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Clarke, Modet & C^o
COLOMBIA

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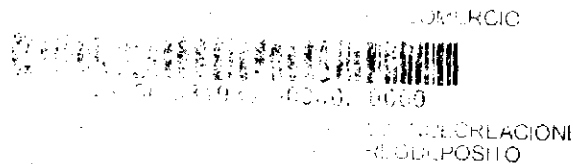
ESCOBAR - URIBE ASOCIADOS
Intellectual Property

As. 2959/P.

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

E. S. D.

Ref.: Expediente No. **06-031.933**
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 - 100,436 de 10 de diciembre de 2007, por la suma de \$404.000.00, 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 - 100,436
FECHA : DICIEMBRE 10 DE 2007

***** CONSIGNACION *****

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

***** CONCEPTO *****

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. _____

DIVISIÓN DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 06-31933

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

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

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES

2020
Bogotá, D.C.,

Abogada
Jimena Escobar U.
(Apoderada)

ASUNTO

Radicación 06 – 31 933
Trámite 002
Evento 001
Actuación 430
Oficio
Folios 050

11305

Patente de Invención

☒

Patente de Modelo de Utilidad

☐

Vía Nacional

☐

Vía PCT (fase nacional)

☐

Cap. I

☐

Cap. II

☐

Solicitud Internacional n.º

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 7 a 34 como se radicó inicialmente

Reivindicaciones:

Folios 35 y 36 como se radicó inicialmente

Dibujos:

Folios 37 a 39 como se radicó inicialmente

Prioridad:

Folios 49 a 82; 2005-03-31, US, 11/096 060

2. Objeto de la invención

Título de la solicitud: *Prueba de integridad de conexión de reprocesador de endoscopio automatizado a través de succión de líquido, folio 1*

endoscopio tiene(n) algún escape que pueda afectar negativamente la esterilización del endoscopio.

El problema planteado en esta solicitud es satisfacer la necesidad de detectar e identificar el canal que presenta algún escape en las operaciones de limpieza o esterilización de un endoscopio.

Para solucionar este problema técnico la solicitud en estudio proporciona un método que se vale de un líquido que rodea al endoscopio, producir un vacío dentro del endoscopio y verificar si hay pérdidas del líquido, lo cual significaría que hay un escape que puede afectar la esterilización del endoscopio.

Clasificación Internacional de Patentes (IPC): A61B 1/015, A61L 2/28, 2/24

3. De la solicitud de Patente

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 nombre de la invención no concuerda con lo que se reclama en las reivindicaciones (un *método* no una prueba).
- 2) En la página 1, folio 7, aparece por primera vez el término *lúmenes*, plural del término *lumen*, cuyo significado (una unidad de medida) según el Diccionario de la Real Academia Española (DRAE), no concuerda con el contexto.
- 3) En la página 2, folio 8, aparece por primera vez una expresión *aplicar presión negativa* que no es clara, se prefiere la expresión *producir vacío* u otra expresión que se ajuste mejor a lo que el solicitante quiere decir.
- 4) En la página 4, folio 10, aparece la expresión *la figura 2 es una ilustración esquemática...* pero en la figura 2, folio 38, aparecen dos ilustraciones separadas, sin conexión evidente entre sí.
- 5) En la página 5, folio 11, aparece por primera vez la sigla *HEPA* cuyo significado no se encuentra acompañándola.
- 6) en la misma página 5 aparece la expresión *un despliegue visual 22 despliega los parámetros...* cuyo significado es oscuro. Incidentalmente, se le recomienda al solicitante que encierre entre paréntesis los números de referencia, con el objeto de evitar confundirlos con otra clase de números que eventualmente aparecen en la solicitud.
- 7) En la misma página 5 aparece la expresión *La figura 2 ilustra esquemáticamente una estación 10...* pero en la figura 2, folio 38, no se encuentra el número de referencia (10). Adelante, en la misma página 5, aparece la expresión *la estación 10 ilustrada en la figura 2* que es objetada por la misma causa.
- 8) En la página 7, folio 13, aparece la expresión *una válvula de mezclado 52 que fluye pero, las válvulas no fluyen.*
- 9) En la misma página 7 aparece por primera vez la expresión *tanque de ruptura* que requiere una explicación.
- 10) En la misma página 7 aparece por primera vez una expresión numérica en la cual se omite usar la coma decimal: *0.2 μ m*.
- 11) En la página 9, folio 15, aparece por primera vez la expresión *una cámara*

1. tr. *Mantener la presión atmosférica normal en un recinto, independientemente de la presión exterior, como en la cabina de pasajeros de un avión.*

Significado que no concuerda con el contexto. El solicitante deberá sustituir este término -y sus derivados: *presurización, despresurizar, sobrepresurización* que aparecen en diversos sitios de la solicitud- por una expresión que se ajuste a lo que desea divulgar.

12) En la página 12, folio 18, aparece la expresión *el estuche de conductor de luz* cuyo significado es ajeno al contexto.

13) En la página 15, folio 21, aparece la sigla ID cuya definición no se encuentra acompañándola.

14) En la misma página 15 aparece la expresión *y/o*. Al respecto, el *Diccionario panhispánico de dudas* de la Real Academia Española y de la Asociación de Academias de la Lengua Española, primera edición, octubre de 2005, página 681, dice:

y/o: Hoy es frecuente el empleo conjunto de las conjunciones copulativa y disyuntiva separadas por una barra oblicua, calco del inglés «and/or», con 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.

15) En la página 16, folio 22, aparecen varios valores numéricos cuyas unidades no se encuentran en el Sistema Internacional.

16) En la página 17, folio 23, aparece la expresión *extraer un vacío* que requiere explicación porque el *vacío* normalmente no se puede *extraer*.

17) En la página 25, folio 31, aparece la expresión 0.2μ en la cual, por una parte, se omitió usar la coma decimal, y, por otra parte, faltan las unidades, sólo está el prefijo: μ (micro).

- 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 observaron los siguientes defectos:

- 1) La reivindicación 1, folio 35, reclama *En un procedimiento para..., un método para...* que debe redactarse de tal forma que quede claro que lo reclamado es el *método* no el *procedimiento*, porque en la misma reivindicación se establece que *el método comprende...*
- 2) En la misma reivindicación 1 aparece la expresión *aplicar presión negativa* que es una forma rebuscada para decir *producir un vacío*. Esta misma expresión objetada se encuentra en diferentes partes de la descripción.
- 3) En la reivindicación 6, folio 36, aparece la expresión *longitud de tiempo* que carece de sentido.

- 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

todas las objeciones que se han hecho arriba. Esto con el fin de evitar -cuando solo se presentan algunas páginas sueltas corregidas- que el lector tenga que desplazarse desde un sitio a otro de la solicitud y luego regresar a donde estaba antes sin perder la ilación de la lectura, porque esto produce confusión y afecta negativamente la claridad de dichos capítulos.

Se le advierte al solicitante que las modificaciones sugeridas 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 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 2006/0224042 A1 del 2006-10-05; y, publicación EP 1 707 221 A1 del 2006-10-04. Se anexa la copia de las primeras páginas de estos documentos junto con la copia del Informe de Búsqueda Europeo y la copia de la negación final (fecha 2008-06-10) por parte de la USPTO. También se encontraron los siguientes documentos que forman parte del estado de la técnica más cercano al objeto de la solicitud:

n.º	Documento	Título	Fecha de publicación
D1	Patente US 5 494 530, cuyo inventor es Marcel Graf, quien le cedió sus derechos a la F. Gehrig & Co. AG	«Method of and apparatus for testing and cleaning of endoscopes»(Un método de, y un aparato para, probar y limpiar endoscopios)	1996-02-27
D2	Patente US 5 749 829, cuyos inventores son Takeshi Yokoi, Takahiro Kishi, Tsutomu Ishiguro, Masaaki Nakazawa, Yukio Takahashi, Ideo Ito, Hisao Yabe y Satoshi Nakawasai, quienes le cedieron sus derechos a la Olympus Optical Co., Ltd.	«Endoscope system»(Un sistema de endoscopio)	1998-05-12
D3	Patente US 6 260 560 B1, cuyo inventor es Johannes Antonius Walta	«Device and method for cleaning and/or disinfecting endoscopes»(Un dispositivo y un método para limpiar o desinfectar endoscopios)	2001-07-17
D4	Publicación EP 1 433 410 A1, cuyos inventores son Hal Williams, Nick Ngoc Nguyen y Cindy L. Ellis, quienes le cedieron sus derechos a la Ethicon Inc.	«Endoscope connection integrity testing»(Prueba de la integridad de la conexión de un endoscopio)	2004-06-30
		«Automated endoscope reprocessor connection integrity testing»(Prueba de la	
	Patente US 6 986 736 B2,		*2006-01-17

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de la USPTO que se menciona arriba. Sin embargo, se aclara que originalmente fue publicada como US 2004/0118413 A1 el 2004-06-24, por lo que esta publicación sí está dentro del estado de la técnica -y es anterior a la fecha de publicación de D4- que es de la familia de patentes.

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 definición y la claridad de las reivindicaciones; esto es, no se pudo practicar un análisis comparativo formal, por ausencia de materia.

A pesar de lo anterior, con base en las enseñanzas de los documentos encontrados hasta ahora y con fundamento en la Negación Final de la USPTO y en el Informe de Búsqueda Europeo citados arriba, respecto a los cuales habría que hacer los respectivos ajustes en cuanto a la legislación aplicable, se prevén objeciones respecto a la novedad y respecto al nivel inventivo del objeto de la solicitud.

5. Análisis preliminar de las anterioridades:

A continuación, los números de referencia que se citan son los propios de cada documento en cuestión.

El documento D1 revela, entre otras cosas, un método de ensayos controlado por computador como un medio para determinar el flujo apropiado y la medición de la cantidad de líquido, por medio de (70), que sale de la primera abertura. También enseña que la limpieza es interrumpida si se descubren fugas relativamente grandes y que la unidad de compresor (38) con una bomba (39) suministra aire comprimido y que se emplea una bomba (13) para producir vacío. D1 también enseña que los ensayos controlados por computador pueden realizar comparaciones entre cantidades y valores.

El documento D2 revela, entre otras cosas, colocar un endoscopio en una segunda abertura dentro de un líquido en (34), producir vacío, durante cierto tiempo, por medio de (55) en una primera abertura, conducir el líquido corriente arriba por el canal desde la segunda abertura, y sacar el líquido a través de la primera abertura. D2 también enseña que la segunda abertura (59) se encuentra ubicada en un extremo distal (6) del endoscopio -ver figuras 1 y 5 de D2-

El documento D3 revela, entre otras cosas, un endoscopio (1) que tiene un canal (6) -ver figura 1 de D3- un accesorio (26) conectado al canal (6) por medio de (3), (4), (8), (9) y un flujo apropiado a través del canal (6), donde el accesorio está conectado por medio de (8) a una primera abertura (16) y el canal (6) tiene una segunda abertura en donde está ubicado el número 6 -ver figura 1 de D3-.

El documento D4 (y su equivalente, el D5) revela, entre otras cosas, un procedimiento de desinfección de un endoscopio (200) que tiene dos aberturas (204) y (206) y que tiene un tubo flexible (208) dentro del cual va un canal (210)

aberturas (226), (228), (228a), (230) y (232) puede fluir líquido para limpieza y desinfección a través de los canales (213), (214), (217) y (218) hasta un extremo distal (252) por entre los canales (210) y (212). Un puerto de fuga (254) en la sección de extremo (224) conduce hacia la porción interior (256) del endoscopio (200) y se emplea para verificar la integridad física del mismo, o en otras palabras, para asegurar que no haya fugas entre cualquiera de los canales y la porción interior (256) o desde el exterior hacia el interior (256). Según las reivindicaciones 1 y 2 de D4, el método comprende colocar el endoscopio en la primera abertura dentro de un líquido; introducir un gas dentro de por lo menos un canal; producir un vacío en el gas a través de una segunda abertura dentro de por lo menos un canal y conducir el líquido dentro de dicho por lo menos un canal; y, detectar fugas de aire en dicho canal por vigilancia (monitoreo) de la presión dentro del canal. D4 también revela un método para detectar una conexión apropiada del accesorio (240) al canal (210) por medio de los canales (213), (214) y un flujo apropiado a través del canal (210), estando el accesorio (240) conectado a una primera abertura (226) dentro del canal (210) y el canal estando provisto de una segunda abertura (252); el método comprende: a) colocar el endoscopio (200) en la segunda abertura (252) dentro de un líquido en (14a); b) producir vacío en la primera abertura (226) por medio de (30), durante cierto tiempo; c) conducir líquido corriente arriba dentro del canal (210) desde la segunda abertura (252); d) sacar el líquido del canal (210) a través de la primera abertura (226); y, e) medir la cantidad de líquido a través de (42) que sale de la primera abertura (226) por medio de (32) y (136) y determinar a partir de la cantidad colectada si el accesorio está correctamente conectado y el flujo apropiado está pasando bien por el canal (210) por medio de (20).

D4 también enseña que por lo menos parte del canal (210) tiene aire antes de la etapa de producir vacío; que una bomba (32) se emplea para producir el vacío en la primera abertura (226) por medio de (30); que las etapas b) a e) se repiten para otro u otros canales; que la etapa de medir la cantidad de líquido que sale de la primera abertura (226) comprende también dirigir dicho líquido hacia un dispositivo de medición (136), por medio de (32); que el vacío es aplicado por medio de (32) durante un lapso predeterminado y que la cantidad del líquido que sale de la primera abertura (226) es comparada con una cantidad predeterminada por medio de (136); y, que la segunda abertura (210) se encuentra en un extremo distal (252) de un endoscopio (200), tal como se muestra en la Figura 3 de D4.

Con relación al eventual análisis del nivel inventivo, se le hacen al solicitante algunas indicaciones generales, que se considera serían aplicables al caso en cuestión:

La simple duplicación de etapas esenciales no es una manifestación de actividad inventiva -a menos que con ellas se alcance un resultado sorprendente o inesperado-.

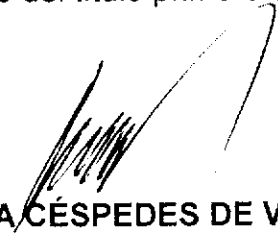
Cuando las condiciones generales de una reivindicación se encuentran dentro del estado de la técnica, descubrir los rangos óptimos o los rangos prácticos no se considera el resultado de una actividad inventiva, sólo es el resultado de experimentos de rutina que puede realizar una persona del nivel medio, sin conocimientos especializados.

6. Conclusión:

Los requisitos de patentabilidad de la presente solicitud se encuentran afectados negativamente por la falta de claridad de la descripción y las reivindicaciones y por la falta de definición de estas últimas.

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.º 10 de 2001.


ALIX CARMENZA CÉSPEDES DE VERGEL
Jefe de División de Nuevas Creaciones

El anterior requerimiento fue notificado por fijación en lista, de fecha
08 OCT. 2009

CONCEPTO TÉCNICO n.º 3383

EXAMINADOR TÉCNICO
Código n.º 202009



US 20060224042A1

(19) **United States**

(12) **Patent Application Publication**
Jackson et al.

