

# ESCOBAR - URIBE ASOCIADOS

A B O G A D O S

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

Tels (571) 6162051 - Fax (571) 6161889

www.escobaruribe.com - info@escobaruribe.com

2838/P.

## SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO DIVISION DE NUEVAS CREACIONES

E. S. D.

SUPERINDUSTRIA Y COMERCIO  
Radicacion : 05051945 00000002 Folios: 90/  
Fecha (AMD): 2005-07-06 16:34:37  
Tramite : 002 PATENTES D 1 REGISTRO/ 444 REPUESTA  
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

Ref.: Expediente No. 05-051.945  
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. 13041 notificado por fijación en lista el día 23 de junio de 2005, atentamente me permito presentar los siguientes documentos.

1. Copia certificada de la solicitud de patente número 10/856,664 presentada en Estados Unidos de América el día 28 de mayo de 2004, con la debida traducción de lo pertinente.
2. Artes finales en tamaño 12 x 12 centímetros (por duplicado) de la figura característica.
3. Anexo (1) documento de cesión suscrito 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, el documento de cesión anexo a este memorial es válidamente presentado en idioma inglés y con la correspondiente Apostilla.

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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 3º, 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

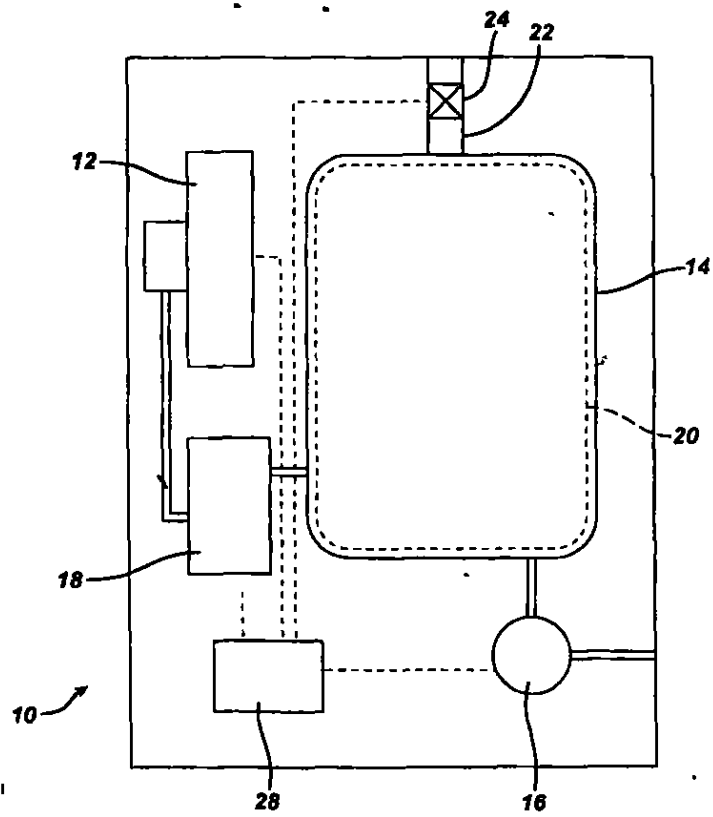
C.C.39.779.452 de Usaquén

T.P. 68228

Cód. 5376

FOL 71: ARTERIAL  
12x12

FIG. 1



73  
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. A228811
9. SEAL/STAMP:
10. SIGNATURE



*John E McCormac*

74  
91

ASP 5019 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 10/856,664 filed MAY 28, 2004.**



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

A S S I G N M E N T

Serial No.  
Filed May 28, 2004

WHEREAS, Su-Syin S. Wu, James P. Kohler and Harold R. Williams, residing at 10 Anzio, Irvine, CA 92614, 25221 Champlain Road, Laguna Hills, CA 92653 and 1223 Llano Street, San Clemente, CA 92673 respectively (hereinafter called "Assignors"), have made certain new and useful inventions or discoveries relating to

STERILIZATION/DISINFECTION CYCLE CONTROL

for which they have on the 16<sup>th</sup> 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 Assignors' 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 them moving, the receipt of which is hereby acknowledged, Assignors have sold, assigned, and transferred, and do hereby sell, assign and transfer unto said Assignee their 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 Assignors if this Assignment and sale had not been made;

And Assignors hereby authorize and request the Commissioner of Patents of the United States to issue said Letters Patent in accordance with this Assignment;

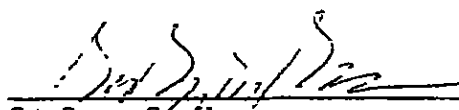
And for the consideration aforesaid, Assignors covenant and agree with said Assignee that he has a full and unencumbered title to the inventions and discoveries above

described and hereby assigned, which title they warrant unto said Assignee, its successors and assigns;

And for the consideration aforesaid, Assignors further covenant and agree that they will, whenever requested, but without cost to them promptly communicate to said Assignee or its representatives any facts known to them 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.

74

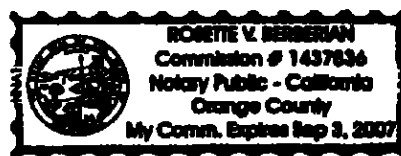
IN TESTIMONY WHEREOF, Assignors have hereunto set  
their hands and seals this 16th day of June, 2004

  
\_\_\_\_\_  
Su-Syin S. Wu (L.S.)

STATE OF California  
COUNTY OF Orange ) ss.

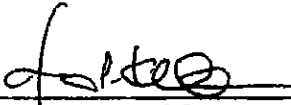
BE IT REMEMBERED, That on this 16<sup>th</sup> day of June,  
2004, before me, a Notary Public, personally appeared Su-Syin S.  
Wu, who I am satisfied is the person named in and who executed  
the foregoing instrument in my presence, and I having first made  
known to her the contents thereof, she did acknowledge that she  
signed, sealed, and delivered the same as her voluntary act and  
deed for the uses and purposes therein expressed.

  
\_\_\_\_\_  
Notary Public



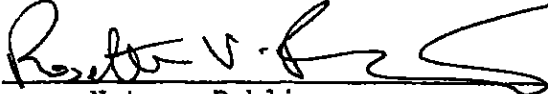
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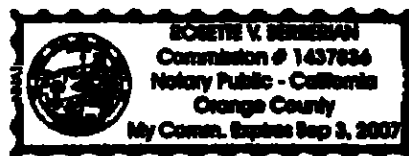
IN TESTIMONY WHEREOF, Assignors have hereunto set  
their hands and seals this 16<sup>th</sup> day of June, 2004.

  
James P. Kohler (L.S.)

STATE OF California  
COUNTY OF Orange ) ss.

BE IT REMEMBERED, That on this 16<sup>th</sup> 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



78  
76

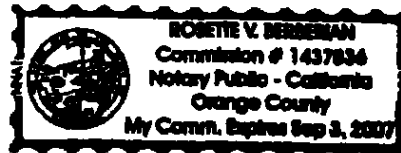
IN TESTIMONY WHEREOF, Assignors have hereunto set  
their hands and seals this 16 day of June, 2004

Harold R. Williams (L.S.)  
Harold R. Williams

STATE OF California  
COUNTY OF Orange ) ss.

BE IT REMEMBERED, That on this 16<sup>th</sup> day of June,  
2004, before me, a Notary Public, personally appeared Harold R.  
Williams, 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.

Rosette V. Berberian  
Notary Public



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|                                                                                                                                      |                                  |                                                                                                                                                                         |                 |
|--------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| <br><b>Industria y Comercio</b><br>SUPERINTENDENCIA |                                  | <b>SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO</b><br><b>DIVISION DE NUEVAS CREACIONES</b><br><b>EXTRACTO PARA PUBLICACIÓN</b><br><b>SOLICITUD DE PATENTE DE INVENCION</b> |                 |
| (21) N° de solicitud                                                                                                                 |                                  | (51) Int Cl      A61                                                                                                                                                    |                 |
| 22) Fecha de solicitud                                                                                                               |                                  | (71) Solicitante(s)      ETHICON, INC.                                                                                                                                  |                 |
| (30) Pnondad<br>Estadinense                                                                                                          | (31) No. Prioridad<br>10/856,664 | 32) Fecha<br>28/05/04                                                                                                                                                   | (33) País<br>US |
|                                                                                                                                      |                                  | (72) Inventor(es)      WU, Su-Syin S.      //<br>KOHLER, James P.    //<br>WILLIAMS, Harold R.                                                                          |                 |
|                                                                                                                                      |                                  | (74) Agente              JIMENA ESCOBAR URIBE                                                                                                                           |                 |
| (54) Título      CONTROL DE CICLO DE ESTERILIZACION/DESINFECCION.                                                                    |                                  |                                                                                                                                                                         |                 |

Reivndicación(es):

1 - Un esterilizador para estenlizar una carga de instrumentos en un ciclo de esterilización, el estenlizador comprende una cámara de vacio, una fuente de esterilizante vaporizable, una bomba de vacio; un sistema de control, y en donde el sistema de control es programado para tomar una o más entradas de datos referentes a la naturazela de la carga y determina uno o más parámetros del ciclo con base en una o más entradas de datos

## **NOVEDAD DE LA INVENCION**

### **REIVINDICACIONES**

5                   1 - Un esterilizador para esterilizar una carga de instrumentos en un ciclo de esterilización, el esterilizador comprende una cámara de vacío, una fuente de esterilizante vaporizable, una bomba de vacío, un sistema de control, y en donde el sistema de control es programado para tomar una o más entradas de datos referentes a la naturaleza de la carga y determina uno  
10 o más parámetros del ciclo con base en una o más entradas de datos

                  2.- El esterilizador de conformidad con la reivindicación 1, caracterizado además porque una de una o más entradas de datos comprende un material de uno o más instrumentos en la carga

                  3 - El esterilizador de conformidad con la reivindicación 2,  
15 caracterizado además porque uno o más parámetros comprenden una cantidad de entrada de esterilizante a la cámara de vacío y en donde el sistema de control es programado para incrementar la cantidad de entrada de esterilizante a la cámara de vacío a partir de la fuente de esterilizante en respuesta a la entrada de un material de uno o más instrumentos de la carga  
20 en donde ese material es absorbente del esterilizante

                  4 - El esterilizador de conformidad con la reivindicación 3, caracterizado además porque el esterilizante es peróxido de hidrógeno y en donde el sistema de control es programado para incrementar la cantidad de

entrada de esterilizante a la cámara de vacío a partir de la fuente de esterilizante en respuesta a la entrada de uno o más de los siguientes materiales: una poliamida, un poliuretano, un hule de silicón, un cloruro de polivinilo, un metacrilato de polimetilo o una polisulfona

5                    5.- El esterilizador de conformidad con la reivindicación 2, caracterizado además porque el sistema de control es programado para incrementar una porción del ciclo de esterilización diseñado para eliminar residuos cuando el material es absorbente del esterilizante

10                   6 - El esterilizador de conformidad con la reivindicación 1, caracterizado además porque una o más entradas de datos comprende una longitud y diámetro interno de un lumen.

7 - El esterilizador de conformidad con la reivindicación 1, caracterizado además porque una o más entradas de datos comprende un peso de la carga

15                   8.- El esterilizador de conformidad con la reivindicación 1, caracterizado además porque una o más entradas de datos comprende un material de un dispositivo que comprende la carga

20                   9 - El esterilizador de conformidad con la reivindicación 1, caracterizado además porque una o más entradas de datos comprende una indicación de si la carga contiene artículos encerrados por una barrera semipermeable

10.- El esterilizador de conformidad con la reivindicación 1, caracterizado además porque uno o más parámetros del ciclo de esterilización

comprende la concentración de esterilizante

11 - El esterilizador de conformidad con la reivindicación 10, caracterizado además porque el sistema de control es programado para proveer una concentración más alta de esterilizante al ciclo para lúmenes de un diámetro interno particular que excede una longitud predeterminada.

12 - El esterilizador de conformidad con la reivindicación 1, caracterizado además porque uno o más parámetros del ciclo de esterilización comprende un tiempo de exposición al esterilizante.

13 - El esterilizador de conformidad con la reivindicación 1, caracterizado además porque está configurado para permitir una o más entradas de datos que han de ser introducidas por un usuario

14 - El esterilizador de conformidad con la reivindicación 1, caracterizado además porque está configurado para leer por lo menos una porción de una o más entradas de datos automáticamente de los instrumentos

15 - El esterilizador de conformidad con la reivindicación 14, caracterizado además porque está configurado para leer un código de barras en un instrumento

16.- El esterilizador de conformidad con la reivindicación 14, caracterizado además porque está configurado para leer una RFID en un instrumento.

17 - El esterilizador de conformidad con la reivindicación 1, caracterizado además porque comprende un sensor que lee uno de los

parámetros del ciclo de esterilización y un circuito de control de retroalimentación para ajustar uno o más de los parámetros del ciclo de esterilización.

18.- El esterilizador de conformidad con la reivindicación 17,  
5 caracterizado además porque los sensores monitorean una concentración de esterilizante en la cámara de vacío

19.- Un método de esterilización de una carga de instrumentos en un esterilizador que comprende los pasos de introducir datos referentes a la naturaleza de la carga en un sistema de control el esterilizador, colocar la  
10 carga en una cámara de vacío en el esterilizador; producir un vacío sobre la cámara de vacío con una bomba de vacío; admitir un esterilizante en la cámara de vacío, el esterilizante estando sustancialmente en su fase de vapor dentro de la cámara de vacío, y poner en contacto la carga con el esterilizante, y con base en los datos referentes a la naturaleza de la carga  
15 introducida en el sistema de control, determinar uno o más parámetros del ciclo.

20 - El método de conformidad con la reivindicación 19, caracterizado además porque comprende un material de uno o más instrumentos en la carga.

20 21 - El método de conformidad con la reivindicación 19, caracterizado además porque uno o más parámetros comprenden una cantidad de entrada de esterilizante a la cámara de vacío

22 - El método de conformidad con la reivindicación 19,

caracterizado además porque el esterilizante es peróxido de hidrógeno y además comprende el paso de incrementar la cantidad de entrada de esterilizante a la cámara de vacío a partir de la fuente de esterilizante en respuesta a la entrada de uno o más de los siguientes materiales una  
5 poliamida, un poliuretano, un hule de silicón, un cloruro de polivinilo, un metacrilato de polimetilo o una polisulfona

23 - El método de conformidad con la reivindicación 20, caracterizado además porque la porción del ciclo de esterilización diseñado para eliminar residuos de esterilizante se incrementa cuando el material es  
10 absorbente del esterilizante.

24 - El método de conformidad con la reivindicación 19, caracterizado además porque una o más entradas de datos comprende una longitud y diámetro interno de un lumen

25 - El método de conformidad con la reivindicación 19,  
15 caracterizado además porque una o más entradas de datos comprende un peso de la carga

26 - El método de conformidad con la reivindicación 19, caracterizado además porque uno o más parámetros del ciclo de esterilización comprende la concentración de esterilizante

20 27.- El método de conformidad con la reivindicación 19, caracterizado además porque uno o más parámetros del ciclo comprende un tiempo de exposición al esterilizante.

28 - El método de conformidad con la reivindicación 19,

caracterizado además porque un usuario introduce manualmente los datos referentes a la naturaleza de la carga

29 - El método de conformidad con la reivindicación 19, caracterizado además porque por lo menos una porción de los datos  
5 referentes a la naturaleza de la carga son leídos automáticamente de por lo menos uno de los instrumentos

30 - El método de conformidad con la reivindicación 29, caracterizado además porque los datos son leídos de un código de barras el un instrumento

10 31 - El método de conformidad con la reivindicación 29, caracterizado además porque los datos son leídos de una RFID en el instrumento

32.- El método de conformidad con la reivindicación 19, caracterizado además porque comprende el paso de medir uno de los  
15 parámetros del ciclo de esterilización y utilizar un circuito de control e retroalimentación para ajustar uno o más de los parámetros del ciclo de esterilización.

