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(54) **PORTABLE CHEMICAL STERILIZER**

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A61L 9/00 (2006.01)

(52) **U.S. Cl.** **422/292**

(58) **Field of Classification Search** 422/299, 422/295, 297, 302, 292

See application file for complete search history.

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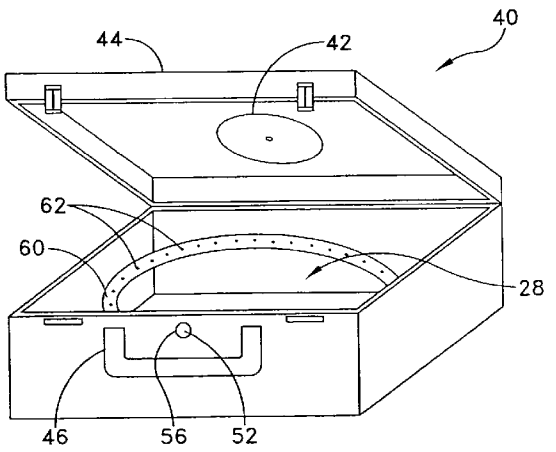
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(57) **ABSTRACT**

A portable, lightweight, easy-to-carry, reusable, durable, and environmentally-friendly assembly for sterilizing contaminated equipment using conditions of a chemical sterilant, heat, and humidity generated in situ without requiring external electricity, fuels, or other exogenous energy sources for operation. The carry assembly includes a plastic carry-case or insulated aluminum pressure vessel having an inner chamber for accepting microbiologically contaminated objects, a vessel disposed in the chamber for serving as a reaction chamber and/or boiler, a chemical combination which upon mixing generates at least minimally sufficient conditions of the sterilant, heat, and humidity to effect sterilization of the objects, and outlet valves mounted on the carry-case for controllably venting pressures above ambient air pressure.

16 Claims, 4 Drawing Sheets



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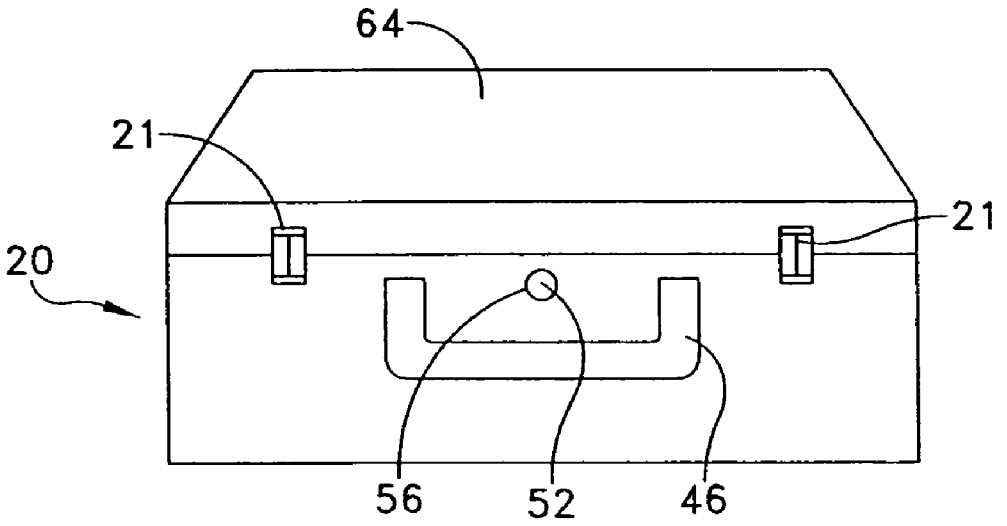


