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3007/P.

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

Ref.: Expediente No. 06-098.335
Solicitud de Patente a nombre de
Ethicon, Inc.

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Rad: 06-090335 - C3001-0000
Fec: 2008-10-10 14:26:46 Dep. 2620 NUEVAS CREACIONES
Tid: 2 PATENTES
Cve: 1 DEPOSITO
As: 329 CTONTOMAGICH Fobos: 36

Yo, JIMENA ESCOBAR URIBE, identificada como aparece al pie de mi firma, domiciliada en la Carrera 11 A No. 94-76, of. 305, obrando como apoderada de la sociedad Ethicon, Inc., domiciliada en Somerville, New Jersey, Estados Unidos de América, solicitante de la patente de la referencia, atentamente me permito presentar copia certificada de la solicitud de patente número 11/240,060 presentarla en Estados Unidos de América el día 30 de septiembre de 2005, con la debida traducción de lo pertinente.

Señor Superintendente,


JIMENA ESCOBAR URIBE
C.C.39.779.452 de Uraquén
T.P. 68228
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SS

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

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

29 de septiembre de 2006

La presente es para certificar que el anexo es una copia fiel de los registros de la Oficina de Patentes y Marcas de los Estados Unidos, de los documentos de la solicitud de patente identificada más adelante, que cumplieron con los requerimientos para concederse una fecha de presentación de acuerdo con 35 USC 111.

Número de Solicitud: 11/240,060

Fecha de Presentación: 30 de septiembre de 2005

EL CÓDIGO DEL PAÍS Y EL NÚMERO DE SU SOLICITUD DE PRIORIDAD, PARA SER USADA EN LA PRESENTACIÓN EXTRANJERA BAJO EL CONVENIO DE PARÍS ES US11/240,060.

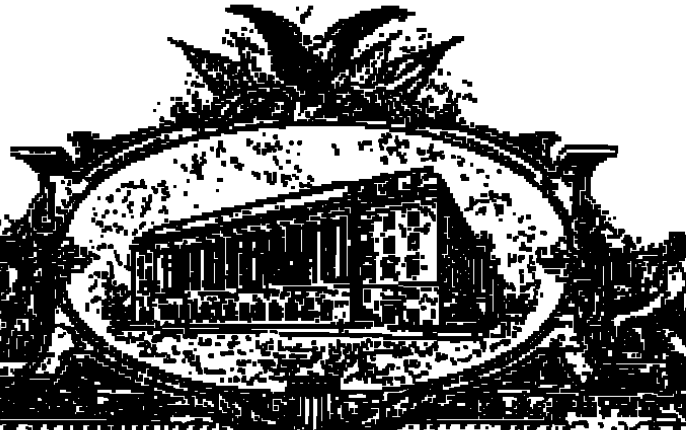
Por la autoridad de
Bajo el Secretario de Comercio para la Propiedad Intelectual y el Director de la
Oficina de Patentes y Marcas de los Estados Unidos de América

(fdo) T. LAWRENCE

Oficial Certificador

Sello oficial de la Oficina de Patentes y Marcas de los
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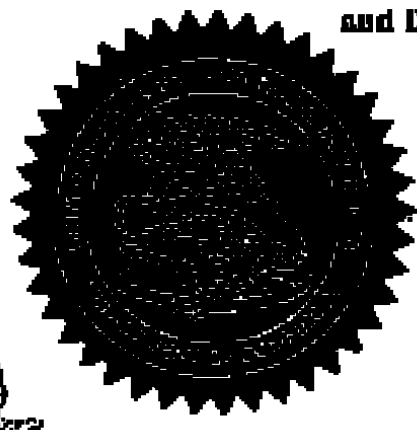
September 29, 2006

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: 11/240,060
FILING DATE: September 30, 2005

THE COUNTRY CODE AND NUMBER OF YOUR PRIORITY APPLICATION, TO BE USED FOR FILING ABROAD UNDER THE PARIS CONVENTION, IS US11/240,060

**By Authority of the
Under Secretary of Commerce for Intellectual Property
and Director of the United States Patent and Trademark Office**



T. Lawrence

T. LAWRENCE
Certifying Officer

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093005

UTILITY
PATENT APPLICATION
TRANSMITTAL

Attorney Docket No.	ASP-5026USNP
Inventors	Richard A. Johnson, Hal Williams
Title	METHOD OF DETECTING CONNECTION OF TEST PORT ON AN OSCilloscope
Express Mail Label No.	EL981541830US

APPLICATION ELEMENTS
See **Chapter 600** concerning utility patent application contents.