33 - El método de conformidad con la reivindicación 19, caracterizado además porque comprende verificar la eficacia de esterilización  
20 con un indicador biológico

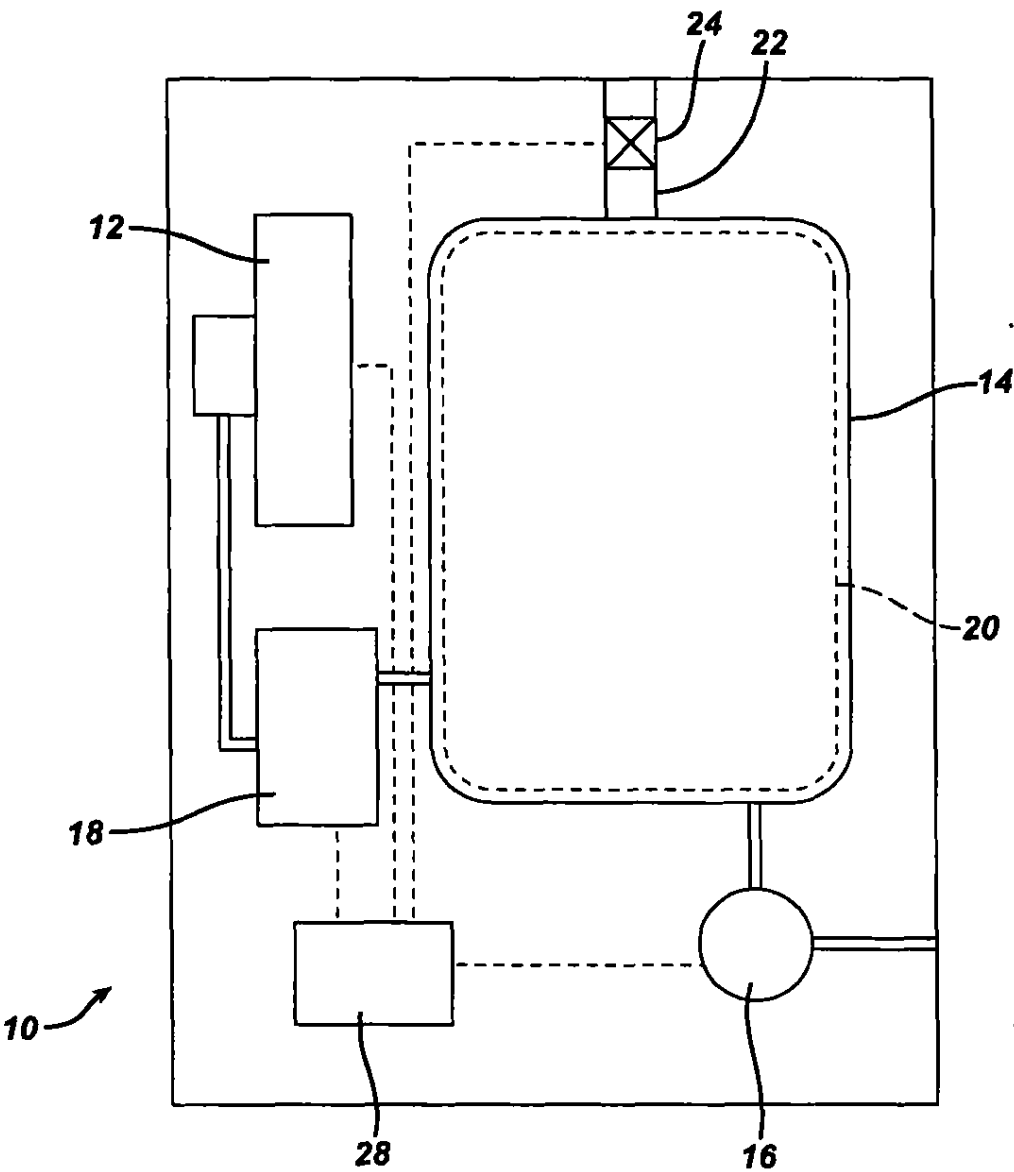
34 - El método de conformidad con la reivindicación 19, caracterizado además porque comprende verificar la eficacia de esterilización midiendo el nivel de exposición e integrar esto con el tiempo para asegurarse

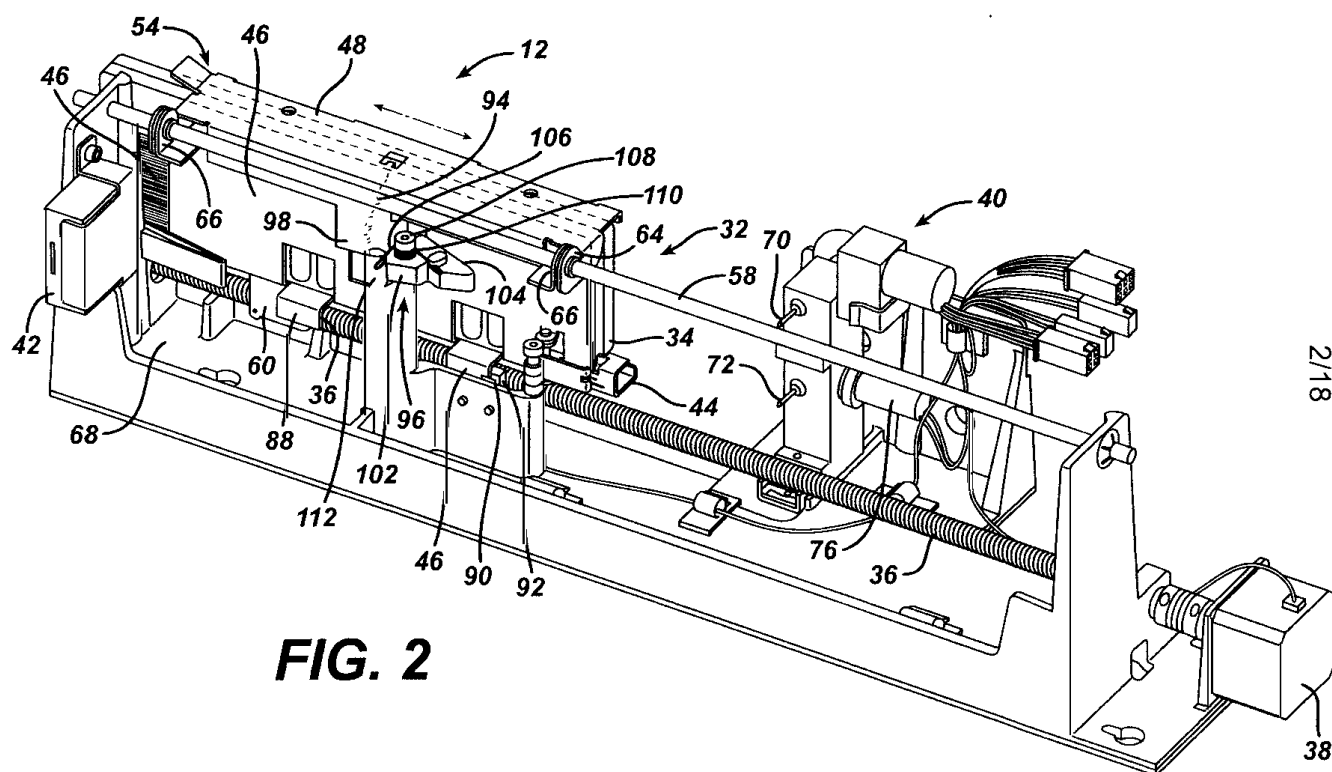
de que se obtenga por lo menos una exposición integrada mínima de la carga al esterilizante

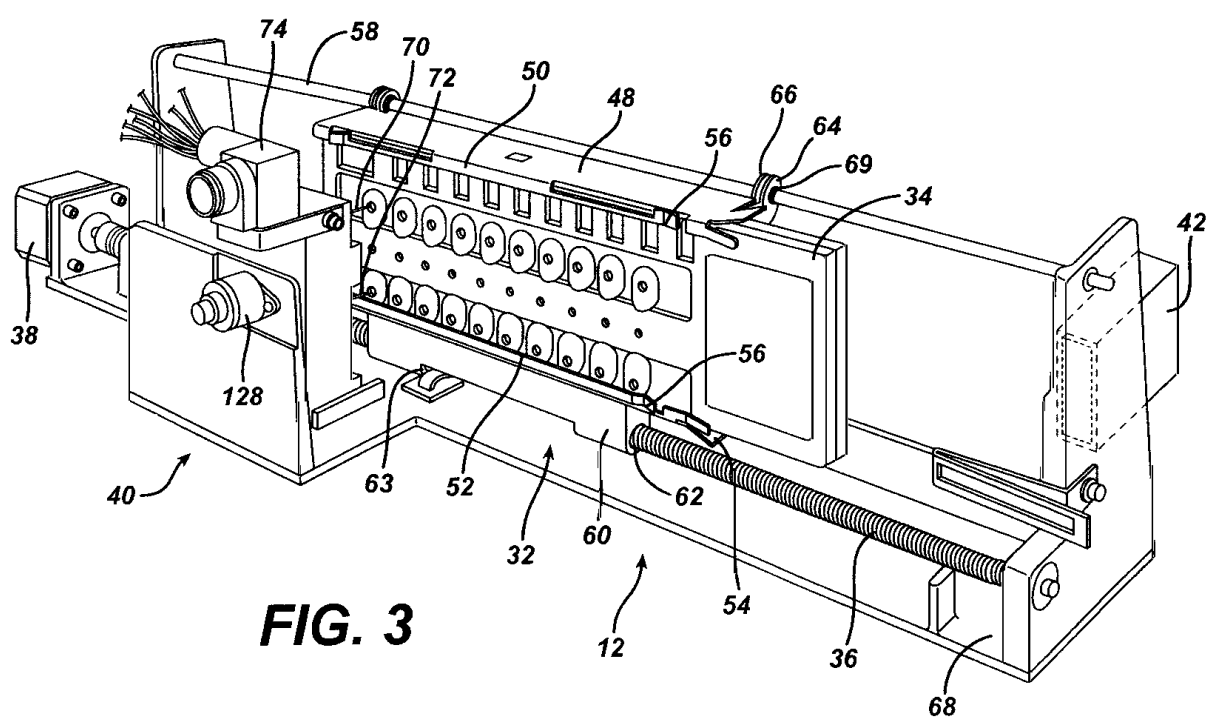
- 35 El método de conformidad con la reivindicación 19, caracterizado además porque comprende ahorrar un perfil de ciclo para uso
- 5 futuro con una carga similar

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FIG. 1







**FIG. 3**

FIG. 4

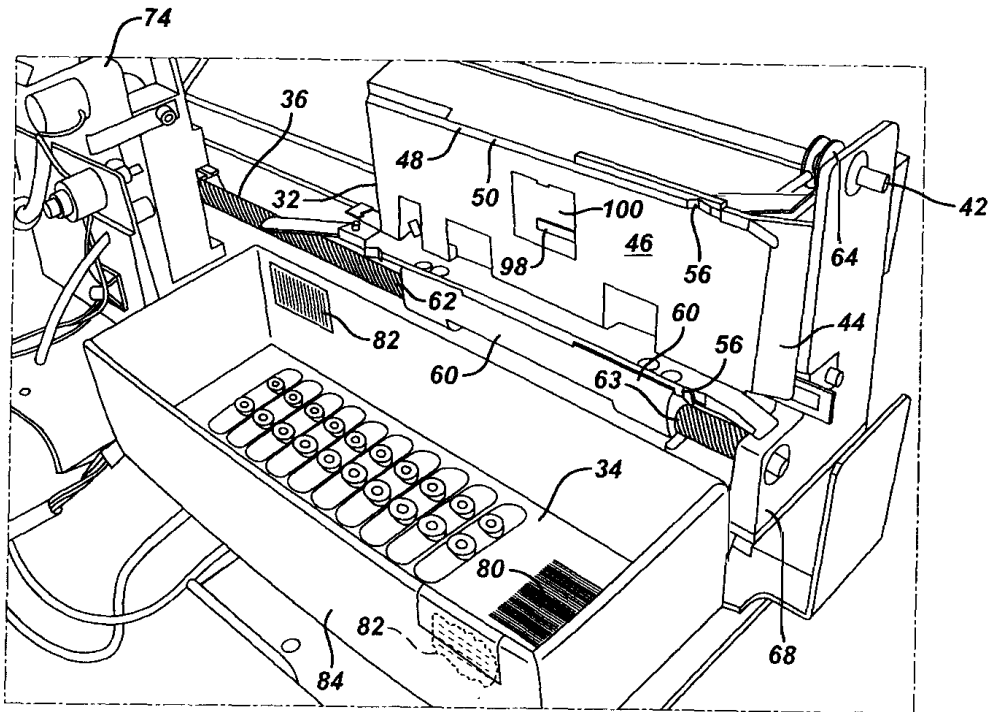
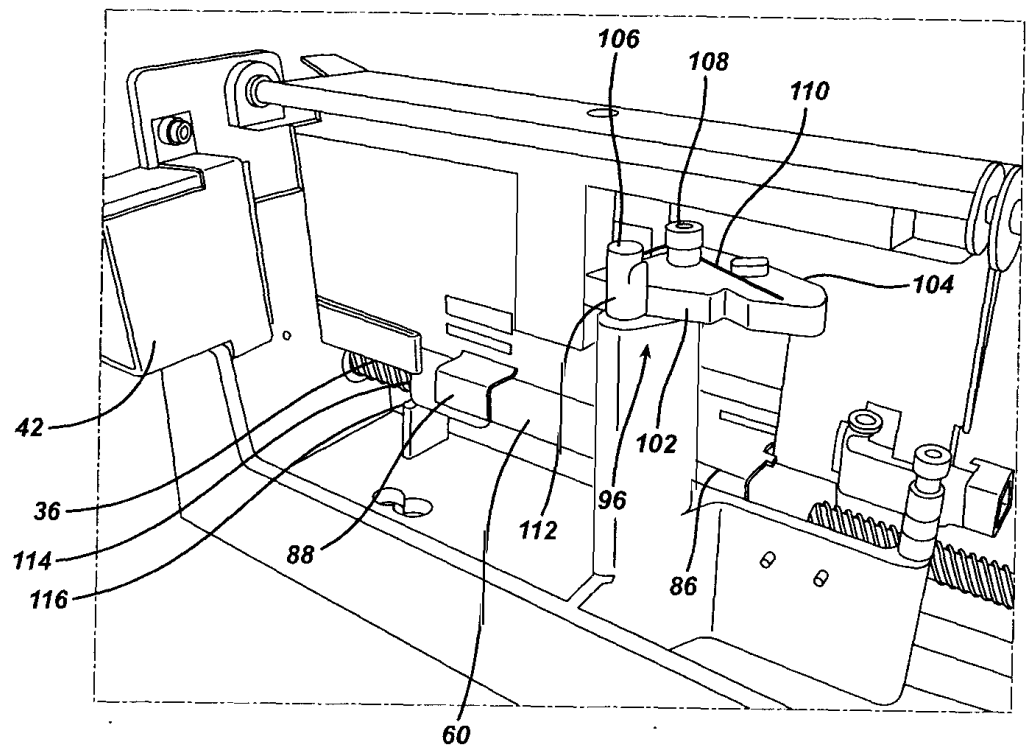
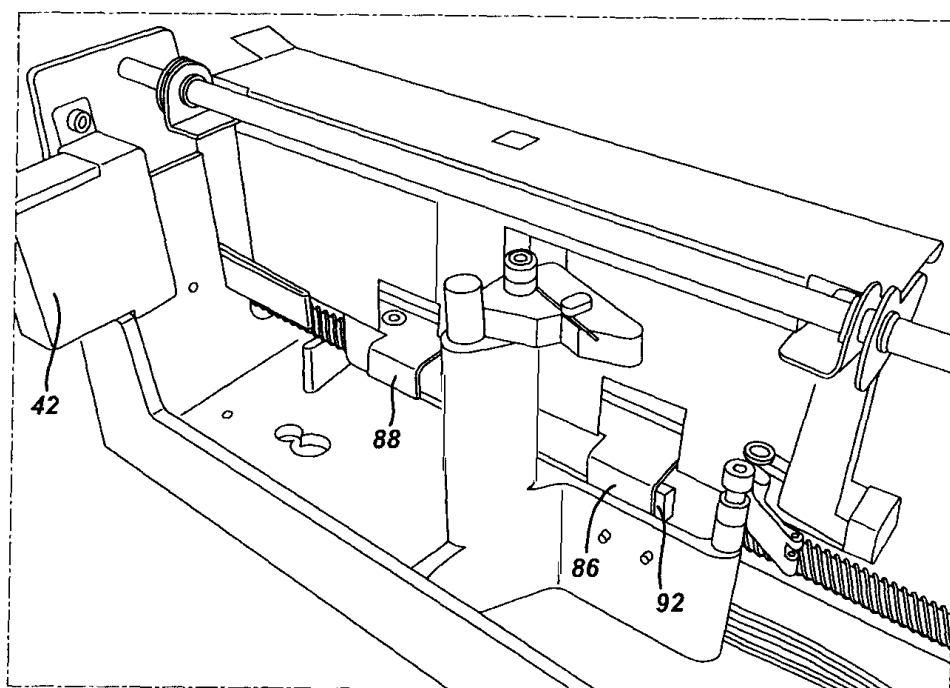