FIG. 1

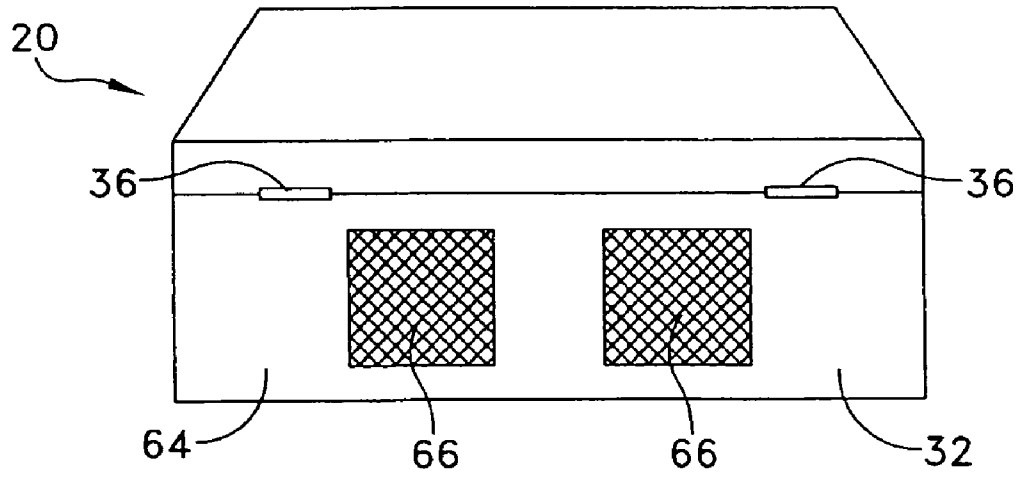


FIG. 2

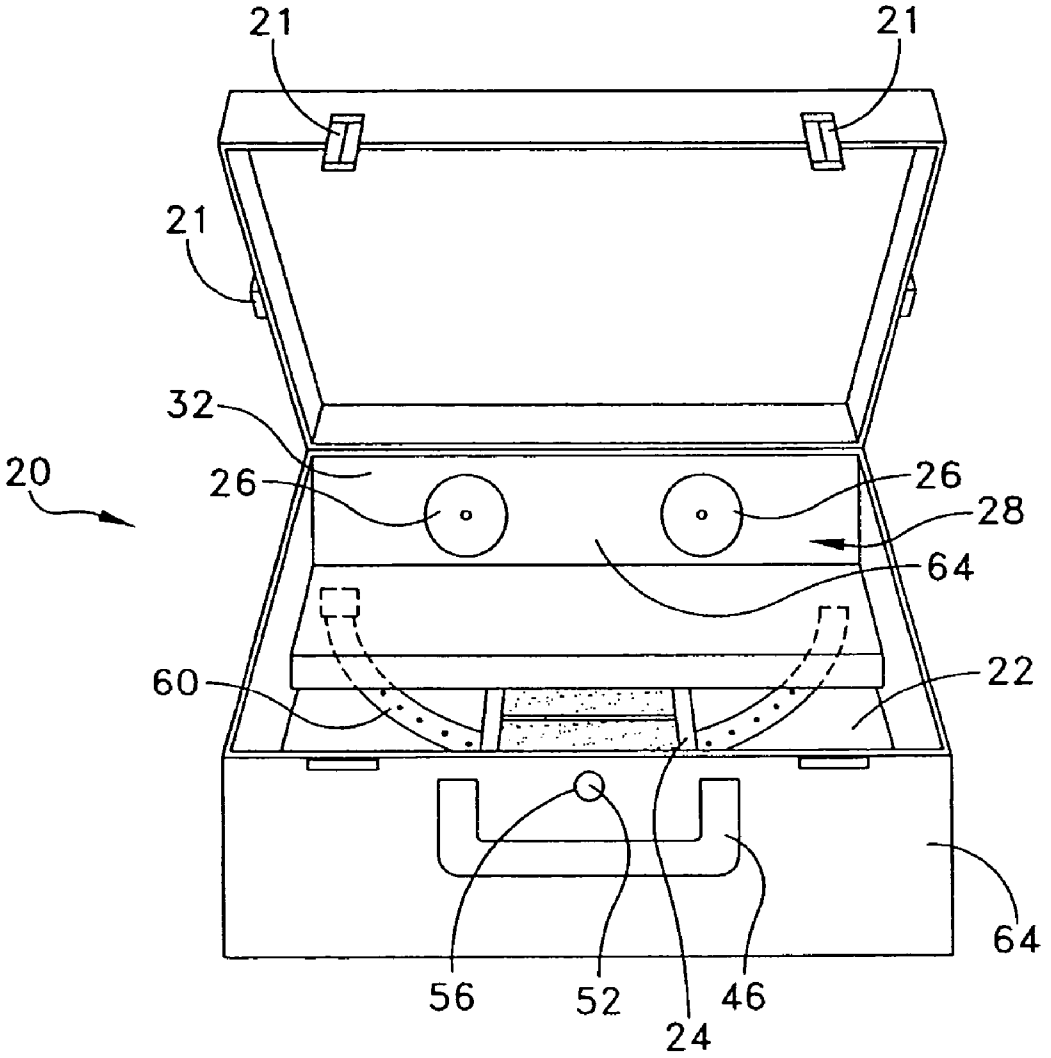


FIG. 3

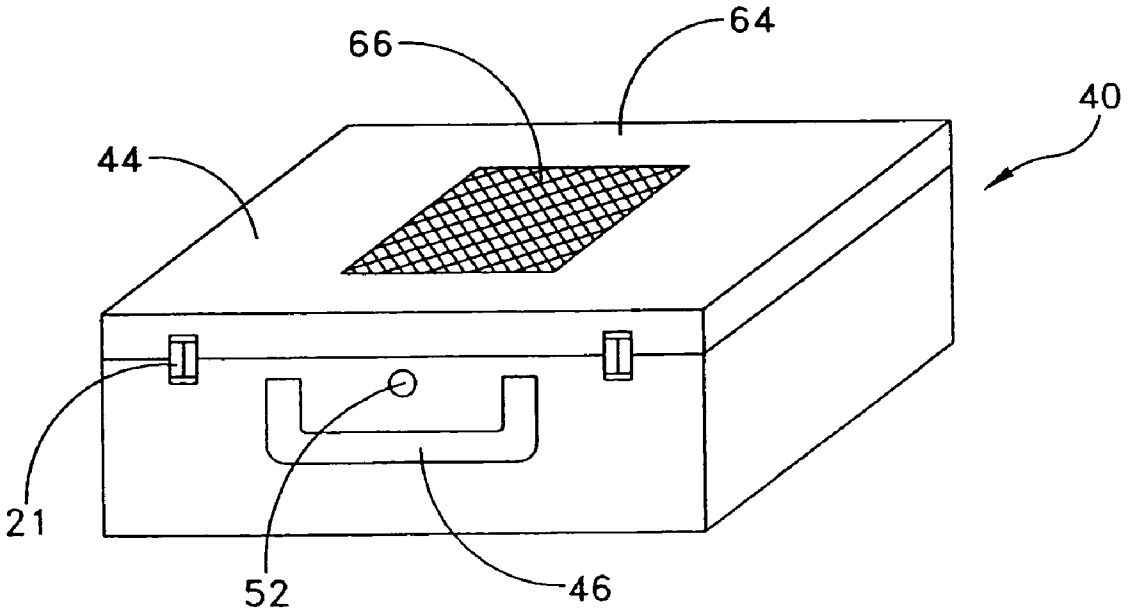


FIG. 4

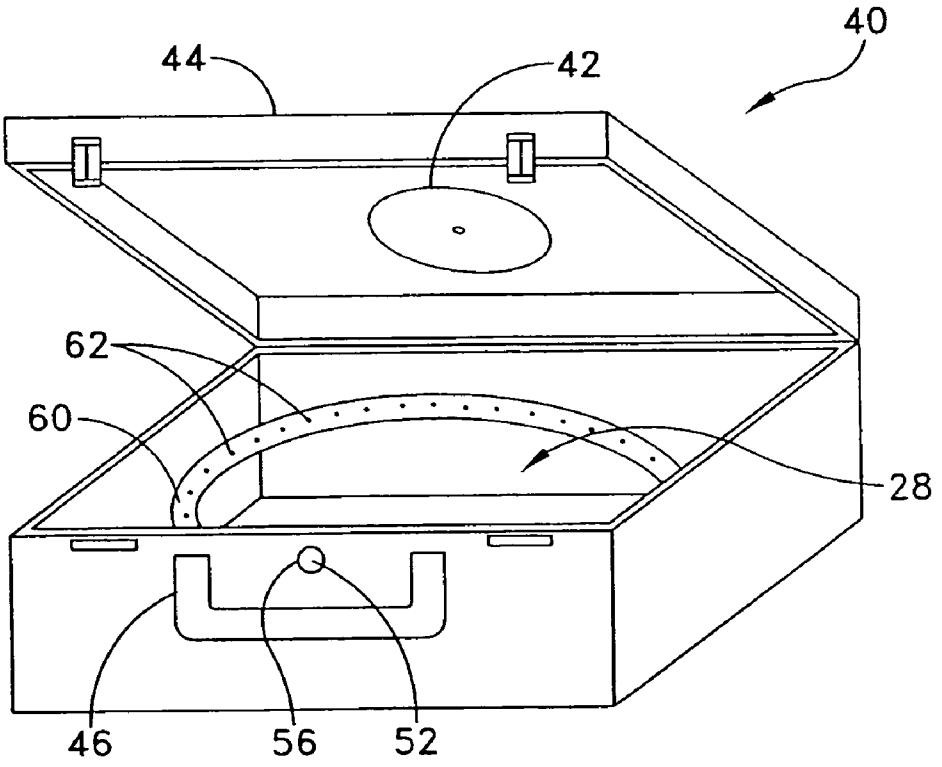


FIG. 5

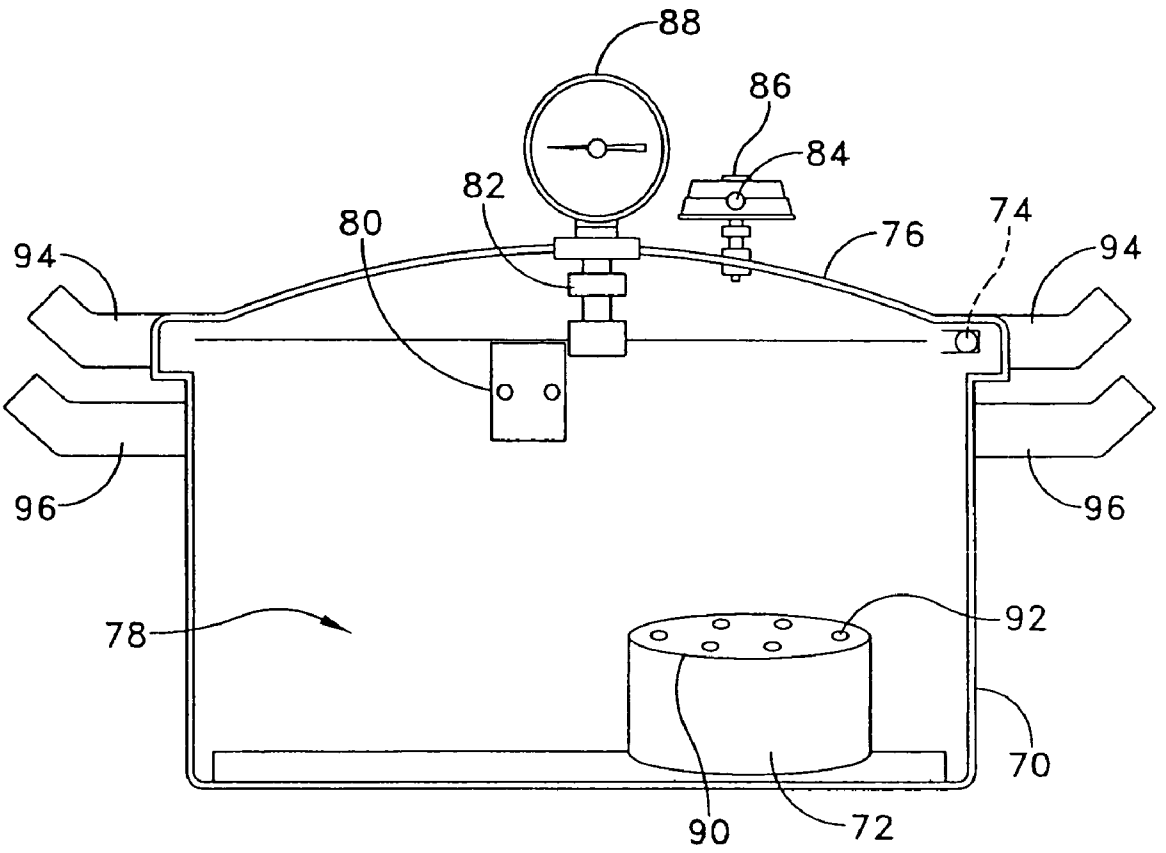


FIG. 6

PORTABLE CHEMICAL STERILIZER

CROSS-REFERENCE TO RELATED APPLICATION

This is a continuation-in-part of U.S. patent application Ser. No. 10/988,442, filed Nov. 10, 2004, in the names of Christopher J. Doona, et al., which application is incorporated herein by reference.

STATEMENT OF GOVERNMENT INTEREST

The invention described herein may be manufactured and used by the U.S. Government for governmental purposes without the payment of any royalty thereon.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to lightweight, portable, self-contained devices whose operation does not require external power sources to sterilize assemblages of microbiologically contaminated equipment therein. The invention, more specifically, relates to such a device that uses chemical methods for sterilization and disinfection of equipment, such as medical and surgical instruments, in field conditions where water, electrical power, and/or fuel sources may be absent, unavailable, or of limited availability.

2. Description of the Prior Art

