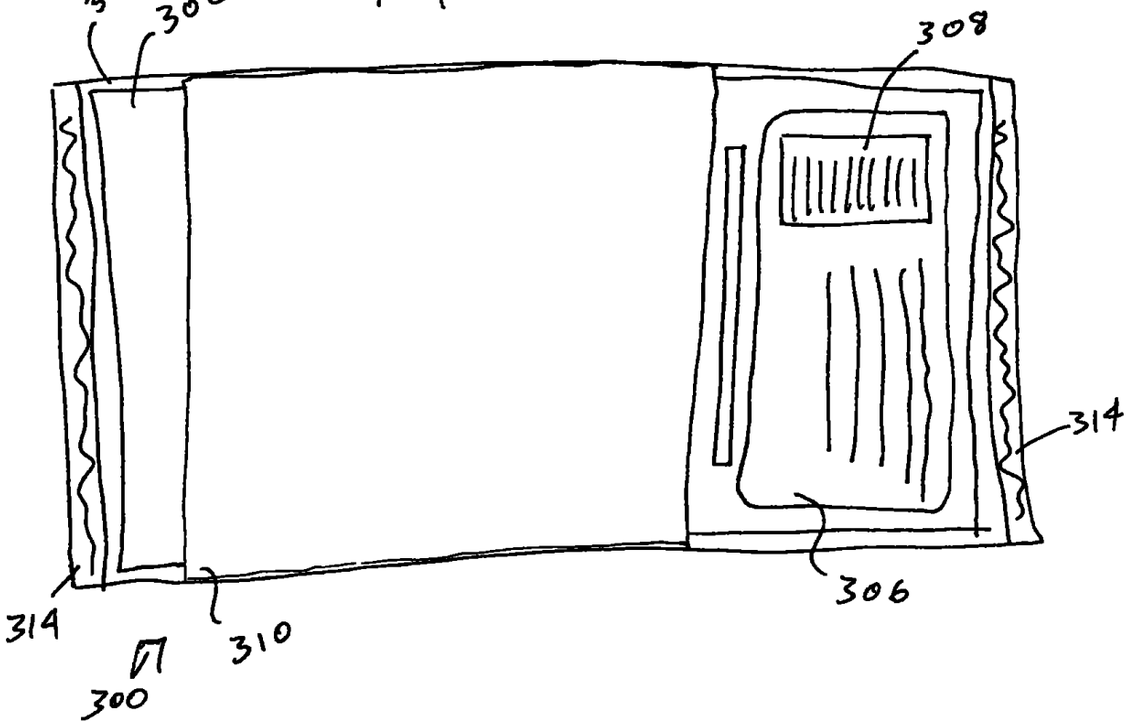
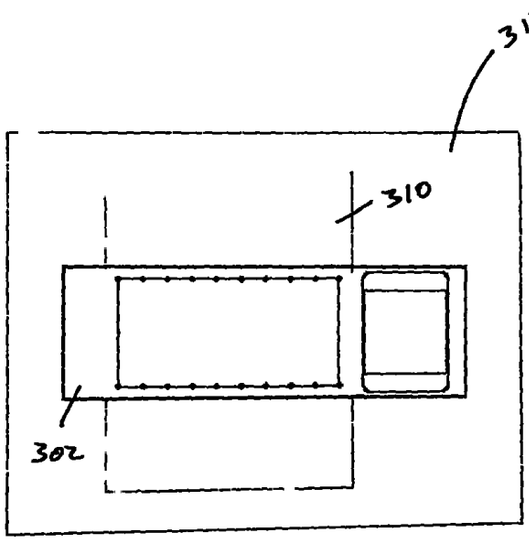


FIG 22



107
105

PTO 1320872

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

May 16, 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: ***10/856,435***
FILING DATE: ***May 28, 2004***

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

T. LAWRENCE
Certifying Officer

108
106

UTILITY PATENT APPLICATION TRANSMITTAL

(37 CFR 1.53(b))

Attorney Docket No.	ASP-5018
First Inventor	James P. Kehler
Title	CASSETTE WITH ENCODED LUMEN CLAIM
Express Mail Label No.	ER127878743US

U.S.PTO 10/856435 052604

APPLICATION ELEMENTS

See MPEP Chapter 600 concerning utility patent application contents.

ADDRESS TO: Mail Stop Patent Application
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 30] *(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 18]
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. 35868
SIGNATURE	
DATE	May 28, 2004

105
107

FEE TRANSMITTAL	Complete If Known	
	Application Number	
	Filing Date	May 28, 2004
	First Named Inventor	James P. Kohler
	Group Art Unit	
	Examiner Name	
	Attorney Docket Number	ASP-5018

17439 U.S. PTO

FEE CALCULATION

CLAIMS AS FILED

(1)	(2)	(3)	(4)	(5)
FOR:	NUMBER FILED	NUMBER EXTRA	RATE	BASIC FEE $770.00
TOTAL CLAIMS	10 - 20 =	0	x 18.00	$ 0.00
INDEPENDENT CLAIMS	1 - 3 =	0	x 86.00	$ 0.00
MULTIPLE DEPENDENT CLAIMS	☐	N/A	$290.00	
			TOTAL FEES	$ 770.00

METHOD OF PAYMENT

☒ Please charge Deposit Account No. 10-0750/ASP-5018/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-5018/ACF. Three copies of this sheet are enclosed.

SUBMITTED BY:			Complete (if applicable)
Typed or Printed Name	Andrew C. Farmer		Reg. No. 35,868
Signature		Date: 5-28-04	Deposit Account No. 10-0750

NO
108

DOCKET NO. ASP-5018

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Applicant: James P. Kohler

For : CASSETTE WITH ENCODED LUMEN CLAIM

Express Mail Certificate

"Express Mail" mailing number: ER127876743US

Date of Deposit: May 28, 2004

I hereby certify that this complete application, including specification pages, claims, drawings and an unexecuted Declaration 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)

CASSETTE WITH ENCODED LUMEN CLAIM

Background of the Invention

This application relates to cassettes for delivering sterilant to an instrument sterilizer, and more particularly to such cassettes having encoded thereon a machine readable lumen claim.

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 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 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 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; 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.

It has been known t employ a bar code on such a cassette. Typically, a particular model of sterilizer employs a particular cassette design. The bar code on the cassette may include such information as the model number of the sterilizer for which it is designed and the expiration date of the cassette. Thus, if the wrong or an expired cassette is inserted, the sterilizer can determine this by reading the code and then reject the cassette.

Summary of the Invention

A cassette for a sterilizer according to the present invention comprises one or more cells in the cassette, at least one of the one or more cells containing a quantity of liquid sterilant. A bar code on the cassette is encoded with a lumen claim.

Preferably, the bar code has encoded therein an identifier for a type or model of sterilizer to which the lumen claim is related.

In one aspect of the invention, the sterilant comprises hydrogen peroxide solution.

The lumen claim, in one aspect of the invention, specifies a length and internal diameter of a lumen. Additionally, it can specify a material from which the lumen is constructed. The encoding can be an identifier representative of the length and internal diameter, or the actual length and internal diameter can be encoded.

Preferably, the bar code resides on label attached to the cassette. Alternatively, it is printed onto the cassette.

In a preferred embodiment, the cassette has a plurality of the cells.

Brief Description of the Drawings

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

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

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 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 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;

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;

112

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

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;

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;

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 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;

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

FIG. 15 is a rear perspective view of an alternative 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;

113

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.

Detailed Description

Sterilizer Overall Configuration

FIG. 1 shows in block diagram form a vapor phase sterilizer 10 employing a cassette handling system 12 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.

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 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

114

with the items t be sterilized and kills micr organisms thereon. Near the end of the cycle, power is again 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. The Jacobs et al. U.S. Patent Application, Publication No. 20030235511, incorporated herein by reference, illustrates in detail such a cycle.

Cassette Handling System

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.

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 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 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 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

openings 69 f r 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.

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 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 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 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.

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 f r receiving additi nal 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 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 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

117

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 c unterclockwise, urging the outwardly facing side 102 into contact with an abutment 112. Inward movements of 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 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 facings side 102 of the disposing cam 96 and the abutment 112 prevents rotation of the disposing cam 96. The 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.

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 t 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 on 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 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.

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

119

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 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 needles 70 and 72.

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.

120

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 pressure air will provide the driving force to empty the cell 118.

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, r substantially so, from an upper part of the cell 118, preferably with such a double lumen needle. This would 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 sterilant above the position would be extracted and sterilant below would remain. This would be particularly convenient with the just mentioned vertically traveling needle.

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 subsystem 40 and a new extraction takes place. Multiple

121

extractions may be empl yed f r 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 rotate the top panel 48 upwardly and project the ejecting tab 98 through the opening 100 to drive the cassette 34 ut of the carriage 32 as described above and as shown in FIG. 13. The cassette 34 falls into the spent cassette c llection box 84 and the carriage 32 returns to the insertion position as shown in FIG. 5.

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.

Lumen Claim

Typically, sterilizers and their cycle parameters have been optimized to enable sterilization of the most challenging loads possible so as to not unduly restrict which devices might be sterilized therein. Long narrow lumens being one of the most challenging areas to sterilize have become the de facto standard in defining the potency of a sterilization process, i.e. its ability to sterilize devices having a lumen of a certain diameter and length. The longer and narrower the lumen which can be sterilized, the more efficacious the sterilizer cycle. A sterilizer is thus said to achieve a lumen claim of lumen diameter by lumen length, as for instance 1 mm x 100 mm. The lumen claim can also include the material forming the lumen. Typically, the lumen claim will be the claim which has been approved by a regulatory agency such as the US Food and Drug Administration, but can represent merely the lumen which the sterilizer and cycle can effectively

sterilize. Typically, sterilization entails a six log reduction in the challenge microorganisms. In hydrogen peroxide based sterilization systems the preferred challenge microorganism is *Geobacillus stearothermophilus*.

Rather than always run the sterilizer to achieve its maximum lumen claim, it may be desirable to run the sterilizer 10 in different cycles depending upon the devices loaded therein for sterilization. Preferably, an operator selects a lumen claim when loading the sterilizer 10 based upon the most challenging lumen device being loaded and then enters that lumen claim into the control system 28. Alternatively, the devices can be coded themselves, such as with a bar code which is scanned as the device is loaded, and the control system 28 selects the appropriate cycle to meet a particular lumen claim based upon the most challenging lumen device which was scanned. A set of lumen claim cycles programmed into the sterilizer might include the following: a) 1 mm x 1,000 mm, b) 1 mm x 500 mm, c) 2 mm x 100 mm, and d) no lumen. The cycles for the less demanding lumen claims can be adjusted, such as injecting less sterilant, employing a lower concentration sterilant, a shorter contact time, or a less demanding vacuum (higher pressure). In general, employing a lower concentration sterilant can provide benefits in gentler processing of the instruments to be sterilized.

To provide flexibility in optimizing differing lumen sterilization cycles, preferably cassettes 34 having loads of sterilant optimized for a given lumen claim cycle are provided. Preferably, the lumen claim is encoded onto th barcode 80 along with other data such as the sterilizer

model for which the cassette 34 is intended and the expiration date.

A suggested data layout for the barcode 80 comprises the following fields: a) sterilizer model for which the cassette 34 is intended (three binary digits - associated with a look-up table); b) expiration date (eight binary digits representing the number of months from a fixed date); c) lumen claim (three binary digits - associated with a look-up table). Alternatively, the lumen claim could be represented by separate lumen internal diameter and length fields, preferably in millimeters and decimeters respectively. Further, as illustrated in the last row of Table 1a some lumens having different dimensions may nonetheless have equivalent processing requirements. Preferably, one of the equivalent lumens would be coded onto the barcode 80, with the sterilizer's control system being programmed with the equivalents. Many coding schemes are possible within the scope of the invention.

Tables 1a and 1b illustrate how certain parameters of the cycle can be modified to treat particular lumens.

Table 1a - 173L chamber with two loads

Device	Peroxide concentration	Peroxide amount	Time required to kill about $1x10^6$ *Geobacillus stearothermophilus* spores
Stainless steel Surface	59% wt	1 g	5 minutes
1mmx1000mm TEFLON* lumen	50% wt	2 g	15 minutes
1mmx125mm, 2mmx250mm or 3mmx400mm Stainless Steel lumen	59% wt	1.7 g	20 minutes

*polytetrafluoroethylene, TEFLON is a trademark of 3M Co.

Table 1b - 51L chamber with one load

Device	Peroxide concentration	Peroxide amount	Time required to kill about $1x10^6$ *Geobacillus stearothermophilus* spores
2mmx400mm Stainless Steel lumen	90% wt	0.23 g	3 minutes
1mmx150mm Stainless Steel lumen	90% wt	0.34 g	3 minutes
1mmx500mm Stainless Steel lumen	90% wt	0.45 g	7 minutes
1mmx350mm TEFLON* lumen	90% wt	0.45 g	3 minutes

*polytetrafluoroethylene, TEFLON is a trademark of 3M Co.

Beyond merely entering lumen data, the control system 28 can be configured to take multiple inputs and use this information to determine how a subsequent sterilization cycle should be performed. Such inputs can include: whether the load is wrapped or unwrapped (such as in Central Supply Room "CSR" wrap), the weight of the load, the number of items (and more preferably the number of certain types of items such as rigid or flexible endoscopes, the materials of the load, such as the proportion of plastics, the presence or proportion of polymers highly absorbtive of hydrogen peroxide such as, but not limited to, polyamides, polyurethanes, silicone rubbers, PVCs, Polymethyl methacrylates and polysulfones, and whether full sterilization or merely high level disinfection is needed. Some of these inputs can be determined by the machine with addition of appropriate sensors, such as for example the weight of the load which

can be determined via some form of scale preferably incorporated into the sterilizer 10 or via measuring plasma power.

The sterilizer 10 has many sensors including those to measure temperature, pressure, sterilant concentration and plasma power. These in conjunction with the user inputs are used by the control system to adjust the parameter of the sterilization cycle in order to adequately treat the load in the most efficient manner. Table 2 illustrates how a cycle can be modified to for several user inputs.

Table 2 - Cycle Response to User Input

Attributes of load	Response	Control mechanism
Sterilization or high level disinfection	**High level disinfection**- low sterilant concentration or/and mass/shorter exposure time **Sterilization**- high sterilant concentration or/and mass	Determine sterilant/disinfectant concentration level and quantity to reach sterilant level required. Monitor concentration/amount by sterilant sensor and maintain at the required level
Wrapped or unwrapped load	Unwrapped- low concentration/mass delivery Wrapped- higher concentration/mass delivery	Determine sterilant/disinfectant concentration level and quantity to reach sterilant level required. Monitor concentration/amount by sterilant sensor and maintain at the required level
Load volume and weight	High volume: possibly more absorption High weight: possibly higher condensation	Monitor and maintain the required sterilant/disinfectant concentration level. Set temperature at higher level to reduce absorption and condensation effects. Pre-heat the load if necessary. High venting/residual removal treatment.
Loads contains materials that are a decomposer or absorber to the sterilant/disinfectant	Higher injection mass/concentration and temperature may be required	Monitor and maintain the required sterilant/disinfectant level. High venting/residual removal treatment if excessive absorb is present (Identify from sterilant concentration sensor output)
Load contains lumens: short vs. long	High concentration and/or mass, longer exposure time and pre-processing pressure gradient	Set concentration and pressure gradient levels accordingly

In one aspect of the invention, the user would first choose between running one or more standard cycles, or ne or more user programmed cycles, or enter load and process

data to design a cycle. Under the option of entering l ad data the user could first select whether sterilization or high level disinfection is required. If sterilization is selected, the user would preferably enter whether the load contained wrapped containers or items. The user would second enter whether the load contained lumens or not. For a load lacking lumens the overall weight and materials in the load would be entered. These entries could be made item by item, or as an aggregate. For lumens, additional data such as the lumen length and internal diameter would be entered. Again, this data could be entered as the most challenging single lumen, or item by item. Thirdly, the user would enter load preparation information such as whether preheating or moisture removal steps should be taken with the load. Alternatively, the control system could recommend or determine whether these steps should be taken based upon the data entered. These steps can lengthen the overall process time and in some instances the user may wish to opt out of their use to speed the cycle. Fourth, the user would enter data as to the source f sterilant (bulk or cassette), sterilant concentration, sterilant volume and type of sterilant. Again, some of this could rather be recommended or determined by the control system based upon the entered data, which could also provide the user with a message as to which type of cassette should be loaded for instance. Finally, information about residual removal would be entered, i.e. whether a residual removal step should be taken at the end of the cycle and whether heat, plasma, sterile air purging, vacuum or some combination thereof should be employed. Again, this information could rather be recommended or determined by the control system based upon the data entered. The user would have the option of saving this cycle set-up so that it could be chosen from a

cycle menu for later cycles f similar devices. Names could be provided to the cycle set-up, such as by procedure instrument set, to allow easy retrieval of the appropriate cycle in the future.

Determinations of cycle changes can be made based upon table look-ups employing cycle corrections based upon known cycle modifications related to load modifications, preferably backed up by test data. For instance, tests run on lumens of varying diameter and ID can determine exposure times and sterilant concentrations that produce reliable sterilization. In addition, calculations of integrated sterilant exposure (quantity and time) can be employed. For instance, experiments have shown that a particular lumen can be successfully sterilized by a particular integrated sterilant exposure; varying the quantity or time while maintaining the overall integrated exposure still achieves a reliable sterilization.

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 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 spend cassette box 84. Each cassette 34 carries a cassette RFID 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 available from Texas Instruments, Dallas, Texas.

130

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 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 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 on the RFID tag. Thus, if the cassette 34 is removed and then reinserted into the sterilizer 10, or even into 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 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 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 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 cassettes 34 within the box 84. When the box 84 is full the control system 28 alerts the operator, as by a message

131

n 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 completely drained the operator can be informed of this t 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 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.

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 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.

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, expirati n 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, Dreseden, 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 (n 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.

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. 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, 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 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 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 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 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 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

134

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 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.

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

WHAT IS CLAIMED IS:

1. A cassette for a sterilizer, the cassette comprising:

one or more cells in the cassette, at least one of the one or more cells containing a quantity of liquid sterilant; and

a bar code on the cassette, the bar code having encoded therein a lumen claim.

2. A cassette according to claim 1 wherein the bar code has encoded therein an identifier for a type or model of sterilizer to which the lumen claim is related.

3. A cassette according to claim 1 wherein the sterilant comprises hydrogen peroxide solution.

4. A cassette according to claim 1 wherein the lumen claim specifies a length and internal diameter of a lumen.

5. A cassette according to claim 4 wherein the lumen claim specifies a material from which the lumen is constructed.

6. A cassette according to claim 1 wherein the bar code has encoded therein a length and an internal diameter for the lumen claim.

7. A cassette according to claim 6 wherein the bar code has encoded therein a material for the lumen claim.

8. A cassette according to claim 1 wherein the bar code is on label attached to the cassette.

9. A cassette according to claim 1 wherein the bar code is printed onto the cassette.

10. A cassette according to claim 1 comprising a plurality of the cells.

ABSTRACT

A cassette for a sterilizer has one or more cells containing a sterilant and carries a bar code which is encoded with a lumen claim. The lumen claim relates to a sterilization cycle for which the cassette is designed.

Please type a plus sign (+) inside this box: [+]

PTO/SB/01 (10-03)
Approved for use through 10/31/2003. 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 (unexecuted) OR ☐ Declaration Submitted after Initial Filing (Surcharge (37 CFR 1.16(e)) required)	Attorney Docket Number	ASP-5018
	First Named Inventor	James P. Kohler
	COMPLETE IF KNOWN	
	Application Number	
	Filing Date	May 28, 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:

CASSETTE WITH ENCODED LUMEN CLAIM
(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

I hereby appoint:

☒ Practitioners at Customer Number 00002*7777* →

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) 524-2626.