ADDRESS TO: Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

- ☒ **Fee Transmittal Form** (e.g., PTO/SB/17) (submit an original and a duplicate for fee processing)
- ☐ Applicant claims small entity status.
- ☒ **Specification** [Total Pages 23] (Prepare attachments set forth below)
 - Descriptive Title of the Invention
 - Cross Reference to Related Applications
 - Statement Regarding Fed sponsored R&D
 - Reference to sequence listing, a table, or a computer program listing appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
- ☒ **Drawing(s)** (35 USC 113) [Total Sheets 3]
- Oath or Declaration** [Total Pages 3]
 - ☒ unexecuted
 - ☐ Copy from a prior application (see 37 CFR 1.53(d)) (for continuation/divisional with Box 18 completed)
 - ☐ **DELETION OF INVENTOR(S)**
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.53(d)(2) and 1.53(b).
- ☐ **Application Data Sheet.** See 37 CFR 1.76

- ☐ **CD-ROM or CD-R** in duplicate, large table or Computer Program (Appendix)
- Nucleotide and/or Amino Acid Sequence Submission** (if applicable, all necessary)
 - ☐ Computer Readable Form (CRF)
 - ☐ Specification Sequence Listing on:
 - ☐ CD-ROM or CD-R (2 copies); or
 - ☐ paper
 - ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

- ☐ Assignment Papers (cover sheet & document(s))
- ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney (when there is an assignee)
- ☐ English Translation Document (if applicable)
- ☐ Information Disclosure Statement (IDS) PTO-1449 ☐ Copies of IDS Citations
- ☐ Preliminary Amendment
- ☒ **Return Receipt Postcard** (MPEP 503) (Should be specifically itemized)
- ☐ Certified Copy of Priority Document(s) (if foreign priority is claimed)
- ☐ Request and Certifications under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/95 or its equivalent.
- ☐ Other

18. ☐ If a CONTINUING APPLICATION, check appropriate box and supply the requisite information below and in a preliminary amendment, or in an Application Data Sheet under 37 CFR 1.76:
☐ Continuation ☐ Divisional ☐ Continuation-in-Part (CIP) of prior application No.: , filed .
Prior application information: Examiner Group Art Unit:
For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

☒ Customer Number or Bar Code Label 880027777 or ☐ Correspondence Address below
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21. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

NAME	Andrew C. Farmer	Reg. No. 35,868
SIGNATURE	/Andrew C. Farmer/	
DATE	September 30, 2005	

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21861 U.S. P.T.O.
093006

FEE TRANSMITTAL

Complete if Known	
Application Number	
Filing Date	September 30, 2005
Inventors	Richard A. Jackson, Paul Williams
Group Art Unit	
Examiner Name	
Attorney Docket Number	ASP-5035USNP

FEE CALCULATION

CLASSES AS FILED

(1)	(2)	(3)	(4)	(5)
FOR:	NUMBER FILED	NUMBER EXTRA	RATE	BASIC FEE \$300.00
TOTAL CLAIMS	14 - 20 =	0	x 50.00	\$ 0.00
INDEPENDENT CLAIMS	1 - 3 =	0	x 200.00	\$ 0.00
SEARCH FEE	NA	NA	NA	\$ 500.00
EXAMINATION FEE	NA	NA	NA	\$ 200.00
APPLICATION SIZE FEE If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.10(a).	0 - 100 =	150	x 250.00 (If the specification and drawings exceed 100 sheets of paper, for each additional 50 sheets or fraction thereof)	\$
MULTIPLE DEPENDENT CLAIMS ☒		N/A	\$300.00	
			TOTAL FEES	\$ 1000.00

METHOD OF PAYMENT

- ☒ Please charge Deposit Account No. 10-0750/ASP-5035USNP/ACF in the amount of \$1,000.00. Three copies of this sheet are enclosed.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required in connection with the filing of this communication, or credit any overpayment, to Account No. 10-0750/ASP-5035USNP/ACF. Three copies of this sheet are enclosed.

SUBMITTED BY:			Complete if applicable
Typed or Printed Name	Andrew C. Farnor		Reg. No. 35,868
Signature	/Andrew C. Farnor/	Date: September 30, 2005	Deposit Account No. 10-0750

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Richard A. Jackson et al.

