



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Antimicrobials Division (7510P)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

90607-3

Date of Issuance:

11/14/16

NOTICE OF PESTICIDE:

Registration
 Reregistration
 (under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

AsepticSure™ Oxidative Catalyst

Name and Address of Registrant (include ZIP Code):

Medizone International, Inc.
 4000 Bridgeway, Suite 401
 Sausalito, CA 94965

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Antimicrobials Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Julie Chao, Product Manager 33
 Regulatory Management Branch 1, Antimicrobials Division (7510P)

Date:

11/14/16

2. You are required to comply with the data requirements described in the DCI identified below:

a. Hydrogen Peroxide GDCI-000595-1127

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Reevaluation Team Leader (Team 36): <http://www2.epa.gov/pesticide-contacts/contacts-office-pesticide-programs-antimicrobial-division>.

3. Make the following label changes before you release the product for shipment:

- Revise the EPA Registration Number to read, “EPA Reg. No. 90607-3.”

4. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 05/24/2016

If you have any questions, please contact Seiichi Murasaki at (703) 347-0163 or murasaki.seiichi@epa.gov.

Sincerely,



Julie Chao, Product Manager 33
Regulatory Management Branch 1

Enclosure: Accepted Label

{MASTER LABEL}

{All text in brackets [xxx] is optional & may or may not be included on a printed label.}

{All text in braces {xxx} is administrative communication & will not appear on a printed label.}

AsepticSure™ Oxidative Catalyst

For Industrial and Institutional Use Only - Not for Food Contact or Household Use

AsepticSure™ Oxidative Catalyst is only for use in conjunction with the AsepticSure™ Ozone Generator™ fogging system.

AsepticSure™ Oxidative Catalyst is for use in hospitals, clinics, food industry, sporting venues, and hotels to disinfect hard non-porous surfaces.

Active Ingredients:

Hydrogen Peroxide	6%
Other Ingredients	94%
Total	100%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

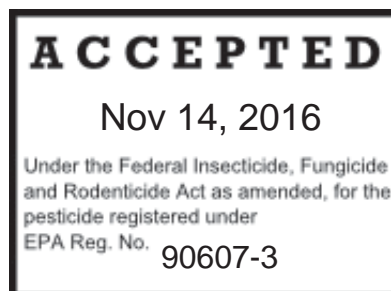
[See [side] [back] panels for additional precautionary statements]

FIRST AID	
IF IN EYES	Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.
IF INHALED	Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
Have the product container or label with you when calling a poison control center or doctor or going for treatment. For medical emergencies, call the poison control center 1-800-222-1222. You may also contact Chemtrec at 800-424-9300 for emergency medical treatment information	

EPA Reg. No. 90607- G

EPA Estab. No. 909607-CAN-001

NET CONTENTS: _____ fl oz (_____ L)



{MASTER LABEL}

{All text in brackets [xxx] is optional & may or may not be included on a printed label.}

{All text in braces {xxx} is administrative communication & will not appear on a printed label.}

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Causes moderate eye irritation. Harmful if inhaled. Avoid contact with eyes or clothing. Avoid breathing vapors or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

[Extended contact with this product may cause a temporary white appearance on the skin of some individuals. Bubbling or foaming may also occur upon contact with dry or damaged skin. These are normal effects from hydrogen peroxide and the white appearance should disappear quickly. To minimize these effects, rinse or wash hands promptly after contact.] [If extended contact with the product results in a temporary white appearance of the skin, or if foaming appears on dry or damaged skin, it is a common reaction to the hydrogen peroxide and will disappear quickly. To minimize the effect, rinse hands after using the product.]

PERSONAL PROTECTIVE EQUIPMENT (PPE):

For early re-entry for the AsepticSure™ Ozone Generator fogging system, the following PPE must be worn:

- Protective eyewear such as goggles, face shield or safety glasses
- R95 Respirator with Activated Charcoal Filter, Powered Air Purifying Respirator or equivalent
- Gloves and a hydrogen peroxide resistant body suit (such as a Tyvek protective suit)

Final selection of additional PPE must be in accordance with hospital site guidelines and take into consideration the product and any infection or exposure hazards related to the environment to be disinfected.

PHYSICAL AND CHEMICAL HAZARDS

This product is incompatible with strong oxidizing and reducing agents.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labelling. Refer to Users' Manual for complete product use directions.

The surface area to be treated must be cleaned thoroughly prior to treatment

AsepticSure™ Oxidative Catalyst is only to be used in conjunction with the AsepticSure™ system to disinfect hard non-porous surfaces in hospitals, health care facilities, clinics, food industry equipment, sporting venues, and hotels.

Preparation of End-Use Product: AsepticSure™ Oxidative Catalyst is added to the AsepticSure™ fogging system and is combined with ozone produced by the ozone generator. When mixed together, they create an end use vapor containing approximately 80 ppm ozone and 1.4% hydrogen peroxide.

To prepare the AsepticSure™ system, pour 2.7 L of distilled water and 816 mls of AsepticSure™ Oxidative catalyst into the identified reservoir on the AsepticSure™ fogging system. Note that the quantity of hydrogen peroxide added is in excess of the amount typically used in a single treatment. Starting the AsepticSure™ system will automatically facilitate the mixing of the hydrogen peroxide with the ozone. The system will create and dispense the hydrogen peroxide/ozone mixture and upon completion of the treatment will automatically engage the

{MASTER LABEL}

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purge cycle to return the room environment to safe ozone levels thereby permitting personnel to re-enter the room.

This product is not to be used as a terminal sterilant/high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.

Treatment Overview

Once the AsepticSure™ system has been placed in the room and connected electrically, the room is sealed, the HVAC Systems are shut off to the room, and entry is restricted to authorized personnel only. The AsepticSure™ system is accessed remotely and the disinfection treatment cycle initiated. The duration of the total disinfection process is dependent upon the necessary time to meet the required treatment parameters and can vary with room size ranging from 15 to 90 minutes. The treatment portion of the cycle is standardized at 40 minutes. Upon completion of the cycle, the AsepticSure™ system will draw air from the room through a set of charcoal air purifiers to remove the residual ozone and hydrogen peroxide vapor. Once the ozone level has been reduced to 0.04 ppm the system will indicate the room is safe for re-entry. Allow an additional 10 minutes after ozone levels of 0.04 ppm have been reached before re-entering the treated area.

Re-entry to the treated area is prohibited before hydrogen peroxide levels reach 0.2 ppm.

OSHA guidelines (2015) for ozone in the workplace:

- 0.2 ppm for no more than 2 hours exposure
- 0.1 ppm for 8 hours per day exposure doing light work
- 0.08 ppm for 8 hours per day exposure doing moderate work
- 0.05 ppm for 8 hours per day exposure doing heavy work

In all applications, always use a new solution to ensure effectiveness. Do not reuse solutions and always dispose of product according to local, state or federal law.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Product should be stored in original container. Never return product to the original container once removed. Store in a dry place no lower in temperature than 50° F or higher than 120° F. Avoid all contaminants, especially dirt, caustic, reducing agents and metals. Contamination and impurities will reduce shelf life and can induce decomposition.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Non-refillable container. Do not reuse or refill this container. Triple rinse as follows: Empty remaining contents into application equipment or mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling, if available or puncture and dispose of in a sanitary landfill or by incineration.

{MASTER LABEL}

{All text in brackets [xxx] is optional & may or may not be included on a printed label.}

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For more information see Material Safety Data Sheet

AsepticSure™ Oxidative Catalyst is a trademark of Medizone International



Medizone International

401- 4000 Bridgeway

Sausalito, CA 94965

{MASTER LABEL}

{All text in brackets [xxx] is optional & may or may not be included on a printed label.}

{All text in braces {xxx} is administrative communication & will not appear on a printed label.}

{Small Container Label, if needed}

AsepticSure™ Oxidative Catalyst

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AsepticSure™ Oxidative Catalyst is intended for use in hospitals, clinics, food industry, sporting venues, and hotels to disinfect hard non-porous surfaces.