Far-Forward Army Surgical Teams currently have no existing technology for conveniently sterilizing surgical instruments on-site. Contaminated instruments are often transported with patients via aircraft to distant hospitals for sterilization in large steam autoclaves, and then returned enclosed in sterile packaging to the surgical teams via aircraft for re-use. Hospital steam autoclaves typically have 18-20 cubic foot chambers, weigh several hundred pounds, and require at a minimum permanent steam lines, water lines, and 110V electricity for operation.

Far-forward teams sometimes transport electric autoclaves into the field for carrying out sterilization. Electric autoclaves are smaller than hospital steam autoclaves, require some installation (such as 120 and 208-240 volt electrical lines), and consume significant amounts of water and power per sterilization cycle. For example, a typical sterilization cycle in an electric autoclave runs for 50-60 minutes and consumes about 1.5 gallons of potable water and approximately 12 kilowatts of power (at 236 volts). These electrical autoclaves are in fact difficult to transport in vehicles due to their weight (>100 lbs.), bulky dimensions, and reliance on generators or other power sources for operation.

Currently, there are no devices available for sterilizing surgical instruments that are portable, sufficiently lightweight (3-35 lbs.) to be easily hand-carried, do not require external power sources, such as electricity, and effect the sterilization process in 15-60 minutes.

