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Clarke, Modet & Cº
COLOMBIA

ESCOBAR - URIBE ASOCIADOS
Intellectual Property

As. 2960/P.

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

Ref.: Expediente No. **06-031.929**
Solicitud de Patente a nombre de
Ethicon, Inc.

Yo, **JIMENA ESCOBAR URIBE**, identificada como aparece al pie de mi firma, domiciliada en Bogotá, en la Carrera 11 No. 86-53, piso 6, obrando como apoderada de la sociedad **Ethicon, Inc.,** con domicilio en Somerville, New Jersey, Estados Unidos de América, solicitante de la patente de la referencia, pido a usted que se proceda a examinar si la invención, cuya patente se tramita en el expediente de la referencia, es patentable.

Adjunto al presente memorial el recibo No. 07 - 100,435 de 10 de diciembre de 2007, por la suma de $404.000.oo, con lo cual queda cubierta la tasa oficial correspondiente a dicho estudio.

Señor Superintendente,

JIMENA ESCOBAR URIBE
C.C.39.779.452 de Usaquén
T.P. 68.228

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 07 - 100,435
FECHA : DICIEMBRE 10 DE 2007

***** C O N S I G N A C I O N *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
CLARKE MODET Y CO. COLOMB	CONSIGNACION	BANCO POPULAR	050-00110-6	72394969	10/12/2007	32.420,000.00

***** C O N C E P T O *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01 SOLICITUDES	85 EXAMEN DE PATENTABILIDAD DE INVEN	404,000.00
		TOTAL : $	404,000.00

SON: CUATROCIENTOS CUATRO MIL PESOS

RESPONSABLE : _____

RECIBO DE CAJA APLICADO AL EXPEDIENTE No._____

225 225

Industria y Comercio
SUPERINTENDENCIA

DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 06-31929

EL EXTRACTO DE LA PRESENTE SOLICITUD DE **PATENTE DE INVENCIÓN**

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **577** DE

FECHA **29 DE JUNIO DE 2007** EL TÉRMINO HÁBIL SEÑALADO POR LA LEY

EXPIRA EL **27 DE SEPTIEMBRE DE 2007**

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI _____ NO X

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIRECCIÓN DE NUEVAS CREACIONES

2020
Bogotá, D.C.,

Abogada
Jimena Escobar U.
(Apoderada)

ASUNTO		
	Radicación	06 – 31 929
	Trámite	002
	Evento	001
	Actuación	430
	Oficio	NE 12422
	Folios	030

Patente de Invención	X	Patente de Modelo de Utilidad	
Vía Nacional			
Vía PCT (fase nacional)		Cap. I	Cap. II
Solicitud Internacional n.°			
Fecha de Presentación Intrnl.			

Como resultado del examen de fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina se le comunica:

1. Documentos estudiados

Descripción:	Folios 8 a 77 como se radicó inicialmente
Reivindicaciones:	Folios 78 a 81 como se radicó inicialmente
Dibujos:	Folios 82 a 102 como se radicó inicialmente
Prioridad:	Folios 116 a 221. 2005-03-31 US. 11/095 251

2. Objeto de la invención

Título de la solicitud *Monitoreo de procedimiento de limpieza*, folio 1.

El objeto de la presente solicitud de patente de invención consiste en suministrar

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suciedad para verificar el estado del dispositivo de soporte después de cada limpieza.

El problema planteado en esta solicitud es satisfacer la necesidad de verificar y comparar, o supervisar, la suciedad remanente en un elemento de uso médico, después de que ha sido limpiado, con el objetivo de pasarlo a esterilización.

Para solucionar este problema técnico, la solicitud en estudio proporciona un dispositivo de soporte como el definido arriba, que básicamente, utiliza un testigo con una cantidad de suciedad predeterminada, lo somete a limpieza junto con los aparatos médicos a limpiar y compara la suciedad remanente después del procedimiento de limpieza con una cantidad suciedad admisible o permitida; y, así se determina si se debe someter a una nueva limpieza o ya se acepta la limpieza alcanzada hasta ese momento y se puede pasar a la esterilización.

Clasificación Internacional de Patentes (IPC): G01N 1/28

3. De la solicitud de Patente

Antes de entrar en detalles específicos, se le dan al solicitante ciertas indicaciones generales, algunas de las cuales son aplicables a este caso y todas deberán ser tenidas en cuenta en las eventuales modificaciones:

El título o nombre de la invención debe concordar con lo que se reclama en el capítulo reivindicatorio. Esto es, si en las reivindicaciones se reclama un producto tal producto debe ser mencionado en el título y si en las reivindicaciones se reclama un procedimiento o un sistema o un método, también debe ser mencionado allí. Normalmente, el título debe contener máximo diez palabras aunque eventualmente pueden ser más.

En Colombia, la máxima autoridad en cuestiones del lenguaje es la Academia Colombiana de la Lengua. En caso de duda sobre el significado de las palabras, se debe acoger la definición que trae el Diccionario de la Real Academia Española (DRAE).

En Colombia, es de uso obligatorio el Sistema Internacional de unidades. Esto implica, también, que la coma decimal es de uso obligatorio. Cuando aparezca algún valor con unidades diferentes a las exigidas, deberá incluirse su correspondiente conversión al Sistema Internacional.

La parte técnica de la solicitud se divide en tres secciones, debidamente separadas, preferiblemente en este orden: Capítulo descriptivo, capítulo reivindicatorio y dibujos o figuras. Ninguna de estas secciones podrá llevar membretes (encabezamientos o pies de página) ajenos al contenido técnico de la solicitud.

Por lo menos el capítulo descriptivo debe estar debidamente paginado y estar escrito a doble espacio, con el fin de facilitar la referencia a los apartados del texto. La terminología empleada en la descripción y en las reivindicaciones debe ser igual para designar las diferentes partes, piezas, elementos, detalles o aspectos de lo que se mencione en ellas; los cuales, a su vez, deben estar designados con

Las reivindicaciones deben estar numeradas individual y consecutivamente (1. 2. .. 5. 6. etc.) El capítulo reivindicatorio no debe tener subtítulos.
Normalmente se pueden encontrar dos categorías de reivindicaciones: una, la de producto y la otra, de procedimiento.
En las reivindicaciones se deben definir los alcances de la protección que desea el solicitante. En consecuencia, las reivindicaciones forman un cuerpo aparte de la descripción y como tal debe ser redactado. la primera vez que se mencione un nombre dentro de las reivindicaciones debería estar acompañado de un artículo indeterminado: y, la inclusión -entre paréntesis- de un número de referencia no sustituye la definición del elemento o aspecto al que se refiere. simplemente sirve de información complementaria. Se debe entender que la descripción sirve para interpretar las reivindicaciones y, en consecuencia, si en una reivindicación se reclama un aparato, por ejemplo, no se deberían mencionar aspectos del funcionamiento del aparato dentro de la reivindicación, limitándose a definir únicamente los elementos que constituyen el aparato.

Cada una de las figuras debe estar debidamente identificada, preferiblemente con un número consecutivo: Figura 1. figura 2. ..
Las figuras deben ser realizadas siguiendo las reglas del dibujo técnico.
Se prefiere que dentro de las figuras no se incluya ningún texto. Cada uno de los detalles ilustrados en las figuras deberá estar señalado con un número o signo de referencia, el cual será el mismo en todas las figuras en donde se encuentre el detalle en cuestión. Si en alguna figura no se encuentran números de referencia, se entiende que no se va a decir nada sobre ella dentro del texto de la descripción y, entonces, es preferible que se omita tal figura. Análogamente, si en una figura no se encuentra señalado algún detalle con el respectivo número de referencia, es preferible que se omita tal detalle.

La patente de modelo de utilidad no puede incluir los procedimientos, por definición. Si alguna de las reivindicaciones de una solicitud de patente de modelo de utilidad reclama un procedimiento, debe ser suprimida.

Descripción *(artículo 28 D. 486)*

Durante el análisis del texto de la descripción y de las ilustraciones anexadas, se observaron los siguientes defectos:

1) El título o nombre de la invención no coincide con lo que se reclama en el capítulo reivindicatorio.
2) En el título, y a lo largo de la solicitud, aparece el término *monitoreo* que supuestamente se deriva del verbo *monitorear* -que se usa, tal cual, varias veces dentro de la solicitud- pero cuyo significado se desconoce según el Diccionario de la Real Academia Española (DRAE). En el DRAE se encuentra *monitor* pero su significado no se ajusta al contexto
3) En la página 2, folio 9, aparece por primera vez un número (*3,640.295*) en el cual se emplea mal la coma. En Colombia, para ser usada junto con los números, la coma es el signo de separación decimal.
4) En la página 3, folio 10, aparece por primera vez la expresión *la patente* [o la invención] ... *no dirige estándares*... que carece de sentido. Se sugiere sustituir el término *dirige* por *señala* o *indica* o *insinúa* o *sugiere* u otra expresión que se ajuste mejor a lo que el solicitante quiere decir.

6) En la página 7, folio 14, aparece la expresión *0.05 mm* en la cual, por primera vez en la solicitud, se utiliza el punto como separador decimal y se omite emplear la coma decimal.

7) En la página 9, folio 16, aparece por primera vez la expresión *aspas de acero inoxidable inoculadas con...* que carece de sentido porque el verbo *inocular* no es aplicable a este contexto. Lo similar es aplicable a la expresión *tiras de politetrafluoroetileno inoculadas con...* que aparece en la página 10, folio 17. Un defecto similar ocurre en la expresión *la inoculación de... en aspas de acero inoxidable* que se encuentra en la página 12, folio 19.

8) En la misma página 9, aparece por primera vez una sigla (*RPMI*) que no está acompañada por su correspondiente significado. Otras siglas que se encuentran en la solicitud y presentan el mismo defecto son: *RPM, EC, SAL, CSR, TSB, UV-VIS, IR, 'I vs. V'.*

9) En la misma página 9 aparece por primera vez la expresión a *23EC* que, aparentemente se refiere a una temperatura, pero se desconocen estas unidades (*EC*). En todo caso, el solicitante debe emplear las unidades del Sistema Internacional.

10) En la página 11, folio 18, aparece la expresión *las figuras 15a-15d* en la cual se deben sustituir las minúsculas por mayúsculas porque es así como se encuentran designadas en las ilustraciones de los folios 93 a 96. Alternativamente, se debe corregir la denominación de las figuras dentro del juego de dibujos -lo cual sería preferible, porque las figuras 16a-16c están denominadas con minúsculas.

11) En la página 12, folio 19, aparece la expresión *6 mg/litros* en la cual se mezclan un símbolo de unidad con un nombre de unidad -lo que no es correcto-: si se escribe un número, se debe acompañarlo por los símbolos y si se escribe la palabra, se la debe acompañar con el nombre, así: *6 mg/L, seis miligramos por litro.*

12) En la tabla denominada Cuadro 1, página 13, folio 20, aparecen, en primer lugar, varias cifras en donde se omite el cero de las unidades y la coma decimal; y, en segundo lugar, aparecen varias fracciones que deben ser sustituidas por números decimales o, alternativamente, por una nueva configuración de las columnas. Un defecto similar ocurre en el Cuadro 2, página 14, folio 21. También en el cuadro 3, página 15, folio 22, se encuentran defectos similares.

13) En la página 15, folio 22, aparece la expresión *Sin embargo agua de la llave que contiene múltiples sales a una concentración relativamente baja presenta menos que un desafío ya que cristales uniformes no son propensos a formarse*, que carece de sentido.

14) En la misma página 15 aparece la expresión *el médium de cultivo* que carece de sentido, según el contexto.

15) En la página 16, folio 23, aparece la expresión *oscilaron de 0-60 segundos* en la cual, en primer lugar, se debe reemplazar el término *de* por *entre*; y, en segundo lugar se deben incluir las unidades, mejor, el símbolo de las unidades, acompañando a cada número; entonces la expresión debe quedar: *oscilaron entre 0 s y 60 s*, o mejor, *oscilaron entre cero segundos y sesenta segundos.*

16) En la página 17 folio 23, aparece la expresión *sangre... citrada* cuyo significado se desconoce

17) En la página 22, folio 29, aparece por primera vez la expresión *y/o*. Al respecto, el Diccionario panhispánico de dudas de la Real Academia Española

la intención de hacer explícita la posibilidad de elegir entre la suma o la alternativa de dos opciones: «Se necesitan traductores de inglés y/o francés». ***Se olvida que la conjunción 'o' puede expresar en español ambos valores conjuntamente.***

El examinador ha subrayado la última frase porque es particularmente aplicable a este caso.

18) En la página 25, folio 32, aparece por primera vez la expresión *cloruro de plata/sulfuro de plata* que puede tener los siguientes significados: *(cloruro de plata) o (sulfuro de plata);* o, también, *(cloruro de plata) sobre (sulfuro de plata)* entre otras interpretaciones posibles. Para resolver la ambigüedad, el solicitante debe expresar en palabras el significado aplicable, omitiendo el uso de la barra (/).

19) En la misma página 25 aparece la expresión *pH/mV/ion* cuyo significado se desconoce. Se le sugiere al solicitante que consulte el apartado BARRA en el *Diccionario panhispánico de dudas* de la Real Academia Española y de la Asociación de Academias de la Lengua Española y, además, las reglas de uso del Sistema Internacional de unidades.

20) En la página 27, folio 34, aparece la expresión *La escala de detección... es de saturada 1.0 x 10 ^{6} M* que carece de sentido.

21) En la página 43, folio 50, aparece por primera vez el término *lumen*. Según el Diccionario de la Real Academia Española (DRAE), el *lumen* es una unidad de medida, por lo que no concuerda su uso con el contexto.

22) En la figura 7, folio 88, aparece la sigla *RPM* cuyo significado no ha sido definido dentro del texto de la descripción. En caso de referirse a *rpm,* el solicitante debe hacer la conversión a unidades del Sistema Internacional. Además, en la misma figura aparece la expresión *1400 RPM + 45 C* cuyo significado se desconoce (se le recuerda al solicitante que C es el símbolo de coulomb o el del carbono, según sea el contexto); en la figura 8, folio 89, aparece un defecto similar al último objetado.