Active Ingredients:

Hydrogen Peroxide	6%
Other Ingredients	94%
Total.....	100%

**KEEP OUT OF REACH OF CHILDREN
CAUTION**

Read complete directions and precautions in the accompanying booklet and manual



Medizone International
401- 4000 Bridgeway
Sausalito, CA 94965

EPA Reg. No. 90607-G

EPA Estab. No. 909607-CAN-001

NET CONTENTS: _____ fl oz (_____ L)

(Device Label)
EPA Reg. # 90607 G

AsepticSure Ozone Generator™ fogging system

For Industrial and Institutional Use Only - Not for Household Use

AsepticSure Ozone Generator™ fogging system is only for use in conjunction with the AsepticSure Oxidative Catalyst.

AsepticSure Ozone Generator™ fogging system is for use in hospitals, clinics, food industry, sporting venues, and hotels to disinfect hard non-porous surfaces.

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read complete directions and precautions in the accompanying booklet and manual



Medizone International, Inc.
4000 Bridgeway, Suite 401
Sausalito, CA 94965

EPA Establishment No.: _____
EPA Reg. # 90607-G

User Manual Operator Instructions

AsepticSure™ Disinfection System (ADS)

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AsepticSure™ is a trademark of Medizone International Inc.



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Introduction

User Manual Information

This manual describes the safety precautions, function, features and methods of use and care for the AsepticSure™ Disinfection System to be referred to as the AsepticSure™ herein. The AsepticSure™ consists of the Aseptic Sure Primary Station, Remote Station (laptop), and three (3) ozone destructors. Each Disinfection Cycle requires the addition of a consumable Disinfection Catalyst. For additional optional accessories, see **System Description** in **Chapter 2 Getting Started**.

Please review this manual entirely before using the system.

Note: For accessories for your AsepticSure™ Disinfection System, please contact your sales representative.

The graphics, figures, and images used in this operator manual are examples only. The actual display and design of these may be slightly different on your system.

How to use this User Manual








Only trained personnel should operate AsepticSure™ Disinfection System. All personnel should review this manual in its entirety before using the system.








Important notes, warnings, or cautions are *italicized* and segregated from the body of the text. If the warning or caution is safety-related or could result in significant damage if it is not heeded, an additional warning/caution symbol will be displayed in the margin to further alert the reader.








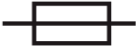
Use of Symbols

Table 1: Packaging and Safety Symbols

Safety Notice	Meaning
 <p>DANGER</p>	<p>A red DANGER symbol is used to identify conditions or actions for which a specific hazard is known to exist. These conditions or actions will cause severe personal injury, death or substantial property damage if the instructions are not followed.</p>
 <p>WARNING</p>	<p>An orange WARNING symbol is used to identify conditions or actions for which a specific hazard is known to exist. These conditions or actions may cause severe personal injury or substantial property damage if the instructions are not followed.</p>
 <p>CAUTION</p>	<p>A yellow CAUTION symbol is used to identify conditions or actions for which a potential hazard may exist. These conditions or actions may cause minor personal injury or property damage if the instructions are not followed.</p>
	<p>Attention: Consult accompanying documents.</p>
	<p>Symbol for Electrostatic Discharge (ESD) sensitivity</p>
	<p>Mass indicates the total weight of the equipment.</p>
	<p>Consult operating instructions before using.</p>

Safety Notice	Meaning
	<p>Indicates the Manufacturer of the device.</p>
	<p>Indicates safety certification.</p>
	<p>Temperature Limitation indicates the range of acceptable temperature conditions for shipping and storage.</p>
	<p>Indicates a potential pinch hazard</p>
	<p>The crossed out wheeled bin symbol is used to mark products that should not be disposed with general household waste, but collected separately for reuse or recycling.</p> <p>No part of the system shall be disposed of in land fill. Return the device to Medizone International Inc. for disposal.</p>
	<p>The batteries and/or battery containing product conform to EU Directive 2006/66/EC. The batteries must be disposed of appropriately and should be separated from the normal municipal waste stream and land fill.</p>
	<p>Single-use only. Do not re-use.</p>





Safety Notice	Meaning
	Non-ionizing electromagnetic radiation
	Service or repair
	Reference number
	Manufactured date
	Serial number
	Fuse rating

Safety


The following are general warning statements pertaining to the user of the AsepticSure™ Disinfection System.

Table 2: General Warnings

Safety Notice	Meaning
 DANGER	All personnel using the system must be instructed in the proper set-up and handling of the system and should be familiar with this User Manual.
	Before starting a Disinfection Cycle, the room or environment must be fully sealed. If the room is not sealed, ozone could be exhausted into the ambient environment at levels hazardous to health.
	When conducting a cycle, immediately abort the cycle if ozone can be smelled or otherwise detected.

Safety Notice	Meaning
	<p>If at any time you suspect that there is ozone in the room at levels above acceptable limits when not running a disinfection cycle, use the ozone detector provided to confirm. If the levels are above 0.05 ppm, evacuate immediately and contact the authorized service representative.</p> <p>Ensure that prior to performing an AsepticSure™ Disinfection Cycle, the appropriate Primary Stations are selected via the Remote Station. Selecting the wrong Primary Stations could result in injury or damage.</p>
 WARNING	<p>Before using the AsepticSure™ Disinfection System, visually inspect it to ensure there is no external damage. Do not operate the AsepticSure™ Disinfection System if there is any visible or suspected damage.</p>
	<p>Do not install any other software on the Remote Station. Do not reconfigure the Remote Station in any way (e.g. enabling the screen saver, sound, brightness, etc.).</p>
	<p>When running an AsepticSure™ Disinfection Cycle, no other applications should be running on the Remote Station</p>
	<p>Ozone can be corrosive. Repeated use of the AsepticSure™ Disinfection System can over time cause minor corrosive damage to ozone-sensitive materials or equipment. Ensure where possible that all such materials are removed from the environment before beginning an AsepticSure™ Disinfection Cycle (see Table 3).</p>
	<p>The AsepticSure™ Disinfection Catalyst contains low concentrations of hydrogen peroxide. As a precaution, ensure that all hydrogen peroxide-sensitive materials or equipment are removed, where possible from the environment before beginning an AsepticSure™ Disinfection Cycle (see Table 4).</p>



Safety Notice	Meaning
	<p>The AsepticSure™ Disinfection Cycle humidifies the room. If necessary, ensure that all humidity-sensitive materials or equipment are removed from the environment before beginning an AsepticSure™ Disinfection Cycle.</p> <p>Any modifications made to the system that are not authorized by Medizone International Inc. may void the product warranty and impact the safety of the system.</p> <p>Service personnel must have specialized training to ensure the safe operating condition of the AsepticSure™ Disinfection System. To ensure continuing safe and effective functioning of the system, only properly trained and qualified personnel are authorized to service any components of this system.</p> <p>If required, suitable Biological Indicators may be used to verify the disinfection cycle. Contact Medizone International or its authorized distributor for the appropriate indicator to use.</p>
 <p>CAUTION:</p>	<p>When conducting a cycle, ensure that all vents on the AsepticSure™ Disinfection System are free of obstruction and located with appropriate clearance from walls or other equipment. Obstruction of the vents may significantly impact system performance.</p> <p>The AsepticSure™ Primary Station needs to be plugged into a wall outlet. Extension cords not approved for use with the system shall not be used with the AsepticSure™ system.</p> <p>No other equipment may be powered on the same circuit as the Primary Station; ensure all other equipment is unplugged or powered off.</p> <p>The three (3) ozone destruct stations and dehumidifier (not provided) should be plugged into the appropriate receptacles on the Primary Station. Not plugging in the ozone destruct stations or the dehumidifier into the Primary Station will result in longer-than-expected Disinfection Cycles and may reduce the effectiveness of the Disinfection Cycle.</p>



Safety Notice	Meaning
	Ensure that the wheels of the AsepticSure™ Primary Station and ozone destruct stations are locked before beginning a disinfection cycle or when storing the system
	Ensure that the AsepticSure™ Disinfection Catalyst that is used for the Disinfection Cycle has not surpassed its expiry date. Using expired Disinfection Catalyst may impair the effectiveness of the Disinfection Cycle.
	Do not transport the AsepticSure™ Primary Station with any liquid (such as Disinfection Catalyst) inside. Always empty the unit of all fluids prior to transport.
	In and around the RF operation range of the system (see the “Specifications” section), only one (1) AsepticSure™ Remote Station can be running at a time. Failure to do so may cause RF interference when running a disinfection cycle.