In considering the design of a conveniently portable sterilizer, a choice must first be made as to which method, conventional moist heat, radiation, or chemical, will be the best to effect sterilization. Conventionally generated heat requires bulky autoclaves and significant amounts of power (usually electrical) to generate steam. Radiation requires a power-supply or shielded enclosures, often both. Chemical methods have the potential to be conveniently portable, which has led to claims of portable disinfection, but not complete sterilization, and the chemical methods generally are not accomplished in convenient times as short as 15 minutes.

Chemical sterilization involves the use of controlled chemical processes to kill microbial contaminants by either i) directly transporting biocidal chemical agents in safety carriers, or ii) transporting the appropriate chemical precursors and chemically generating biocidal agents or sterilization conditions on-site, which often requires heavy-duty generating equipment. In these cases, it is important to distinguish the possibility of transporting chemicals or heavy-duty equipment in vehicles from a truly portable system. A truly portable system can be conveniently moved, lifted, or carried by the individual user, and includes the device, equipment, and chemicals involved in effecting the sterilization process.

Disinfectants such as chlorine, ethylene oxide, and fluorine-containing interhalogens are stable but highly reactive chemicals that must be transported in bulky, secure containers to ensure safety. While these chemicals can be transported, they are not truly portable because of their inconvenient weight and the safety precautions that must be taken to prevent accidents during shipping.

Many other potent chemical disinfectants are unstable and must be generated on-site from stable chemical precursors. The art of generating these chemical disinfectants has not been directed toward portability. For example, methods for generating disinfectants, such as hydrogen peroxide, ozone and chlorine gas, teach synthetic and electrochemical techniques that utilize heavy and bulky power supplies, solution reservoirs, fluid pumps, vacuum lines and other gas-handling systems. While this equipment can possibly be transported, it is not truly portable because of its large weight and size. Additionally, controlling this equipment requires electrical power and electrical circuitry, and transporting this equipment requires additional steps for removal and installation before operation can commence.

As indicated above, the established chemical methods currently being used to dispense or generate biocidal chemical agents or to chemically generate conditions for sterilization are not suited to lightweight portability. There is a need for a portable assembly for the sterilization or disinfection of microbiologically contaminated medical instruments, and the like, particularly one that involves using only a small amount (approximately 0.25 lb.) of safe, dry, chemical reagents. The chemical combination must be convenient to carry and mix with water readily to generate biocidal chemical agents or conditions sufficient for effecting sterilization.

Accordingly, an object of the invention is to provide such a portable apparatus adapted to use a chemical combination, and a number of variants thereof, that consist of mixtures of specially formulated iron-activated magnesium Mg(Fe) containing salt, sodium chlorite ($NaClO_2$), sodium sulfite (Na_2SO_3), and sodium hydrogen ascorbate ($C_6H_7O_6Na$) that react in water to controllably generate sterilization conditions inside the apparatus that include the production of biocidal chlorine dioxide, heat, and relative humidity.

Chlorine dioxide (ClO_2) is a potent, broad-based biocide that is effective against a wide variety of pathogenic microorganisms and bacterial spores. Chlorine dioxide is the EPA-registered disinfectant that was used to decontaminate the Hart Senate Office Building and the Brentwood postal facility in Washington, D.C. during the Anthrax attacks. In addition, chlorine dioxide is FDA-approved for disinfecting dental equipment and wastewater stores, and is used to kill pathogens and spoilage microorganisms that decrease the shelf-life of fresh and fresh-cut vegetables. Industrially, ClO_2 is produced from large chlorine dioxide generators and is used to treat wastewater and kill disease-carrying vectors, while pro-

tecting the environment by reducing the production of chlorinated organic by-products to very low levels compared with chlorine.

SUMMARY OF THE INVENTION

With the above and other objects in view, a feature of the present invention is the provision of a closable, portable (easy-to-carry), non-powered assembly for the sterilization of a collection of contaminated objects. This portable, power-free assembly accommodates controlled chemical reactions that generate in situ conditions of chemical sterilant, heat, and humidity sufficient to effect the sterilization of objects contaminated with microorganisms.

The assembly includes a closable apparatus defining an outer chamber having an inner chamber for accepting microbiologically contaminated objects, an interior vessel to act as a reaction chamber, a chemical combination that upon being mixed with water generates at least minimally sufficient conditions of chemical sterilant, heat, and humidity to effect sterilization, and valves dedicated to controllably preventing the accumulation of pressures above ambient air pressures and venting and deactivating chemical reaction products.

The preferred embodiment for this apparatus is a sterilization unit constructed from a plastic carry-case preferably weighing about 3.0-35 lbs, and of compact dimensions. The sterilization procedure entails placing the microbiologically contaminated equipment inside the carry case, combining the dry chemicals and water in a reactor vessel within the case, then closing and locking the case. Built-in outlet valves prevent the accumulation of excess pressure inside the case by allowing controlled release of heated gaseous products. An inlet valve is used to flow air into the apparatus after the sterilization process and expel gaseous products through the outlet valves.

In an alternative embodiment, the apparatus comprises a thermally insulated sterilizer unit with a vessel serving as a reaction chamber that is also called an internal boiler. This embodiment can be constructed from an aluminum vessel similar to a pressure cooker, preferably weighing about 17.5 lbs. and equipped with Teflon-covered foam-insulation. The vessel is provided with a locking cover and is adapted to receive contaminated objects, and the internal boiler receives the dry chemicals and water. A vent pipe covered by a pressure regulator allows internal pressures to exceed atmospheric pressure to the extent needed for thermal sterilization. The vent pipe ensures user safety by releasing enough gas to prevent the internal pressure from becoming too high, and an accompanying dial gauge safely monitors the pressure. This embodiment is simply opened to expel gaseous products after the sterilization process, although it could be fitted with additional outlet and inlet valves to carry out flushing.

In general, the chemical combination used to effect sterilization is an ensemble of dry chemicals that react in water to controllably generate various levels of chlorine dioxide, heat, and relative humidity. The ensemble of dry chemicals consists of iron-activated magnesium {Mg(Fe)}, sodium chlorite ($NaClO_2$), sodium sulfite (Na_2SO_3), and sodium hydrogen ascorbate (chemical formula $C_6H_7O_6Na$ and designated with the symbol AH^-). Variants of the ensemble can be formulated by removing chemicals, or by adjusting the relative concentrations of the chemicals, and these systems are still capable of inactivating contaminating microorganisms.

