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(54) **DISINFECTANT TRANSFER SYSTEM**

(52) **U.S. CL. 137/212**

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(57) **ABSTRACT**

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A disinfectant transfer system, which is essentially vapor tight, for transferring toxic and/or noxious fluid from a container to a reservoir without releasing fumes including: a transfer cap for securing onto a mouth of a container containing toxic and/or noxious fluid, the transfer cap having a first opening for letting a gas in through a valve, the transfer cap further having a second opening for allowing toxic and/or noxious fluid to be forced out of the container when the toxic and/or noxious fluid is displaced by the gas entering through the first opening, the gas forces the toxic and/or noxious fluid within the container to enter and flow through a first conduit, which is connected to the bottom of the second opening and leads to the bottom of the container, and to continue to flow through a second conduit which is connected to the top of the second opening and leads to a reservoir into which the toxic and/or noxious fluid can enter.

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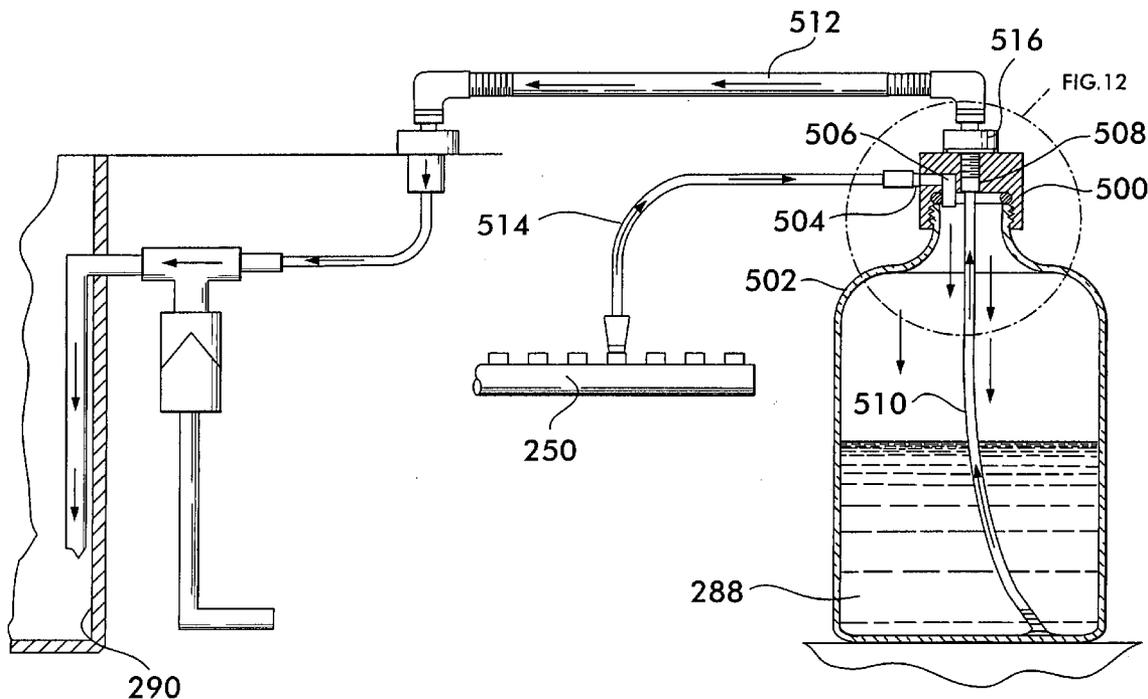
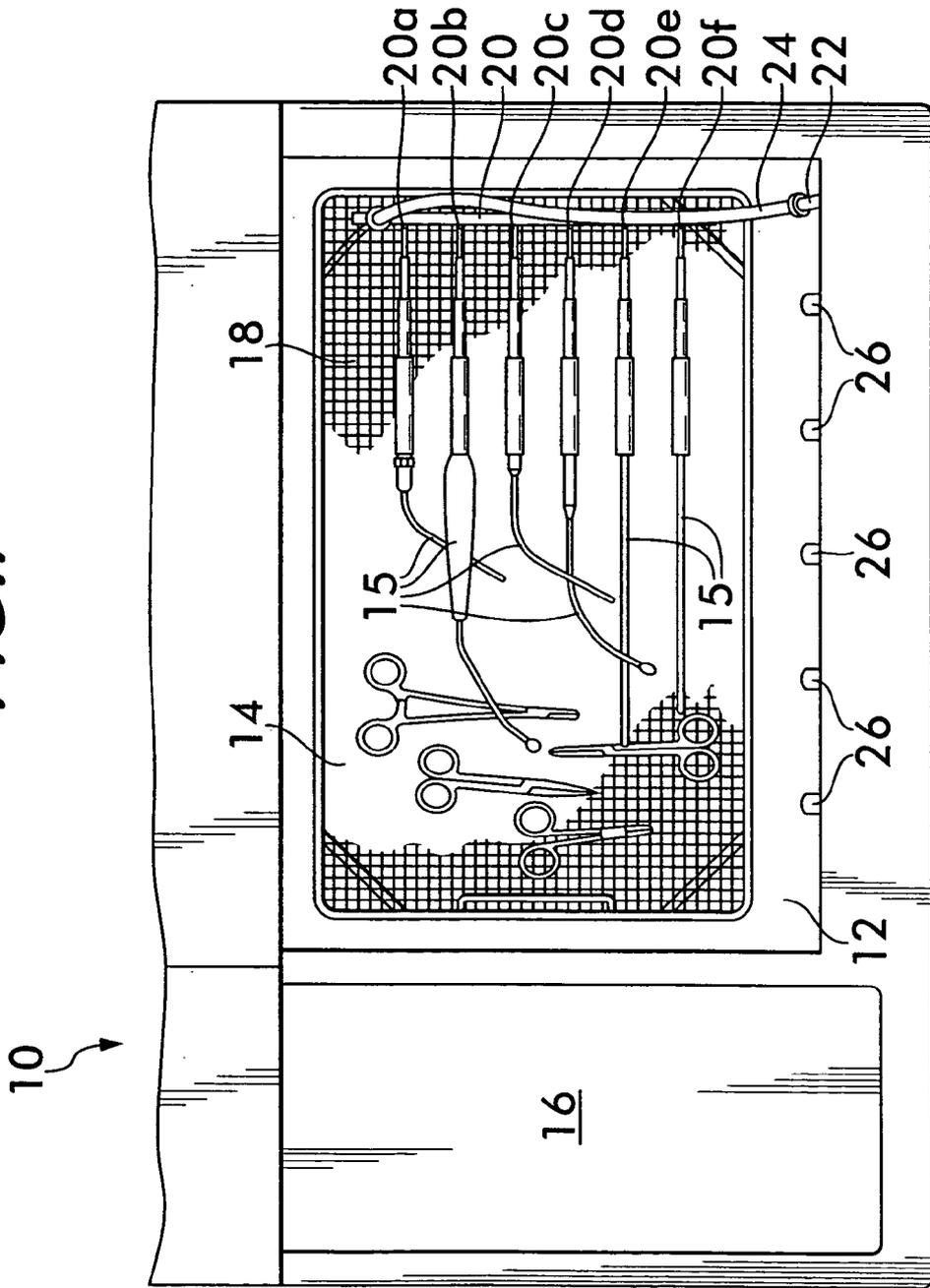
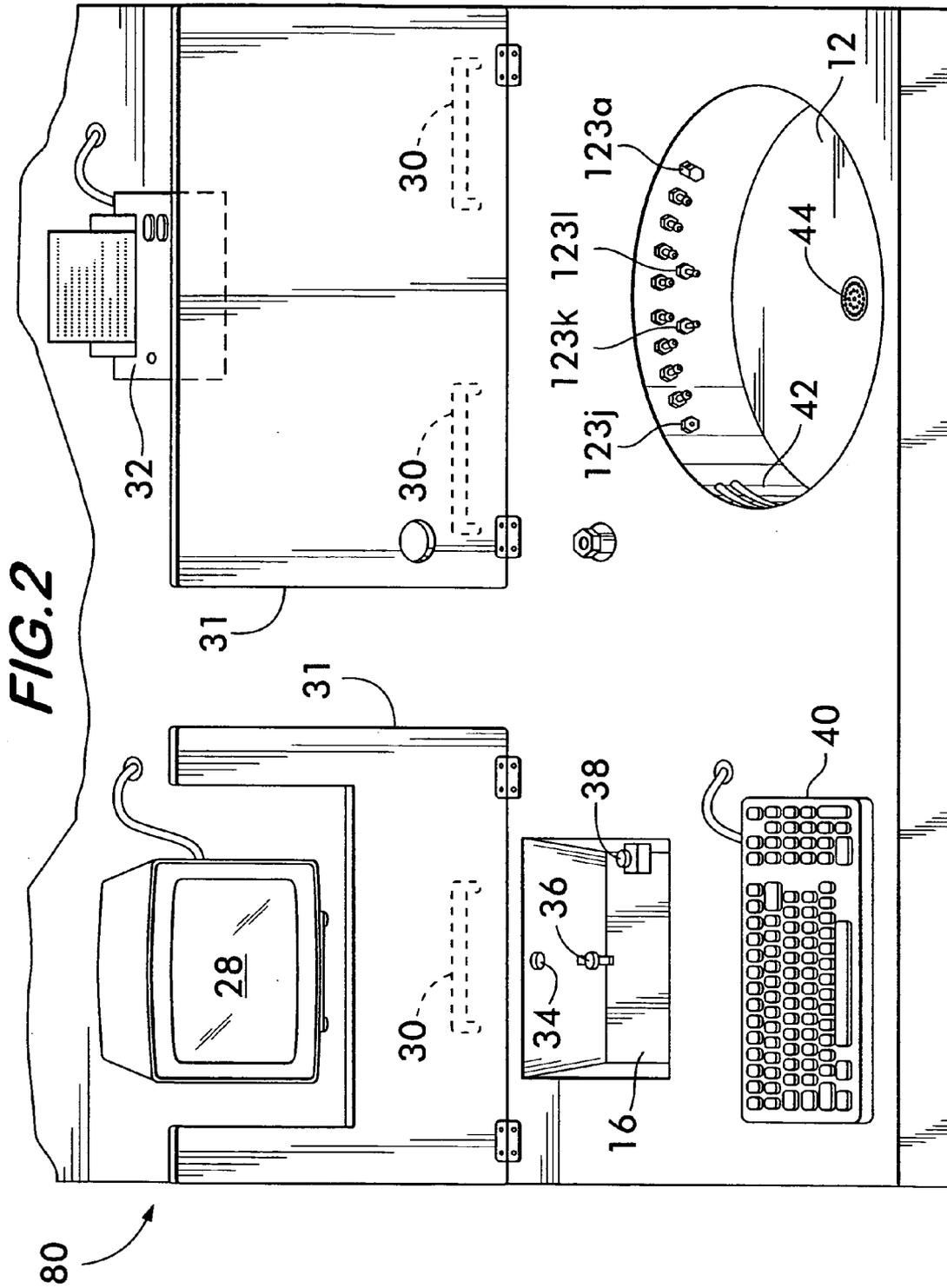