Classification

The AsepticSure™ Disinfection System has been evaluated to comply with IEC 61010-1.



Incident Reporting

The operator should contact a service representative immediately to report an incident and/or injury to any individual that occurred as a result of operation of the AsepticSure™ Disinfection System.



If an accident occurs as a result of use of the AsepticSure™, do not operate the equipment until an investigation by authorized personnel has been conducted.

Additional Precautions

The AsepticSure™ Disinfection System should not be stacked on other equipment or AsepticSure™ Disinfection Systems.

Additional Precautions (EMC)

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should ensure that it is used in such an environment.

- The AsepticSure™ Disinfection System complies with IEC 61326-1.



Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources could result in performance disruption of the AsepticSure™ Disinfection System. Evidence of disruption may include distortion of the display, erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site to determine the source of disruption.

To avoid the risk of increased electromagnetic emissions or decreased immunity, use only accessories and peripherals recommended by Medizone International Inc. Connection of accessories and peripherals not recommended by Medizone could result in malfunctioning of the AsepticSure™ Disinfection System or other medical electrical devices in the area.

Contact Medizone or Medizone authorized representative for a list of accessories and peripherals available from or recommended by Medizone.

Additional Precautions (ESD)



Electrostatic discharge (ESD), or static shock, is a naturally occurring phenomenon. ESD is common in conditions of low humidity, which can be caused by heating or air conditioning. Static shock is a discharge of the electrical energy from a charged body to a lesser or non-charged body. The degree of discharge can be significant enough to cause damage to the AsepticSure™ Disinfection System or its accessories.

The following precautions can help reduce ESD:

- anti-static spray on carpets
- anti-static spray on linoleum
- anti-static mats





AsepticSure™ Service

The AsepticSure™ Disinfection System can only be serviced by a trained representative.

If your system has been ordered from Medizone International Inc., please use the following contact information:

Phone: (North America) 1-415-331-0303 or (International) +1 415-331-0303

Email: operations@medizoneint.com

Address: Medizone International Inc.
2330 Marinship Way, Suite 300
Sausalito, CA
94965

Medizone International, Inc.
2330 Marinship Way, Suite 300
Sausalito, CA
94965

Phone: (North America) 1-415-331-0303
(International) +1 415-331-0303

www.medizoneint.com



Getting Started

Guidelines for Use

The AsepticSure™ Disinfection System is a disinfection system that delivers a proprietary dosage profile of ozone and hydrogen peroxide to a manually-sealed environment. The disinfection takes place via a discrete cycle of approximately 2 hours that is user-initiated and is remotely controlled and monitored in real-time.



DANGER: Before initiating the cycle, the user must ensure that the room is sealed “air-tight”. If the room is not sealed, ozone may be exhausted into the ambient environment at levels hazardous to health.



WARNING: Because the gas formula is highly oxidative, care must be taken that the room to be disinfected be appropriate and compatible. Any sensitive equipment that may be adversely affected by ozone or hydrogen peroxide should be removed from the room prior to the start of a disinfection cycle.



WARNING: AsepticSure™ Disinfection System must be continuously monitored by the operator during a cycle.

Prior to each disinfection cycle, the proprietary Disinfection Catalyst must be poured into the system and the ozone destruct stations must be plugged into their appropriate receptacles.

If the humidity level of the room to be disinfected is greater than 40%, a dehumidifier (not provided) must be plugged into its appropriate receptacle.



CAUTION: Failure to pour the Disinfection Catalyst into the system may impair the effectiveness of the Disinfection Cycle.

At the completion of a Disinfection Cycle, the AsepticSure™ monitors the conditions of the environment in order to ensure that the room is safe for re-entry.

Indications for Use/Contraindications

Indications for Use

The AsepticSure™ Disinfection System is intended for the disinfection of exposed surfaces within an enclosed space including whole rooms and facilities. The system has been designed to deliver multiple disinfections as determined necessary by facility management.



DANGER: Do not use AsepticSure™ for anything other than its intended use.

Contraindications and Material Compatibility

WARNING: Ozone can be corrosive and is poisonous in high quantities. Hydrogen peroxide at high concentrations can be corrosive.



Ozone:

The operator should be aware of the following material compatibilities with ozone and hydrogen peroxide and should ensure that equipment that is comprised of incompatible materials is either removed from the environment to be disinfected or appropriately protected. The list in the table below, although extensive, is not exhaustive. If the ozone compatibility properties of a material or equipment are unknown, it is recommended to remove the material or equipment from the room prior to disinfection.

Table 3: Ozone Compatible Materials

Material	Rating*
ABS plastic	B – Good
Acetal (Delrin®)	C – Fair
Aluminum	B – Good
Brass	B – Good
Bronze	B – Good
Buna-N (Nitrile)	D – Severe Effect
Butyl	A – Excellent
Cast iron	C – Fair
Chemraz	A – Excellent
Copper	B – Good



Material	Rating*
CPVC	A – Excellent
Durachlor-51	A – Excellent
Durlon 9000	A – Excellent
EPDM	A – Excellent up to 100°F
EPR	A – Excellent
Epoxy	N/A
Ethylene-Propylene	A – Excellent
Flexelene	A – Excellent
Fluorosilicone	A – Excellent
Galvanized Steel	In water (C – Fair), In Air (A – Excellent)
Glass	A – Excellent
Hastelloy-C®	A – Excellent
HDPE	A – Excellent
Hypalon®	C – Fair
Hytre®	C – Fair
Inconel	A – Excellent
Kalrez	A – Excellent up to 100°F
Kel-F® (PCTFE)	A – Excellent
LDPE	B – Good
Magnesium	D – Poor
Monel	C – Fair
Natural rubber	D – Severe Effect
Neoprene	C – Fair
NORYL®	N/A
Nylon	D – Severe Effect
PEEK	A – Excellent



Material	Rating*
Polyacrylate	B – Good
Polyamide (PA)	C-D (Not recommended)
Polycarbonate	A – Excellent
Polyethylene	In Water (B-Good), In Air (C-Fair)
Polypropylene	C – Fair
Polysulfide	B – Good
Polyurethane, Millable	A – Excellent
PPS (Ryton®)	N/A
PTFE (Teflon®)	A – Excellent
PVC	B – Good
PVDF (Kynar®)	A – Excellent
Santoprene	A – Excellent
Silicone	A – Excellent
Stainless steel (304)	B – Good/excellent
Stainless steel (316)	A – Excellent
Steel (Mild, HSLA)	D – Poor
Teflon	A – Excellent
Titanium	A – Excellent
Tygon®	B – Good
Vamac	A – Excellent
Viton ®	A – Excellent
Zinc	D – Poor

***Ratings Legend:**

A – Excellent = No effect

B – Good = Minor effect, slight corrosion or discoloration

C – Fair = Moderate effect, not recommended for continuous use.