FIG. 5



TITLE STERILIZATION/ DISINFECTION  
FIRST NAMED INVENTOR  
APP#  
ATTY Andrew C Farmer TEL # 732.424.2825  
DOCKET # ASP-5019 CUST # 00027777

FIG. 6

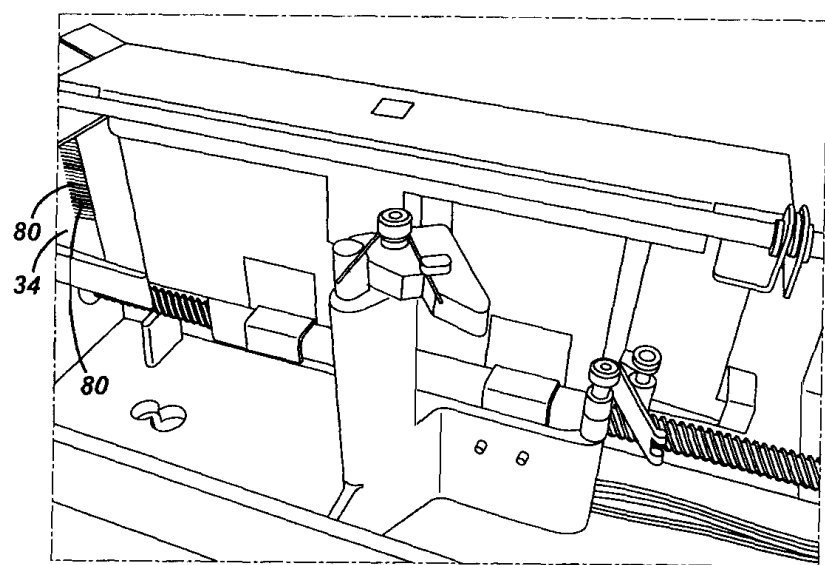


TITLE: STERILIZATION / DISINFECTION  
FIRST NAMED INVENTOR:  
ATTY: Andrew C. Farmer TEL: # 732-524-2825  
DOCKET # ASP-9019 CUST # 000027777

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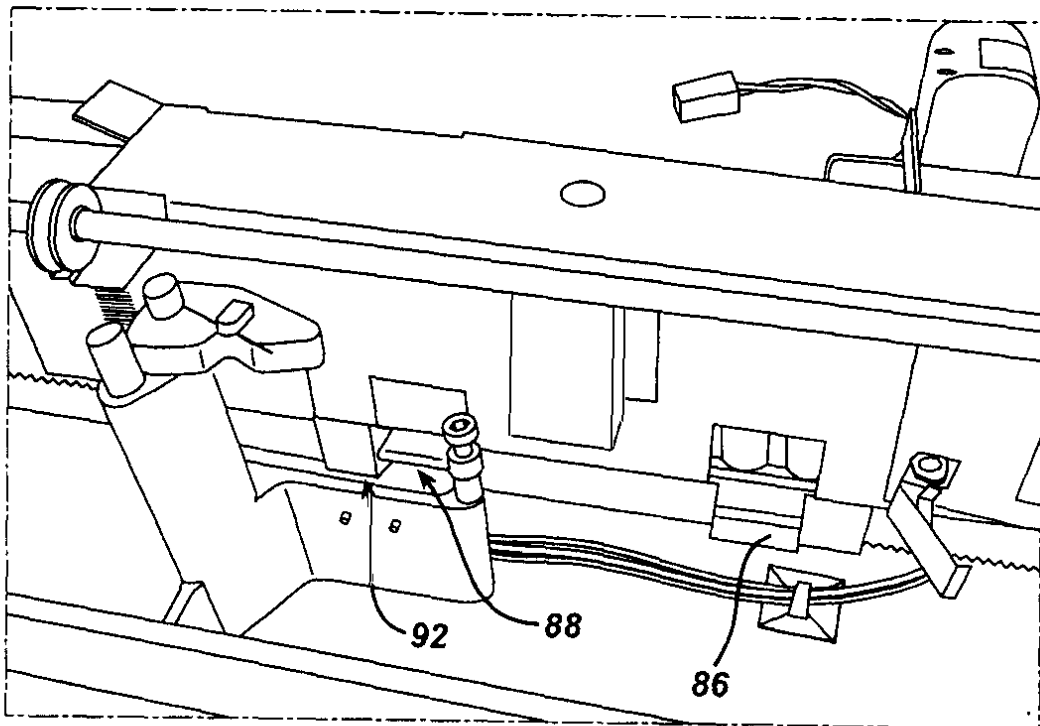
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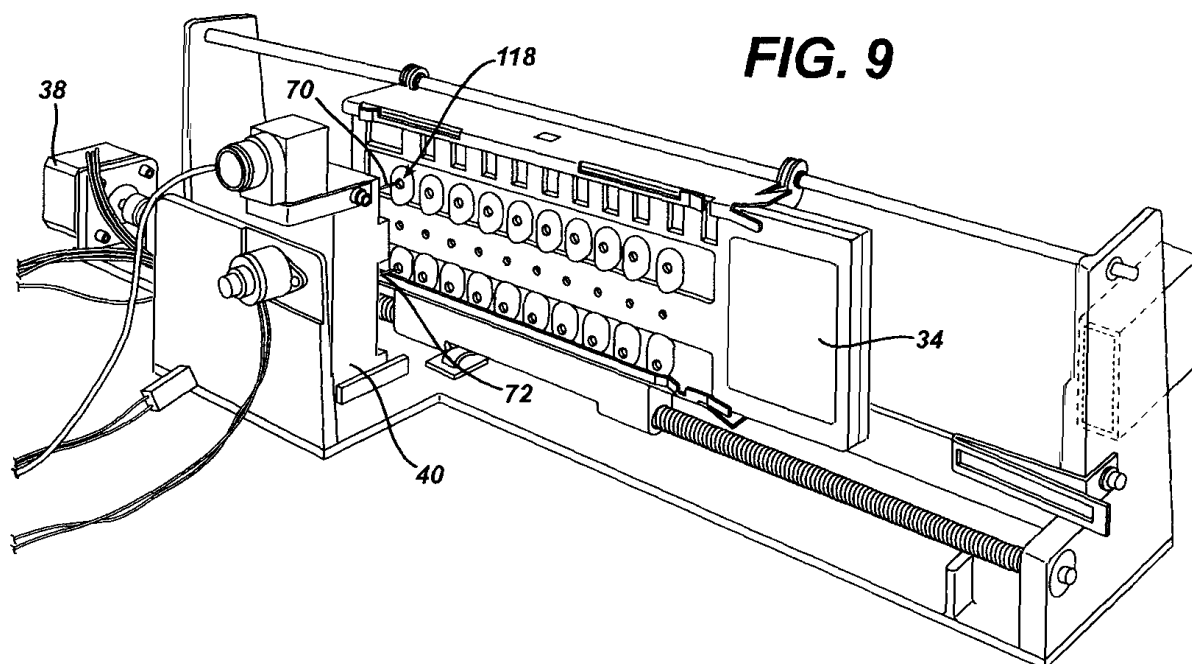
FIG. 7



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**FIG. 8**





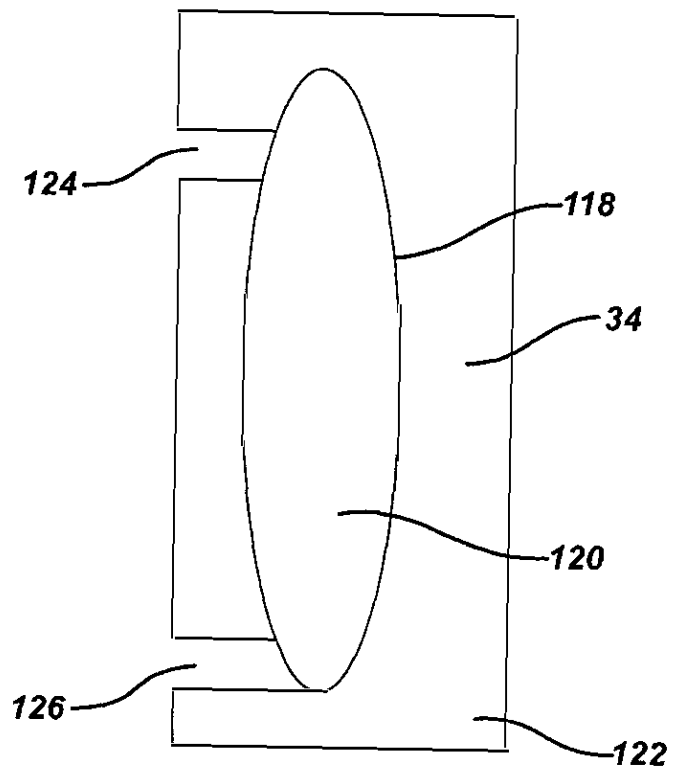
**FIG. 9**

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TITLE: STERILIZATION / DISINFECTION  
FIRST NAMED INVENTOR:  
ASP  
ATTY: Andrew C. Farmer TEL: # 732-524-2925  
DOCKET # ASP-5019 CUST # 000027777

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**FIG. 10**



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**FIG. 11**

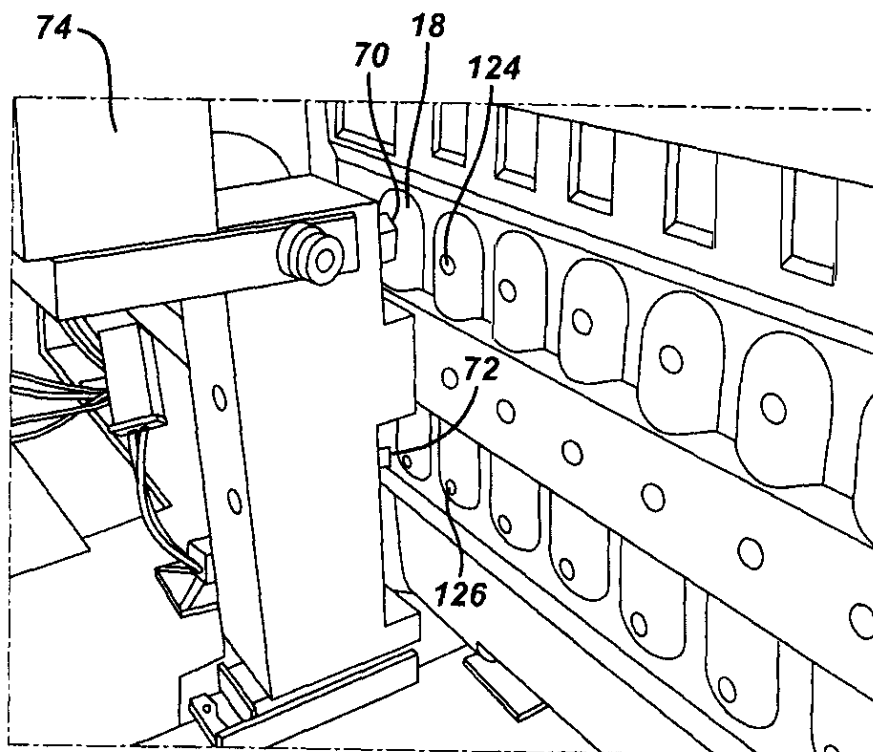
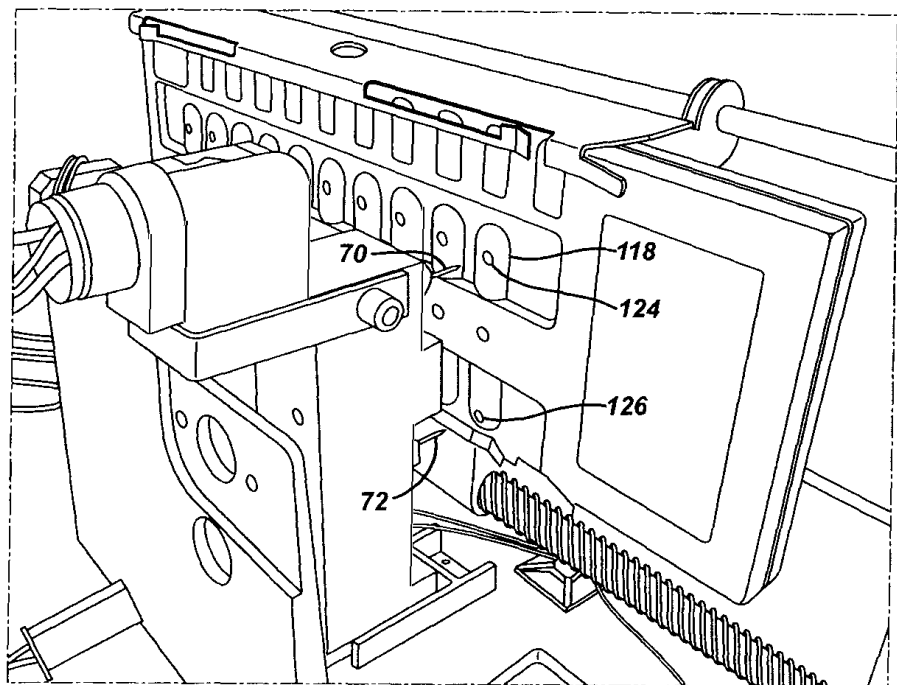


FIG. 12



TITLE: STERILIZATION/DISINFECTION  
 FIRST NAMED INVENTOR  
 APP#  
 ATTY Andrew C. Farmer TEL # 732.524.2825  
 DOCKET # ASP-5019 CUST # 00002777