FIG. 1





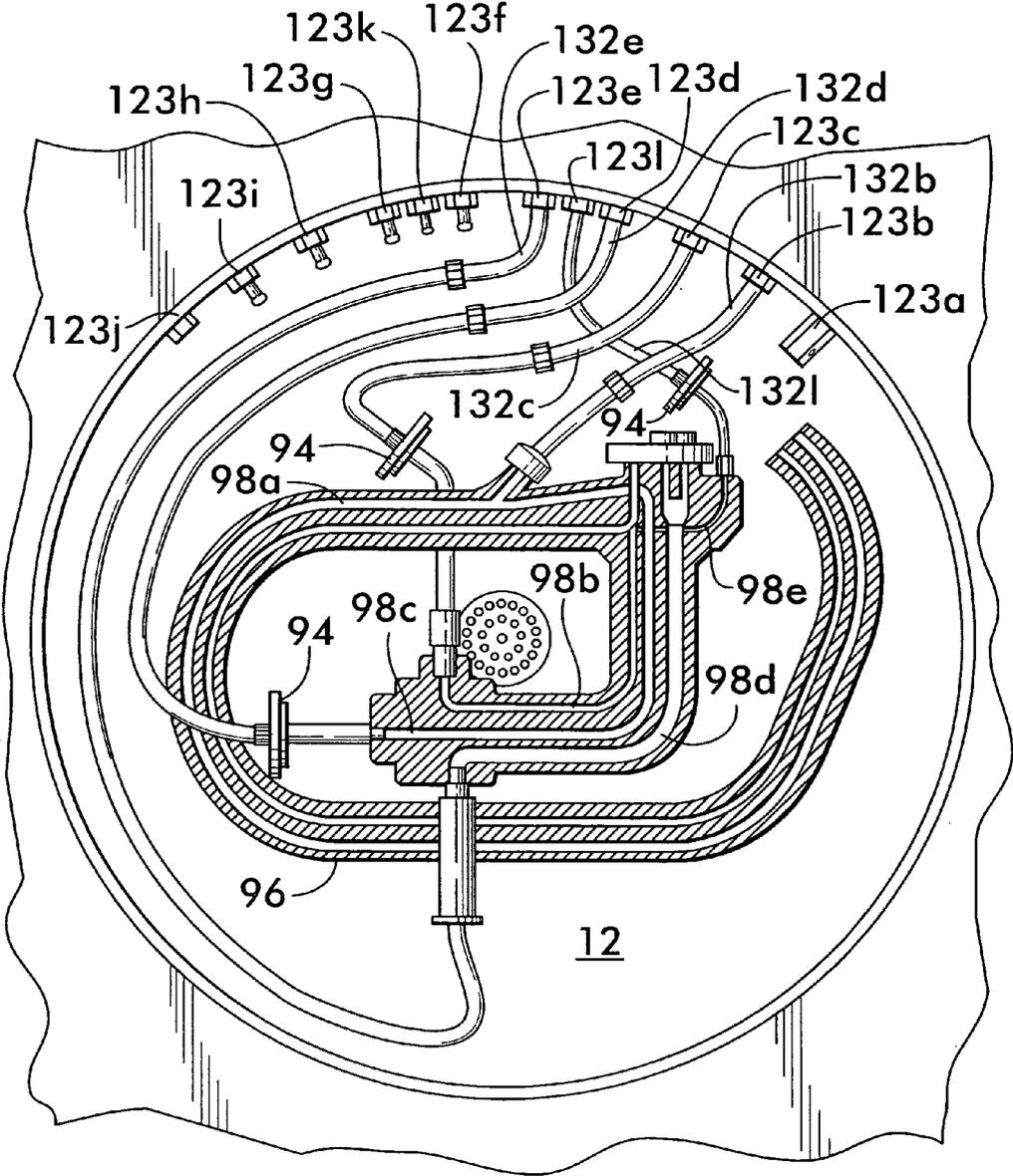


FIG. 3

FIG. 4A

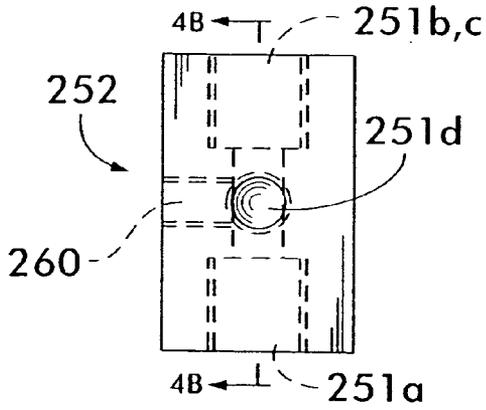


FIG. 4B

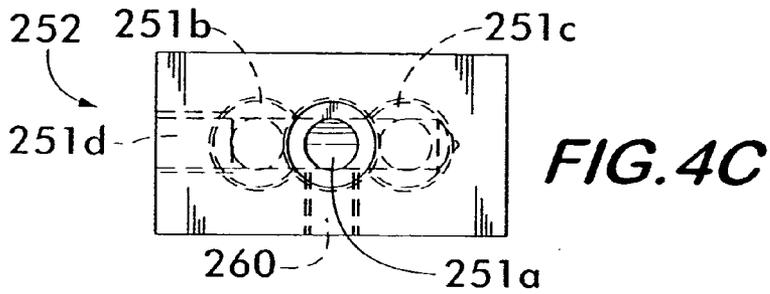
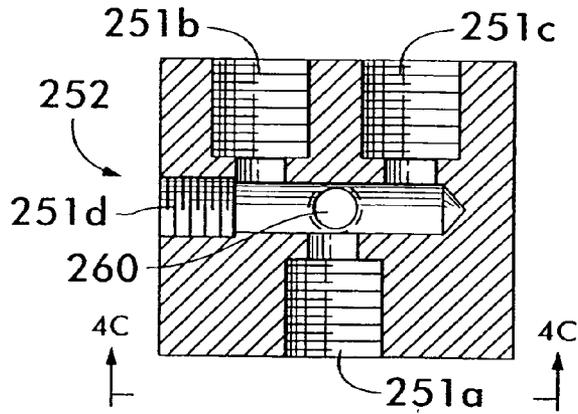


FIG. 4C

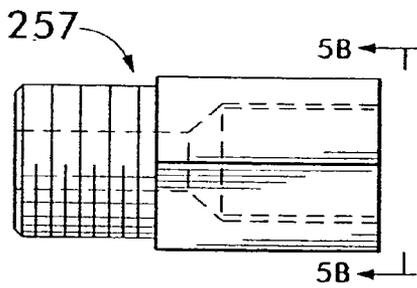


FIG. 5A

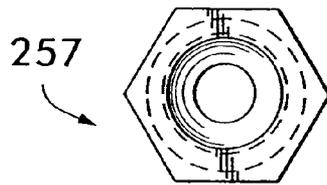


FIG. 5B

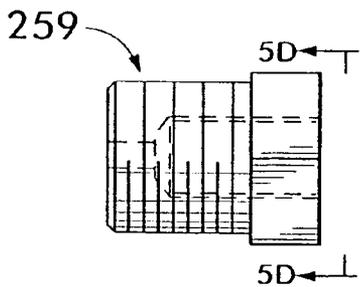


FIG. 5C

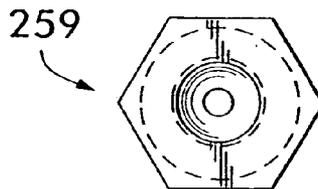


FIG. 5D

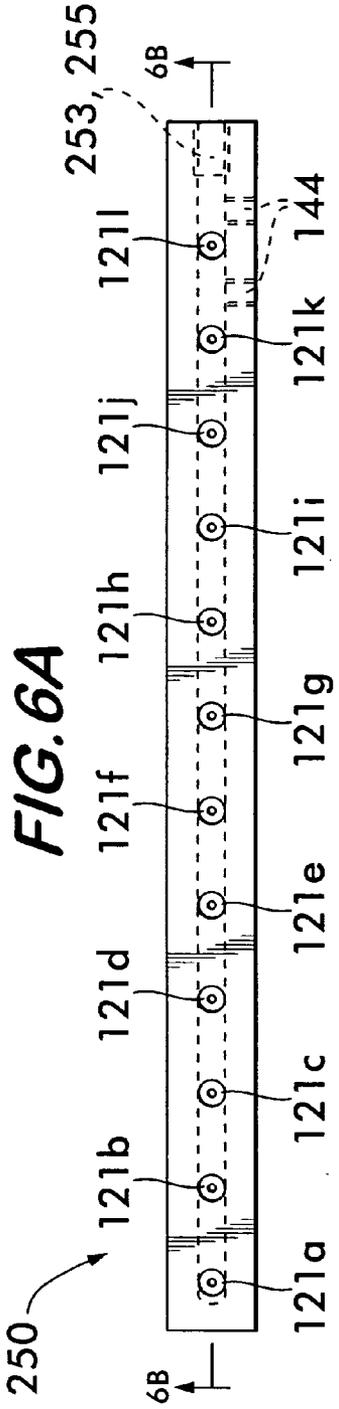


FIG. 6C

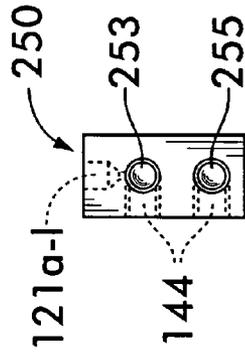
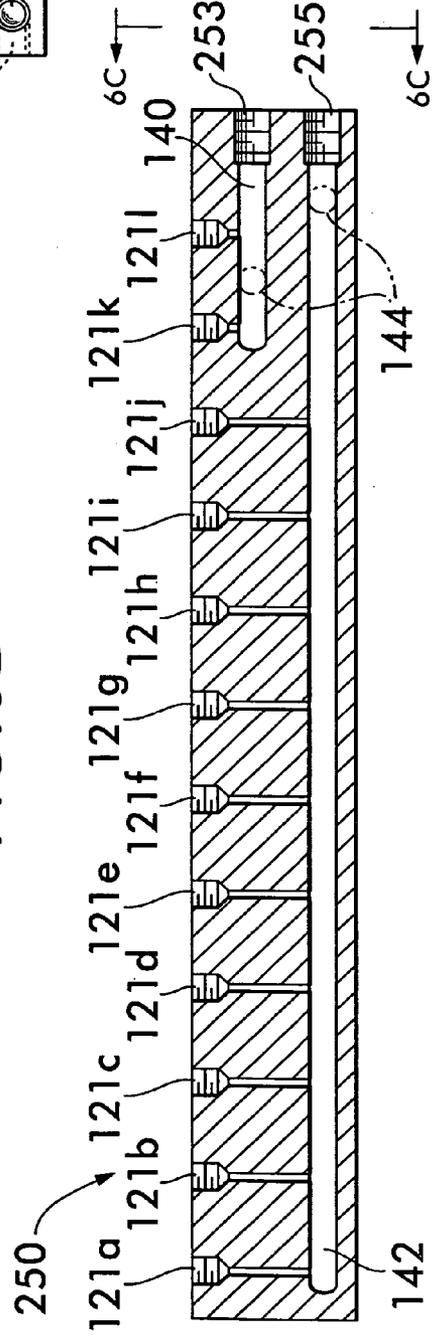