For : METHOD OF DETECTING CONNECTION OF TEST PORT ON AN
ENDOSCOPE

Express Mail Certificate

"Express Mail" mailing number: HL961541809US

Date of Deposit: September 30, 2005

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

Laurie Phillips

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

/Laurie Phillips/

(Signature of person mailing paper or fee)

**METHOD OF DETECTING CONNECTION
OF TEST PORT ON AN ENDOSCOPE**

5 BACKGROUND OF THE INVENTION

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
10 having channels or lumens that must be decontaminated after use.

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
15 decontamination of these devices between use, both in terms of the speed of the decontamination and the effectiveness of the decontamination.

One popular method for cleaning and disinfection or sterilization of such endoscopes employs an automated endoscope reprocessor which both washes and then
20 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
25 cycle and rinse. Most flexible endoscopes have a flexible sheath, such as polyurethane, which cover its bundles of wires, conduits and fiber optics. It is not desirable to perform a cleaning procedure on the endoscope if its sheath is compromised. Testing for such involves pressurizing the sheath and measuring pressure decay. Such testing might not identify a failed connection at the test port.

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SUMMARY OF THE INVENTION

A method, according to the present invention, during a cleaning procedure of detects proper connection of a test connection to an endoscope port, said port leading to
5 an interior space beneath a sheath on the endoscope. The method comprises the steps of: a) pressurizing an air buffer, which is connected to the endoscope port to a predetermined pressure in excess of a pressure in the interior space; b) isolating the air buffer from the test connection with an isolation valve; c) opening the isolation valve and measuring the pressure of the air buffer; and d) if the pressure in the air buffer has
10 not decreased by a predetermined amount, determining that the test connection is not properly connected to the endoscope port.

Preferably, the volume of the air buffer is between 10% to 300% of the volume of the interior space, more preferably it is between 50% to 200% and most preferably
15 about equal to or between 80% to 120% of the volume of the interior space.

In one aspect of the invention, the air buffer has a fixed volume. Alternatively, it can be variable so that the volume in the air buffer can more closely match the volume in the interior space.
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Preferably, the predetermined amount in step d) is between 9% to 91% of the predetermined pressure, and more preferably between 25% to 75%.

The user can be informed that the test connection is not properly connected to
25 the port.

Preferably, after step d) a leak test is performed on the interior space by measuring pressure degradation therein over time.

30 The air buffer can be pressurized while it is in fluid communication with the interior space and then prior to step c) venting pressure through a vent located between the isolation valve and the test connection. Preferably, after this the interior space is

repressurized to between to a pressure over 240 mbar and then a leak test is performed on the interior space by measuring pressure degradation therein over time.

Step b) can occur prior to step a).

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In one aspect of the invention, a model designation of the endoscope is entered into a control system and wherein that information is verified by comparing the pressure in the air buffer during step d) with a known pressure expected for such model designation.

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BRIEF DESCRIPTION OF THE DRAWINGS

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

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

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

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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

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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

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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 simultaneously or in series. First and second decontamination 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.

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.

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.

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

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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 line 30 is connected. The isolation of each flush line 30 relative to the others allows the particular blocked channel to be easily identified and isolated, depending upon which sensor 42 senses excessive pressure.

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 μ m 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.

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.

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

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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.

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.

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.

Endoscopes and other reusable medical devices often include a flexible outer housing or sheath 102 surrounding the individual tubular members and the like that form the interior channels and other parts of the device. This housing 102 thus forms a closed interior space 104, between it and the interior parts of the endoscope, which is isolated from patient tissues and fluids during medical procedures. It is important that the sheath be maintained intact, without cuts or other holes that would allow contaminants into the interior space 104. The interior space can also be compromised by an internal leak, such as through a cut in an endoscope lumen. Therefore, the decontamination apparatus includes means for testing the integrity of such as sheath.

An air pump, either the pump 38 or another pump 110, pressurizes the interior space 104 through a conduit 112 and a valve 55 and a test connection 106, preferably a flexible tube 108 connects to port 254 which leads to the interior space 104 (see FIG. 3). These structures will be more fully described in the full description of FIG. 3 to follow. Preferably, a filter 113 removes particles from the pressurizing air. An

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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 smooths out pulsation of pressure from the air pump 110.

The air buffer 120 can also be used to determine whether the test connection 106 is properly mated with the port 254. The test connection 106 incorporates a normally closed valve 109 which opens only upon proper connection to the flexible tube 108. If the connection is not made the aforementioned leak determination test will not by itself identify this failed connection. The air buffer 120 would pressurize and no leakage would occur due to the closed valve at the test connection 106. Similarly the port 254 incorporates a normally closed valve which opens only upon proper connection to the tube 108. When both these connections are not properly made the leak test of the interior space 104 may give false results. Unconnected status can be examined by determining whether a volume other than the air buffer 120 is being pressurized.