(10) Pub. No.: US 2006/0224042 A1

(43) **Pub. Date:** **Oct. 5, 2006**

(54) **AUTOMATED ENDOSCOPE REPROCESSOR
CONNECTION INTEGRITY TESTING VIA
LIQUID SUCTION**

Publication Classification

(51) Int. Cl.
A61B 1/00 (2006.01)

(52) U.S. Cl. 600/133

(76) Inventors: **Richard Jackson**, Huntington Beach, CA (US); **Harold R. Williams**, San Clemente, CA (US)

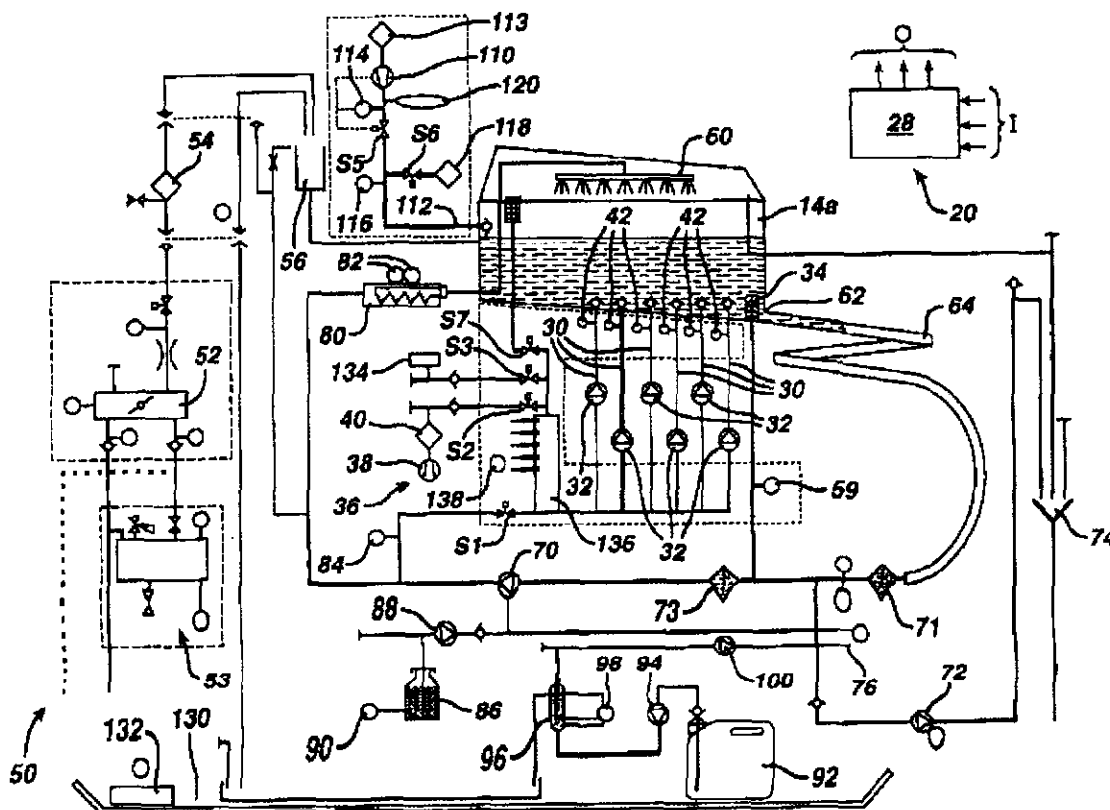
(57) **ABSTRACT**

Correspondence Address:
PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003 (US)

A method detects proper connection of fixtures to a channel in an endoscope and proper flow through the channel during a cleaning or disinfection procedure. The endoscope has a first opening into one of its channels to which is connected a fixture and a second opening which is placed into a liquid. Negative pressure at the first opening draws an amount of liquid through the channel which is measured. If the channel is blocked insufficient liquid will flow and be measured. If the fixture is not connected properly air will leak in and insufficient liquid will flow and be measured.

(21) Appl. No.: 11/096,060

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



(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 1 707 221 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:

04.10.2006 Bulletin 2006/40

(51) Int Cl.:

A61L 2/24 (2006.01)

A61L 2/26 (2006.01)

G01M 3/02 (2006.01)

(21) Application number: 06251742.0

(22) Date of filing: 30.03.2006

(84) Designated Contracting States:

AT BE BG CH CY CZ DE DK EE ES FI FR GB GR
HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI
SK TR

Designated Extension States:

AL BA HR MK YU

(72) Inventors:

- Jackson, Richard
Huntingdon Beach, CA 92649 (US)
- Williams, Harold R.
San Clemente, CA 92673 (US)

(30) Priority: 31.03.2005 US 96060

(71) Applicant: ETHICON, INC.

Somerville,
New Jersey 08876 (US)

(74) Representative: Fisher, Adrian John et al

CARMAELS & RANSFORD
43-45 Bloomsbury Square
London WC1A 2RA (GB)

(54) **Automated endoscope reprocessor connection integrity testing via liquid suction**

(57) A method detects proper connection of fixtures to a channel in an endoscope and proper flow through the channel during a cleaning or disinfection procedure. The endoscope has a first opening into one of its channels to which is connected a fixture and a second opening which is placed into a liquid. Negative pressure at the

first opening draws an amount of liquid through the channel which is measured. If the channel is blocked insufficient liquid will flow and be measured. If the fixture is not connected properly air will leak in and insufficient liquid will flow and be measured.

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EP 1 707 221 A1



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 06 25 1742

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	EP 1 433 410 A (ETHICON, INC) 30 June 2004 (2004-06-30) * paragraph [0015]; claims 1,11 * -----	1-7	INV. A61L2/24 A61L2/26 G01M3/02
A	US 3 360 981 A (BADGER EVERETT H) 2 January 1968 (1968-01-02) * the whole document * -----		
A	US 4 979 390 A (SCHUPACK ET AL) 25 December 1990 (1990-12-25) * column 5, line 37 - line 39 * -----		
			TECHNICAL FIELDS SEARCHED (IPC)
			A61L A61B G01M
The present search report has been drawn up for all claims			
Place of search		Date of completion of the search	Examiner
Munich		14 July 2006	Fischer, M
CATEGORY OF CITED DOCUMENTS			
X : particularly relevant if taken as one Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document			

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: the abstract contains typographical errors. On lines 6 and 7 of the abstract, the word "an" is construed to be --and--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. **Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Williams 6,986,736.**

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

4. With respect to claim 1, Williams teaches a disinfecting procedure of an endoscope 200 having a channel 210, a method of detecting proper connection of a fixture 240 to the channel 210 via 213, 214 and proper flow through the channel 210, the endoscope 200 having the fixture 240 connected to a first opening 226 into the channel 210 and the channel having a second opening at 252 (col. 5, lines 13-19, col. 5, lines 41-67), the method comprising: a) placing the endoscope 200 at the second opening 252 into a liquid in 14a, b) applying negative pressure at

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the first opening 226 for a time period via 30, c) drawing liquid up into the channel 210 from the second opening at 252, d) passing the liquid out of the channel 210 through the first opening at 226 (col. 3, lines 1-11), and e) measuring the amount of liquid via 42 passed out of the first opening 226 via 32 and 136 determining based upon the amount whether the fixture is connected properly and proper flow is passing through the channel 210 via 20 (col. 7, lines 1-13).

5. With respect to claim 2, Williams teaches at least a portion of the channel 210 contains air prior to the step of applying negative pressure (col. 6, lines 48-51).

6. With respect to claim 3, Williams teaches a constant volume pump 32 is used to apply negative pressure at the first opening 226 via 30 (col. 3, lines 1-11, col. 7, lines 3-5).

7. With respect to claim 4, William teaches steps b) through e) as recited in claim 1 are repeated for one or more additional channels 213, 214, 217, 218 (col. 7, lines 23-26).

8. With respect to claim 5, Williams teaches the step of measuring the amount of liquid passed out of the first opening 226 comprises directing that liquid into a measuring device 136 via 32 (col. 4, lines 49-67).

9. With respect to claim 6, Williams teaches the negative pressure is applied via 32 for a predetermined length of time and the amount of liquid passed out of the first opening 226 is compared to a predetermined amount via 136 (col. 9, lines 17-26).

10. With respect to claim 7, Williams teaches the second opening 210 is at a distal end 252 of an endoscope 200 (fig. 3).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walta 6,260,560 in view of Yokoi 5,749,829 further in view of Graf 5,494,530.

13. With respect to claim 1, Walta discloses an endoscope 1 having a channel 6 (fig. 1), connection of a fixture 26 to the channel 6 via 3,4,8, 9 (col. 3, lines 44-50) and proper flow through channel 6, the endoscope 1 having the fixture 26 connected via 8 (fig. 1) to a first opening 16 and the channel 6 and the channel 6 having a second opening at 6 (fig. 1).

14. However, Walta does not disclose placing an endoscope at the second opening into a liquid, applying negative pressure at the first opening for a time period, drawing liquid up into the channel from the second opening, passing the liquid out of the channel through the first opening.

15. Yokoi teaches placing an endoscope at the second opening into a liquid in 34 (col. 5, lines 3-9), applying negative pressure via 55 at the first opening for a time period, drawing liquid up into the channel from the second opening (fig. 5), passing the liquid out of the channel through the first opening (fig. 5, col. 5, lines 10-11).

16. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Walta in view of the limitations taught by Yokoi in order to provide the automatic drainage of liquids remaining in aeration and perfusion channels using a suction tube of a suction unit, as taught by Yokoi (col. 4, lines 43-45).

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17. Furthermore, Walta does not disclose measuring the amount of liquid passed out of the first opening and determining based upon the amount whether the fixture is connected properly and proper flow is passing through the channel.

18. Graf teaches a method for program-controlled testing (col. 6, line 46) as means for determining proper flow (col. 6, lines 54-57), and measuring via 70 the amount of liquid passed out of the first opening (fig. 3, col. 4, lines 17-20).

19. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Walta and Yokoi further in view of the limitations taught by Graf in order to provide a method in which the testing is carried out at the start and preferably before each cleaning state of an endoscope, and the cleaning is discontinued if relatively large leaks are detected, as taught by Graf (col. 2, lines 18-21 et seq. lines 11-12).

20. With respect to claim 2, Walta in view of Yokoi in view of Graf disclose the invention as discussed above. However, Walta in view of Yokoi in view of Graf do not disclose at least a portion of the channel containing air prior to the step of applying negative pressure.

21. Graf further teaches compressor unit 38 with a pump 39 which supplies compressed air (col. 3, lines 31-33).

22. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the invention of Walta and Yokoi and Graf in view of the limitation taught by Graf in order to detect potential leaks in an endoscope by adding air in order to detect air pressure variations indicating that the endoscope is losing air, as taught by Graf (col. 6, lines 24-25). Regarding the channel containing air prior to the step of applying negative pressure, it would have been obvious to one of ordinary skill in the art to have pumped air into the

endoscope because it has been held that rearranging parts of an invention involves only routine skill in the art. In re Japikse, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950) (MPEP 2144.04 VI C).

23. With respect to claim 3, Walta in view of Yokoi in view of Graf disclose the invention as discussed above. However, Walta in view of Yokoi in view of Graf do not disclose a constant volume pump is used to apply negative pressure at the first opening.

24. Graf further teaches a pump 13 used to apply negative pressure (col. 3, line 7).

25. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Walta and Yokoi and Graf in view of the limitation taught by Graf in order to drain off excess debris and liquid from the endoscope channels.

26. With regards to claim 4, Walta in view of Yokoi in view of Graf disclose the invention as discussed above. It would be obvious to one of ordinary skill in the art to repeat the steps b) through e) as recited in claim for one or more additional channels because it has been held that mere duplication of essential steps has no patentable significance unless a new and unexpected result is produced. In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) (MPEP 2144.04 [R-1] VI B).

27. With respect to claim 5, Walta in view of Yokoi in view of Graf disclose the invention as discussed above. However, Walta in view of Yokoi in view of Graf do not disclose the step of measuring the amount of liquid passed out of the first opening comprising of directing that liquid into a measuring device.

28. Graf further teaches the step of measuring the amount of liquid passed out of the first opening comprises directing that liquid into a measuring device 70 (col. 4, lines 17-20).

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29. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Walta and Yokoi and Graf in view of the limitations taught by Graf in order to provide a method in which the testing is carried out at the start and preferably before each cleaning state of an endoscope, and the cleaning is discontinued if relatively large leaks are detected, as taught by Graf (col. 2, lines 18-21 et seq. lines 11-12).

30. With respect to claim 6, Walta in view of Yokoi in view of Graf disclose the invention as discussed above. However, Walta in view of Yokoi in view of Graf do not positively disclose the negative pressure being applied for a predetermined length of time and the amount of liquid passed out of the first opening is compared to a predetermined amount.

31. Graf further teaches a program-controlled testing (col. 6, line 46) that can make comparison of amounts and values (col. 4, lines 50-67).

32. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the device of Walta and Yokoi and Graf in view of the limitations taught by Graf in order to provide testing that is carried out together with the cleaning in a program-controlled manner and automatically, as taught by Graf (col. 2, lines 25-26 et seq. 30-31). With regards to "the negative pressure being applied for a predetermined length of time" and "the predetermined amount of liquid" as recited in claim 6, it has been held that, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (MPEP 2144.05 II A).

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33. With respect to claim 7, Walta in view of Yokoi in view of Graf disclose the invention as discussed above. However, Walta in view of Yokoi in view of Graf do not positively disclose the second opening is at a distal end of the endoscope.

34. Yokoi further teaches the second opening 59 is at a distal end 6 of an endoscope 1 (col. 5, lines 7-8, figs. 1 and 5).

35. It would have been obvious to one ordinary skill in the art at the time of the invention to have modified the device of Walta and Yokoi and Graf in view of the limitations taught by Yokoi in order to provide an endoscope system permitting excellent cleaning workability by reducing the frequency of injecting a cleaning solution using a cleaning instrument, as taught by Yokoi (col. 1, lines 64-67).

Formalities

36. The IDS included in the Supplemental Response filed on March 6th, 2008 has been considered by the examiner. The IDS filed on February 14th, 2008 has also been considered.

Response to Amendment

Specification

37. The substitute specification filed February 14th, 2008 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because: the format of amended specification is not consistent with the format of the specification filed on March 31, 2005 with the application. The specification filed on March 31, 2005 contains page and line numbers only. It does not contain paragraph numbers. Therefore, it is unclear as to which part (page and line numbers) of the specification is to be amended, since the format of the amended specification only refers to paragraph numbers.

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38. A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

Response to Arguments

39. **Applicant's arguments filed February 14th, 2008 have been fully considered but they are not persuasive.**

40. Regarding the rejection of claims 1-7 under 35 U.S.C. 102(e) as being anticipated by Williams 6,986,736:

41. In response to Applicant's argument that "*Williams '736 does not anticipate Independent Claim 1, or Claims 2-7 depending therefrom, as Williams '736 does not explicitly or inherently disclose each of the recited features of Claim 1. Therefore, the 35 U.S.C. §102(e) rejection in view of Williams '736 must be withdrawn*", the Examiner respectfully disagrees.

42. The Applicant has further argued that "*Independent Claim 1 includes subject matter that is not anticipated by Williams '736. Paragraph [0046] of the Subject Application, for example, discloses: '[t]he volume of liquid which is drawn into the metering tube 136 in a given amount*

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of time is measured and compared against a known standard for that particular endoscope model and channel. If the volume varies from the standard amount it indicates a failure. If the connection to the port 226 etc. is not tight, air will leak in and prevent sufficient volume entering the metering tube 136. Similarly, an obstruction within the endoscope channel will prevent sufficient volume entering the metering tube 136.' The above-referenced subject matter is not disclosed by Williams '736 (compare Williams '736, col. 7, lines 1-13). The Summary of the Invention of the Subject Application also includes subject matter which is not disclosed by Williams '736 (compare Williams '736, Summary of the Invention). Further, the subject matter of Claim 1 is not inherent in Williams '736'. The Applicant's argument is drawn to the specification of the subject application. Therefore, Applicant's argument that suggests the limitations in the claims at issue must be interpreted in light of the specification is unpersuasive. While the limitations asserted to be lacking in the prior art are found as examples or embodiments in the specification, such limitations do not find support in the claims at issue. In addition, the terms used in the claims at issue are not defined in the specification so as to require the specific limitations found within the specification. Accordingly, a reading of the specification provides no evidence to indicate that these limitations must be imported into the claims to give meaning to disputed terms. Constant v. Advanced Micro-Devices Inc., 848 F.2d 1560, 7 USPQ2d 1064 (Fed Cir. 1988). Applicant is reminded that during examination before the Patent and Trademark Office (Office), claim limitations are to be given their broadest reasonable reading. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989). Specifically, it is improper to read limitations from the specification into the claims during proceedings before the Office. In re Winkhaus, 527 F.2d 637, 188 USPQ 129 (CCPA 1975).

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43. In this case, Williams '736 anticipates the limitations and structures recited in independent claims 1 and as well as those recited in claims 2-7 depending therefrom per the reasons stated above (see rejection under 35 U.S.C. 102(e) of claims 1-7 as stated above).

44. In light of the above discussed reasons and responses, the Examiner has maintained the rejection of independent claim 1 as well as claims 2-7, depending therefrom, under 35 U.S.C. 102(e) as being anticipated by Williams 6,986,736.

45. Furthermore, Applicant argument that *"In addition, Williams is not a reference under 35 U.S.C. § 103(a) to the Subject Application in view of 35 U.S.C. § 103(c), which states in pertinent part: (1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person. More particularly, Williams '736 has been assigned to Ethicon, Inc. since at least March 21, 2003, as evidenced by an Assignment recorded at Reel/Frame 013903/0651 and the Subject Application has been subject to an obligation of assignment to Ethicon, Inc., as evidenced by an Assignment recorded at Reel/Frame 016785/0768. Therefore, for the reasons advanced above, Williams is not a reference under 35 U.S.C. § 103(a) to the Subject Application"* is irrelevant and moot since the Williams '736 reference was not used in a 103(a) rejection.

46. **Thus, the rejection of claims 1-7 under 35 U.S.C. 102(e) as being anticipated by Williams 6,986,736 stands.**

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47. With regards to the rejection of claims 1-7 under 35 U.S.C. 103(a) as being unpatentable over Walta 6,260,560 in view of Yokoi 5,749,829 further in view of Graf 5,494,530:

48. With respect to Applicant's argument that *"the references cited in the Office Action do not render obvious Independent Claim 1 and thus the 35 U.S.C. § 103(a) rejection of Independent Claim 1, and Claims 2-7 depending therefrom, must be withdrawn"*, the Examiner respectfully disagrees with Applicant.