FIG. 6B



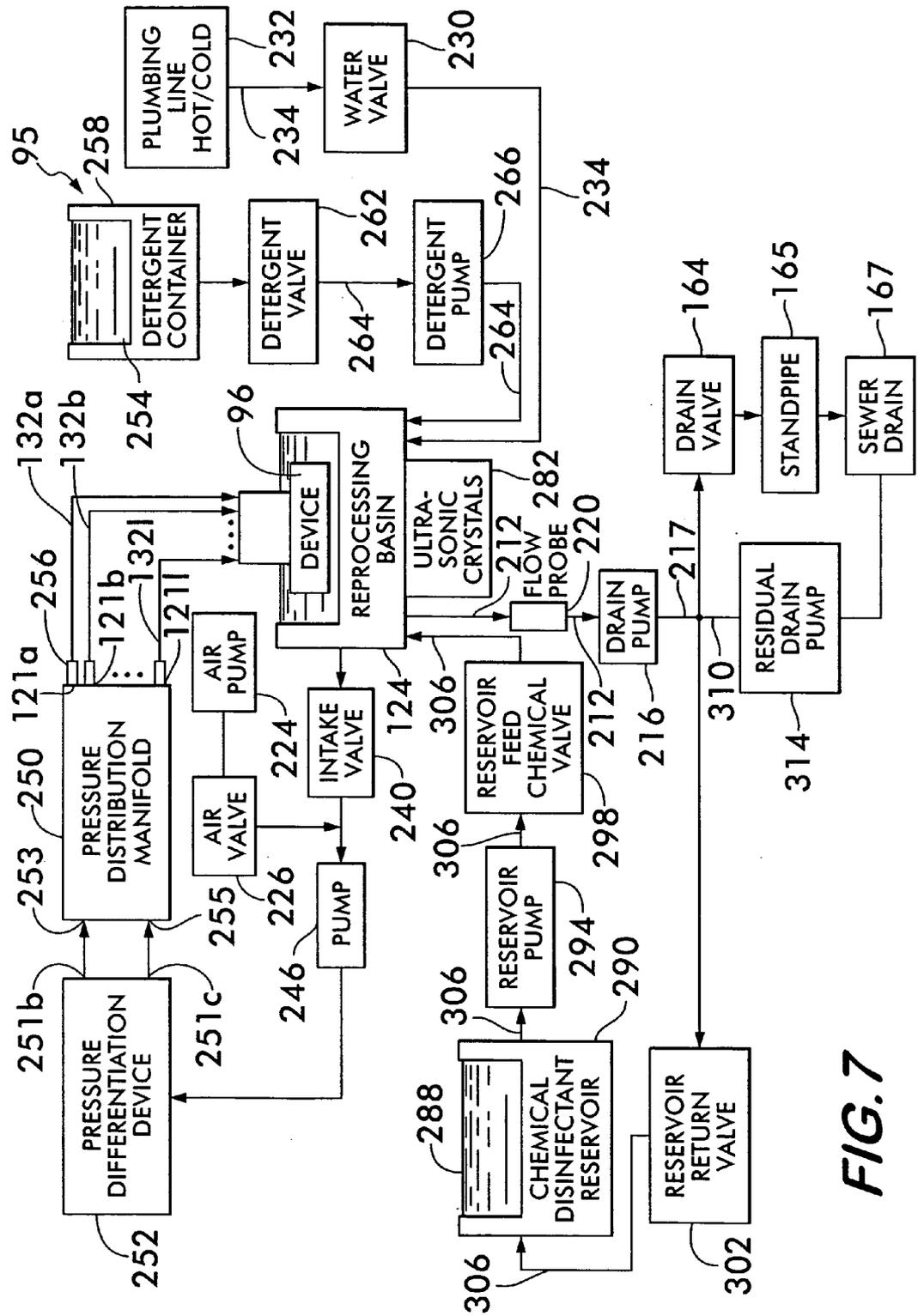


FIG. 7

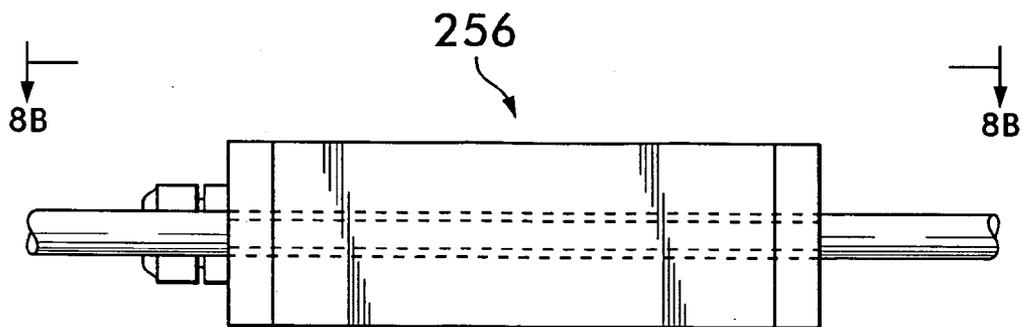


FIG. 8A

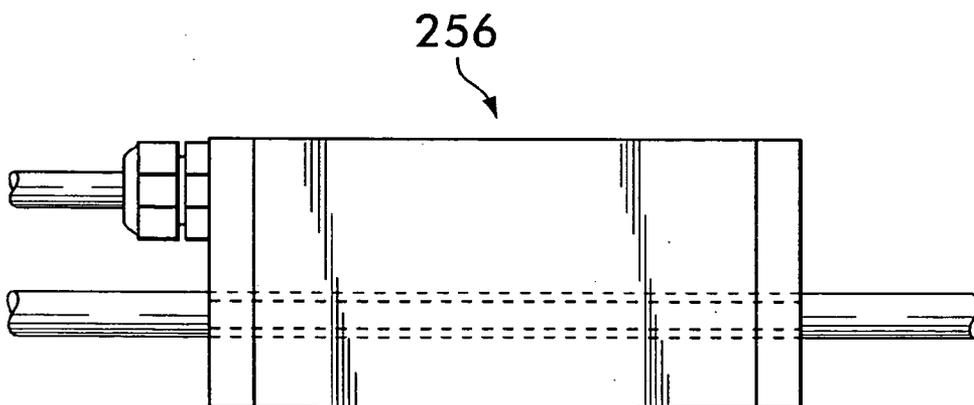


FIG. 8B

FIG. 9A

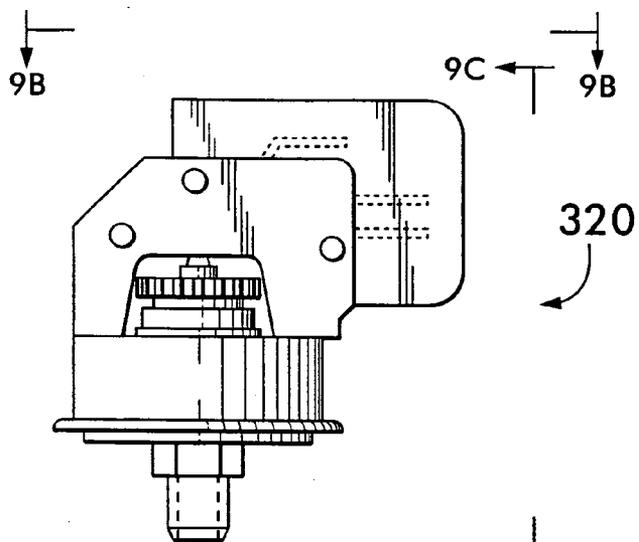


FIG. 9B

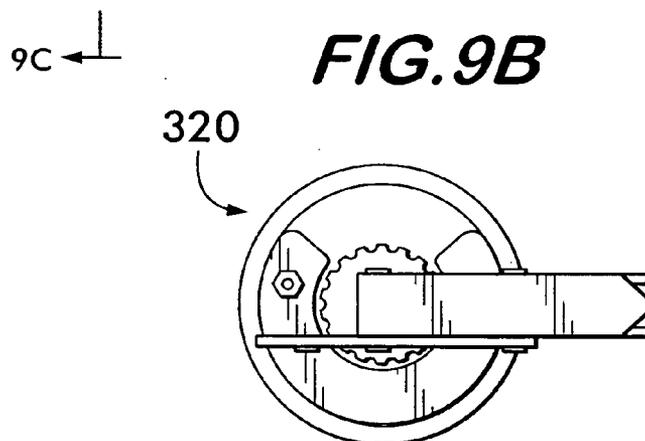


FIG. 9C

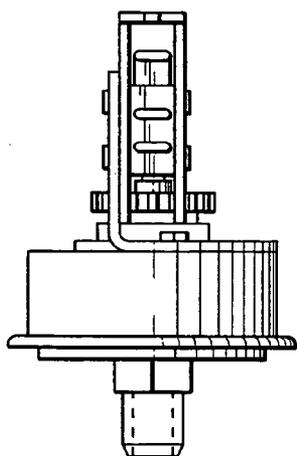
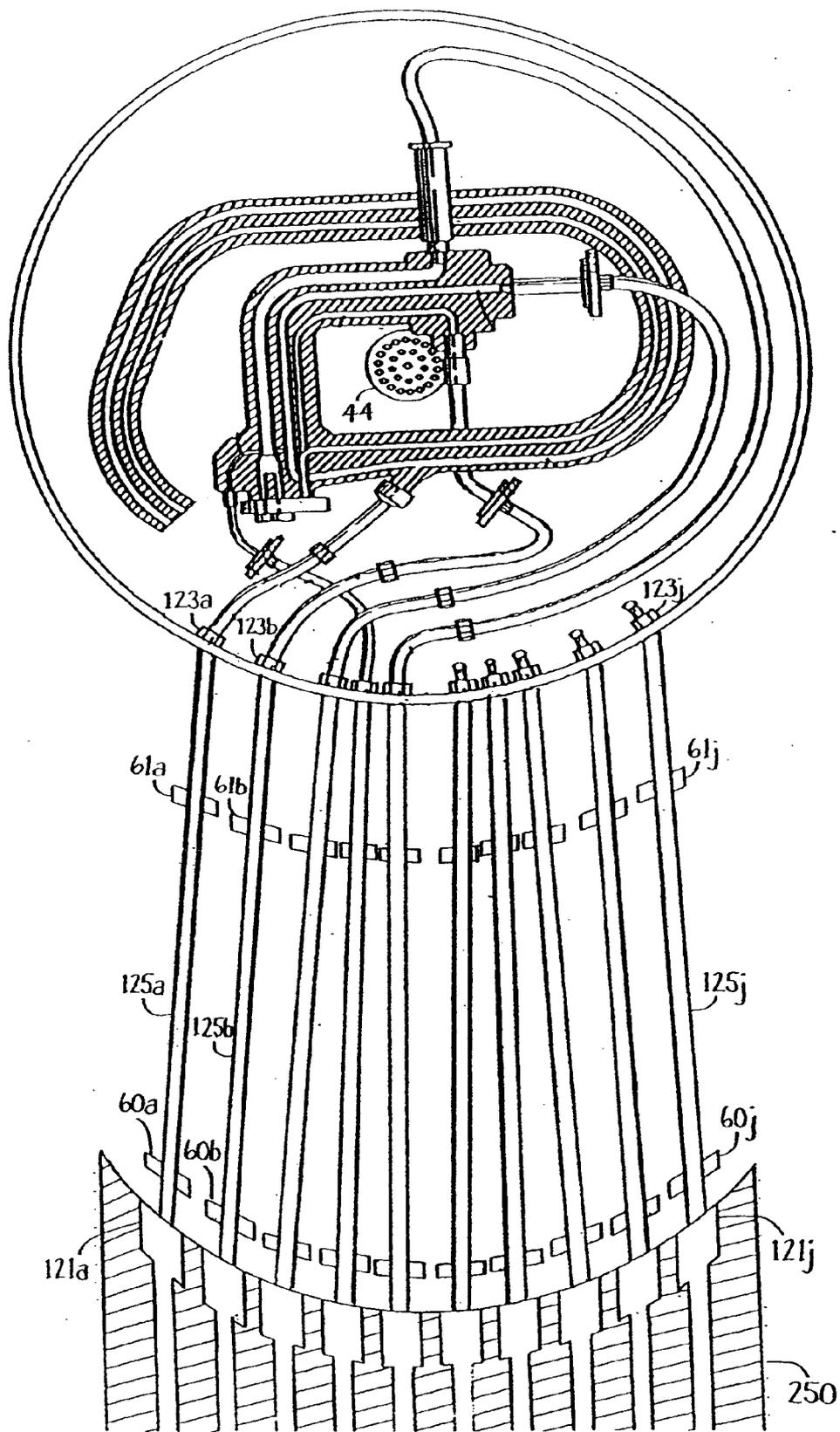
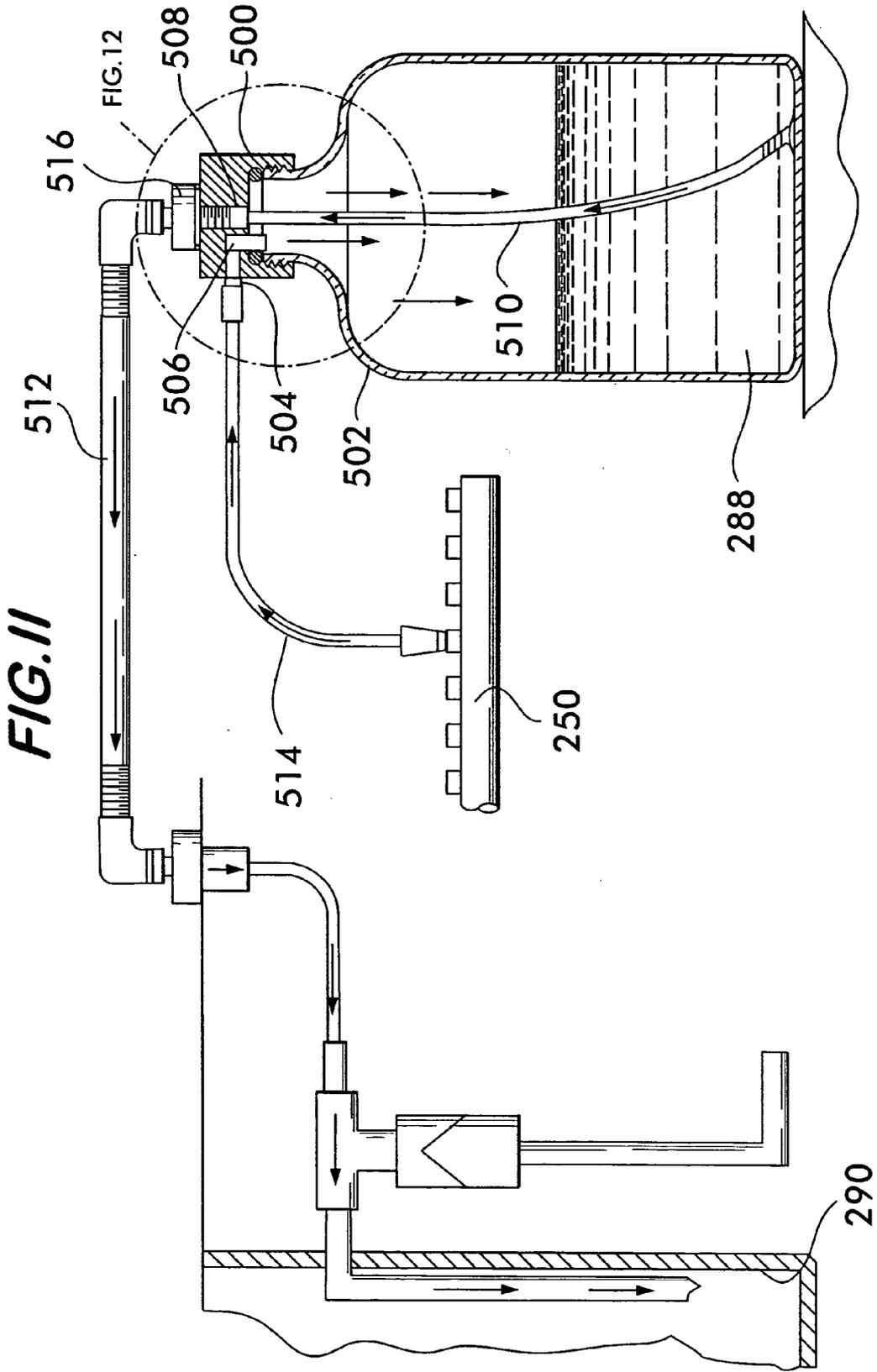
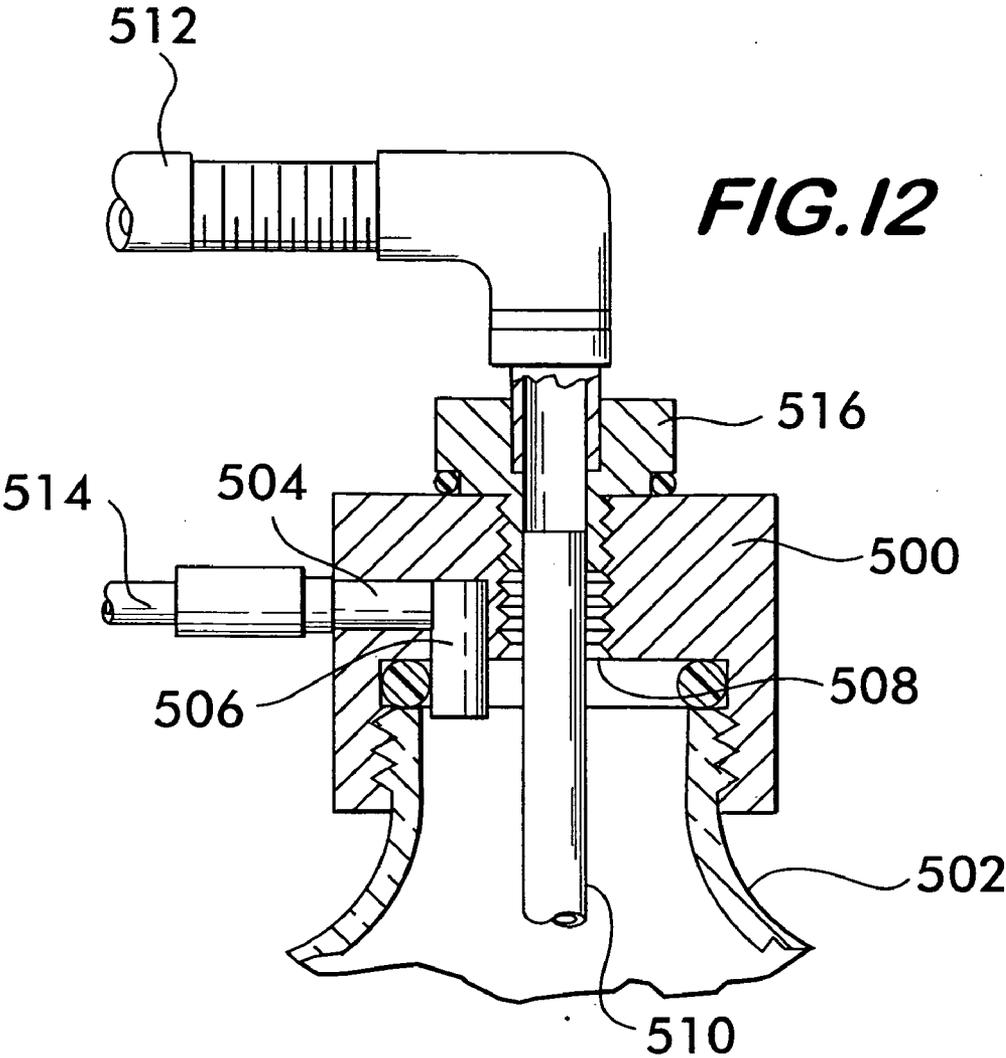


Fig. 10







DISINFECTANT TRANSFER SYSTEM

BACKGROUND OF THE INVENTION

[0001] 1. Field of Invention

[0002] This invention relates generally to a system and method for the reprocessing of a contaminated device having internal passageways before such a device is reused in a clean environment.

[0003] 2. Description of Related Art

[0004] Automated systems for reprocessing devices having internal passageways for reuse are generally available and are commonly relied upon. For example, systems for reprocessing medical instruments having passageways are used by hospitals to safeguard patients and hospital employees from exposure to infection and cross-contamination. Such prior art reprocessing units are manufactured by several different companies including, Custom Ultrasonics, Inc., of Ivyland, Pa., the assignee of the present invention and application. For example, there are reprocessing units in the prior art adapted for cleaning, disinfecting and sterilizing flexible scopes, e.g., upper and lower gastrointestinal scopes, colonoscopes and duodoscopes.

[0005] The term “reprocessing,” as used herein constitutes the washing, disinfecting, sterilizing and/or pasteurizing of such a device. The term “device” as used herein constitutes any devices having internal passageways that require such reprocessing, including, but not limited to, medical instruments and medical devices. The terms “medical instrument” and “medical device” are understood to constitute devices having one passageway or a plurality of passageways, including, but not limited to endoscopes, colonoscopes, and other flexible and rigid medical instruments.

[0006] Prior art reprocessing systems, suitable in particular for reprocessing medical instruments, operate in accordance with a predetermined protocol of reprocessing steps. The protocol is based upon the specific cleaning requirements of the particular instruments being cleaned. The reprocessing steps are precisely timed and sequenced in order to assure optimal results, based upon the correct combination of water temperature, detergent and chemical agents.

[0007] Thus, parameters such as wash and rinse cycle time, chemical immersion cycle time, and water temperature and pressure were preset by the reprocessing unit manufacturer and could not be altered by an end user of the system. U.S. Pat. No. 5,761,069, issued to Weber, et. al., teaches a system for cleaning medical instruments having a database of protocols corresponding to differing medical instruments for permitting a user to load and execute the protocol corresponding to the instrument being reprocessed.