When all of the dry chemicals are present and mixed together in water, the chemical combination generates large quantities of chlorine dioxide, heat, and humidity; this method is referred to herein as "combined sterilization." Specifically, the combined sterilization method consists of Mg(Fe), ClO_2^-, SO_3^{2-}, and AH^- mixed in water. In this case, the chemical combination produces copious amounts of chlorine dioxide, heat, and humidity, all of which act in concert to inactivate contaminating microorganisms.

A variant of the chemical combination can be formulated to generate large quantities of chlorine dioxide while concomitantly producing relatively low levels of heat and humidity; this method is referred to herein as "chlorine dioxide sterilization." In chlorine dioxide sterilization, the chemical combination consists of ClO_2^-, SO_3^{2-}, and AH^- mixed in water (Mg(Fe) is excluded).

Another variant of the chemical combination generates large quantities of heat and humidity without producing chlorine dioxide; this method is referred to herein as "thermal sterilization." In the thermal method, the Mg(Fe)—H_20 reaction acts alone to produce substantial heat (Temperature≧121° C.) and steam in the absence of ClO_2. In certain low temperature or high-altitude environments, the Mg(Fe)—H_2O reaction can also contribute a source of heat to pre-warm or thaw the portable chemical sterilizer or frozen water.

The present invention provides for the removal of chlorine dioxide and other gases following the sterilization treatment. For outdoor environments the apparatus is simply opened to release the remaining sterilant gas.

For indoor environments, air flushing is used in conjunction with simple chemical methods to safely purge ClO_2 from the sterilization apparatus. Flowing air into the apparatus causes the expulsion of the chlorine dioxide gas through the outlet valves of the apparatus. The ClO_2 gas passes through specially designed scrubber devices engrafted onto these outlet valves, and common reductants embedded in the scrubber such as sulfite (SO_3^{2-}) dithionite ($S_2O_5^{2-}$), or thiosulfate ($S_2O_3^{2-}$) safely deactivate the chlorine dioxide gas. The reduction of ClO_2 occurs readily with these ions and these chemical reactions convert chlorine dioxide and the reductant to the environmentally safe and inert ionic products of chloride (Cl^-) and sulfate (SO_4^{2-}), respectively.

Additionally, chlorine dioxide features chlorine atoms in the +4 intermediate oxidation state (the oxidation states of chlorine range from −1 to +7). When chlorine dioxide comes in contact with a base such as sodium carbonate (Na_2CO_3), the chlorine dioxide can disproportionate into likewise environmentally benign, unreactive products chloride and chlorate (ClO_3^-).

The above and other features of the invention, including various novel details of construction and combinations of parts, will now be more particularly described with reference to the accompanying drawings and pointed out in the claims. It will be understood that the particular devices embodying the invention are shown by way of illustration only and not as limitations of the invention. The principles and features of this invention may be employed in various and numerous embodiments without departing from the scope of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Reference is made to the accompanying drawings in which are shown illustrative embodiments of the invention, from which its novel features and advantages will be apparent.

In the drawings:

FIG. **1** is a front perspective view of one form of portable carry-case illustrative of the preferred embodiment of the invention;

FIG. **2** is a rear perspective view of the case of FIG. **1**;

FIG. **3** is a front perspective view of the case of FIG. **1** with a top portion in an open position;

FIG. **4** is a perspective view of an alternative embodiment of a portable carry-case;

FIG. **5** is a perspective view of the case of FIG. **4**, but shown with a top member in an open position; and

FIG. **6** is a side elevation view of a further alternative embodiment of a portable sterilizer.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is directed toward a lightweight, portable apparatus in the form of a convenient carry-case or handled vessel or box for carrying out chemical reactions that convert chemical energy to forms usable for the sterilization of microbiological contaminants without the use of external sources of power. Within the apparatus, sterilization is achieved in situ by chemically generating conditions involving a lethal sterilant, heat, and humidity, such that exposure of the contaminated objects to this environment sterilizes objects contaminated with harmful pathogens or infectious microorganisms.

The preferred use of the portable sterilizers includes using a chemical combination that ensures the complete destruction of contaminating microorganisms in an optimal time. Therefore, there follows below a detailed description of the chemical combination, followed by descriptions of the embodiments of the apparatus in which the chemical combination is activated to effectuate sterilization.

The chemical combination in the preferred method for sterilization is a mixture that can be decreased or increased proportionately, or that can be varied in the relative proportions of the components, depending on factors such as the size of the container in which sterilization is to occur or to emphasize different characteristics of the chemical combination. A representative chemical combination used for "combined sterilization" utilizes about 600 mL of water and the following approximate proportions of dry chemicals: 3.3 mole iron-activated magnesium (85 g Mg(Fe)), 2.04 mole chlorite ion (185 g $NaClO_2$), 1.0 mole sulfite ion (126 g Na_2SO_3), and 0.25 mole hydrogen ascorbate ion (50 g $NaC_6H_7O_6$). In one aspect designated "chlorine dioxide sterilization," the Mg(Fe) can be omitted from the chemical combination (300 mL H_20, 93 g $NaClO_2$, 63 g Na_2SO_3, and 25 g $NaC_6H_7O_6$); in another aspect designated "thermal sterilization," only the Mg(Fe)—H_20 chemical reaction (600 mL H_20 and 140 g Mg/Fe) is used, and the remaining 3 components of the chemical combination are omitted.

Alternative chemical combinations are also possible. For example, the magnesium can be activated by several different transition metals, such as cobalt or nickel. Other metallic reductants, such as calcium or sodium amalgam, can be used as simple substitutions.

The chlorine-containing oxidant (ClO_2^-) can derive from any one of several salts featuring different counter ions, such as lithium, sodium, potassium, or calcium cations. The hydrogen ascorbate salt acts as an effector and can be replaced by any appropriate effector such as ascorbic acid, erythorbic acid, tartaric acid, or any of their respective ions. Any chemical combination, such as those described in U.S. patent application Ser. No. 10/988,442, incorporated herein by reference, can be used. In the following description, reference will be made to the chemical combination used in the preferred embodiment, but this invention is not limited to the use of only this chemical combination and this preferred embodiment. Other reasonable substitutions for components of the chemical combination of the preferred embodiments, which produce equivalent chemical or microbiological processes, are obvious variants of the system described herein.