First the air buffer 120 and interior space 104 are pressurized to a predetermined level, such as 250 mbar. Then valve S5 is closed, thus isolating the air buffer 120 from the test connection 106. Pressure is vented through valve S6, which if the test connection 106 is properly attached should be venting the interior space 104, but if not properly attached this merely vents a portion of the conduit 112. Valve S6 is closed and valve S5 opened to put the test connection 106 back into fluid communication with the air buffer 120. After the pressure settles, it is measured. It should have dropped to a measurable degree through the action of air in the air buffer 120 filling the interior space 104. If however, it drops by a small amount that indicates that air is not flowing into the interior space 104 but is trapped by the valve in the test connection 106. Proper pressures can be easily determined based upon the volume of the air buffer 120 and interior space 104. To accommodate most commercial endoscopes the air buffer 120 should have a volume of between about 20 ml (which is about 10% of small endoscopes) to about 1000 ml (which is about 300% of large endoscopes). Ideally the

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volume should be between about 50% and 200% of the volume of the endoscope and most ideally it would approximate the volume of the endoscope interior space 104. Given the variability in endoscope volumes, the volume of the air buffer can be adjustable, such as by providing multiple air buffers 120 and control valves for each one. Given the starting pressure of 250 mbar, a proper connection should typically result in a final pressure below 190 mbar. Proper pressure for a particular endoscope can be calculated based upon the volumes of the air buffer 120 and endoscope interior space 104. The interconnection piping should be kept to a minimal volume to enhance the accuracy.

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An alternative method to check the proper connection at the test connection 106 is to close valve S5 while pressurizing the air buffer 120, let the pressure settle, and then open valve S5. Accurate pressurization of the air buffer 120 would require a pressure sensor (not shown) at the air buffer 120 so located as to not be blocked by closure of valve S5. Pressure is then checked. If the pressure has not dropped sufficiently it indicates that air is not flowing into the interior space 104, but is instead being blocked at the test connection 106 by the valve 108.

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

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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.

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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

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32 cycles off can also be used to estimate the flow rate, with faster decay rates being associated with higher flow rates.

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 the time and the volume of fluid emptied from the metering tube.

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, 34, 70, 72, 88, 94, 100, 110, the valves S1-S7, and the heater 80 to control these devices for effective decontamination and other operations.

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.

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5 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.

10 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.

15 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.

20 A connection 226 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 226 is in use, connection 228a is closed off. A connection 232 for the biopsy channel 218 is arranged on the head part 202.

25 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 conical insert 248 on the plug member 244 extends inwardly of the opening 204 and terminates in an annular flange 250 which occludes a portion of the opening 204 to separate channel 213 from 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

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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.

The leakage port 254 on the end section 224 leads into the interior portion space 104 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.

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

15 **Step 1. Open the Lid**

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

20 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.

25 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

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 barcode wand (not shown).

Step 4. Close the basin lid

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

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

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.

Once the pressure has stabilized, valve S5 is closed and valve S6 opened to vent pressure from the interior space 104 beneath the sheath 102. Valve S6 is closed and S5 opened. Pressure is allowed to stabilize for one to six seconds and the new pressure is checked. If it is greater than 190 mbar, it is determined that the test connection 106 is not connected properly or at all to the port 254. The cycle is stopped and the user notified of the condition. Assuming proper connection, pressure is then 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.

5 **Step 7. Check Connections**

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

20 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

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

25 **Step 9. Pump water through channels**

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.

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Step 10. Drain

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.

5 Step 11. Blow air through channels

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

- 10 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

- 15 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

- 20 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 three minutes, by the channel pumps 32 and the external circulation pump 70. The inline heater 80 keeps the temperature at about 35 °C.

Step 15. Start block test

- 25 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

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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.

10 Step 16. Drain

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

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

RINSE

Step 18. Fill basin

20 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

25 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.

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Step 20. Continue Block test

5 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 channel, the channel is identified as blocked, the program is stopped, and the user is notified of the condition.

Step 21. Drain

The drain pump is activated to remove the rinse water from the basin and the channels.

Step 22. Blow air

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

Step 23. Repeat rinse

Steps 18 through 22 are repeated to ensure maximum rinsing of enzymatic detergent solution from the surfaces of the endoscope and the basin.