Direct all correspondence to: ☒ Customer Number or Bar Code Label 00002*7777* 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]) James P.		Family Name or Surname Kohler	
Inventor's Signature		Date	
Residence: City Laguna Hills	State CA	Country USA	Citizenship USA
Mailing Address 25221 Champlain Road			
City Laguna Hills	State CA	ZIP 92653	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])		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	ZIP	Country

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])		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address			
City	State	ZIP	Country

14

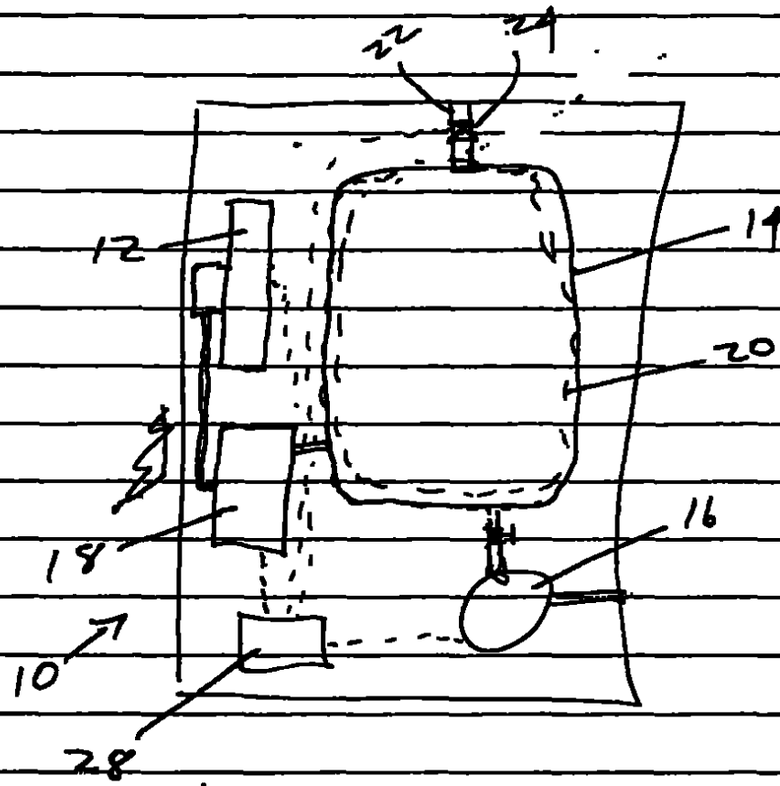


FIG. 1

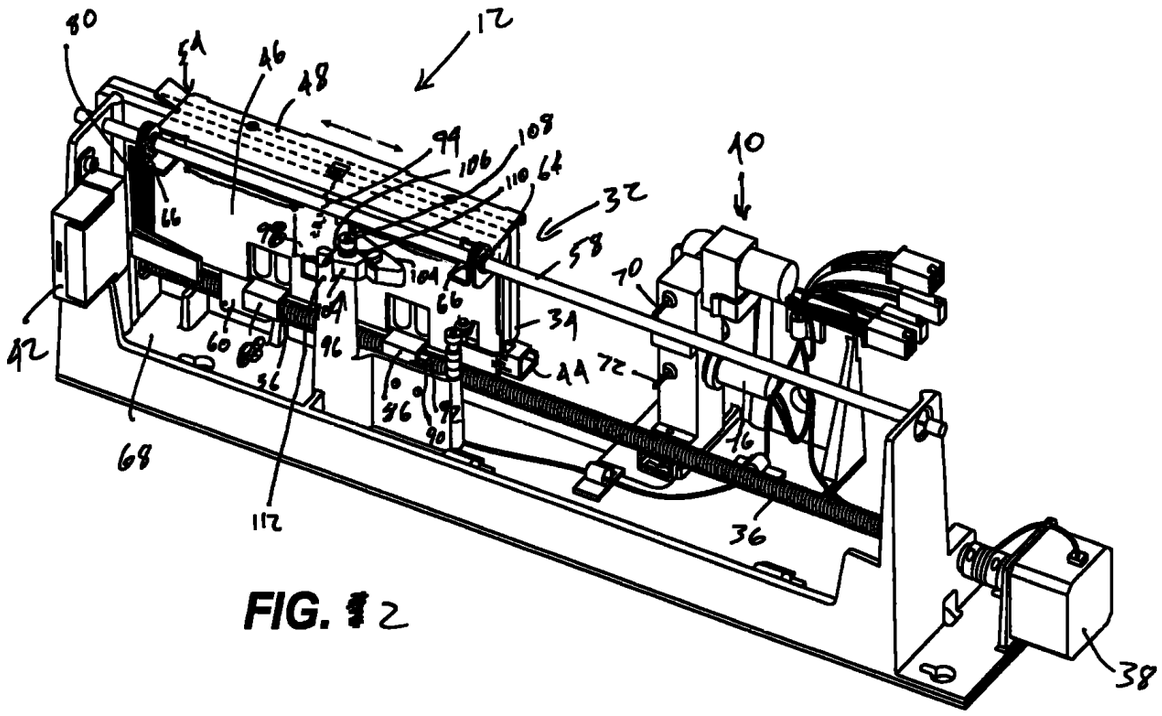


FIG. 12

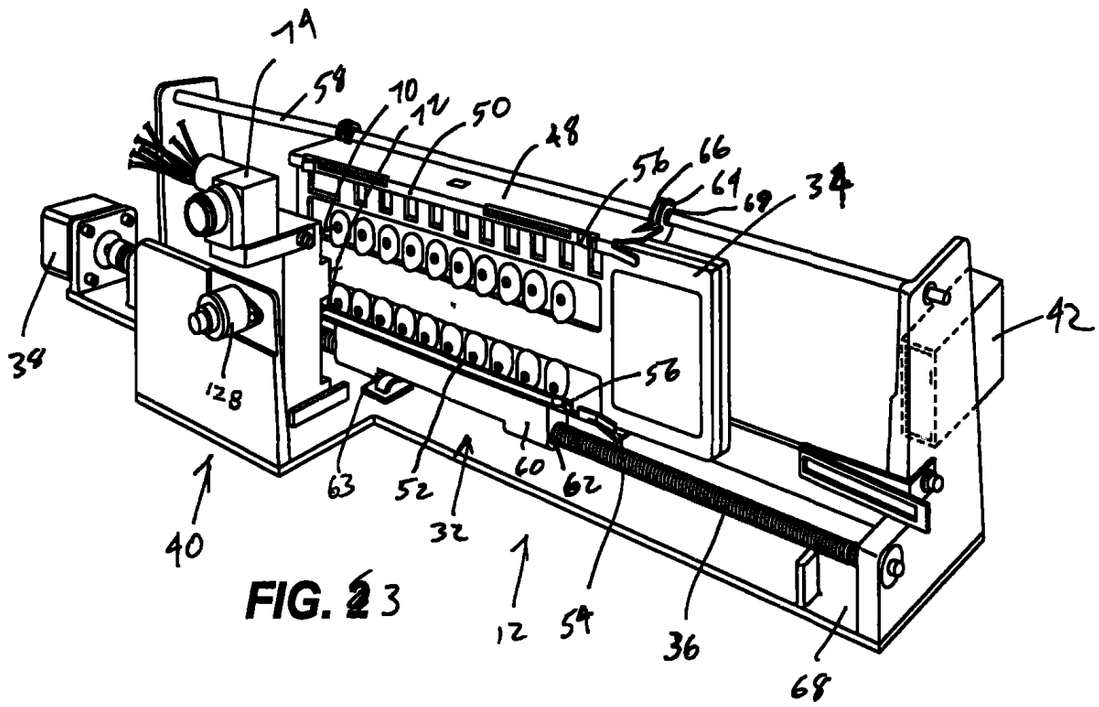
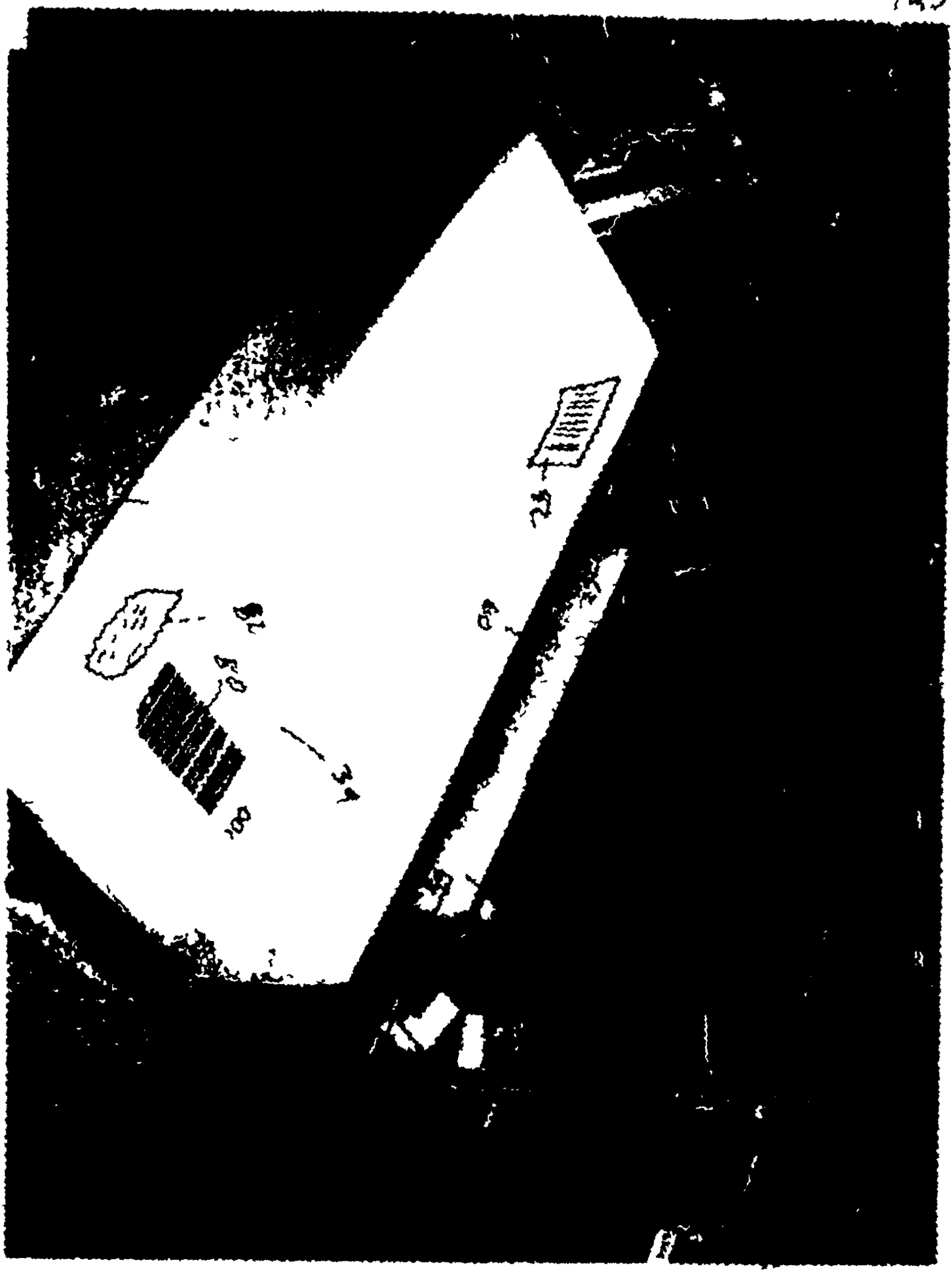
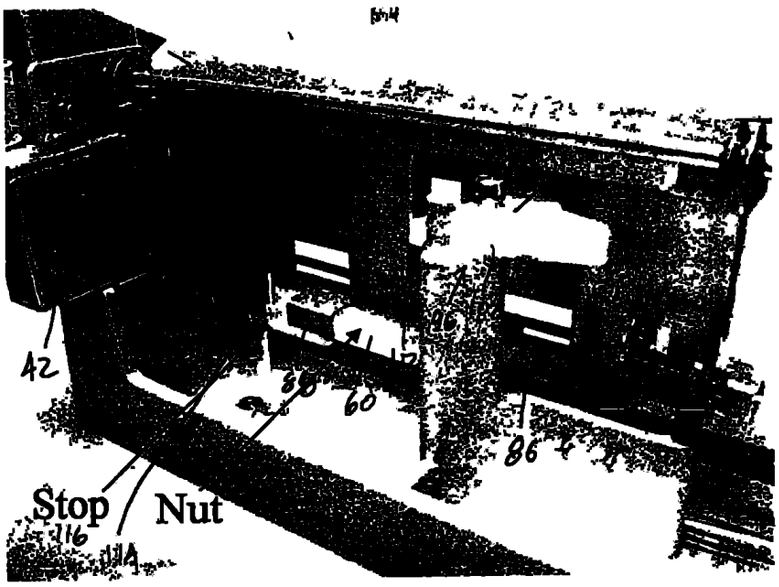


FIG. 23



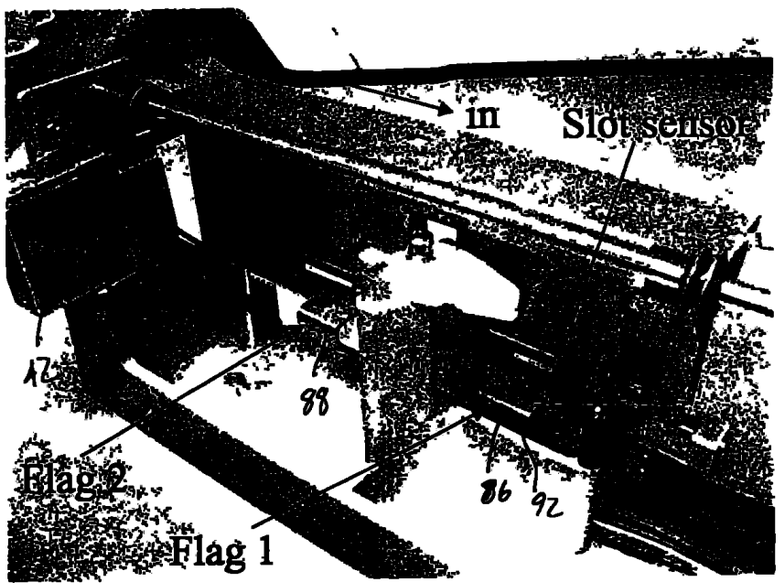
Insert Position: detail of slide 1



Nut on lead screw touches a hard stop

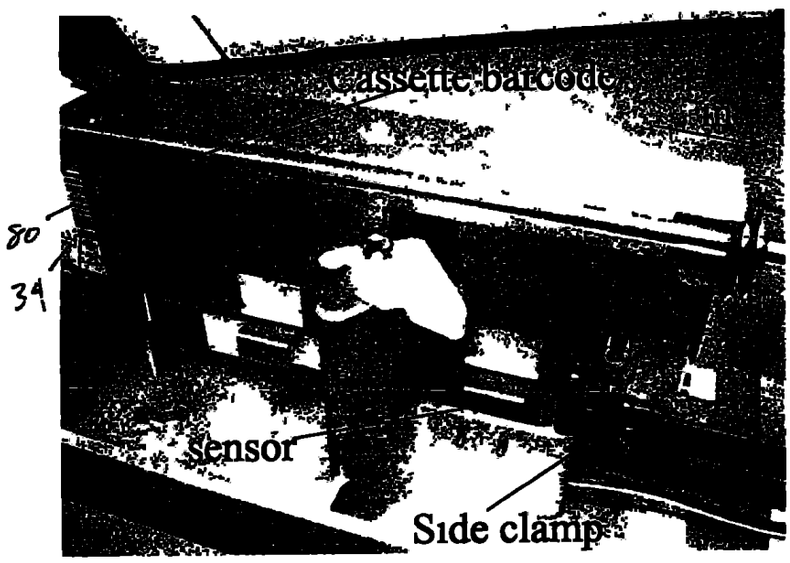
FIG. 7

Barcode start



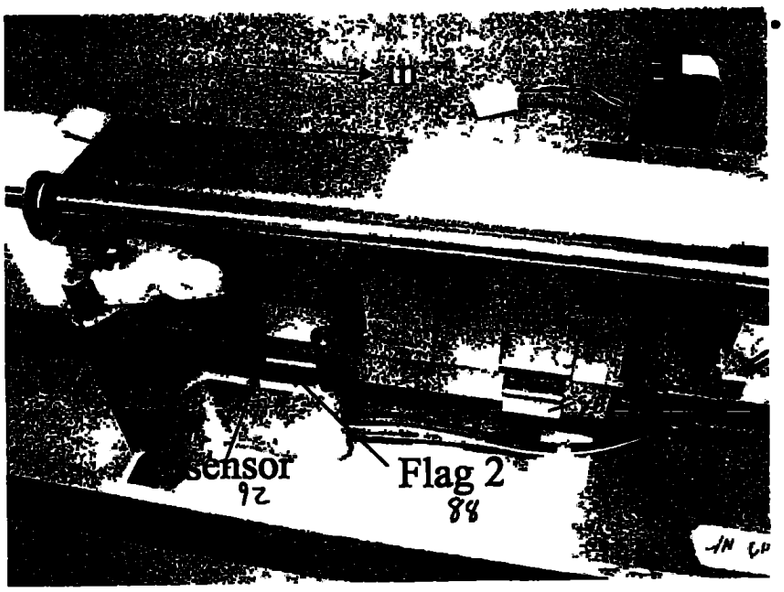
- Inserted cassette (not shown) pushes flag 1 of carriage to block beam of slot sensor, triggering stepper motor to move the carriage in while scan engine reads barcode on cassette

Barcode reading



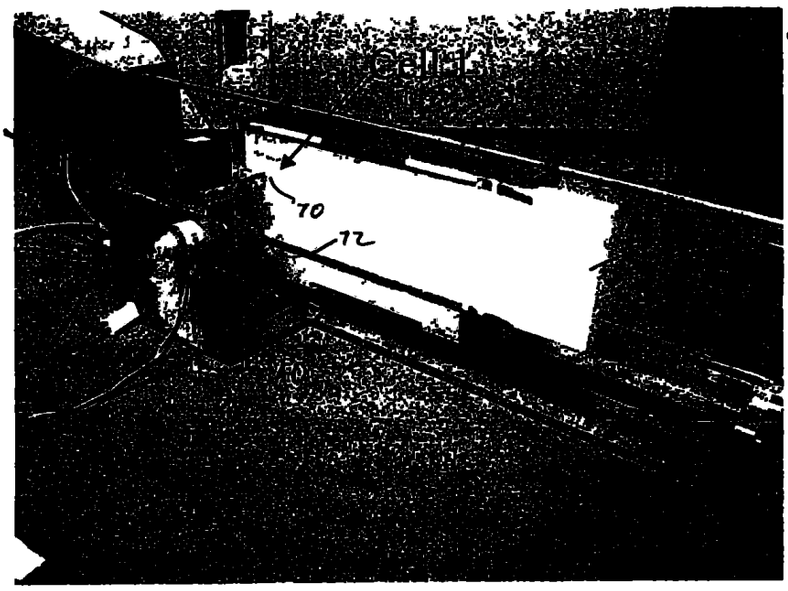
- Cassette is being moved in while scan engine (not shown) reads barcode
- Side clamp holds cassette fixed to carriage