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**FIG. 13**

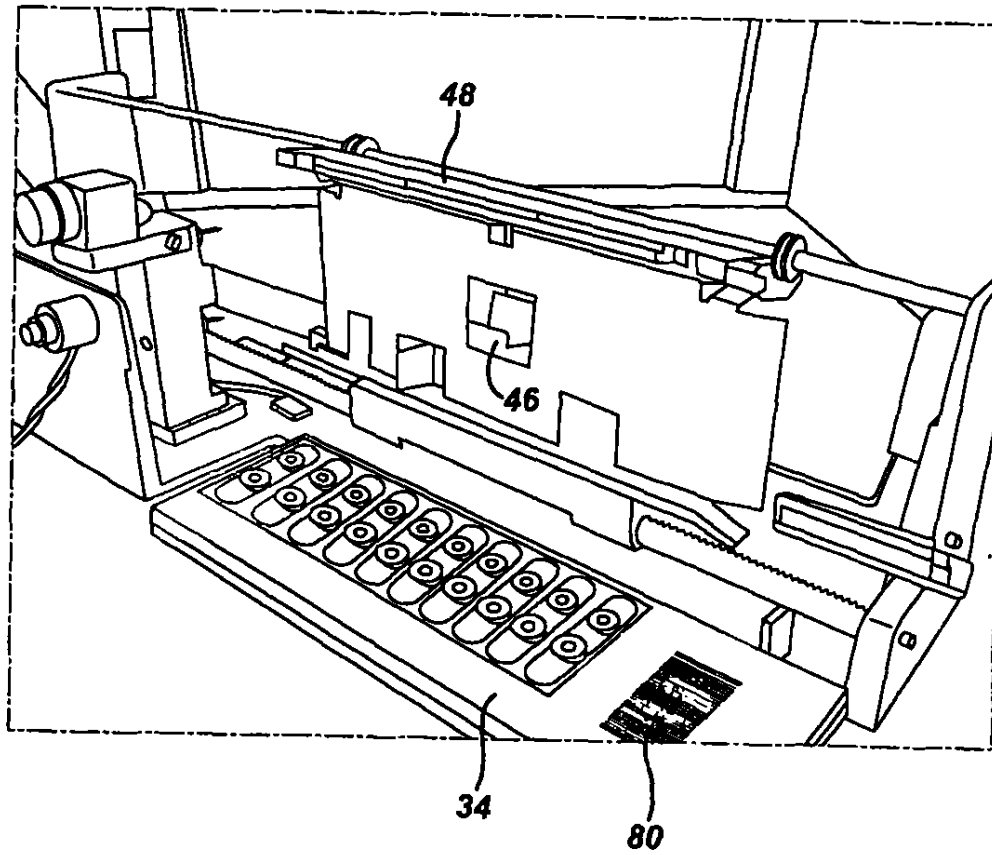
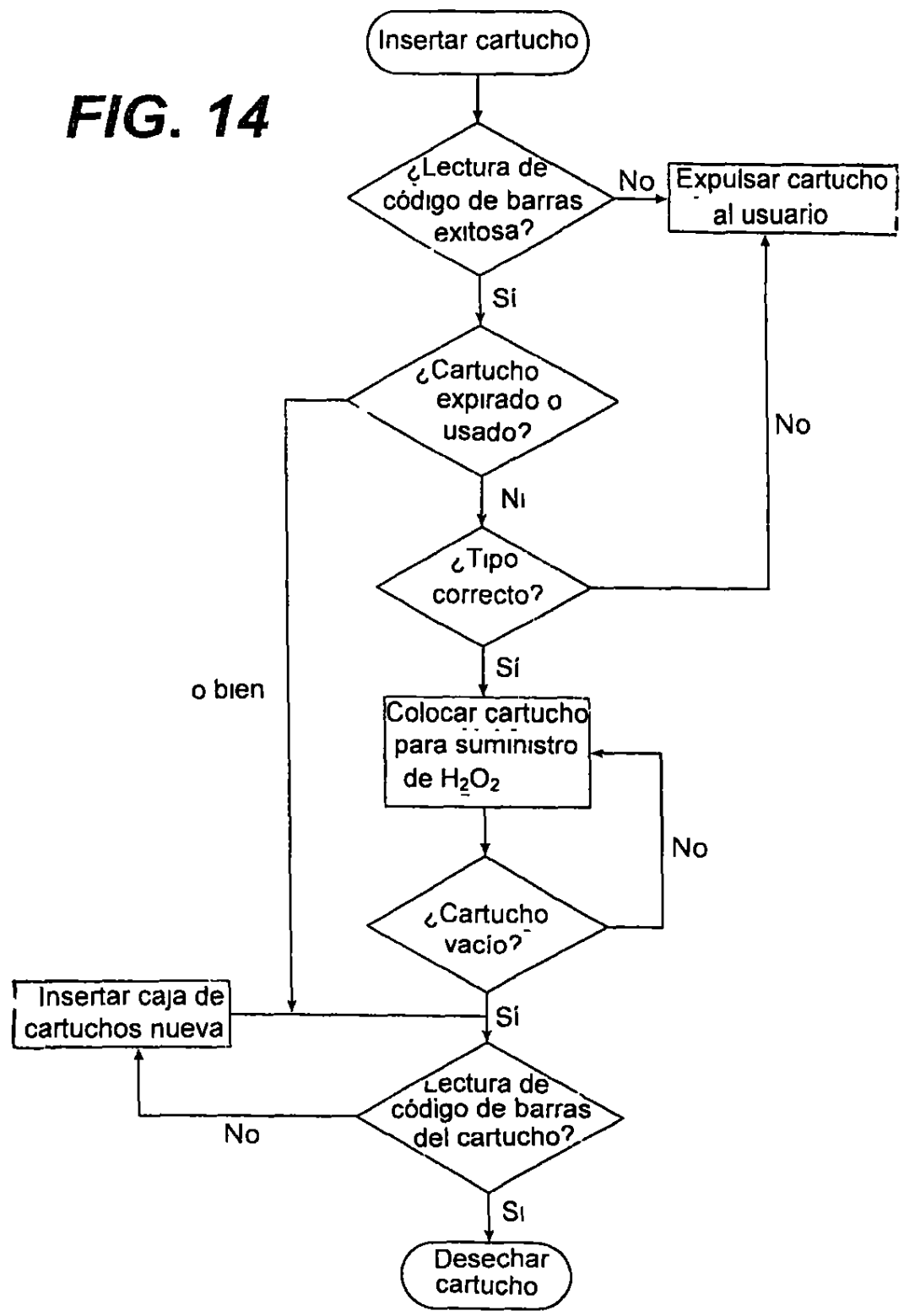


FIG. 14



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**FIG. 15**

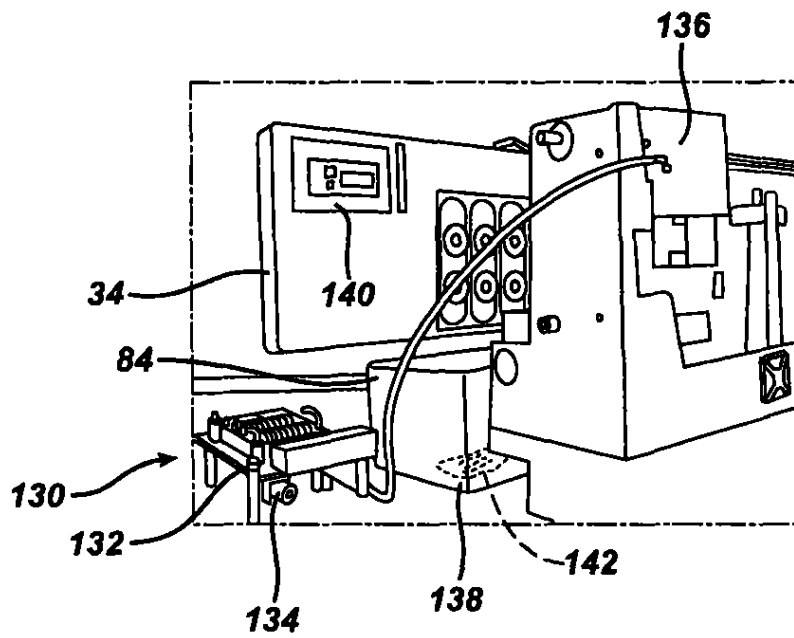


FIG. 16

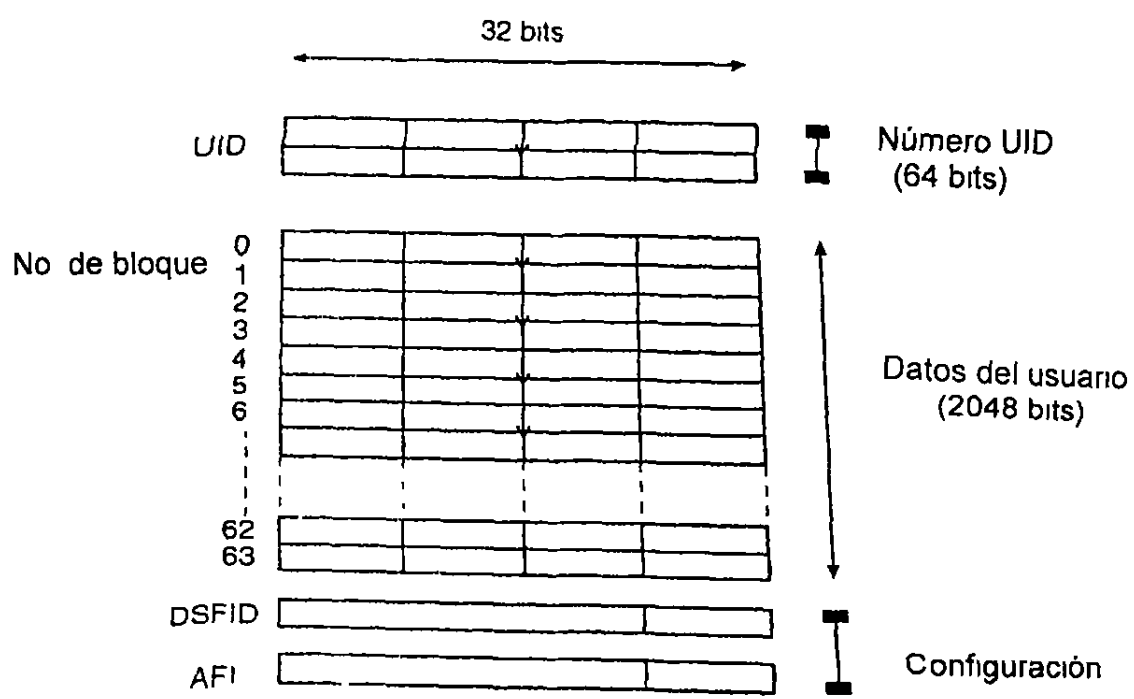
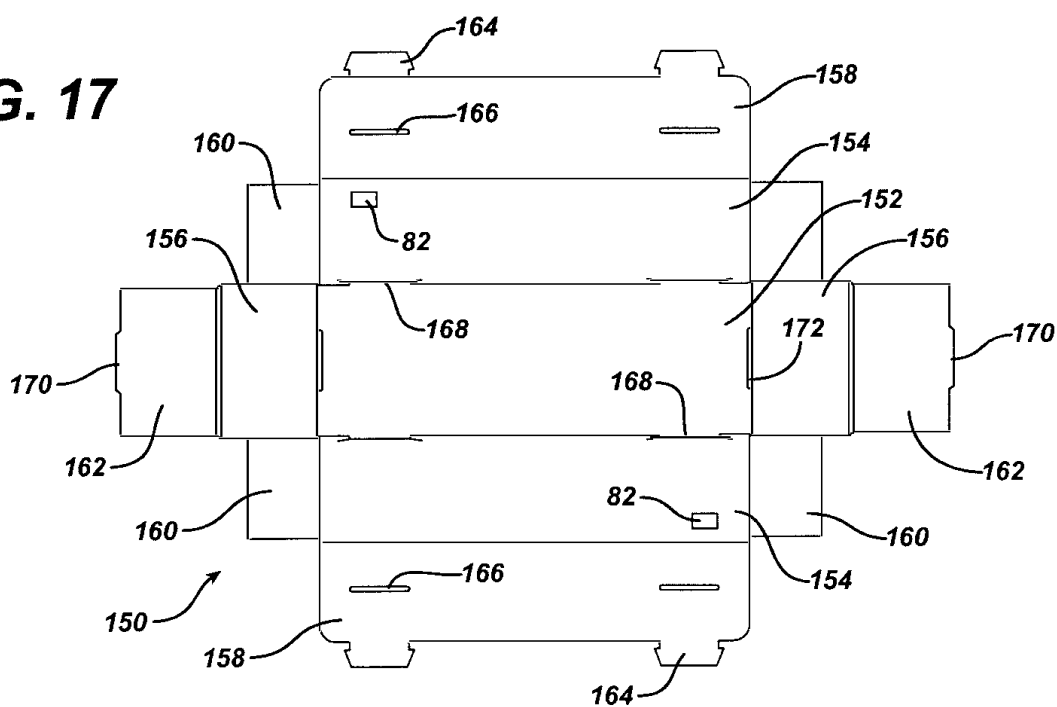
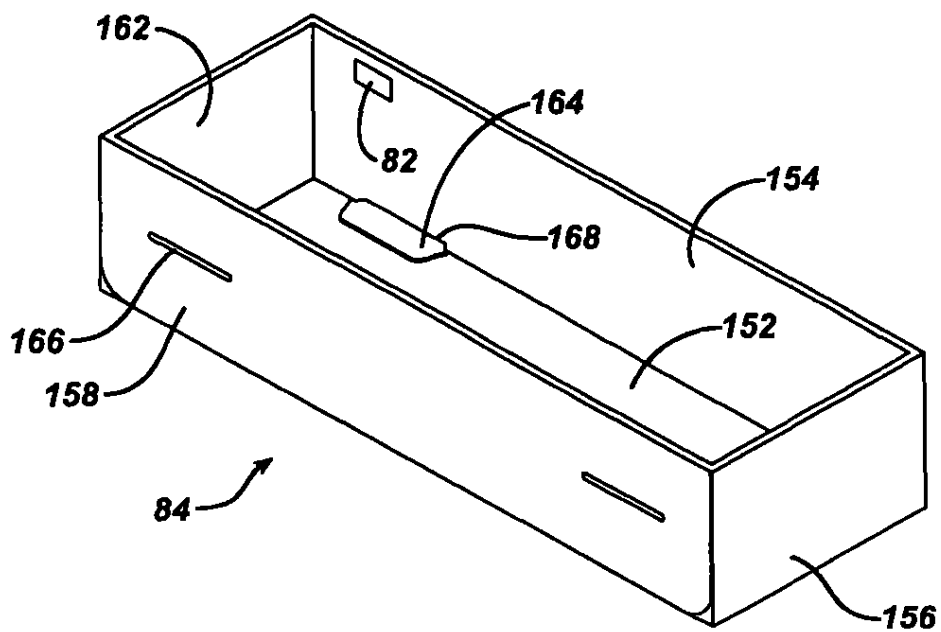


FIG. 17



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**FIG. 18**



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

16 de mayo 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: 10/856,644

Fecha de Presentación: Mayo 28 de 2004

Por la autoridad del  
Comisionado de Patentes y Marca

(fdo) H.L. JACKSON  
Oficial Certificador  
Sello oficial de la Oficina de Patentes y Marcas de los  
Estados Unidos de América

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PA 1320880



# THE UNITED STATES OF AMERICA

**TO ALL TO WHOM THESE PRESENTS SHALL COME:**

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**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.**

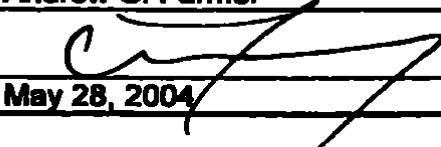
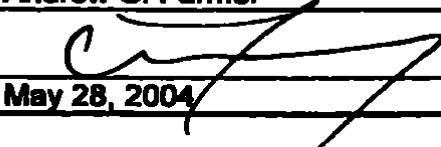
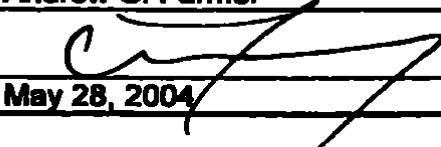
**APPLICATION NUMBER: 10/856,664**