49. In response to applicant's arguments against the references of Walta, Yokoi, and Graf individually (see pages 9-11 of Applicant's Arguments filed February 14th, 2008), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

50. In response to Applicant's argument that *"Page 4 of the Office Action asserts that Walta '560 discloses 'an endoscope 1 having a channel 6 (fig. 1), connection of a fixture 26 to the channel 6 via 8, 9 (col. 3, lines 44-50) and proper flow through channel 6, the endoscope 1 having the fixture 26 connected via 8 (fig. 1) to a first opening 16 and the channel 6 having a second opening at 6 (fig. 1)."* However, after reviewing Walta '560, "fixture 26" is not attached to a first opening 16 on an end of the endoscope, but instead is positioned within openings 3 and 4 (see col.3, lines 45-46) on an intermediate portion of the endoscope", it is the Examiner's position that Walta '560 positively discloses the recitations of the preamble of claim 1. For, the preamble of claim 1 recites "the endoscope having the fixture connected to a first opening" in line 3, and the term "having" is inclusive or open-ended, since it has been held that The transitional term "comprising", which is synonymous with "including," "having," "containing,"

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or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., > Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term comprising," the terms containing' and mixture' are open-ended."); < Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). It has also been held that "Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.; Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) (MPEP 2111.03 [R-3]). Therefore, an endoscope 1 having a channel 6 (fig. 1), connection of a fixture 26 to the channel 6 via 3,4,8, 9 (col. 3, lines 44-50) and proper flow through channel 6, the endoscope 1 having the fixture 26 connected via 3,4,8,9 (fig. 1) to a first opening 16 and the channel 6 and the channel 6 having a second opening at 6 (fig. 1). In light of the above the responses discussed above, Walta '560 positively discloses the limitations recited in the preamble of claim 1.

51. In response to applicant's argument that there is no suggestion to combine the reference of Yokoi '829 with Walta and that "*Yokoi '829 discloses a device for rinsing the channel of an endoscope (see Fig. 5), using a vat 34 of liquid and a suction unit 55. Yokoi '829 does not disclose or suggest any reason why it would be appropriate to measure the amount of liquid drawn through the channel. Additionally, Yokoi '829 would not function properly when combined*

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with Walta in that the "finger 60" placed over opening 32a, as illustrated in Fig. 5, is not likely to adequately seal the channel such that the proper connection of the fixture and the proper flow through the channel can be determined," the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Yokoi '829 teaches and is capable of performing the steps a) – d) as recited in lines 5-8 of claim 1 since Yokoi '829 positively teaches placing an endoscope at the second opening into a liquid in 34 (col. 5, lines 3-9), applying negative pressure via 55 at the first opening for a time period, drawing liquid up into the channel from the second opening (fig. 5), passing the liquid out of the channel through the first opening (fig. 5, col. 5, lines 10-11). Moreover, applicant's argument that "*Yokoi '829 has nothing to do with measuring the amount of liquid passed out of the first opening and determining based upon the amount of liquid whether the fixture is connected properly and proper flow is passing through the channel*" is irrelevant since the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

52. With respect to Applicant's argument that "*Graf '530 clearly teaches away from the suggested combination made by the Office Action*", simply that there are differences between two

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references is insufficient to establish that such references "teach away" from any combination thereof. In re Beattie, 974 F.2d 1309, 1312-13, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992). Also, in response to applicant's argument that there is no suggestion to combine the references of Graf with those of Walta in view of Yokoi, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Graf teaches a method for program-controlled testing (col. 6, line 46) as means for determining proper flow (col. 6, lines 54-57), and measuring via 70 the amount of liquid passed out of the first opening (fig. 3, col. 4, lines 17-20). Thus, the teachings of Graf is capable of measuring the amount of liquid passed out of a first opening and determining based upon the amount whether the fixture is connected properly and proper flow is passing through the channel. Furthermore, the Examiner points out that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

53. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper ("impermissible") hindsight reasoning "to 'build' the Applicants' invention based on the Subject Application's disclosure", it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so

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long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Furthermore, regarding Applicant's arguments that "to reach a proper determination under 35 U.S.C. § 103, the Examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made. In view of all factual information, the Examiner must then make a determination whether the claimed invention 'as a whole' would have been obvious at that time to that person. Knowledge of applicant's disclosure must be put aside in reaching this determination. The tendency to resort to 'hindsight' based upon Applicants' disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. See MPEP §2142", the Examiner respectfully points out that the reasons/motivation to combine were not "impermissible hindsight" and were not based on Applicants' disclosure since the reasons/motivations to combine were explicitly suggested/taught by the respective references with references made to the corresponding line and page numbers within the respective references for Applicant's convenience.

54. In light of the reasons and responses discussed above, the Examiner has maintained the rejection of independent claim 1 as well as claims 2-7, depending therefrom, under 35 U.S.C. 103(a) as being unpatentable over Walta 6,260,560 in view of Yokoi 5,749,829 further in view of Graf 5,494,530.



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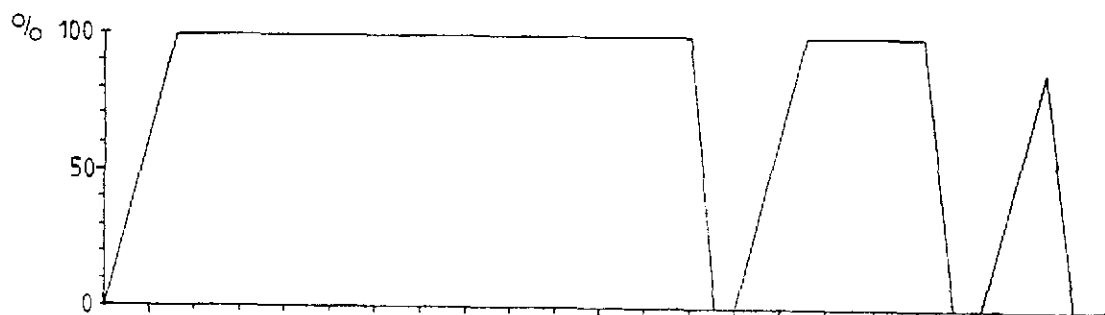
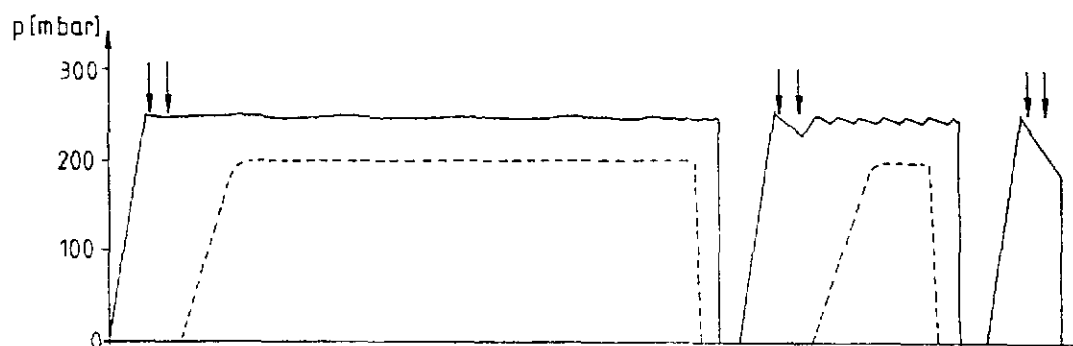
United States Patent [19] Graf

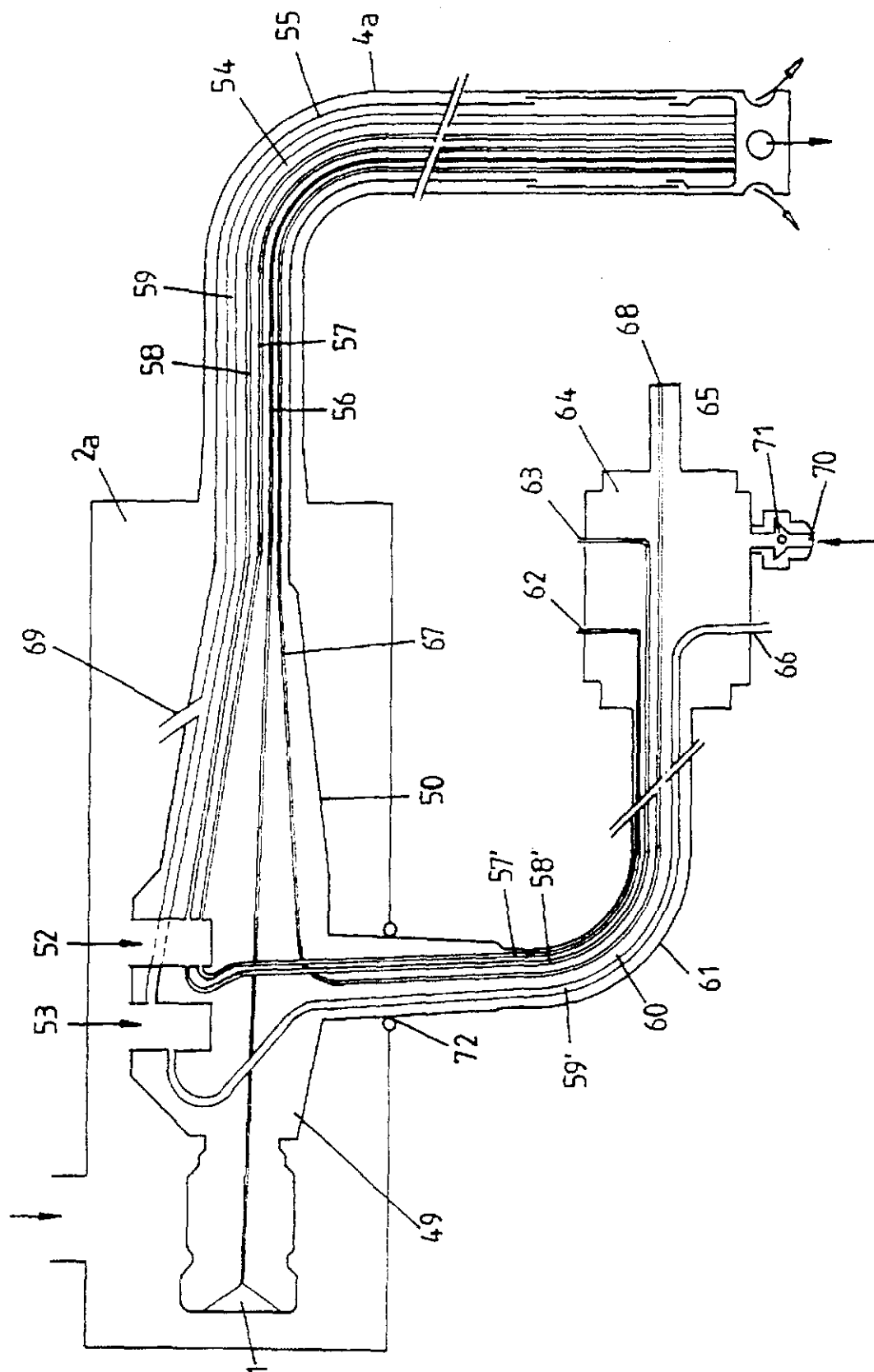
[11] Patent Number: **5,494,530**[45] Date of Patent: **Feb. 27, 1996**[54] **METHOD OF AND APPARATUS FOR
TESTING AND CLEANING OF
ENDOSCOPES***Primary Examiner—W. Gary Jones
Assistant Examiner—Sean Vincent
Attorney, Agent, or Firm—Cushman Darby & Cushman*[75] Inventor: **Marcel Graf**, Altishofen, Switzerland[73] Assignee: **F. Gehrig & Co. AG**, Ballwil,
Switzerland[21] Appl. No.: **163,871**[22] Filed: **Dec. 8, 1993**[51] Int. Cl.⁶ **B08B 7/04**[52] U.S. Cl. **134/18; 134/22.12; 134/56 R;
134/102.2; 134/113; 134/166 R; 134/168 C;
134/170; 73/40; 73/45.5; 422/112; 422/119;
422/295**[58] **Field of Search** **134/18, 22.12,
134/56 R, 113, 102.2, 166 R, 168 C, 170;
73/40, 45.5; 422/112, 119, 295**[56] **References Cited****U.S. PATENT DOCUMENTS**

5,279,799 1/1994 Moser 422/292

FOREIGN PATENT DOCUMENTS0089605 9/1983 European Pat. Off. .
0271157 6/1988 European Pat. Off. .
0483059 4/1992 European Pat. Off. .
675064 8/1990 Switzerland .[57] **ABSTRACT**

In the program-controlled cleaning of endoscopes in a cleaning apparatus, the head parts are cleaned, rinsed, disinfected and rinsed clean in pressure chambers and, at the same time, the insertion tubes are cleaned, rinsed, disinfected and rinsed clean in pipes, attached to these pressure chambers, in a number of cleaning stages using cleaning liquid which is introduced via a circulation pump at a pressure of approximately 200 mbar. Prior to each of these cleaning stages, compressed air generated in the compressed air unit of the cleaning apparatus is introduced from there through the pressure test attachment of each endoscope, which pressure test attachment is connected by means of a pressure test adaptor to a compressed air attachment of the cleaning apparatus, until an internal pressure of 250 mbar is reached. If this pressure is not reached within 5 min or if the internal pressure of the endoscope drops by more than 30 mbar during a subsequent holding time of 30 sec, the circulation pump is not set in operation and the cleaning is discontinued. Otherwise, the internal pressure in the endoscope is kept at 250 mbar during the cleaning stage. The endoscope is tested in this way for leakproofness and is protected from penetration of cleaning liquid, even when a leak occurs during cleaning.

14 Claims, 4 Drawing Sheets



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METHOD OF AND APPARATUS FOR TESTING AND CLEANING OF ENDOSCOPES

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention relates to a method for program-controlled testing and cleaning of endoscopes having a head part with an attached insertion tube and a pressure test attachment, and to a cleaning apparatus for carrying out testing and cleaning.

2. Description of the Related Art

Endoscopes are used for examining the stomach or intestine and have a head part made of strong material, usually plastic, with an ocular and, usually, one or more attachments and buttons for triggering certain functions of the endoscope, as well as a flexible insertion tube which is attached to the head part and contains, protected by a tubular plastic sheath, a glass fibre bundle which connects a lens, arranged at the distal end, to the ocular, and a further light guide serving for illumination, and channels through which liquid can be drawn off by suction, water or air can be introduced and instruments can be inserted, for example for the removal of tissue samples.

A supply part is usually connected to the head via a supply tube which likewise contains, protected by a plastic sheath, a number of channels which can be connected to the channels in the insertion tube, on which supply part the said channels and the light guide serving for illumination open into attachments for the supply of water, air and light and for the removal of liquid by suction. Head part, insertion tube, supply tube and supply part are surrounded by an envelope, which consists of the housings of the head part and supply part and the sheaths of the insertion tube and supply tube and which encloses a continuous inner space containing both the channels and light guide mentioned as well as the delicate ocular. Also arranged on the supply part is a pressure test attachment which forms a connection to the inside of the endoscope.

The cleaning of endoscopes, which must be carried out very thoroughly for reasons of hygiene and must include disinfecting, is extremely involved and usually comprises a number of cleaning stages in which at least the insertion tube is exposed to a cleaning liquid under pressure. In a known method of the generic type (CH-A-675 064) the head part of the endoscope is therefore protected by a foam-filled housing, into the inside of which compressed air is fed. By this means, cleaning liquid cannot penetrate into the endoscope at the head part. However, if the insertion tube has a leak, and it is mainly the lower end thereof which is particularly susceptible to leaks, cleaning liquid can nevertheless penetrate into the inside of the endoscope and damage the ocular of the expensive instrument. One further disadvantage is that the head part is not cleaned.

It is also known to pump the endoscope up, using a hand pump, via the pressure test attachment prior to cleaning and in this way to detect any leaks. However, this method is not very reliable, mainly because very small leaks are rarely detectable, and affords no certainty against leaks appearing or increasing in size during cleaning, which can easily

A proven cleaning apparatus of the generic type, whose use nevertheless necessitates a leakproofness test prior to cleaning, is known from the brochure "Wasch- und Desinfektionsautomat für Endoskope SME 2000" (Automatic washing and disinfection apparatus for endoscopes SME 2000) from the company Belimed AG, 5608 Stetten, Switzerland.

SUMMARY OF THE INVENTION

The object of the invention involves a method for the integrated testing and cleaning of endoscopes, in which method there is no risk of cleaning liquid penetrating into the inside of the endoscope even if very small, undetectable leaks are present and if leaks appear or increase in size in the course of the cleaning. A further object is to propose a suitable cleaning apparatus for carrying out the method.