Softening, loss of strength, swelling may occur.

D – Severe Effect = Not recommended for **ANY** use.



Hydrogen Peroxide:

The list in the table below, although extensive, is not exhaustive. If the hydrogen peroxide compatibility properties of a material or equipment are unknown, it is recommended to remove the material or equipment from the room prior to disinfection.

Table 4: Hydrogen Peroxide compatibility

Material	Effects of exposure to Hydrogen Peroxide
Metals:	
Aluminum 5251/H22 (unprotected)	Discoloration and signs of oxidation; avoid use
Aluminum alloy (niproloy coated)	No apparent effect
Aluminum bronze	No apparent effect
Anodized aluminum	No apparent effect
Brass	Slight discoloration
Copper	Slight discoloration
Mild Steel	Rusting and shallow pitting; not suitable
Stainless Steel	No apparent effect
Coated/painted metals:	
Brush painted mild steel	Severe blistering of painted surface; not suitable
Epoxy painted mild steel	No apparent effect
Galvanized steel	No apparent effect
Passivated (coated) metal materials	Slight discoloration
Passivated steel	Slight discoloration
Polyester powder coated aluminum	No apparent effect
Stove enamel painted mild steel	Some bubbling or flaking from repeated cycles
Plastics, rubbers, etc.:	
ABS	No apparent effect



Material	Effects of exposure to Hydrogen Peroxide
Acrovyn	No apparent effect
Glass-reinforced Plastic	No apparent effect; recommend careful consideration in application as it is porous
Machinable Nylube	Some color bleaching observed
Natural rubber	Decomposes when exposed to hydrogen peroxide
Neoprene	No apparent effect
Perspex	No apparent effect; some out gassing observed
Polypropylene	No apparent effect; effects of long term exposure unknown
Polythene	No apparent effect, should not be used for long term exposure; readily absorbs hydrogen peroxide
PTFE	No apparent effect
PVC and PVC foam	No apparent effect; out gassing experienced
Silicone rubber (seal)	No apparent effect
Torlon	No apparent effect
Viton	No apparent effect
Component	Effects of exposure to Hydrogen Peroxide
Smoke alarm	No apparent effect
Computer system with monitor	Suitable
Linear bearing	Some discoloration of lubricant
Double-glazed window and aluminum frame	No apparent effect
Rubber floor tiles	No apparent effect
Ceramic tiles	No apparent effect
Desmopan (timing drive belt)	Slight discoloration



System Description

The AsepticSure™ Disinfection System can be configured with various accessories, as appropriate for the particular environment and application.

In areas where the environmental humidity is high, an optional dehumidifier (not provided) may be incorporated with the AsepticSure™ by plugging it into the appropriate receptacle on the Primary Station.



CAUTION: Failure to plug the dehumidifier into the appropriate receptacle on the Primary Station may impair the effectiveness of the Disinfection Cycle.

Three (3) ozone destruct stations expedite the removal of ozone from the room after completion of a disinfection cycle. In order to function appropriately, the ozone destruct stations must be plugged into the appropriate receptacles on each AsepticSure™ Primary Station. Also, for larger spaces that have sufficient power available, multiple AsepticSure™ Primary Stations can be connected, controlled by one Remote Station, for increased output. Each Primary Station would have three (3) ozone destruct stations plugged into them.

The AsepticSure™ Disinfection System consists of the following components:

- AsepticSure™ Primary Station
- Three (3) ozone destruct stations
- AsepticSure™ Remote Station (portable laptop)
- Disinfection Catalyst (consumable, new catalyst used for each cycle)
- Ozone detector/Ozone sniffer
- Laptop lock
- Room sealing tape (available from Medizone)
- Warning Sign

Where appropriate, the following accessories may be incorporated into the AsepticSure™ Disinfection System:

- Dehumidifier (plugged into the Primary Station)
- Biological Indicators

General System Function and Components

AsepticSure™ Primary Station

Figure 1 illustrates the AsepticSure™ Disinfection System and components.



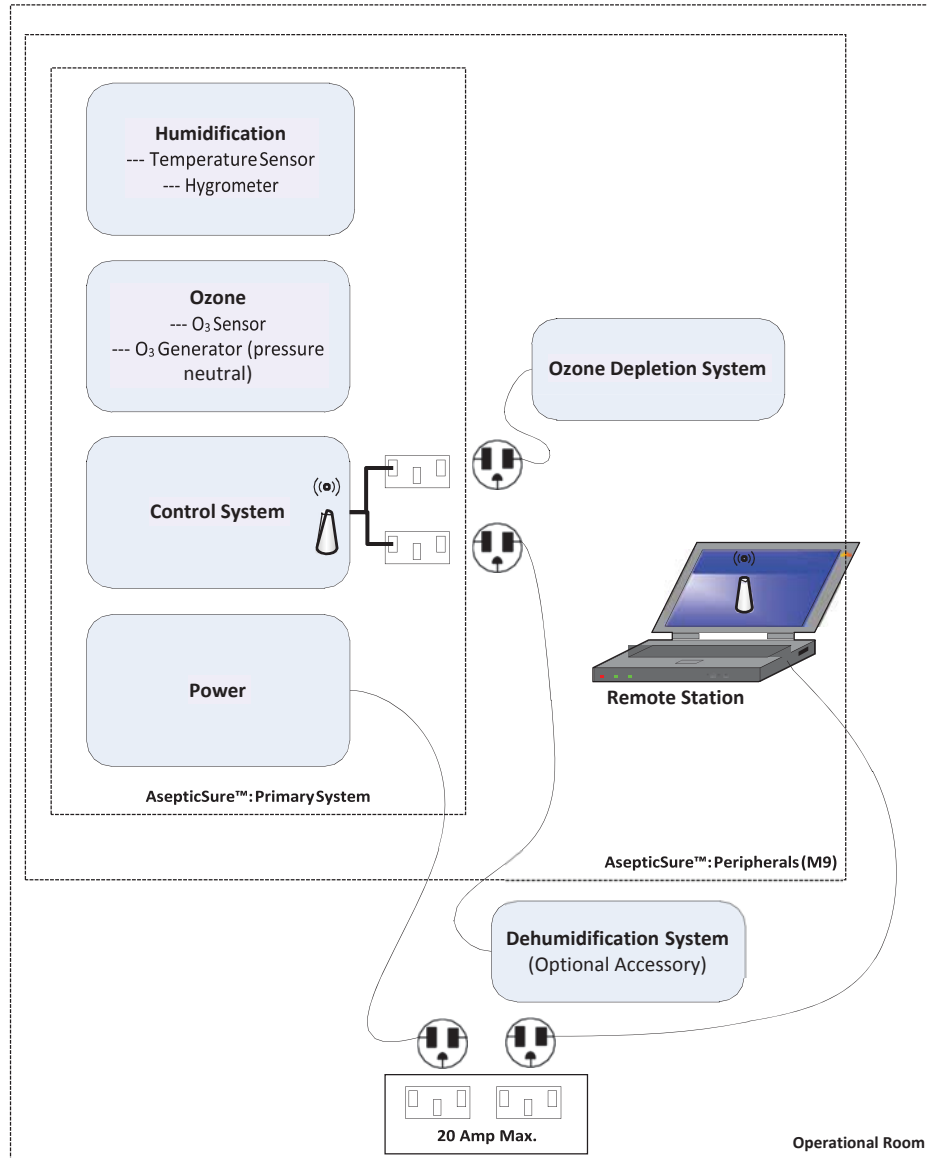


Figure 1: AsepticSure™ Disinfection System and Components

The AsepticSure™ Primary Station delivers the dosage of ozone and Disinfection Catalyst into the environment, controlled and monitored remotely via the Remote Station.