- La descripción no cumple con los requisitos de claridad y divulgación completa, lo que dificulta o impide su comprensión y ejecución de acuerdo al Art. 28 de la Decisión 486

Reivindicaciones *(artículo 30 D 486)*

Durante el análisis del texto de las reivindicaciones se observó el siguiente defecto:

En la reivindicación 1, folio 78, aparece por primera vez en el capítulo reivindicatorio el término *monitorear* que fue objetado arriba, con relación a la descripción.

En la reivindicación 10, folio 80, aparece la expresión *0.05 mm* en la cual se omite la coma decimal.

Debe entenderse que las reivindicaciones dependientes de las reivindicaciones objetadas son, asimismo, objetadas, por razones análogas.

Las reivindicaciones no cumplen con los requisitos de definición y claridad de acuerdo al Art. 30 de la Decisión 486

Se deben presentar, entonces, nuevos capítulos descriptivo y reivindicatorio, ambos completos junto con un nuevo juego de dibujos, donde se hayan corregido

Se le advierte al interesado que las modificaciones sugeridas arriba podrían resultar inconducentes si se mantienen las objeciones a la patentabilidad que se insinúan adelante.

4. Determinación del Estado de la Técnica

- La fecha que se ha tenido en cuenta para determinar el Estado de la Técnica es la

Fecha de presentación de la solicitud prioritaria 2005-03-31

Se deben aclarar las diferencias con respecto a la solicitud colombiana número de radicación 06 - 31 931 perteneciente al mismo solicitante. Y, se debe considerar la fusión de las dos solicitudes en una, en el caso de que tengan unidad de concepto inventivo, es decir, en el caso de que las diferencias no sean técnicamente significativas.

- Se realizó la búsqueda en el estado de la técnica de documentos relacionados con la solicitud teniendo en cuenta la fecha indicada y durante la búsqueda de anterioridades se encontraron los siguientes documentos que forman parte de la familia de patentes de la presente solicitud: Publicación US 2006/0219261 A1 del 2006-10-05; y, Patente US 7 563 329 B2 del 2009-07-21. Se anexan las copias de las primeras páginas de estos documentos junto con la copia del capítulo reivindicatorio admitido por la USPTO. También se encontraron los siguientes documentos que forman parte del estado de la técnica más cercano al objeto de la solicitud:

n.°	Documento	Título	Fecha de publicación
D1	Patente US 4 777 020, cuyo inventor es David J. Brigati, quien le cedió sus derechos a la Fisher Scientific Company	«Sheetlike object such as microscope slide»(Un objeto en forma de hoja, como por ejemplo una lámina para microscopio)	1988-10-11
D2	Patente US 5 928 948, cuyo inventor es Paul S. Malchesky quien le cedió sus derechos a la Steris Corporation	«Method for the assessment and validation of cleaning processes»(Un método para asegurar y validar procedimientos de limpieza)	1999-07-27
D3	Patente US 6 193 931 B1 cuyos inventores son Szu Min Lin y Paul Taylor Jacobs, quienes le cedieron sus derechos a la Ethicon, Inc	«Container monitoring system»(Un sistema para supervisar un recipiente)	2001-02-27
D4	Patente US 6 394 111, cuyos inventores son Szu-Min Lin, Jenn-Han Wang y Paul Taylor Jacobs, quienes le cedieron sus derechos a la Ethicon, Inc.	«Detection of cleanliness of a medical device during a washing process»(Detección de falta de limpieza de un dispositivo de uso médico durante un proceso de lavado)	2002-05-28
D5	Patente US 6 447 990 B1, cuya inventora es Michelle J. Alfa, quine le cedió sus derechos a la University of	«Artificial test soil»(Un ensayo con suciedad artificial)	2002-09-10

n.°	Documento	Título	Fecha de publicación
D6	Patente US 6 454 874 B1, cuyos inventores son Szu-Min Lin, Jenn-Han Wang y Paul Taylor Jacobs, quienes le cedieron sus derechos a la Ethicon, Inc.	«Method of detecting the cleanliness of a medical device»(Un método para detectar la falta de limpieza en un dispositivo de uso médico)	2002-09-24
D7	Patente US 6 494 964 B1, cuyos inventores son Szu-Min Lin, Jenn-Han Wang y Paul Taylor Jacobs, quienes le cedieron sus derechos a la Ethicon, Inc.	«Monitoring of cleaning process»(Supervisión de un procedimiento de limpieza)	2002-12-17
D8	Patente US 6 516 817 B2 cuyos inventores son Szu-Min Lin, Jenn-Han Wang y Paul T. Jacobs	«Monitoring of cleaning process»(Supervisión de un procedimiento de limpieza)	2003-02-11
D9	Patente US 6 516 818 B2, cuyos inventores son Szu-Min Lin, Jenn-Han Wang y Paul T. Jacobs	«Monitoring of cleaning process»(Supervisión de un procedimiento de limpieza)	2003-02-11

Se anexa la copia de las páginas pertinentes de estos documentos

NOTAS: No se realizaron las evaluaciones de los demás requisitos de patentabilidad, porque se hicieron algunas objeciones respecto a la claridad y completitud de la descripción, lo cual afecta al sustento que deben tener las reivindicaciones; esto es, no se pudo practicar un análisis comparativo, por ausencia de materia.

En el documento D4, se enseña, entre otras cosas un aparato como el reclamado en las reivindicaciones 1 a 10 a la vez que se insinúa un método como el de las reivindicaciones 11 a 20 (ver columna 5 de D4).

A pesar de lo anterior, con base en los conocimientos normales de una persona del nivel medio en el arte; y, con base en las enseñanzas de los documentos encontrados hasta ahora, en especial, las reivindicaciones admitidas por la USPTO y los documentos D4 y siguientes, se prevén objeciones respecto al nivel inventivo de la solicitud en estudio.

5. Conclusión:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el número 5.2, letra e), del capítulo quinto del título primero de la Circular Única n.° 10 de 2001.

ALIX CARMENZA CÉSPEDES DE VERGEL
Directora de Nuevas Creaciones (C)

El anterior requerimiento fue notificado por fijación en lista, de fecha 12 NOV. 2009

CONCEPTO TÉCNICO n.° 3753

EXAMINADOR TÉCNICO
Código n.° 202009

US 20060219261A1

United States
Patent Application Publication
Lin et al.

(10) Pub. No.: US 2006/0219261 A1
(43) Pub. Date: Oct. 5, 2006

(54) MONITORING OF CLEANING PROCESS

(75) Inventors: Szu-Min Lin, [illegible] CA (US); Paul E. Jacobs, [illegible] (US); Jenn-Hann Wang, Northridge, CA (US); Robert C. Platt, Laguna Niguel, CA (US); Peter C. Zhu, [illegible] CA (US)

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(21) Appl. No.: 11/095,251

(22) Filed: Mar. 31, 2005

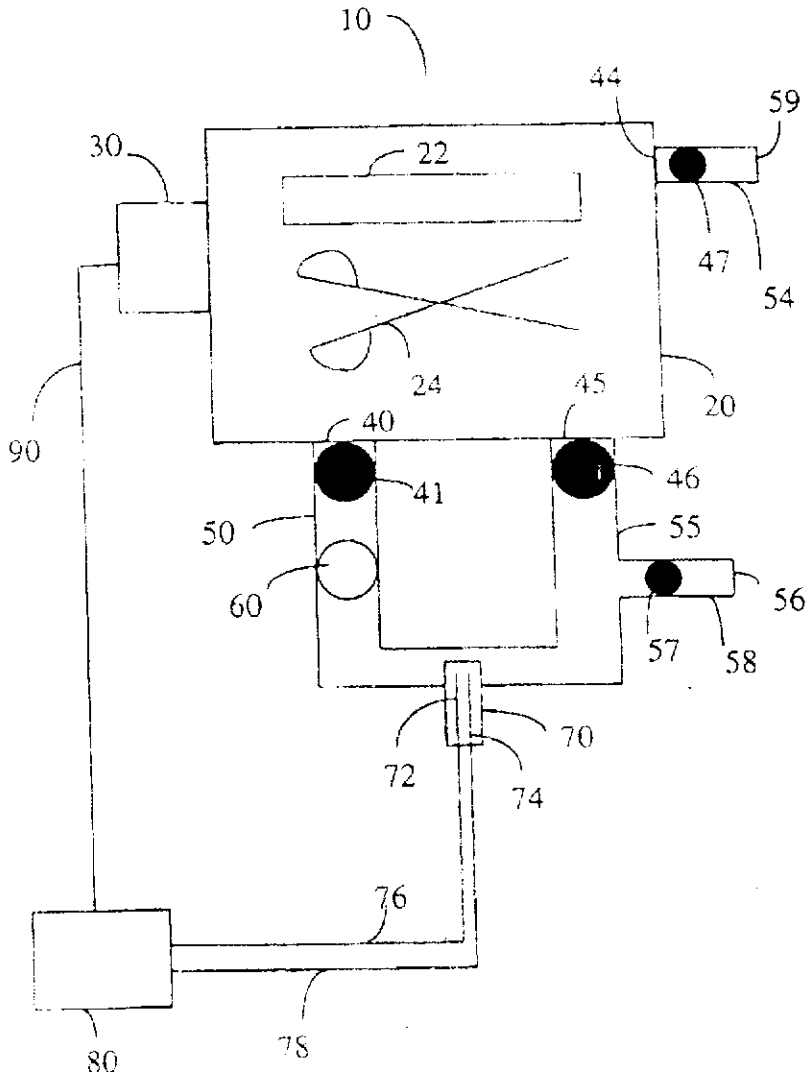
Publication Classification

(51) Int. Cl.
B08B 3/04 (2006.01)
B08B 3/00 (2006.01)

(52) U.S. Cl. ..... 134/18; 134/26; 134/56 R

(57) ABSTRACT

A method of monitoring a cleaning process for a medical instrument includes the steps of placing the instrument in a cleaning chamber; placing a soil standard in the cleaning chamber; cleaning the instrument and the soil standard with a cleaning solution; and detecting whether soil remains on said soil standard. The soil standard includes two substantially parallel substrates separated with two substantially equal thickness spacers wherein a gap is formed between the [illegible] with soil in the gap.



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US007563329B2

(12) **United States Patent**
Lin et al.

(10) **Patent No.: US 7,563,329 B2**
(45) **Date of Patent: Jul. 21, 2009**

(54) **MONITORING OF CLEANING PROCESS**

(75) Inventors: **Szu-Min Lin**, Irvine, CA (US); **Paul T. Jacobs**, Bicknell, UT (US); **Jenn-Hann Wang**, Northridge, CA (US); **Robert C. Platt**, Laguna Niguel, CA (US); **Peter C. Zhu**, Irvine, CA (US)

(73) Assignee: **Ethicon Inc.**, Somerville, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 594 days.

(21) Appl. No.: **11/095,251**

(22) Filed: **Mar. 31, 2005**

(65) **Prior Publication Data**

US 2006/0219261 A1 Oct. 5, 2006

(51) **Int. Cl.**
B08B 13/00 (2006.01)
G01N 21/94 (2006.01)
G01N 21/84 (2006.01)

(52) **U.S. Cl.** **134/18**; 356/237.2

(58) **Field of Classification Search** 134/18, 134/113; 73/60.11; 356/237.2, 237.3, 237.5, 237.8, 356/243.4, 243.6, 243.8; 436/102
See application file for complete search history.

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[illegible] A *	8/1955	[illegible]	....	73/60.11
[illegible] A *	1/1956	Mackenzie et al.	....	73/60.11
[illegible] A	2/1972	Peterson		
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[illegible] A	[illegible]	Stone		
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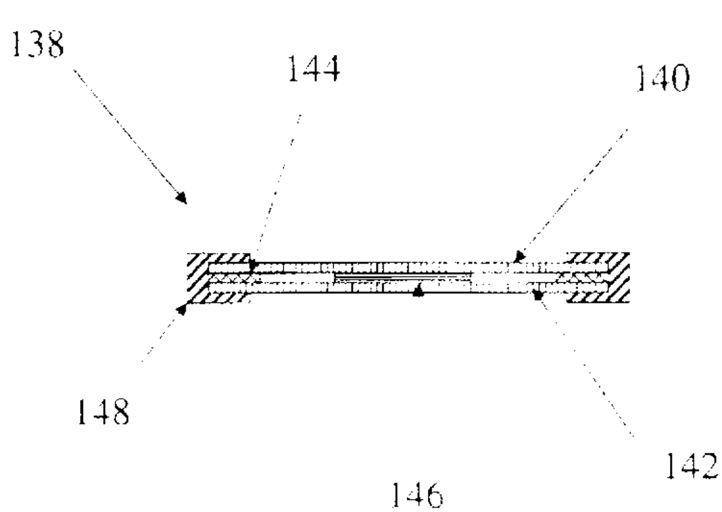
Primary Examiner—Thomas P Noland
(74) *Attorney, Agent, or Firm*—K&L Gates LLP

(57) **ABSTRACT**

A method for monitoring a cleaning process for a medical instrument includes the steps of placing the instrument in a cleaning chamber along with a soil standard in the cleaning chamber, cleaning the instrument and the soil standard with a cleaning solution, and detecting whether soil remains on said soil standard. The soil standard includes two substantially parallel substrates separated with two substantially equal thickness spacers, wherein a gap is formed between the two substrates with soil in the gap.

10 Claims, 21 Drawing Sheets



The overall shape of the standard **138** can be rectangular, circular, or any other appropriate shape. Preferably, it has a rectangular shape of about [illegible] in size. The substrates **140** and **142** may be the same [illegible] shape or material or different. [illegible] An additional substrate **150** [illegible] can be employed to form a standard **138**[illegible] [illegible] For instance, it may be desirable [illegible] trapped between a silicone surface and a stainless steel surface. As silicone is flexible, the substrate **150** can be formed of silicone and supported by the rigid substrate **142***b* with the soil **146***b* trapped between the substrate **150** and the substrate **140***b* and located between spacers **144***b*. Holders **148***b* hold all of the pieces together with one of the holders **148***b* having a locating pin **152** for interfacing with a cleaning apparatus (not shown in FIG. 16*b*).