[0008] An exemplary protocol for cleaning a medical instrument could include the following reprocessing steps, after the instrument has been placed in the cleaning basin of the reprocessing unit: (1) wash the internal and external surfaces of the instrument with a measured detergent-water mixture for a preset period of time; (2) activate ultrasonic crystals while washing; (3) drain the detergent-water mixture after the wash cycle is completed; (4) after draining, rinse the internal and external surfaces of the instrument with water at a preset temperature for a preset period of time;

(5) introduce and circulate disinfectant over and through the instrument for a preset period of time; (6) drain the disinfectant from the wash basin; and (7) after draining of the disinfectant is complete, rinse the instrument with water; and (8) re-rinse the instrument with water.

[0009] Prior art reprocessing units adapted, in particular, for reprocessing medical equipment, typically comprise a variety of mechanical components, e.g., pumps, tubes, solenoid valves, ultrasonic transducers, heaters and probes that perform the various reprocessing steps. The pumps used in these units must be very precise and reliable over extended periods of time. Thus, pumps that are suitable for these units can be quite expensive.

[0010] In many cases it is necessary to reprocess devices having passageways of differing diameters. The differing diameters can occur in a single device having passageways of differing diameters, or in multiple devices, each having passageways of differing diameters. The presence of differing diameter passageways creates a need for fluid flows of corresponding differing pressures, because more narrow passageways require a higher pressure to force fluid there-through. Prior art reprocessing units suitable for reprocessing devices having passageways of differing diameters included a plurality of pumps and associated tubing systems, wherein each pump provided one of the differing pressures required to reprocess the differing passageways of the devices.

[0011] Furthermore, some devices can have extremely narrow passageways, requiring dedicated high-pressure pumps that are capable of providing extremely high pressures. Pumps for such extremely narrow, high-pressure passageways have very low flow rates. Flow rates that are this low are difficult to monitor. For example, the flow rates of fluids through the passageways of some devices can be on the order of a drop a minute. Passageways this narrow can be found, for example, in flexible medical instruments, such as endoscopes.

[0012] Known reprocessing units are typically equipped with a pressure sensor for measuring the overall flow of fluid through the pump for the purpose of detecting obstructions in the passageways of the devices. However, is possible for an obstruction preventing flow of in one of the passageways to go undetected by the pressure sensor since the flow can continue through the remaining passageways and only the overall pressure of the liquid is determined.

[0013] Several governmental and independent agencies have issued guidelines for reprocessing particular types of medical instruments. For example, such guidelines often require that certain types of medical instruments be washed and sterilized using a chemical disinfectant, while other types of instruments need only be washed. The design of reprocessing units and the reprocessing steps they perform must conform to such guidelines. Additionally, guidelines have been created to reliably prevent instruments from being reused if an obstruction occurs in a single passageway of a plurality of passageways during reprocessing. Prior art reprocessing units are not reliably able to meet these guidelines.

[0014] Chemical disinfectants useful for reprocessing medical instruments or devices include glutaraldehyde or ortho-phthalaldehyde (OPA). One particularly effective type

of chemical disinfectant is 2% or 3% glutaraldehyde which is marketed by a number of different companies under various brand names such as Cidex manufactured by Johnson & Johnson. However such disinfectants are dangerous to handle because they can cause asthma, headaches, or hives, or maybe be sensitizing or carcinogenic. Typically workers handling such disinfectants pour them into a reservoir where the disinfectant can then be used to reprocess medical instruments or devices. Pouring, however, is disadvantageous because it may result in spilling or splashing of the disinfectant. The spilled or splashed disinfectant may get onto a worker or may fall onto a floor and be missed thereby causing a hazard. Additionally, noxious and/or toxic fumes are given off by the disinfectants when they are poured. Because of the danger such fumes pose they need to be controlled. The fumes are very heavy and tend to fall. Use of a vent overhead of the reservoir would not be useful because it would pull the fumes into a worker's face, and fumes from spilled or splashed disinfectant would likely be missed. Moreover, expensive equipment would be needed for the vent to work since it would have to be articulated to the area of the reservoir.

[0015] In addition to pouring, it is also known to pump rather than to displace the chemical disinfectant. However, a problem with pumping the liquid is that not all of it is removed. The push of pump acting on a liquid leaves some liquid in the conduits through which the liquid passes and this liquid will fall back into bottle once the pump is turned off.

[0016] While applicant is aware that devices for displacement of liquid with a gas, e.g. air, are known in the prior art, such devices are not suitable for situations in which there is a danger posed by toxic and/or noxious fumes. Nor do such devices involve the transfer of toxic and/or noxious liquid. See for example, U.S. Pat. Nos. 349,598, 2,628,744, 4,619,072, 4,676,404, 5,299,608, 5,893,385, 6,341,628, and 6,435,379.

[0017] The present invention would result in essentially no fumes being released when the disinfectant is transferred from a bottle to a reservoir. Thus resulting in increased safety and eliminating any need to exhaust outside.

[0018] All references cited herein are incorporated herein by reference in their entireties.

BRIEF SUMMARY OF THE INVENTION

[0019] A disinfectant transfer system, which is essentially vapor tight, for transferring toxic and/or noxious fluid from a container to a reservoir without releasing fumes including: a transfer cap for securing onto a mouth of a container containing toxic and/or noxious fluid, the transfer cap having a first opening for letting a gas in through a valve, the transfer cap further having a second opening for allowing toxic and/or noxious fluid to be forced out of the container when the toxic and/or noxious fluid is displaced by the gas entering through the first opening, the gas forces the toxic and/or noxious fluid within the container to enter and flow through a first conduit, which is connected to the bottom of the second opening and leads to the bottom of the container, and to continue to flow through a second conduit which is connected to the top of the second opening and leads to a reservoir into which the toxic and/or noxious fluid can enter.

BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWINGS

[0020] The invention will be described in conjunction with the following drawings in which like reference numerals designate like elements and wherein:

[0021] FIG. 1 is a top plan view of a prior art reprocessing unit wherein the cover of the reprocessing unit is disposed in an opened position to permit a view of a reprocessing basin containing devices to be reprocessed.

[0022] FIG. 2 is an elevational view of a reprocessing unit suitable for use with the system and method for reprocessing of a device.

[0023] FIG. 3 shows a top view of the reprocessing basin of the reprocessing unit of FIG. 2 including a device to be reprocessed.

[0024] FIGS. 4A-C show top, front and plan views of the pressure differentiation device of the reprocessing unit of FIG. 2.

[0025] FIGS. 5A-D are front and side views of the pressure control devices of the pressure differentiation manifold of FIGS. 4A-C.

[0026] FIGS. 6A-C show top, front and plan views of the pressure distribution manifold of a system for reprocessing of a device.

[0027] FIG. 7 shows a schematic block diagram illustrating the process flow of the operations performed by the reprocessing unit of FIG. 2.

[0028] FIGS. 8A-B show top and front views of a flow-meter of a system for reprocessing of a device.

[0029] FIGS. 9A-C show top, front and plan views of a pressure sensor of a system for reprocessing of a device.

[0030] FIG. 10 shows a top view of an embodiment of a system for reprocessing of a device, with a distribution manifold with pressure sensors mounted at two points of the flow path on each output port of the distribution manifold.

[0031] FIG. 11 is a view of a disinfectant transfer system according to the present invention.

[0032] FIG. 12 is a cross-sectional blow-up view of the transfer cap shown in FIG. 11 according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0033] Referring now to the drawings, wherein like reference numerals refer to like parts, there are shown representations of reprocessing systems and methods suitable for using conventional reprocessing protocols to reprocess devices having internal passageways, such as medical instruments. An example of such a reprocessing protocol is disclosed in U.S. Pat. No. 5,761,069, issued to Weber, et. al., which is incorporated by reference herein.

[0034] FIG. 1 shows a top view of a prior art reprocessing unit 10, wherein a cover (not shown) is disposed in an open position. The reprocessing unit 10 includes a reprocessing basin 12, the instrument carrier 14, and a chemical disinfectant reservoir 16. The instrument carrier 14 is shown seated within the reprocessing basin 12. The instrument

carrier 14 can be generally rectangular in shape and comprises a mesh-like bottom 18 which is arranged to hold the surgical instruments 15 during reprocessing, wherein the surgical instruments 15 each include a single passageway therethrough requiring reprocessing. The reprocessing basin 12 is also provided with a plurality of spray nozzles 26 for use during the rinse cycle.

[0035] The instrument carrier 14 includes a manifold assembly 20 having a plurality of ports 20a-f, each of which is shown applied to an internal passageway of a respective surgical instrument 15. In order to reprocess the surgical instruments 15 having a single passageway within the reprocessing unit 10, the surgical instruments 15 are disposed on the instrument carrier 14 for coupling to the ports 20a-f. Since the surgical instruments 15 have a single passageway, only a single one of the ports 20a-f is required for each surgical instrument 15. The manifold assembly 20 is connected to a port 22 by means of a tubing segment 24, which conducts fluid flow from the port 22 to the manifold assembly 20 for distribution by way of the ports 20a-f.

[0036] The fluid flow of the port 22 is driven by an oscillating pump (not shown). The oscillating pump operates to draw fluid, e.g., wash water, rinse water or chemical disinfectant, from the reprocessing basin 12, circulate that fluid through the ports 20a-f and the manifold assembly 20, and through the respective passageways of the surgical instruments 15 disposed on the instrument carrier 14, to effect the decontamination process during the wash, rinse and chemical immersion phases of the reprocessing protocol.

[0037] In this manner, the pressure delivered to each of the passageways of the surgical instruments 15 can be substantially equal in the reprocessing unit 10. Reprocessing unit 10 is thus suitable for reprocessing a plurality of surgical instruments 15 requiring such a single pressure to be applied to all of the passageways of the surgical instruments 15. However, many surgical instruments are provided with passageways of differing diameters. Such surgical instruments require differing pressures, corresponding to the differing diameters, for providing the required circulation of wash water, rinse water and chemical disinfectants through the passageways.

[0038] Referring now to FIGS. 2, 3, there is shown a reprocessing unit 83 suitable for use with the system and method for reprocessing of a device, and a view of a reprocessing basin 12 within the reprocessing unit 83. The reprocessing basin 12 holds a device 96 having internal passageways 98a-e for reprocessing of the device 96 by the reprocessing unit 83. In a preferred embodiment, the device 96 being reprocessed by the reprocessing unit 83 can be a medical instrument 96. In particular, the system and method for reprocessing of a device are well suited for application to medical instruments including flexible scopes such as endoscopes that are used for upper and lower gastrointestinal studies.

[0039] The reprocessing unit 83 includes a keyboard 40, a monitor 28, a printer 32, and an associated personal computer (not shown) for permitting a user of the reprocessing unit 83 to communicate with and control the reprocessing unit 83. The reservoir 16 of the reprocessing unit 83 includes the sensors 34, 36, 38 for controlling devices such as a heater, a pump and a vacuum device (not shown) in order to

protect against failure conditions such as overflow conditions in the reservoir 16. A removable door 42 within the reprocessing basin 12 covers additional sensors (not shown) for providing further operational capability and safety protection during the operation of the reprocessing unit 83. The door stops 30 are provided to stop the motion of the rotatable doors 31 covering the reservoir 16 and the reprocessing basin 12 when they are opened.