Referring to FIGS. **1-3**, it will be seen that a preferred embodiment of the present invention is a sterilizer unit that uses a carry-case **20** that has sufficient capacity to hold at least a standard surgical autoclave tray (not shown). The carry-case **20** preferably defines a volume of about 46 L. Two pressure-release check valves **26** (FIG. **3**) are integrated into the back **32** of the case **20** using a protective framework (not shown) so that the valves **26** do not protrude beyond the structure of the carry-case **20**, and do not interfere with stacking of the carry-cases. A smaller carry-case **40** defining a volume of about 3.5 L is shown in FIG. **4** and features the capacity to hold a loose assemblage of contaminated instruments. The smaller carry-case **40** features a single 2-inch check valve **42** (FIG. **5**) installed in its roof **44**. The valves **26**, **42** are identical and are designed to withstand a maximum pressure of 50 psi (gauge). The carry cases **20**, **40** typically weigh about 3½-35 lbs. and are provided with suitcase-handles **46**, such that portability is readily facilitated.

The sterilization procedure for case **20** entails the simple steps of placing the microbiologically contaminated equipment (not shown) inside the case **20** on a support structure **22**, adding the chemical combination (including water) in a small interior reactor vessel **24**, and closing and locking the case **20**, as with latches **21**. A similar sterilization procedure is carried out for case **40**.

Depending on the selected chemical reaction conditions, the corresponding chemical combination controllably generates sufficient conditions of ClO_2, heat, and humidity to sterilize the contaminating microorganisms within 15-120 minutes. Built-in pressure-release valves **26**, **42** on cases **20** and **40**, respectively, prevent pressure from accumulating inside the apparatus chambers (**28** for both case **20** and **40**, see FIGS. **3** and **5**) by allowing the controlled release of heated gaseous products formed by the chemical combination.

The valves **26**, **42** are initially in the closed position, but open to relieve pressure inside the chamber **28** at minimal levels. The valves **26**, **42** accommodate the initial rapid pressure increase in the interior chambers **28** of carry cases **20** and **40** caused by the rapid chemical production of gaseous chemicals, heat, and steam by the activated chemical combination. As a slight pressure builds up inside the cases from the formation of heated gases, the valves **26**, **42** open slightly, and the heated gases vent outside of the cases through the opened valves. When the pressure has subsided sufficiently due to the escape of heated gases, the valves flap shut and return to their original closed position. During the early parts of the reaction with the preferred chemical combination, the pressure surges temporarily due to the chemical production of heated gaseous chemical products such as carbon dioxide (CO_2) and ClO_2, and the valves **26**, **42** open to alleviate the pressure. As the pressure subsides, the valves close again.

After the sterilization (or disinfection) process is complete, the units **20**, **40** may be flushed with air to remove the remaining ClO_2 gas. Following the air-flushing process, the user wears sterile gloves to open the case **20**, **40** and remove the sterilized (disinfected) objects, which were preferably wrapped in autoclave paper prior to the sterilization process.

The sterilizer carry-case units **20**, **40** are designed to control the removal of ClO_2 remaining after the sterilization procedure in the following manner. A stainless steel inlet valve **52** (for both case **20** and case **40**) does not allow gases to flow out of the case. After the sterilization treatment, the inlet valve **52** is connected to an air pump (not shown) that inflows air into the case. A filter **56** is placed in the inlet valve

52 to prevent the introduction of air-borne particulate matter that might re-contaminate the sterilized objects. Any portable hand-held or foot-operated pedal pump may be used to flow air into the apparatus. There may be instances where it may be possible, desired, or advantageous to employ compressed air tanks or electrically operated air pumps to carry out the flushing procedure. Electricity or external power is in no case required to effect either the sterilization procedures or flushing of the apparatus; however, the carry-case sterilizer unit can accommodate battery-operated air pumps for flushing in circumstances where their use may prove convenient.

The incoming air is distributed within the carry-case units via 0.25 inch plastic tubing **60** disposed in a semi-circular (FIG. **3**) or circular (FIG. **5**) fashion around the interior perimeter of the carry-case. Perforations **62** in the plastic tubing **60** are spaced at approximately 1-inch intervals, allowing the incoming air to circulate throughout the carry-case and mix with the remaining chlorine dioxide gas. This influx of air slightly increases the pressure inside the apparatus chambers **28**, and the mixture of air and chlorine dioxide gas flows out of the check valves **26** and **42**, integrated into the back wall **32** of the carry-case **20** (FIG. **3**) and into the roof **44** of the carry case **40** (FIG. **5**), respectively. The valves **26**, **42** open and close periodically to ensure that the gases mix and that the flushing operation proceeds smoothly and safely.

A gas scrubber **66** (FIG. **2** and FIG. **4**) is connected to each check valve **26**, **42** and absorbs the chlorine dioxide gas exiting the apparatus during any stage of the sterilization process, including flushing. Each scrubber **66** may consist of two layers of wire gauze (not shown) sandwiching a porous sponge material filled with a common reductant, such as sodium sulfite. The reductant readily inactivates the ClO_2 gas in the stream flow exiting the apparatus and safely limits user exposure and environmental off-gassing of ClO_2.

An alternative embodiment of the present invention is an aluminum pressure vessel that is equally suited for non-powered, lightweight, portable sterilization of microbiologically contaminated objects by the in situ generation of sufficient conditions of chlorine dioxide, heat, and humidity using the chemical methods described above. This alternative embodiment (FIG. **6**) of the sterilizer unit uses an aluminum pressure vessel **70** of about 20 liter capacity with its exterior covered in insulating foam and wrapped in a Teflon jacket, and its lid **76** snugly fitted with a sealing ring **74** and securely locked into place using brackets **80**. An air vent **82** exhausts air from the pressurized vessel **70** and provides the first indication that heat and gases are building pressure inside the pressurized vessel. A vent pipe **84** covered by a pressure regulator **86** allows the controlled release of excess pressure, and an accompanying pressure gauge **88** registers the pressure inside the aluminum vessel chamber **78**. The pressure vessel **70** typically weighs about 35 lbs or less, and is provided with handles **94** and **96**, rendering the vessel **70** and lid **76** readily portable as a single, carryable unit.

Inside the pressurized aluminum vessel **70**, an 1800 mL volume aluminum pot **90**, of approximately 7 inch diameter, covered with a perforated lid **92** is placed at the interior base of the vessel to act as the internal boiler **72** and to allow for efficient mixing of the chemical combination. The apparatus in this arrangement is suitable for generating conditions capable of sterilizing microbiologically contaminated objects using various chemical combinations corresponding to the sterilization methods described above.