**FILING DATE: May 28, 2004**

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



  
**H. L. JACKSON**  
**Certifying Officer**

| UTILITY<br>PATENT APPLICATION<br>TRANSMITTAL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                     | Attorney Docket No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | ASP-5019                                 |      |                  |                |           |                                                                                     |  |      |              |  |
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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                     | Title                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | STERILIZATION/DISINFECTION CYCLE CONTROL |      |                  |                |           |                                                                                     |  |      |              |  |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                     | Express Mail Label No                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | ER127876743US                            |      |                  |                |           |                                                                                     |  |      |              |  |
| APPLICATION ELEMENTS<br><i>See MPEP Chapter 600 concerning utility patent application contents</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                     | ADDRESS TO: Mail Stop Patent Application<br>Commissioner for Patents<br>P.O. Box 1450<br>Alexandria, VA 22313-1450                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                          |      |                  |                |           |                                                                                     |  |      |              |  |
| <p>1. <input checked="" type="checkbox"/> Fee Transmittal Form (e.g., PTO/SB/17)<br/><i>(submit an original and a duplicate for fee processing)</i></p> <p>2. <input type="checkbox"/> Applicant claims small entity status.</p> <p>3. <input checked="" type="checkbox"/> Specification [Total Pages 35]<br/><i>(Preferred arrangement set forth below)</i></p> <ul style="list-style-type: none"><li>- Descriptive Title of the Invention</li><li>- Cross Reference to Related Applications</li><li>- Statement Regarding Fed sponsored R&amp;D</li><li>- Reference to sequence listing, a table, or a computer program listing appendix</li><li>- Background of the Invention</li><li>- Brief Summary of the Invention</li><li>- Brief Description of the Drawings <i>(if filed)</i></li><li>- Detailed Description</li><li>- Claim(s)</li><li>- Abstract of the Disclosure</li></ul> <p>4. <input checked="" type="checkbox"/> Drawing(s) (35 USC 113) [Total Sheets 18]</p> <p>5. Oath or Declaration [Total Pages 3]</p> <p>a. <input checked="" type="checkbox"/> unexecuted</p> <p>b. <input type="checkbox"/> Copy from a prior application (37 CFR 1.63(d))<br/><i>(for continuation/divisional with Box 18 completed)</i></p> <p>i. <input type="checkbox"/> <b>DELETION OF INVENTOR(S)</b><br/>Signed statement attached deleting Inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).</p> <p>6. <input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76</p> |                                                                                     | <p>7. <input type="checkbox"/> CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)</p> <p>8. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)</p> <p>a. <input type="checkbox"/> Computer Readable Form (CRF)</p> <p>b. <input type="checkbox"/> Specification Sequence Listing on:</p> <p>i. <input type="checkbox"/> CD-ROM or CD-R (2 copies); or</p> <p>ii. <input type="checkbox"/> paper</p> <p>c. <input type="checkbox"/> Statement verifying identity of above copies</p> <p><b>ACCOMPANYING APPLICATION PARTS</b></p> <p>9. <input type="checkbox"/> Assignment Papers (cover sheet &amp; document(s))</p> <p>10. <input type="checkbox"/> 37 CFR 3.73(b) Statement <input type="checkbox"/> Power of Attorney<br/><i>(when there is an assignee)</i></p> <p>11. <input type="checkbox"/> English Translation Document <i>(if applicable)</i></p> <p>12. <input type="checkbox"/> Information Disclosure Statement (IDS)/PTO-1449 <input type="checkbox"/> Copies of IDS Citations</p> <p>13. <input type="checkbox"/> Preliminary Amendment</p> <p>14. <input checked="" type="checkbox"/> Return Receipt Postcard (MPEP 503)<br/><i>(Should be specifically itemized)</i></p> <p>15. <input type="checkbox"/> Certified Copy of Priority Document(s)<br/><i>(if foreign priority is claimed)</i></p> <p>16. <input type="checkbox"/> Request and Certifications under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.</p> <p>17. <input type="checkbox"/> Other</p> |                                          |      |                  |                |           |                                                                                     |  |      |              |  |
| <p>18. <input type="checkbox"/> 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:</p> <p><input type="checkbox"/> Continuation <input type="checkbox"/> Divisional <input type="checkbox"/> Continuation-in-Part (CIP) of prior application No.: , filed</p> <p>Prior application Information: Examiner Group Art Unit:</p> <p>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 <u>can only</u> be relied upon when a portion has been inadvertently omitted from the submitted application parts.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                          |      |                  |                |           |                                                                                     |  |      |              |  |
| <p>19. CORRESPONDENCE ADDRESS</p> <p><input checked="" type="checkbox"/> Customer Number or Bar Code Label 000027777 or <input type="checkbox"/> Correspondence Address below</p> <p>Name: Philip S. Johnson, Esq.</p> <p>Address: Johnson &amp; Johnson<br/>One Johnson &amp; Johnson Plaza<br/>New Brunswick, NJ 08933-7003 USA</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                          |      |                  |                |           |                                                                                     |  |      |              |  |
| <p>20. TELEPHONE CONTACT</p> <p>Please direct all telephone calls or telefaxes to Andrew C. Farmer at:</p> <p>Telephone: (732) 524-2825 Fax: (732) 524-2808</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                          |      |                  |                |           |                                                                                     |  |      |              |  |
| <p>21. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED</p> <table border="1"><tr><td>NAME</td><td>Andrew C. Farmer</td><td>Reg. No. 35868</td></tr><tr><td>SIGNATURE</td><td colspan="2"></td></tr><tr><td>DATE</td><td colspan="2">May 28, 2004</td></tr></table>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                          | NAME | Andrew C. Farmer | Reg. No. 35868 | SIGNATURE |  |  | DATE | May 28, 2004 |  |
| NAME                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Andrew C. Farmer                                                                    | Reg. No. 35868                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                          |      |                  |                |           |                                                                                     |  |      |              |  |
| SIGNATURE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                          |      |                  |                |           |                                                                                     |  |      |              |  |
| DATE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | May 28, 2004                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                          |      |                  |                |           |                                                                                     |  |      |              |  |

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|------------------------|--------------------------|---------------|
| <b>FEE TRANSMITTAL</b> | <i>Complete if Known</i> |               |
|                        | Application Number       |               |
|                        | Filing Date              | May 28, 2004  |
|                        | First Named Inventor     | Su-Syin S. Wu |
|                        | Group Art Unit           |               |
|                        | Examiner Name            |               |
|                        | Attorney Docket Number   | ASP-5019      |

**FEE CALCULATION**

**CLAIMS AS FILED**

| (1)                       | (2)                      | (3)          | (4)        | (5)                   |
|---------------------------|--------------------------|--------------|------------|-----------------------|
| FOR:                      | NUMBER FILED             | NUMBER EXTRA | RATE       | BASIC FEE<br>\$770.00 |
| TOTAL CLAIMS              | 35 - 20 =                | 15           | x 18.00    | \$ 270.00             |
| INDEPENDENT CLAIMS        | 2 - 3 =                  | 0            | x 88.00    | \$ 0.00               |
| MULTIPLE DEPENDENT CLAIMS | <input type="checkbox"/> | N/A          | \$290.00   |                       |
|                           |                          |              | TOTAL FEES | \$ 1040.00            |

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☒ Please charge Deposit Account No. 10-0750/ASP-5019/ACF in the amount of \$1040.00.  
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|-----------------------|-------------------------------------------------------------------------------------|---------------------------------|
| <b>SUBMITTED BY:</b>  |                                                                                     | <i>Complete (if applicable)</i> |
| Typed or Printed Name | Andrew C. Farmer                                                                    | Reg. No. 35,868                 |
| Signature             |  | Date: 5.28.04                   |
|                       |                                                                                     | Deposit Account No. 10-0750     |

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DOCKET NO. ASP-5019

IN THE UNITED STATES  
PATENT AND TRADEMARK OFFICE

Applicant: Su-Syin S. Wu et al.

For : Sterilization/Disinfection Cycle Control

Express Mail Certificate

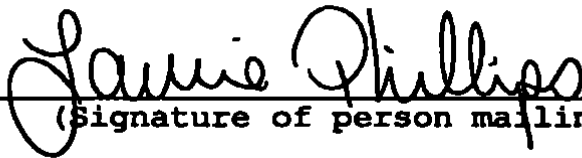
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Date of Deposit: May 28, 2004

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

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STERILIZATION/DISINFECTION CYCLE CONTROL

Background of the Invention

5           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.

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

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

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Flexibility in controlling such machines has typically been lacking and typically they have a single fixed cycle. It is believed that some steam sterilizers may employ two, or perhaps more, fixed user selectable  
5 cycles. Even here the user must himself or herself choose the cycle. The machine does not determine the cycle for the user. The present invention overcomes these and other limitations in the prior art.

10 Summary of the Invention

A sterilizer according to the present invention for sterilizing a load of instruments in a sterilization cycle comprises a vacuum chamber, a source of vaporizable  
15 sterilant, a vacuum pump, and a control system. The control system is programmed to take one or more data inputs regarding the nature of the load and determine one or more parameters of the cycle based upon the one or more data inputs.

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The data inputs can include a material of one or more instruments in the load. For instance, the control system can be programmed to increase the amount of sterilant input to the vacuum chamber from the sterilant source in  
25 response to the input of a material of one or more instruments in the load where that material is absorbent of the sterilant. Such materials include: a polyamide, a polyurethane, a silicone rubber, a polyvinyl chloride, a polymethyl methacrylate or a polysulfone. In one aspect  
30 of the invention, the control system is programmed to enhance a portion of the sterilization cycle designed to eliminate sterilant residuals when the material is absorbent of the sterilant.

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Preferably, the one or more data inputs comprise a length and internal diameter of a lumen. They could also include the weight of the load and an indication of whether the load contains items enclosed by a semi-permeable barrier, such as by being wrapped in CSR wrap or enclosed in pouches.

The parameters of the sterilization cycle which can be varied include the concentration of sterilant, the time of exposure to the sterilant, the level of the vacuum, and whether and how vigorously to employ a residuals reduction step.

In one aspect of the invention, the control system is programmed to provide a higher concentration of sterilant to the cycle for lumens of a particular internal diameter which exceed a predetermined length.

The data can be manually input by the user, such as via a touch screen or keyboard, or some or all of it can be read automatically from the instruments, such as by reading a barcode or RFID tag on the instrument.

A feedback control loop in connection with sensor input about the cycle can be used to adjust one or more of the sterilization cycle parameters. Inputs might include pressure, temperature and sterilant concentration within the vacuum chamber.

A method according to the present invention of sterilizing a load of instruments in a sterilizer comprises the steps of: entering data regarding the nature of the load into a control system of the sterilizer; placing the load into a vacuum chamber in the sterilizer;

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drawing a vacuum upon the vacuum chamber with a vacuum pump; admitting a sterilant into the vacuum chamber, the sterilant being substantially in its vapor phase within the vacuum chamber, and contacting the load with the sterilant; and based upon the data regarding the nature of the load entered into the control system, determining one or more parameters of the cycle.

The efficacy of sterilization can be verified with a biological indicator. It can also be verified by measuring exposure level and integrating this over time to ensure that at least a minimum integrated exposure of the load to the sterilant is achieved.

In one aspect of the invention, a cycle outline is saved for future use with a similar load. The cycle outline can be saved in many fashions such as the data inputs, or the resulting cycle parameters.

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;

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

5        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;

10       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;

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

20       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;

25       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;

30       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;

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

5 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  
10 invention employing RFID technology;

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

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

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

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#### Detailed Description

##### Sterilizer Overall Configuration

FIG. 1 shows in block diagram form a vapor phase sterilizer 10 employing a cassette handling system 12  
25 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  
30 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

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control system 28 ties in to all of the major components, sensors and the like within the sterilizer 10 to control the sterilization cycle.

5 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  
10 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  
15 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  
20 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  
25 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  
30 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

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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.

5           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  
10 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  
15 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  
20 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.

25           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  
30 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

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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  
5 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  
10 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  
15 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.

20

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  
25 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.

30 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

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117

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.

10 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 to FIG. 5, it mounts for rotation upon an upwardly extending spindle 108. A spring 110 biases the disposing cam 96 counterclockwise, urging the outwardly facing side 102 into contact with an abutment 112. Inward movements of 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 facing 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

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118

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

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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.

5           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  
10   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  
15   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  
20   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.

25           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  
30   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

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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

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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 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

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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  
5 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  
10 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  
15 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  
20 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  
25 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  
30 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

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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  
5 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  
10 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.

15 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  
20 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  
25 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.  
30 Many coding schemes are possible within the scope of the invention.

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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 $1 \times 10^6$ <i>Geobacillus stearothermophilus</i> 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.

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Table 1b - 51L chamber with one load

| Device                          | Peroxide concentration | Peroxide amount | Time required to kill about $1 \times 10^6$ <i>Geobacillus stearothermophilus</i> 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 absorptive 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

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1.26

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

5        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  
10 load in the most efficient manner. Table 2 illustrates how a cycle can be modified to for several user inputs.

12/12/27

**Table 2 - Cycle Response to User Input**

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

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

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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  
5 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  
10 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  
15 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  
20 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  
25 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  
30 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

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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.

5

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  
10 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  
15 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.

20 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  
25 insertion antenna 136 located on the carriage 32 and a cassette disposal antenna 138 located beneath the spent cassette box 84. Each cassette 34 carries a cassette RFID tag 140. Similarly, each spent cassette collection box 84 carries a collection box RFID tag 142. Preferably, the  
30 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.

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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

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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  
5 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;  
10 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  
15 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  
20 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.

25 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  
30 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.

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Some sterilants are affected by heat. The RFID tag 140 can optionally include temperature collection instrumentation and update that information on the tag.

5 If design temperature profiles are exceeded, such as a maximum temperature or excessive temperature over a time period, then the cassette 34 can be rejected by the control system 28. Temperature measuring RFID tags are available from KSW-Microtec, Dresden, Germany and from  
10 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  
15 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  
20 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.

25 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.

30

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

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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

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BA

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

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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  
5 the way and also allows easy closure of the box 84 once it  
has become filled.

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

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WHAT IS CLAIMED IS:

1. A sterilizer for sterilizing a load of instruments in a sterilization cycle, the sterilizer comprising:

- a vacuum chamber;
- a source of vaporizable sterilant;
- a vacuum pump;
- a control system; and

wherein the control system is programmed to take one or more data inputs regarding the nature of the load and determine one or more parameters of the cycle based upon the one or more data inputs.

2. A sterilizer according to claim 1 wherein one of the one or more data inputs comprises a material of one or more instruments in the load.

3. A sterilizer according to claim 2 wherein the one or more parameters comprises an amount of sterilant input to the vacuum chamber and wherein the control system is programmed to increase the amount of sterilant input to the vacuum chamber from the sterilant source in response to the input of a material of one or more instruments in the load where that material is absorbent of the sterilant.

4. A sterilizer according to claim 3 wherein the sterilant is hydrogen peroxide and wherein the control system is programmed to increase the amount of sterilant input to the vacuum chamber from the sterilant source in response to the input of one or more of the following materials: a polyamide, a polyurethane, a silicone rubber,

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a polyvinyl chloride, a polymethyl methacrylate or a polysulfone.

5        5.    A sterilizer according to claim 2 wherein the control system is programmed to enhance a portion of the sterilization cycle designed to eliminate sterilant residuals when the material is absorbent of the sterilant.