The substrates **140**, **142** and **150** can be transparent, semi-transparent, or opaque, with transparent materials being preferred for easy inspection. The substrate can be stainless steel, aluminum, Teflon, polyethylene, polypropylene, polystyrene, polycarbonate, silicone, glass, quartz, and many other suitable metals and polymers. Preferably, the substrate is rigid material. More preferably, the substrate is transparent. The soil **146** can be any artificial test soil or animal blood. The soil can be any of the organic soil, inorganic soil and combination of organic soil and inorganic soil. Preferably, the soil is dried in place between the substrates and located between the spacers **144**.

The spacers **144** create a defined gap between the substrates **140** and **142**. The spacers can be any rigid material with defined thickness. They can be formed of the same material as the substrates **140** and **142**, and can be formed as an integral part thereof. Preferably, the spacers **144** have a thickness of about 0.05 [illegible]

The holder **148** can be a clamp, clip, tape, screw, rubber band, snap-on cap, or any other holding method to hold all of the pieces together. Rather than two separate holders **148** a single holder design can be employed. The holders **148** can be removable or permanent. The holder **148** can be glue or adhesive. The holder **148** can be a mechanism by [illegible] bonding, melting, clamping substrates together or any other means to hold the substrates **140** and **142** together.

FIG. 16*c* shows a cleaning indicator **138***c* in which a substrate **140***c* and spacer **144***c* are formed as one part, two of which fit together to form the indicator **138***c*. A projection **156** protrudes from the spacer **144***c* and snaps into an opening **154** of another identical substrate **140***c*. Locating pins **152***c* are provided.

During a cleaning cycle, the cleaning indicator **138** can be located in a wired cage. It can also be fixed or suspended in a cleaning apparatus.

The cleaning efficiency can be determined visually or via an instrument. Preferably, for an integrated washer-disinfector or washer-sterilizer, the cleaning efficiency is determined with a [illegible]

[illegible] examples are presented by way of illustration [illegible] the present invention [illegible] without departing [illegible]

What is claimed is:

1. A method for [illegible] cleaning process for a medical instrument, comprising the steps of:

placing the instrument into a cleaning chamber;

placing a soil standard in said cleaning chamber, said soil standard comprising:

two substantially parallel substrates separated with two [illegible] spacers, wherein a gap is formed between said two substrates;

a soil [illegible] said gap; and

at least one holder to secure said two substrates and said two spacers together;

cleaning said instrument and said soil standard with a cleaning solution; and

detecting the soil remains on said soil standard.

2. A method according to claim **1** wherein the steps of cleaning and detecting are repeated until the soil standard is cleaned.

3. A method according to claim **1** and further comprising a step of rinsing the instrument and soil standard with a rinsing solution.

4. A method according to claim **3** wherein the steps of cleaning, detecting and rinsing are repeated until the soil standard is cleaned.

5. A method according to claim **1** wherein said detecting the soil comprises the step of transmitting a light with a known wavelength and an intensity from a light source through the soil standard.

6. A method according to claim **5** wherein said detecting the soil comprises the step of detecting the light intensity with a detector.

7. A method according to claim **6** wherein the step of placing the soil standard in the cleaning chamber comprises [illegible] the soil standard between the light source and the detector.

8. A method according to claim **7** and further comprising the step of determining the cleaning efficiency by examining the light intensity received by the detector.

9. A method according to claim **8** and further comprising the step of comparing the light intensity received by the detector to a pre-determined value.

10. A method according to claim **9** wherein the instrument is cleaned when the light intensity received by the detector is the same or higher than the pre-determined value.

United States Patent [19]

Brigati

[11] Patent Number: 4,777,020

[45] Date of Patent: Oct. 11, 1988

[54] SHEETLIKE OBJECT SUCH AS MICROSCOPE SLIDE

[75] Inventor: David J. Brigati, Hummelstown, Pa.

[73] Assignee: Fisher Scientific Company, Pittsburgh, Pa.

[21] Appl. No.: 33,073

[22] Filed: Mar. 31, 1987

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 775,864, Sep. 13, 1985, Pat. No. 4,731,335.

[51] Int. Cl.[4] G02B 21/34; B01L 1/00

[52] U.S. Cl. 422/99; 350/354; 428/210

[58] Field of Search 422/70, 100, 99, 102, 422/101; 73/864, 72; 350/534–536; 428/210

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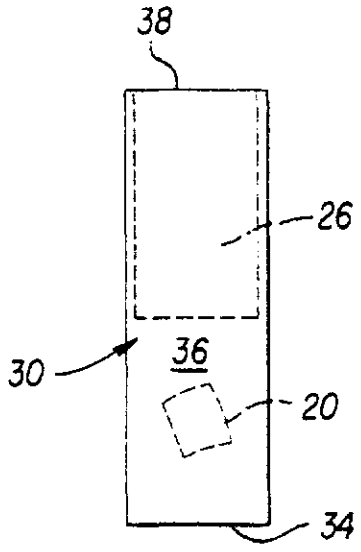
Primary Examiner—Michael S. Marcus

Attorney, Agent, or Firm—Alan M. Doernberg

[57] ABSTRACT

A sheetlike object with a planar front face, a linear lower edge, a thickness about 0.5–5 mm and a raised pattern on a portion of the front face about 50–500 micrometers forwardly of the front face. For example, a rectangular microscope slide 25 mm wide, 75 mm high and 1 mm thick coated on one side by an adherent coating 50–500 micrometers thick. Two such slides with abutting coating portions of 50–125 micrometer thickness form a capillary gap between the remainder of the planar surfaces of 100–250 micrometer thickness. One such slide with a coating of 100–250 micrometer thickness forms a corresponding gap when placed against a flat (uncoated) slide. A similar raised portion is created by affixing a thin object (e.g., a 150 micrometer thick cover slip) to a portion of a microscope slide. Liquid is drawn into and out of the capillary gap by contacting the edge of the gap with liquids and then by absorbent.

8 Claims, 5 Drawing Sheets



US005928948A

United States Patent [19]

[11] **Patent Number: 5,928,948**

[45] **Date of Patent: Jul. 27, 1999**

Malchesky

[54] **METHOD FOR THE ASSESSMENT AND VALIDATION OF CLEANING PROCESSES**

[75] Inventor: **Paul S. Malchesky**, Painesville Township, Ohio

[73] Assignee: **Steris Corporation**, Mentor, Ohio

[21] Appl. No.: **08/814,804**

[22] Filed: **Mar. 10, 1997**

[51] **Int. Cl.**[6] **C12M 1/00**

[52] **U.S. Cl.** **436/2**; 422/28; 422/40; 422/82.05; 422/82.09; 436/5; 436/27; 436/28; 436/31; 436/56; 73/60.11; 250/339.11; 250/339.12; 250/341.8

[58] **Field of Search** 422/28, 40, 82.05, 422/82.09; 436/2, 5, 27, 28, 31, 56; 73/60.11, 250/339.11, 339.12, 341.8; 8/158

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Primary Examiner—Harold Y. Pyon

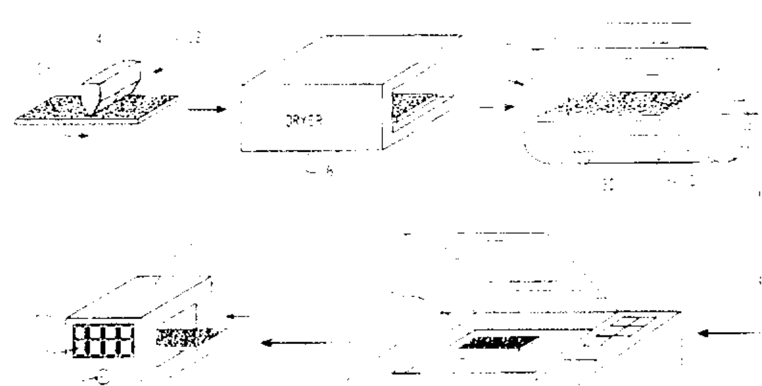
Assistant Examiner—S. Carrillo

Attorney, Agent, or Firm—Fay, Sharpe, Beall, Fagan, Minnich & McKee

[57] **ABSTRACT**

A porous material (**10**) is contaminated with soil (**14**). Optionally, the porous material is partially shielded by an impermeable layer. The contaminated porous material is packaged and shipped to a user site. The contaminated porous material is removed from the package and placed in an automated processor containing medical equipment (**22**). The medical equipment and porous material are subjected to a cleaning, disinfecting, or sterilizing cycle in the processor. The cleaning process is evaluated by examining the porous material with an infrared or other electronic reader (**24**) to determine the presence of remaining soil which has not be removed during the cleaning, disinfecting, or sterilizing cycle.

14 Claims, 3 Drawing Sheets



METHOD FOR THE ASSESSMENT AND VALIDATION OF CLEANING PROCESSES

BACKGROUND OF THE INVENTION

The present invention relates to the washing, decontamination and sterilization arts. It finds particular application in conjunction with cleaning apparatus for medical, dental, surgical, veterinary, and other devices and equipment and will be discussed with particular reference thereto. It is to be appreciated, however, that the invention is also applicable to washing, decontaminating or sterilizing devices and equipment in other fields.

Reusability of medical devices is becoming increasingly important in an effort to provide cost effective health care. Traditionally, the effectiveness of processes for cleaning medical equipment has been assessed by measuring the ability of the process to sterilize the processed items. Frequently, a biological or chemical indicator is included with the process load. After completion of the process cycle, the indicator is evaluated to give a measure of the effectiveness of the cycle in terms of an estimation of the likelihood that microorganisms present in the load have been destroyed.

Recently, it has been shown that for many purposes, killing efficiency is not a complete measure of the decontamination process. Non-living, organic contamination may remain on the apparatus which is not detected by chemical and biological indicators. This contamination, known as soil, includes biological materials such as dried blood, mucous, feces, saliva, and bile. This soil can compromise the efficient use of the device or inhibit its sterilization and lead to infections when the equipment is reused. In particular, microorganisms that have been destroyed in the decontamination process, but which remain on the surfaces of the apparatus, can be a health hazard. The dead remains of those microorganisms degrade to form products which are harmful to humans. For example, the walls of Gram negative bacteria degrade to form endotoxins which can cause pyrogenic reactions in patients with which the equipment is used.

In addition, materials such as blood and other medical wastes, which remain on medical equipment, provide sites which encourage microorganisms to grow. Further, if the soil is not thoroughly removed during the cleaning process, it may become fixed to the surface of the apparatus in such a manner that makes future cleaning difficult if not impossible. For example, glutaraldehyde solutions, used for the disinfection of medical devices, have been shown to create a layer of cross-linked soil on endoscopes which proves to be highly resistant to removal. Robert C. Tucker, Brian J. Lestini & Roger E. Marchant, ASAIO J. Vol. 42, No. 4 (1996) p. 306. Residual soil also hinders the ability of subsequent sterilization or disinfection processes to destroy infectious microorganisms by insulating the organisms from the sterilant or disinfectant and impeding penetration.

In one technique to assess the ability of a cleaning process to remove soils, two metal plates are soiled, clipped together, and subjected to the cleaning cycle. Removal of the soil is an indication that the cleaning process has been effective. A protrusion on one end of one of the plates creates a variably sized crevice between the plates when the two are sandwiched together. This could allow an estimate of the degree of cleaning if the soil is removed from only a portion of the crevice, usually the wider part.

cleaning, such as endoscopes. Medical equipment currently in use often contains designs which readily absorb medical soils and do not release them easily during the cleaning process. Moreover, although a rough assessment of the effectiveness of cleaning may be made visually, the method is not readily amenable to accurate assessment of the extent of soil remaining.

The present invention provides a new and improved apparatus and method for testing the effectiveness of soil removal which overcomes the above referenced problems and others. The method may be used both for process validation testing and for periodic testing of the cleaning apparatus in use.

SUMMARY OF THE INVENTION

In accordance with one aspect of the invention, an apparatus for the assessment and validation of a cleaning process is provided. A porous material resistant to destruction by the cleaning process is contaminated with a known soil.

In accordance with another aspect of the present invention, a method for the assessment and evaluation of a cleaning process is provided. A porous material is contaminated with a known soil. The contaminated porous material is subjected to a cleaning process. The porous material is then evaluated for remaining soil.

One advantage of the present system is that it enables the effectiveness of a cleaning process to be evaluated.

Another advantage of the invention is that it can assure cleanliness.

Another advantage of the present system is that it enables optimum cleaning conditions and the selection of optimum cleaning agents and processes to be determined.

Still further advantages of the present invention will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description of the preferred embodiments.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and are not to be construed as limiting the invention.

FIG. **1** illustrates a method of monitoring cleanliness in accordance with the present invention.

FIG. **2** illustrates a preferred embodiment of an apparatus or devices for the assessment and validation of cleaning processes in accordance with the present invention.

FIG. **3** illustrates another embodiment of an apparatus or devices for the assessment and validation of cleaning processes in accordance with the present invention.

FIG. **4** illustrates an exemplary soil spectrum.

FIG. **5** illustrates an exemplary reader for evaluating the devices of FIGS. **1**, **2**, and **3**.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

With reference to FIG. **1**, porous material **10** is contaminated **12** with soil. Preferably, the soil is applied in a slurry for easier handling. Optionally, the soil is dried **16** to emulate dried soil in other applications in which it is

which prevents contamination of the material with foreign soil and which maintains the controlled moisture level within the porous material. The soiled porous material is placed in a processor **22** at the beginning of a cleaning, disinfecting, or sterilizing cycle. The soiled material may be placed in the processor by itself to validate the processor. Alternately, the soiled material may be placed in the processor along with a load of analogously soiled instruments. After the process is complete, the soiled material is removed from the processor **22** and examined for cleanliness. Preferably, the material is placed in an electronic reader **24** which examines the soiled material and assesses its cleanliness. The assessment is displayed on a gauge **26** or with a warning light **28**. The warning light might be a green light to indicate a satisfactory level of cleaning or a red light for indicating an unsatisfactory level of cleaning.

Preferably the soil **14** is selected to represent the type of contamination that the cleaning process or **22** is required to remove. The soil may be one of a number of composite standard, or "synthetic," soils that are commercially available, or could be formulated from known recipes such as HUCKER'S SOIL, EDINBURG SOIL or V.A. SOIL. Alternatively, samples of protein or other biological materials may be used, including blood, mucous, feces, saliva and bile. Preferably the soil is added to the porous material as a slurry and then dried, although other methods of application are contemplated. Drying renders the soil more difficult to be removed and thus representative of contaminated medical equipment which may have been left to stand a little before cleaning.