Home position



- Trailing edge of flag 2 just passes slot sensor

Cell 1



- Stepper motor moves cassette in 5 55 mm from home to arrive at cell 1

FIG 7

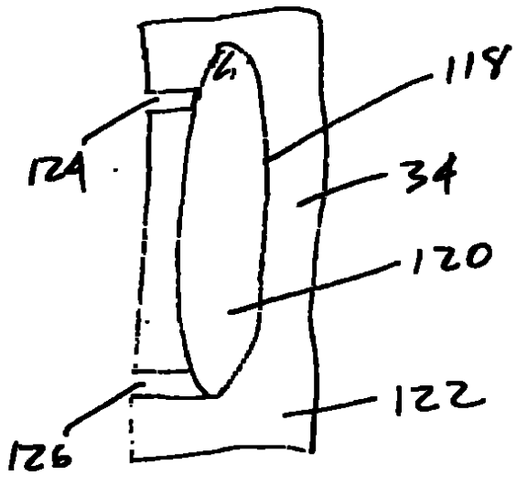


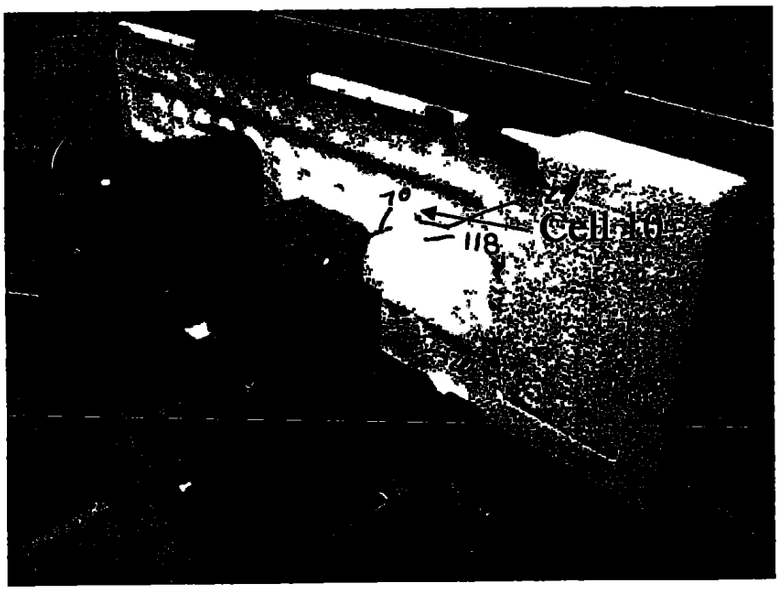
FIG. 10

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

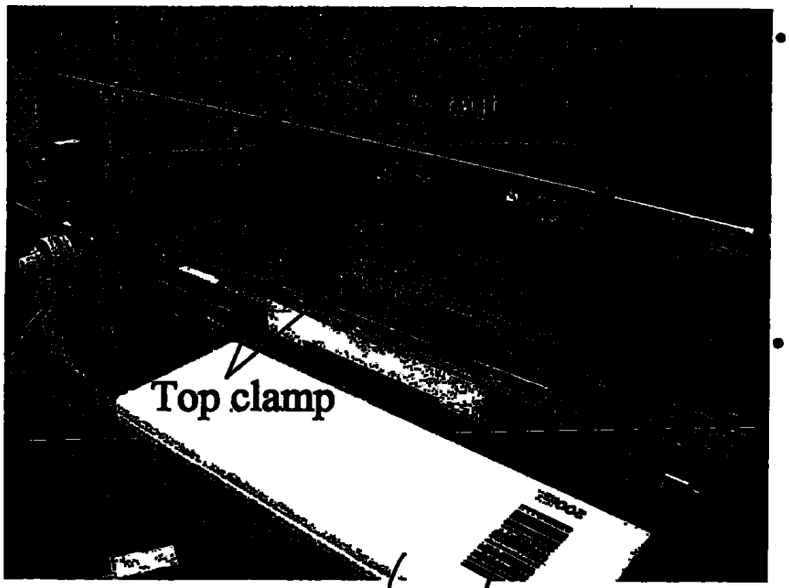
Cell 10



- 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 C

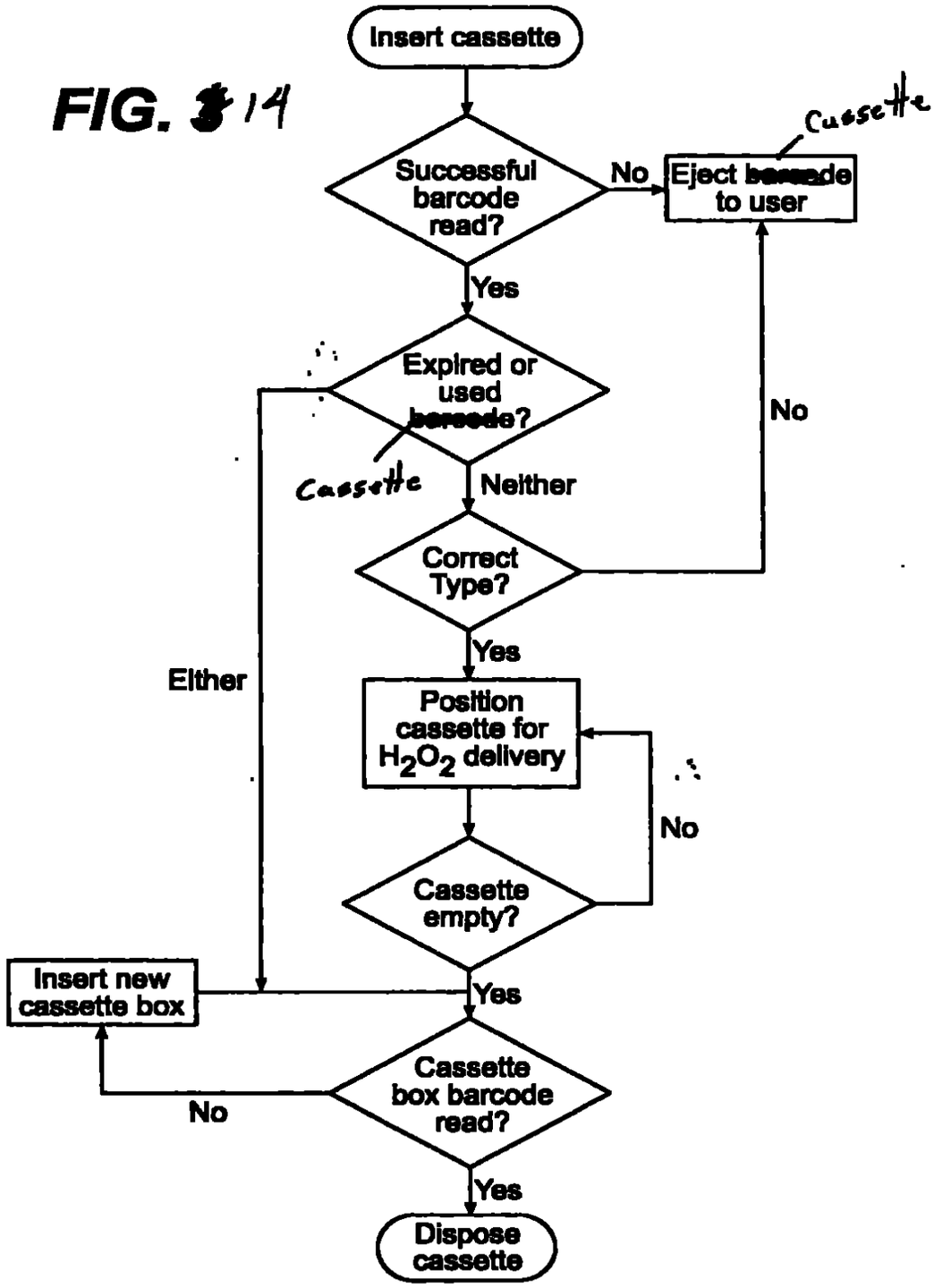
Cassette disposed



- 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 3

FIG. 14



Insert Consumable

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

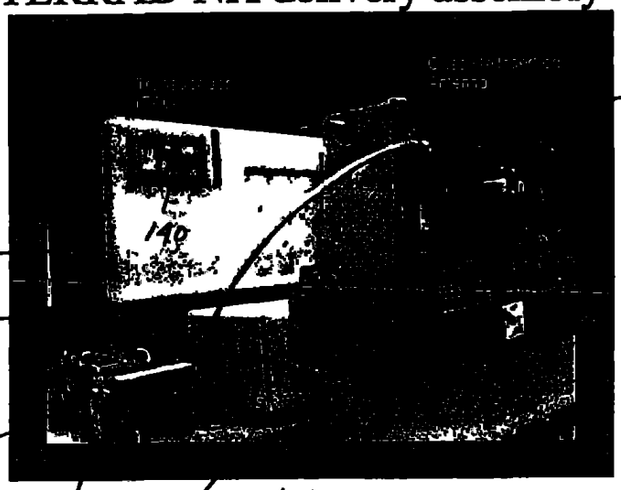


FIG 15

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

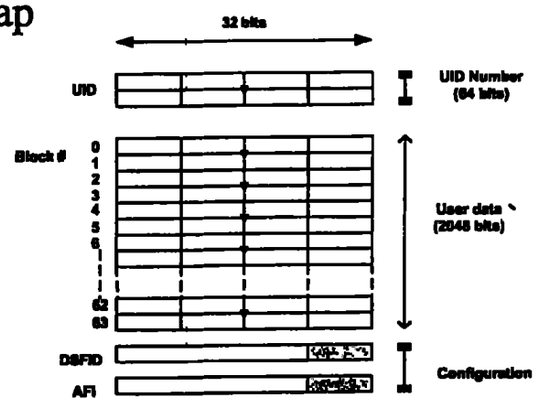


FIG 16

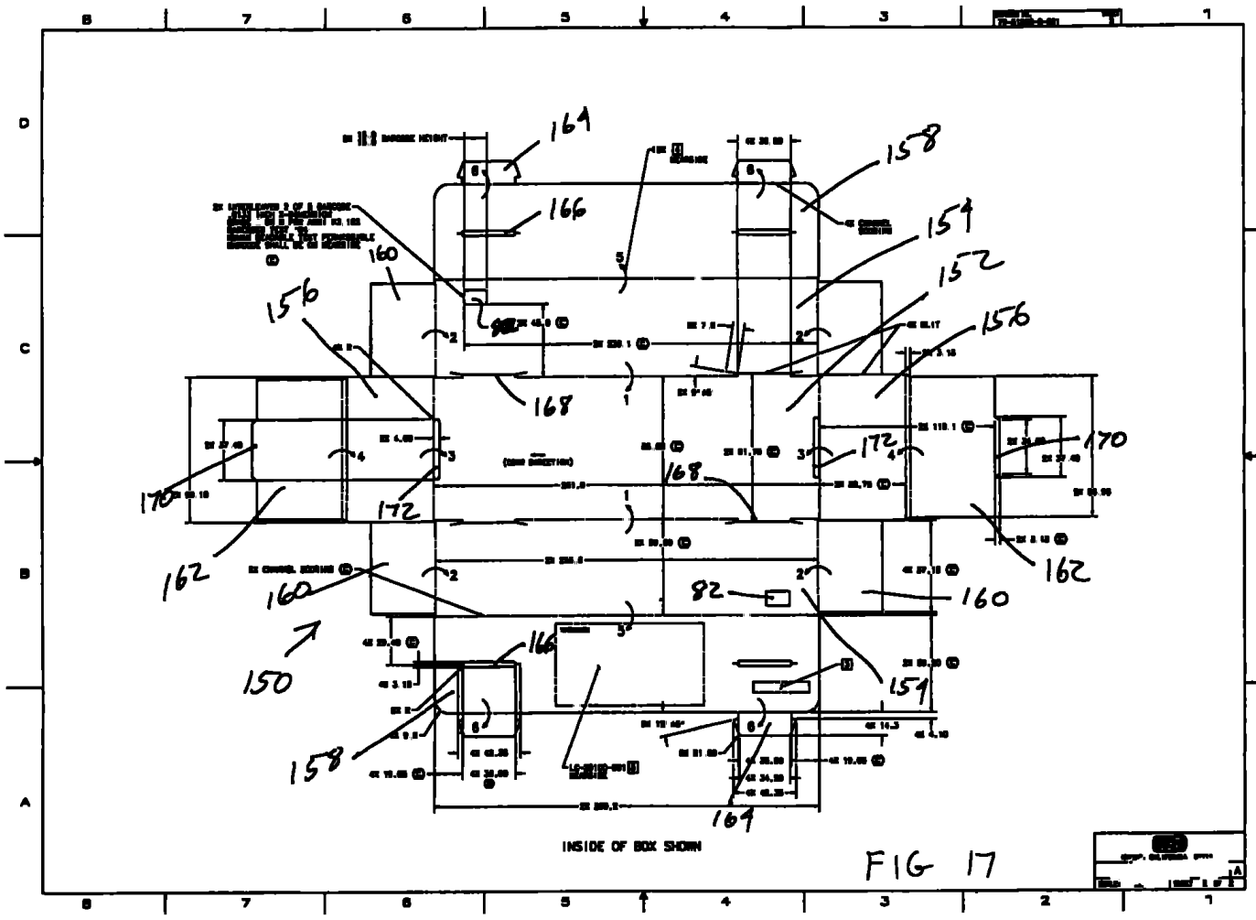


FIG 17

159

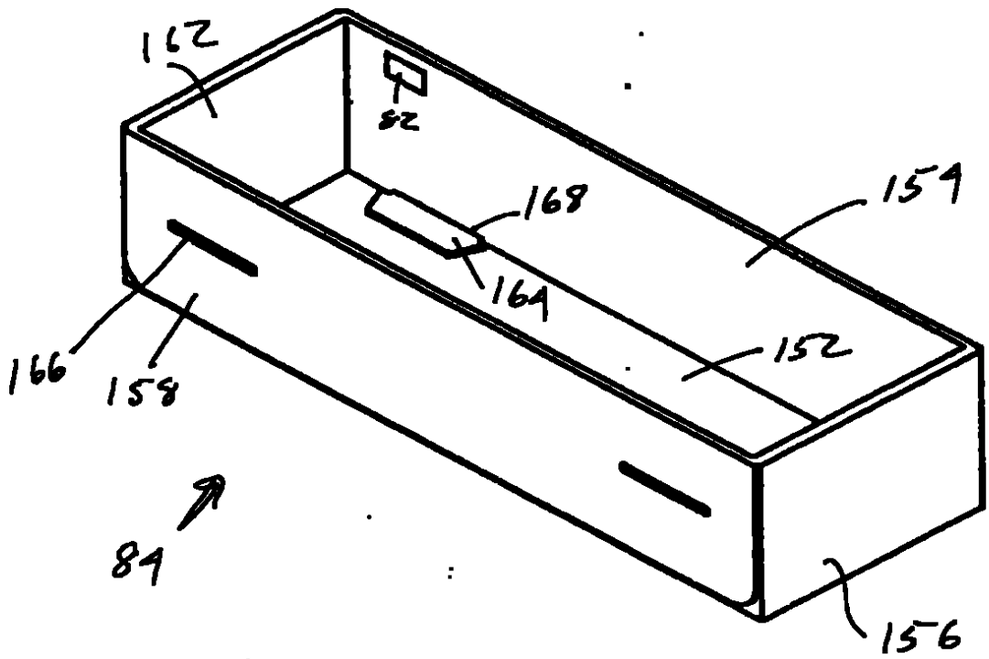


FIG. 18

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

Mayo 19 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: 10/978,034

Fecha de Presentación: 29 de octubre de 2004

Por la autoridad del
Comisionado de Patentes y Marca

(fdo) Trudie Wallace
Oficial Certificador
Sello oficial de la Oficina de Patentes y Marcas de los Estados Unidos de América

161

N VEDAD DE LA INVENCION

REIVINDICACIONES

1.- Un cartucho para un esterilizador, el cartucho comprende: un cuerpo; una o más celdas en el cuerpo, por lo menos una de una o más celdas contiene una cantidad de esterilizante líquido; y un código de barras asociado con el cartucho, el código de barras tiene codificado en el mismo una cláusula de lumen.

2.- El cartucho de conformidad con la reivindicación 1, caracterizado además porque el código de barras tiene codificado en el mismo un identificador para un tipo o modelo de esterilizador al cual está relacionada la cláusula de lumen.

3.- El cartucho de conformidad con la reivindicación 1, caracterizado además porque el esterilizante comprende solución de peróxido de hidrógeno.

4.- El cartucho de conformidad con la reivindicación 1, caracterizado además porque la cláusula de lumen especifica una longitud y diámetro interno de un lumen.

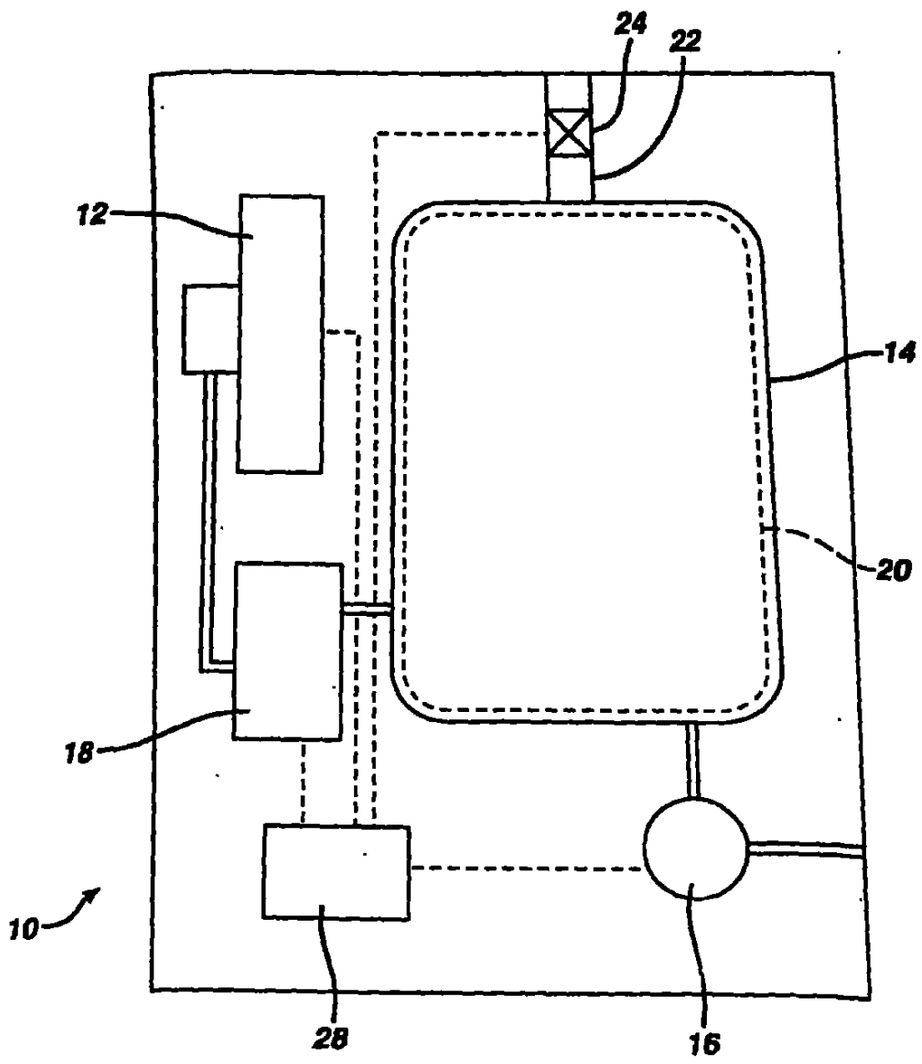
5.- El cartucho de conformidad con la reivindicación 4, caracterizado además porque la cláusula de lumen especifica un material del cual está construido el lumen.

6.- El cartucho de conformidad con la reivindicación 1,

caracterizado además porque el código de barras tiene codificado en el mismo una longitud y un diámetro interno para la cláusula de lumen.

7.- El cartucho de conformidad con la reivindicación 6, caracterizado además porque el código de barras tiene codificado en el mismo un material para la cláusula de lumen.

FIG. 1



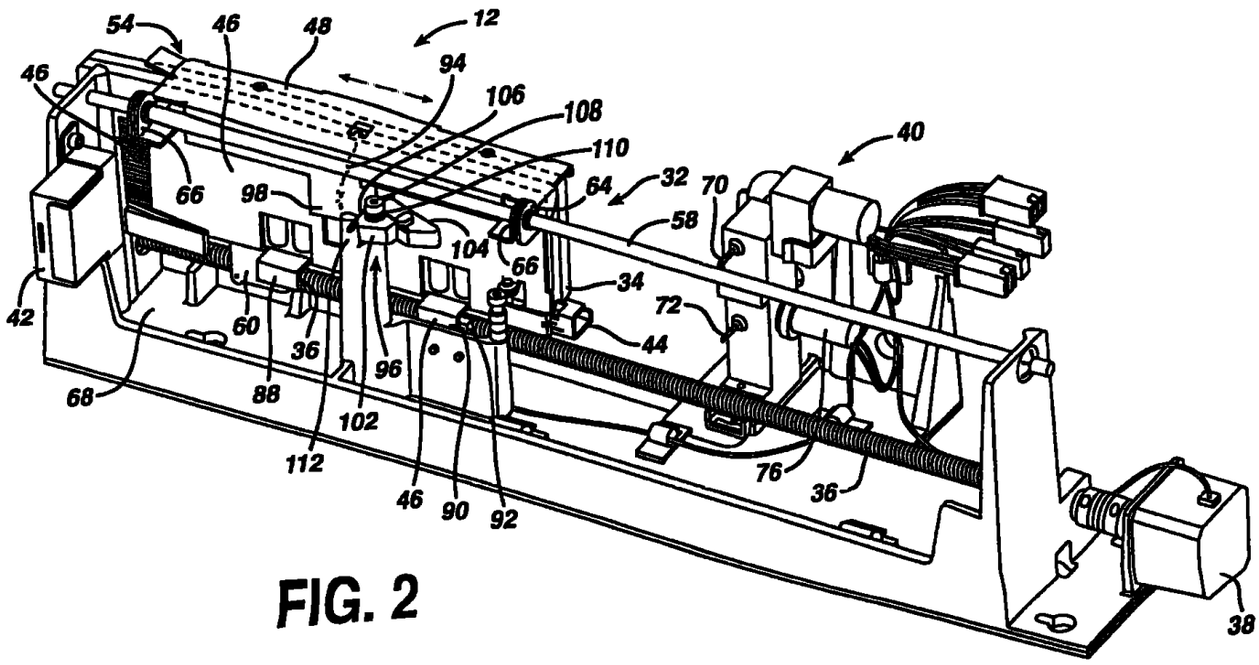

54
46
48
12
94
106
108
110
40
46
66
98
64
32
70
58
104
66
34
72
42
60
36
44
96
68
88
102
112
46
90
92
76
36
38