10       6.    A sterilizer according to claim 1 wherein the one or more data inputs comprise a length and internal diameter of a lumen.

15       7.    A sterilizer according to claim 1 wherein the one or more data inputs comprise a weight of the load.

      8.    A sterilizer according to claim 1 wherein the one or more data inputs comprise a material of a device comprising the load.

20       9.    A sterilizer according to claim 1 wherein the one or more data inputs comprise an indication of whether the load contains items enclosed by a semi-permeable barrier.

25       10.   A sterilizer according to claim 1 wherein the one or more parameters of the sterilization cycle comprises the concentration of sterilant.

30       11.   A sterilizer according to claim 10 wherein the control system is programmed to provide a higher concentration of sterilant to the cycle for lumens of a particular internal diameter which exceed a predetermined length.

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12. A sterilizer according to claim 1 wherein the one or more parameters of the cycle comprises time of exposure to the sterilant.

5 13. A sterilizer according to claim 1 configured to allow the one or more data inputs to be input by a user.

14. A sterilizer according to claim 1 configured to read at least a portion of the one or more data inputs  
10 automatically from the instruments.

15. A sterilizer according to claim 14 configured to read a bar code on an instrument.

15 16. A sterilizer according to claim 14 configured to read an RFID tag on an instrument.

17. A sterilizer according to claim 1 further comprising a sensor reading one of the parameters of the  
20 sterilization cycle and a feedback control loop to adjust one or more of the sterilization cycle parameters.

18. A sterilizer according to claim 17 wherein the sensor monitors a concentration of sterilant in the vacuum  
25 chamber.

19. A method of sterilizing a load of instruments in a sterilizer comprising the steps of:  
entering data regarding the nature of the load into a  
30 control system of the sterilizer;  
placing the load into a vacuum chamber in the sterilizer;  
drawing a vacuum upon the vacuum chamber with a vacuum pump;

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admitting a sterilant into the vacuum chamber, the sterilant being substantially in its vapor phase within the vacuum chamber, and contacting the load with the sterilant; and

5 based upon the data regarding the nature of the load entered into the control system, determining one or more parameters of the cycle.

20. A method according to claim 19 the data  
10 comprises a material of one or more instruments in the load.

21. A method according to claim 19 wherein the one or more parameters comprises an amount of sterilant input  
15 to the vacuum chamber.

22. A method according to claim 19 wherein the sterilant is hydrogen peroxide and further comprising the step of increasing the amount of sterilant input to the  
20 vacuum chamber from the sterilant source in response to the input of one or more of the following materials: a polyamide, a polyurethane, a silicone rubber, a polyvinyl chloride, a polymethyl methacrylate or a polysulfone.

25 23. A method according to claim 20 wherein the portion of the sterilization cycle designed to eliminate sterilant residuals is enhanced when the material is absorbent of the sterilant.

30 24. A method according to claim 19 wherein the one or more data inputs comprise a length and internal diameter of a lumen.

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25. A method according to claim 19 wherein the one or more data inputs comprise a weight of the load.

26. A method according to claim 19 wherein the one  
5 or more parameters of the sterilization cycle comprises the concentration of sterilant.

27. A method according to claim 19 wherein the one  
or more parameters of the cycle comprises time of exposure  
10 to the sterilant.

28. A method according to claim 19 wherein a user manually enters the data regarding the nature of the load.

15 29. A method according to claim 19 wherein at least a portion of the data regarding the nature of the load is read automatically from at least one of the instruments.

30 30. A method according to claim 29 wherein the data is read from a bar code on the instrument.

31. A method according to claim 29 wherein the data is read from an RFID tag on the instrument.

25 32. A method according to claim 19 further comprising the step of measuring one of the parameters of the sterilization cycle and employing a feedback control loop to adjust one or more of the sterilization cycle parameters.

30 33. A method according to claim 19 and further comprising verifying efficacy of sterilization with a biological indicator.

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34. A method according to claim 19 and further comprising verifying efficacy of sterilization by measuring exposure level and integrating this over time to ensure that at least a minimum integrated exposure of the  
5 load to the sterilant is achieved.

35. A method according to claim 19 and further comprising saving a cycle outline for future use with a similar load.

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**Abstract**

A sterilizer includes a vacuum chamber, a source of vaporizable sterilant, a vacuum pump, and a control  
5 system. The control system is programmed to take one or more data inputs regarding the nature of the load, such as lumen length and diameter, and determine one or more parameters of the sterilization cycle based upon the inputs.

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

PTO/SB/01 (10-00)  
Approved for use through 10/31/2002. OMB 0651-0032  
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

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|                                                                                                                                                                                                                                                                                                                                             |                        |              |  |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|--|
| <b>DECLARATION<br/>AND<br/>POWER OF ATTORNEY<br/>FOR UTILITY OR DESIGN<br/>PATENT APPLICATION<br/>(37 CFR 1.63)</b><br><br><input checked="" type="checkbox"/> Declaration Submitted with<br>Initial Filing (unexecuted) OR <input type="checkbox"/> Declaration Submitted after<br>Initial Filing (Surcharge<br>(37 CFR 1.16(e)) required) | Attorney Docket Number | ASP-5019     |  |
|                                                                                                                                                                                                                                                                                                                                             | First Named Inventor   | Su-Syn S. Wu |  |
|                                                                                                                                                                                                                                                                                                                                             | 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:

Sterilization/Disinfection Cycle Control  
(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<br>Application<br>Number(s) | Country | Foreign Filing Date<br>(MM/DD/YYYY) | Priority<br>Not Claimed                                                                                      | Certified Copy<br>Attached?                                                                                  |                                                                                                              |
|-------------------------------------------|---------|-------------------------------------|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
|                                           |         |                                     |                                                                                                              | YES                                                                                                          | NO                                                                                                           |
|                                           |         |                                     | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> | <input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/><br><input type="checkbox"/> |

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

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| 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) | <input type="checkbox"/> 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:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                          |                                                                                                                                                  |
| <input checked="" type="checkbox"/> Practitioners at Customer Number <b>000027777</b> --                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          | Place Customer Number Bar Code Label Here                                                                                                        |
| AND                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                          |                                                                                                                                                  |
| <input type="checkbox"/> Practitioner(s) named below:<br>Name _____ Registration Number _____                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                          |                                                                                                                                                  |
| as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith                                                                                                                                                                                                                                                                                                                                                                                                                          |                          |                                                                                                                                                  |
| Address all telephone calls to Andrew C. Farmer at telephone number (732) 524-2825.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                          |                                                                                                                                                  |
| Direct all correspondence to: <input checked="" type="checkbox"/> Customer Number <b>000027777</b> OR <input type="checkbox"/> Correspondence address below                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                          |                                                                                                                                                  |
| Name:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                          |                                                                                                                                                  |
| Address:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                                                                                                                                                  |
| Address:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                          |                                                                                                                                                  |
| City:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | State:                   | ZIP                                                                                                                                              |
| Country                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Telephone:               | Fax:                                                                                                                                             |

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |          |                                                                               |                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|-------------------------------------------------------------------------------|-------------------|
| I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon. |          |                                                                               |                   |
| NAME OF SOLE OR FIRST INVENTOR:                                                                                                                                                                                                                                                                                                                                                                                                                                           |          | <input type="checkbox"/> A petition has been filed for this unsigned inventor |                   |
| Given Name<br>(first and middle [if any]) Su-Syn S                                                                                                                                                                                                                                                                                                                                                                                                                        |          | Family Name<br>or Surname Wu                                                  |                   |
| Inventor's<br>Signature                                                                                                                                                                                                                                                                                                                                                                                                                                                   |          | Date                                                                          |                   |
| Residence: City Irvine                                                                                                                                                                                                                                                                                                                                                                                                                                                    | State CA | Country USA                                                                   | Citizenship USA   |
| Mailing Address 10 Anzio                                                                                                                                                                                                                                                                                                                                                                                                                                                  |          |                                                                               |                   |
| City Irvine                                                                                                                                                                                                                                                                                                                                                                                                                                                               | State CA | ZIP 92614                                                                     | 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:                                                                                                                                                                                                                                                                                                                                                                                                                                                  |          | <input type="checkbox"/> A petition has been filed for this unsigned inventor |                   |
| Given Name<br>(first and middle [if any]) James P.                                                                                                                                                                                                                                                                                                                                                                                                                        |          | Family Name<br>or Surname Kohler                                              |                   |
| Inventor's<br>Signature                                                                                                                                                                                                                                                                                                                                                                                                                                                   |          | Date                                                                          |                   |
| Residence: City Laguna Hills                                                                                                                                                                                                                                                                                                                                                                                                                                              | State CA | Country USA                                                                   | Citizenship India |
| 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 THIRD INVENTOR:                                                                                                                                                                                                                                                                                                                                                                                                                                                   |          | <input type="checkbox"/> A petition has been filed for this unsigned inventor |                   |
| Given Name<br>(first and middle [if any]) Harold R.                                                                                                                                                                                                                                                                                                                                                                                                                       |          | Family Name<br>or Surname Williams                                            |                   |
| Inventor's<br>Signature                                                                                                                                                                                                                                                                                                                                                                                                                                                   |          | Date                                                                          |                   |
| Residence: City San Clemente                                                                                                                                                                                                                                                                                                                                                                                                                                              | State CA | Country USA                                                                   | Citizenship USA   |
| Mailing Address 1223 Liano Street                                                                                                                                                                                                                                                                                                                                                                                                                                         |          |                                                                               |                   |
| City San Clemente                                                                                                                                                                                                                                                                                                                                                                                                                                                         | State CA | ZIP 92673                                                                     | Country USA       |