In one preferred embodiment, the soil is added to the porous material during manufacturing, before the packaging **18** of the apparatus. The reproducibility in the quantity of soil added and method of drying applied is thereby improved. In another preferred embodiment, the soil is added to the porous material by the user of the cleaning process. This allows greater flexibility in the choice of soil, with the result that a soil is selected which most closely matches the contamination of the equipment to be cleaned.

Certain soils, such as plasma and mucous, have little natural color, making visual or spectroscopic detection difficult. In one preferred embodiment, an additive or colorant, for example a dye or carbon black, is added to the soil to improve detection of remaining soil after cleaning. The additive may be detected by visual or spectroscopic means. Preferably the additive is one which is absorbed by the soil and is removed from the porous material, during the cleaning process, as the soil is removed.

With reference to FIG. **2**, suitable, porous materials include sintered or foamed metals, ceramics, open celled expanded plastics, plastic foams, and the like. A particularly preferred material is an expanded poly-olefin matrix or foam. The material is preferably pigmented white or another color that provides strong contrast with the selected soil. The porous material is preferably selected to create a structure which is at least as challenging to the cleaning process as the medical equipment to be cleaned.

With reference to FIG. **2**, in the alternative embodiment of an apparatus for the assessment and validation of cleaning, the porous material **10** is packaged by an impermeable material or wall **30**. The impermeable wall limits penetration through the outer surfaces of the porous material of the soil by the cleaning process to the ends of the impermeable material **30**. In the illustrated embodiment, the porous material **10** defines a tube with an open end and a fluid way interior **32**. The impermeable layer **30** surrounds the tube. The tubular construction simulates a particularly difficult to clean piece of medical equipment such as an endoscope or other device containing lumen. In the illustrated embodiment, the porous material is disposed on the inner surface of the tube, although other methods of disposition are also contemplated. In one preferred embodiment, the tube has an open end which is connected to one end of a piece of medical equipment having a lumen such that the porous material is subject to substantially the same cleaning conditions as the interior of the lumen.

The porous material is preferably disposed on the plate or within the tube created by the impermeable wall, in such a way that it is not affected during the cleaning process.

The wall is preferably constructed of a material which is impenetrable to the chemicals used in the cleaning process, thereby creating a barrier which resembles the difficult to clean areas of medical equipment.

A number of methods for the analysis of residual soil are currently known in the art, for example visual inspection, spectroscopic means, chemical extraction and microbiological analysis.

Where the assessment of the cleaning process is to be by spectroscopically, the porous material and the impermeable wall are preferably constructed of materials which are substantially spectro-inert in the same regions as the soil.

Where the assessment of cleaning effectiveness is to be by visual inspection, the porous material is preferably of a color contrasting color to the soil so that the presence of soil may be detected more easily. For improved visual inspection, the impermeable wall, where present, is preferably in the shape of a plate or in the shape of a tube can be opened to permit inspection.

Where the method of assessment is microbiological, a calibrated population of a microorganism is added to the soil before cleaning. The presence of viable microorganisms after cleaning is an indication that the cleaning was inadequate. Preferably, the micro-organism selected is one which is not destroyed during the cleaning process.

With reference to FIG. **4**, a typical infrared spectra of the selected soil will have two or more reflection or absorption such as λ_{s1}, λ_{s2}. The wavelength and amplitude of the peaks, of course, vary with the selected soil. Preferably, the porous material, **10** also has one or more peaks such as at wavelength λ_{s3}. Typically, when the porous media is soiled, the soil prevents the infrared light from reaching the media and the peak λ_{s3} is suppressed. When the porous media is cleaned, the peaks λ_{s1}, λ_{s2} from the soil are eliminated and the peaks λ_{s3} from the porous material is strongly present.

With reference to FIG. **5**, an operator uses an input device such as a keyboard or touch screen **40**, to select one of a plurality of potential soil types. A soil characteristic look-up table **42** is preprogrammed with the characteristic peaks of the selected soil and of the porous media substrate. For simplicity of illustration, three peaks are illustrated in FIG. **5**. Of course, a larger number of peaks can also be used for more accurate accuracy.

A infrared light source **44** is focused to illuminate the porous material, **10**. Light reflected from the porous material is received by a photodetector **46**. It is contemplated that the reader may work with either reflected photo peaks or with absorption peaks. The electric signal from the photodetector **46** is fed to the spectrum analyzer **48**, which identifies

US006193931B1

(12) **United States Patent**
Lin et al.

(10) **Patent No.: US 6,193,931 B1**
(45) **Date of Patent: *Feb. 27, 2001**

(54) **CONTAINER MONITORING SYSTEM**

(75) Inventors: **Szu-Min Lin**, Laguna Hills; **Paul Taylor Jacobs**, Trabuco Canyon, both of CA (US)

(73) Assignee: **Ethicon, Inc.**, Somerville, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **09/172,360**

(22) Filed: **Oct. 14, 1998**

Related U.S. Application Data

(63) Continuation-in-part of application No. 08/931,576, filed on Sep. 19, 1997, now Pat. No. 5,834,315.

(51) **Int. Cl.**[7] **A61L 2/16**; G01N 31/22; C12Q 1/22

(52) **U.S. Cl.** **422/28**; 422/34; 422/36; 422/37; 422/300; 436/1; 436/126; 436/128; 435/31; 435/287.4

(58) **Field of Search** 436/1, 126, 127, 436/128; 422/26, 28, 34, 61, 36, 37, 292, 300; 435/31, 287.4

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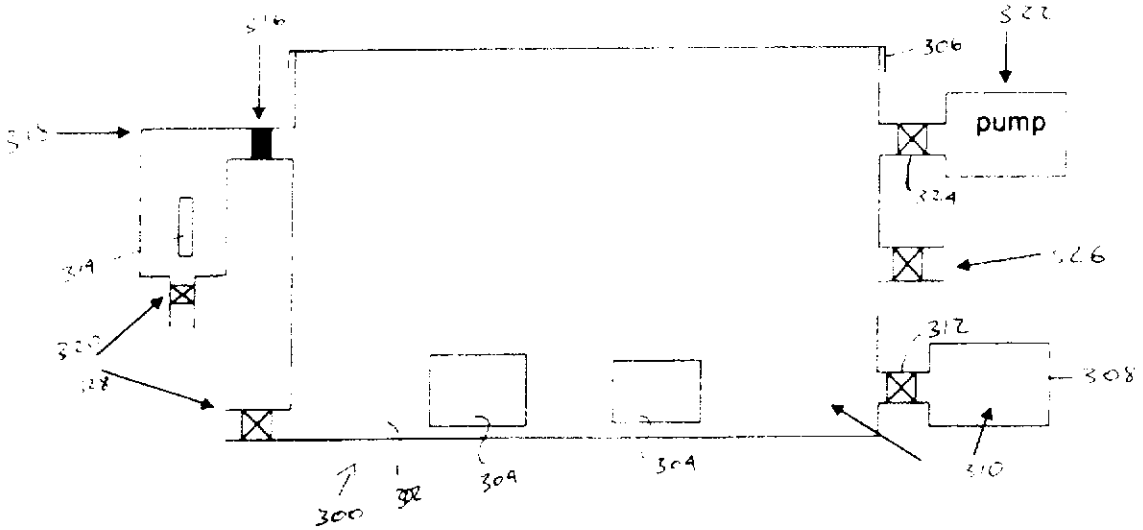
Primary Examiner—Randy Gulakowski
Assistant Examiner—Hien Tuan Le
Attorney, Agent, or Firm—Tonya L. Cross

(57) **ABSTRACT**

A sterilization system using a sterilization process monitoring device which is capable of indicating the efficacy of the sterilization process in an enclosed sterilization container which still maintaining the sealed state of the sterilization container. The process monitoring device comprises at least one biological indicator and at least one chemical indicator. Upon completion of the sterilization cycle, the process monitoring device can be advantageously removed from the system to determine chemical and/or biological efficacy of the sterilization process. The removal of the biological and/or chemical indicators does not disturb the sterilized state of the articles inside the sterilization container.

20 Claims, 13 Drawing Sheets



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US006394111B1

(12) United States Patent

Jacobs et al.

(10) Patent No.: **US 6,394,111 B1**

(45) Date of Patent: **May 28, 2002**

D4

(54) DETECTION OF CLEANLINESS OF A MEDICAL DEVICE DURING A WASHING PROCESS

(75) Inventors: **Paul T. Jacobs**, Trabuco Canyon; **Jenn-Han Wang**, Mission Viejo; **Szu-Min Lin**, Laguna Hills, all of CA (US)

(73) Assignee: **Ethicon, Inc.**, Sommerville, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/075,714**

(22) Filed: **May 11, 1998**

Related U.S. Application Data

(60) Provisional application No. 60/046,351, filed on Jun. 11, 1997.

(51) **Int. Cl.**[7] **B08B 3/04**

(52) **U.S. Cl.** .... **134/113**; 134/58 R; 134/166 R; 134/166 C

(58) **Field of Search** .... 134/116 R, 113, 134/56 R, 58 R, 200, 166 C; 68/12.02; 435/287.4; 422/28

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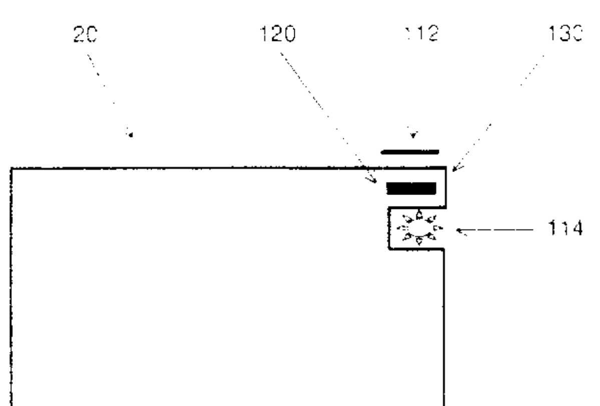
Primary Examiner—Frankie L. Stinson

(74) *Attorney, Agent, or Firm*—Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

An apparatus and method for monitoring a cleaning process for a medical device. The apparatus comprises a soil detector. The soil detector is capable of detecting inorganic and/or organic soil on a medical device or in a liquid utilized in a cleaning, decontaminating or rinsing process or on a surrogate device which can serve as a surrogate indicator of cleanliness for the medical device. The method of the invention for monitoring a cleaning process for a medical device comprises the step of measuring the soil removed from a medical device with the apparatus of the invention comprising a soil detector. Preferably, the method further comprises the step of determining when the device is sufficiently cleaned so that it can be sterilized.