The invention provides a method in which the testing is carried out at the start and preferably before each cleaning stage, and the cleaning is discontinued if relatively large leaks are detected. The endoscope is additionally protected against the damaging effects of relatively small leaks, as can also occur during cleaning. Damage due to penetration of cleaning liquid can therefore be ruled out with a high degree of certainty. The testing is carried out together with the cleaning in a program-controlled manner. It requires rarely any additional expenditure in terms of time and no human intervention or attention. In the cleaning apparatus according to the invention, both steps can be performed automatically.

BRIEF DESCRIPTION OF THE DRAWING

The invention will be explained in greater detail hereinbelow with reference to figures which represent only one exemplary embodiment, and in which:

FIG. 1a shows a cleaning apparatus according to the invention in a front view, without door,

FIG. 1b shows the components of the cleaning apparatus according to FIG. 1a in a side view,

FIG. 2 shows a schematic representation of the construction of the cleaning apparatus according to FIGS. 1a, 1b,

FIG. 3 shows diagrammatically a longitudinal section through an endoscope in a cleaning apparatus according to FIGS. 1a, 1b, 2, and

FIGS. 4a and 4b show various parameters as functions of time during the implementation of the method according to the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The cleaning apparatus has a cleaning chamber 1, in which two pressure chambers 2a, b made of stainless steel are incorporated, these consisting in each case of a lower part and of an upper part which can be swivelled open, and also a basket 3. Plastic pipes 4a, b of helical line configuration are attached to the pressure chambers 2a, b. Washing arms 5a, b are suspended in a rotatable manner in the vicinity of the lid and the base of the cleaning chamber 1. Arranged on the back wall are two pressurized water attachments 6a, b, which are connected to the pressure chambers

As can be seen from FIG. 2, the lower part of the cleaning chamber 1 is formed by a tank 10 which is connected via a circulation pump 11 to a collecting line 12, which supplies the washer arms 5a, b via a first branch 12a and supplies the compressed water attachments 6a, b via a second branch 12b. The tank 10 can be emptied by means of a suction pump 13. It is additionally provided with a heating arrangement 14 and a temperature sensor 15, and also with a pressure sensor 16 for monitoring its degree of filling. A heater fan 17 is connected to the first branch 12a of the collecting line 12.

The cleaning apparatus is supplied with water via three attachments. One attachment for demineralized water 18 is connected via a first valve 19a directly to the cleaning chamber 1 and via a second valve 19b to a boiler 20. A hot water attachment 21 is connected via a valve 22 and a decalcifier (ion exchanger) 23 likewise to the cleaning chamber 1, while a cold water attachment 24 is connected via a first valve 25a likewise to the decalcifier 23, via a second valve 25b to a regenerating salt storage unit 26, upstream of the decalcifier 23, and finally via a third valve 25c to a heat exchanger 27 which is arranged in the boiler 20. A line leads in each case through the boiler 20 and from the heat exchanger 27 via a valve 28 and 29, respectively, into the cleaning chamber 1, a further line additionally leading via a valve 30 to an outlet 31. A storage unit 36 for a cleaner and a storage unit 37 for disinfectant are likewise connected to the cleaning chamber 1 in each case via a pump 32 and 33, respectively, and a flow rate indicator 34 and 35, respectively.

The cleaning apparatus additionally has a compressed air unit 38 with a pump 39, which supplies the compressed air attachments 8a, b via two branches. The first branch has, downstream of the pump 39, a line 40a in which a throttle 41a and an admission valve 42a lie, and from which there branch a rapid venting valve 43a, a mechanical pressure relief valve 44a, with a response pressure of 500 mbar, a throttle outlet valve 45a and a compensating medium storage unit 46a for compensating for pressure variations. The second branch of the compressed air unit 38 is constructed in exactly the same way with a line 40b etc.

The line 40a leads to a compressed air storage unit 47a which is connected to the compressed air attachment 8a and is monitored by a pressure sensor 48a which controls the admission valve 41a and thus regulates the pressure. The line 40b is connected in an analogous manner to the compressed air attachment 8b via a compressed air storage unit 47b.

The endoscope shown in FIG. 3 has a head part 49 with a strong plastic housing 50, which lies in the pressure chamber 2a, and an ocular 51, a delicate component, which must not come into contact with water or any other cleaning liquid, and also, in openings 52 and 53 respectively, an air/water valve and a suction valve which, however, are removed for cleaning the endoscope and are therefore not shown. Secured on the head part 49 is a flexible insertion tube 54 which lies in the pipe 4a and contains, surrounded by a plastic sheath 55, a glass fibre bundle 56 which connects a lens at the distal end of the insertion tube 54 to the ocular 51, and also a water channel 57, an air channel 58 and a suction channel 59.

The water channel 57 and the air channel 58 open into the opening 52, from which continuations 57' and 58' of these channels emerge, these leading via a flexible supply tube 60

suction channel 59 and its continuation 59', which leads via the supply tube 60 to a suction attachment 66 on the supply part 64, similarly open into the opening 53. An optical fibre 67 runs from a light attachment 68 on the supply part 64 via the supply tube 60, the head part 49 and the insertion tube 54 as far as the distal end of the latter. On the head part 49 an attachment 69 branches off from the suction channel 59, through which attachment 69 various instruments can be led into the suction channel and through this to the distal end of the insertion tube 54.

The plastic sheath 55 of the insertion tube 54, the plastic housing 50 of the head part, the plastic sheath 61 of the supply tube 60, and the plastic housing 65 of the supply part 64 enclose a continuous inner space of the endoscope which, as has already been mentioned, also contains the ocular 51 and other delicate components. For the leakproofness testing, therefore, a pressure test attachment 70 is provided on the plastic housing 65 of the supply part 64, with a check valve 71 which forms a connection to the inside of the endoscope.

In order to clean an endoscope, the insertion tube 54 is introduced completely into the pipe 4a and the head part 49 is placed in the pressure chamber 2a. The supply tube 60, or more exactly an attachment piece for the latter on the head part 49, is passed outward in a sealed manner through a feed-through opening 72, which is sealed off by means of two rubber half-rings and consists of two semicircular recesses in the upper part and lower part of the pressure chamber 2a, and introduced into the basket 3. The pressure chamber 2a is then closed. The pressure test attachment 70 is connected in a sealed manner to the compressed air attachment 8a by means of a pressure test adaptor, a plastic tube, which is secured on it by means of an attachment piece. A second endoscope is introduced in the same way into the second pressure chamber 2b and is connected to the compressed air attachment 8b. The cleaning chamber 1 is then closed.

At the start of cleaning, demineralized water is passed into the boiler 20 via the attachment 18 and the valve 19b and is preheated to 85° C. The endoscope is then tested for leakproofness and the first cleaning stage, the actual cleaning, is initiated. In this context, reference is made to FIGS. 4a and 4b where the degree of filling of the tank 10 is shown at the bottom and the internal pressure of the endoscope (continuous lines) and the pressure of the cleaning liquid in the pressure chamber 2a (broken lines) above are shown in all cases as functions of time. While hot water coming from the hot water attachment 21 via the valve 22 and the decalcifier 23 is passed into the tank 10, which lasts approximately 100 sec, the pressure in the compressed air storage unit 47a and thus also in the endoscope is increased to a test pressure of 250 mbar by means of the pump 39 via the throttle 41a and the admission valve 42a. After a compensation time of approximately 5 sec, the air pressure in the compressed air storage unit 47a is established (first arrow in FIG. 4a). After a holding time of 30 sec, the measurement is repeated (second arrow). The same measurements are carried out in the compressed air chamber 47b, which has been brought at the same time to a pressure of 250 mbar via the second branch of the compressed air unit. If the pressure measured at the end of the holding time in both compressed air storage units 47a, b lies by less than a limit value of 30 mbar below the value established at the start of the holding time, the endoscope is recorded as being sufficiently leak-

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the storage unit 36 so that the pressure chambers 2a,b fill with cleaning liquid. The installation is designed in such a way that the pressure of the cleaning liquid lies at approximately 200 mbar. The internal pressure of the endoscope is in the meantime held at 250 mbar plus ± 30 mbar by means of the pressure sensors 48a,b, which control the admission valves 42a,b. This pressure is tolerated satisfactorily by the endoscopes, whereas it would not be possible to exclude damage at pressures above 300 mbar.

The cleaning liquid is now circulated for approximately 10 minutes. It penetrates in each case into the openings 52, 53 of the endoscope and flushes through the water channel 57, the air channel 58 and the suction channel 59 and emerges at their distal ends and is passed back via the open end of the tube 4a and 4b, respectively, into the tank 10. Similarly, cleaning liquid flows along the outside of the insertion tube 54 through the pipe 4a and 4b, respectively, as a result of which not only is the plastic sheath 55 of the insertion tube 54 cleaned, but also suction is generated at the distal end of the insertion tube 54 as a result of the flow breaking off, which suction increases the pressure difference in relation to the openings 52, 53 and effects a good flushing-through of the channels at a comparatively low static pressure.

Cleaning liquid also flows from the openings 52, 53 through the continuations 57', 58' and 59' of the above mentioned channels and emerges at the water attachment 62, at the air attachment 63 and at the suction attachment 66 on the supply part 64. The supply tube 60 and the supply part 64 are cleared on the outside by means of the rotating washer arms 5a,b, through which cleaning liquid is likewise pumped by the circulation pump 11.

Towards the end of the cleaning stage, during which the boiler 20 has been heated to a disinfection temperature of 93° C., the circulation pump 11 is shut off and the tank 10 is emptied via the suction pump 13, while at the same time compressed air from the compressed air storage units 47a,b and thus the endoscopes is let off through the throttle outlet valves 45a,b and the pressure is reduced.

In principle, the next cleaning stage, the rinsing, takes place, including the preceding testing of the endoscope, in a completely analogous manner to the first stage, except that no cleaner is added and the circulation pump 11 runs for only approximately 3 min.

The next cleaning stage too, the disinfection, which is also preceded by an endoscope testing, as described, differs from the preceding stages only in the preparation of the cleaning liquid and the duration. Cold water is passed into the tank 10 from the cold water attachment 24 via the valve 25c, the heat exchanger 27, where it is heated in the boiler 20 with cooling of the demineralized water, and the valve 29, and disinfectant is metered in from the storage unit 37. During the disinfection cold water is furthermore passed through the heat exchanger 27 and via the valve 30 to the outlet 31, as a result of which the content of the boiler 20 is cooled to below 55° C. During disinfection, the circulation pump 11 runs for somewhat more than 8 min.

For the last cleaning stage, the rinsing clean, the demineralized water is passed from the boiler 20, which was held at 93° C. for approximately 10 min and thus disinfected and then cooled to below 55° C., since higher temperatures are badly tolerated by endoscopes, via the valve 28 into the tank 10 and circulated for approximately 2 min. Otherwise, the

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Of course, the cleaning described here represents only one example. The cleaning program can be adapted to the requirements and the circumstances and can be varied. The only respect in which nothing is altered is in the basic sequence of a cleaning stage, with preceding endoscope testing by building up an internal pressure in the endoscope, and subsequently circulating the cleaning liquid, while simultaneously maintaining the internal pressure above the pressure of the cleaning liquid.

If, for example, the endoscope to be cleaned reveals a large leak in the pressure chamber 2b, then the test pressure of 250 mbar in the endoscope and, consequently, in the compressed air storage unit 47b is not reached within a test interval of 5 min prior to the first cleaning stage. The circulation pump 11 is not set into operation and the cleaning is discontinued. An error message appears on the control panel 9.

FIGS. 4a and 4b show the case in which, during cleaning, a leak appears and increases in size in the endoscope being cleaned in the pressure chamber 2a. During the first cleaning stage, the actual cleaning, the endoscope is still leakproof; only towards the end do the air pressure variations, which are increasing but still lie appreciably below 30 mbar, indicate that the endoscope is losing air and the compressed air storage unit 47a must be frequently topped up. In the test prior to rinsing out, a pronounced pressure drop occurs during the holding time of 30 sec, which pressure drop is smaller, however, than the limit value of 30 mbar. This points to a relatively small leak. The pressure losses can be compensated without difficulty from the compressed air unit. The cleaning stage progresses normally, but the pressure in the compressed air storage unit 47a fluctuates significantly as a result of the losses and the topping-up, which is triggered by the pressure sensor 48a controlling the admission valve 42a.

In the test preceding the disinfection, a pressure drop of more than 30 mbar occurs during the holding time. This points to a relatively large leak, and the result of this is that the circulation pump 11 is not switched on and the filling of the tank 10 is discontinued. The latter is emptied via the suction pump 13. The compressed air is let off via the throttle outlet valves 45a,b and the cleaning is discontinued with an error message, without it having been possible for the cleaning stage to be initiated.

I claim:

1. A method for program-controlled testing and cleaning of an endoscope comprising the steps of
 - placing the endoscope inside a cleaning chamber, and testing the endoscope by
 - conveying compressed gas into the inside of the endoscope via a pressure test attachment of the same while checking whether the internal pressure of the endoscope reaches a test pressure,
 - terminating the testing and cleaning program if the test pressure has not been reached at the end of a test interval,
 - otherwise discontinuing gas supply and checking whether the internal pressure drops by more than a limit difference during a holding interval,
 - terminating the testing and cleaning program if the internal pressure has dropped by more than the limit difference.



US005749829A

United States Patent [19]

Yokoi et al.

[11] Patent Number: 5,749,829

[45] Date of Patent: May 12, 1998

[54] ENDOSCOPE SYSTEM

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[21] Appl. No.: 593,341

[22] Filed: Jan. 29, 1996

[30] Foreign Application Priority Data

May 16, 1995 [JP] Japan 7-117525

[51] Int. Cl.⁶ A61B 1/00

[52] U.S. Cl. 600/153; 600/155

[58] Field of Search 600/121, 133, 600/153, 154, 155, 156, 157

[56]

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[57] ABSTRACT

An endoscope system in accordance with the present invention comprises: an endoscope having an insertional part, operation unit, and connector unit set in array, and including channels that communicate with an opening formed in the distal section of the insertional part and an opening formed in the operation unit or connector unit; and at least one cleaning instrument having a flexible tube that can be connected to the opening formed in the operation unit or connector unit of the endoscope and that has the overall length thereof set to 30 cm or larger.