Multiple AsepticSure™ Primary Stations can be used within the same environment, controlled and monitored remotely via Remote Station.

Each AsepticSure™ Primary Station has a unique identifier (to ensure the appropriate control and protection against inappropriate usage).



The AsepticSure™ Primary Station is comprised of ozone generators that use UV to generate the appropriate level of ozone. Intake vents underneath the AsepticSure™ Primary Station chassis provide ambient air into the ozone generators.

The Primary Station also contains a reservoir into which the user pours the AsepticSure™ Disinfection Catalyst. After each disinfection cycle, the reservoir must be emptied. Before starting a Disinfection Cycle, the Primary Station must be refilled with new Disinfection Catalyst. During the Disinfection Cycle, the Primary Station emits the appropriate level of Disinfection Catalyst into the environment.

Primary Station

The Primary Station has four (4) receptacles into which the three (3) ozone destruct stations must be plugged in (in order to be appropriately controlled via the Remote Station). The fourth receptacle is used for the dehumidifier

There is also a Graphical User Interface on the AsepticSure™ Primary Station that is used to place the device into “Standby”, begin an automated self-test diagnostic, place the Station into “Ready” mode, and display any pertinent device information.

Remote Station (portable laptop)

The Remote Station is used to initiate, execute, and, if needed, abort the Disinfection Cycles of the Primary Station(s), in real-time. It is also used to continually monitor the dosage profile to verify that the cycle remains within specification. If the cycle goes outside of specification, the remote station automatically aborts the cycle and begins the Purge stage to bring the ozone level within the room down to safe levels.

At any time, the user can choose to abort the cycle.

If, at any time, the communication between the Remote Station and the Primary Station is lost, cannot occur or is otherwise severed, the cycle will automatically abort.

When the dehumidifier is attached to the Primary Station, it is also controlled by the Remote Station through Primary Station.

Ozone Destruct Stations

Three (3) ozone destruct stations must be plugged into each AsepticSure™ Primary Station in order to facilitate clearing ozone from the environment after the completion of a disinfection cycle or in the event that the cycle is aborted.

Ozone breaks down naturally in the environment, however, the ozone destruct stations significantly reduce the wait time after disinfection to allow reentry into the room.





The location of where the ozone destruct stations are situated will impact the amount of time it takes to reduce the room to safe ozone levels

CAUTION: Do not move the ozone destruct stations to a different location while they are plugged into the Primary Station. Always ensure that they are unplugged before moving.

Dehumidifier (not provided)

A dehumidifier can be attached to the AsepticSure™ system in order to provide pre-conditioning to bring humidity levels to optimal conditions prior to starting the Disinfection Cycle.

The dehumidifier must be plugged into the appropriate outlet on the AsepticSure™ Primary Station in order to be controlled by the Remote Station.



CAUTION: Do not move the dehumidifier to a different location while they are plugged into the Primary Station. Always ensure that they are unplugged before moving.

AsepticSure™ Disinfection Catalyst

The Disinfection Catalyst is single-use only with an expiry date.

If, at the conclusion of a disinfection cycle, there is Disinfection Catalyst remaining in the reservoir, it should be drained and properly disposed.

Before every Disinfection Cycle, the catalyst reservoir must be verified to be empty and then filled with the appropriate amount of Disinfection Catalyst.

The Disinfection Catalyst is a proprietary solution that is required to ensure effective disinfection. Prior to pouring the Disinfection Catalyst into the Catalyst Reservoir of the AsepticSure™ Primary Station, ensure that its expiry date has not been surpassed.

Biological Indicators

Optional Biological Indicators (BI's) may be provided with the AsepticSure™ Disinfection System.

The BI's can be placed within the environment prior to a disinfection cycle and after completion of the cycle, can be used to verify that the disinfection was effective.



Room-Sealing Tape

Room sealing tape is available from Medizone International Inc. Prior to the initiation of a disinfection cycle, the room to be disinfected **must** be sealed to prevent egress of harmful ozone into the ambient environment.

In addition, all Heating Ventilation and Air Conditioning (HVAC) vents and all potential gas leak points must also be sealed off.

Warning Sign

When performing a Disinfection Cycle, the Warning Sign should be prominently displayed on or in front of the door of the room being disinfected. This is to ensure that the room is not inadvertently entered while a Disinfection Cycle is in progress and prevent hazards to health or the environment.

Ozone Detector/Sniffer

Medizone provides an ozone detector to be used to verify that the ozone levels in the vicinity are at a safe level.

For instructions on how to operate the ozone detector, consult the provided manufacturer's instructions.

Using the AsepticSure™ Software

The following describes how to navigate the AsepticSure™ software.

Commands:

To make a selection, drag your mouse pointer over the selection which will highlight it

To advance to the next screen (and accept the selection), click on the **Green** right arrowhead.

To return to the previous screen, click the **Green** left arrowhead

A user may abort the cycle at any time (except the Purge stage) during the process by pressing the "Abort" button at the bottom of the screen and following the instructions.

Available AsepticSure™ Software Application Modes

There are three (3) main applications of the Software:

- **AsepticSure™ Disinfection Cycle*** – this launches the process for disinfecting a room
- **AsepticSure™ Service*** – this is an application for advanced users where parameters can be customized and real-time parameter values can be graphically displayed in real time for any specific or all Primary Stations.
- **AsepticSure™ Administration**



AsepticSure™ Disinfection Cycle and Administration are discussed in the next sections. For AsepticSure™ Service, see the *Service Manual*.

- * The AsepticSure™ will automatically generate and save a data log for each Disinfection Cycle. There is a default folder location for all generated data logs. However, the user will be prompted at the start of each cycle, if they would like to select (or create) a different folder. The data log is saved via the following filename convention: <yyyy-mm-dd-**T**hh-mm-ss.xls> which corresponds to the timestamp at which the Cycle is started (where “**T**” is not variable)



System Installation

System Installation



AsepticSure™ Primary Station

Unless otherwise indicated, the installation of the device needs to be done by Medizone personnel or a Medizone authorized representative.

Remote Station

The Remote Station will already be provided appropriately configured. Do not alter the configurations in any way or the effectiveness of the AsepticSure™ Disinfection System may be impaired.

For example:

- DO NOT increase the screen brightness
- DO NOT disable screen-saver
- DO NOT configure Remote Station to go into sleep mode
- DO NOT disable the audio capability (as some information is transmitted sonically to the user)
- DO NOT install any other applications onto the Remote Station



AsepticSure™ Disinfection Cycle

Description of Disinfection Cycle

The AsepticSure™ system is designed such that the primary systems are controlled remotely via a Remote Station (laptop) that externally communicates.

Up to four (4) AsepticSure™ primary stations can be controlled simultaneously to disinfect the same environment. The Remote Station monitors the overall environmental conditions (humidity and ozone level) as well as the individual AsepticSure™ Primary Station's performance in order to ensure that an effective and safe disinfection takes place.

Additionally, a dehumidifier can also be attached to the Primary Stations in order to optimize delivery of the oxidative gas formula controlled by the Remote Station.

In order to disinfect a room or environment, the user performs the following steps.

The user first prepares the room for disinfection by removing any items that could be adversely affected by the disinfection cycle, see **Chapter 2 Getting Started**. The user then positions the desired number of Primary Stations within the room and "readies" them by placing them into "Standby". The user would then turn on the Remote Station, select the stations, verify that appropriate communication can take place with the selected Primary Station(s), and seal the room. Outside of the room, the user will plug in the Remote Station and initiate the Disinfection Cycle from the Remote Station.

Upon completion of the disinfection, the system will automatically begin the clearance of the oxidative gas and notify the user when the room is safe to re-enter (and that the disinfection cycle has been successful).