15 DISINFECT

Step 24. Fill basin

20 The basin 14a is filled with very warm water (53 °C). Water temperature is controlled by controlling the mix of heated and unheated water. The water level is detected by the pressure sensor 59. During the filling process, the channel pumps 32 are off in order to ensure that the disinfectant in the basin is at the in-use concentration prior to circulating through the channels.

Step 25. Add disinfectant

25 A measured volume of disinfectant 92, preferably CIDEX OPA orthophalaldehyde concentrate solution, available from Advanced Sterilization Products division Ethicon, Inc., Irvine, CA, is drawn from the disinfectant metering tube 96 and delivered into the water in the basin 14a via the metering pump 100. The

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disinfectant volume is controlled by the positioning of the fill sensor 98 relative to the bottom of the dispensing tube. The metering tube 96 is filled until the upper level switch detects liquid. Disinfectant 92 is drawn from the metering tube 96 until the level of the disinfectant in the metering tube is just below the tip of the dispensing tube. After the necessary volume is dispensed, the metering tube 96 is refilled from the bottle of disinfectant 92. Disinfectant is not added until the basin is filled, so that in case of a water supply problem, concentrated disinfectant is not left on the endoscope with no water to rinse it. While the disinfectant is being added, the channel pumps 32 are off in order to insure that the disinfectant in the basin is at the in-use concentration prior to circulating through the channels.

Step 26. Disinfect

The in-use disinfectant solution is actively pumped throughout the internal channels and over the surface of the endoscope, ideally for a minimum of 5 minutes, by the channel pumps and the external circulation pump. The temperature is controlled by the in-line heater 80 to about 52.5 °C.

Step 27. Flow check

During the disinfection process, flow through each endoscope channel is verified by timing the delivering a measured quantity of solution through the channel. Valve S1 is shut, and valve S7 opened, and in turn each channel pump 32 delivers a predetermined volume to its associated channel from the metering tube 136. This volume and the time it takes to deliver provides a very accurate flow rate through the channel. Anomalies in the flow rate from what is expected for a channel of that diameter and length are flagged by the control system 20 and the process stopped.

Step 28. Continue Block Text

As disinfectant in-use solution is pumped through the channels, the flow rate through the channels is also measured as in Step 15.

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27**Step 29. Drain**

The drain pump 72 is activated to remove the disinfectant solution from the basin and the channels.

Step 30. Blow air

- 5 During the drain process sterile air is blown through all endoscope channels simultaneously to minimize potential carryover.

FINAL RINSE**Step 31. Fill basin**

- 10 The basin is filled with sterile warm water (45 °C) that has been passed through a 0.2 μ filter.

Step 32. Rinse

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

15 **Step 33. Continue Block test**

As rinse water is pumped through the channels, the flow rate through the channels is measured as in Step 15.

Step 34. Drain

- 20 The drain pump 72 is activated to remove the rinse water from the basin and the channels.

Step 35. Blow air

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

END -

Step 36. Repeat rinse

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.

5 FINAL LEAK TEST

Step 37. Pressurize the endoscope body and measure leak rate

Repeat Step 6.

Step 38. Indicate program completion

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

10 Step 39. De-pressurize the endoscope

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

- 15** 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

- 20** 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

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

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
5 both the hardware and software buttons as described in step 4, above.

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
10 construed as including all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.

NOVEDAD DE LA INVENCION**REIVINDICACIONES**

5 1.- Un método durante un procedimiento de limpieza para
detectar la conexión adecuada de una conexión de prueba a un puerto de
endoscopio, conduciendo dicho puerto a un espacio interior debajo de una
funda en el endoscopio, caracterizado porque el método comprende los pasos
de: a) presurizar un amortiguador de aire, el cual está conectado al puerto del
10 endoscopio hasta una presión previamente determinada en exceso de una
presión en el espacio interior; b) aislar el amortiguador de aire de la conexión
de prueba con una válvula de aislamiento; c) abrir la válvula de aislamiento y
medir la presión del amortiguador de aire; d) si la presión en el amortiguador
de aire no ha disminuido en una cantidad previamente determinada,
15 determinar que la conexión de prueba no está conectada en forma adecuada
al puerto del endoscopio.

 2.- El método de conformidad con la Reivindicación 1,
caracterizado además porque el volumen del amortiguador de aire se
encuentra entre el 10% hasta el 300% del volumen del espacio interior.

20 3.- El método de conformidad con la Reivindicación 1,
caracterizado además porque el volumen del amortiguador de aire se
encuentra entre el 50% hasta el 200% del volumen del espacio interior.