FIG. 2

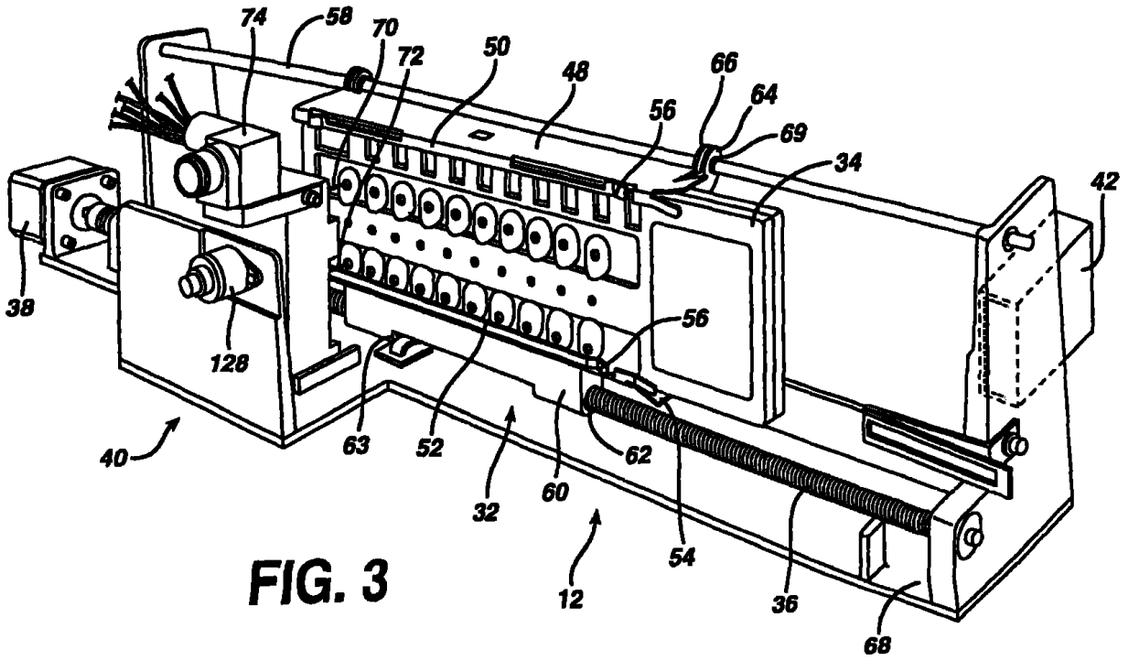

74
58
70
72
50
48
66
64
56
69
34
42
38
128
56
40
63
52
32
60
62
54
12
36
68

FIG. 3

FIG. 4

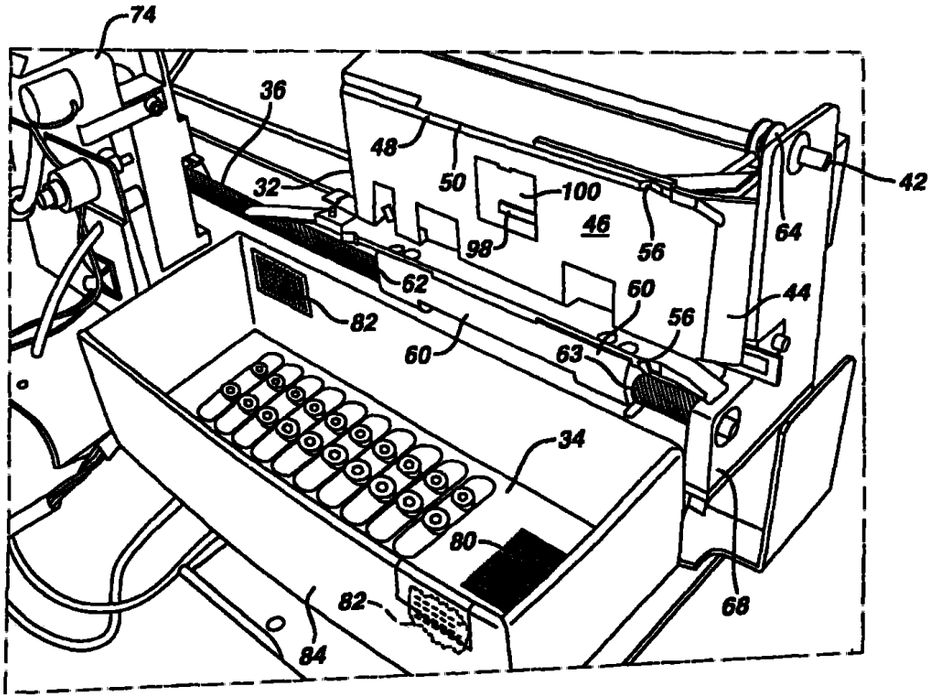


FIG. 5

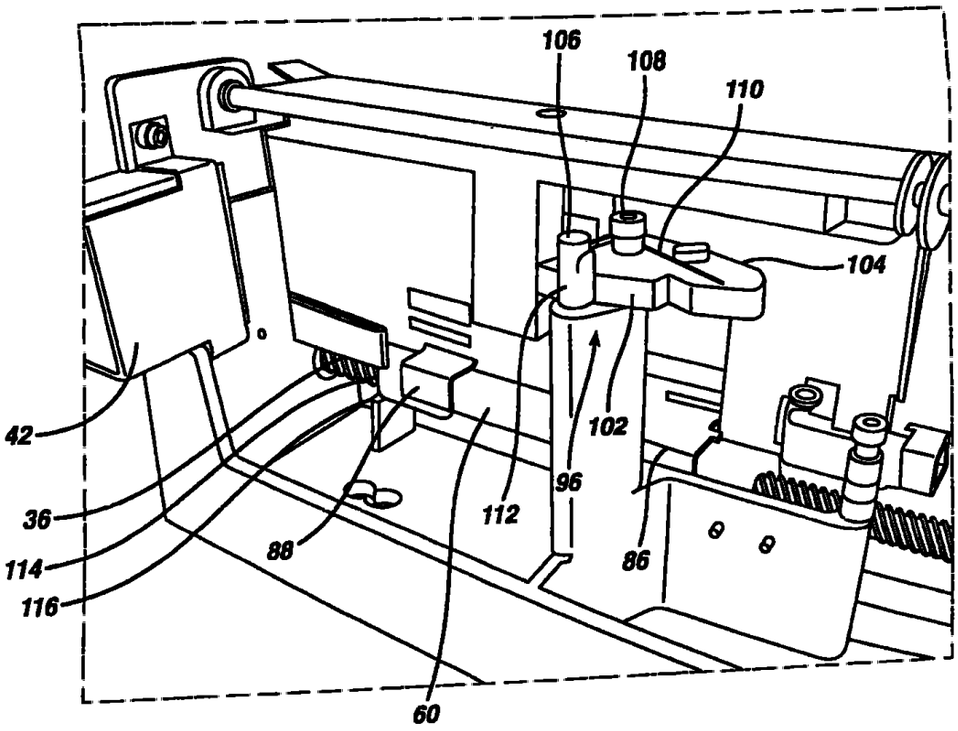


FIG. 6

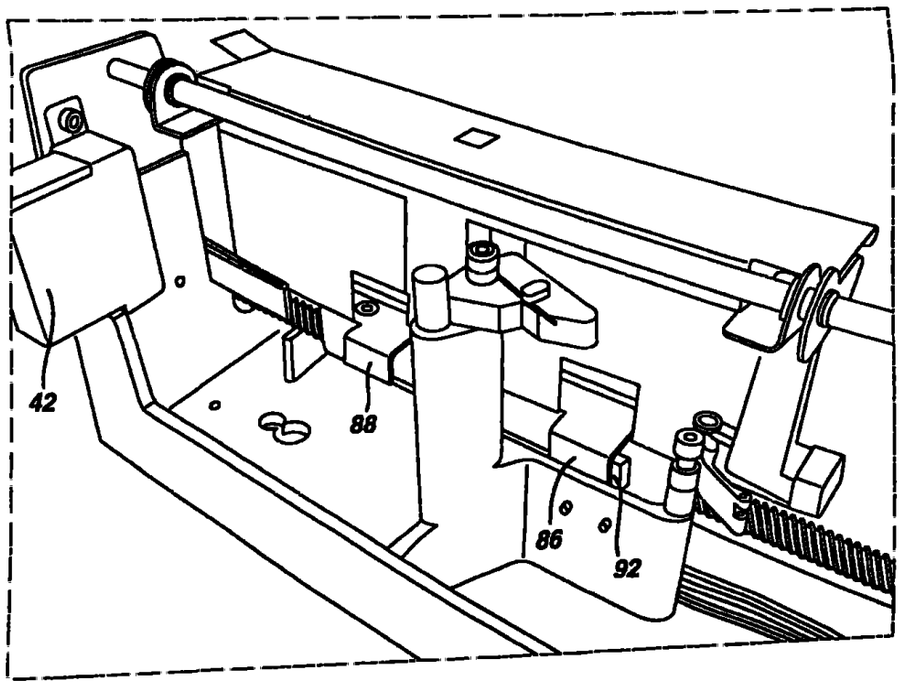


FIG. 7

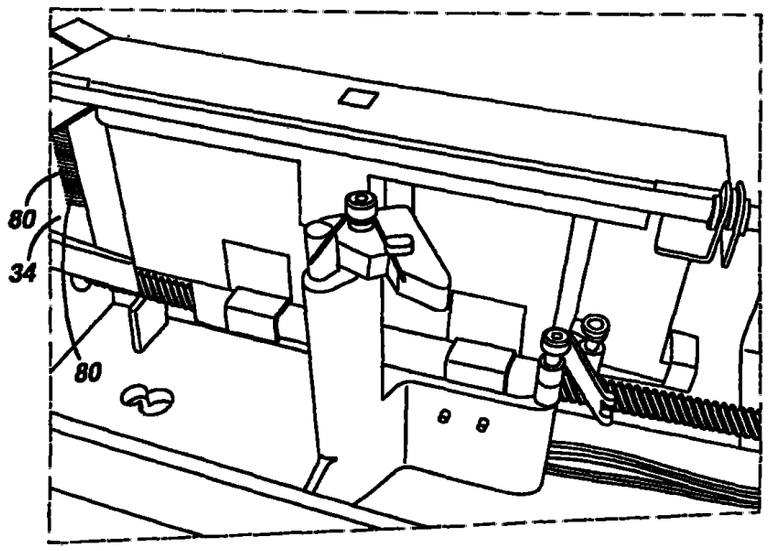


FIG. 8

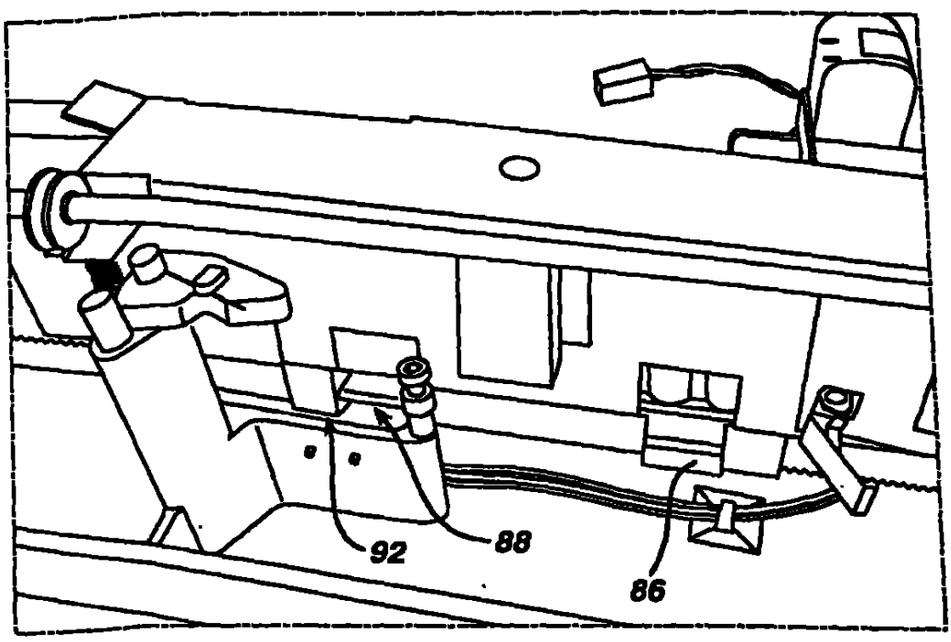


FIG. 9

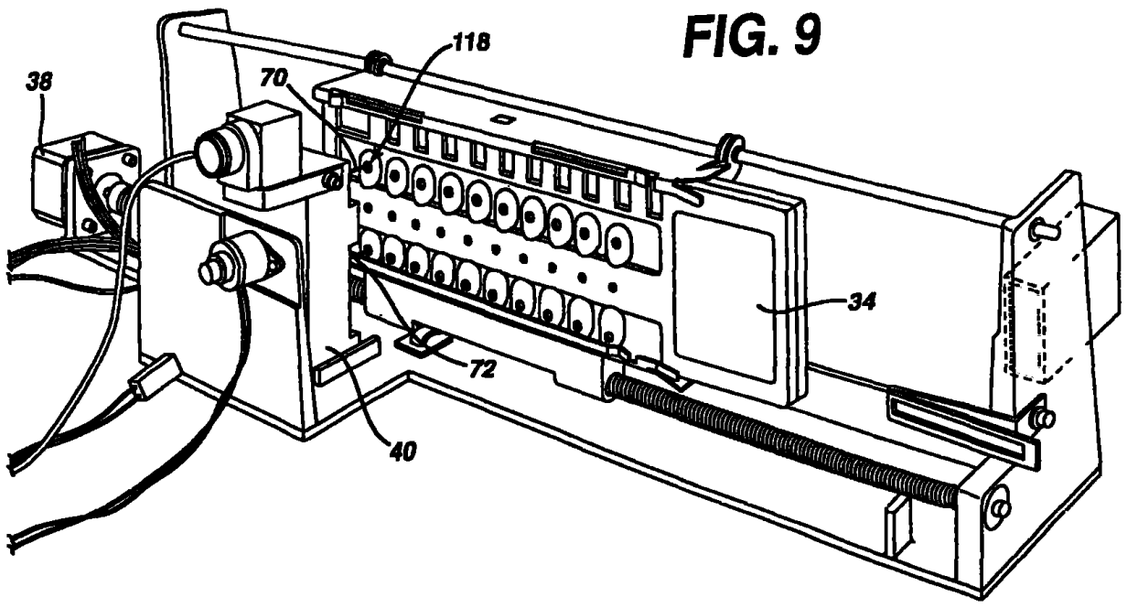


FIG. 10

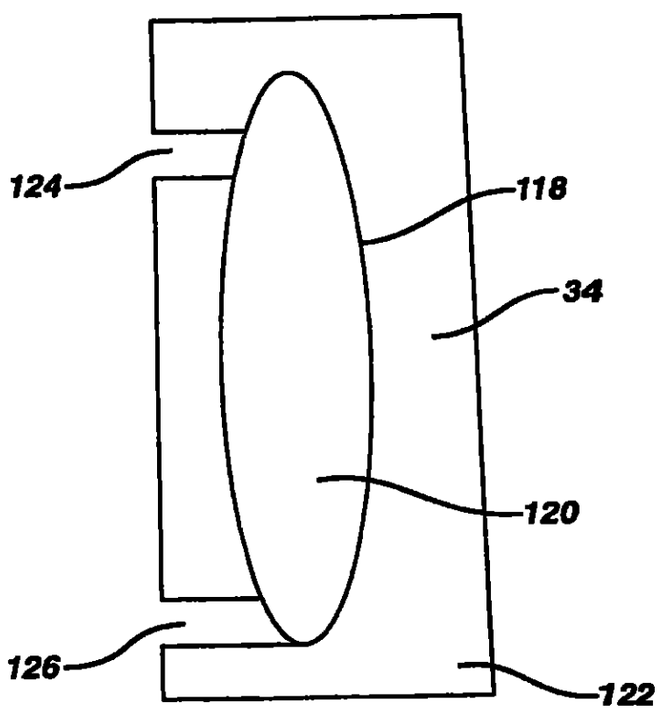


FIG. 11

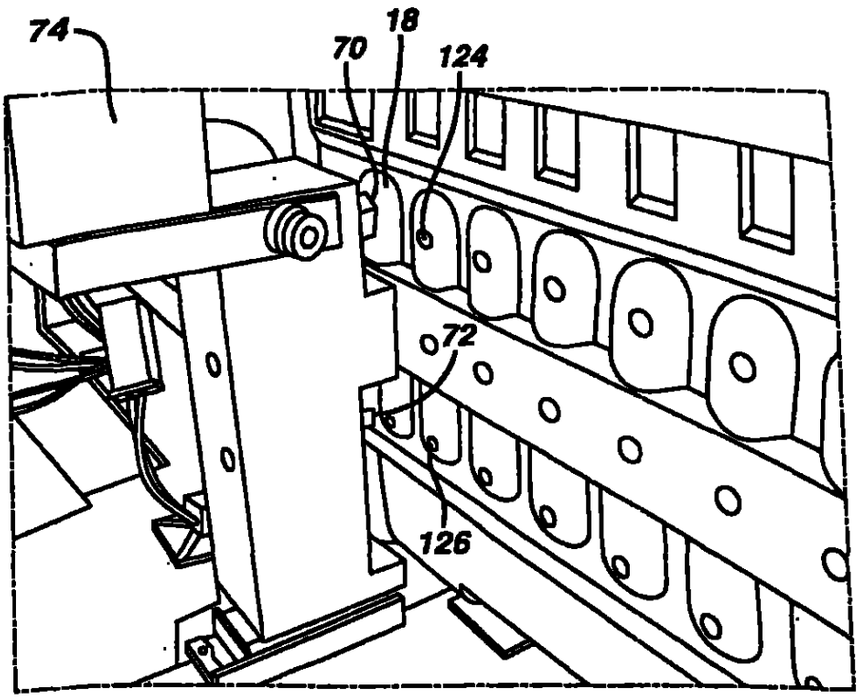


FIG. 12

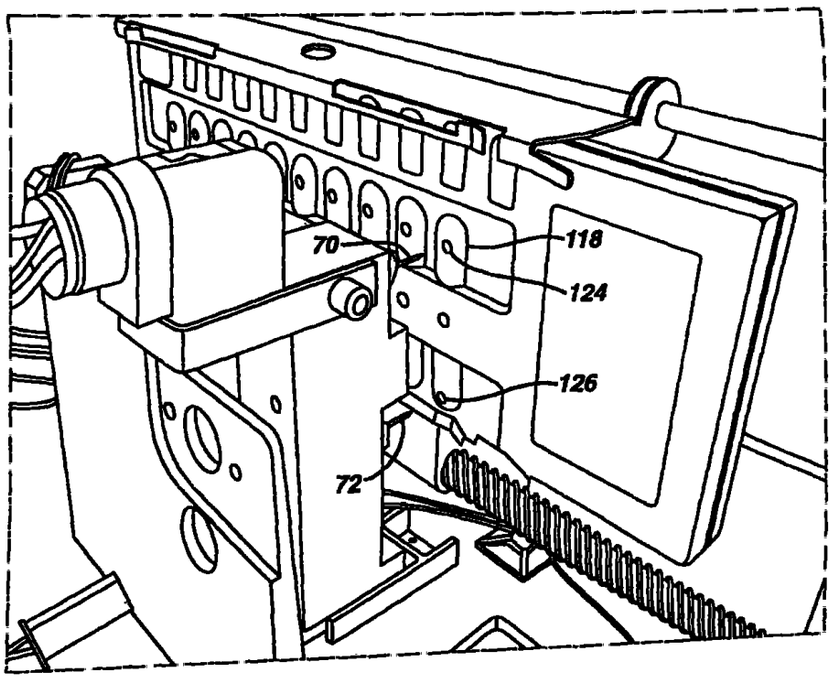


FIG. 13

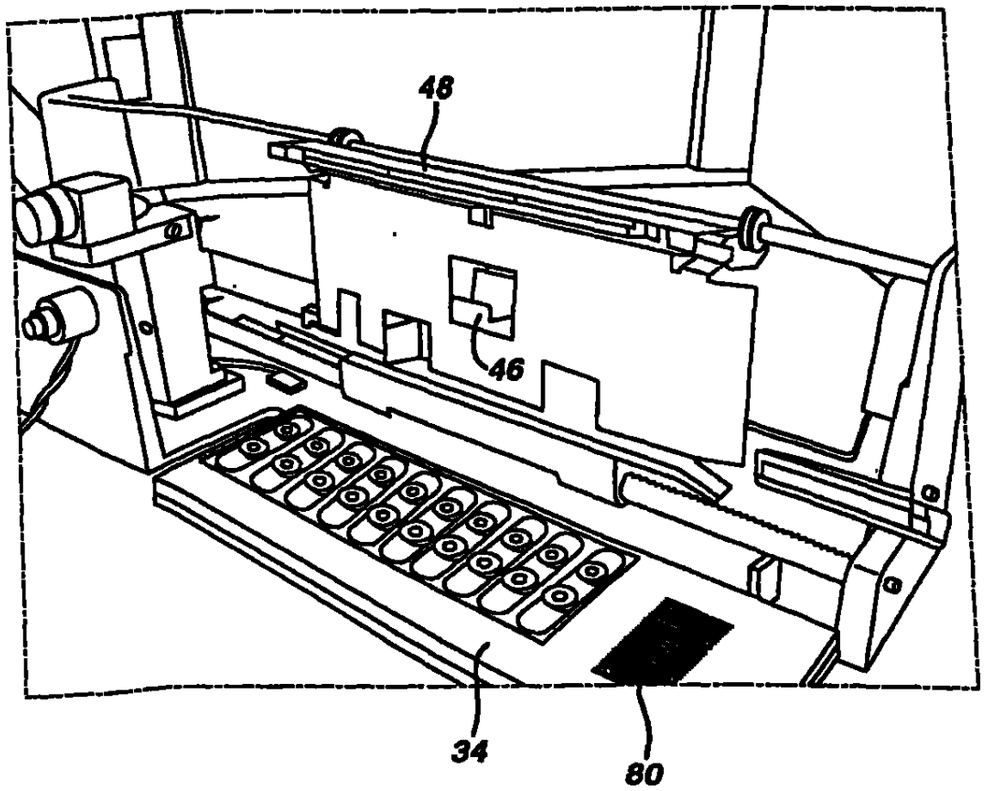


FIG. 14

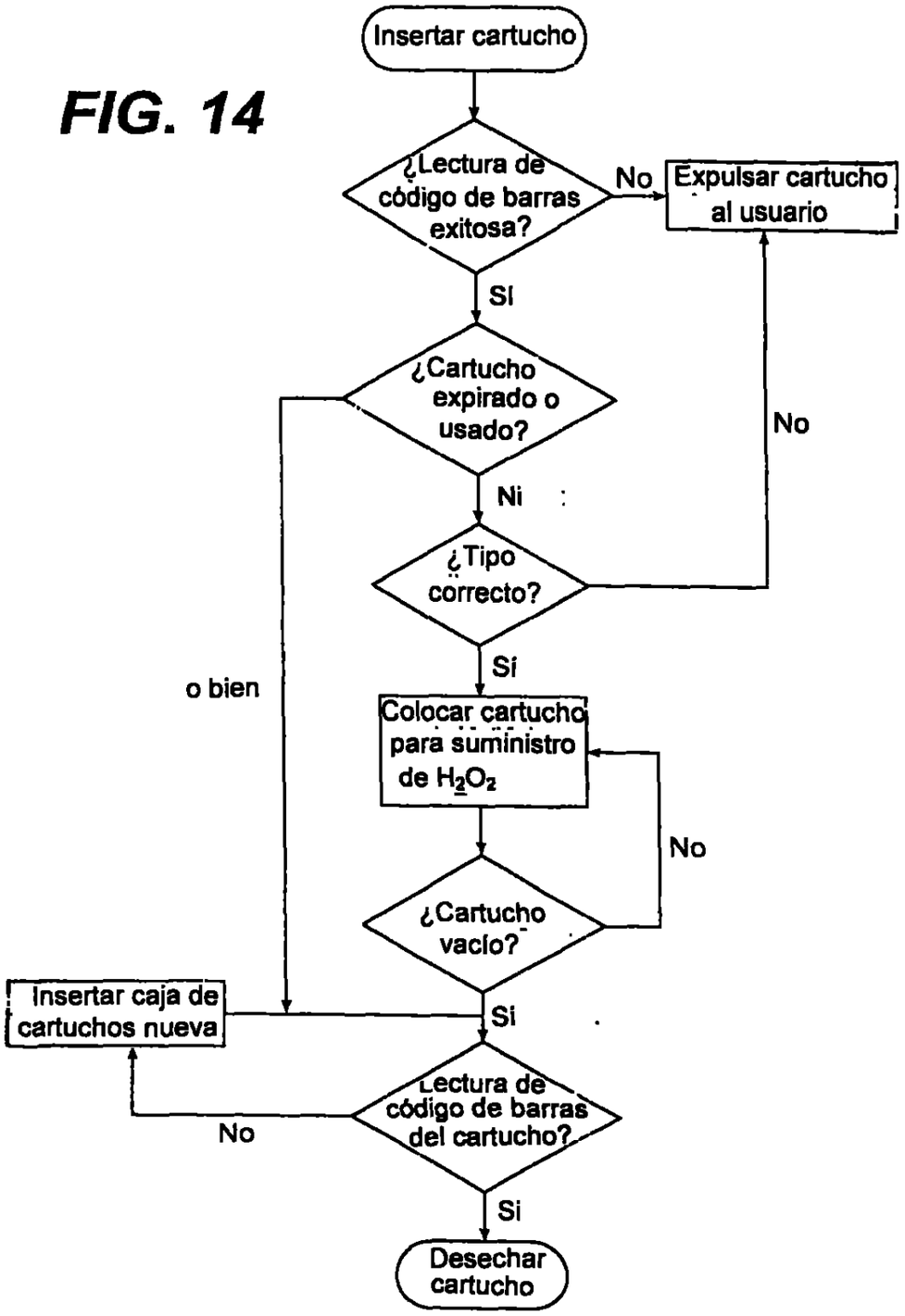

Insertar cartucho
¿Lectura de código de barras exitosa?
No
Expulsar cartucho al usuario
Sí
¿Cartucho expirado o usado?
No
Ni
¿Tipo correcto?
Sí
o bien
Colocar cartucho para suministro de H_2O_2
No
¿Cartucho vacío?
Insertar caja de cartuchos nueva
Sí
Lectura de código de barras del cartucho?
No
Sí
Desechar cartucho