19 Claims, 23 Drawing Sheets

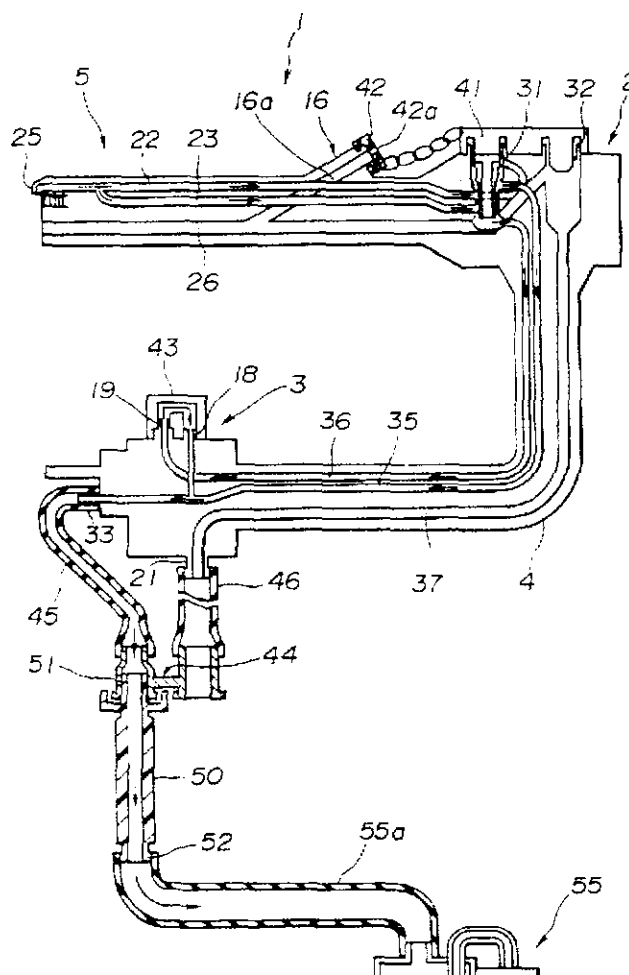


FIG. 1

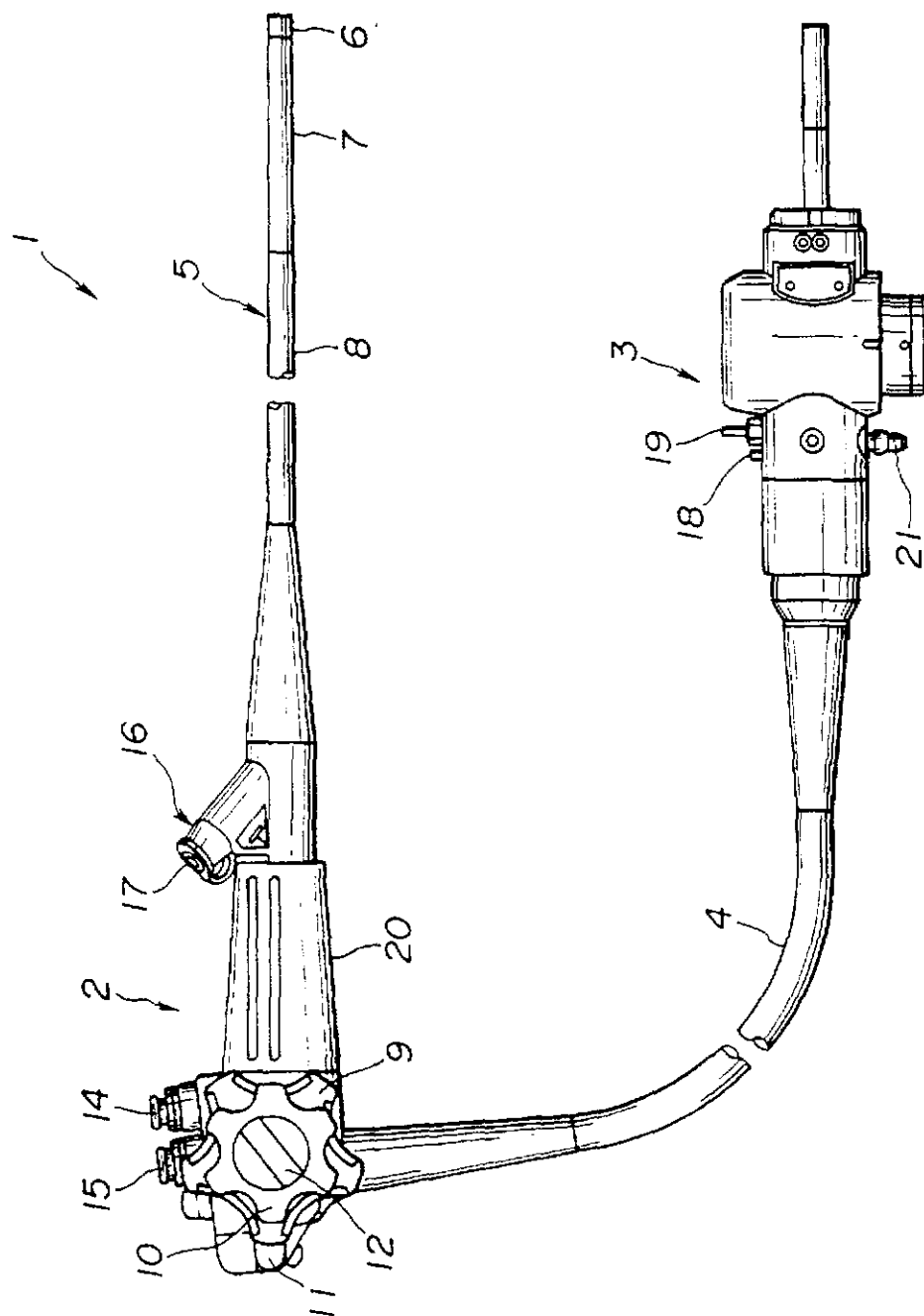
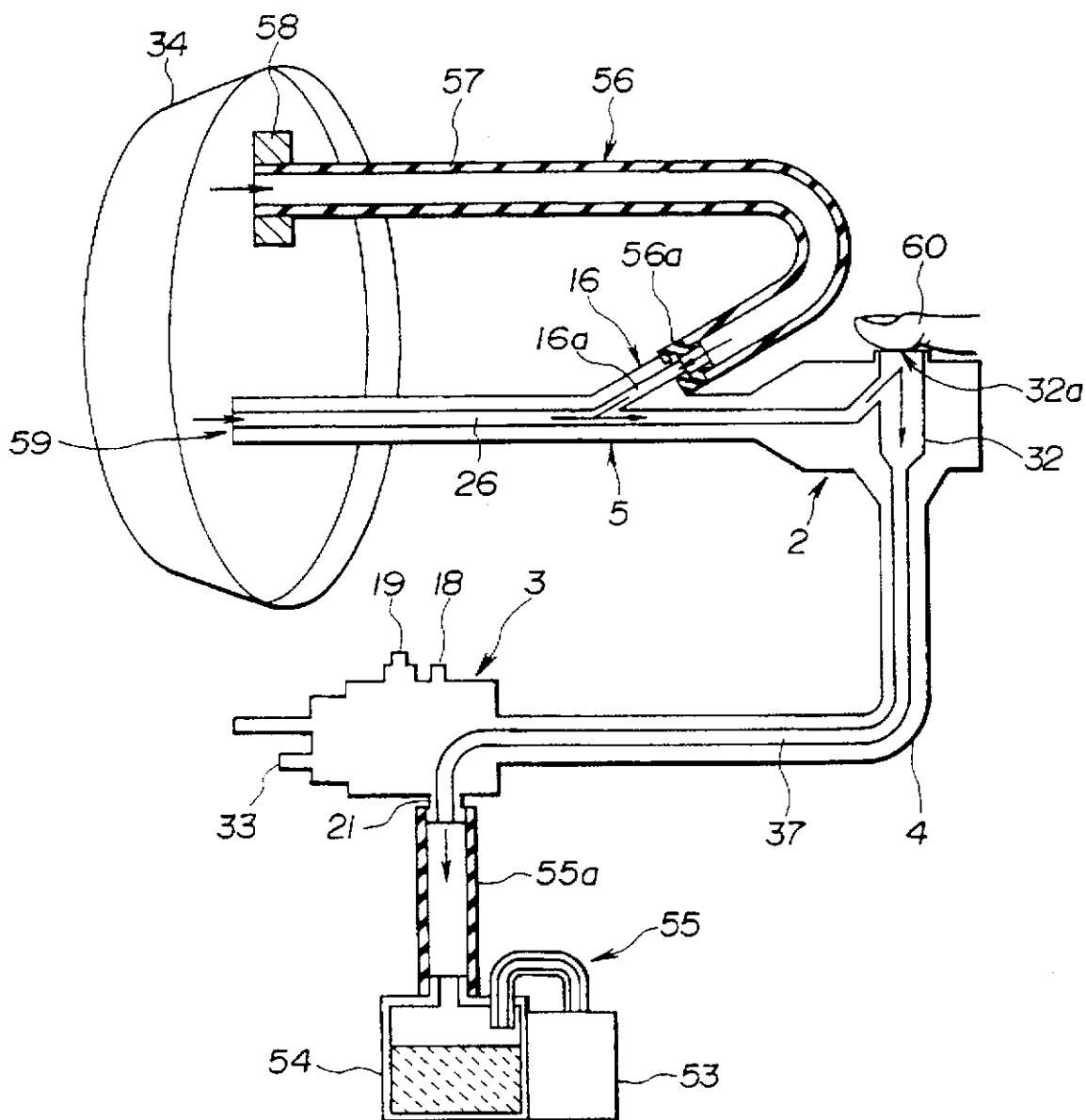


FIG. 5



ENDOSCOPE SYSTEM

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to an endoscope system having an endoscope for observing or treating a subject and a cleaning instrument for keeping the endoscope clean.

2. Description of the Related Art

In the past, it has been known in an endoscope system that cleaning is performed after every use by supplying a cleaning solution to various kinds of channels that are designed for aeration, perfusion, suction, and the like and that lie through an endoscope. An endoscope channel cleaning device disclosed in Japanese Patent Laid-Open No. 3-8213 is a known instrument for cleaning channels in an endoscope. The disclosed endoscope channel cleaning device has a structure in which two short tubes and a long tube joined with one another using a branch tube shaped like a letter Y. Another structure in which the overall length of one of the short tubes is made longer and the terminal of the tube is connected to an aeration base has also been disclosed. In either of the structures, a Y-shaped branch tube is used to bifurcate a single channel into two channels.

For supplying a liquid, a syringe is attached to an end of one long tube. Either an aeration/perfusion syringe and suction syringe or both a suction syringe and aeration base are attached to the other end thereof, whereby a liquid is fed simultaneously for cleaning.

However, the endoscope channel cleaning device disclosed in the Japanese Patent Laid-Open No. 3-8213 is of a type in which a liquid is injected into two positions simultaneously through one inlet. Although an injection balance is kept by means of an orifice or similar, since the inner diameters of channels vary greatly in the range from 2 mm to 6 mm, it is difficult to inject a liquid through one inlet into two channels having different inner diameters simultaneously in a well-balanced manner without any loss. The syringe manipulation frequency increases by the number of losses. Consequently, a worker must incur a larger burden, and it takes much time to complete cleaning.

For cleaning an endoscope, the endoscope is placed on a sink or in or by a cleaning vessel on a work desk. At this time, depending on the length of a flexible tube of a cleaning instrument, a cleaning worker is obliged to assume an unnatural posture that is a state in which he/she is lifting an endoscope for a prolonged period of time or stooping for a prolonged period of time.

If the flexible tube of the cleaning instrument is too long, the total amount of liquid increases by the amount of liquid filling the tube. The liquid cannot therefore be injected into channels with a single manipulation of a syringe. The syringe must therefore be manipulated repeatedly. Thus, not only the manipulation frequency increases but also liquid injection and drainage become necessary.

OBJECTS AND SUMMARY OF THE INVENTION

An object of the present invention is to provide an endoscope system in which when cleaning an endoscope, a worker can work on the endoscope in a posture not burdening him/her.

Another object of the present invention is to provide an

Briefly, an endoscope system of the present invention comprises an endoscope having an insertional part, operation unit, and connector unit set in array, and including channels communicating with an opening formed in the distal portion of the insertional part and with an opening formed in the operation unit or connector unit, and at least one cleaning instrument having a flexible tube that can be connected to the opening formed in the operation unit or connector unit of the endoscope and has an overall length thereof set to 30 cm or larger.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGS. 1 to 5 relate to an embodiment of the present invention:

FIG. 1 is a side view showing the configuration of an endoscope;

FIG. 2 shows the operation exerted when cleaning water is injected to a distal aeration channel and distal perfusion channel using an aeration/perfusion channel cleaning adaptor;

FIG. 3 shows the operation exerted when cleaning water is injected through a connector-side aeration channel and connector-side perfusion channel;

FIG. 4 shows the operation exerted when a suction tube of a suction unit is used to automatically drain liquids remaining in the aeration and perfusion channels;

FIG. 5 shows the operation exerted when a mounting rubber of a suction cleaning adaptor is mounted in a forceps inlet and a suction tube of a suction unit is coupled to a suction base in order to clean all suction-related channels;

FIG. 6 is a sectional view showing the structure of an aeration/perfusion channel cleaning adaptor;

FIG. 7 is an I—I sectional view of FIG. 6;

FIG. 8 is a view in a direction of an arrow B in FIG. 6;

FIG. 9 is a view in a direction of an arrow C in FIG. 6;

FIG. 10 is a view in a direction of an arrow D in FIG. 6;

FIG. 11 is a view in a direction of an arrow E in FIG. 9;

FIG. 12 is a sectional view for explaining another structure of an aeration/perfusion channel cleaning adaptor;

FIG. 13 is a sectional view for explaining an all-channel cleaning adaptor;

FIG. 14 is an II—II sectional view of FIG. 13;

FIG. 15 is a sectional view showing a major portion of a coupling plug;

FIG. 16 is a sectional view showing a major portion of an injection tube assembly;

FIG. 17 is a top view of the all-channel cleaning adaptor;

FIG. 18 is a bottom view of the all-channel cleaning adaptor;

FIG. 19 is a detailed view showing a portion indicated with an arrow G in FIG. 13;

FIG. 20 is an III—III sectional view of FIG. 13;

FIG. 21 is a sectional view showing a major portion of the coupling plug that is developed;

FIG. 22 is a top view showing the coupling plug that is developed;

FIG. 23 is a bottom view showing the coupling plug that is developed;

FIG. 24 is an IV—IV sectional view of FIG. 16;

FIG. 27 is a VI—VI sectional view of FIG. 25;
FIG. 28 is a view showing the injection adaptor on the side thereof to which a syringe is connected;
FIG. 29 is a view in a direction of an arrow M in FIG. 28;
FIG. 30 is a VII—VII sectional view of FIG. 25;
FIG. 31 is a sectional view of a drainage adaptor;
FIG. 32 is a view in a direction of an arrow O in FIG. 31;
FIG. 33 is a view in a direction of an arrow P in FIG. 31;
FIG. 34 is a VIII—VIII sectional view of FIG. 31;
FIG. 35 shows another structure of a drainage adaptor;
FIG. 36 is an IX—IX sectional view of FIG. 35; and
FIG. 37 shows another structure of a drainage adaptor.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to the drawings, embodiments of the present invention will be described below.

Referring to FIGS. 1 to 5, an embodiment of the present invention will be described.

As shown in FIG. 1, an endoscope 1 has a universal cord 4 linking an operation unit 2 and connector unit 3 and being realized with a flexible tube, and an insertional part 5 that extends from the operation unit 2, is inserted, for example, to a body cavity, and has an elongated shape and flexibility.

The insertional part 5 has a distal section 6, bending section 7, and soft section 8, set in array, in that order, from the distal end thereof. Formed in the vicinity of a grip section 20 of the operation unit 2 located at the back end of the insertional part 5 are an up/down or UD angling knob 9 used for vertical (UD) angling of the bending section 7, an right/left or RL angling knob 10 used for lateral (RL) angling thereof, an UD angle releasing knob 11 for releasing vertical angling, and an RL angle releasing knob 12 for releasing lateral angling.

On the grip section 20, an aeration/perfusion button 14 for use in performing aeration or perfusion via a channel system, which will be described later, running through the endoscope is mounted in an aeration/perfusion cylinder that will be described later, and a suction button 15 used for suction is mounted in a suction cylinder that will be described later.

On the side of the insertional part of the grip section 20, a forceps inlet 16 is formed. A semi-disposable forceps plug 17 is mounted in the forceps inlet 16. Reference numeral 18 written in the connector unit 3 denotes a pressurization base. 19 denotes an aeration base. 21 denotes a suction base.

To begin with, injection of cleaning water or the like into a distal aeration channel and distal perfusion channel using an aeration/perfusion channel cleaning adaptor will be described.

As shown in FIG. 2, assuming that dirt is washed away from the inside of an aeration channel 22 serving as a distal aeration channel and lying through the insertional part 5 of the endoscope 1, the inside of a perfusion channel 23 serving as a distal perfusion channel, and the inside of an aeration/perfusion nozzle 25, first, an aeration/perfusion channel cleaning adaptor 30 is attached to an aeration/perfusion cylinder 31 in the operation unit 2 of the endoscope 1. A syringe 24 serving as a cleaning instrument is connected to the aeration/perfusion channel cleaning adaptor 30 via a flexible tube 27. A liquid, for example, a cleaning solution, disinfectant solution, rinsing water with which the syringe 24 is filled is injected to the aeration channel 22, perfusion channel 23, and aeration/perfusion nozzle 25 for the purpose of cleaning.

Next, injection of cleaning water or similar into a

As shown in FIG. 3, assuming that a liquid, for example, a cleaning solution, disinfectant solution, or rinsing water is injected into the aeration channel 22 and perfusion channel 23 by way of an aeration tube 35 serving as a connector-side aeration channel, a perfusion tube 36 serving as a connector-side perfusion channel, and the aeration/perfusion cylinder 31, an all-channel cleaning adaptor 41 is attached to the aeration/perfusion cylinder 31 and a suction cylinder 32 loosely to such an extent that the liquid slightly leaks out. A plug 42 having a leakage hole 42a is then mounted in the forceps inlet 16. A coupling plug 43 is attached to the pressurization base 8 and perfusion base 19 of the connector unit 3.

In this state, an aeration/perfusion channel tube 45 included in an injection tube assembly 44 is press-fitted onto the aeration base 33 of the connector unit 3, and a suction channel tube 46 is press-fitted onto the suction base 21 of the connector unit 3. An injection adaptor 47 is mounted in a tapered section 48 of the injection tube assembly on the side of the aeration/perfusion channel tube 45. In this situation, when a liquid such as a cleaning solution, disinfectant solution, or rinsing water preserved in a vat 34 is injected to the aeration tube 35 and perfusion tube 36 using a syringe 24 whose capacity ranges from 30 cc to 50 cc, the cleaning solution or similar flows into the aeration channel 22 and perfusion channel 23 by way of the aeration/perfusion cylinder 31 and then flows out through the aeration/perfusion nozzle 25.