8 Claims, 18 Drawing Sheets



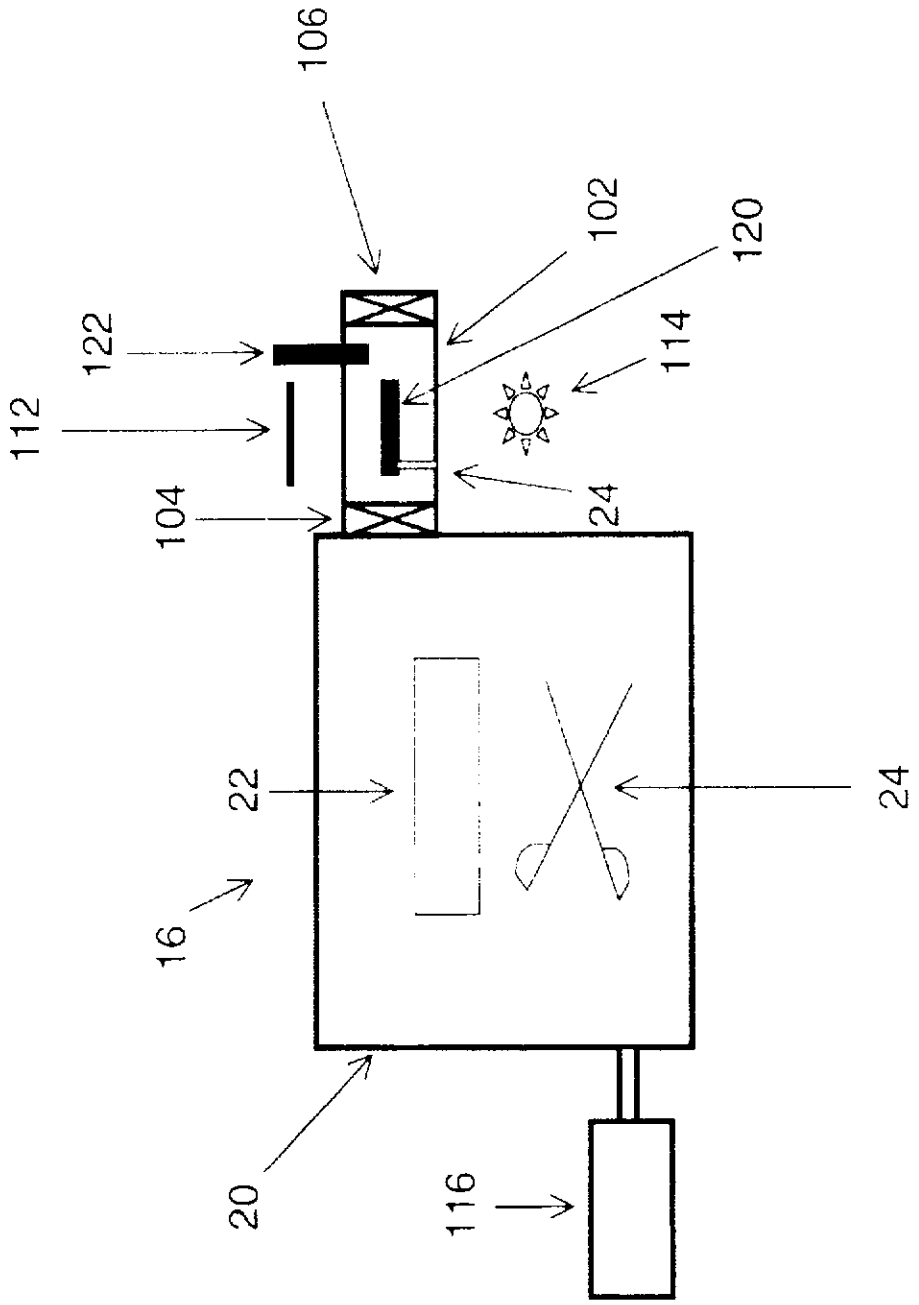


Figure 15A

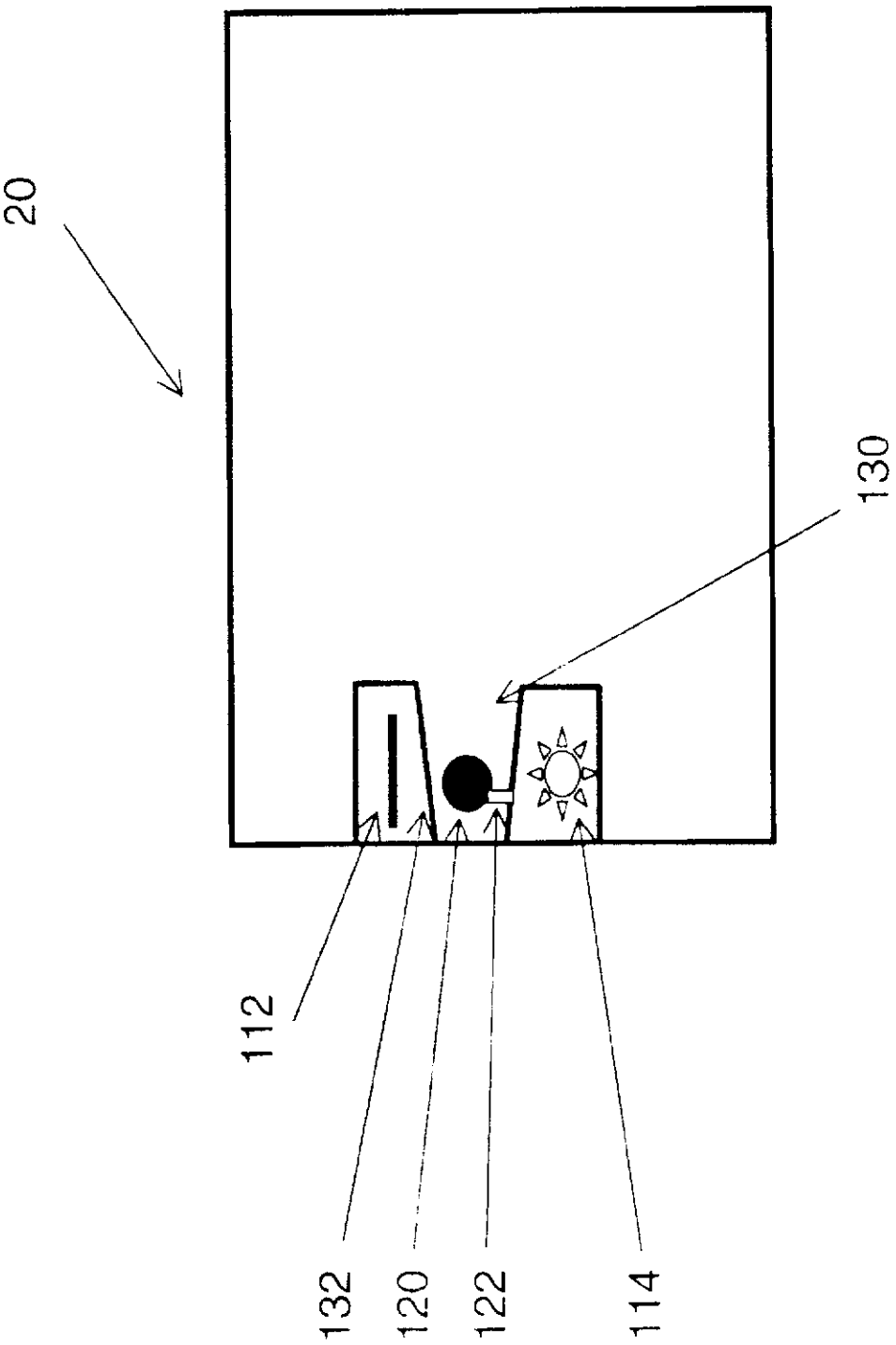


Figure 15B

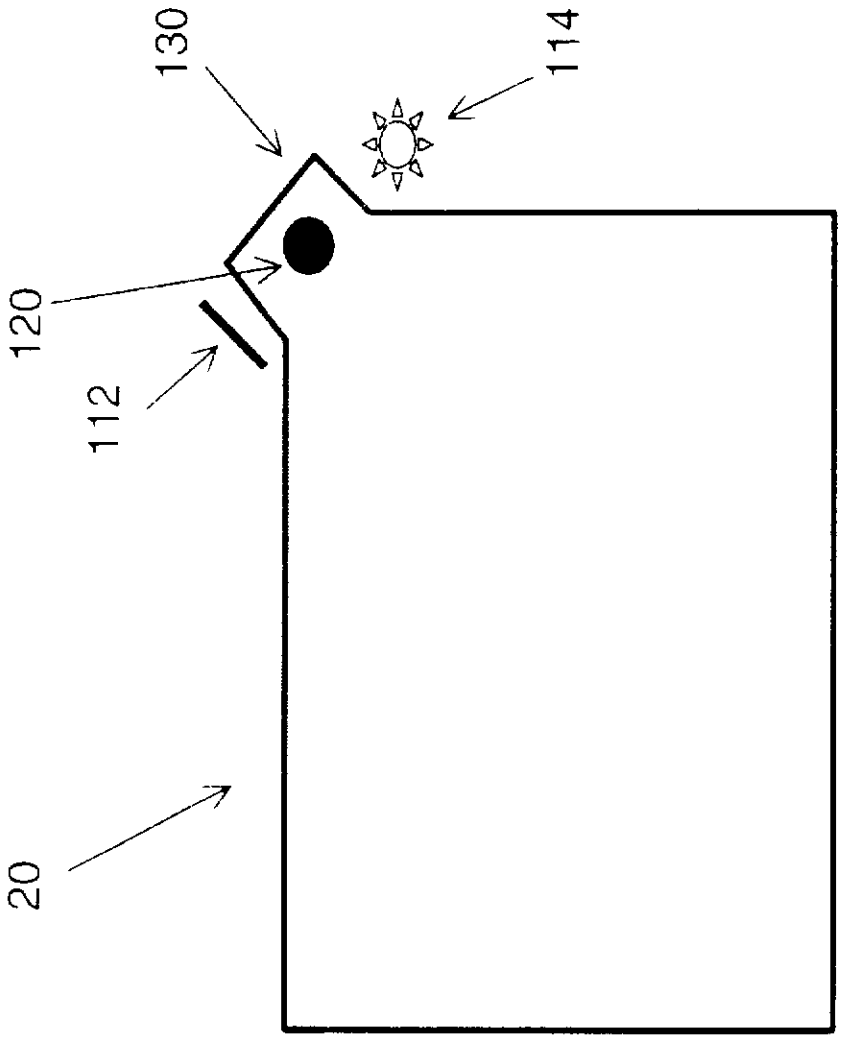


Figure 15D

phase in which a flushing solution is applied to the surfaces of the instrument, a purging phase in which a volatile liquid is applied to the surfaces of the instruments and a drying phase in which a drying gas is passed over the surfaces of the instrument. The cleaning phase is described as a period sufficient to thoroughly clean the endoscope both externally and internally. Again, the invention does not address means for assuring adequacy of cleaning.

None of the aforementioned apparatus and methods provide the means for assuring adequacy of cleaning of a medical device or instrument. Therefore, a need remains for an improved apparatus and method for monitoring cleaning processes for medical devices.

SUMMARY OF THE INVENTION

Before a detailed discussion of the present invention is given, it should be mentioned that certain terms have been used in this disclosure in their broadest meaning. Thus, the term "sterilization" or "sterilize" as used herein also include the meaning of disinfection. Similarly, the terms "cleaning" and "cleaning liquid" as used herein also cover rinsing or a rinsing liquid.

The invention relates to an apparatus and method for monitoring a cleaning process for a medical device, capable of determining when the device is sufficiently clean so that the device can be sterilized.

A soil detector is provided in the apparatus of the invention, which may utilize a variety of detection technologies for monitoring cleaning, alone or in combination. Generally, the detection technology is selected from the group consisting of ion-selective electrodes, conductivity, spectrophotometry, ion chromatography, capillary electrophoresis, high performance liquid chromatography, liquid chromatography, cyclic voltammetry, radioactivity, quartz crystal microbalance and other gravimetric techniques, infra-red spectroscopy and other spectroscopic techniques.

The apparatus of the invention may employ detection technology wherein the detection technology is suitable for detecting the presence of the soil on a surface of a medical device. The detection technology which is suitable for detecting the presence of soil on a surface of a medical device may operate without contacting the surface of the device. Alternatively, detection technology suitable for detecting the presence of soil on the surface of a medical device may operate via direct surface contact. Alternatively, an indirect detection technology may also be employed. This approach employs the same physical-chemical detection technologies previously mentioned for other approaches. However, the medical device itself is not monitored for the degree of cleaning. Rather, a soil-deposited standard is inserted in the apparatus and monitored in place of the medical device itself. A correlation between the degree of cleaning of the soiled device to be cleaned and the degree of cleaning of the soiled standard can be established, so that when the standard is cleaned to certain degree the sufficient cleaning of the device to be cleaned is achieved.

Thus, in one aspect of the present invention, there is provided an apparatus for monitoring a cleaning process for a medical instrument. The apparatus comprises a cleaning chamber for receiving and cleaning the instrument with a cleaning liquid. A soil detector is coupled to the cleaning chamber and adapted to provide a measure of the amount of the soil ... detector can be movable, and by moving the detector it can be made in or out of fluid communication with the chamber. The soil detector may comprise an electrode located in an enclosure, and the enclosure is so coupled to the chamber that the cleaning liquid has controllable access to the enclosure.

In another aspect of the present invention, there is provided a method for cleaning and sterilizing a soiled medical device. The method comprises the steps of: a) providing a cleaning chamber for receiving the soiled device; b) providing a soil detector coupled with the cleaning chamber; c) introducing a cleaning liquid into the cleaning chamber; d) cleaning the soiled device in the cleaning chamber; e) exposing the detector to the cleaning liquid so as to measure the amount of soil removed from the soiled device; f) determining that a sufficient amount of the soil has been removed from the soiled device so that the soiled device can be sterilized; and g) sterilizing the soiled device. Preferably, the detector is at least partially obstructed from the cleaning liquid during step d). Exposing the detector to the cleaning liquid and obstructing the detector from the cleaning liquid can be achieved by moving the detector in and out of fluid communication with the chamber, or by locating the detector in an enclosure so coupled to the chamber that the cleaning liquid has controllable access to the enclosure.

In another aspect of the present invention, there is provided an apparatus for monitoring a cleaning process for a soiled medical instrument. The apparatus comprises a chamber for receiving and cleaning the instrument. An enclosure is in controllable fluid communication with the chamber. A chemical source is coupled to the enclosure for providing a chemical capable of reacting with the soil of the instrument to generate a detectable signal in the enclosure. A detector for detecting the signal is provided with the apparatus. The chemical can be selected from $Hg(SCN)_2$, OPA (o-phthaldialdehyde), Bromocresol purple ($C_{21}H_{16}Br_2O_5S$), biuret reagent and Micro protein-PR. The apparatus may further comprise a light source for sending a light beam through the cleaning liquid in the enclosure to the detector. The enclosure may be separated from the chamber by a valve. The chamber has an inlet and an outlet, and a second detector can be coupled to the inlet, and the first detector and the enclosure are coupled to the outlet.

In another aspect of the present invention, there is provided a method for cleaning and sterilizing a soiled medical device. The method comprises the steps of: a) providing a cleaning chamber for receiving the soiled device; b) providing a chemical source coupled to an enclosure in controllable fluid communication with the cleaning chamber, the source containing a chemical capable of reacting with the soil on the device to generate a detectable signal; c) introducing a cleaning liquid into the cleaning chamber; d) cleaning the soiled device in the cleaning chamber; e) releasing the chemical from the source into the enclosure; f) detecting the signal generated through reaction between the chemical and soil in the cleaning fluid to determine if a sufficient amount of soil has been removed form the device; and g) sterilizing the device. A portion of the cleaning fluid can be introduced into the enclosure before the chemical is released into the enclosure, and before the introduction of the portion of the cleaning liquid, the enclosure can be separated from the cleaning chamber so that substantially there is no fluid communication therebetween. The signal can be detected by absorption at certain wave length.

In another aspect of the present invention, there ...

receiving and cleaning the instrument. A standard containing a predetermined amount of soil is positioned in the chamber or in controllable fluid communication with the chamber. A detector adapted to provide an indication of the amount of the soil on the standard is coupled to the apparatus. The apparatus may comprise a cleaning system which is adjustable so as to change relative cleaning efficiency in different locations of the apparatus. The standard can be positioned so that the instrument is cleaned more efficiently than the standard. The indication can be a signal such as concentration of the soil in a liquid used to clean the device, electrical potential of a liquid used to clean the device, conductivity, transparency to certain wavelengths of light of a liquid used for the cleaning. Preferably, the standard may comprise a surface covered with the soil. At least one light source may be provided which generates light beams of a predetermined wavelength which travels through the standard and reaches the detector. The standard can be placed in an enclosure in controllable fluid communication with the chamber. The enclosure can be provided with a chemical source capable of controllably releasing a chemical to the enclosure, which chemical reacts with the soil removed from or remained on the standard to generate a detectable signal. The detector may comprise an electrode located in the enclosure.