FIG. 15

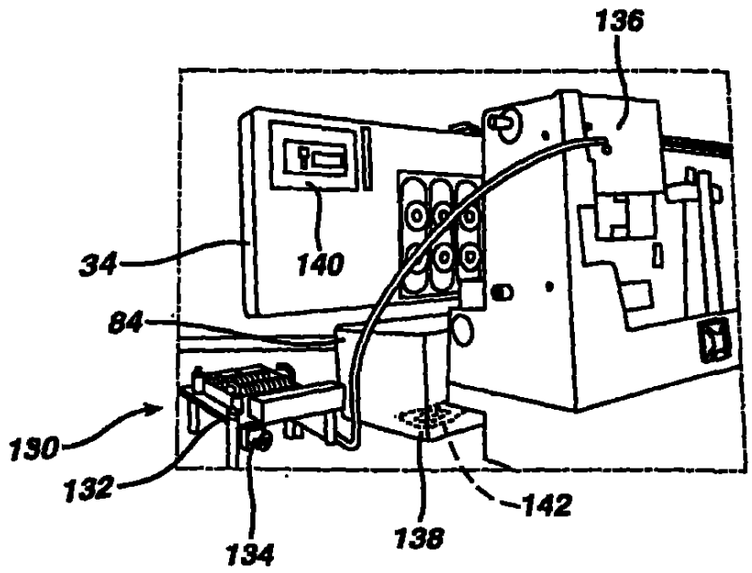


FIG. 16

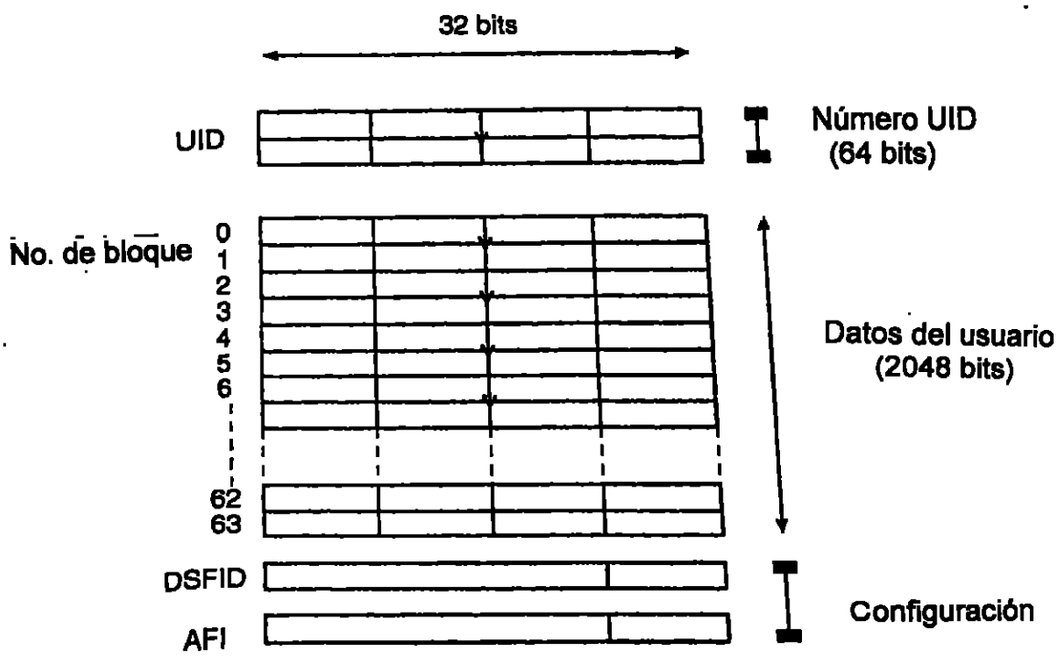

32 bits
UID
Número UID
(64 bits)
No. de bloque
0
1
2
3
4
5
6
62
63
Datos del usuario
(2048 bits)
DSFID
AFI
Configuración

FIG. 17

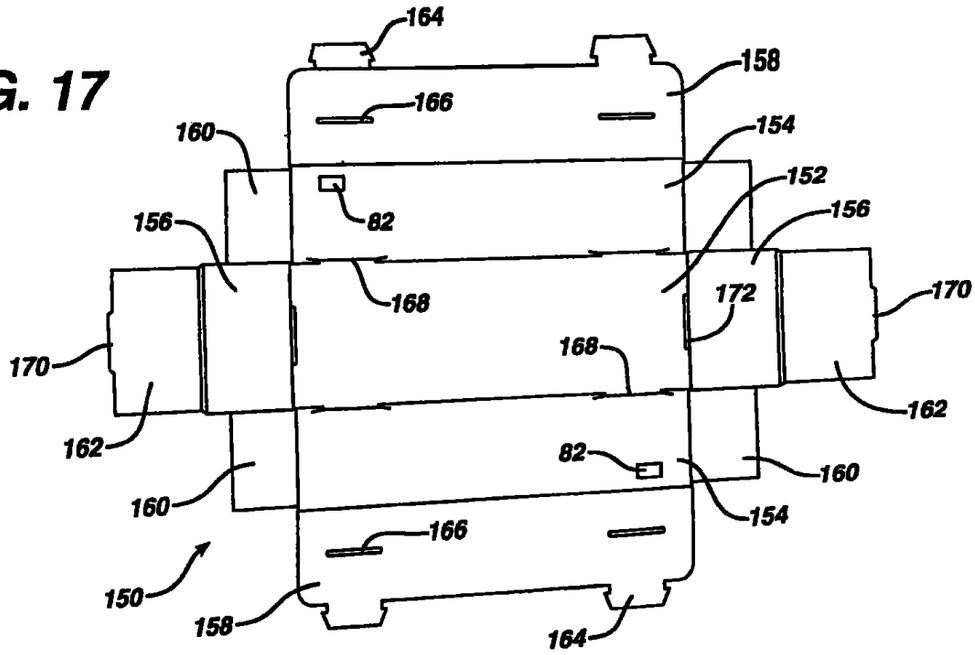

164
158
166
160
154
152
82
156
156
168
172
170
170
168
162
162
82
160
160
154
166
150
158
164

FIG. 18

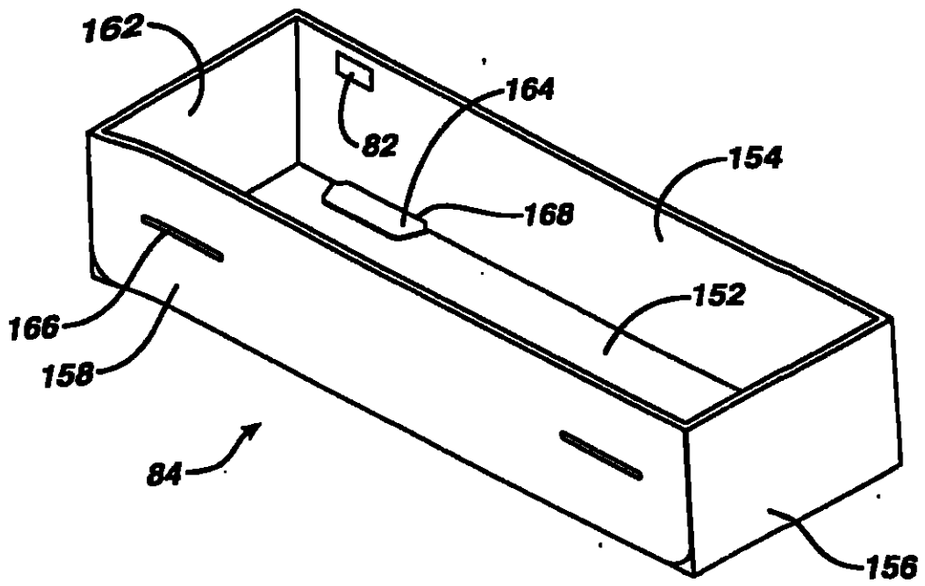


FIG 19

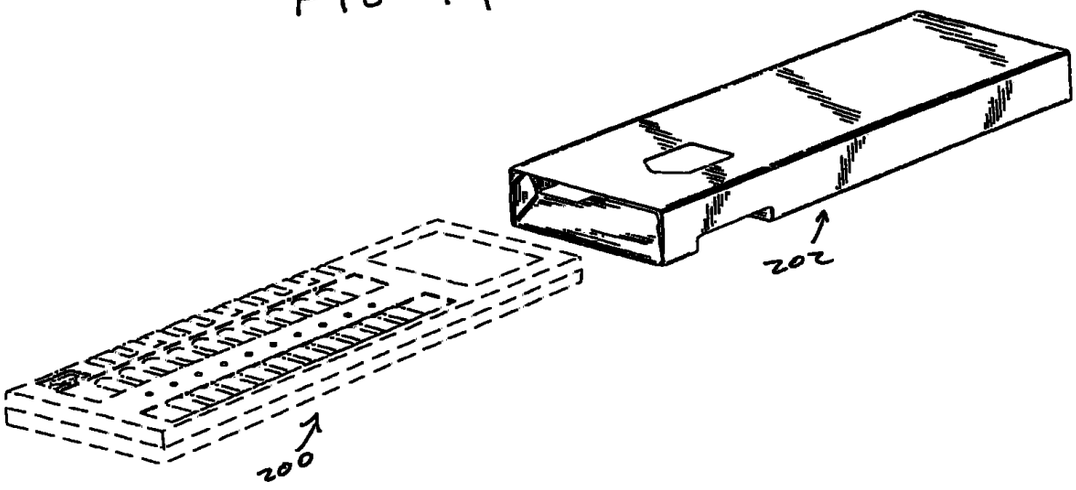


FIG. 20

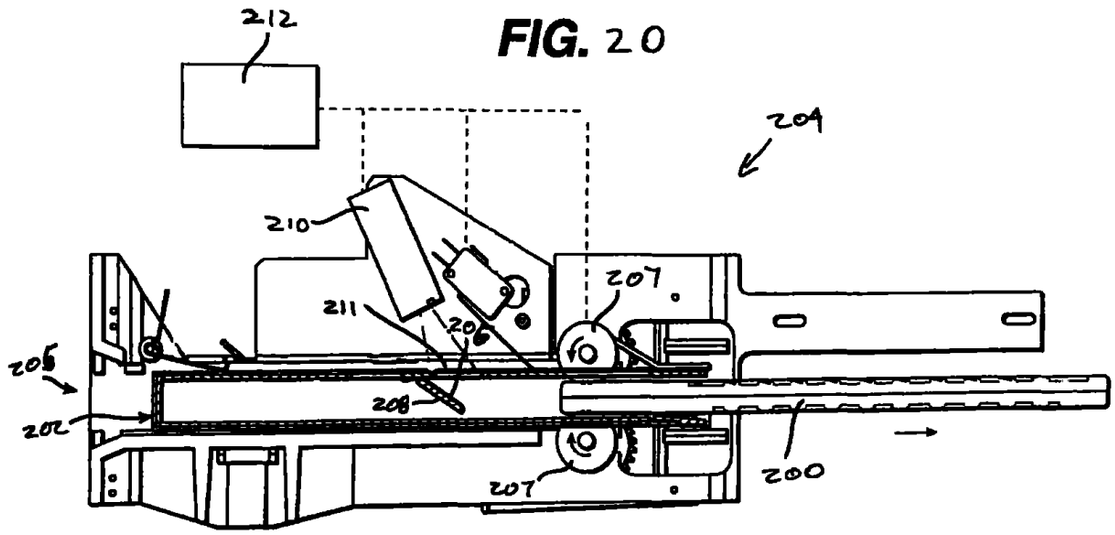


FIG 21

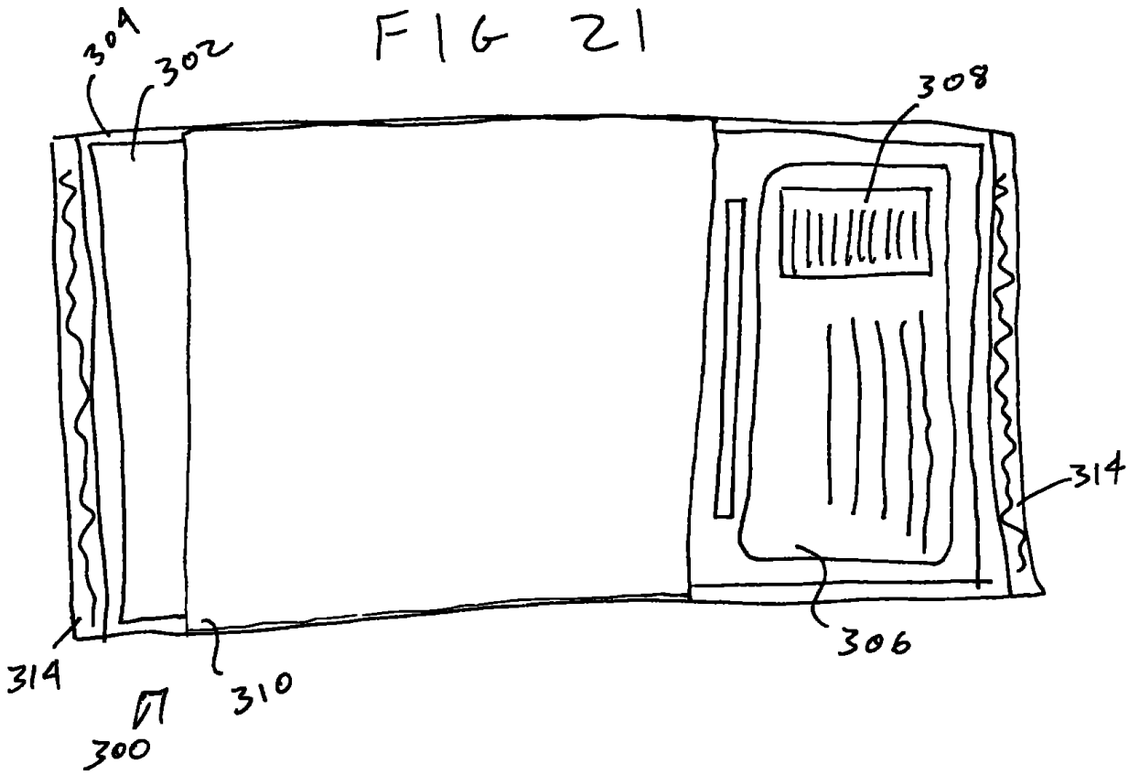
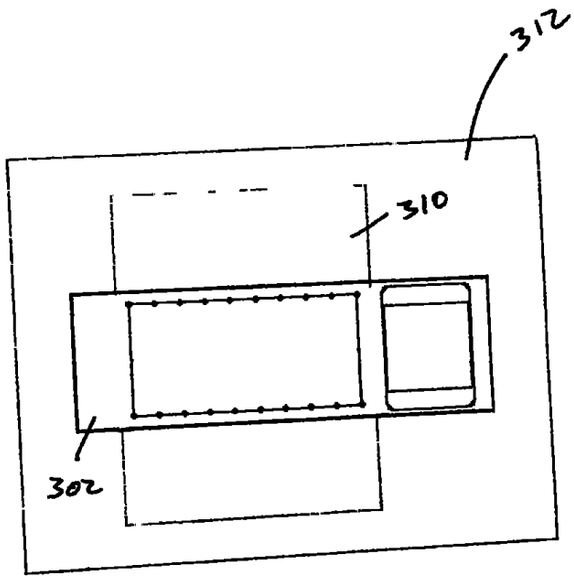


FIG 22



PTO 1330870

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

May 19, 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: ***10/978,034***
FILING DATE: ***October 29, 2004***

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

TRUDIE WALLACE
Certifying Officer

190
186

UTILITY PATENT APPLICATION TRANSMITTAL

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

Attorney Docket No.	ASP-5018 CIP
First Inventor	James P. Kohler
Title	CASSETTE ASSEMBLY
Express Mail Label No.	EL981541483US

17541 U.S. PTO 10/978034

APPLICATION ELEMENTS

See MPEP Chapter 600 concerning utility patent application contents.

ADDRESS TO: Mail Stop Patent Application
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 32]
(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 22]
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.: 10/856,435, filed May 28, 2004. Prior application information: Examiner Group Art Unit: 1744
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 0000277777 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	
DATE	10.26.04

FEE TRANSMITTAL	Complete if Known	
	Application Number	
	Filing Date	October 29, 2004
	First Named Inventor	James P. Kohler
	Group Art Unit	
	Examiner Name	
	Attorney Docket Number	ASP-5018 CIP

FEE CALCULATION

CLAIMS AS FILED

(1)	(2)	(3)	(4)	(5)
FOR:	NUMBER FILED	NUMBER EXTRA	RATE	BASIC FEE $790.00
TOTAL CLAIMS	10 - 20 =	0	x 18.00	$ 0.00
INDEPENDENT CLAIMS	1 - 3 =	0	x 86.00	$ 0.00
MULTIPLE DEPENDENT CLAIMS	☐	N/A	$290.00	
			TOTAL FEES	$ 790.00

METHOD OF PAYMENT

☒ Please charge Deposit Account No. 10-0750/ASP-5018CIP/ACF in the amount of 790.00. 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-5018CIP/ACF. Three copies of this sheet are enclosed.

SUBMITTED BY:			Complete (if applicable)
Typed or Printed Name	Andrew C. Farmer		Reg. No. 35,868
Signature		Date: 10-28-04	Deposit Account No. 10-0750

DOCKET NO. ASP-5018CIP

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

Applicant: James P. Kohler

For : CASSETTE ASSEMBLY

Express Mail Certificate

"Express Mail" mailing number: EL961541463US

Date of Deposit: October 29, 2004

I hereby certify that this complete application, including specification pages, claims, drawings and an unexecuted Declaration 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 t the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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

Margaret Turner
(Signature of person mailing paper or fee)

189

CASSETTE ASSEMBLY

This application is a continuation-in-part of U.S. Patent Application Serial No. 10/856,435 filed May 28, 2004, the contents of which are incorporated herein by reference.

Background of the Invention

This application relates to cassettes for delivering sterilant to an instrument sterilizer, and more particularly to such cassettes and their packaging.

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 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 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 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;

190

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.

It has been known to employ a bar code on such a cassette or a sleeve into which is received the cassette. Typically, a particular model of sterilizer employs a particular cassette design. The bar code on the cassette may include such information as the model number of the sterilizer for which it is designed and the expiration date of the cassette. Thus, if the wrong or an expired cassette is inserted, the sterilizer can determine this by reading the code and then reject the cassette.

Summary of the Invention

A cassette for a sterilizer according to the present invention comprises a body having one or more cells containing a quantity of liquid sterilant. The body is received within a sleeve and a bar code on the sleeve is encoded with a lumen claim.

Preferably, the bar code has encoded therein an identifier for a type or model of sterilizer to which the lumen claim is related.

In one aspect of the invention, the sterilant comprises hydrogen peroxide solution.

The lumen claim, in one aspect of the invention, specifies a length and internal diameter of a lumen. Additionally, it can specify a material from which the lumen is constructed. The encoding can be an identifier

representative of the length and internal diameter, or the actual length and internal diameter can be encoded.

The bar code in one aspect of the invention resides on a label attached to the sleeve. Alternatively, it is printed onto the sleeve.

In a preferred embodiment, the cassette has a plurality of the cells.

Brief Description of the Drawings

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

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

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 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 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;

192

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;

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

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;

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;

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 last cell of the cassette;

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

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

FIG. 15 is a rear perspective view of an alternative 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;

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

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

FIG. 19 is a perspective view of a cassette according to the present invention having an outer sleeve;

FIG. 20 is a side elevational view of a cassette handling system for processing the cassette and sleeve of FIG. 19;

FIG. 21 is a top plan view of a cassette according to the present invention received within a packaging system according to the present invention; and

FIG. 22 is a top plan view of the cassette and packaging system of FIG. 21 prior to final closure of the package.

Detailed Description

Sterilizer Overall Configuration

FIG. 1 shows in block diagram form a vapor phase sterilizer 10 employing a cassette handling system 12 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.

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 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 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. The Jacobs et al. U.S. Patent Application, Publication No. 20030235511, incorporated herein by reference, illustrates in detail such a cycle.

Cassette Handling System

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.

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 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 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 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 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.

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 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 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 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.

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 f 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 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 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 104 and rearwardly facing side 106. Turning also now t 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 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 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 facings side 102 of the disposing cam 96 and the abutment 112 prevents rotation of the disposing cam 96. The 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.

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 on 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 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.

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 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 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 needles 70 and 72.

The control system 28 uses the home position f 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.

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 pressure air will provide the driving force to empty the cell 118.

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 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 sterilant above the position would be extracted and sterilant below would remain. This would be particularly convenient with the just mentioned vertically traveling needle.

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 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 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.

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.