At this time, a distal portion 49a of a filter unit 49 of the injection adaptor 47 projects outwardly from the liquid in the vat 34 into the air, and the syringe 24 is manipulated for injection. Air is then fed into the channels, whereby the liquids remaining in the channels can be drained off.

When the injection adaptor 47 is mounted in the other tapered section 48 of the injection tube assembly 44 on the side of the suction channel tube 46, if the liquid in the syringe 24 is injected into the suction tube 37 in the same manner as it is injected to the aeration tube 35 and perfusion tube 36, the liquid in the vat can be injected to the suction tube 37, suction cylinder 32, suction channel 26, and forceps passage 16a lying through the forceps inlet 16. When the filter unit 49 projected outwardly from the liquid into the air, if the syringe 24 is manipulated for injection, air can be fed into the channels for easy drainage.

Next, automatic drainage of liquids remaining in aeration and perfusion channels using a suction tube of a suction unit will be described.

As shown in FIG. 4, a syringe tapered section 51 of a drainage adaptor 50 is mounted in the injection tube assembly 44 in place of the injection adaptor 47. In addition, a suction tube 55a of a suction unit 55 composed of a suction pump 53 and suction tank 54 is connected to a tube connecting section 52 of the drainage adaptor 50. A switch on the suction unit 55 is then turned on in order to supply air, whereby liquids remaining in the aeration and perfusion channels can be drained off automatically. When the drainage adaptor 50 is mounted in the suction-channel side of the injection tube assembly 44, a liquid remaining in the suction channel can be drained off automatically.

Compared with the drainage using the syringe 24 shown in FIG. 3, the automatic drainage by means of the drainage adaptor 50 permits a smaller amount of liquid to remain because of a longer suction period. The automatic drainage is therefore suitable for a pre-process of chamber gas sterilization using ethylene oxide gas, formalin gas, or similar. Moreover, since a remaining liquid can be drained upstream through a nozzle, it can be prevented that the nozzle is clogged or water scales adhere to lenses.

inlet and the suction tube of a suction unit connected to a suction base will be described.

As shown in FIG. 5, a mounting rubber 56a attached to one end of a tube 56 constituting a suction cleaning adaptor 57 is mounted in the forceps inlet 16. In addition, the other end of the tube 56 having a weight 58 such as a ring made of stainless steel, and a suction port 59 formed in the distal section 6 of the insertional part 5 are immersed in a cleaning solution or rinsing water preserved in the vat 34.

The suction tube 55a of the suction unit 55 is connected to the suction base 21 of the connector 3.

An opening 32a of the suction cylinder 32 is blocked by a finger 60, and the switch on the suction unit 55 is turned on. This causes the cleaning solution or rinsing water in the vat 34 to flow into the forceps passage 16a, suction channel 26, and suction tube 37. Thus, all the suction channels are cleaned or rinsed.

At this time, since the weight 58 is attached to the end of the tube 56 constituting the suction cleaning adaptor 57, the end of the suction cleaning adaptor 57 can be reliably immersed in a liquid in the vat 34. When the length of the tube of the suction cleaning adaptor 57 is set to a length permitting easy immersion in the vat 34, the cleaning and rinsing workability improves.

In other words, when cleaning, disinfection, rinsing, and drainage are carried out by connecting a flexible tube to an opening of an insertional part or connector unit of an endoscope and placing the endoscope in a sink or in or by a cleaning vessel, if the tube is too short, freedom is lost to deteriorate workability. By contrast, if the length of the tube is, for example, larger than or equal to 1 m, the tube interferes with handling because it is too long. Moreover, the overall content volume increases by the content volume of the tube. Therefore, liquid supply by means of a syringe becomes insufficient. This poses a drawback that the injection frequency increases.

It has been discussed what the length of a flexible tube included in a cleaning instrument should be in order to lighten the burden a worker must incur during cleaning of an endoscope and to prevent an excessive load from being imposed on the endoscope. The results are listed in Table 1.

TABLE 1

Item	Result
Height of a general work desk from the floor (a)	70 cm
Height of a sink or cleaning vessel from the floor (b)	60 cm
Height permitting excellent workability	
For a worker 160 cm tall (h1)	95 cm
For a worker 180 cm tall (h2)	115 cm
Length of a tube from an opening when a work desk is used	
For a worker 160 cm tall (h1 - a + a)	30 cm (a = 5 cm)
For a worker 180 cm tall (h2 - a - a)	50 cm (a = 5 cm)
Length of a tube from an opening when a sink or cleaning vessel is used	
For a worker 160 cm tall (h1 - b + a)	40 cm (a = 5 cm)
For a worker 180 cm tall (h2 - b + a)	60 cm (a = 5 cm)

Incidentally, the capacity of a syringe generally used for cleaning of an endoscope ranges from 30 ml to 50 ml. From this viewpoint, the inner diameter of a flexible tube is set to a minimum necessary limit so that the single manipulation

In other words, the relationship below is set up among the capacity of a syringe, the capacity of a tube included in the syringe, and the capacity of a formed channel such as the aeration tube 35 or perfusion tube 36.

Tube capacity + Channel capacity < Syringe capacity

Referring to the results listed in Table 1 with this relationship taken into account, it is apparent that when the length of a flexible tube of a cleaning instrument is set to a minimum of 30 cm, or preferably, to 60 cm, a cleaning worker need not to assume such a posture that he/she keeps stretching his/her arm while lifting an endoscope or keeps stooping for a prolonged period of time.

When a cleaning instrument is connected to an opening of a connector installed at an end of a universal cord of an endoscope or when a multi-branch tube branching out in a plurality of different directions from the same end is connected, if the bending length of a tube, α , is 5 cm as listed in Table 1, it is insufficient. The discussion has revealed that approximately 15 cm is needed for the bending length α . Consequently, an appropriate length of a tube ranges from 40 cm to 70 cm due to the increase of 10 cm in the α value from 5 cm to 15 cm.

As a result of the foregoing discussion, the length of a flexible tube is in the range from 30 cm or larger to 70 cm or smaller. For example, when the length of a tube is smaller than 20 cm, the tube is too short. A worker must therefore stoop for cleaning. An excessive load is imposed on the worker's lumbar vertebrae. This causes the worker to feel fatigued. By contrast, when the length of a tube is larger than or equal to 80 cm, an excess injection and drainage of a liquid into and from the flexible tube become necessary. The syringe manipulation frequency increases, and the tube becomes a hindrance.

As mentioned above, after endoscopic examination is completed, when an endoscope is placed in a sink or cleaning vessel in order to perform cleaning, disinfection, rinsing, drainage, and the like, since the dimension of a tube is set to the range from 30 cm or larger to 70 cm or smaller, a worker need not assume such a posture that he/she keeps stretching his/her arm while lifting an endoscope or keeps stooping but can achieve cleaning in a natural standing posture.

Since the length of a tube is set properly, the capacity of the tube is set properly. A liquid will therefore not be injected excessively from a syringe into the tube. Since work can be completed by feeding a liquid to all channels with one manipulation for injection, a work loss can be eliminated.

Furthermore, since an end of a tube of a suction cleaning adaptor or injection adaptor is made of a metal in order to exert the effect of a weight, when cleaning or similar is performed, it become unnecessary to support the tube end by a hand and immerse it in a liquid. The workability therefore improves drastically.

Ends of an injection tube assembly have the same shapes as the mounting ports of a syringe or injection adaptor and a drainage adaptor and lie adjacently, so that the ends thereof can be attached airtightly. The syringe or injection adaptor and drainage adaptor can be switched over readily.

For cleaning an endoscope, the whole procedure of cleaning, disinfection, rinsing, and drainage need not always be carried out. A user can select any of the processes in terms of dirt level of an endoscope and of workability. As shown in FIG. 3, the coupling plug 43 and injection tube assembly 44 may be joined with each other by a chain 263 having a



US006260560B1

(12) **United States Patent**
Walta

(10) **Patent No.:** **US 6,260,560 B1**
(45) **Date of Patent:** **Jul. 17, 2001**

(54) **DEVICE AND METHOD FOR CLEANING
AND/OR DISINFECTING ENDOSCOPES**

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

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(57) **ABSTRACT**

(21) **Appl. No.:** **09/078,287**

(22) **Filed:** **May 13, 1998**

(30) **Foreign Application Priority Data**

May 14, 1997 (NL) 1006053

(51) **Int. Cl.** A61H 2/00; B08B 9/032

(52) **U.S. Cl.** 134/22.12; 134-166 R;
134-169 R; 134-169 C; 422-28; 422-33;
422-292

(58) **Field of Search** 422-1, 28, 33,
422-292, 297, 293, 300; 134-166 R, 169 R,
169 C, 22-1, 22-11, 22-12, 22-18, 22-13,
22-14, 22-16, 22-17, 22-19; 604-264

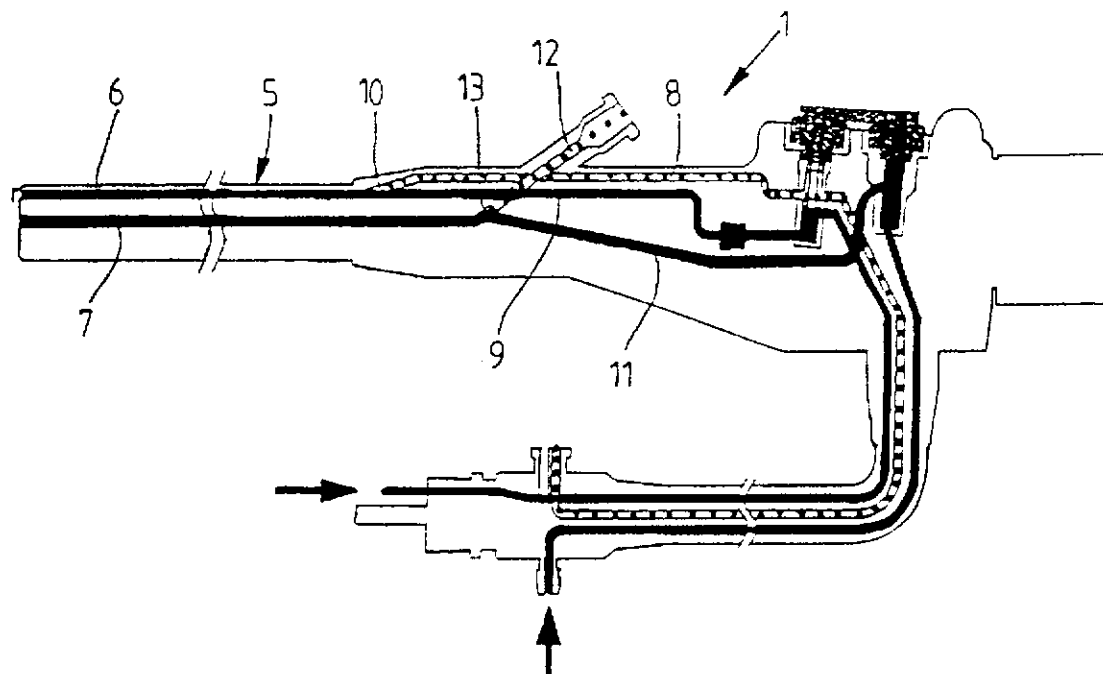
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For the purpose of cleaning and/or disinfecting endoscopes having a plurality of channels, each channel is connected to a feedline, which is provided with a shut-off valve, for a cleaning and/or disinfecting agent, and each channel is flushed with a cleaning and/or disinfecting agent. If necessary, before flushing the channels, separating means are arranged in the endoscope in order to separate channels from one another, in such a manner that during flushing only single channels are present in the endoscope. Each single channel is connected to a feedline for a cleaning and/or disinfecting agent and is flushed separately. The single channels which merge in the endoscope into a common channel part are flushed one after the other. Advantageously, if single channels of mutually different passage width are flushed simultaneously, an additional flow restriction is arranged in at least the feedline connected to the channel with the greater passage width.

14 Claims, 7 Drawing Sheets



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FIGS. 6 to 8 show the phases of flushing the channels in an endoscope of the type shown in FIG. 2 during the cleaning and/or disinfecting.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

FIG. 1 shows an endoscope 1 with a head part 2, in which openings 3 and 4 are formed, in which, during normal use of the endoscope, an air/water valve and a suction valve are arranged. A flexible insertion hose 5 is attached to the head part 2, in which hose a combined air/water channel 6 and a combined suction/biopsy channel 7 are accommodated.

A separate air channel 8 and water channel 9, which at the location of a joining point 10 merge into the air/water channel 6, are arranged in the head part 2. Furthermore, a separate suction channel 11 and biopsy channel 12, which at the location of the joining point 13 merge into the suction/biopsy channel 7, are accommodated in the head part 2.

In the head part 2, the air channel 8 and the water channel 9 open into the opening 3 for the air/water valve. The suction channel 11 opens into the opening 4 for the suction valve. Furthermore, a flexible feed hose 14 is connected to the head part 2, in which hose there are accommodated channels 8', 9' and 11' which, via the openings 3 and 4, are connected to the air channel 8, the water channel 9 and the suction channel 11, respectively. In practice, the feed hose 14 is also referred to as the light-conductor casing.

The mutually connecting channels 8 and 8', 9 and 9', 11 and 11' will be referred to below overall as the air channel 8, the water channel 9 and the suction channel 11.

A connection 16 for the air channel 8, connections 17 and 17a for the water channel 9 and a connection 18 for the suction channel 11 are arranged on the end section 15 (also referred to as the light-conductor connector) of the flexible hose 14. When connection 16 is in use, connection 17a is closed off. A connection 19 for the biopsy channel 12 is arranged on the head part 2.

FIG. 2 shows an endoscope 20 which differs from the endoscope illustrated in FIG. 1 by the fact that it is provided with an additional channel 21 with connection 22 and an additional channel 23 with the connection 24. In the head part 2, the channel 23 is connected to the air channel 8 at the joining point 25.

In the endoscopes illustrated in FIGS. 1 and 2, for the purpose of cleaning and/or disinfecting, an auxiliary separating piece 26 is arranged in the openings 3 and 4 instead of the air/water valve and the suction valve, in such a manner that the air channel 8 and the water channel 9 are channels which are continuous but separate from one another and the suction channel 11 is a continuous channel. In this way, there are only single channels present in the endoscope during the cleaning and disinfection process, or at least the channels are separated from one another in such a manner that they can be flushed separately.

FIG. 3 diagrammatically depicts the connection of an endoscope 30 which is to be cleaned and/or disinfected to a device for cleaning and disinfecting endoscopes. The various channels in the endoscope 30, as described with reference to FIGS. 1 and 2, are connected to feedlines 31 for cleaning and/or disinfecting agent. The feedlines 31 are connected to a common line 32, in which a feed pump 33 is incorporated. A shut-off valve 34 and a pressure sensor 35 is incorporated in each feedline 31. An additional pump (lifting pump) 36 is accommodated in one of the feedlines 31, the feedline to the lift channel in the endoscope. The shut-off

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Such an unit 37 may be part of a known device known for cleaning and disinfecting endoscopes which is described extensively in European patent application EP 0 709 056, which document should be regarded as part of the present description.

In the device according to the invention, as can be seen in FIG. 3, an extra flow restriction 39 is incorporated in each feedline 31 between the shut-off valve 34 and the connection 38 to an endoscope channel. In FIG. 3, the various restrictions 39 are accommodated in a connection block 40 which is positioned between the unit 37 and the connections 38.

When flushing the channels in the endoscope, the restrictions have a balancing effect on the pressure and the flow of the cleaning or disinfecting agent. Using the restrictions makes it possible to simultaneously flush an endoscope channel having a wide passage width and an endoscope channel having a narrow passage width, without one of the channels being insufficiently flushed through, which would result in insufficient cleaning and/or disinfection of the channel in question. The flow resistance of the flow restrictions is usually in the order of magnitude the flow resistance of the endoscope channel having the narrow passage width.

In the method according to the invention, after the above-mentioned separating means (auxiliary separating piece 26) have been arranged in the endoscope and the single channels in the endoscope have been connected to the feedlines 31 for cleaning and/or disinfecting agent, the single channels in the endoscope are flushed separately.

In an endoscope 1 of the type shown in FIG. 1, the channels are flushed through in two phases, which are depicted in FIGS. 4 and 5.

In the first phase (FIG. 4), the water channel 9 and the suction channel 11 are flushed. The shut-off valves 34 in the feedlines 31 to the water channel 9 and the suction channel 11 are then opened. The shut-off valves 34 in the feedlines 31 to the air channel 8 and the biopsy channel 12 are closed. As a result, the rinsing liquid cannot flow back via the joining point 10 and the air channel 8 and via the joining point 13 and the biopsy channel 12, respectively.

Owing to the restrictions 39 in the feedlines 31, it is possible in this phase to simultaneously flush a channel having a small passage width (water channel 9) and a channel having a large passage width (suction channel 11), while ensuring that both channels are flushed adequately.