4.- El método de conformidad con la Reivindicación 1, caracterizado además porque el volumen del amortiguador de aire se encuentra entre el 80% hasta el 120% del volumen del espacio interior.

5.- El método de conformidad con la Reivindicación 1,
5 caracterizado además porque el amortiguador de aire tiene un volumen fijo.

6.- El método de conformidad con la Reivindicación 1, caracterizado además porque la cantidad previamente determinada en el paso d) se encuentra entre el 9% hasta el 91% de la presión previamente determinada.

10 7.- El método de conformidad con la Reivindicación 6, caracterizado además porque la cantidad previamente determinada en el paso d) se encuentra entre el 25% hasta el 75% de la presión previamente determinada.

8.- El método de conformidad con la Reivindicación 1,
15 caracterizado además porque comprende adicionalmente el paso de informar a un usuario de la determinación de que la conexión de prueba no está conectada en forma adecuada al puerto.

9.- El método de conformidad con la Reivindicación 1, caracterizado además porque comprende adicionalmente presurizar el
20 amortiguador de aire mientras que está en comunicación de fluido con el espacio interior y posteriormente, antes del paso c) descargar la presión a través de un conducto de ventilación localizado entre la válvula de aislamiento y la conexión de prueba.

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10.- El método de conformidad con la Reivindicación 9, caracterizado además porque comprende adicionalmente después del paso d) presurizar nuevamente el espacio interior hasta una presión sobre los 240 mbar y posteriormente realizar una prueba de fuga en el espacio interior
5 midiendo la degradación de presión en el mismo durante el tiempo.

11.- El método de conformidad con la Reivindicación 1, caracterizado además porque después del paso d) se realiza una prueba de fuga en el espacio interior midiendo la degradación de presión en el mismo con el transcurso del tiempo.

10 12.- El método de conformidad con la Reivindicación 1, caracterizado además porque el paso b) ocurre antes del paso a).

13.- El método de conformidad con la Reivindicación 1, caracterizado además porque un modelo de diseño del endoscopio es ingresado en un sistema de control y en donde esa información es verificada
15 comparando la presión en el amortiguador de aire durante el paso d) con una presión conocida esperada para dicho modelo de diseño.

14.- El método de conformidad con la Reivindicación 1, caracterizado además porque comprende adicionalmente el paso de ajustar el volumen del amortiguador de aire antes del paso a) mediante lo cual se hace
20 coincidir de manera más cercana del volumen en el amortiguador de aire con el volumen en el espacio interior.

WHAT IS CLAIMED IS:

1. A method during a cleaning procedure of detecting proper connection of a test connection to an endoscope port, said port leading to an interior space beneath a sheath on the endoscope, the method comprising the steps of:
 - a) pressurizing an air buffer, which is connected to the endoscope port to a predetermined pressure in excess of a pressure in the interior space;
 - b) isolating the air buffer from the test connection with an isolation valve;
 - c) opening the isolation valve and measuring the pressure of the air buffer;
 - d) if the pressure in the air buffer has not decreased by a predetermined amount, determining that the test connection is not properly connected to the endoscope port.
2. A method according to claim 1 wherein the volume of the air buffer is between 10% to 300% of the volume of the interior space.
3. A method according to claim 1 wherein the volume of the air buffer is between 50% to 200% of the volume of the interior space.
4. A method according to claim 1 wherein the volume of the air buffer is between 80% to 120% of the volume of the interior space.
5. A method according to claim 1 wherein the air buffer has a fixed volume.
6. A method according to claim 1 wherein the predetermined amount in step d) is between 9% to 91% of the predetermined pressure.
7. A method according to claim 6 wherein the predetermined amount in step d) is between 25% to 75% of the predetermined pressure.
8. A method according to claim 1 and further comprising the step of informing a user of the determination that the test connection is not properly connected to the port.

9. A method according to claim 1 and further comprising pressurizing the air buffer while it is in fluid communication with the interior space and then prior to step c) venting pressure through a vent located between the isolation valve and the test connection.

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10. A method according to claim 9 and further comprising after step d) repressurizing the interior space to between to a pressure over 240 mbar and then performing a leak test on the interior space by measuring pressure degradation therein over time.

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11. A method according to claim 1 and after step d) performing a leak test on the interior space by measuring pressure degradation therein over time.

12. A method according to claim 1 wherein step b) occurs prior to step a).

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13. A method according to claim 1 wherein a model designation of the endoscope is entered into a control system and wherein that information is verified by comparing the pressure in the air buffer during step d) with a known pressure expected for such model designation.