Lumen Claim

Typically, sterilizers and their cycle parameters have been optimized to enable sterilization of the most challenging loads possible so as to not unduly restrict which devices might be sterilized therein. Long narrow lumens being one of the most challenging areas to sterilize have become the de facto standard in defining the potency of a sterilization process, i.e. its ability to sterilize devices having a lumen of a certain diameter and length. The longer and narrower the lumen which can be sterilized, the more efficacious the sterilizer cycle. A sterilizer is thus said to achieve a lumen claim of lumen diameter by lumen length, as for instance 1 mm x 100 mm. The lumen claim can also include the material forming the lumen. Typically, the lumen claim will be the claim which has been approved by a regulatory agency such as the US Food and Drug Administration, but can represent merely the lumen which the sterilizer and cycle can effectively sterilize. Typically, sterilization entails a six log reduction in the challenge microorganisms. In hydrogen peroxide based sterilization systems the preferred challenge microorganism is *Geobacillus stearothermophilus*.

Rather than always run the sterilizer to achieve its maximum lumen claim, it may be desirable to run the sterilizer 10 in different cycles depending upon the devices loaded therein for sterilization. Preferably, an operator selects a lumen claim when loading the sterilizer 10 based upon the most challenging lumen device being

loaded and then enters that lumen claim into the control system 28. Alternatively, the devices can be coded themselves, such as with a bar code which is scanned as the device is loaded, and the control system 28 selects the appropriate cycle to meet a particular lumen claim based upon the most challenging lumen device which was scanned. A set of lumen claim cycles programmed into the sterilizer might include the following: a) 1 mm x 1,000 mm, b) 1 mm x 500 mm, c) 2 mm x 100 mm, and d) no lumen. The cycles for the less demanding lumen claims can be adjusted, such as injecting less sterilant, employing a lower concentration sterilant, a shorter contact time, or a less demanding vacuum (higher pressure). In general, employing a lower concentration sterilant can provide benefits in gentler processing of the instruments to be sterilized.

To provide flexibility in optimizing differing lumen sterilization cycles, preferably cassettes 34 having loads of sterilant optimized for a given lumen claim cycle are provided. Preferably, the lumen claim is encoded onto the barcode 80 along with other data such as the sterilizer model for which the cassette 34 is intended and the expiration date.

A suggested data layout for the barcode 80 comprises the following fields: a) sterilizer model for which the cassette 34 is intended (three binary digits - associated with a look-up table); b) expiration date (eight binary digits representing the number of months from a fixed date); c) lumen claim (three binary digits - associated with a look-up table). Alternatively, the lumen claim could be represented by separate lumen internal diameter and length fields, preferably in millimeters and

decimeters respectively. Further, as illustrated in the last row of Table 1a some lumens having different dimensions may nonetheless have equivalent processing requirements. Preferably, one of the equivalent lumens would be coded onto the barcode 80, with the sterilizer's control system being programmed with the equivalents. Many coding schemes are possible within the scope of the invention.

Tables 1a and 1b illustrate how certain parameters of the cycle can be modified to treat particular lumens.

Table 1a - 173L chamber with two loads

Device	Peroxide concentration	Peroxide amount	Time required t kill about $1x10^6$ *Geobacillus stearothermophilus* spores
Stainless steel Surface	59% wt	1 g	5 minutes
1mmx1000mm TEFLON* lumen	50% wt	2 g	15 minutes
1mmx125mm, 2mmx250mm or 3mmx400mm Stainless Steel lumen	59% wt	1.7 g	20 minutes

*polytetrafluoroethylene, TEFLON is a trademark of 3M Co.

Table 1b - 51L chamber with one 1 ad

Device	Peroxide concentration	Peroxide amount	Time required to kill about $1x10^6$ *Geobacillus stearothermophilus* spores
2mmx400mm Stainless Steel lumen	90% wt	0.23 g	3 minutes
1mmx150mm Stainless Steel lumen	90% wt	0.34 g	3 minutes
1mmx500mm Stainless Steel lumen	90% wt	0.45 g	7 minutes
1mmx350mm TEFLON* lumen	90% wt	0.45 g	3 minutes

*polytetrafluoroethylene, TEFLON is a trademark of 3M Co.

Beyond merely entering lumen data, the control system 28 can be configured to take multiple inputs and use this information to determine how a subsequent sterilization cycle should be performed. Such inputs can include: whether the load is wrapped or unwrapped (such as in Central Supply Room "CSR" wrap), the weight of the load, the number of items (and more preferably the number of certain types of items such as rigid or flexible endoscopes, the materials of the load, such as the proportion of plastics, the presence or proportion of polymers highly absorbtive of hydrogen peroxide such as, but not limited to, polyamides, polyurethanes, silicone rubbers, PVCs, Polymethyl methacrylates and polysulfones, and whether full sterilization or merely high level disinfection is needed. Some of these inputs can be determined by the machine with addition of appropriate sensors, such as for example the weight of the load which

can be determined via some form of scale preferably incorporated into the sterilizer 10 or via measuring plasma power.

The sterilizer 10 has many sensors including those to measure temperature, pressure, sterilant concentration and plasma power. These in conjunction with the user inputs are used by the control system to adjust the parameter of the sterilization cycle in order to adequately treat the load in the most efficient manner. Table 2 illustrates how a cycle can be modified to for several user inputs.

Table 2 - Cycle Response to User Input

Attributes of load	Response	Control mechanism
Sterilization or high level disinfection	**High level disinfection**- low sterilant concentration or/and mass/shorter exposure time **Sterilization**- high sterilant concentration or/and mass	Determine sterilant/disinfectant concentration level and quantity to reach sterilant level required. Monitor concentration/amount by sterilant sensor and maintain at the required level
Wrapped or unwrapped load	Unwrapped- low concentration/mass delivery Wrapped- higher concentration/mass delivery	Determine sterilant/disinfectant concentration level and quantity to reach sterilant level required. Monitor concentration/amount by sterilant sensor and maintain at the required level
Load volume and weight	High volume: possibly more absorption High weight: possibly higher condensation	Monitor and maintain the required sterilant/disinfectant concentration level. Set temperature at higher level to reduce absorption and condensation effects. Pre-heat the load if necessary. High venting/residual removal treatment.
Loads contains materials that are a decomposer or absorber to the sterilant/disinfectant	Higher injection mass/concentration and temperature may be required	Monitor and maintain the required sterilant/disinfectant level. High venting/residual removal treatment if excessive absorb is present (Identify from sterilant concentration sensor output)
Load contains lumens: short vs. long	High concentration and/or mass, longer exposure time and pre-processing pressure gradient	Set concentration and pressure gradient levels accordingly

In one aspect of the invention, the user would first choose between running one or more standard cycles, or one or more user programmed cycles, or enter load and process

208

data to design a cycle. Under the option of entering load data the user could first select whether sterilization or high level disinfection is required. If sterilization is selected, the user would preferably enter whether the load contained wrapped containers or items. The user would second enter whether the load contained lumens or not. For a load lacking lumens the overall weight and materials in the load would be entered. These entries could be made item by item, or as an aggregate. For lumens, additional data such as the lumen length and internal diameter would be entered. Again, this data could be entered as the most challenging single lumen, or item by item. Thirdly, the user would enter load preparation information such as whether preheating or moisture removal steps should be taken with the load. Alternatively, the control system could recommend or determine whether these steps should be taken based upon the data entered. These steps can lengthen the overall process time and in some instances the user may wish to opt out of their use to speed the cycle. Fourth, the user would enter data as to the source of sterilant (bulk or cassette), sterilant concentration, sterilant volume and type of sterilant. Again, some of this could rather be recommended or determined by the control system based upon the entered data, which could also provide the user with a message as to which type of cassette should be loaded for instance. Finally, information about residual removal would be entered, i.e. whether a residual removal step should be taken at the end of the cycle and whether heat, plasma, sterile air purging, vacuum or some combination thereof should be employed. Again, this information could rather be recommended or determined by the control system based upon the data entered. The user would have the option of saving this cycle set-up so that it could be chosen from a

cycle menu for later cycles of similar devices. Names could be provided to the cycle set-up, such as by procedure instrument set, to allow easy retrieval of the appropriate cycle in the future.

Determinations of cycle changes can be made based upon table look-ups employing cycle corrections based upon known cycle modifications related to load modifications, preferably backed up by test data. For instance, tests run on lumens of varying diameter and ID can determine exposure times and sterilant concentrations that produce reliable sterilization. In addition, calculations of integrated sterilant exposure (quantity and time) can be employed. For instance, experiments have shown that a particular lumen can be successfully sterilized by a particular integrated sterilant exposure; varying the quantity or time while maintaining the overall integrated exposure still achieves a reliable sterilization.

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 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 spend cassette box 84. Each cassette 34 carries a cassette RFID 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 available from Texas Instruments, Dallas, Texas.

210

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 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 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 on the RFID tag. Thus, if the cassette 34 is removed and then reinserted into the sterilizer 10, or even into 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 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 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 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 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 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 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.

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 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.

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, Dreseden, 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.

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

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.

Fig. 19 shows a cassette 200, similar to the cassette 34. However, the cassette 200 fits within an outer sleeve 20 which protects the cassette 200 and which is preferably absorptive of the liquid sterilant such that any droplets thereof which might remain on the cassette 200 after a sterilization cycle would be absorbed by the sleeve 202 thereby preventing user contact with the sterilant. FIG. 20 shows the cassette 200 within an alternate cassette handling system 204.

In this system 204 the cassette 200 and sleeve 202 enter through an opening 205. Rollers 207 move the cassette 200 and sleeve 202 into the system 204 where a bar code 206 on a flap 208 is read by a bar code reader 210 through a window 211 through the sleeve 202 and the information passed to a control system 212. The control system 212 checks that a proper cassette 200 has been inserted into the system 204 and then signals the rollers 207 to extract the cassette 200 from the sleeve 202. Preferably, the bar code 206 is encoded with a lumen claim as previously discussed.

When the cassette 200 returns to the sleeve 202 the flap 208 is pushed out of the way so that it will not be read if the cassette 200 and sleeve 202 are reinserted into the system 204, thereby preventing use of a spent cassette 200. Of course, rather than employ the flap 208

the bar code can be printed on the sleeve 202 without a flap, or on the cassette 200 and be visible through the window 211. In this case the previously discussed methods for ensuring that the cassette has not been used are preferably employed.

PACKAGING FOR THE CASSETTE

FIG. 21 illustrates a packaging system 300 for a cassette 302 similar to the cassette 34. The cassette 302 is received within a clear, liquid impermeable outer wrap 304. A label 306 and bar code 308 are visible through the wrap 304. An RFID or other tag could substitute for or compliment the bar code 308. The wrap 304 is preferably formed of clear oriented polypropylene. An absorbent web 310 attached to the inside of the wrap 304 encircles the cassette 302 about the portion which contains the hydrogen peroxide. The absorbent web 310 is preferably formed of a non-woven matrix of melt blown polypropylene impregnated with a superabsorbent polymer. For the purposes of the present invention, the term "superabsorbent polymer" refers to materials which are capable of absorbing and retaining at least about 30 times their weight in the liquid sterilant of the cassette 302 under a 0.5 psig pressure. Suitable super absorbent polymers include polyacrylamides and polyacrylates, and in particular crosslinked sodium polyacrylate. One suitable superabsorbent web is Korma HY0301038 available from BPA Fiberweb of Nashville, TN.

The packaging system is preferably formed by attaching, as for instance by adhesive bonding, the absorbent web 310 to a sheet 312 of clear polypropylene and the cassette 302 positioned thereon (see FIG. 22).

The sheet 312 and web 310 are wrapped around the cassette 302 and edges thereof attached to form a seal 314.

The absorbent web 310 is preferably fire resistant and preferably forms no hazardous reactions with the sterilant. The amount of superabsorbent polymer is preferably sufficient to absorb all of the sterilant within the cassette and retain it without release even under externally applied pressure of 2 or 3 pounds per square inch. A sleeve as in the previous embodiment can be employed, but is preferably formed of a material which also is fire resistant and forms no hazardous reactions with the sterilant. A color change indicator showing the presence of sterilant is present within the outer wrap 304 and visible therethrough to warn a user not to open the wrap if sterilant has leaked out of the cassette 302. When using a sterilant in solution with water, the indicator can indicate the presence of the water, such as the ULTRA THIN WATER CONTACT INDICATOR TAPE 5559 available from 3M.

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.

WHAT IS CLAIMED IS:

1. A cassette assembly for a sterilizer, the cassette assembly comprising:

a body having one or more cells, at least one of the one or more cells containing a quantity of liquid sterilant;

a sleeve receiving the body; and

a bar code on the sleeve, the bar code having encoded therein a lumen claim.

2. A cassette assembly according to claim 1 wherein the bar code has encoded therein an identifier for a type or model of sterilizer to which the lumen claim is related.

3. A cassette assembly according to claim 1 wherein the sterilant comprises hydrogen peroxide solution.

4. A cassette assembly according to claim 1 wherein the lumen claim specifies a length and internal diameter f a lumen.

5. A cassette assembly according to claim 4 wherein the lumen claim specifies a material from which the lumen is constructed.

6. A cassette assembly according to claim 1 wherein the bar code has encoded therein a length and an internal diameter for the lumen claim.

7. A cassette assembly according to claim 6 wherein the bar code has encoded therein a material for the lumen claim.

8. A cassette assembly according to claim 1 wherein the bar code is on a label attached to the sleeve.

9. A cassette assembly according to claim 1 wherein the bar code is printed on the sleeve.

10. A cassette assembly according to claim 1 comprising a plurality of the cells.

ABSTRACT

A cassette for a sterilizer has one or more cells containing a sterilant, is received within a sleeve and the sleeve carries a bar code which is encoded with a lumen claim. The lumen claim relates to a sterilization cycle for which the cassette is designed.

222

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
10/856,435	May 28, 2004	pending

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) 524-2625.

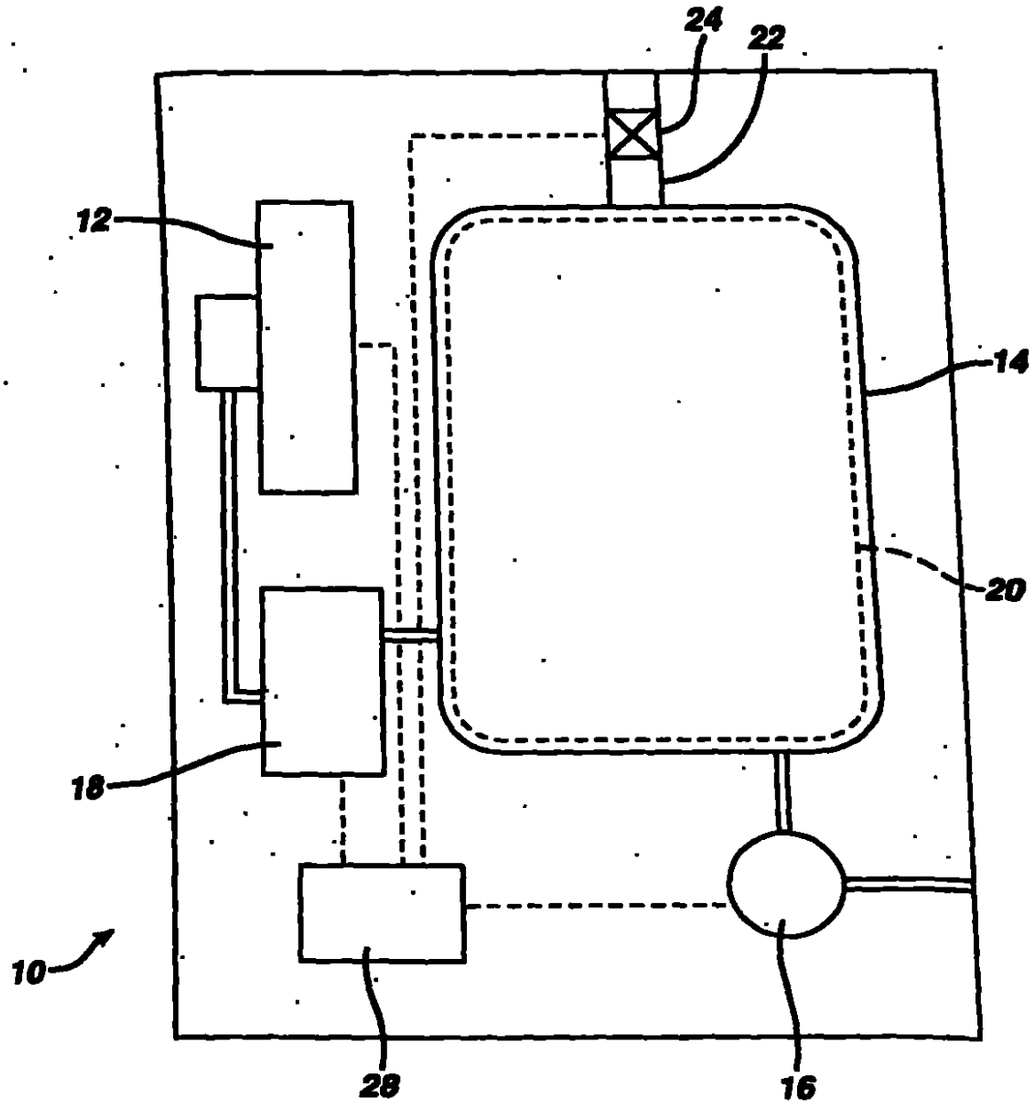
Direct all correspondence to: ☒ Customer Number or Bar Code Label 000027777 OR ☐ Correspondence address below

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]) James P.	Family Name or Surname Kohler		
Inventor's Signature	Date		
Residence: City Laguna Hills	State CA	Country USA	Citizenship USA
Mailing Address 25221 Champlain Road			
City Laguna Hills	State CA	ZIP 92653	Country USA