Using the pressurized aluminum vessel **70** to carry out "combined sterilization" is accomplished by either combining all of the reagents into the single boiler **72**, or judiciously dividing the reactants into separate boilers (not shown). The heat output of the Mg(Fe)—H_2O chemical combination is intensified by the presence of chlorite, peroxodisulfate, or copper(II) ions that also act to decrease the volume of dihydrogen gas produced by scavenging specific chemical precursors. With chlorite as the scavenger, the chemical combination is postulated to generate chlorine dioxide as an undetectable, short-lived reactive intermediate. The pressurized aluminum vessel **70** readily accommodates the methods of "chlorine dioxide sterilization" and "thermal sterilization." During "thermal sterilization," temperatures inside the pressurized vessel **70** can exceed 121° C.

After sterilization is complete for all of the chemical combinations, the aluminum pressure vessel **70** can be opened outdoors to release any gaseous chemical reaction products or heat to the environment, and the wrapped sterile instruments are removed using sterile gloves. The reaction vessel **72** is easily rinsed and cleaned, and the entire apparatus can be re-used on a new set of contaminated instruments.

Test Results

A series of sterilization tests were conducted using commercially available biological indicators, live bacterial cells, or live bacterial spores to demonstrate the Portable Chemical Sterilizer using the presently available variants of hardware configurations and chemical combinations. Specifically, the sterilization tests used BT Sure Biological Indicator Tests for Steam Sterilizers (designated BT strips and available from Barnstead International, Dubuque, Iowa, USA), Difco Hy-check disinfection control for hygiene monitoring contact slides (designated Hy-check and available from Becton-Dickinson, Sparks, Md., USA), live cells of *Staphylococcus aureus* (10^7), *Escherichia coli* ATCC 11229 and 11220 (10^7 each), and *Listeria monocytogenes* (10^6), and live spores of *Bacillus stearothermophilus* (10^8).

Cultures were suspended in Butterfield's phosphate buffer solution and placed inside the Portable Chemical Sterilizer and exposed to the conditions of biocidal chemical agent, heat, and humidity generated by the chemical combination inside the apparatus. *S. aureus* was plated on Baird-Parker Agar supplemented with Egg-Yolk tellurite and incubated at 35° C. for 48 hours, both *E. coli* strains and *L. monocytogenes* were plated on Nutrient Agar and incubated at 35° C. for 24 and 48 hours, respectively, and *B. stearothermophilus* spores were plated on Antibiotic Assay Medium with 1% soluble Starch (AAMS) and incubated for 24 hours at 55° C. (F E Feeherry, D T Munsey, and D B Rowley 1987 Appl Environ Microbiol 53(2), 365-370). The results of the sterilization tests are shown in Tables 1-3.

TABLE 1

Sterilization tests in large plastic carry-case. Negative results (–) indicate sterility.

ClO_2^- (g)	SO_3^{2-} (g)	ascorbate (g)	water (mL)	Exposure time (min)	Results	Flush time (min)
93	63	25	300	15	– (BT strip in blue paper)	15
140	94	37.5	450	15	– (BT strip in blue paper)	10
186	126	50	600	15	– (BT strip in blue paper)	15
93.12	63.12	25.02	300	24-15	– (BT strip) – (Hy-check) – (wet live BT spores at 24 &	15

TABLE 1-continued

Sterilization tests in large plastic carry-case. Negative results (–) indicate sterility.

ClO_2^- (g)	SO_3^{2-} (g)	ascorbate (g)	water (mL)	Exposure time (min)	Results	Flush time (min)
102.48	69.4	27.82	300	15	48 h) – dry live BT spores – Hy-check – wet live BT spores at 24 & 48 h)	15

TABLE 2

Sterilization tests in small plastic carry-case. Negative results (–) indicate sterility.

ClO_2^- (g)	SO_3^{2-} (g)	ascorbate (g)	water (mL)	Exposure time (min)	Results	Flush time (min)
7.81	5.49	2.10	25	15	– BT strip/ blue paper	5
9.36	6.37	2.50	30	15	– BT strip/ blue paper	5
15.55	10.58	4.23	50	15	– BT strip/ blue paper	5
23.19	15.82	6.25	75	15	– BT strip/ blue paper	5
31.6	21.4	8.6	100	20-30	– BT strip	0
39.5	27	10.8	125	30	– BT strip	0

TABLE 3

Sterilization tests in a modified 20-Liter aluminum pressure vessel. Negative results (–) indicate sterility.

ClO_2^- (g)	SO_3^{2-} (g)	ascorbate (g)	Mg/Fe (g)	water (mL)	Exposure time (min)	Results
0	0	0	140	600	50	–
185	126	50	85	600	50	–
93	63	50	61	300	50	–
185	101	75	0	600	50	–
185	126	50	0	600	50	–
93	63	75	0	300	50	–
93	63	75	0	300	50	–
46.5	31.5	12.5	0	300	50	–
46.5	31.5	12.5	0	150	50	–
23.3	31.5	12.5	0	150	50	–
186	126	50	0	600	15	–
140	94	37.5	0	450	15	–
93	63	25	0	300	15	–
93	63	25	0	300	15	–
93	63	50	0	300	15	–
46.5	31.5	12.5	0	300	50	live SA, EC, LM. BT

It will be understood that many additional changes in the details, materials, and arrangement of parts, which have been herein described and illustrated in order to explain the nature of the invention, may be made by those skilled in the art within the principles and scope of the invention as expressed in the appended claims.

What is claimed is:

1. An assembly for sterilizing of a plurality of microbiologically contaminated objects, using in situ generated chlorine dioxide sterilant, heat, and- humidity, the assembly comprising:

a unit comprising a closable, portable, hand carried carry case weighing up to about 35 pounds and having an inner chamber for accepting microbiologically contaminated objects;

an interior vessel disposed in the inner chamber for serving as a reaction chamber, said vessel for receiving and combining dry chemical precursors with water, within the case, said vessel being adapted for rinsing and cleaning, independently from the case, for reusing the vessel on other contaminated objects;