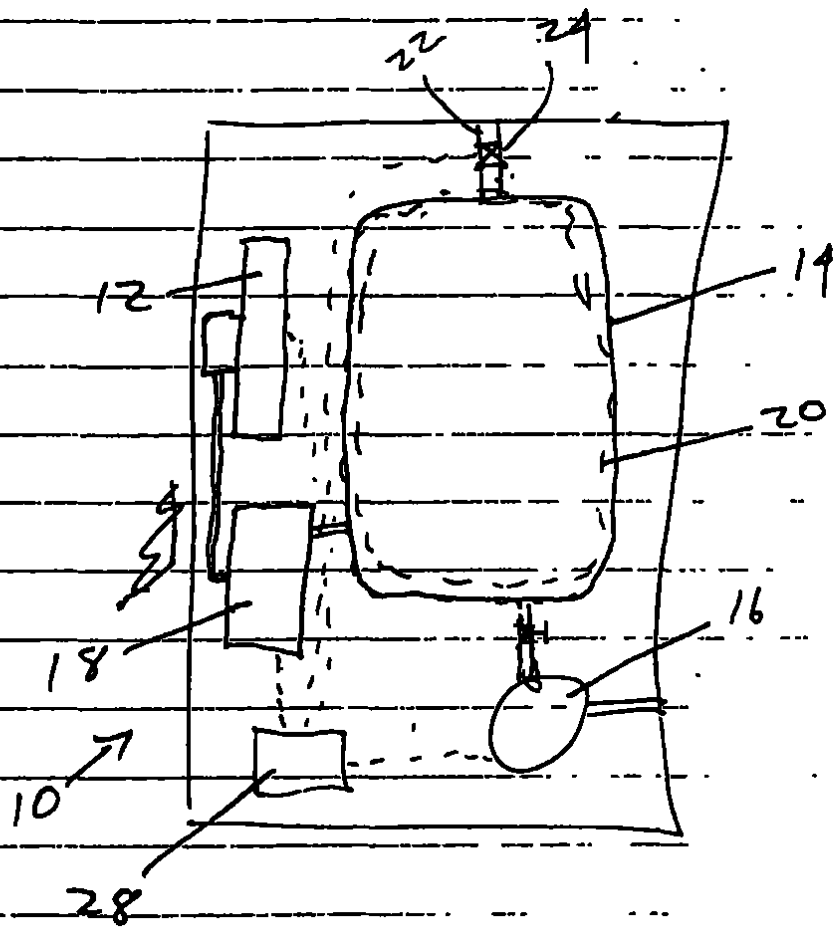


FIG. 1

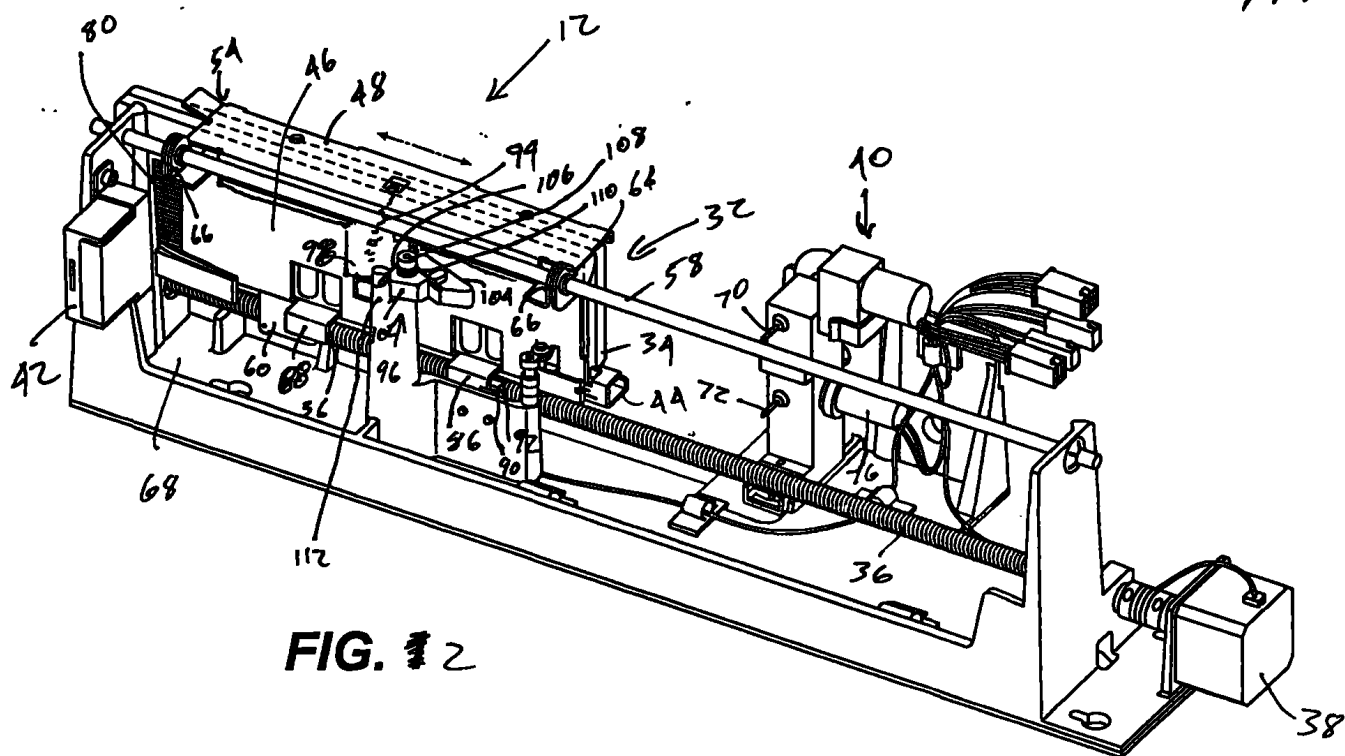
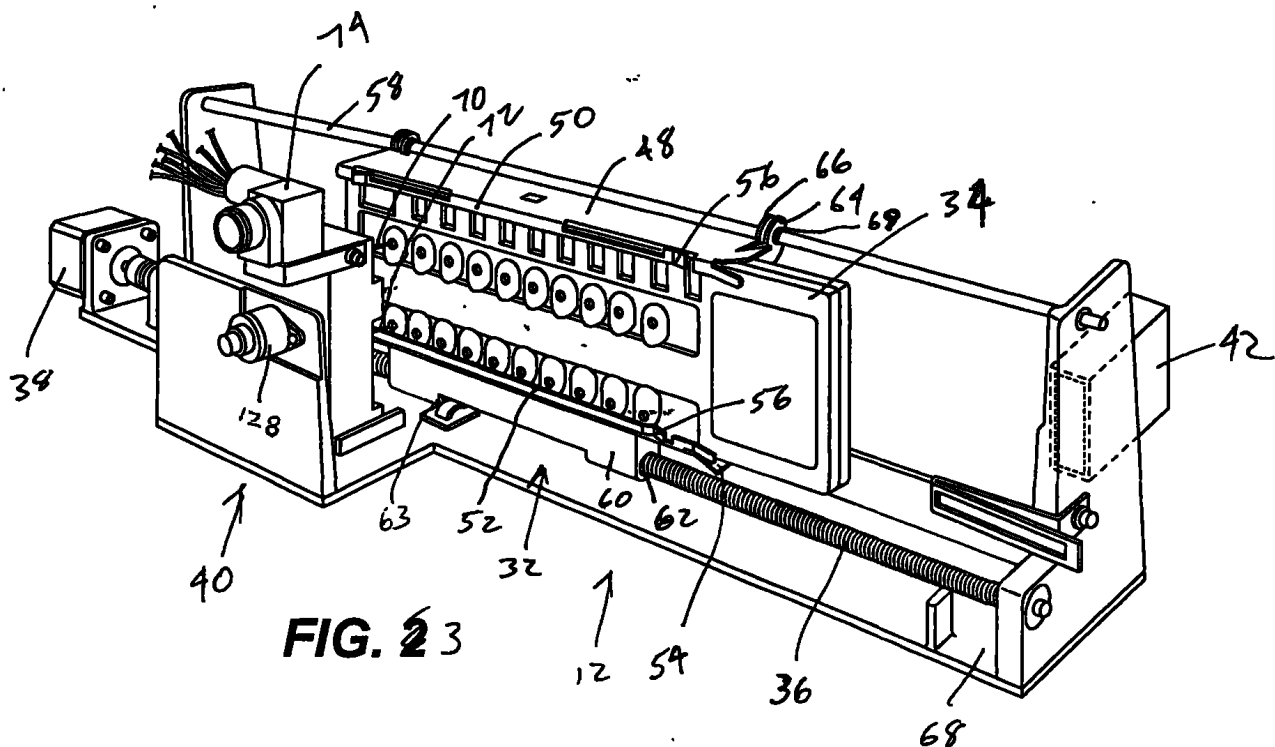
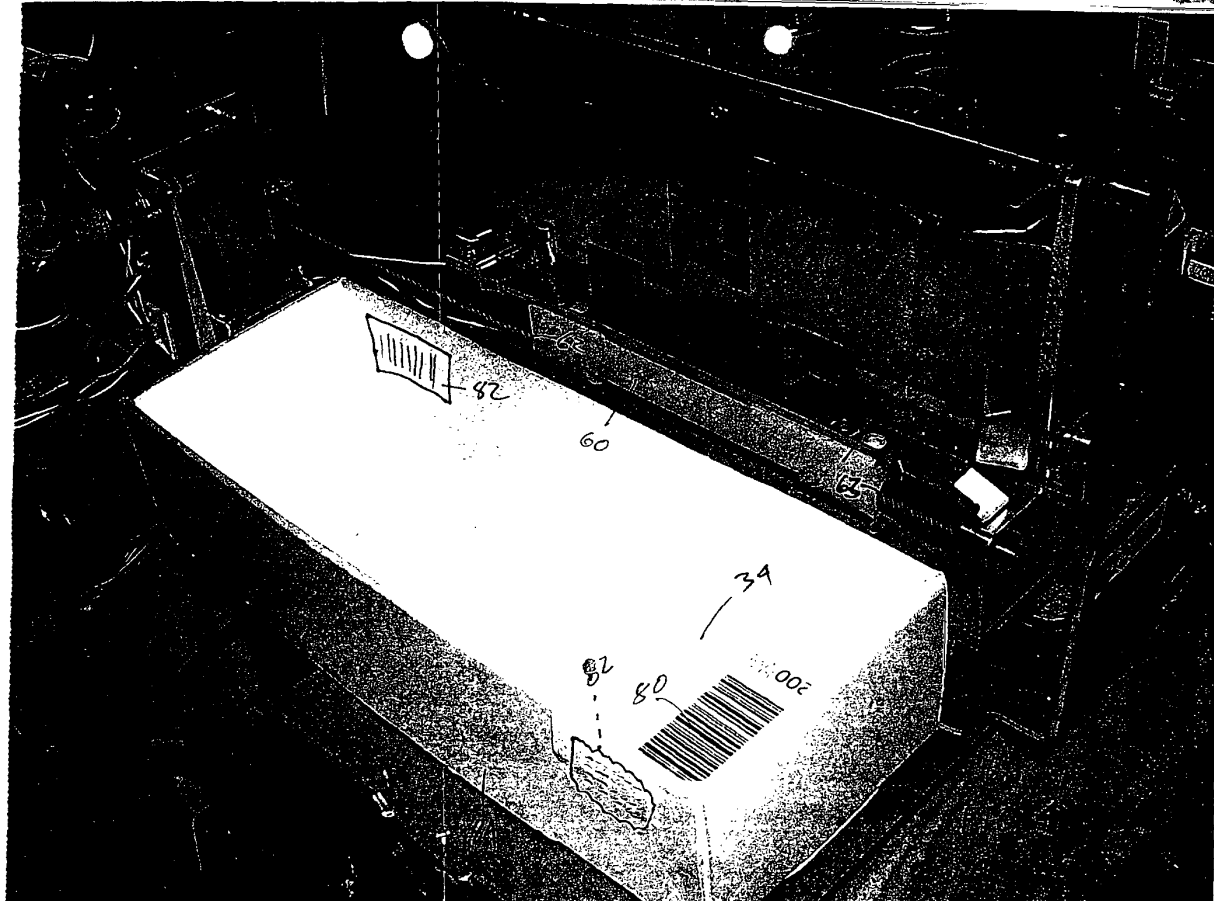


FIG. 2

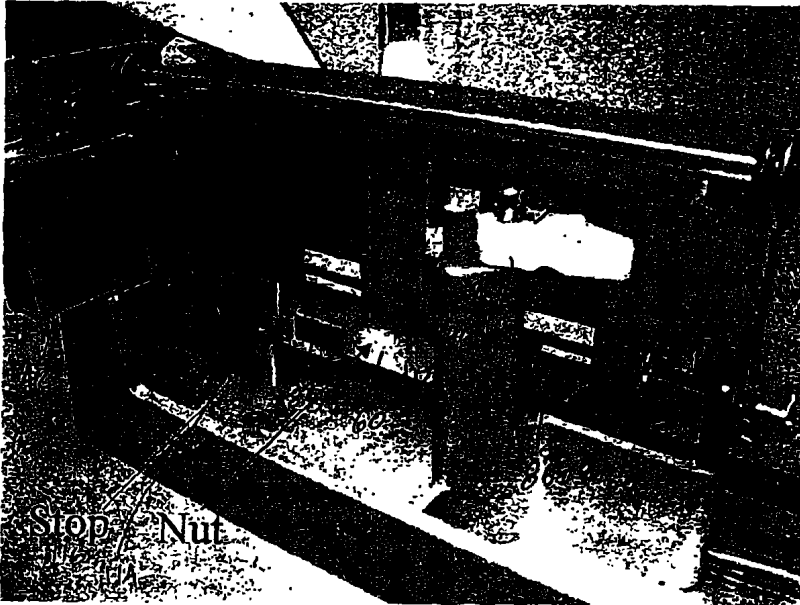
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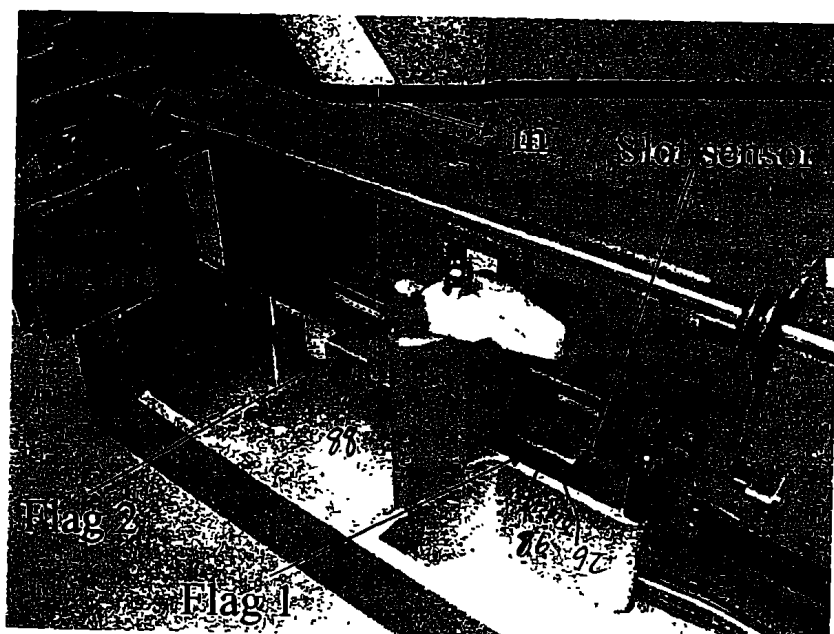
# Insert Position: detail of slide 1



Nut on lead screw  
touches a hard stop.

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# Barcode start



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

Fig. 6

# Barcode reading

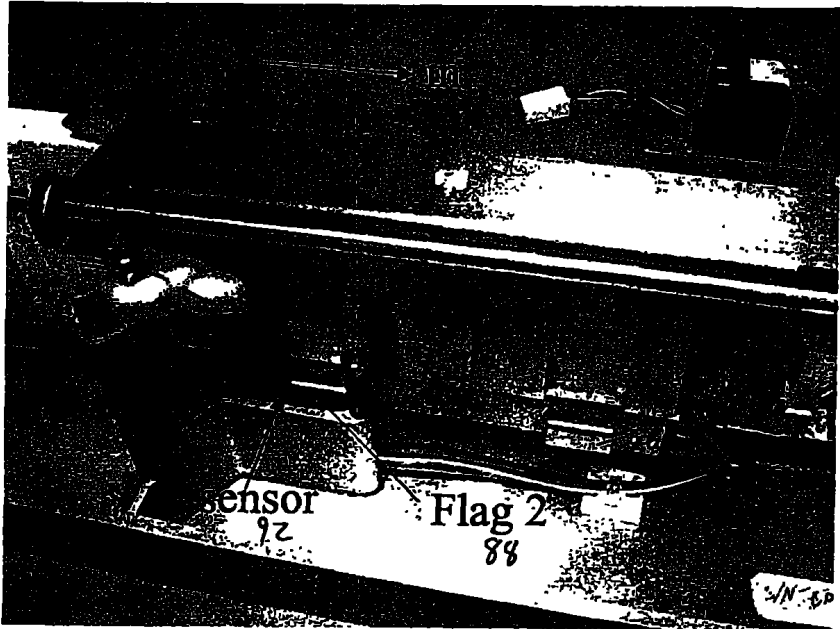


- Cassette is being moved in while scan engine (not shown) reads barcode.
- Side clamp holds cassette fixed to carriage.

Fig. 1

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# Home position



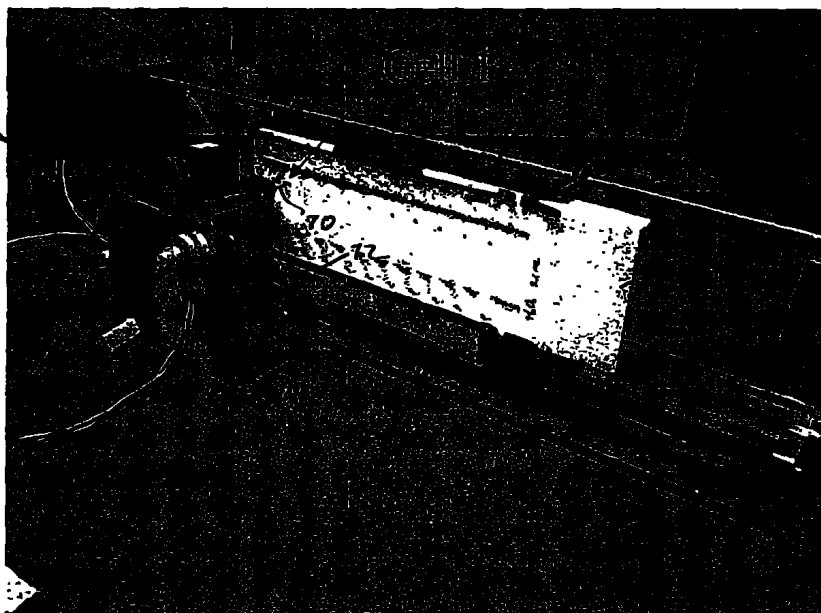
• Trailing edge of flag 2 just passes slot sensor.

FIG 3.

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# Cell 1

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

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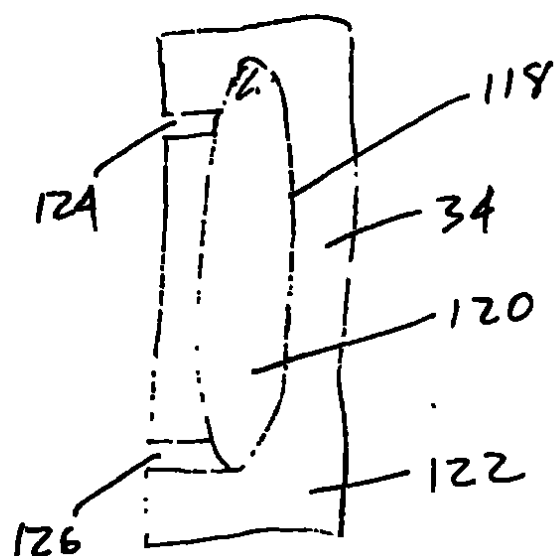


FIG. 10

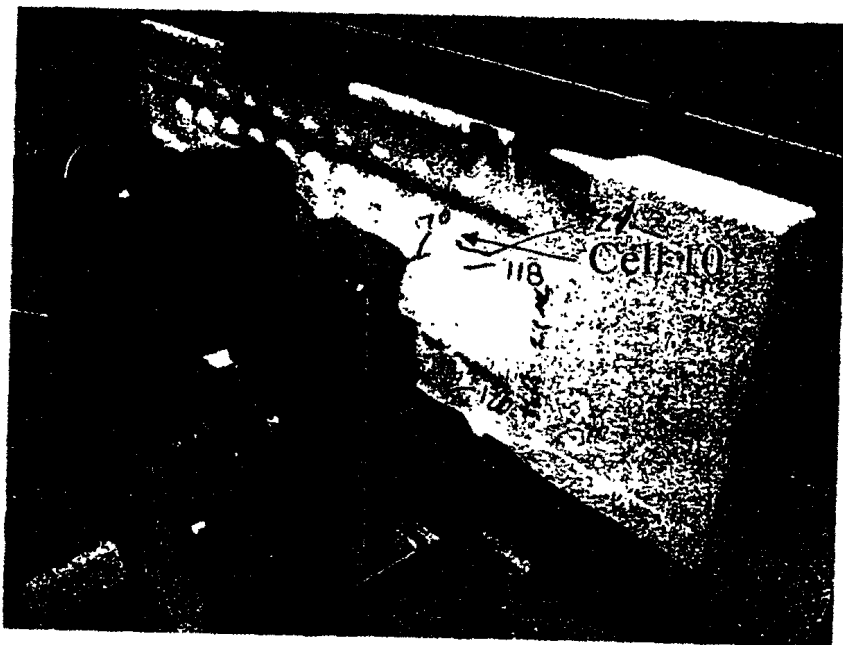
# Cell 1: Injection



- 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

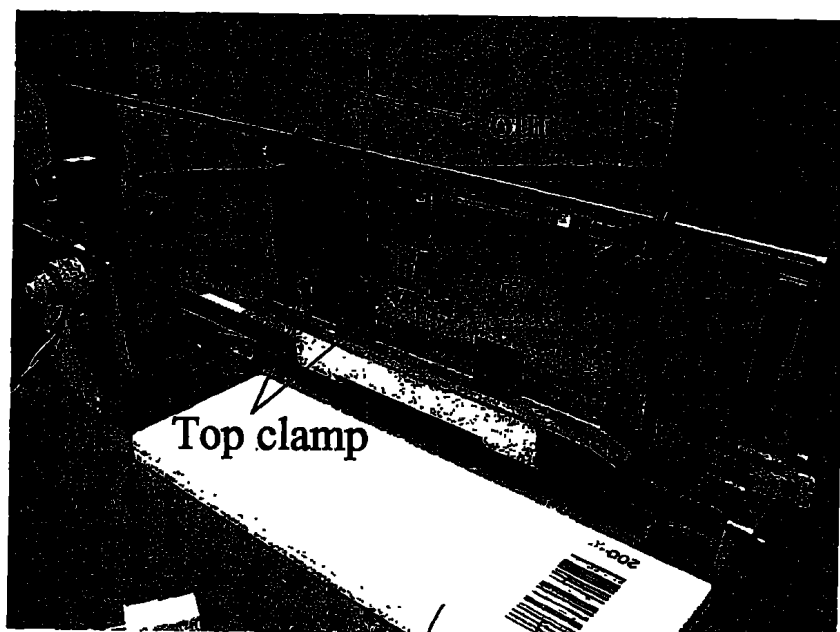


- Stepper motor moves cassette in 15 mm to arrive at the next cell.
- Once at a cell position, injection (described in page 11) takes place.
- The indexing and injection process repeat for all 10 cells.