224

FIG. 1



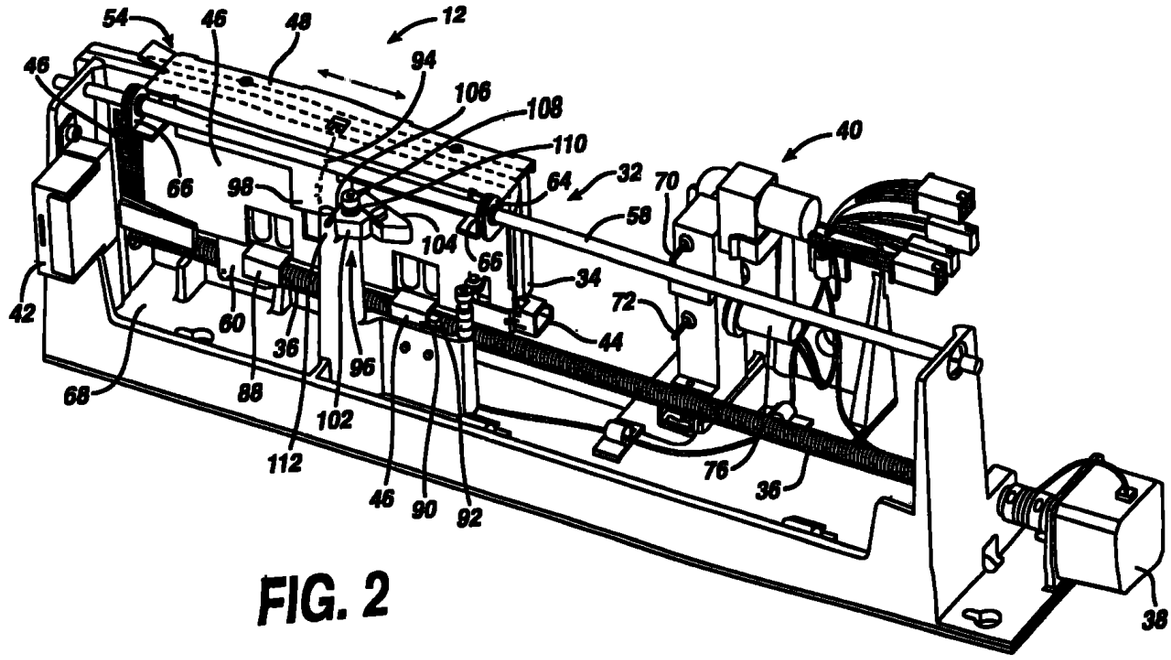


FIG. 2

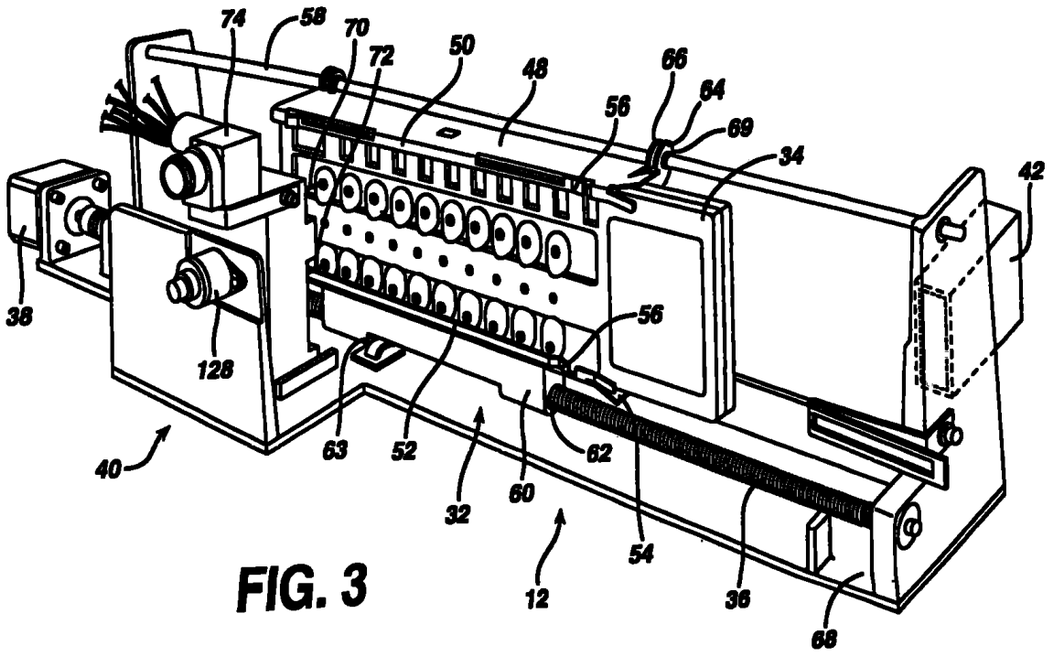


FIG. 3

FIG. 4

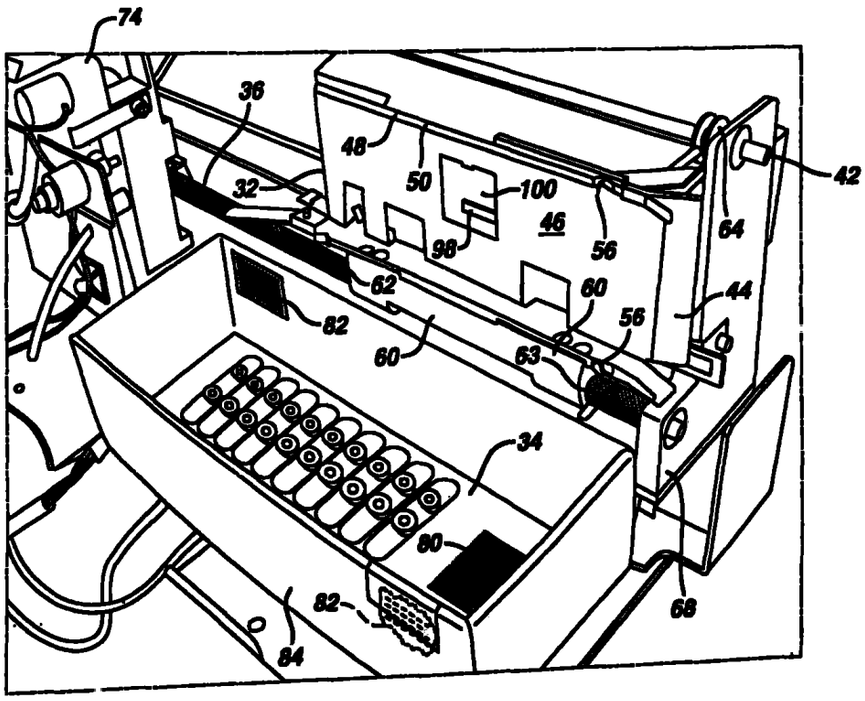


FIG. 5

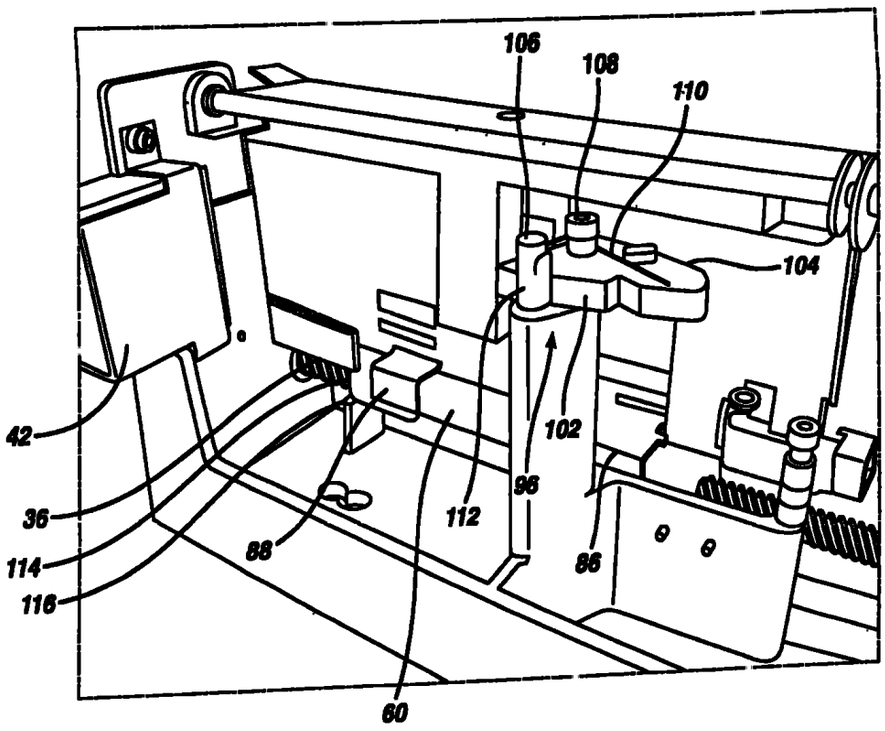


FIG. 6

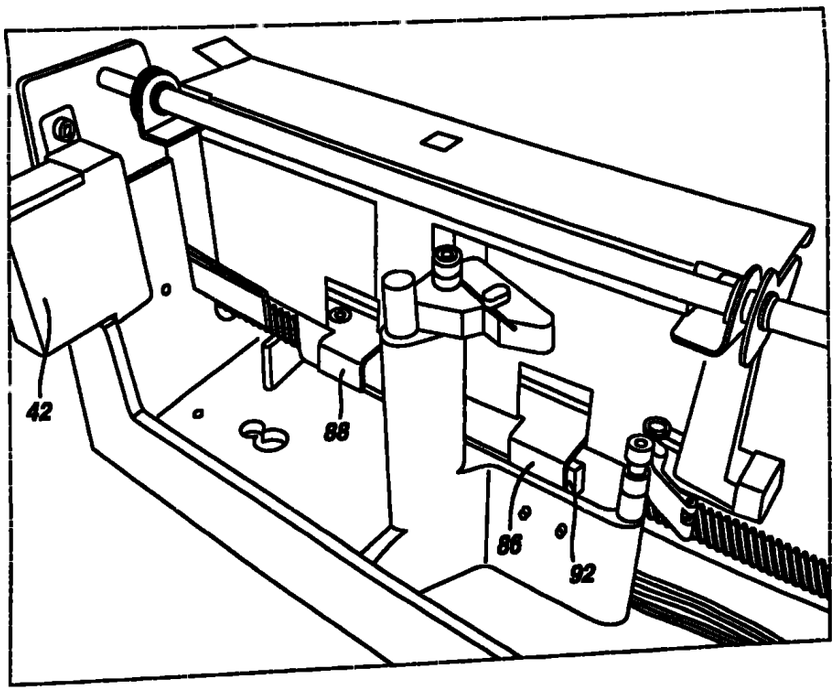


FIG. 7

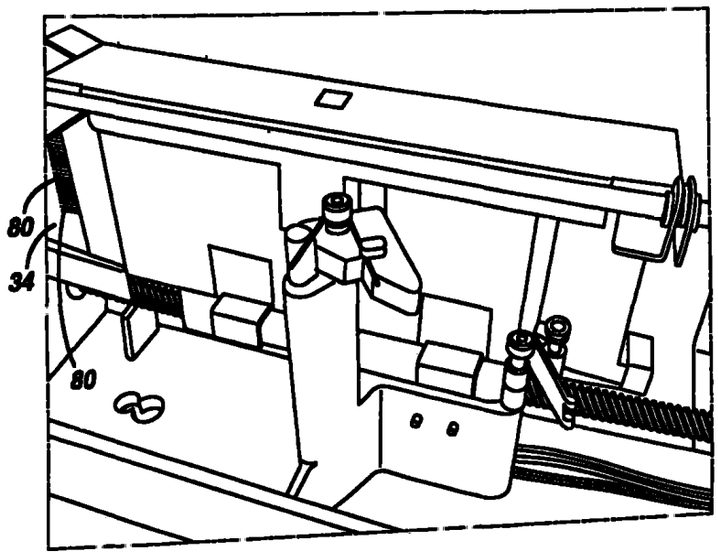


FIG. 8

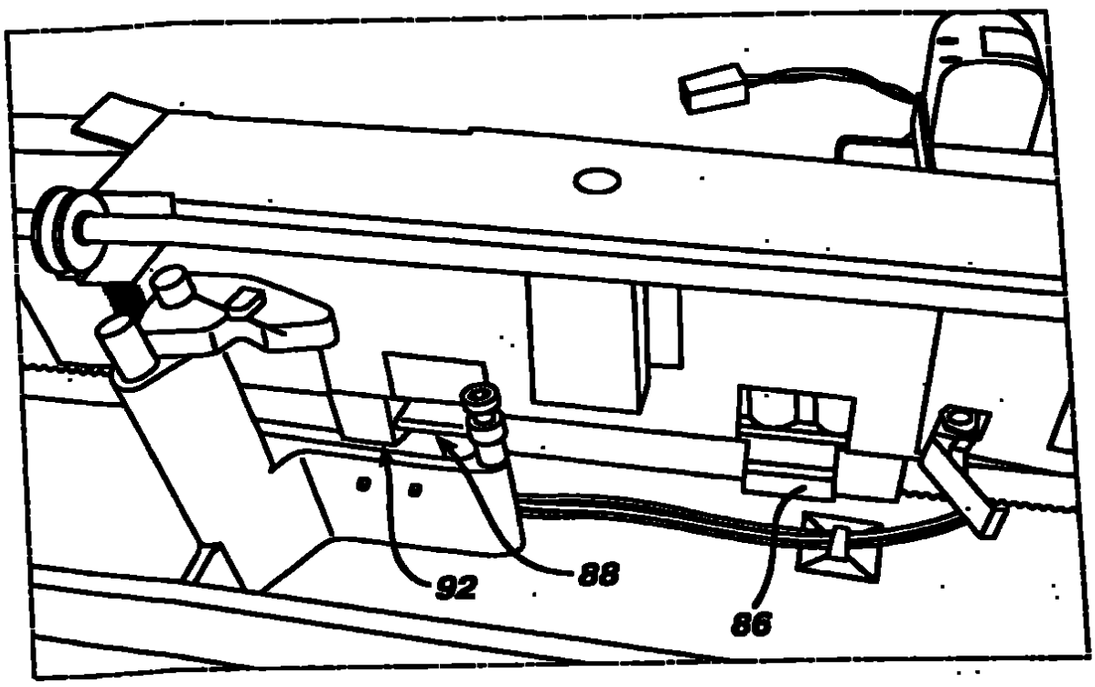


FIG. 9

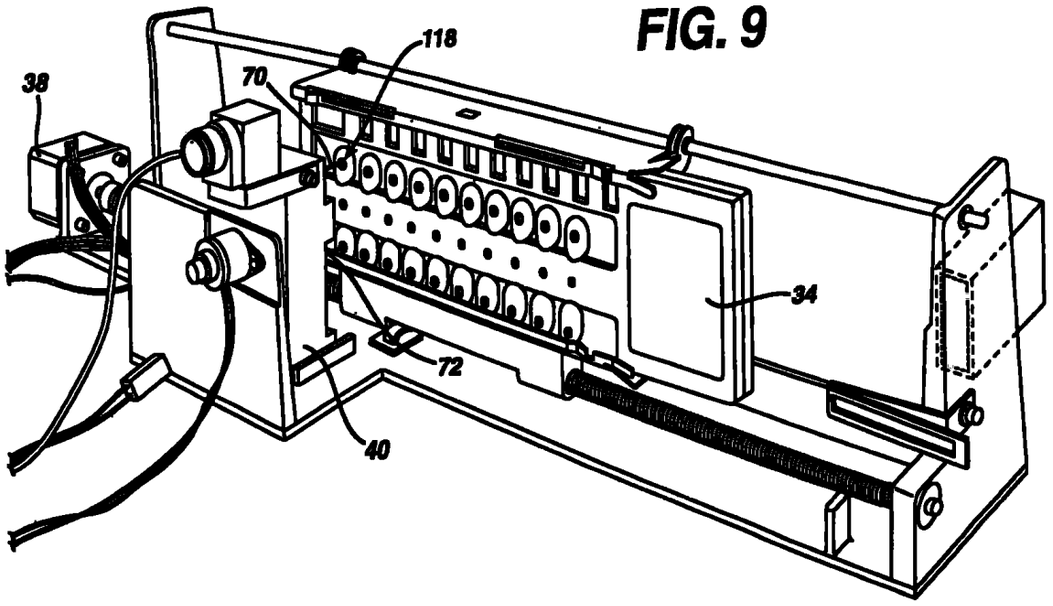


FIG. 10

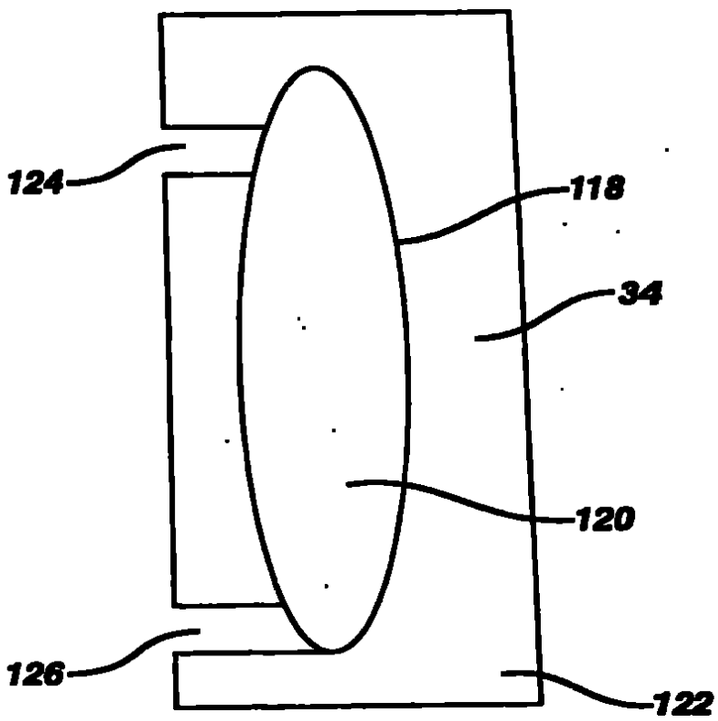


FIG. 11

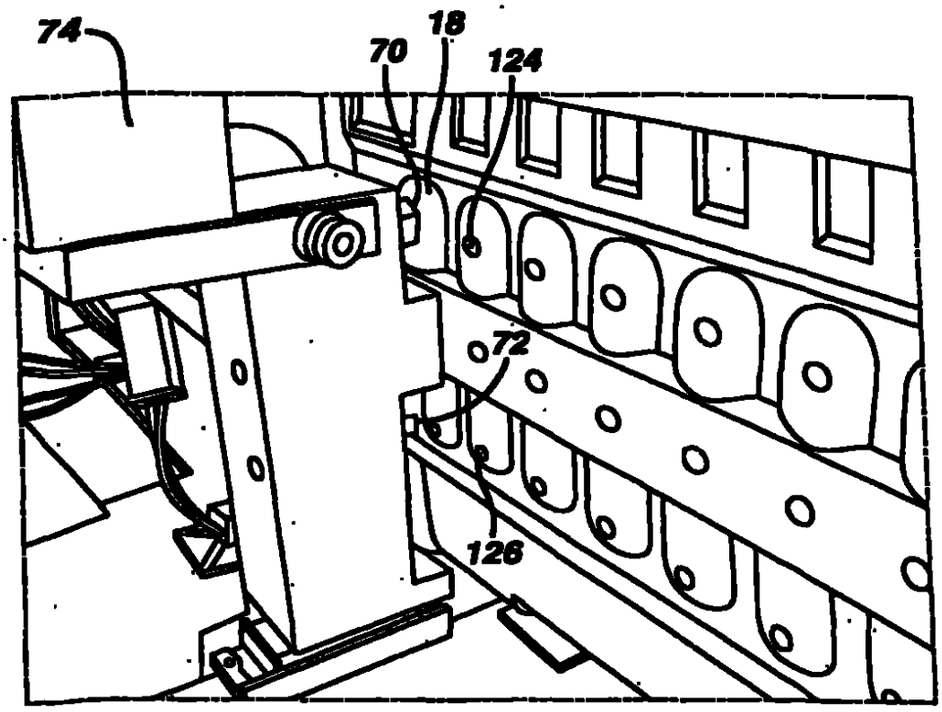


FIG. 12

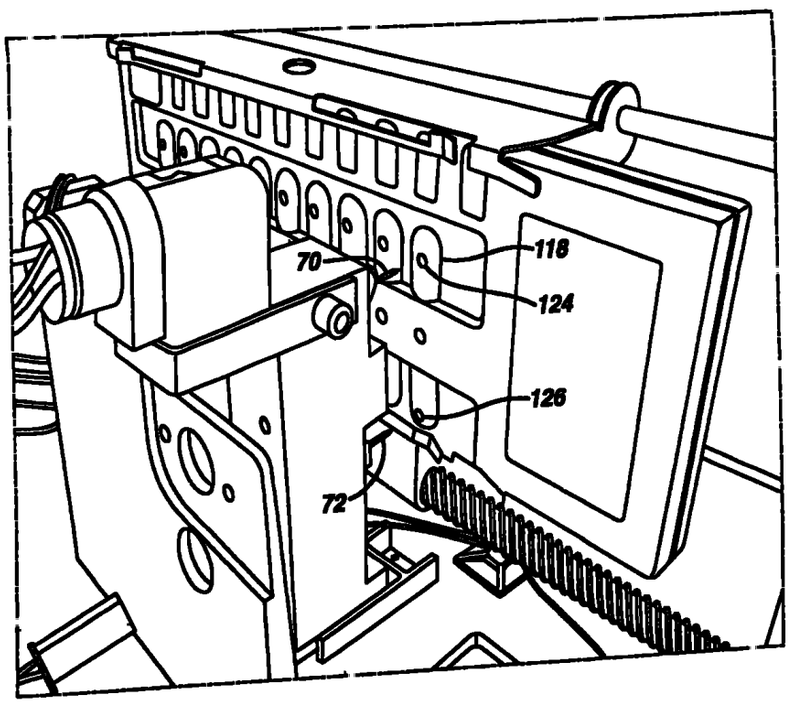


FIG. 13

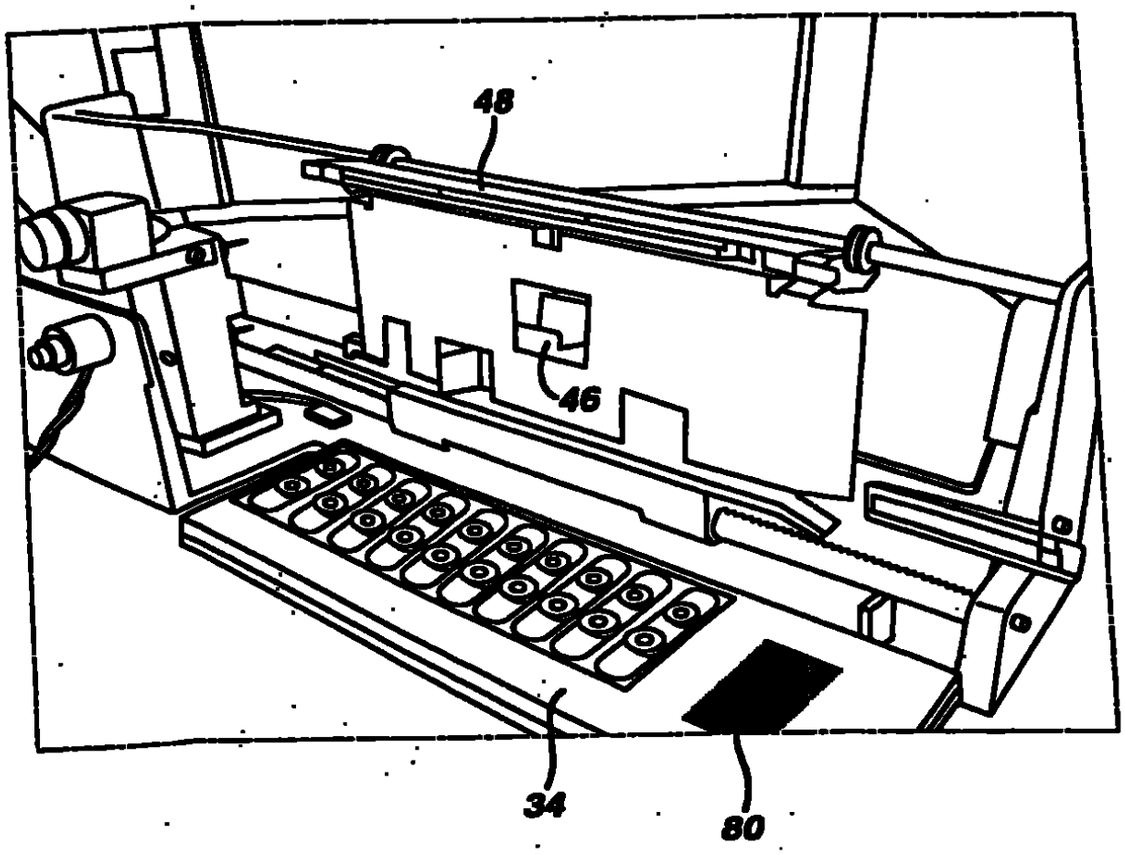


FIG. 14

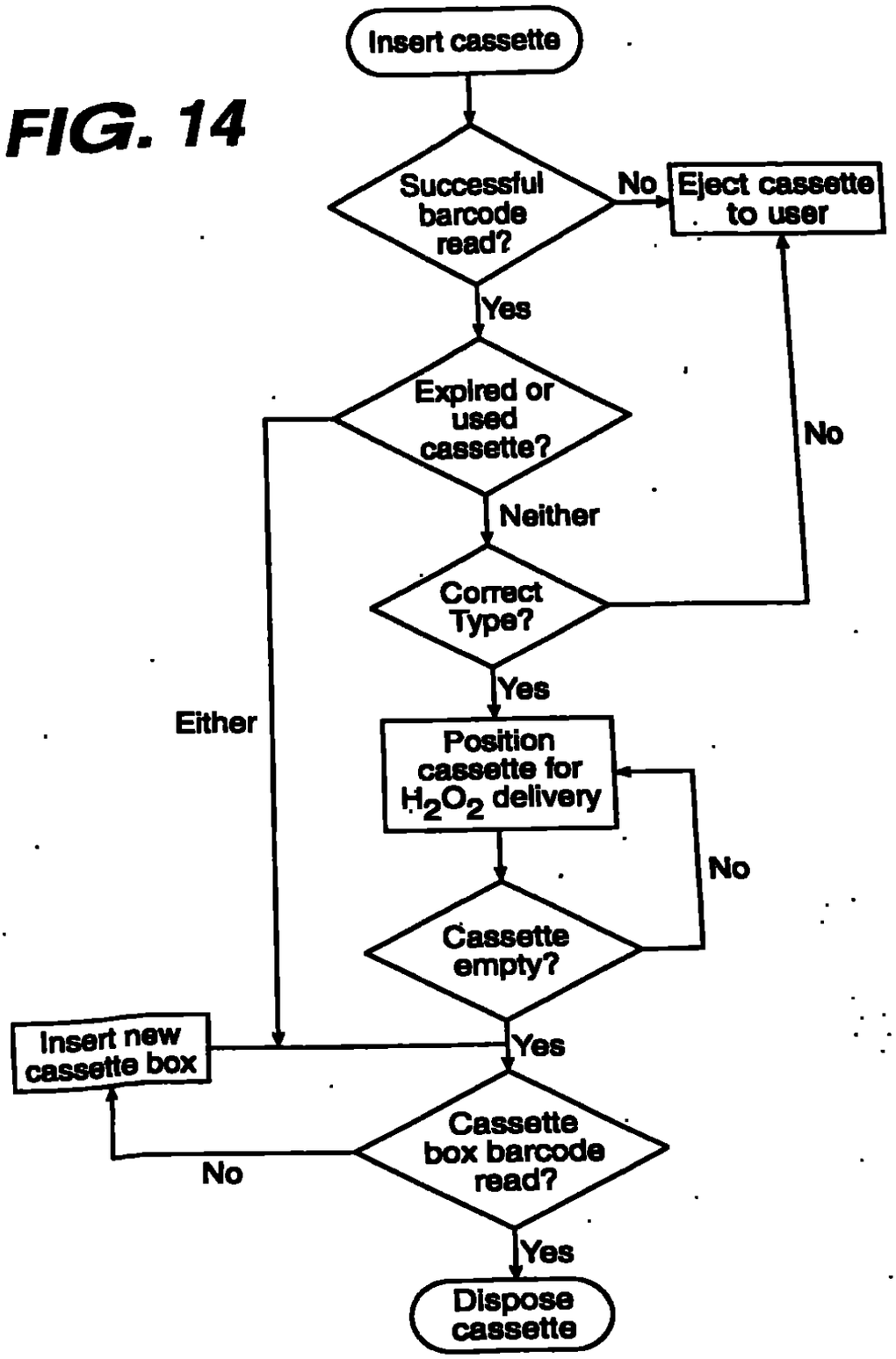


FIG. 15

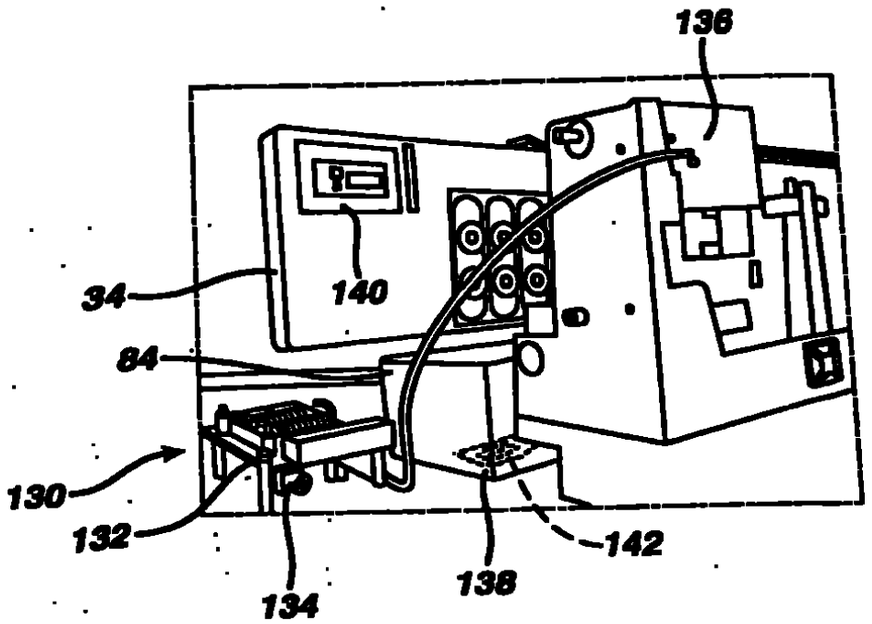


FIG. 16

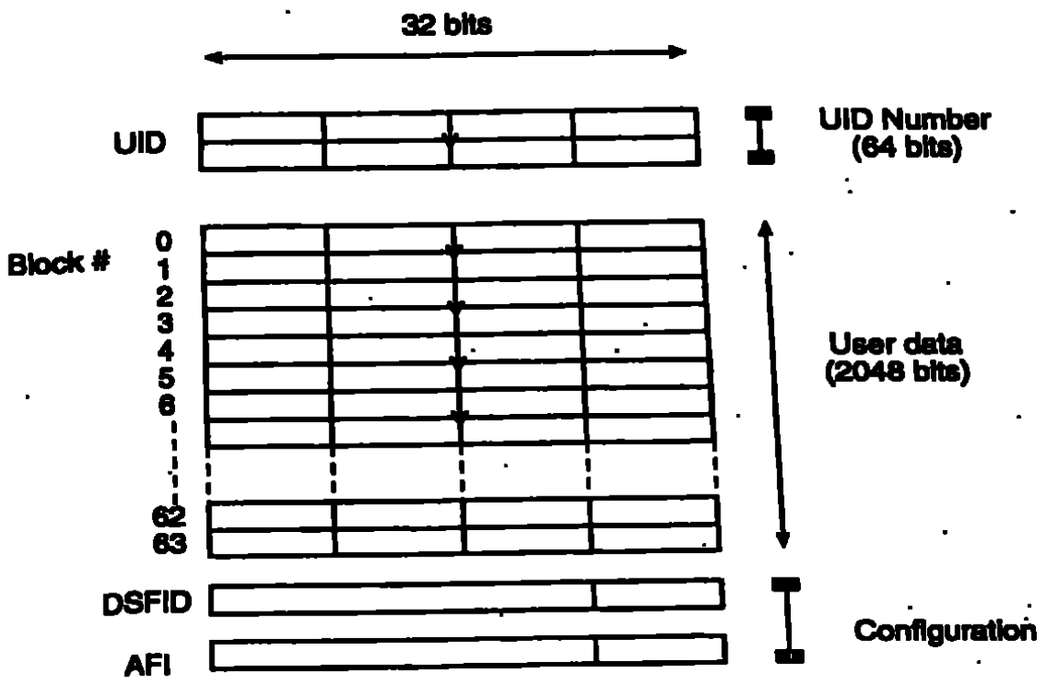


FIG. 17

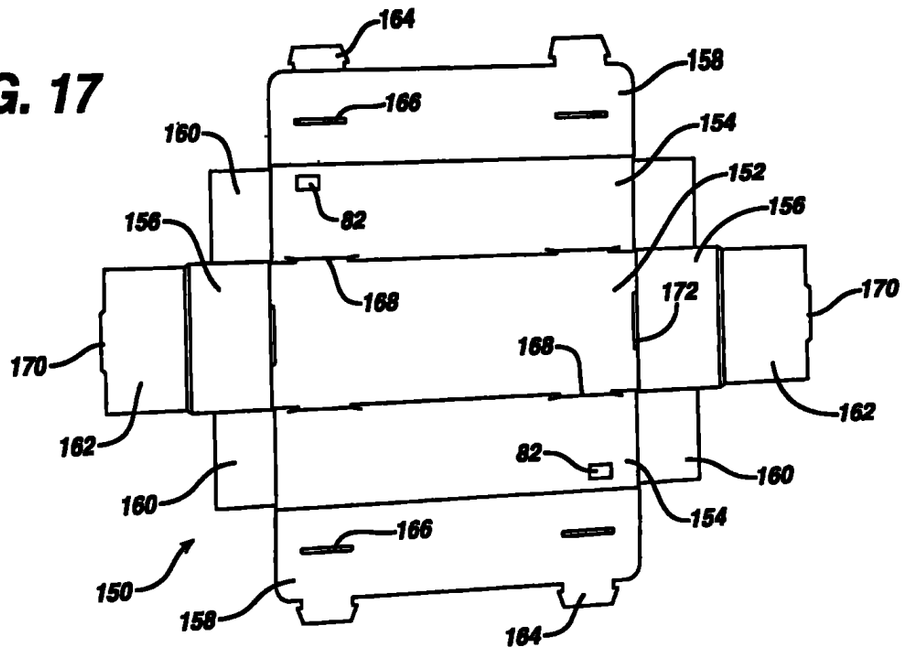


FIG. 18

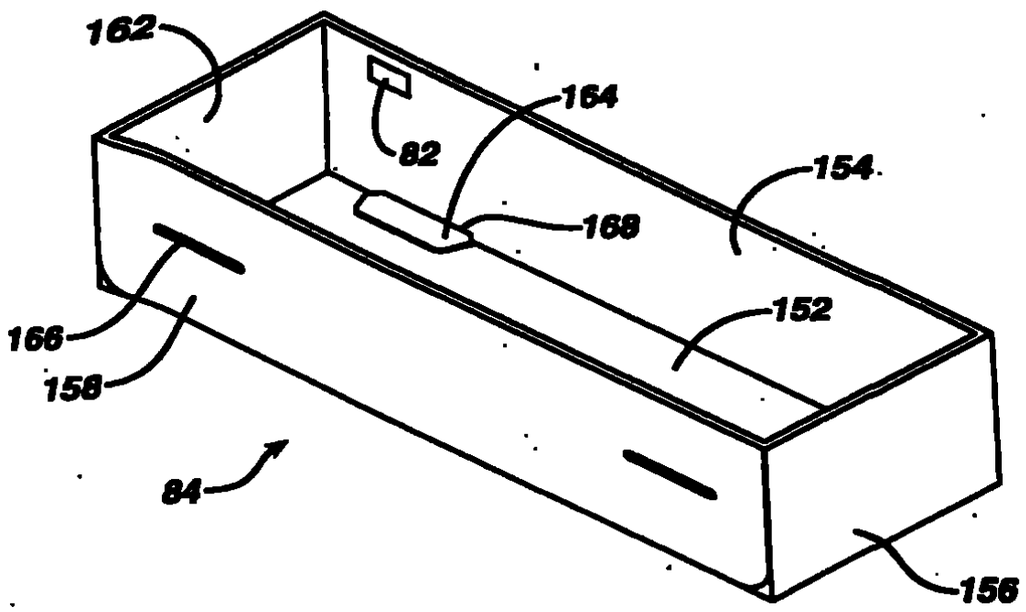


FIG 19

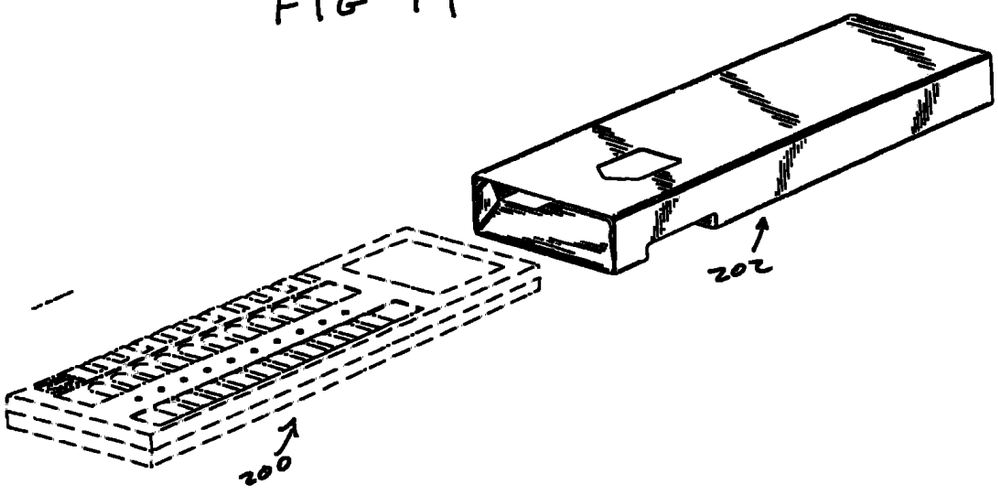


FIG. 20

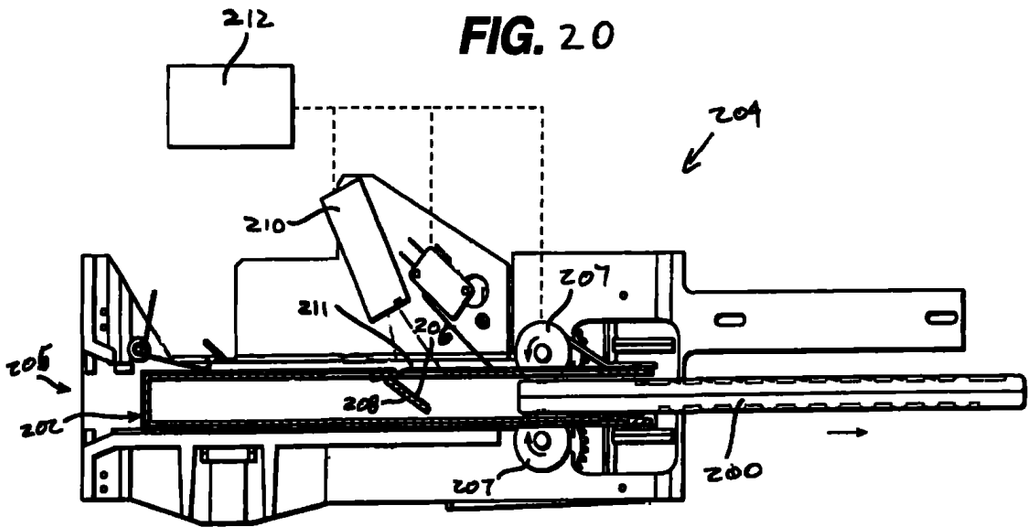
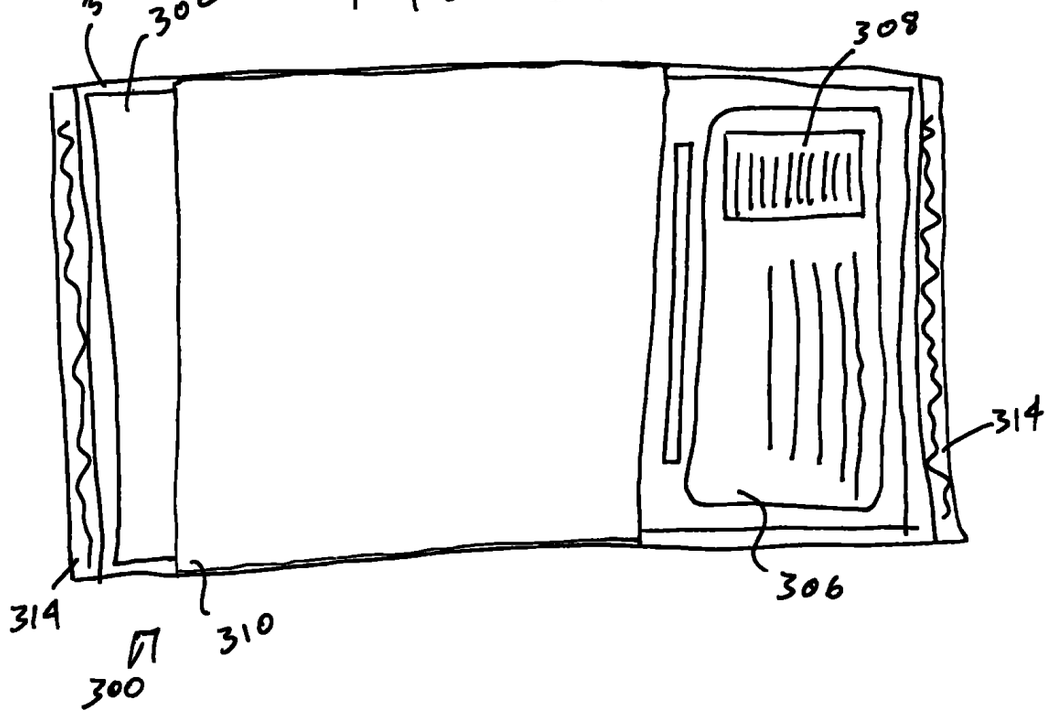


FIG 21



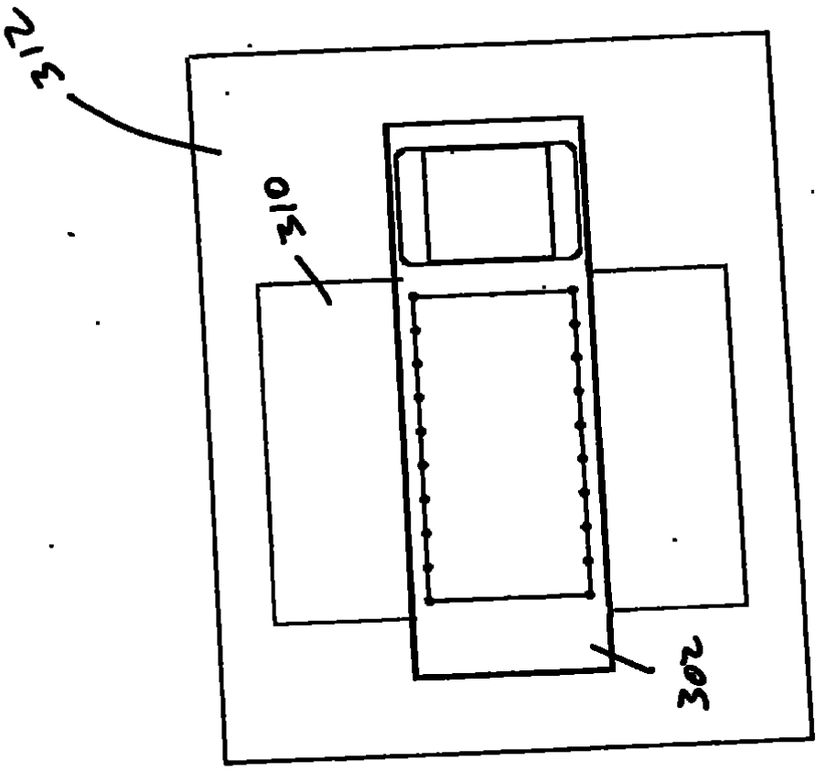


FIG. 22

246

Industria y Comercio
SUPERINTENDENCIA

2° EXAMEN DE FORMA, PATENTE DE INVENCION

Radicación N° **05-51944** Folio 249

Concepto Técnico N° **841**
Clasificación Internacional de Patentes: **A61L 2/00**

Practicado el examen de acuerdo a lo establecido en el Art. 38 de la Decisión 486, se determinó que esta solicitud de **Patente:**

SI [✓] NO [ ] Contiene un resumen de la invención (Art. 26-e)

SI [✓] NO [ ] Contiene el título o nombre de la invención (Art. 27-d)

SI [✓] NO [ ] Contiene la descripción de la invención (Art. 26-b)

SI [✓] NO [ ] NO ES APLICABLE [ ] Contiene los dibujos necesarios para comprender la invención (Art. 26-d)

SI [✓] NO [ ] Contiene una o más reivindicaciones (Art. 26-c)