In the second phase (FIG. 5), the air channel 8 and the biopsy channel 12 are flushed. The shut-off valves 34 in the feedlines which were opened in the first phase are now closed, and vice versa.

The channels 6 and 7 in the insertion hose 5 are flushed in both phases.

Obviously, it is also possible to flush the biopsy channel 12 in the first phase and the suction channel 11 in the second phase.

In an endoscope 20 of the type illustrated in FIG. 2, the flushing takes place in three phases, which are illustrated in FIGS. 6 to 8.

The first and third phases (FIGS. 6 and 8) substantially correspond to the first and second phases of FIGS. 4 and 5, provided that in both the first and the third phase the shut-off valves 34 in the feedlines to the channels 21 and 23 are also closed.

In the second phase (FIG. 7), the shut-off valves 34 in the feedlines 31 to the lines 21 and 23 are opened and the shut-off valves 34 in the feedlines 31 to the air channel 8

(19)



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11)

EP 1 433 410 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:
30.06.2004 Bulletin 2004/27

(51) Int Cl.7: A61B 1/00, A61B 1/015

(21) Application number: 03258094.6

(22) Date of filing: 22.12.2003

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR
HU IE IT LI LU MC NL PT RO SE SI SK TR
Designated Extension States:
AL LT LV MK

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(30) Priority: 23.12.2002 US 328233

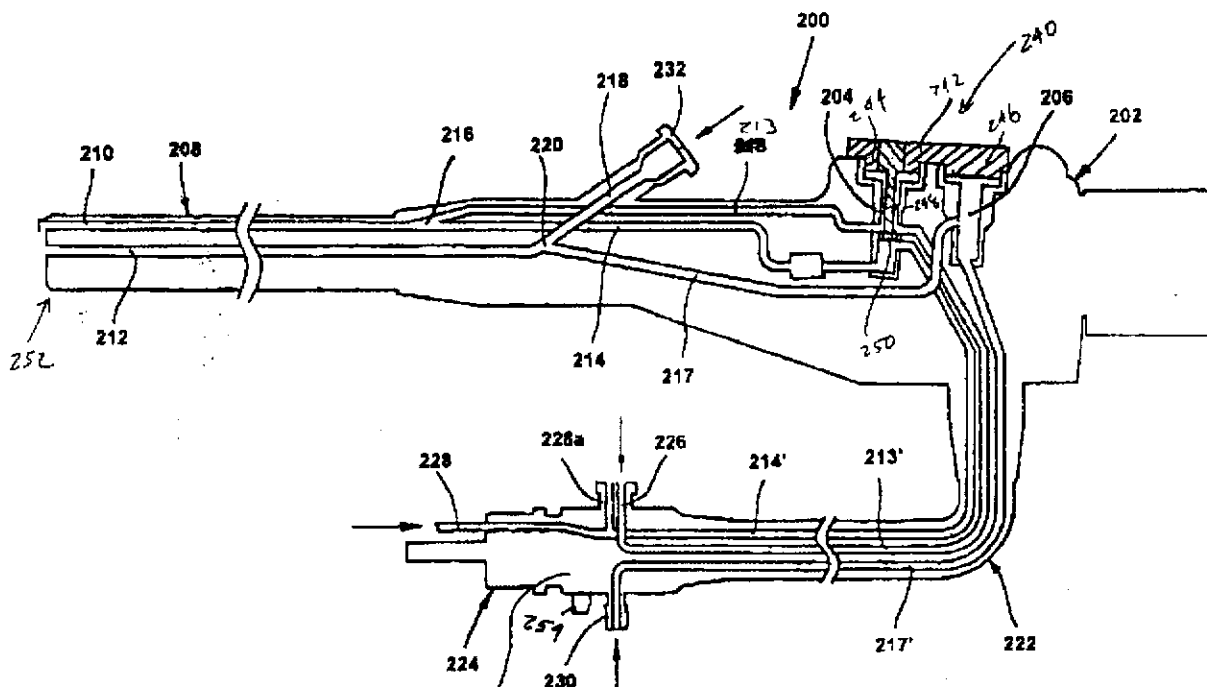
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(54) Endoscope connection integrity testing

(57) A method detects proper connection of fixtures to one or more channels in an endoscope during a cleaning or disinfection procedure. The endoscope has a first opening into one of its channels. The method includes the steps of placing the endoscope at the first

opening in a liquid while leaving a gas within the channel, drawing a vacuum on the gas through a second opening into the channel and thereby drawing some of the liquid into the channel, and detecting for air leaking into the channel.



Description

BACKGROUND OF THE INVENTION

[0001] The present invention relates to the decontamination arts including the sterilization arts. It finds particular application in conjunction with the decontamination of medical devices, especially medical devices such as endoscopes and other devices having channels or lumens that must be decontaminated after use.

[0002] Endoscopes and similar medical devices having channels or lumens formed therethrough are being used on an ever increasing basis in the performance of medical procedures. The popularity of these devices has led to calls for improvements in the decontamination of these devices between use, both in terms of the speed of the decontamination and the effectiveness of the decontamination.

[0003] One popular method for cleaning and disinfection or sterilization of such endoscopes employs an automated endoscope reprocessor which both washes and then disinfects or sterilizes the endoscope. Typically such a unit comprises a basin with a selectively opened and closed cover member to provide access to the basin. Pumps connect to various channels through the endoscope to flow fluid therethrough and an additional pump flows fluid over the exterior surfaces of the endoscope. Typically, a detergent washing cycle is followed by rinsing and then a sterilization or disinfection cycle and rinse. Various connections must be made to the endoscope to achieve flow through its channels. If any of the connections leaks the process may not work properly possibly leaving the endoscope contaminated. Typically, such automated systems check for blockages in the channels, but such testing can be fooled if one of the connections is not tight.

SUMMARY OF THE INVENTION

[0004] A method of detecting proper connection of fixtures to one or more channels in an endoscope according to the present invention comprises the steps of:

- placing a first opening into at least one of the one or more channels into a liquid;
- having a gas within the channel;
- drawing a vacuum on the gas through a second opening into the channel and thereby drawing some of the liquid into the channel;
- detecting for air leaking into the channel.

[0005] Preferably, the step of detecting for air leaking into the at least one channel comprises monitoring the pressure within the channel. If it falls below a given amount in a given time period an indication can be given that the channel is leaking.

[0006] When the endoscope has two channels and

from each other internally, the method preferably further includes the step of individually testing each of the two channels so as to detect gas leaking past the fixture which separates the two channels from each other. If leakage is detected in testing each of the two channels an indication is given that the fixture separating the two channels is leaking.

[0007] Preferably, a first one of the fixtures connects to the second opening and this fixture is exposed to atmosphere, and if leakage of air into the channel is detected an indication is given that first one of the fixtures is leaking. If leakage of air into the channel is detected an indication is given to a user that the channel failed the leakage test. Such indication is preferably provided visually on a screen.

[0008] Preferably, the first opening is at a distal end of an endoscope.

[0009] In one aspect of the invention, the step of detecting for air leaking into the at least one channel comprises monitoring for air bubbles within the at least one channel. Such a monitor could comprise a turbidity meter or even a visual inspection by the user. Alternatively, the step of detecting for air leaking into the at least one channel comprises monitoring a flow of the liquid through the at least one channels.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The invention may take form in various components and arrangements of components and in various steps and arrangements of steps. The drawings are for purposes of illustrating preferred embodiments only, and are not to be construed as limiting the invention.

FIG. 1 is a front elevational view of a decontamination apparatus in accordance with the present invention;

FIG. 2 is a diagrammatic illustration of the decontamination apparatus shown in FIG. 1, with only a single decontamination basin shown for clarity; and,

FIG. 3 is a cut-away view of an endoscope suitable for processing in the decontamination apparatus of FIG. 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0011] FIG. 1 shows a decontamination apparatus for decontaminating endoscopes and other medical devices which include channels or lumens formed therethrough; FIG. 2 shows the apparatus in block diagram form. The decontamination apparatus generally includes a first station 10 and a second station 12 which are at least substantially similar in all respects to provide for the decontamination of two different medical devices

ination basins 14a, 14b receive the contaminated devices. Each basin 14a, 14b is selectively sealed by a lid 16a, 16b, respectively, preferably in a microbe-blocking relationship to prevent the entrance of environmental microbes into the basins 14a, 14b during decontamination operations. The lids can include a microbe removal or HEPA air filter formed therein for venting.

[0012] A control system 20 includes one or more microcontrollers, such as a programmable logic controller (PLC), for controlling decontamination and user interface operations. Although one control system 20 is shown herein as controlling both decontamination stations 10, 12, those skilled in the art will recognize that each station 10, 12 can include a dedicated control system. A visual display 22 displays decontamination parameters and machine conditions for an operator and at least one printer 24 prints a hard copy output of the decontamination parameters for a record to be filed or attached to the decontaminated device or its storage packaging. The visual display 22 is preferably combined with a touch screen input device. Alternatively, a keypad or the like is provided for input of decontamination process parameters and for machine control. Other visual gauges 26 such as pressure meters and the like provide digital or analog output of decontamination or medical device leak testing data.

[0013] FIG. 2 diagrammatically illustrates one station 10 of the decontamination apparatus. Those skilled in the art will recognize that the decontamination station 12 is preferably similar in all respects to the station 10 illustrated in FIG. 2. However, the station 12 has not been shown in FIG. 2 for clarity. Further, the decontamination apparatus can be provided with a single decontamination station or multiple stations.

[0014] The decontamination basin 14a receives an endoscope 200 (see FIG. 3) or other medical device therein for decontamination. Any internal channels of the endoscope 200 are connected with flush lines 30. Each flush line 30 is connected to an outlet of a pump 32. The pumps 32 are preferably peristaltic pumps or the like that pump fluid, such as liquid and air, through the flush lines 30 and any internal channels of the medical device. Specifically, the pumps 32 either can draw liquid from the basin 14a through a filtered drain 34 and a first valve S1, or can draw decontaminated air from an air supply system 36 through a valve S2. The air supply system 36 includes a pump 38 and a microbe removal air filter 40 that filters microbes from an incoming air stream. It is preferable that each flush line 30 be provided with a dedicated pump 32 to ensure adequate fluid pressure and to facilitate the individual monitoring of the fluid pressure in each flush line 30. A pressure switch or sensor 42 is in fluid communication with each flush line 30 for sensing excessive pressure in the flush line. Any excessive pressure sensed is indicative of a partial or complete blockage, e.g., by bodily tissue or dried bodily fluids, in a device channel to which the relevant flush

relative to the others allows the particular blocked channel to be easily identified and isolated, depending upon which sensor 42 senses excessive pressure.

[0015] The basin 14a is in fluid communication with a water source 50 such as a utility or tap water connection including hot and cold inlets and a mixing valve 52 flowing into a break tank 56. A microbe removal filter 54, such as a 0.2 μm or smaller absolute pore size filter, decontaminates the incoming water which is delivered into the break tank 56 through the air gap to prevent backflow. A pressure type level sensor 59 monitors liquid levels within the basin 14a. An optional water heater 53 can be provided if an appropriate source of hot water is not available.

[0016] The condition of the filter 54 can be monitored by directly monitoring the flow rate of water therethrough or indirectly by monitoring the basin fill time using a float switch or the like. When the flow rate drops below a select threshold, this indicates a partially clogged filter element that requires replacement.

[0017] A basin drain 62 drains liquid from the basin 14a through an enlarged helical tube 64 into which elongated portions of the endoscope 200 can be inserted. The drain 62 is in fluid communication with a recirculation pump 70 and a drain pump 72. The recirculation pump 70 recirculates liquid from the basin drain 62 to a spray nozzle assembly 60 which sprays the liquid into the basin 14a and onto the endoscope 200. Coarse and fine screens 71 and 73, respectively, filter out particles in the recirculating fluid. The drain pump 72 pumps liquid from the basin drain 62 to a utility drain 74. A level sensor 76 monitors the flow of liquid from the pump 72 to the utility drain 74. The pumps 70 and 72 can be simultaneously operated such that liquid is sprayed into the basin 14a while it is being drained to encourage the flow of residue out of the basin and off of the device. Of course, a single pump and a valve assembly could replace the dual pumps 70, 72.

[0018] An inline heater 80, with temperature sensors 82, downstream of the recirculation pump 70 heats the liquid to optimum temperatures for cleaning and disinfection. A pressure switch or sensor 84 measures pressure downstream of the circulation pump 70.

[0019] Detergent solution 86 is metered into the flow upstream of the circulation pump 70 via a metering pump 88. A float switch 90 indicates the level of detergent available. Typically, only a small amount of disinfectant 92 is required. To more accurately meter this, a dispensing pump 94 fills a pre-chamber 96 under control of a hi/low level switch 98 and of course the control system 20. A metering pump 100 meters a precise quantity of disinfectant as needed.

[0020] Endoscopes and other reusable medical devices often include a flexible outer housing or sheath surrounding the individual tubular members and the like that form the interior channels and other parts of the device. This housing defines a closed interior space, which

procedures. It is important that the sheath be maintained intact, without cuts or other holes that would allow contamination of the interior space beneath the sheath. Therefore, the decontamination apparatus includes means for testing the integrity of such as sheath.

[0021] An air pump, either the pump 38 or another pump 110, pressurizes the interior space defined by the sheath of the device through a conduit 112 and a valve S5. Preferably, a HEPA or other microbe-removing filter 113 removes microbes from the pressurizing air. An overpressure switch 114 prevents accidental over pressurization of the sheath. Upon full pressurization, the valve S5 is closed and a pressure sensor 116 looks for a drop in pressure in the conduit 112 which would indicate the escape of air through the sheath. A valve S6 selectively vents the conduit 112 and the sheath through an optional filter 118 when the testing procedure is complete. An air buffer 120 smoothes out pulsation of pressure from the air pump 110.

[0022] Preferably, each station 10 and 12 each contain a drip basin 130 and spill sensor 132 to alert the operator to potential leaks.

[0023] An alcohol supply 134 controlled by a valve S3 can supply alcohol to the channel pumps 32 after rinsing steps to assist in removing water from the endoscope channels.

[0024] Flow rates in the supply lines 30 can be monitored via the channel pumps 32 and the pressure sensors 42. The channels pumps 32 are peristaltic pumps which supply a constant flow. If one of the pressure sensors 42 detects too high a pressure the associated pump 32 cycles off. The flow rate of the pump 32 and its percentage on time provide a reasonable indication of the flow rate in an associated line 30. These flow rates are monitored during the process to check for blockages in any of the endoscope channels. Alternatively, the decay in the pressure from the time the pump 32 cycles off can also be used to estimate the flow rate, with faster decay rates being associated with higher flow rates.

[0025] A more accurate measurement of flow rate in an individual channel may be desirable to detect more subtle blockages. A metering tube 136 having a plurality of level indicating sensors 138 fluidly connects to the inputs of the channel pumps 32. One preferred sensor arrangement provides a reference connection at a low point in the metering tube and a plurality of sensors 138 arranged vertically thereabove. By passing a current from the reference point through the fluid to the sensors 138 it can be determined which sensors 138 are immersed and therefore determine the level within the metering tube 136. Other level sensing techniques can be applied here. By shutting valve S1 and opening a vent valve S7 the channel pumps 32 draw exclusively from the metering tube. The amount of fluid being drawn can be very accurately determined based upon the sensors 138. By running each channel pump in isolation the flow therethrough can be accurately determined based upon

tering tube.

[0026] In addition to the input and output devices described above, all of the electrical and electromechanical devices shown are operatively connected to and controlled by the control system 20. Specifically, and without limitation, the switches and sensors 42, 59, 76, 84, 90, 98, 114, 116, 132 and 136 provide input I to the microcontroller 28 which controls the decontamination and other machine operations in accordance therewith. For example, the microcontroller 28 includes outputs O that are operatively connected to the pumps 32, 38, 70, 72, 88, 94, 100, 110, the valves S1-S7, and the heater 80 to control these devices for effective decontamination and other operations.

[0027] Turning also to FIG. 3, an endoscope 200 has a head part 202, in which openings 204 and 206 are formed, and in which, during normal use of the endoscope 200, an air/water valve and a suction valve are arranged. A flexible insertion tube 208 is attached to the head part 202, in which tube a combined air/water channel 210 and a combined suction/biopsy channel 212 are accommodated.

[0028] A separate air channel 213 and water channel 214, which at the location of a joining point 216 merge into the air/water channel 210, are arranged in the head part 202. Furthermore, a separate suction channel 217 and biopsy channel 218, which at the location of the joining point 220 merge into the suction/biopsy channel 212, are accommodated in the head part 202.