[0040] In the preferred embodiment, the reprocessing basin 12 can hold more than one device 96 upon a mesh for reprocessing of the internal passageways 98a-e thereof according to conventional reprocessing protocols. The reprocessing unit 83 is adapted to provide fluid flows of differing pressures to the device 96 or devices 96 being reprocessed when the internal passageways 98a-e have differing diameters. The reprocessing unit 83 is adapted to perform the multi-pressure reprocessing operations using a single pump (not shown), and to provide an indication of an obstruction in any of the internal passageways 98a-e of the device or devices 96 as described in more detail below. The single pump of the reprocessing unit 83 can be a diaphragm pump, an oscillating pump, or any other type of pump known to those skilled in the art. Alternatively, the reprocessing unit 83 can be adapted to perform the multi-pressure reprocessing operations using more than one pump. These pumps could supply pressurized fluid flows of differing pressures to the inputs ports 253, 255 of the pressure distribution manifold 250.

[0041] The reprocessing basin 12 includes the supply ports 123a-l that can be selectively used to apply fluids at different fluid flow rates to the medical instruments 96 for reprocessing of the medical instruments 96. For example, the supply port 123j can be capped and reserved for use when needed. The supply port 123a can be used to blow off a fluid flow which is unusable due to difficulty in regulating and measuring their flow rates, as described in more detail below. In this example, at least the supply ports 123a-l that are not capped or blown off can be vented into the reprocessing basin 12 or coupled to the internal passageways 98a-e of a medical instrument 96 as needed.

[0042] For example, an internal biopsy passageway 98a of the medical instrument 96 can be coupled to the supply port 123b by way of the tubing segment 132b, and an internal water channel passageway 98b of the medical instrument 96 can be coupled to the supply port 123c by way of the tubing segment 132c. The internal passageway 98c can be coupled to the supply port 123d by way of the tubing segment 132d, and the internal suction passageway 98d can be coupled to the supply port 123e by way of the tubing segment 132e. The internal elevator water channel passageway 98e can be coupled to the supply port 123f by way of the tubing segment 132f.

[0043] The fluid applied in the reprocessing method can be either liquid or gas. Gases that are used for the reprocessing of a medical device include, but are not limited to, ethylene oxide, hydrogen peroxide, and plasma gases.

[0044] The disk filters 94 and their tubing extensions can be disposed in line with the selected passageways 98a-e for preventing debris from reaching the medical instrument 96. For example, the disk filters 94 can be provided in the tubing segments 132c,d,e. The device for coupling the selected tubing segments 132a-l to the tubing extensions of the disc

filters as shown can be the well known lure lock type of coupling. Typical diameters for some of the passageways 98a-e can be 0.508 millimeters to 4.8 millimeters.

[0045] Referring now to FIGS. 4A-C, there is shown a pressure differentiation device 252 for providing fluid flows of differing pressures from the output of a single conventional pump that provides a single pump output pressure. It is the different output pressures at the output of the pressure differentiation device 252 that are applied by way of the selected supply ports 123a-l to the internal passageways 98a-e of the medical instrument 96 for reprocessing the medical instrument 96 or any other device 96 having such passageways 98a-e. The single pump applied to the pressure differentiation device 252 can be a conventional diaphragm type pump, an oscillating pump, or any other type of pump known to those skilled in the art. The pressure differentiation device 252 can be a conventional T-manifold that is known to those skilled in the art.

[0046] The single pump output pressure is applied to the pressure differentiation device 252 at an input port 251a for application to the two output ports 251b,c of the pressure differentiation device 252. The output ports 251b,c threadably receive and secure different pressure control devices which can have openings of different diameters, as described in more detail below. The pressure control devices secured in the output ports 251b,c permit the pressure differentiation device 252 to provide two different pressures for the internal passageways 98a-e of the medical instruments 96. In the preferred embodiment the output port 251b can be a high pressure output port and the output port 251c can be a low pressure output port.

[0047] In a typical embodiment, the higher pressure of the high pressure output port 251b of the pressure differentiation device 252 can be approximately 25 to 50 pounds per square inch. The lower pressure of the low pressure output port 251c can be approximately 2 to 20 pounds per square inch. The pressures at the output ports 251b,c can fluctuate within these ranges depending on factors such as the number of medical instruments 96 coupled to the reprocessing unit 83. It will be understood by those skilled in the art that a pressure differentiation device 252 having additional output ports with different pressure control devices can be used for reprocessing systems 83 requiring more than two differing pressures.

[0048] Referring now to FIGS. 5A-D, there are shown the pressure control devices 257, 259 of the pressure differentiation device 252 for providing the two different pressures to the internal passageways 98a-e of the medical instrument 96. The pressure control devices 257, 259 can be conventional pressure control orifice fittings 257, 259 that are threadably received and secured in the output ports 251b,c of the pressure differentiation device 252. The two different pressures are provided at the output ports 251b,c when a single pressure is applied to the input port 251a of the pressure differentiation device 252 because of the different diameters of the openings within the pressure control orifice fittings 257, 259. The pressure control orifice fitting 257 is a high pressure orifice fitting and the pressure control orifice fitting 259 is a low pressure orifice fitting.

[0049] In the preferred embodiment, the pressure differentiation device 252 can be formed with an entrance 260 for permitting an FDA approved liquid chemical sterilant as

well as alcohol to be injected into the fluid stream passing through the device 252 for transmission through the selected supply ports 123a-l of the reprocessing basin 12 to the medical instruments 96. A disinfectant injection bulkhead communicating with the entrance 260 can be located on the exterior of the reprocessing unit 83 for convenience. Additionally, a filter (not shown) can be disposed in a conduit from the pump to the input port 251a of the device 252 for filtering fluid in transit to the internal passageways 98a-e. The filter can be, for example, a one-hundredth micron filter.

[0050] Referring now to FIGS. 6A-C, there are shown representations of the pressure distribution manifold 250 of the reprocessing unit 83, including the manifold input ports 253, 255, and the manifold output ports 121a-l. The pressure distribution manifold 250 can be a conventional air manifold understood by those skilled in the art. It is adapted to receive the fluid flows of the two different pressures from the output ports 251b,c of the pressure differentiation device 252 by way of the manifold input ports 253, 255. The fluid flows from the pressure distribution manifold 250 are applied by way of the manifold output ports 121a-l directly to the corresponding supply ports 123a-l of the reprocessing unit basin 12. Therefrom, they are selectively applied to the devices 96 such as the medical instruments 96. In the preferred embodiment, the manifold output ports 121a-j are low pressure ports and the manifold output ports 121k,l are high pressure ports.

[0051] A high pressure fluid flow is received at the high pressure manifold input port 253 of the pressure distribution manifold 250 from the orifice port 251b of the pressure differentiation device 252. A short longitudinal bore hole 140, opening at the high pressure manifold input port 253, is provided at one end of the pressure distribution manifold 250. The pressure distribution manifold 250 is bored transversely from each of the high pressure manifold output ports 121k,l to the longitudinal high pressure bore hole 140 in order to permit the high pressure output ports 121k,l to communicate with the high pressure bore hole 140. Thus, a high pressure fluid flow applied to the input port 253 of the pressure distribution manifold 250 is distributed to the high pressure, or narrower inner diameter, passageways of the medical instruments 96 by way of the high pressure bore hole 140 and the manifold output ports 121k,l.

[0052] A low pressure fluid flow is received at the low pressure input port 255 of the pressure distribution manifold 250 from the output port 251c of the pressure differentiation device 252. A long longitudinal bore hole 142, opening at the low pressure manifold input port 255, is provided within the pressure distribution manifold 250. Substantially as described with respect to the high pressure output ports 121k,l, transverse bore holes extending from the low pressure output ports 121a-j to the longitudinal low pressure bore hole 142 are provided. Thus, the low pressure manifold output ports 121a-j communicate with the low pressure bore hole 142. In this manner, a low pressure fluid flow applied to the low pressure input port 255 of the pressure distribution manifold 250 is distributed to the low pressure passageways of the medical instruments 96 by way of the low pressure bore hole 142 and the manifold output ports 121a-j.

[0053] Those skilled in the art will understand that possible turbulence at the distal end of the pressure distribution manifold 250, in the region of the manifold output port 121

a can make the flow rates difficult to measure and/or difficult to control. Therefore, in the preferred embodiment, the fluid flows provided by way of the supply port **123a** can be blown off into the reprocessing basin **12**, rather than applied to a medical instrument **96**.

[0054] The pressure measurement openings **144** on the side of the pressure distribution manifold **250** individually communicate with the longitudinal bore holes **140,142**. The presence of the pressure measurement openings **144** on the pressure distribution manifold **250** permits measurement of the pressures within the bore holes **140, 142**, as described in more detail below.

[0055] Referring now to FIG. 7, there is shown a block diagram representation of a process flow **95** for performing a reprocessing protocol within the reprocessing unit **83** suitable for reprocessing devices such as the medical instruments **96**. During a fill step of the process flow **95**, a solenoid-type water valve **230** is placed in an open position to enable water to flow from an outside hot/cold water source **232** through a water line **234**, into the reprocessing basin **12** to immerse the medical instrument **96**. The reprocessing basin **12** is provided with a drain **44** (shown in FIG. 2) located in the bottom of the reprocessing basin **12**. The drain **44** is connected to a drain line **212**. During the fill step, as wash water flows into the reprocessing basin **12** it begins to drain through the drain line **212**. A drain valve **164**, provided below the drain line **212** is normally in a closed state to prevent the draining of the water out of the system. This action enables the filling of the reprocessing basin **12**.

[0056] A flow probe **220** is located adjacent the drain line **212** and is operative to detect the presence of liquid as wash water begins to fill the drain line **212** during filling of the reprocessing basin **12**. Once the probe **220** detects the presence of moisture, the probe **220** sends a signal indicative thereof to a system controller which provides an indication to the user that the reprocessing basin **12** is filling with water. Additionally, an operational float (not shown) is located within the reprocessing basin **12**. During filling, the operational float is buoyed upwardly and eventually reaches a predetermined height corresponding to a particular volume of wash water being present in the reprocessing basin **12**. When the operational float reaches this predetermined level, the reprocessing unit **83** indicates to the user that the reprocessing basin **12** has been filled and that the washing step can begin. Thereafter, the water valve **230** is closed so that no additional wash water enters the reprocessing basin **12**.

[0057] As wash water fills into the reprocessing basin **12** over the immersed medical instruments **96**, a solenoid-type detergent valve **262** and a detergent pump **266** operate to withdraw a predetermined amount, e.g., three ounces, of detergent **254** from a detergent container **258** located adjacent the reprocessing unit **83** and inject the predetermined amount of detergent into the reprocessing basin **12** through a detergent line **264**. The detergent **254** may be of any suitable composition. One particularly effective type of detergent is sold under the trademark TERGAL 800 by Custom Ultrasonics, Inc.