SI [ ] NO [ ] NO ES APLICABLE [✓] Han sido desarrollados los productos a partir de recursos genéticos o de sus productos derivados de los que cualquiera de los Países Miembros es país de origen (Art. 26-h)

SI [ ] NO [ ] NO ES APLICABLE [✓] Los productos y o procedimientos han sido obtenidos o desarrollados a partir a partir de los conocimientos tradicionales de las comunidades indígenas, afro americanas, o locales de los Países Miembros, de acuerdo a lo establecido en la Decisión 391 y sus modificaciones y reglamentaciones vigentes (Art. 26-i)

SI [ ] NO [✓] La invención se refiere a un producto relativo a un material biológico (Art. 26-j)

SI [✓] NO [ ] NO ES APLICABLE [ ] La prioridad coincide con la materia reivindicada.

SI [✓] NO [ ] CUMPLE LOS REQUISITOS TÉCNICOS

OBSERVACIONES Y OTROS: SI [ ] NO [ ] Ver hoja(s) anexa(s)

EXAMINADOR TÉCNICO: 202051

Bogotá D C, octubre 28 de 2005.

247

Industria y Comercio

Folio ~~250~~

2020
Bogotá D C

Doctor(a):
JIMENA ESCOBAR URIBE.
Apoderado

REFERENCIA:	Radicación N°	05-51944
	Trámite	002
	Evento	001
	Actuación	416
	Oficio N°	1255
	Folios	001

Teniendo en cuenta que la solicitud de privilegio de patente que se tramita bajo el expediente indicado en la referencia, reúne los requisitos de forma establecidos en los artículos 26 y 27 de la Decisión 486, de la Comisión de la Comunidad Andina, y en las demás disposiciones vigentes sobre la materia, se envía el extracto de la solicitud a la oficina de comunicaciones para efecto de su publicación en la Gaceta de Propiedad Industrial, conforme lo establece el artículo 40 de la Decisión 486, a **partir del 27 de noviembre de 2005,** por indicación del solicitante.

Cúmplase
Dado en Bogotá D C, 31 OCT. 2005

ALIX CARMENZA CÉSPEDES DE VERGEL
Jefe División de Nuevas Creaciones.

202051