In another aspect of the present invention, there is provided a method for cleaning and sterilizing a soiled medical device. The method comprises the steps of: a) providing a chamber for receiving the soiled device; b) providing a soiled standard coupled to the chamber; c) introducing a cleaning liquid into the chamber; d) cleaning the soiled device and the soiled standard; e) measuring the amount of soil removed from the soiled standard; f) determining that a sufficient amount of the soil has been removed from the soiled standard so that the soiled device can be sterilized; and g) sterilizing the soiled device. Preferably, the cleaning step comprises exposing the standard to a cleaning environment as effective or less effective than that to which the soiled device is exposed, and the determining step comprises determining that the soiled standard has been cleaned to a predetermined level. The soiled standard can be more heavily soiled or more difficult to clean than the soiled device. The method may further comprise measuring soil level of the cleaning liquid before the liquid is introduced into the chamber. Step d) may comprise measuring an inorganic soil such as inorganic electrolytes, alkaline and alkaline earth salts, inorganic metal-containing compounds and other inorganic compounds present in the human body which may come in contact with a medical device, and/or measuring an organic soil such as proteins, glycoproteins, lipoproteins, mucous, amino acids, polysaccharides, sugars, lipids, glycolipids, other organic compounds present in the human body which may come in contact with a medical device, microorganisms and viruses. The step of measuring the amount of soil removed from the soiled device can be conducted by detecting soil remained on the soiled standard or soil removed from the soiled standard and contained in the cleaning liquid. Preferably, the soiled standard is placed in an enclosure in controllable fluid communication with the chamber, so that by controlling the degree of fluid communication between the chamber and the enclosure, the relative cleaning efficiency of the chamber and the enclosure can be adjusted. Step e) may comprise measuring the soil level of the cleaning liquid at these locations.

In another aspect of the present invention, there is provided an apparatus for cleaning and sterilizing a soiled medical device. The apparatus comprises a chamber for receiving and cleaning the instrument, and at least a first soil detector and a second soil detector adapted to provide an indication of the amount of soil removed from or remained on the instrument. The first and second soil detectors are placed in fluid communication with the cleaning chamber. The first and the second soil detectors may be selected from respective electrodes, conductivity spectrophotometry, ion chromatography, capillary electrophoresis, high performance liquid chromatography, gas chromatography, radioactivity, gravimetry, infrared spectroscopy, perthometry and turbidimetry. One of the soil detectors may be adapted to detect inorganic soil, and the other detect organic soil. One detector can be located adjacent to the cleaning chamber, and the other detector is located adjacent to an outlet of the cleaning chamber. The apparatus may further comprise a second chamber coupled to the cleaning chamber with the cleaning chamber and the second chamber each having a soil detector, so that the measuring results from the two soil detectors can be compared and used to determine the degree of cleaning.

In still another aspect of the present invention, there is provided a method for cleaning and sterilizing a soiled medical device. The method comprises the steps of: a) providing a cleaning chamber for receiving the soiled device; b) introducing a cleaning liquid into the cleaning chamber; c) cleaning the soiled device in the cleaning chamber; d) measuring the amount of soil removed from the soiled device with at least two detectors; e) determining that a sufficient amount of the soil has been removed from the soiled device so that the soiled device can be sterilized; and f) sterilizing the device. Step d) may comprise measuring soil level of the cleaning liquid with a first detector prior to the cleaning step, and measuring the soil level of the cleaning liquid with a second detector during or after cleaning. Step e) may comprise comparing the soil level of the cleaning liquid measured by the first detector with the soil level of the cleaning liquid measured by the second detector. If the difference between the two soil levels is within a predetermined range, the sufficient amount of soil has been removed from the soiled device. Step d) may comprise measuring, with one detector, an inorganic soil such as inorganic electrolytes, alkaline and alkaline earth salts, inorganic metal-containing compounds and other inorganic compounds present in the human body which may come in contact with a medical device, and measuring, with another detector, an organic soil such as proteins, glycoproteins, lipoproteins, mucous, amino acids, polysaccharides, sugars, lipids, glycolipids, other organic compounds present in the human body which may come in contact with a medical device, microorganisms and viruses. The step of measuring the amount of soil removed from the soiled device may be conducted by detecting soil remained on the soiled device or soil removed from the soiled device and contained in the cleaning liquid.

The apparatus of the present invention as discussed above may further comprise a vacuum pump connected to the chamber, so that the chamber also functions as a vacuum chamber.

The apparatus of the present invention as discussed above may further comprises a sterilization system.

In the method according to the present invention, the sterilizing step can be conducted by a vapor phase [illegible]

14. In one embodiment, valve **104** is opened at a predetermined level during a cleaning process, and the soil level in the washing solution in the enclosure **102** is monitored with detector **122**.

In another embodiment, the apparatus similar to that shown in FIG. **14** is used, the only difference is that a soil covered standard **120** is placed in enclosure **102**. In this case standard **120** is made of material transparent to a predetermined wave length range. Preferably, standard **120** has a flat surface covered with soil which reacts with the chemical contained in the chemical source **108** (see FIG. **14**) producing certain compound that absorbs light in a certain range of wave length. It is also possible to use light source **114** and spectrophotometer **112** alone without a chemical source.

FIG. **15***b* shows another embodiment in which standard **120** is not placed in an enclosure, instead it is placed in an indentation. As shown in this figure, standard **120** is removably coupled to a support **122**. Preferably, standard **120** is a flat plate with its surface covered with soil on one side or both sides. Support **122** is mounted on the wall of the indentation **130**. Preferably, support **122** is movable, or standard can be coupled to support **122** at several positions, so that the position of standard **120** in the indentation **130** can be adjusted. Indentation **130** may have different shapes. For example, it can be an inclined gap with its two side walls **132** divergent from the wall of chamber **20** as shown in FIG. **15***b*. The two side walls **132** can also be made parallel to each other. If desired, indentation **130** may also have a surrounded side wall with only one end open to chamber **20**. Because of the limited space, the cleaning efficiency in indentation **130** is lower than the area where the items **22** and **24** are placed, and the deeper and narrower the indentation **130**, the less the cleaning efficiency is. Thus, the relative cleaning efficiency of standard **120** can be adjusted by placing it in different positions in the indentation **130**. Agitation level in chamber **20** can also be used to adjust the cleaning efficiency.

A light source **114** and a detector **112** are provided at two opposite sides of indentation **130**. Side walls **132** are made of material transparent to the light from light source **114**. Standard **120** is also made of material transparent to the light from light source **114**. Thus, quartz is a suitable material for both the side walls **132** and the standard **120**. FIGS. **15***c* and **15***d* illustrate two other configurations of the indentation **130**. In the arrangement shown in FIG. **15***c*, indentation **130** is located at a corner of the chamber **20**. Light source **114** is placed outside chamber **20** at a space next to indentation **130**. In the arrangement shown in FIG. **15***d*, indentation **130** is also located at a corner of the chamber **20**, but extending outwardly. Light source **114** and detector **112** are placed outside chamber **20** in a space next to indentation **130**. If the standard **120** to be used has a flat surface, the surface can be put in any proper orientation, vertical, horizontal, or with an angle. The light beam from the light source **114** can be vertical, horizontal, or any other angle.

The apparatus illustrated in FIGS. **15***a*–**15***d* can be easily adapted to further include one or more other detectors of proper type, a vacuum pump or vacuum source for vacuum drying the items after cleaning, a sterilization system.

Generally, the embodiments of the apparatus of the invention illustrated in FIGS. **9**–**15***d* can employ one or more additional soil detectors. Soil detectors suitable for detecting protein are particularly useful additions. In such embodiments, it is preferable to use one more detectors for detecting inorganic soil in combination with an ultraviolet-visible spectroscopy detector suitable for detecting protein and other organic species. An example of the latter type of detector is a spectrophotometer employing a wavelength or wavelengths common to all proteins and many organic molecules found in the body. Many other wavelengths are also suitable, including 260, 265, and 280 nm. Another preferred soil detector combination employs one or more electrodes together with a conductivity autoanalyzer for detecting protein. Yet, the preferred detector combination employs an ion-selective electrode and a turbidimetry detector. Examples of other detectors, other than those listed may also be employed. As the apparatus illustrated in FIGS. **9**–**15***d* comprises a single chamber **20** which also serves as a vacuum chamber, soil detection, drying can be conducted in the chamber with a vacuum source. Various sterilization systems, for instance plasma or vapor phase sterilizer, can be employed in the apparatus of the present invention illustrated in FIGS. **9**–**15***d*. When a long and narrow lumen device is to be cleaned and sterilized, chamber **20** can be further divided into two sub-chambers separated by a sealable interface with the two open ends of the lumen positioned in the two sub-chambers separately. A pressure difference can be generated between the two sub-chambers, so that cleaning or sterilant fluid flows through the lumen. Thus, the lumen can be cleaned and sterilized more efficiently.

The foregoing examples are provided by way of illustration only and are not intended as a limitation of the present invention, many variations of which are possible without departing from the spirit and scope thereof.

What is claimed is:

1. An apparatus for monitoring a cleaning process for a medical instrument, comprising:

a chamber for receiving and cleaning the instrument with a cleaning liquid;

a standard containing a predetermined amount of soil positioned in the chamber or in controllable fluid communication with the chamber, wherein said standard is in fluid communication with the liquid in said chamber; and

a detector adapted to provide an indication of the amount of the soil on the standard without removing the standard from said chamber; and a sterilizer suitable to sterilize the cleaned instrument in the apparatus.

2. The apparatus of claim **1**, wherein the indication is a signal selected from the group consisting of concentration of the soil, electrical potential, conductivity, transparency to certain wave length, pH of a cleaning rinsing liquid used in the cleaning.

3. The apparatus of claim **2**, additionally comprising a light source which generates a light beam of a predetermined wave length which travels through said standard and reaches said detector.

4. The apparatus of claim **2**, wherein the standard is placed in an enclosure in controllable fluid communication with the chamber.

5. The apparatus of claim **4**, wherein the detector comprises an electrode located in the enclosure.

6. The apparatus according to claim **1**, wherein the detector is selected from the group consisting of ion-selective electrodes, conductivity, spectrophotometry, ion chromatography, capillary electrophoresis, high performance liquid chromatography, liquid chromatography, radio activity, gravimetry, infra-red spectroscopy, potentiometry, and combinations.

7. The apparatus according to claim **1**, further comprising a vacuum pump connected to said chamber, wherein said chamber also functions as a vacuum chamber.

8. The apparatus according to claim **1**, further comprising a sterilization system.

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249

US006447990B1

(12) **United States Patent**
Alfa

(10) **Patent No.: US 6,447,990 B1**
(45) **Date of Patent: Sep. 10, 2002**

(54) **ARTIFICIAL TEST SOIL**

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(73) Assignee: **University of Manitoba**, Winnipeg (CA)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/762,288**

(22) PCT Filed: **Aug. 9, 1999**

(86) PCT No.: **PCT/CA99/00727**

§ 371 (c)(1),
(2), (4) Date: **May 25, 2001**

(87) PCT Pub. No.: **WO00/09743**

PCT Pub. Date: **Feb. 24, 2000**

Related U.S. Application Data

(60) Provisional application No. 60/095,932, filed on Aug. 10, 1998.

(51) **Int. Cl.**[7] **C12Q 1/00**

(52) **U.S. Cl.** **435/4**; 510/114; 510/226; 510/305

(58) **Field of Search** 435/4, 134.2, 510/114, 510/226, 305

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Primary Examiner—Ralph Gitomer
(74) *Attorney, Agent, or Firm*—Bereskin & Parr; Michael Gross

(57) **ABSTRACT**

An artificial test soil (ATS) for "simulated-use" testing and cleaning validation studies of medical devices (including narrow lumened flexible endoscopes and other difficult to clean medical devices) is described. In addition, a cleaning validation test kit is described for users of medical devices to determine if adequate cleaning rinsing has been performed on the medical device. The ATS formulations are based on the "worst-case" types and amounts of physiologic soil components present in material recovered from patient used flexible narrow-lumened endoscopes used for gastroscopy, colonoscopy and duodenoscopy, but is applicable to a wide range of medical devices that might encounter similar types of soil.

21 Claims, 7 Drawing Sheets

280 250

In view of the foregoing, there is a need in the art to provide test soil formulations that can effectively simulate soil levels from an actual clinical setting. There is also a need for cleaning validation kits to enable users to confirm that they have adequately cleaned a medical device.

SUMMARY OF THE INVENTION

The present invention provides an artificial test soil for simulated use testing and cleaning validation studies of medical devices. The artificial test soil (ATS) comprises base medium, serum, blood and endotoxin. The artificial test soil may optionally contain bilirubin and a protein or carbohydrate.

In a preferred embodiment, the artificial test soil comprises base medium, up to 20% v/v serum, up to 50% v/v blood, and up to 2,000,000 EU/ml endotoxin. If present, the bilirubin will be in the amount of about 1,000 nmoles/ml and the protein or carbohydrate will be in the amount up to 10,000 μg/ml.

The artificial test soil (ATS) can be used in many applications including (a) use by manufacturers to test equipment and cleaning and/or sterilization/disinfection compositions; (b) use by hospitals and other institutions to test the adequacy of reprocessing; and (c) use to train staff in proper reprocessing procedures. In all these applications the ATS is used to evaluate the efficiency of a reprocessing method on a device. Accordingly, the present invention provides a method of evaluating a reprocessing method on a device comprising:

(a) applying an artificial test soil (ATS) comprising base medium, serum, blood and endotoxin to the device;

(b) subjecting the device to the reprocessing method to be evaluated; and

(c) determining the presence or absence of at least one contaminant on the device.

The ATS can also be used to evaluate the efficiency of a reprocessing method on the killing of micro-organism(s).

Accordingly, the present invention provides a method of determining whether a reprocessing method can kill a microorganism on a device comprising:

(a) inoculating an artificial test soil (ATS) with a microorganism wherein the ATS comprises base medium, serum, blood and endotoxin;

(b) applying the inoculated ATS to the device;

(c) subjecting the device to the reprocessing method to be evaluated; and

(d) determining the presence or absence of the microorganism on the device.

The present invention also relates to a cleaning validation test kit comprising the artificial test soil of the invention and an indicator to determine if the contamination has been adequately removed from the medical device.

Other features and advantages of the present invention will become apparent from the following detailed description. It should be understood, however, that the detailed description and the specific examples while indicating preferred embodiments of the invention are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 2 is a bar graph showing the amount of hemoglobin present on colonoscopes.

FIG. 3 is a bar graph showing the amount of endotoxin present on colonoscopes.

FIG. 4 is a bar graph showing the bacterial count on colonoscopes.

FIG. 5 is a bar graph showing the amount of bilirubin present on colonoscopes.

FIG. 6 is a bar graph showing the amount of sodium ions present on colonoscopes.

FIG. 7 is a schematic drawing showing the cleaning of a flexible endoscope.