The disinfection cycle is separated into the following discrete phases:

- Room preparation and set up
- Cycle preparation (configuration of AsepticSure™ system(s))



- Disinfection Cycle
- Purge and Clearance of the room to acceptable ozone levels

Room Preparation & Set Up

The AsepticSure™ Disinfection Cycle consists of delivery of a proprietary oxidative gas formula.



The following table summarizes clinical applications where the AsepticSure™ Disinfection System **should not** be used.

Table 5: Applications where the AsepticSure™ should not be used

Do Not Use the AsepticSure™ for the following applications:
Rooms containing equipment, components, or materials that are not compatible with ozone, hydrogen peroxide, or humidity (which cannot be removed from the room or otherwise protected.)
Rooms containing equipment, components, or materials that are used in high-risk, life support, patient or safety-critical applications where the equipment, components, or materials are not compatible with ozone, hydrogen peroxide, or humidity.
Rooms containing equipment, components, or materials whose compatibility with ozone, hydrogen peroxide, or humidity is not known.

The room to be disinfected should be cleared of all patient-critical, safety-critical, ozone-sensitive, hydrogen peroxide-sensitive or humidity-sensitive equipment, material or components, in accordance with the table above. Surfaces to be treated must be thoroughly cleaned in accordance with the standard institutional cleaning protocol prior to treatment.



Prior to initiation of the Disinfection Cycle, the room must also be fully sealed (including all vents in the Heating Ventilation and Air Conditioning system) in order to ensure that ozone does not exhaust to the environment, resulting in hazards



Minimize the path for ozone gas penetration (e.g. open drawers and closet doors and leave open, etc.) in order to maximize the AsepticSure's™ disinfection effectiveness.

Determine the approximate size of the room to be disinfected.

Determine the number of Primary Stations to be used. To help determine the number of Primary Stations to employ, refer to “Specifications” **section**, and take note of the total electrical load required.



Position the Primary Station(s) in the desired location(s) and the locking mechanism on the wheels to prevent inadvertent motion of the Stations. The Primary Station(s) should be placed in the approximate center of the room, away from any potential impediments to both airflow toward the Station intake vent and ozone exhaust from the Station. When more than one Primary Station is used, subdivide the room into approximately equivalent sections and place each Station within the approximate center of each of these subdivisions, ensuring that the airflow both toward and away from each Station will not be impeded.



CAUTION: Placing the Primary Station(s) in an inappropriate location (for example, in the corner of the room with the ozone exhaust pointing toward the wall) may result in ineffective disinfection.



WARNING: Failure to lock the wheels could result in potential injury or damage.

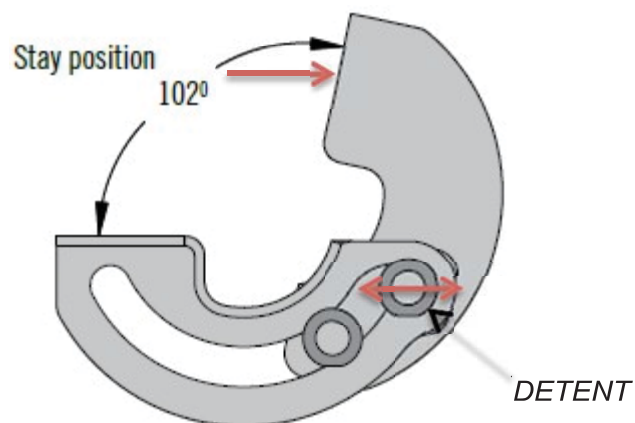
Plug in the ozone destruct stations into the appropriate Primary Stations and place them in the appropriate location(s). Lock the wheels on the ozone destruct stations. Subdivide the room into approximately equivalent sections and place each ozone destruct station within the approximate center of each of these subdivisions.



NOTE: Placing the Ozone Destruct Stations in an inappropriate location may cause the reduction of the ozone levels in the room to take longer than expected.



NOTE: Take caution when opening the humidifier filler door. The hinge has a detent that holds the filler door in an open position. To place the door in the open position, open the door fully and then bring it slightly forward. To release the door from the detent, gently push the door in the open direction and then push the door downward to close.



Cycle Preparation (and configuration of AsepticSure™ station(s))

When the AsepticSure™ Primary Station is powered on, it automatically performs a self-test diagnostic. The diagnostic verifies the functionality of:

- The ozone destruct
- The ozone sensor
- The humidity sensor



NOTE: The self-test of ozone sensor also checks for the ozone level of the room. The detection of ozone level too high will also be report as a self-test failure of ozone sensor.

Service and preventive maintenance by trained Medizone service personnel is required. Refer to *Service Manual*.

If maintenance is required, please contact service.



DANGER: In the event that ozone is detected at a level above the safe limit, immediately leave the room and contact service.

When running the diagnostic, the system determines whether a dehumidifier should be incorporated. The effectiveness of the Disinfection Cycle is affected by starting humidity levels above 40%

Cycle Preparation (AsepticSure™ Primary Station)

1. Ensure the catalyst reservoir is empty.
2. Ensure the AsepticSure™ Primary Station passes self-test.
3. Pour in the appropriate amount of Disinfection Catalyst in the catalyst reservoir.



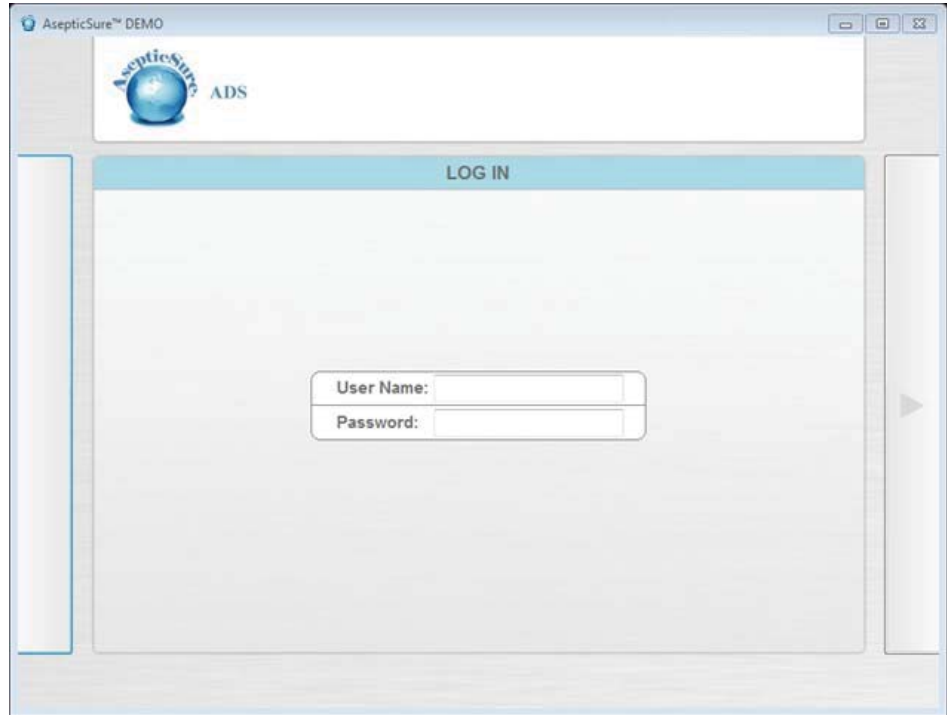
NOTE: Ensure that the expiry date has not been surpassed. If Disinfection Catalyst is used that has surpassed its expiry date, the effectiveness of the Disinfection Cycle may be impaired.

4. Connect to the AsepticSure network on the Remote Station.
5. Turn on the Remote Station and launch the AsepticSure™ application.