a combination of dry chemical precursors which upon combining with water generates in situ biocidal sterilization agents, and subsequently generates at least minimally sufficient conditions of the chlorine dioxide sterilant, heat, and humidity to effect microbiological sterilization of the objects, said combination of dry chemicals excluding acids and consisting of chlorite ion ClO_2^- as an oxidant, sulfite ion SO_3^{2-} as a reductant, and sodium hydrogen ascorbate ion AH^- as an effector, said sodium hydrogen ascorbate being in an amount less than a stoichiometric amount, and said combination of dry chemical precursors being combined with water causing a reaction by electron transfer, and not acidification, during sterilization, at neutral pH, for producing heat and humidity and chlorine dioxide in amounts sufficient to effect said sterilization, under which reaction by electron transfer the ascorbate initiates a reduction of chlorite by a transfer of an electron from chlorite to ascorbate for causing a release of heat, a decrease in solution pH, and a release of chlorine dioxide in heated gaseous and acqueous forms, said reaction between ascorbate and chlorite inducing chemical reaction between chlorite and sulfite for producing heat and increasing solution pH for generating heated chlorine dioxide at neutral pH for affecting said objects to expose any contaminating microorganisms to said chlorine dioxide and sterilizing said objects;

a pressure release outlet check valve mounted on said unit for automatically periodically controlling pressures at ambient during sterilzation and venting pressures above ambient and releasing any heated gases and sterilant after sterilization whereby said outlet check valve prevents accumulation of pressures above ambient air pressures in the inner chamber during a sterilization process cycle, and vents pressures above ambient and releases any heated gases and sterilant after sterilization of the objects for flushing said gases and sterilant from the unit for allowing access to said objects;

a dry gas scrubber, comprising, porous sponge material, engrafted onto and with a protective framework of said outlet check valve, a reductant comprising sulfur ions being embedded in the sponge material, said scrubber, valve and framework not protruding beyond the unit, for absorbing any chlorine dioxide gas exiting the unit during any stage of a sterilization process, said gas scrubber for inactivating the chlorine dioxide gas passing through the scrubber, the chlorine dioxide being reduced by the ions for forming a reaction converting chlorine dioxide and the reductant to inert ionic chloride and sulfate, respectively; and

an inlet valve, being a filtered one way valve, mounted on said unit, for permitting incoming air to flow into the unit after sterilization, said incoming air being distributed within the unit and mixing with any gaseous products remaining in the unit, said incoming air increasing pressure from ambient to greater than ambient in the unit and thereby flushing any remaining gaseous products from

the unit through the outlet valve after sterilization of the objects, said inlet valve preventing any gases from flowing out of the unit through the inlet valve, and said inlet valve having a filter for filtering incoming air and preventing introduction of contaminating air-borne particulate matter and microbiological contaminants to re-contaminate the sterilized objects, whereby the outlet check valve and the inlet valve cooperate to maintain ambient pressure during sterilization, to increase pressure, after sterilization, and to flush any gaseous products from the unit;

wherein the assembly, including the unit, vessel, combination of dry chemical precursors with water, outlet check valve and dry scrubber, and filtered inlet valve, is self-contained, reusable and is free of any external source of power for controllably generating sufficient amounts of chlorine dioxide, heat, and humidity to sterilize the contaminated objects, for preventing accumulation of pressures above ambient air pressures during sterilization, for increasing pressure after sterilization, and for venting and deactivating chemical reaction products from the unit.

2. The assembly in accordance with claim **1**, wherein said unit comprises a generally rectangular-shaped bottom wall, four side walls respectively upstanding from side edges of said bottom wall, and a top wall pivotally mounted on one of said side walls and adapted to be moved between an open position and a closed position so as to define, in conjunction with said bottom wall and said side walls, the inner chamber, said vessel being placed in the inner chamber and adapted to receive said combination of dry chemical precursors for combining with water, and a support structure for receiving and supporting the contaminated objects, said outlet check valve and said dry gas scrubber, being mounted in at least one of said walls, and said filtered inlet valve being mounted in one of said walls, and wherein said filtered inlet valve is in communication with an air circulator tube, said tube being perforated and disposed within said chamber, and wherein the chemical combination comprises water, chlorite ion, sulfite ion, and hydrogen ascorbate ion.

3. The assembly in accordance with claim **1** and further comprising an air circulator tube in communication with said inlet valve and said chamber, said tube being perforated and disposed within the chamber in a manner, generally circular, for circulating incoming air throughout the unit and mixing said air with said any gaseous products for forming a mixture and increasing pressure inside the chamber, said mixture flowing out of said outlet check valve, said outlet check valve automatically opening and closing periodically for assuring said mixing and for flowing said mixture out of the unit.

4. The assembly in accordance with claim **1** wherein said unit is insulated aluminum.

5. The assembly in accordance with claim **1** wherein said combination, of dry chemical precursors which excludes acids, consists of about 300 mL H_20, 93 g $NaClO_2$, 63 g Na_2SO_3, and 25 g $NaC_6H_7O_6$.

6. The assembly in accordance with claim **1** wherein said unit is plastic.

7. The assembly in accordance with claim **3** wherein said inlet valve is connected to a portable air pump for flowing air into the unit and providing a flow of air into the chamber and acting in concert with operation of the outlet valve engrafted with the scrubber for flushing and removing sterilant gas from the chamber after a sterilization process is completed.

8. The assembly in accordance with claim **1** wherein said reductant for the scrubber is selected from the group consisting of sulfite (SO_3^{2-}), dithiomte ($S_2O_5^{2-}$), and thiosulfate ($S_2O_3^{2-}$).

9. The assembly in accordance with claim **1**, wherein said combination of chemical precursors and water is varied in relative proportions of chemical components depending on size of unit in which sterilization occurs.

10. The assembly in accordance with claim **1**, wherein said combination of chemical precursors and water is varied in relative proportions of chemical components depending on different characteristics of the combination of chemicals.

11. The assembly in accordance with claim **1**, wherein a chlorine-containing oxidant is derived from any one of several salts having different counter ions.

12. The assembly in accordance with claim **11**, wherein any one of several salts is selected from the group consisting of lithium, sodium, potassium, and calcium cations.

13. The assembly in accordance with claim **1**, wherein a hydrogen ascorbate salt is an effector.

14. The assembly in accordance with claim **13**, wherein said effector is selected from the group consisting of ionic conjugate base forms of ascorbic acid (ascorbate), erythorbic acid (erythorbate), tartaric acid (tartarate), and any of their respective ions.

15. The assembly in accordance with claim **1**, wherein said scrubber consists of two layers of wire gauze sandwiching a said porous sponge material, said sponge material being embedded with said reductant for inactivating chlorine dioxide gas exiting the unit.

16. The assembly in accordance with claim **15**, wherein the reductant is sodium sulfite.

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