DETAILED DESCRIPTION OF THE INVENTION

I. Artificial Test Soil

The present invention provides an artificial test soil for simulated use testing and cleaning validation studies of medical devices. The artificial test soil comprises base medium, serum, blood and endotoxin. The artificial test soil may optionally contain bilirubin and/or protein or carbohydrate.

In a preferred embodiment, the artificial test soil comprises base medium, up to 20% v/v serum, up to 50% v/v blood and up to 2,000,000 EU/ml endotoxin. If present, the bilirubin will be in the amount of about 1,000 nmoles/ml and the protein or carbohydrate will be in the amount up to 10,000 μg/ml.

The base medium can be any medium that mimics physiological human fluids. A preferred base medium is RPMI. The serum can be derived from any serum source. A preferred serum is calf serum. The blood can be from any source and is preferably whole blood. A preferred blood is sterile sheep blood. The endotoxin can be derived from any source. A preferred endotoxin is derived from lipopolysaccharide (LPS), preferably purified LPS from a gram negative bacterium and preferably from *Escherichia coli*. The ATS may optionally contain bilirubin, for example when preparing ATS that mimics the gastrointestinal site. When present the bilirubin is preferably derived from oxgall bile such as bovine oxgall bile. The ATS may also optionally contain a carbohydrate source. When present, the carbohydrate is preferably derived from L-Glutamine, glucose or oxgall bile. The ATS may also contain a source of sodium which is added to the RPMI base to provide osmolarity that mimics physiological solutions. The sodium source may be derived from sodium chloride, sodium bicarbonate and/or sodium pyruvate.

The ATS formulations of the present invention are based on experimental data representing the "worst-case" soil levels from patient-used medical devices and therefore represent a standardized soil formulation that would be applicable to a wide range of medical device simulated-use testing.

In a particular embodiment, the present invention provides an artificial test soil that mimics the gastrointestinal site (referred to herein as ATS-GI) comprising:

RPMI 1640
LPS
Calf Serum
Bovine oxgall
Sterile Sheep Blood
Sodium Bicarbonate

US006454874B1

(12) **United States Patent**
Jacobs et al.

(10) **Patent No.: US 6,454,874 B1**
(45) **Date of Patent: Sep. 24, 2002**

(54) **METHOD FOR DETECTING THE CLEANLINESS OF A MEDICAL DEVICE**

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(73) Assignee: **Ethicon, Inc.**, Somerville, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/417,648**

(22) Filed: **Oct. 14, 1999**

Related U.S. Application Data

(62) Division of application No. 08/875,714, filed on May 14, 1998.

(60) Provisional application No. 60/049,361, filed on Jun. 11, 1997.

(51) **Int. Cl.**[7] **B08B 3/00**

(52) **U.S. Cl.** ..... **134/18**; 134/56 R; 134/113; 134/26; 422/3

(58) **Field of Search** ..... 422/3, 28; 134/113; 134/57 R, 58 R, 59 R, 18, 26, 27, 28, 29, 30

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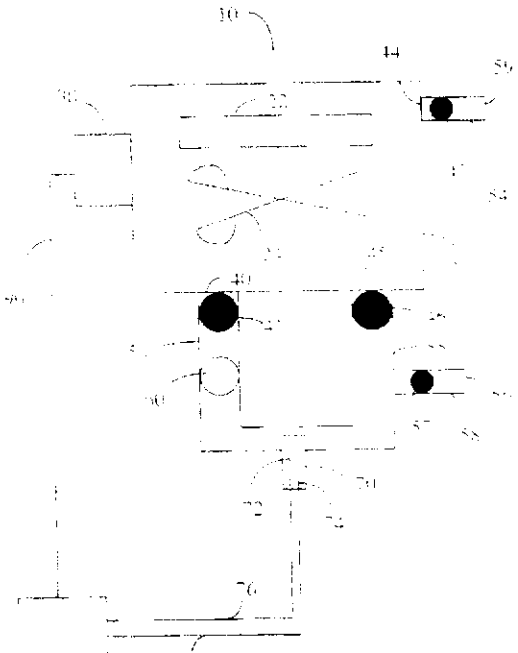
Primary Examiner—Alexander Markoff
(74) *Attorney, Agent, or Firm*—Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

A method for testing a cleaning process for a soiled medical device. The method involves cleaning the soiled device with a cleaning liquid in a cleaning chamber, exposing a detector to the cleaning liquid to measure the amount of soil removed, determining whether a sufficient amount of the soil has been removed from the soiled device so that the soiled device can be sterilized, and sterilizing the soiled device. One method of determining the amount of soil is by detecting the signals generated from the reaction between a chemical and the soil. Another method is to provide a soiled standard and measure the amount of soil removed from the soiled standard to determine whether enough soil has been removed to make the soiled standard so that the soiled device can be sterilized. Another method involves measuring the amount of soil removed from the soiled device with a laser-based system.

13 Claims, 18 Drawing Sheets



US006494964B1

(12) **United States Patent**
Jacobs et al.

(10) **Patent No.:** **US 6,494,964 B1**
(45) **Date of Patent:** **Dec. 17, 2002**

(54) **MONITORING OF CLEANING PROCESS**

(75) Inventors: **Paul T. Jacobs**, Trabuco Canyon, CA (US); **Jenn-Han Wang**, Mission Viejo, CA (US); **Szu-Min Lin**, Laguna Hills, CA (US)

(73) Assignee: **Ethicon, Inc.**, Sommerville, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/132,745**

(22) Filed: **Apr. 25, 2002**

Related U.S. Application Data

(62) Division of application No. 09/[illegible]75,774, filed on May [illegible], 1998, now Pat. No. [illegible].

(60) Provisional application No. [illegible], filed on Jun. [illegible], 1997.

(51) **Int. Cl.**[7] **B08B 3/04**

(52) **U.S. Cl.** .... **134/18**; 134/25.4; 134/113; 134/56 R; 134/166 R

(58) **Field of Search** .... 134/18, 25.4, 25.1, 134/115 R, 113, 56 R, 58 R, 166 R; 435/287.4; 422/28

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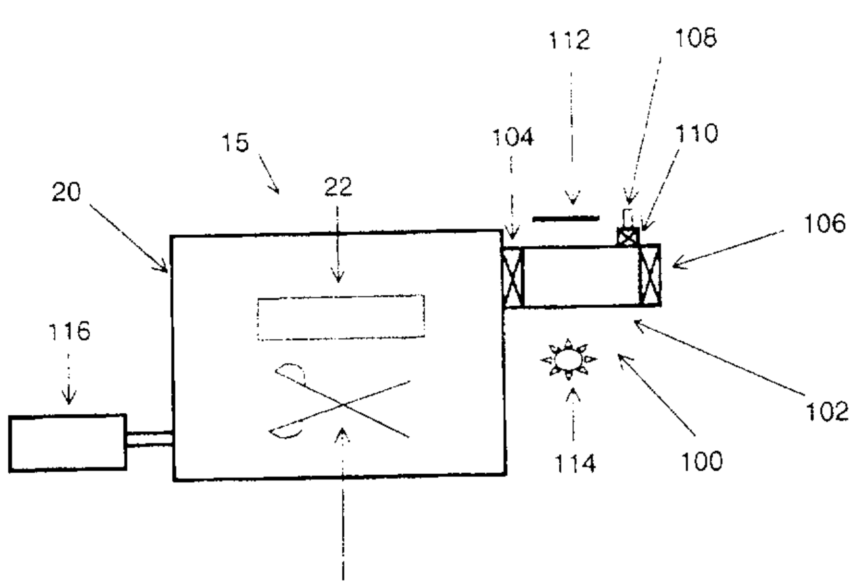
Primary Examiner—[illegible] Stinson
(74) *Attorney, Agent, or Firm*—Knobbe, Martens, Olson & Bear LLP

(57) **ABSTRACT**

An apparatus and method for monitoring a cleaning process for a medical device. The apparatus comprises a soil detector. The soil detector is capable of detecting inorganic and/or organic soil on a medical device or in a liquid utilized in a cleaning or cleaning monitoring process or on a soil-covered standard which can serve as a surrogate indicator of cleanliness for the medical device. The method of the invention for monitoring a cleaning process for a medical device comprises the step of measuring the soil removed from a medical device with the apparatus of the invention comprising a soil detector. Preferably, the method further comprises the step of determining when the device is sufficiently cleaned so that it can be sterilized.

11 Claims, 18 Drawing Sheets



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US006516817B2

(12) **United States Patent**
Jacobs et al.

(10) **Patent No.: US 6,516,817 B2**
(45) **Date of Patent: Feb. 11, 2003**

D7

(54) **MONITORING OF CLEANING PROCESS**

(75) Inventors: **Paul E. Jacobs**, 8 Rachel, Trabuco Canyon, CA (US) 92679; **Jenn-Han Wang**, 21622 Marguerita Pkwy, Apt# 341, Mission Viejo, CA (US) 92692; **Szu-Min Lin**, 25632 Rain Tree Rd., Laguna Hills, CA (US) 92653

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/871,219**

(22) Filed: **May 31, 2001**

(65) **Prior Publication Data**

US 2001/0038805 A1 Oct. 25, 2001

Related U.S. Application Data

(62) Division of application No. 09/078,714, filed on May 14, 1998, now Pat. No. 6,394,111.

(60) Provisional application No. 60/047,351, filed on May 21, 1997.

(51) **Int. Cl.**[7] **B08B 3/04**

(52) **U.S. Cl.** ..... **134/113**; 134/58 R; 134/166 R; 134/166 C; 134/200

(58) **Field of Search** ..... 134/113, 134/58 R, 113, 134/56 R, 58 R, 200, 166 C, 68; 12/02; 435/287.4; 422/28

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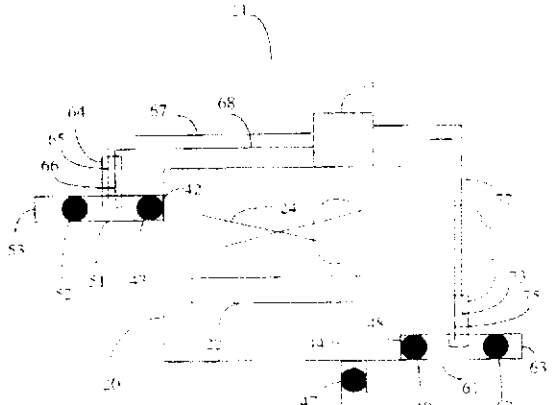
Primary Examiner—Frankie L. Stinson
(74) *Attorney, Agent, or Firm*—Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

A method of monitoring a cleaning process for a soiled medical device. The method involves cleaning the soiled device with a cleaning agent in a cleaning chamber, exposing a detector to the cleaning liquid to measure the amount of soil removed, determining whether a sufficient amount of the soil has been removed from the soiled device so that the soiled device can be sterilized, and sterilizing the soiled device. One method of determining the amount of soil is by detecting the signal generated from the reaction between a chemical and the soil. Another method is to provide a soiled standard and measure the amount of soil removed from the soiled standard to determine whether enough soil has been removed from the soiled standard so that the soiled device can be sterilized. Another method involves measuring the amount of soil removed from the soiled device with at least two detectors.

16 Claims, 18 Drawing Sheets



through valve **106**. Enclosure **102** may have a other clean washing liquid inlet (not shown) for introducing fresh washing liquid to clean enclosure **102**. The amount of the chemical added to each time **102** is controlled. Preferably, concentration of the chemical in the washing liquid in the enclosure **102** is above the same at different measurements, so that intensity of the signal generated by the reaction between the chemical and the washing liquid will reflect only the content of soil in the washing liquid, but not affected by the chemical concentration itself.

A spectrophotometer **100** having a detector **112** and a light source **114** is provided to detect the signal generated by the chemical. The detector **112** and light source **114** can be placed inside or outside enclosure **102**. In case they are located outside enclosure **102** as shown in FIG. **14**, at least a portion of the wall of enclosure **102** should be transparent to the light from the light source **114** so that the light can travel through the body of the washing liquid in the enclosure and reach to detector **112**. When the generated signal is a color, it can be observed visually, thus, human eyes can serve as a detector.

The structures as described previously with FIGS. **9–13** can be combined with the apparatus **15** of FIG. **14**. Optionally, chamber **20** can be also connected to a vacuum pump or a vacuum source **116**. When the cleaning is completed, vacuum can be applied to chamber **20** to facilitate the drying of the cleaned items **22** and **24**. A sterilizing system can be also provided so that chamber **20** can be used as a sterilizing chamber. After the cleaning, sterilization can be conducted in the same chamber **20** without removing the instruments to be cleaned and sterilized. There are no limitations on the sterilization system to be used with the cleaning process of the present invention. Thus, any proper sterilization system can be used in combination with the cleaning process. If desired, cleaning and sterilization can be conducted simultaneously by using a combined cleaning and sterilizing solution, such as one with dissolved ozone or chlorine dioxide.

FIGS. **15***a*–**15***d* show various apparatus according to other embodiments of the present invention. In these embodiments, a standard **120** covered with soil is provided. The purpose of the soil covered standard is to provide a standardized indication of the cleanness of the items to be cleaned during a cleaning process. In other words, the soiled standard **120** will be cleaned simultaneously with the item or items to be cleaned, and the cleanness of the soil covered standard **120** will be monitored. A correlation between the cleanness of the item to be cleaned and the cleanness of the soil covered standard **120** for a particular apparatus configuration can be established through experiments. Thus, when the standard is cleaned to a certain degree, that will indicate a complete cleaning of the items to be cleaned has been achieved.

There are several advantages associated with the use of a soiled standard. For example, by using such a standard, one can focus on the standard for monitoring and the detection of soil removed from or remaining on the standard during a cleaning process, thus the monitoring procedure can be standardized. The soil level and the cleaning efficiency of the standard **120** can be controlled. The standard **120** can be exposed to a cleaning environment which is equally efficient as or less efficient than that the items to be cleaned are exposed to, or standard **120** can be soiled more heavily than the items **22** and **24**, so that when the standard is completely cleaned the items to be cleaned is guaranteed to be cleaned. For example, standard **120** can be exposed to a cleaning environment which is more efficient than that the items to be cleaned are exposed to, or standard is covered with less soils, but put the standard **120** in a comparatively less efficient cleaning environment, so that when the standard is cleaned the items to be cleaned will be completely cleaned. This option allows to reduce the soil level to which the detector exposes, thus, reducing the potential problems associated with the contamination of the detector surface by the soil. In general, conditions can be set up such that when the standard **120** is cleaned to certain level, the items **22** and **24** will be cleaned completely. This will allow the use of less sensitive detectors. The standard **120** can be covered with any proper soils such as those mentioned previously, or their combinations. Preferably, standard **120** is covered with the same soils as those contained in the items **22** and **24** to be cleaned. However, if desirable, the standard **120** can be covered with soil different from that of the items **22** and **24** to be cleaned. This will allow the use of certain soil on the standard and a preferred detection technology particularly suitable to that type of soil. Many different examples are available as long as a proper correlation between the cleaning of the standard **120** and the cleaning of the items to be cleaned is established through experiments associated with particular apparatus configurations.