Cycle Preparation (Remote Station)

6. At the Splash Screen, enter your ID and password.



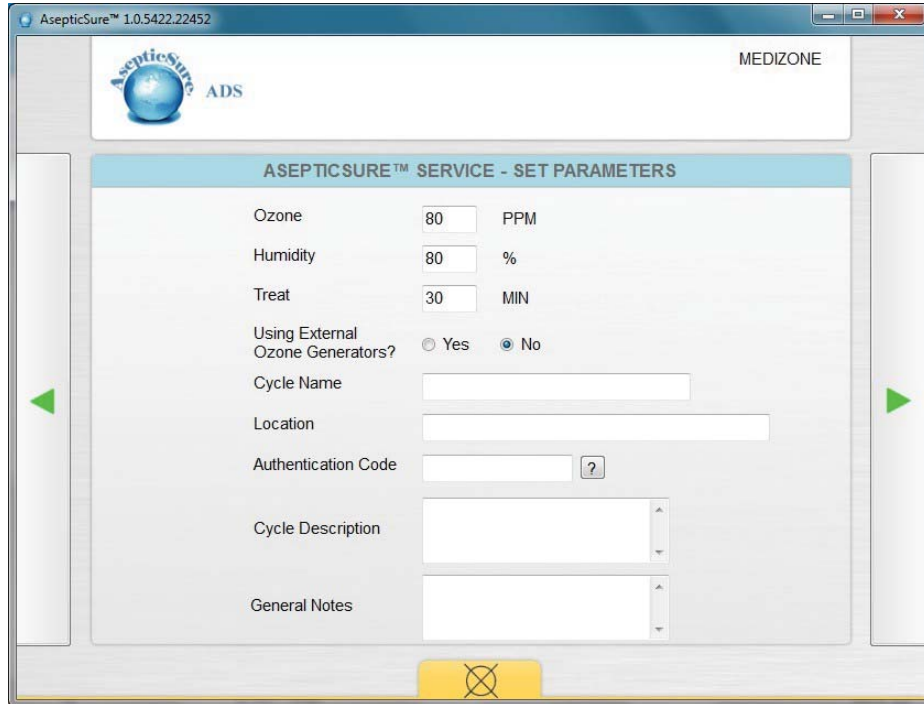


7. Select *AsepticSure™ Disinfection Cycle* from the offered available modes to be run.




8. Set parameters and input any pertinent information (eg. Cycle name and location)



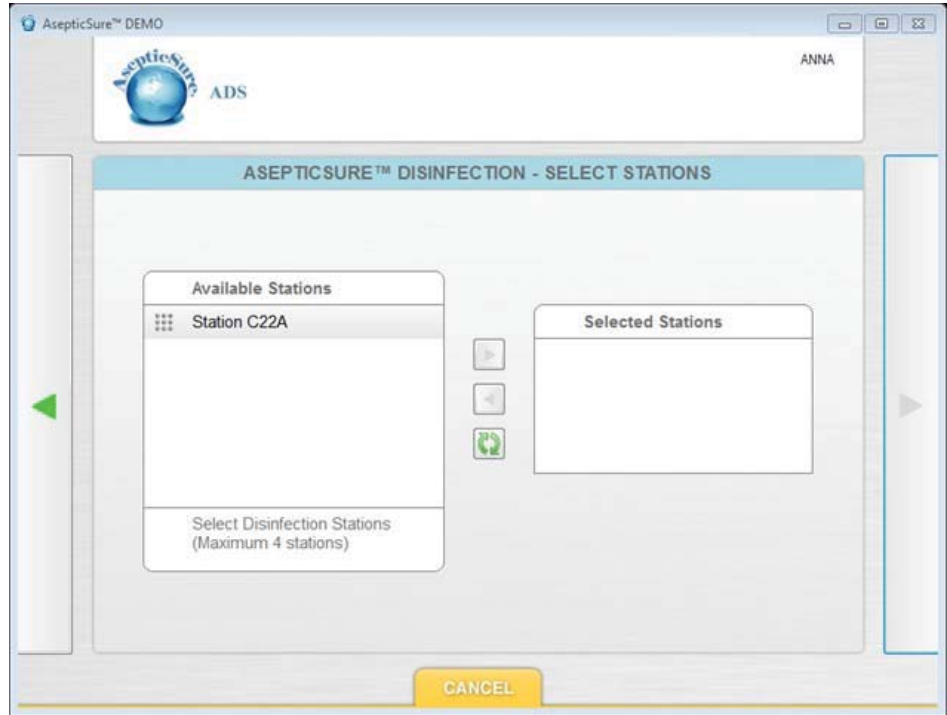


Disinfection Cycle

To prepare the AsepticSure™ system, pour 2.7 L of distilled water and 816 mls of AsepticSure™ Oxidative catalyst into the identified reservoir on the AsepticSure™ fogging system.

9. Place the AsepticSure™ Primary Station into “Waiting for connection” state from the Primary Station GUI. When there are more than one (1) stations, assign the sequence (1-4) of the Primary Stations from “Waiting for connection” screen. Press the refresh  button in the Select Stations screen on the Remote Station and the Remote Station automatically displays the unique ID(s) of all available stations within communication range and in the “Ready” mode.
10. Select the desired Station(s) to be used for the Disinfection Cycle.

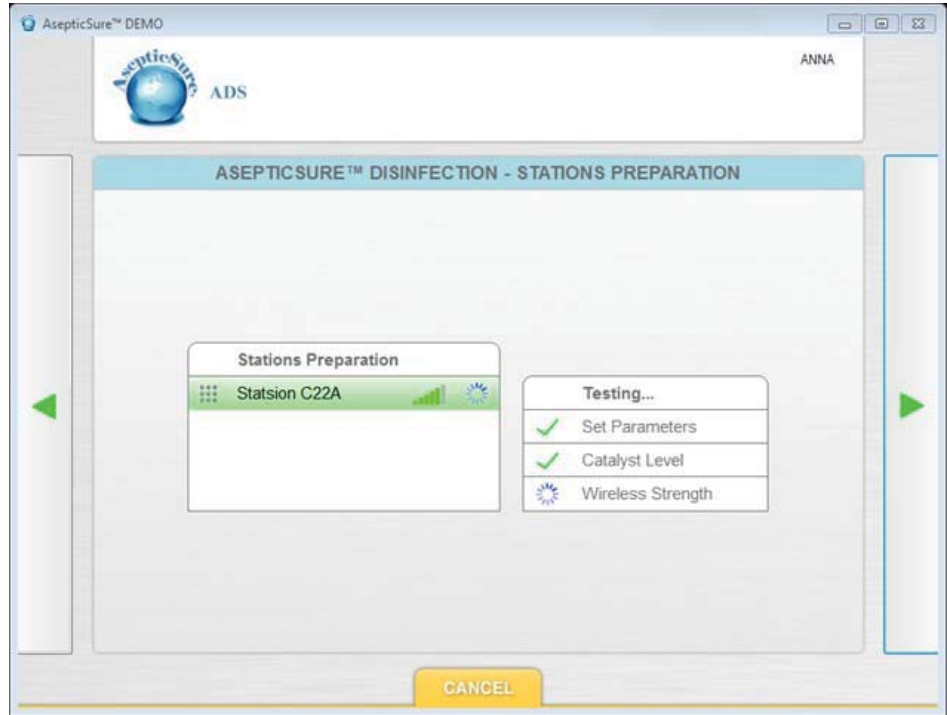




WARNING: Ensure that the IDs of the selected stations match the IDs of the stations in the room. If the wrong station is selected, it is possible that a station in a different room may be selected and emit ozone in an environment that is not AsepticSure-ready. It is recommended that the ID of the station be verified by physically viewing the ID on the station (within the room).