FIG. 12

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# Cassette disposed



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

FIG. 14

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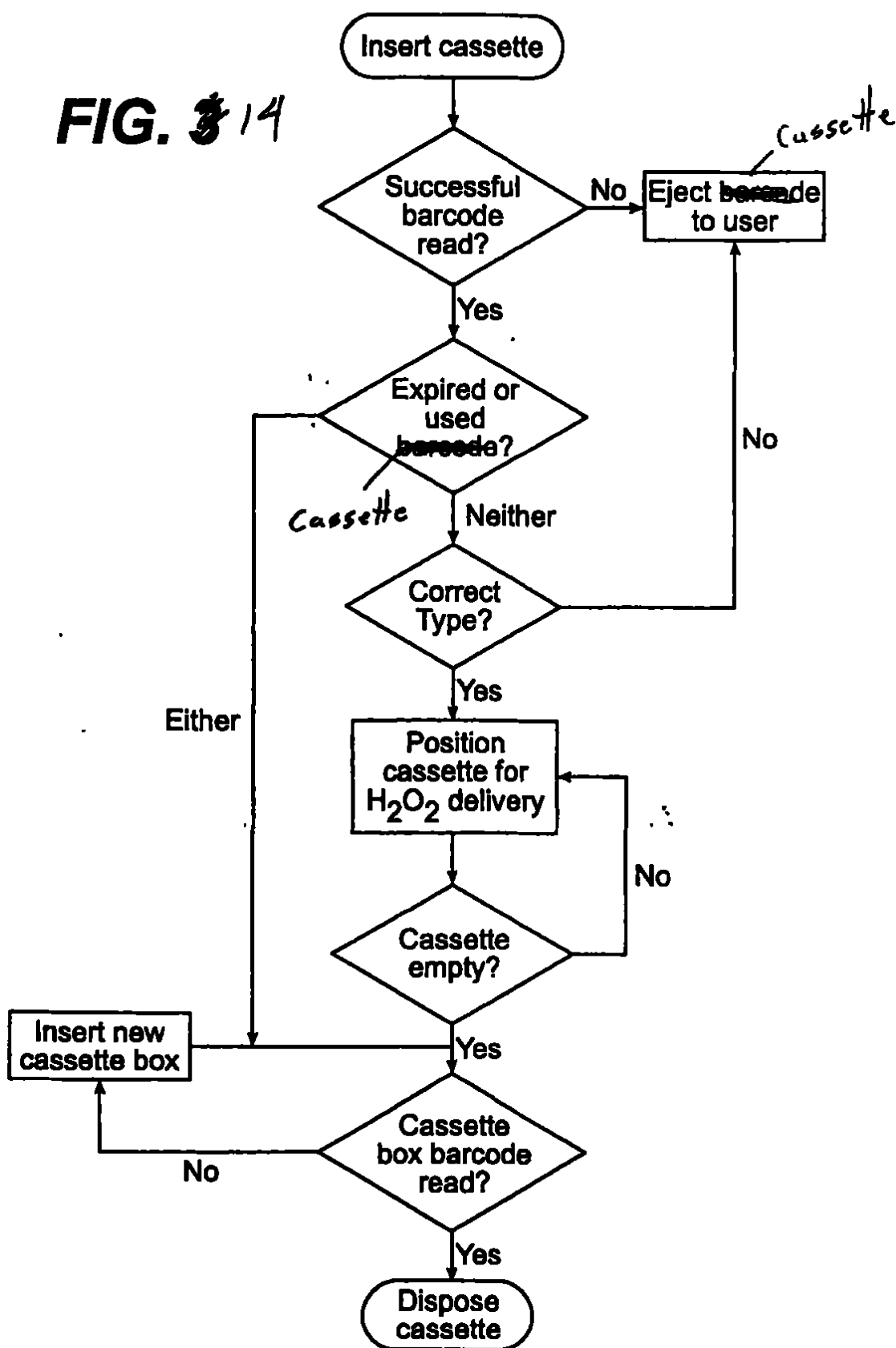
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FIG. 3 14



# Insert Consumable

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

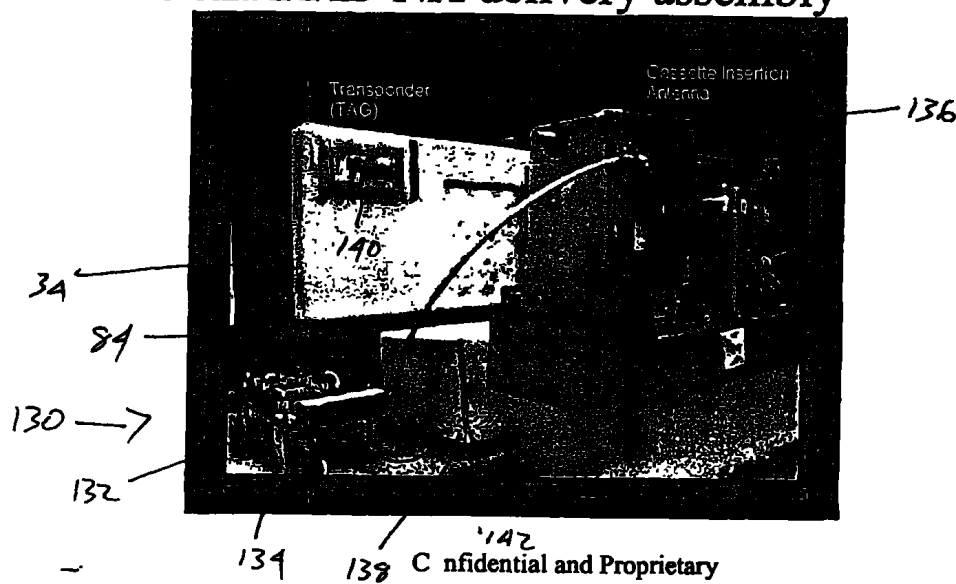
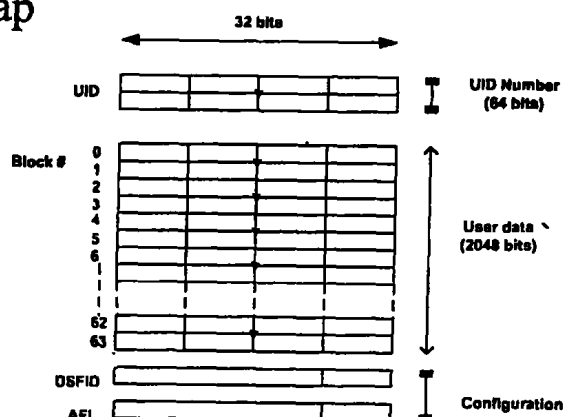


FIG. 15

Confidential and Proprietary  
Information of ASP

# RFID Transponder (Tag)

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



Confidential and Proprietary  
Information of ASP

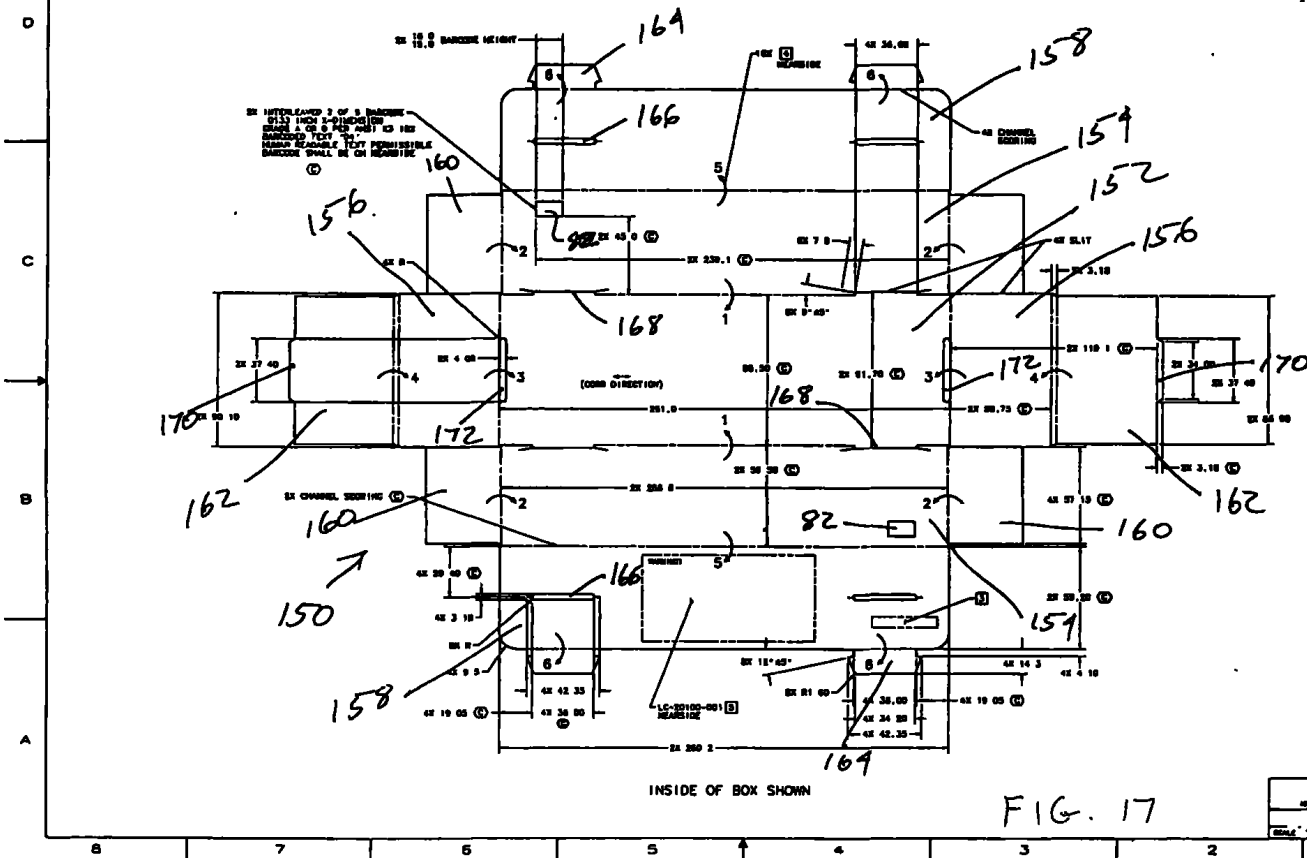


FIG. 17

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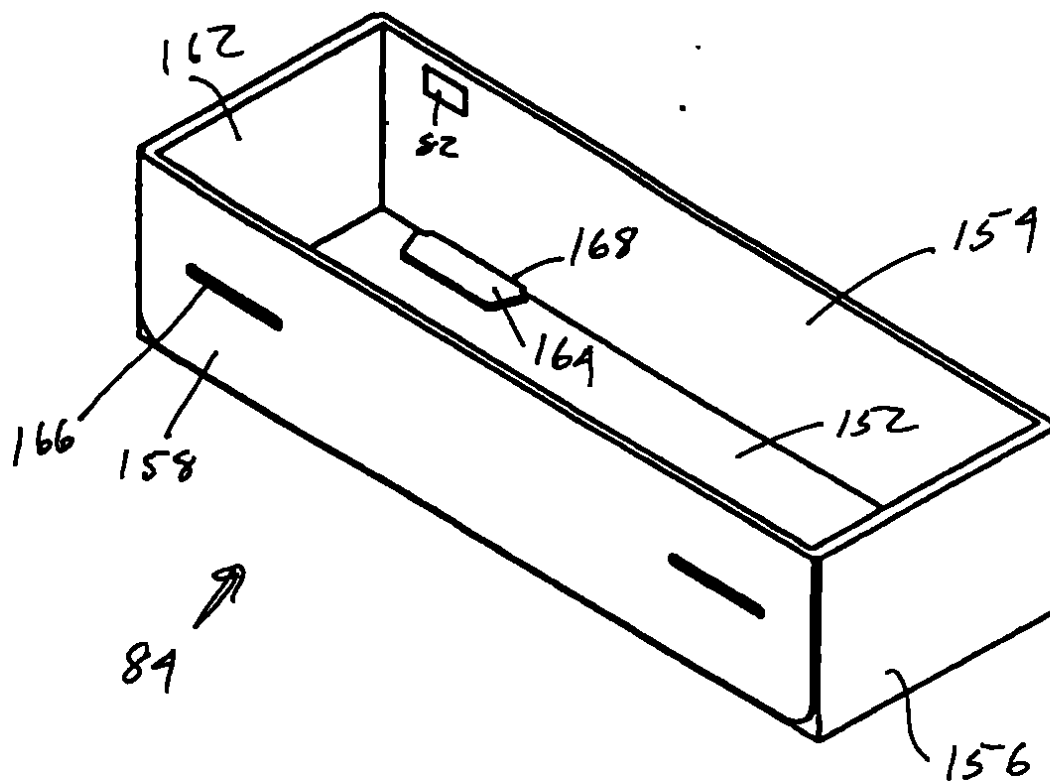


FIG. 18

**2° EXAMEN DE FORMA, PATENTE DE INVENCION**

Radicación N°      **05-51945**

Folio ~~187~~

Concepto Técnico N°      **840**

Clasificación Internacional de Patentes:      **A61L 2/07**

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.

2020  
Bogotá D C

Doctor(a):  
JIMENA ESCOBAR URIBE.  
Apoderado

|                    |               |          |
|--------------------|---------------|----------|
| <b>REFERENCIA:</b> | Radicación N° | 05-51945 |
|                    | Trámite       | 002      |
|                    | Evento        | 001      |
|                    | Actuación     | 416      |
|                    | Oficio N°     | 1254     |
|                    | 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