FIG. **15***a* illustrates an apparatus **16** with an soil covered standard **120** and a soil detector **122** positioned in an enclosure **102**. Standard **120** can be any suitable surface covered with soils. For example, standard **120** can be a plate or a piece of substrate material preferably removably coupled to a support. Preferably, the connection between the standard **120** and the support **124** is made in such a way that the contact area of the standard is not soiled. There are several ways for controlling the cleaning efficiency of the standard **120** relative to that of the items **22** and **24**. For example, valve **104** can be adjusted at different levels to control the fluid communication between chamber **20** and enclosure **102**. A larger valve **104** will provide a better fluid communication, thus the cleaning efficiency in chamber **20** and enclosure **102** will be closer to each other. Another option is to provide an adjustable agitation system in enclosure **102** or chamber **20**, or both. By adjusting the agitation level, the cleaning efficiency in enclosure **102** or chamber **20** can be adjusted to a predetermined level. Detector **122** can be any suitable type, for example, it can be an electrode. Other parts of the apparatus **16** are similar to those of FIG. **14**. In one embodiment, valve **104** is opened at a predetermined level during a cleaning process, and the soil level in the washing solution in the enclosure **102** is monitored with detector **122**.

In another embodiment, an apparatus similar to that shown in FIG. **14** is used, the only difference is that a soil covered standard **120** is placed in enclosure **102**. In this case, standard **120** is at least partial transparent to a predetermined wavelength range. Preferably, standard **120** has a flat surface covered with soil which reacts with the chemical introduced in the chemical source **108** (see FIG. **14**) producing certain color that absorbs light in a certain range of wavelength. It is also possible to use light source **114** and spectrophotometer **112** alone without a chemical source.

FIG. **15***b* shows another embodiment, in which standard **120** is not placed in an enclosure, instead it is placed in an illumination. As shown in this figure, standard **120** is removably coupled to a support **122**. Preferably, standard **120** is a flat plate with its surface covered with soil on one side or both sides. Support **122** is mounted on the wall of an inspection **130**. Preferably, support **122** is movable, e.g.

can be adjusted. Indentation **130** may have different shapes. For example, it can be an inclined groove with its two side walls **132** divergent from the wall of chamber **20** as shown in FIG. **15***b*. The two side walls **132** can also be made parallel to each other. If desired, indentation **130** may also have a surrounded side wall with only one end open to chamber **20**. Because of the limited space, the cleaning efficiency in indentation **130** is lower than the area where the items **22** and **24** are placed, and the deeper and narrower the indentation **130**, the less the cleaning efficiency is. Thus, the relative cleaning efficiency of standard **120** can be adjusted by placing it in different positions in the indentation **130**. Agitation level in chamber **20** can also be used to adjust the cleaning efficiency.

Light source **114** and detector **112** are preferably at two opposite sides of indentation **130**. Side walls **132** are made of material transparent to the light of the light source **114**. Standard **120** is also made of material transparent to the light from light source **114**. Thus, quartz is a suitable material for both the side walls **132** and the standard **120**. FIGS. **15***c* and **15***d* illustrate two other arrangements of the indentation **130**. In the arrangement shown in FIG. **15***c*, indentation **130** is located at a corner of the chamber **20**. Light source **114** is placed outside chamber **20** in a space next to indentation **130**. In the arrangement shown in FIG. **15***d*, indentation **130** is also located at a corner of the chamber **20**, but extending outwardly. Light source **114** and detector **112** are placed outside chamber **20** in a space next to indentation **130**. If the standard **120** to be used has a flat surface, the surface can be put in any proper orientation, vertical, horizontal, or with an angle. The light beam from the light source **114** can be vertical, horizontal, or any other angle.

The apparatus illustrated in FIGS. **15***a*-**15***d* can be easily adapted to further include one or more other detectors of proper type, a vacuum pump or vacuum source for vacuum drying the items after cleaning, a sterilization system.

Generally, the embodiments of the apparatus of the invention illustrated in FIGS. **9**-**15***d* can employ one or more additional soil detectors. Soil detectors suitable for detecting protein are particularly useful additions. In such embodiments, it is preferable to use one more detectors for detecting inorganic soil in combination with an ultraviolet-visible spectroscopy detector suitable for detecting protein and other organic species. An example of the latter type of detector is a spectrophotometer employing a detection wavelength of 220 nm, one of the principle ultraviolet absorption wavelengths common to all proteins and many organic molecules found in the body. Many other wavelengths are also suitable, including 260, 265, and 280 nm. Another preferred soil detector combination employs one or more detectors along with a colorimetric acid indicator for detecting protein. Another preferred detector combination employs an ion-selective electrode detector and a turbidimetry detector. Combinations of detectors other than those listed may also be employed. All the apparatus illustrated in FIGS. **9**-**15***d* can employ a chamber **20** which also serves as a vacuum chamber, so that vacuum drying can be conducted in the chamber with a vacuum source. Various sterilization systems for liquid phase or vapor phase sterilization can be combined into the apparatus of the present invention illustrated in FIGS. **9**-**15***d*. When a long and narrow lumen device is to be cleaned and or sterilized, chamber **20** can be further divided into two sub-chambers separated by a sealable interface with two open ends of the lumen positioned in the two sub-chambers separately. A pressure difference can be generated between the two sub-chambers so that cleaning

The foregoing examples are provided by way of illustration only and are not intended as a limitation of the present invention. Many variations of which are possible without departing from the spirit and scope thereof.

What is claimed is:

1. An apparatus for monitoring a cleaning process for a medical instrument, comprising:

a cleaning chamber for receiving and cleaning the instrument with a cleaning liquid;

a soil detector coupled to the cleaning chamber and adapted to provide an indication of the amount of the soil on the instrument;

wherein the soil detector is at least partially exposed to the cleaning chamber so that access to the detector by the cleaning liquid in the chamber is possible during the cleaning process.

2. The apparatus of claim **1**, wherein said soil detector is removable so that by removing the detector it can be placed in communication with the chamber.

3. The apparatus of claim **1**, wherein said soil detector comprises an electrode located in an enclosure, the enclosure is so coupled to the chamber that the cleaning liquid has controlled access to said enclosure.

4. An apparatus for monitoring a cleaning process for a medical instrument, comprising:

a cleaning chamber for receiving and cleaning the instrument; and

at least a first soil detector and a second soil detector adapted to provide an indication of the amount of soil removed from or remained on the instrument, the first and second soil detector being placeable in fluid communication with the cleaning chamber, wherein the first soil detector and the second soil detector are not identical.

5. The apparatus of claim **4**, wherein the first detector is located adjacent to an inlet of the cleaning chamber, the second detector is located adjacent to an outlet of the cleaning chamber.

6. The apparatus of claim **4**, further comprising a second chamber in fluid communication with the cleaning chamber, and the first detector is located in the second chamber.

7. The apparatus of claim **4**, wherein the first soil detector and the second soil detector detect different types of soil.

8. The apparatus according to any one of claims **1** and **4**, wherein the detector is selected from the group consisting of ion-selective electrodes, conductivity, spectrophotometry, ion chromatography, capillary electrophoresis, high performance liquid chromatography, liquid chromatography gas chromatography, gravimetry, infrared spectroscopy, protein-specific dyes, and enzymes.

9. The apparatus according to any one of claims **1** and **4**, further comprising a vacuum pump connected to said cleaning chamber, wherein said chamber also functions as a vacuum chamber.

10. The Apparatus according to any one of claims **1** and **4**, further comprising a sterilization system.

11. An apparatus for monitoring a cleaning process for a medical instrument, comprising:

a cleaning chamber for receiving and cleaning the instrument; and

at least a first soil detector and a second soil detector adapted to provide an indication of the amount of soil removed from or remained on the instrument, the first and second soil detector being placeable in fluid communication with the cleaning chamber,

wherein the first soil detector is adapted to detect [illegible]

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US006516818B2

(12) United States Patent
Jacobs et al.

(10) **Patent No.: US 6,516,818 B2**

(45) **Date of Patent: Feb. 11, 2003**

D4

(54) **MONITORING OF CLEANING PROCESS**

(76) Inventors: **Paul T. Jacobs**, 8 Rainier, Trabuco Canyon, CA (US) 92679; **Jenn-Han Wang**, 21622 Marguerite Pkwy. Apt# 341, Mission Viejo, CA (US) 92692; **Szu-Min Lin**, 25632 Rain Tree Rd., Laguna Hills, CA (US) 92653

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **10/132,811**

(22) Filed: **Apr. 25, 2002**

(65) **Prior Publication Data**

US 2002/[illegible] A1 Dec. 5, 2002

Related U.S. Application Data

(63) Continuation of application No. 09/075,714, filed on May 11, 1998, now Pat. No. 6,394,111.

(60) Provisional application No. 60/043,351, filed on Jan. 11, 1997.

(51) **Int. Cl.**[7] **B08B 3/04**

(52) **U.S. Cl.** .... **134/113**; 134/58 R; 134/166 R; 134/169 C; 134/200

(58) **Field of Search** .... 134/116 R, 113, 134/56 R, 58 R, 200, 166 C; 435/287.4; 422/28

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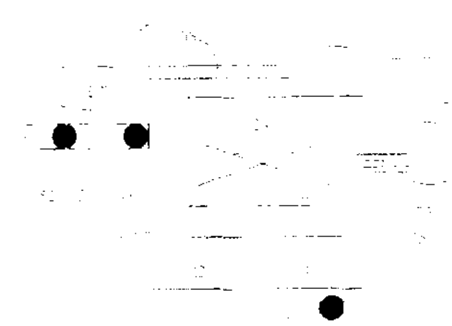
Primary Examiner—Frankie L. Stinson
(74) *Attorney, Agent, or Firm*—Knobbe, Martens, Olson & Bear, LLP

(57) **ABSTRACT**

An apparatus and method for monitoring a cleaning process for a medical device. The apparatus comprises a soil detector. The soil detector is capable of detecting inorganic and/or organic soil on a medical device or in a liquid [illegible] cleaning or cleaning monitoring process or on a soil covered state [illegible] serves as a surrogate indicator [illegible] of the medical device. The method of the invention for monitoring a cleaning process for a medical device comprises the step of measuring the soil removed from a medical device with the apparatus of the invention comprising the soil detector. Preferably, the method further comprises the step of determining when the device is sufficiently cleaned so that it can be sterilized.

9 Claims, 18 Drawing Sheets



Industria y Comercio
SUPERINTENDENCIA

REPUBLICA DE COLOMBIA

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

RESOLUCION 15516

Por la cual se niega una patente de invención

Rad. Nº 06-31929

EL SUPERINTENDENTE DE INDUSTRIA Y COMERCIO
en ejercicio de sus facultades legales, en especial de las que se confirieron en el artículo 3, numeral 30 del decreto 3523 de 2009, y

CONSIDERANDO:

PRIMERO: Que mediante escrito radicado en esta Superintendencia el 31 de marzo del 2006 bajo el número 06031929 00000000 se presentó la solicitud de patente para la invención denominada: "MONITOREO DE PROCEDIMIENTO DE LIMPIEZA", contenida en el expediente de la referencia.

SEGUNDO: Que efectuado el examen de forma en cuanto a los requisitos que debe llenar la solicitud y cumplidas las exigencias legales, se ordenó publicar el extracto sin que se hubieran presentado oposiciones por parte de terceros.

TERCERO: Que el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina establece que: *"Si la oficina nacional competente encontrara que la invención no es patentable o que no cumple con alguno de los requisitos establecidos en esta Decisión para la concesión de la patente, lo notificará al solicitante. Este deberá responder a la notificación dentro del plazo de sesenta días contados a partir de la fecha de la notificación. Este plazo podrá ser prorrogado por una sola vez por un período de treinta días adicionales.(...) Si el solicitante no respondiera a la notificación dentro del plazo señalado, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, la oficina nacional competente denegará la patente".*

CUARTO: Que realizado el examen de fondo, se requirió al solicitante en los términos del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, para que presentara respuesta a las observaciones de carácter técnico visibles a folios 226 a 256 del cuaderno administrativo, relacionadas con la patentabilidad o cumplimiento de los requisitos establecidos por esta Decisión para la concesión de la patente. Frente a dicho requerimiento no hubo pronunciamiento alguno por parte del mismo, por lo cual es procedente negar el privilegio de patente solicitado con fundamento en lo dispuesto en el artículo 45 de la Decisión 486.

Industria y Comercio
SUPERINTENDENCIA

REPUBLICA DE COLOMBIA

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

RESOLUCION 15516

Por la cual se niega una patente de invención

Rad. Nº 06-31929

RESUELVE:

ARTICULO PRIMERO: Negar el privilegio de patente de invención para la solicitud correspondiente a "MONITOREO DE PROCEDIMIENTO DE LIMPIEZA".

ARTICULO SEGUNDO: Notificar personalmente el contenido de la presente resolución a la doctora Jimena Escobar Uribe, en su calidad de apoderada de Ethicon, Inc., o a quien haga sus veces, entregándole copia de la misma, advirtiéndole que contra ella procede el recurso de reposición interpuesto ante el Superintendente de Industria y Comercio, al momento de la notificación o dentro de los 5 días hábiles siguientes a ella.

NOTIFÍQUESE Y CUMPLASE
Dada en Bogotá, D.C., a los 23 MAR. 2010

EL SUPERINTENDENTE DE INDUSTRIA Y COMERCIO,

GUSTAVO VALBUENA QUIÑONES

Doctora
JIMENA ESCOBAR URIBE
Carrera 11 Nº 86 – 53, Piso 6.
Bogotá D.C.