[0058] During the wash step, a pump **246**, such as a diaphragm pump, is activated to draw the water/detergent mixture contained in the reprocessing basin **12** through an intake valve **240** and to circulate the mixture through the

circular reprocessing basin **12**, the output ports **121a-i** of the pressure distribution manifold **250**, the tubing segments **132a-l**, and through the internal passageways **98a-e** of the immersed medical instrument **96**. Any unused output ports **121a-l** can be blown off into the basin **12**. The pump **246** is a single output pressure pump. In this manner fluid is recirculated through the immersed medical instrument **96** for a predetermined period of time in order to reprocess the internal passageways of the internal medical instrument **96** in accordance with a predetermined reprocessing protocol.

[0059] Referring now to FIGS. 8A-B, there is shown a flowmeter **256** for selectively coupling to the manifold output ports **121a-l** and individually measuring the flow rates of the fluids within the manifold output ports **121a-l** of the reprocessing unit **83** coupled thereto. The flowmeter **256** can be any conventional flow sensor suitable for measuring the flow rate through the ports **121a-l**, and thereby through the tubing segments **132a-l**. For example, the flowmeter **256** can be an in line straight-through flow tube sensor that uses ultrasonic sensing technology to measure the rate of flow of a fluid passing therethrough, such as the M-1500 Series provided by Malema Flow Sensors. The flowmeter **256** can be omitted from any unselected output ports **121a-l** not supplying fluid to any internal passageways, for example the output ports **121a** which is blown off into the reprocessing basin **12**.

[0060] An ultrasonic sensing flowmeter **256** is preferred because it is non intrusive, thereby permitting the fluid flow to the internal passageways **98a-e** of the medical instruments **96** to be measured without interference by the flowmeter **256**. Ultrasonic sensing flowmeters **256** of this type are believed to be accurate from one-half cubic centimeter per minute to infinity for a multiple number of outputs.

[0061] The flowmeter **256** provides a flow rate signal according to the measured flow rate, for example by tripping a switch within the flowmeter **256** when the flow rate falls below a predetermined value.

[0062] In another embodiment, the flowmeters **256** can be of the well know piston type, wherein the force of the fluid flow through the flowmeter **256** raises and suspends a piston therein, until the flow rate falls below a predetermined value. When the flow rate falls below the predetermined value, the piston falls and a switch within the flowmeter **256** is tripped. The tripping of the switch within the flowmeter **256** indicates that the predetermined flow rate through the flowmeter **256** has not been maintained. It is believed that a flowmeter **256** of this type is not as accurate the ultrasonic type since it can interfere with the fluid flow being measured.

[0063] In one preferred embodiment, the minimum flow rate through the high pressure ports **121k,l** can be approximately one cubic centimeter per minute. The minimum flow rate through the two lower pressure ports **121a,b** at the distal end of the pressure distribution manifold **250** can be approximately fifty cubic centimeters per minute. The minimum flow rate through the remaining low pressure ports **121c-j** can be 0.05 gallons per minute.

[0064] Thus, the flowmeters **256** disposed in line with the internal passageways **98a-e** provide an indication to the user of the reprocessing system **83** when the flow through any of the passageways **98a-e** of the surgical instruments **96** coupled to the reprocessing unit **83** is obstructed. When any

of the internal passageways **98a-e** is determined to be obstructed in this manner, the reprocessing operation set forth in the process flow **95** is aborted, and the abort condition is communicated to the user of the reprocessing unit **83**. This feature prevents the inadvertent reuse of any device **96** that has not been completely reprocessed due to an obstruction in any of the internal passageways **98a-e** being reprocessed. Without such a feature the operator can be left with a false sense of security regarding the success of the reprocessing operation.

[0065] In the preferred embodiment, individual indicator lights (not shown) corresponding to each flowmeter **256** coupled to the pressure distribution manifold **250** are mounted on the exterior of the reprocessing unit **83**. The indicator lights permit an easy visual determination of which internal passageway **98a-e** is obstructed when the reprocessing operation is aborted. Additionally, in one preferred embodiment, a lag time of approximately ten seconds can be provided between the detection of an obstruction by a flowmeter **256** and the abort of the reprocessing operation to allow for the breaking up of an obstruction due to back pressure provided by the pump.

[0066] Referring now to FIGS. **9A-C**, there are shown representations of the pressure sensing switch **320** of the reprocessing unit **83**. The pressure sensing switch **320** is adapted to measure the pressure of the longitudinal bore holes **140**, **142** within the pressure distribution manifold **250**, and to provide an electrical pressure signal according to the measured pressure of the bore holes **140**, **142**.

[0067] In an alternate embodiment (not shown) a flowmeter **256** coupled to a manifold output port **121a-l** of the pressure distribution manifold **250** can be omitted. In such an embodiment, the pressure sensing switch **320** is mounted in a pressure measurement opening **144** communicating with a longitudinal bore **140**, **142** of the pressure distribution manifold **250**. For example, the flowmeters **256** can be removed from the manifold output ports **121k,l**, and the high pressure flow rate can be measured by a pressure sensing switch **320** mounted in the pressure measurement opening **144** disposed in communication with the longitudinal bore hole **140**.

[0068] Thus, the pressure of the manifold output ports **121k,l** is monitored using the pressure sensing switch **320** rather than measuring the fluid flow rate using a flowmeter **256**. In this alternate embodiment, an obstruction within a high pressure passageway of the medical instrument **96** is detected by sensing a change in pressure rather than a change in flow rate.

[0069] Thus, the reprocessing of the instrument **96** is aborted according to the pressure measured by the pressure sensing switch **320** rather than a direct measurement of flow rate. In one embodiment the pressure sensing switch **320** can be adapted to provide an electrical pressure signal when the measured pressure is at a level in the range of 1.5 to 15 psi.

[0070] Referring now to FIG. **10**, there is shown a portion of the reprocessing unit **350**. The reprocessing unit **350** is an alternate embodiment wherein the flow paths **125a-j** transmit fluid from the manifold output ports **121a-j** of the distribution manifold **250** to the supply ports **123a-j**. The flow paths **125a-j** can be, for example, tubing segments. Each flow path **125a-j** is provided with two pressure sensors

60a-j, **61a-j**. The two pressure sensors **60a-j**, **61a-j** of each flow path **125a-j** are spaced apart and mounted at two points on each of the flow paths **125a-j**.

[0071] The flowmeters **256** can be omitted in this embodiment, as flow is monitored using the pressure sensors **60a-j**, **61a-j**. In a preferred embodiment, the pressure sensors **60a-j**, **61a-j** will measure two pressure values for each output port **121a-j**. These values can then be used to determine the flow rates through the flow paths **125a-j**. This calculation can easily be performed by one skilled in the art. For example, the two pressures can be applied to the well-known Bernoulli equation to calculate the flow through the output ports **121a-j**.

[0072] Preferably, the pressure sensors **60a-j**, **61a-j** should be positioned not to obstruct or restrict the flow path. This will ensure a more accurate pressure reading. Additionally, in a preferred embodiment the flow through the flow paths **125a-j** should be as close to laminar as possible. This also will increase the accuracy of the pressure readings. Preferably, the distribution manifold **250** is designed to achieve laminar flow.

[0073] In this embodiment, the reprocessing of the instrument or device **96** is aborted according to the flow rate determined from the two measured pressures on each output port **121a-j**. Preferably, signals representing the pressure values detected by the pressure sensors **60a-j**, **61a-j** are transmitted to a computer equipped with software designed to process the signals. The software will translate the pressure values into flow rates, for example, by using the Bernoulli equation. When the pressure differential signifies no flow or minimum flow, according to predetermined minimum flow levels, the cycle is aborted.

[0074] The reprocessing unit can include a plurality of pumps (not shown) and associated tubing systems **132a-l**, wherein each pump provides one of the differing pressures required to reprocess the differing passageways of the devices **96**. Each individual tube of the tubing assembly can have its flow monitored separately by flow determining sensors on each tube. The flow determining sensors can be pressure sensors, or flow meters (piston type or ultrasonic).

[0075] In another embodiment, the reprocessing unit can include individual pumps (not shown) associated with each individual flow path **125a-j**. The single pump **246** with the pressure differentiation device **252** would be omitted, as well as the pressure distribution manifold **250**. In this embodiment, the fluid is pulled from within the reprocessing basin **124**, through the purge intake filter **240**, feeding the inputs of the individual pumps (not shown). Each pump then supplies a flow path **125a-j**, for example tubing segments, to the supply ports **123a-j** located on the reprocessing basin **124** at a predetermined flow and/or pressure rate. This predetermined flow and/or pressure rate is monitored separately by flow determining sensors. The flow determining sensors can be pressure sensors, or flow meters (piston type or ultrasonic).

[0076] In the preferred embodiment, individual indicator lights (not shown) corresponding to each pair of pressure sensors **60a-j**, **61a-j** mounted to the pressure distribution manifold **250** are mounted on the exterior of the reprocessing unit. The indicator lights permit an easy visual determination of which internal passageway **98a-e** is obstructed

when the reprocessing operation is aborted. Additionally, in one preferred embodiment, an adjustable lag time can be provided between the detection of an obstruction by the pressure differential and the abort of the reprocessing operation to allow for the breaking up of an obstruction due to back pressure provided by the pump.

[0077] In another alternate embodiment (not shown) of the reprocessing unit **83** an ultrasonic flow sensor such as the flowmeter **256** can be mounted on the pressure distribution manifold **250**, for example, at the input end of the pressure distribution manifold **250**. This type of ultrasonic measurement of flow rate is extremely sensitive, allowing the detection of changes in flow rate as small as a few drops per minute. The reprocessing operations of the process flow **95** are aborted when the flow detected by such an ultrasonic measurement device mounted on the pressure distribution manifold **250** in this manner is below the predetermined level.

[0078] Once the water/detergent mixture has passed through the internal passageways **98a-e** of the immersed medical instrument **96**, it flows back into the reprocessing basin **12** where it is again recirculated by the pump **246** for a predetermined minimum period of time based upon guidelines provided by the detergent manufacturer, e.g., one-hundred eighty seconds. During the wash step, the ultrasonic crystals **282** located below the reprocessing basin are activated. When activated, the ultrasonic crystals **282** generate ultrasonic vibrations that act in combination with the detergent-water mixture to cause a cleansing action that breaks down, loosens and removes contaminants from the exterior and interior surfaces of the flexible medical instrument **96** to provide enhanced cleaning.

[0079] Once the predetermined time period for the wash step has elapsed, the drain step begins.

[0080] During the drain step, the drain valve **164** is opened and the drain pump **216** is activated. While the pump **246** continues to pump the water/detergent mixture through the medical instrument **96**, the mixture begins to drain out of the reprocessing basin **12** by means of the drain pump **216** which pumps the water/detergent mixture down the drain line **212** and into a T-assembly **217**. The mixture travels through drain valve **164**, through a standpipe **165** and into a sewer drain **167**. Once the flow probe **220** detects the absence of moisture in the drain line **212**, the drain pump **216** is shut off and the drain valve **164** is returned to its closed position.