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14. A method according to claim 1 and further comprising the step of adjusting the volume of the air buffer prior to step a) whereby to more closely match the volume in the air buffer to the volume in the interior space.

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ABSTRACT

5 A method detects proper connection of a test connection to an endoscope port which leads to an interior space beneath a flexible sheath on an endoscope. Both the interior space and an air buffer are pressurized and then isolated from each other. Pressure in the interior space is vented and the isolation is removed. After the pressure settles out the new pressure is compared with the first pressure. If it has not dropped substantially it is determined that the test connection is not properly attached and the interior space is in fact not being pressurized.

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PTO/SB/01 (10-03)

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DECLARATION
AND
POWER OF ATTORNEY
FOR UTILITY OR DESIGN
PATENT APPLICATION
(37 CFR 1.53)

☒ Declaration Submitted with
Initial Filing OR ☐ Declaration Submitted after
Initial Filing (Surcharge
(37 CFR 1.16(a)) required)

Attorney Docket Number

ASP-5035USNP

First Named Inventor

Richard A. Jackson

COMPLETE IF KNOWN

Application Number

Filing Date

September 30, 2005

Group Art Unit

Examiner Name

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if
plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention
entitled:

METHOD OF DETECTING CONNECTION OF TEST PORT ON AN ENDOSCOPE
(Title of the Invention)

the specification of which

☒ is attached hereto

OR

☐ was filed on (MM/DD/YYYY) as United States Application Number or PCT International Application Number
 and was amended on (MM/DD/YYYY)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as
amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for
continuation-in-part applications, material information which became available between the filing date of the prior application
and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or
inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the
United States of America, listed below and have also identified below, by checking the box, any foreign application for patent
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priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			☐ ☐ ☐	☐ ☐ ☐	☐ ☐ ☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/026 attached hereto;

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DECLARATION - Utility or Design Patent Application		
I hereby claim the benefit under 35 U.S.C. 119(g) of any United States provisional application(s) listed below.		
Application Number(s)	Filing Date (MM/DD/YYYY)	☐ Additional provisional application numbers are listed on a supplemental priority data sheet (PDS) attached hereto.
I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.58(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.		
Application Serial No.	Filing Date	Status
		Patented Patented Patented
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NAME OF SOLE OR FIRST INVENTOR:		☐ A petition has been filed for this unsigned inventor	
Given Name (First and middle (if any)) Richard A.		Family Name or Surname Jackson	
Inventor's Signature		Date	
Residence: City Huntington Beach	State CA	Country USA	Citizenship Canadian
Mailing Address 3972 Sparler Drive			
City Huntington Beach	State CA	ZIP 92649	Country USA
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.			
NAME OF SECOND INVENTOR:		☐ A petition has been filed for this unsigned inventor	
Given Name (First and middle (if any)) Hal		Family Name or Surname Williams	
Inventor's Signature		Date	
Residence: City San Clemente	State CA	Country USA	Citizenship USA
Mailing Address 1223 Lions			
City San Clemente	State CA	ZIP 92673	Country USA
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NAME OF THIRD INVENTOR:		☐ A petition has been filed for this unsigned inventor	
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FIG. 1