[0029] In the head part 202, the air channel 213 and the water channel 214 open into the opening 204 for the air/water valve. The suction channel 217 opens into the opening 206 for the suction valve. Furthermore, a flexible feed hose 222 connects to the head part 202 and accommodates channels 213', 214' and 217' which via the openings 204 and 206, are connected to the air channel 213, the water channel 214 and the suction channel 217, respectively. In practice, the feed hose 222 is also referred to as the light-conductor casing.

[0030] The mutually connecting channels 213 and 213', 214 and 214', 217 and 217' will be referred to below overall as the air channel 213, the water channel 214 and the suction channel 217.

[0031] A connection 228 for the air channel 213, connections 228 and 228a for the water channel 214 and a connection 230 for the suction channel 217 are arranged on the end section 224 (also referred to as the light conductor connector) of the flexible hose 222. When the connection 228 is in use, connection 228a is closed off. A connection 232 for the biopsy channel 218 is arranged on the head part 202.

[0032] A channel separator 240 is shown inserted into the openings 204 and 206. It comprises a body 242, and plug members 244 and 246 which occlude respectively openings 204 and 206. A coaxial insert 248 on the plug member 244 extends inwardly of the opening 204 and terminates in an annular flange 250 which occludes a

channel 214. By connecting the lines 30 to the openings 226, 228, 228a, 230 and 232, liquid for cleaning and disinfection can be flowed through the endoscope channels 213, 214, 217 and 218 and out of a distal tip 252 of the endoscope 200 via channels 210 and 212. The channel separator 240 ensures the such liquid flows all the way through the endoscope 200 without leaking out of openings 204 and 206 and isolates channels 213 and 214 from each other so that each has its own independent flow path. One of skill in the art will appreciate that various endoscopes having differing arrangements of channels and openings will likely require modifications in the channel separator 240 to accommodate such differences while occluding ports in the head 202 and keeping channels separated from each other so that each channel can be flushed independently of the other channels. Otherwise a blockage in one channel might merely redirect flow to a connected unblocked channel.

[0033] A leakage port 254 on the end section 224 leads into an interior portion 256 of the endoscope 200 and is used to check for the physical integrity thereof, namely to ensure that no leakage has formed between any of the channels and the interior 256 or from the exterior to the interior 256.

[0034] The cleaning and sterilization cycle in detail comprises the following steps.

Step 1. Open the Lid

[0035] Pressing a foot pedal (not shown) opens the basin lid 16a. There is a separate foot pedal for each side. If pressure is removed from the foot pedal, the lid motion stops.

Step 2. Position and connect the endoscope

[0036] The insertion tube 208 of the endoscope 200 is inserted into the helical circulation tube 64. The end section 224 and head section 202 of the endoscope 200 are situated within the basin 14a, with the feed hose 222 coiled within the basin 14a with as wide a diameter as possible.

[0037] The flush lines 30, preferably color-coded, are attached, one apiece, to the endoscope openings 226, 228, 228a, 230 and 232. The air line 112 is also connected to the connector 254. A guide located on the on the station 10 provides a reference for the color-coded connections.

Step 3. Identify the user, endoscope, and specialist to the system

[0038] Depending on the customer-selectable configuration, the control system 20 may prompt for user code, patient ID, endoscope code, and/or specialist code. This information may be entered manually (through the touch screen) or automatically such as by using an attached

Step 4. Close the basin lid

[0039] Closing the lid 16a preferably requires the user to press a hardware button and a touch-screen 22 button simultaneously (not shown) to provides a fail-safe mechanism for preventing the user's hands from being caught or pinched by the closing basin lid 16a. If either the hardware button or software button is released while the lid 16a is in the process of closing the motion stops.

Step 5. Start Program

[0040] The user presses a touch-screen 22 button to begin the washing / disinfection process.

Step 6. Pressurize the endoscope body and Measure the Leak Rate

[0041] The air pump is started and pressure within the endoscope body is monitored. When pressure reaches 250 mbar, the pump is stopped, and the pressure is allowed to stabilize for 6 seconds. If pressure has not reached 250 mbar in 45 seconds the program is stopped and the user is notified of the leak. If pressure drops to less than 100 mbar during the 6-second stabilization period, the program is stopped and the user is notified of the condition.

[0042] Once the pressure has stabilized, the pressure drop is monitored over the course of 60 seconds. If pressure drops more than 10 mbar within 60 seconds, the program is stopped and the user is notified of the condition. If the pressure drop is less than 10 mbar in 60 seconds, the system continues with the next step. A slight positive pressure is held within the endoscope body during the rest of the process to prevent fluids from leaking in.

Step 7. Check Connections

[0043] A second leak test checks the adequacy of connection to the various ports 226, 228, 228a, 230, 232 and the proper placement of the channel separator 240. A quantity of water is admitted to the basin 14a so as to submerge the distal end of the endoscope in the helical tube 64. Valve S1 is closed and valve S7 opened and the pumps 32 are run in reverse to draw a vacuum and to ultimately draw liquid into the endoscope channels 210 and 212. The pressure sensors 42 are monitored to make sure that the pressure in any one channel does not drop by more than a predetermined amount in a given time frame. If it does, it likely indicates that one of the connections was not made correctly and air is leaking into the channel. In any event, in the presence of an unacceptable pressure drop the control system 20 will cancel the cycle and indicate a likely faulty connection, preferably with an indication of which channel failed.

PRE-RINSE

[0044] The purpose of this step is to flush water through the channels to remove waste material prior to washing and disinfecting the endoscope 200.

Step 8. Fill basin

[0045] The basin 14a is filled with filtered water and the water level is detected by the pressure sensor 59 below the basin 14a.

Step 9. Pump water through channels

[0046] The water is pumped via the pumps 32 through the interior of the channels 213, 214, 217, 218, 210 and 212 directly to the drain 74. This water is not recirculated around the exterior surfaces of the endoscope 200 during this stage.

Step 10. Drain

[0047] As the water is being pumped through the channels, the drain pump 72 is activated to ensure that the basin 14a is also emptied. The drain pump 72 will be turned off when the drain switch 76 detects that the drain process is complete.

Step 11. Blow air through channels

[0048] During the drain process sterile air is blown via the air pump 38 through all endoscope channels simultaneously to minimize potential carryover.

WASH**Step 12. Fill basin**

[0049] The basin 14a is filled with warm water (35 °C). Water temperature is controlled by controlling the mix of heated and unheated water. The water level is detected by the pressure sensor 59.

Step 13. Add detergent

[0050] The system adds enzymatic detergent to the water circulating in the system by means of the peristaltic metering pump 88. The volume is controlled by controlling the delivery time, pump speed, and inner diameter of the peristaltic pump tubing.

Step 14. Circulate wash solution

[0051] The detergent solution is actively pumped throughout the internal channels and over the surface of the endoscope 200 for a predetermined time period, typically of from one to five minutes, preferably about

nal circulation pump 70. The inline heater 80 keeps the temperature at about 35 °C.

Step 15. Start block test

[0052] After the detergent solution has been circulating for a couple of minutes, the flow rate through the channels is measured. If the flow rate through any channel is less than a predetermined rate for that channel, the channel is identified as blocked, the program is stopped, and the user is notified of the condition. The peristaltic pumps 32 are run at their predetermined flow rates and cycle off in the presence of unacceptably high pressure readings at the associated pressure sensor 42. If a channel is blocked the predetermined flow rate will trigger the pressure sensor 42 indicating the inability to adequately pass this flow rate. As the pumps 32 are peristaltic, their operating flow rate combined with the percentage of time they are cycled off due to pressure will provide the actual flow rate. The flow rate can also be estimated based upon the decay of the pressure from the time the pump 32 cycles off.

Step 16. Drain

[0053] The drain pump 72 is activated to remove the detergent solution from the basin 14a and the channels. The drain pump 72 turns off when the drain level sensor 76 indicates that drainage is complete.

Step 17. Blow air

[0054] During the drain process sterile air is blown through all endoscope channels simultaneously to minimize potential carryover.

RINSE**Step 18. Fill basin**

[0055] The basin 14a is filled with warm water (35 °C). Water temperature is controlled by controlling the mix of heated and unheated water. The water level is detected by the pressure sensor 59.

Step 19. Rinse

[0056] The rinse water is circulated within the endoscope channels (via the channel pumps 32) and over the exterior of the endoscope 200 (via the circulation pump 70 and the sprinkler arm 60) for 1 minute.

Step 20. Continue Block test

[0057] As rinse water is pumped through the channels, the flow rate through the channels is measured and if it falls below the predetermined rate for any given

Step 34. Drain

[0071] The drain pump 72 is activated to remove the rinse water from the basin and the channels.

Step 35. Blow air

[0072] During the drain process sterile air is blown through all endoscope channels simultaneously to minimize potential carryover.

Step 36. Repeat rinse

[0073] Steps 31 through 35 are repeated two more times (a total of 3 post-disinfection rinses) to ensure maximum reduction of disinfectant residuals from the endoscope 200 and surfaces of the reprocessor.

FINAL LEAK TEST**Step 37. Pressurize the endoscope body and measure leak rate**

[0074] Repeat Step 6.

Step 38. Indicate program completion

[0075] The successful completion of the program is indicated on the touch screen.

Step 39. De-pressurize the endoscope

[0076] From the time of program completion to the time at which the lid is opened, pressure within the endoscope body is normalized to atmospheric pressure by opening the vent valve S5 for 10 seconds every minute.

Step 40. Identify the user

[0077] Depending on customer-selected configuration, the system will prevent the lid from being opened until a valid user identification code is entered.

Step 41. Store program information

[0078] Information about the completed program, including the user ID, endoscope ID, specialist ID, and patient ID are stored along with the sensor data obtained throughout the program.

Step 42. Print program record

[0079] If a printer is connected to the system, and if requested by the user, a record of the disinfection program will be printed.

Step 43. Remove the endoscope

[0080] Once a valid user identification code has been entered, the lid may be opened (using the foot pedal as in step 1, above). The endoscope is then disconnected from the flush lines 30 and removed from the basin 14a. The lid can then be closed using both the hardware and software buttons as described in step 4, above.

[0081] The invention has been described with reference to the preferred embodiments. Obviously, modifications and alterations will occur to others upon reading and understanding the preceding detailed description. It is intended that the invention be construed as including all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

Claims

1. A method of detecting proper connection of fixtures to one or more channels in an endoscope, the endoscope having a first opening into at least of the channels, the method comprising the steps of:

placing the endoscope at the first opening into a liquid;
having a gas within the at least one channel;
drawing a vacuum on the gas through a second opening into the at least one channel and thereby drawing some of the liquid into the at least one channel;
detecting for air leaking into the at least one channel.

2. A method according to claim 1 wherein the step of detecting for air leaking into the at least one channel comprises monitoring the pressure within the at least one channel.

3. A method according to claim 2 wherein the pressure is monitored and if it falls below a given amount in a given time period an indication is given that the at least one channel is leaking.

4. A method according to claim 1 wherein the endoscope has at least two channels and where one of the fixtures separates two of the channels from each other and further comprising the step of individually testing each of the two channels whereby to detect gas leaking past the fixture which separates the two channels from each other.

5. A method according to claim 4 wherein if leakage is detected in testing each of the two channels an indication is given that the fixture separating the two channels is leaking.

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6. A method according to claim 1 wherein a first one of the fixtures connects to the second opening and this fixture is exposed to atmosphere, and if leakage of air into the at least one channel is detected an indication is given that first one of the fixtures is leaking. 5
7. A method according to claim 1 wherein if leakage of air into the at least one channel is detected an indication is given to a user that the at least one channel failed the leakage test. 10
8. A method according to claim 7 wherein the indication is provided visually on a screen. 15
9. A method according to claim 1 wherein the first opening is at a distal end of an endoscope.
10. A method according to claim 1 wherein the step of detecting for air leaking into the at least one channel comprises monitoring for air bubbles within the at least one channel. 20
11. A method according to claim 1 wherein the step of detecting for air leaking into the at least one channel comprises monitoring a flow of the liquid through the at least one channels. 25

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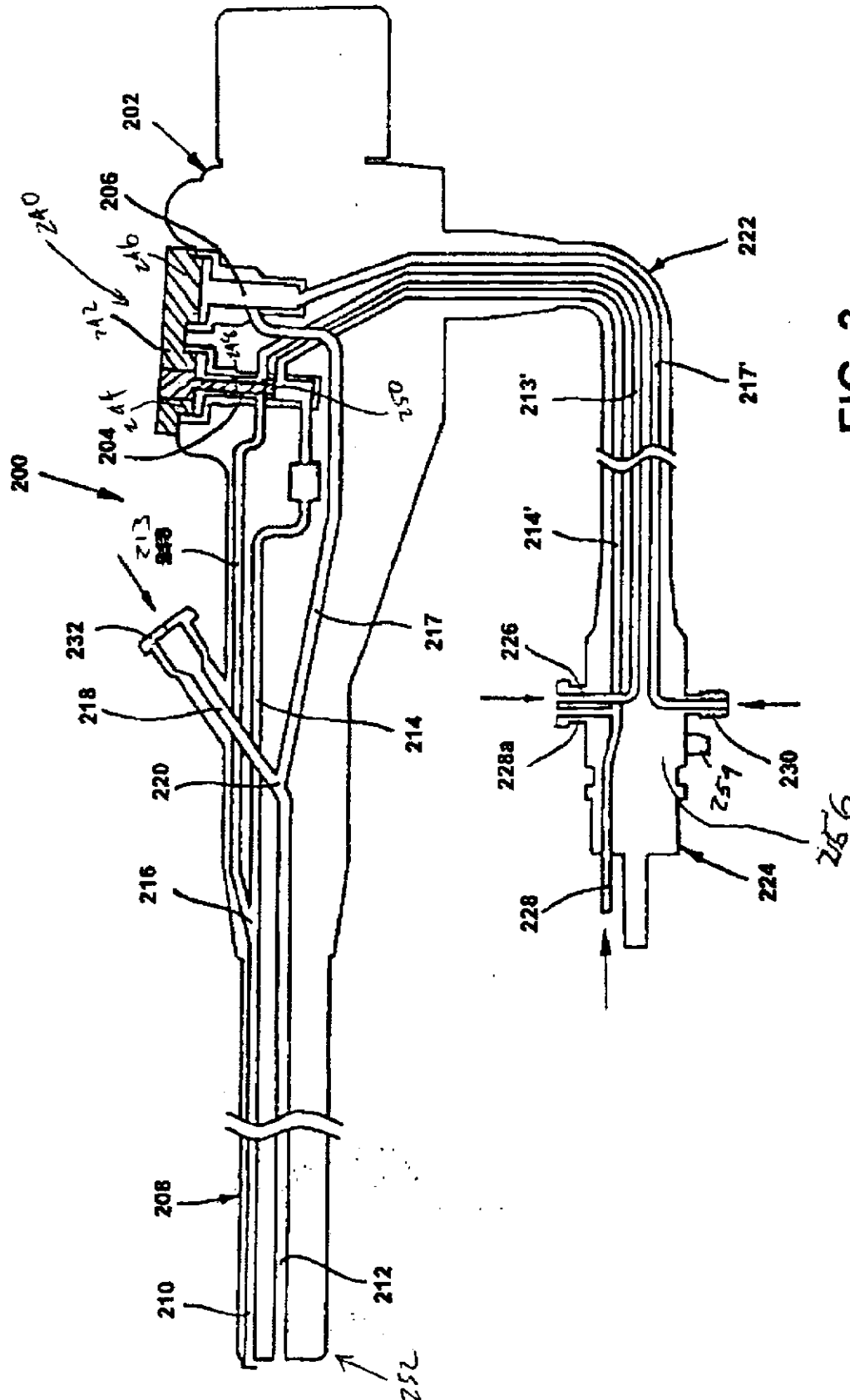


FIG. 3



US006986736B2

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

(10) Patent No.: **US 6,986,736 B2**
(45) Date of Patent: **Jan. 17, 2006**

(54) **AUTOMATED ENDOSCOPE REPROCESSOR CONNECTION INTEGRITY TESTING**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 244 days.

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(57) **ABSTRACT**

A method detects proper connection of fixtures to one or more channels in an endoscope during a cleaning or disinfection procedure. The endoscope has a first opening into one of its channels. The method includes the steps of placing the endoscope at the first opening in a liquid while leaving a gas within the channel, drawing a vacuum on the gas through a second opening into the channel and thereby drawing some of the liquid into the channel, and detecting for air leaking into the channel.

11 Claims, 3 Drawing Sheets

(21) Appl. No.: **10/328,233**

(22) Filed: **Dec. 23, 2002**

(65) **Prior Publication Data**

US 2004 0118413 A1 Jun. 24, 2004

(51) Int. Cl.
A61B 1/00 (2006.01)

(52) U.S. Cl. **600/101; 73/40; 73/1.58**

(58) Field of Classification Search **600/101; 422:3, 28**

See application file for complete search history.

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