[0081] After the drain pump **216** is shut off, an air pump **224** is activated and a solenoid-type air valve **226** is opened. By use of the air pump **224** forced air is directed through the pump **246**, the manifold assembly **250**, the tubing segments **132a-e**, and through the internal channels of the medical instrument **96**. The forced air acts to purge and clear away any residual water/detergent mixture remaining in the interior channels of the medical instrument **96**. The purged residual water/detergent mixture flows down the drain line **212** located below the reprocessing basin **12** and collects in the bottom of the T-assembly **217** located below the drain line **212**. The purged residual water/detergent mixture is removed from the bottom of the T-assembly **217** by means of a residual drain line **310** and a residual drain pump **314** that is activated simultaneously with the air pump **224**.

[0082] The first rinse cycle comprises the steps of fill, rinse and drain steps. During the fill step, water is introduced

into the reprocessing basin **12** from the outside source **232** by means of water valve **230** and water line **234**. Since this is a rinse cycle, as opposed to a wash cycle, no detergent **254** is introduced during the fill step. During the rinse step of the process flow **95**, the pump **246** draws the rinse water contained in the reprocessing basin **12** through the intake valve **240** and recirculates the rinse water for a predetermined minimum period of time in a manner as previously described above in connection with the wash step. Also, during the rinse step, the ultrasonic crystals **282** are activated.

[0083] Thereafter, the drain step begins. During the drain step, rinse water is pumped out of the reprocessing basin **12** by the drain pump **216**. The water travels down the drain line **212** through the drain pump **216** and into the T-assembly **217**. Because the drain valve **164** is in the opened position, the water travels through drain valve **164** and through standpipe **165** and into a sewer drain **167**.

[0084] Once the flow probe **220** detects the absence of moisture in the drain line **212**, the drain pump **216** is shut off. Some residual water remains in the bottom of the T-assembly **217** that cannot be removed by the drain pump **216**. This residual rinse water is removed from the bottom of the T-assembly **217** by means of the residual drain line **310** and the residual drain pump **314** in the manner previously described. By removing all residual rinse water from the T-assembly **217**, chemical disinfectant introduced in the next step of the protocol will not become diluted with any residual rinse water.

[0085] Once the drain step **141** is complete and all residual rinse water has been removed from the T-assembly **217**, the next fill step begins and a chemical disinfectant **288** is introduced into the reprocessing basin **12**. One particularly effective type of chemical disinfectant is 2% or 3% glutaraldehyde which is marketed by a number of different companies under various brand names such as Cidex manufactured by Johnson & Johnson. The introduction of the disinfectant **288** is effected by opening a reservoir feed valve **298** to cause a reservoir pump **294** to pump the chemical disinfectant **288** from a chemical disinfectant reservoir **290** through a chemical line **306** into the reprocessing basin **12**. The chemical disinfectant **288** enters and fills the reprocessing basin **12** to a predetermined height as previously described.

[0086] Once the reprocessing basin **12** has been filled with the chemical disinfectant **288** to the predetermined level, the pump **246** is activated to draw the chemical disinfectant **288** contained in the reprocessing basin **12** through the intake valve **240**. This action circulates the chemical disinfectant **288** through the ports of the manifold **250**, the tubing segments **132a-e** and through the internal passageways **98a-e** of the immersed medical instrument **96**. Once the chemical disinfectant **288** has passed through the internal passageways of **98a-l** of the immersed medical instrument **96**, it flows back into the reprocessing basin **12** where it is recirculated by the pump **246** for a predetermined minimum period of time based upon guidelines provided by the manufacturer of the chemical disinfectant **288**. Once the predetermined minimum time period for the chemical immersion step has elapsed, the pump **246** is turned off.

[0087] Thereafter, the chemical disinfectant **288** is returned to the chemical disinfectant reservoir **290** for reuse.

To enable the return of the chemical disinfectant **288** to the reservoir **290**, the drain valve **164** is closed and the reservoir return valve **302** is opened. The drain pump **216** is activated and the chemical disinfectant **288** is pumped through the chemical line **306**, through the reservoir return valve **302** and back into the chemical reservoir **290**. Once the flow probe **220** detects the absence of moisture in the drain line **212**, the drain pump **216** is tuned off. Thereafter, two additional rinse cycles are performed. The first rinse cycle comprises a first rinse and a drain phase. The rinse cycle is performed in a manner similar to the rinse cycle previously described. However, this rinse cycle does not include use of the residual drain line **310** and residual drain pump **314**. The ultrasonic crystals **282** are activated during the rinse step of this rinse cycle.

[**0088**] The second rinse cycle comprises fill, second rinse and drain phases. This rinse cycle is performed in a manner similar to the rinse cycle previously described, i.e., fill, rinse and drain phases, and includes use of the residual drain line **310** and residual drain pump **314**. The ultrasonic crystals **282** are activated during the rinse step of this rinse cycle. Once this rinse cycle has been completed, the reprocessing protocol is complete and the instrument may be removed from the reprocessing chamber for reuse.

[**0089**] Referring now to FIGS. **11** and **12**, there is shown a disinfectant transfer system according to the invention. A transfer cap **500** is fitted onto a bottle **502** containing a chemical disinfectant **288**. The transfer cap **500** has a first opening **504** for letting air, or some other gas, in through a valve **506** which is inserted in the first opening **504**. A second opening **508** on the transfer cap **500** is provided for allowing the chemical disinfectant **288** to exit the bottle **502** when the chemical disinfectant **288** is displaced by air entering through the valve **506** in the first opening **504**. Preferably the valve **506** is a spring loaded self-closing locking valve of a type well known to those skilled in the art. A first conduit **510** connected to the bottom of the second opening **508** and extending to the bottom of the bottle **502**, allows for a pathway by which the chemical disinfectant **288** can exit the bottle **502**. From the first conduit **510** the chemical disinfectant can then enter a second conduit **512**, which is connected to the top of the second opening **508**, and flow into a reservoir **290** into which the chemical disinfectant **288** can enter.

[**0090**] In a preferred embodiment, a manifold **250** linked to the first opening **504** by a third conduit **514** can be used to supply the air which enters the bottle **502** through the first opening **504**. However, any source of air can be used. Additionally, in a preferred embodiment an o-ring **516** is fitted between the second opening **508** and the second conduit **512** to assist in creating an essentially vapor tight seal. Still furthermore, in a preferred embodiment the valve **506** is a one-way check valve for only allowing air to enter the bottle **502**.

[**0091**] It should be appreciated that the disinfectant transfer system described is a closed system from inside of the bottle, or other suitable container, to inside of the reservoir. Therefore, essentially no fumes escape during the transfer of the disinfectant from the bottle to the reservoir.

[**0092**] It should further be appreciated that the transfer cap detachably attaches onto the bottle, or other suitable container, and can therefore be removed and detachably

attached onto another bottle, or other suitable container. As a result, disinfectant contained in multiple bottles, or other suitable containers, can be easily transferred to a reservoir through the closed system.

[**0093**] Without further elaboration, the foregoing will so fully illustrate the invention that others may, by applying current or future knowledge, readily adapt the same for use under the various conditions of service.

What is claimed is:

1. A disinfectant transfer system, which is essentially vapor tight, for transferring toxic and/or noxious fluid from a container to a reservoir without releasing fumes comprising:

a transfer cap for securing onto a mouth of a container containing toxic and/or noxious fluid, the transfer cap having a first opening for letting a gas in through a valve, the transfer cap further having a second opening for allowing toxic and/or noxious fluid to be forced out of the container when the toxic and/or noxious fluid is displaced by the gas entering through the first opening, the gas forces the toxic and/or noxious fluid within the container to enter and flow through a first conduit, which is connected to the bottom of the second opening and leads to the bottom of the container, and to continue to flow through a second conduit which is connected to the top of the second opening and leads to a reservoir into which the toxic and/or noxious fluid can enter.

2. The disinfectant transfer system of claim 1, wherein an o-ring is fitted between the second opening and the second conduit.

3. The disinfectant transfer system of claim 1, further comprising a third conduit having a first end connecting to the valve through which the gas enters the container, the second end of the third conduit connected to a manifold which pumps the gas.

4. The disinfectant transfer system of claim 1, further comprising a third conduit having a first end connecting to the valve through which the gas enters the container, the second end of the third conduit connected to a manifold wherein the manifold provides differential pressure for cleaning of medical instruments.

5. The disinfectant transfer system of claim 1, wherein the valve through which the gas enters the container is a one-way check valve.

6. The disinfectant transfer system of claim 1, wherein the transfer cap is secured to the container by being screwed onto the container using thread patterns already on the mouth of the container.

7. The disinfectant transfer system of claim 1, wherein the toxic and/or noxious fluid is a disinfectant.

8. The disinfectant transfer system of claim 1, wherein the gas is air.

9. A method of transferring toxic and/or noxious fluid from a container containing toxic and/or noxious fluid to a reservoir comprising the steps of: (1) detachably attaching a transfer cap onto the mouth of the container containing toxic and/or noxious fluid, the transfer cap having a first opening for letting a gas in through a valve, the transfer cap further having a second opening for allowing toxic and/or noxious fluid to be forced out of the container when the toxic and/or noxious fluid is displaced by the gas entering through the first opening, the gas forces the toxic and/or noxious fluid at the bottom of the container to enter and flow through a first

conduit, which is connected to the bottom of the second opening and leads to the bottom of the container, and to continue to flow through a second conduit which is connected to the top of the second opening and leads to a reservoir into which the toxic and/or noxious fluid can drain; (2) connecting the second conduit to the second opening; (3) connecting the first end of a third conduit to the valve through which the gas can enter the container; (4) connecting the second end of the third conduit connected to a manifold which is attached to a pump which pumps the gas; (5) turning on the pump and running until tubing is cleared; (6) turning off the pump; (7) removing the first end of the third conduit from the valve; (8) remove the second conduit from the second opening; (9) detachably attaching the transfer cap to a new container; (10) repeating steps 3 through 9 until reservoir is full.

10. The method of transferring toxic and/or noxious fluid of claim 9, wherein an o-ring is fitted between the second opening and the second conduit.

11. The method of transferring toxic and/or noxious fluid of claim 9, further comprising a third conduit having a first end connecting to the valve through which the gas enters the

container, the second end of the third conduit connected to a manifold which pumps the gas.

12. The method of transferring toxic and/or noxious fluid of claim 9, further comprising a third conduit having a first end connecting to the valve through which the gas enters the container, the second end of the third conduit connected to a manifold wherein the manifold provides differential pressure for cleaning of medical instruments.

13. The method of transferring toxic and/or noxious fluid of claim 9, wherein the valve through which the gas enters the container is a one-way check valve.

14. The method of transferring toxic and/or noxious fluid of claim 9, wherein the transfer cap is secured to the container by being screwed onto the container using thread patterns already on the mouth of the container.

15. The method of transferring toxic and/or noxious fluid of claim 9, wherein the toxic and/or noxious fluid is a disinfectant.

16. The method of transferring toxic and/or noxious fluid of claim 9, wherein the gas is air.

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