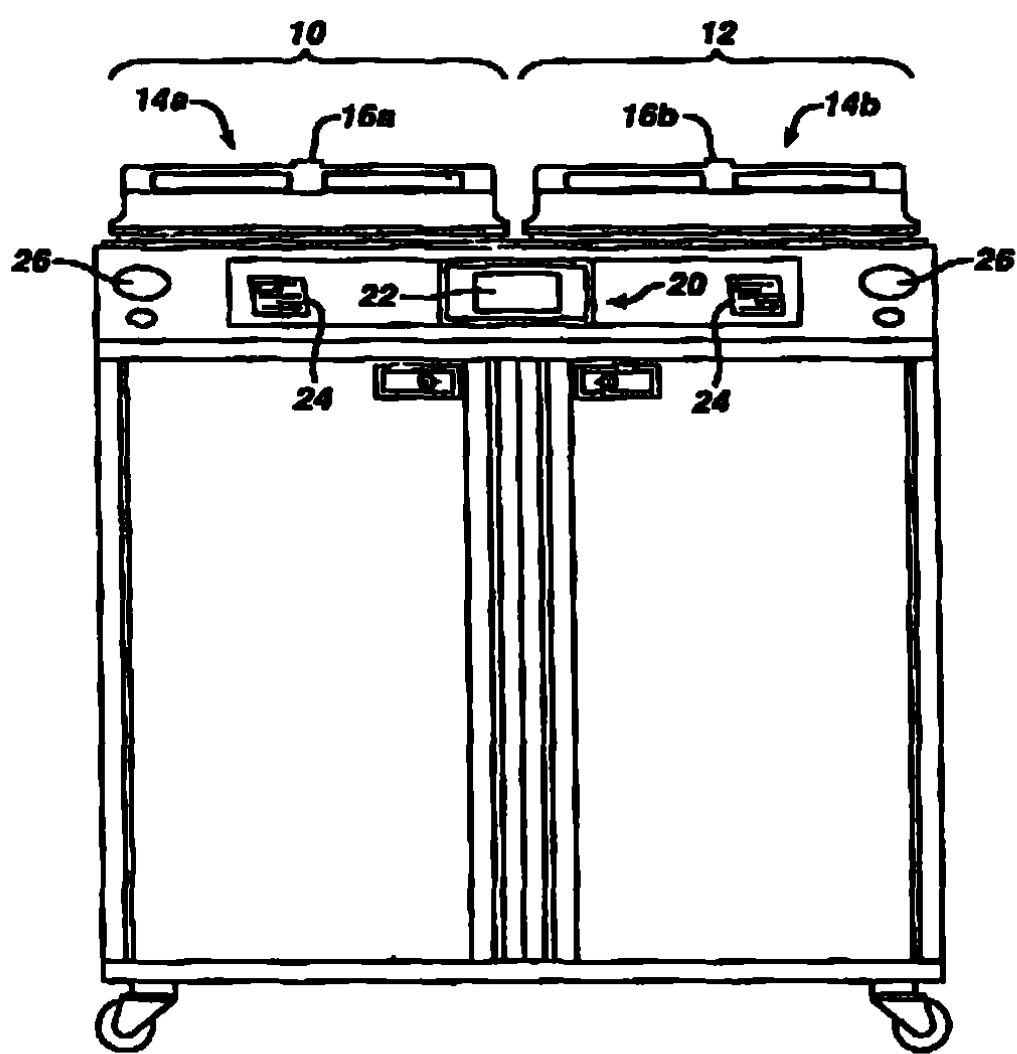
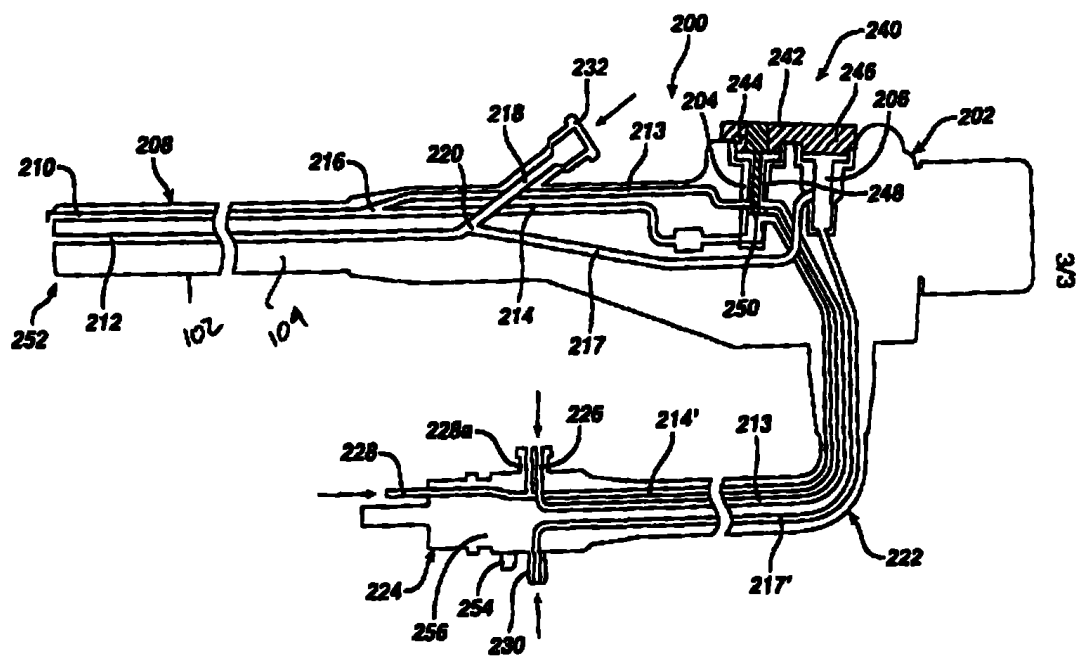


FIG. 3



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