11. After the user selects the stations to be used for the cycle, the Remote Station automatically checks the signal strength between the selected AsepticSure™ Stations and the Remote Station.





NOTE: In order to accurately determine the expected signal strength, proceed to where the Remote Station will likely be physically located for the duration of the Disinfection Cycle.

12. The system will automatically check the relative humidity of the room and may suggest to the user to attach the dehumidifier. If applicable, plug the dehumidifier(s) into the Primary Station dehumidifier receptacle and place the dehumidifier(s) in the appropriate location(s) within the room. Turn the dehumidifier and set it to a humidity level less than 40%.



13. Place the dehumidifier in the approximate center of the room. If more than one dehumidifier is used, subdivide the room into approximately equivalent sections and place each dehumidifier within the approximate center of each of these subdivisions.

NOTE: Placing the dehumidifier(s) in an inappropriate location may cause the Pre-Conditioning stage to take longer than expected.

14. If desired, place the optional Biological Indicators at appropriate places within the room.

15. Ensure that the room is **fully sealed**.

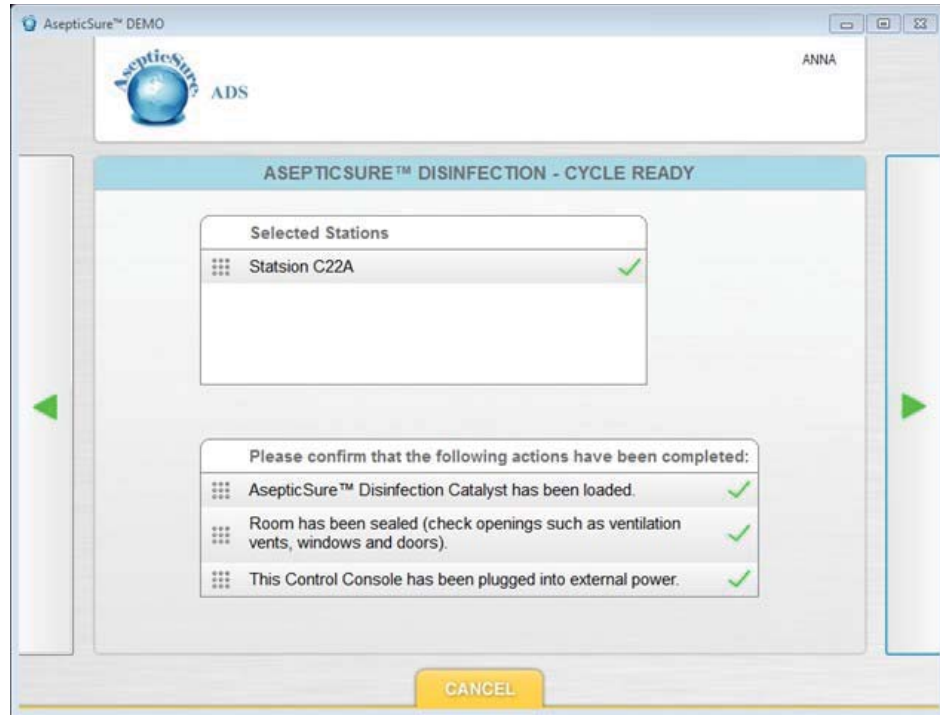


DANGER: ozone is poisonous and corrosive, the room, including all HVAC openings, must be fully sealed. Failure to fully seal the room may result in personnel and other environments being exposed to hazardous levels of ozone.



16. The Remote Station will then prompt the User to:

- Confirm that the Disinfection Catalyst was added.
- Confirm that the Room is sealed.
- Confirm that the remote station has been plugged into the wall before starting the Disinfection Cycle.



NOTE: As a safety precaution, if the communication between the Remote Station and any of the Primary Stations is lost for 150 seconds, the cycle will automatically abort (and the ozone destruct will come on to clear the ozone in the room to safe levels). If the laptop is not plugged in, the battery in the Remote Station may fully deplete during the Disinfection Cycle, causing the cycle to abort.



WARNING: If it is not clear whether or not the room is safe for re-entry (e.g the Remote Station is unable to display information about ozone levels in the room), do not enter room and contact the authorized service representative.

17. Launch the Disinfection Cycle on the Remote Station.





18. Prominently display the Warning Sign on or in front of the door.



NOTE: Do not close the Remote Station (laptop) screen during a Disinfection Cycle as this will result in the laptop losing communication with the Primary Stations and aborting the Cycle. A laptop lock is provided to secure the laptop when unsupervised.

19. The Remote Station controls/monitors the cycle, adjusting the quantities of ozone and hydrogen peroxide being emitted based on real-time feedback from the Primary Station(s).



NOTE: It is recommended to periodically use the ozone detector or ozone sniffer to determine if ozone levels outside of the room are at higher-than-expected levels. Consult the manufacturer's instructions for how to appropriately use the ozone detector.

Upon launch of the Disinfection Cycle, the software displays the Cycle Progress screen to communicate to the user what stage of the process the disinfection cycle currently is within.

There are four (4) stages of the Disinfection Cycle that are automatically controlled by the Remote Station once the cycle has been launched by the user:

- Pre-conditioning
- Conditioning
- Treat
- Purge



Both the elapsed time of the cycle and the estimated amount of time until completion of the cycle are displayed on the Remote Station to the user during all phases of the Disinfection Cycle.

20. Periodically monitor the progress of the Disinfection Cycle from the Remote Station.

The **Pre-conditioning** stage takes place when a dehumidifier has been incorporated into the AsepticSure™. If no dehumidifier is installed, the Pre-conditioning stage will be bypassed.

The system will automatically move to the Conditioning stage once the room has been brought to (optional) optimal environmental conditions or it is unable to bring the humidity to optimal within 40 minutes.

The **Conditioning** stage consists of delivering the proprietary oxidative gas formula until the required specification level is reached in the room.

If the Remote Station detects that the specification does not appear to be able to be reached within an expected time (120 minutes maximum), the cycle will automatically abort and inform the user.

The **Treat** stage consists of maintaining the proprietary oxidative gas formula at the appropriate levels for the appropriate duration.

If at any time, the required levels of ozone and humidity cannot be maintained or go below the specifications, the system will automatically abort and the **Purge** stage will automatically be launched.

Table 6: Conditions where Disinfection Cycle will abort (not exhaustive)

Conditions that can initiate an automatic abort (not exhaustive)
Communication is lost between the Remote Station and any AsepticSure™ Primary Stations
Relative Humidity specification cannot be maintained during Treat stage
Ozone specification cannot be maintained during Treat stage
Remote Station loses power during any stage of the Disinfection Cycle
A hardware failure is detected (of the hygrometer, thermometer, ozone sensor, etc.)
User-initiated abort (for example, if ozone is detected)



The **Purge** stage consists of reducing the ozone levels in the room to safe levels. Once safe levels have been reached, the system informs the user that it is now safe to enter. The Remote Station estimates how long it will take to clear the room to safe levels of ozone.

When the room has returned to safe ozone levels, the Remote Station communicates to the user that the Disinfection Cycle has been completed successfully.

21. Remove the sealing tape from the door and enter the room.
22. In the event, that Biological Indicators were used, verify that all of them confirm that the appropriate level of disinfection took place. Dispose of the BI's appropriately.



CAUTION: The BI's must be disposed of as biohazard material.

NOTE: The BI's are single-use only. They must not be re-used.

23. Dispose of any Disinfection Catalyst remaining in the catalyst reservoir by placing the drainage valve below the bottom level of the catalyst reservoir within a receptacle and opening the valve. Ensure that all of the residual catalyst drains out of the reservoir. It is recommended to use the empty container from the original Disinfection Catalyst container as the receptacle.
24. Dispose of the residual catalyst in accordance with the appropriate process.

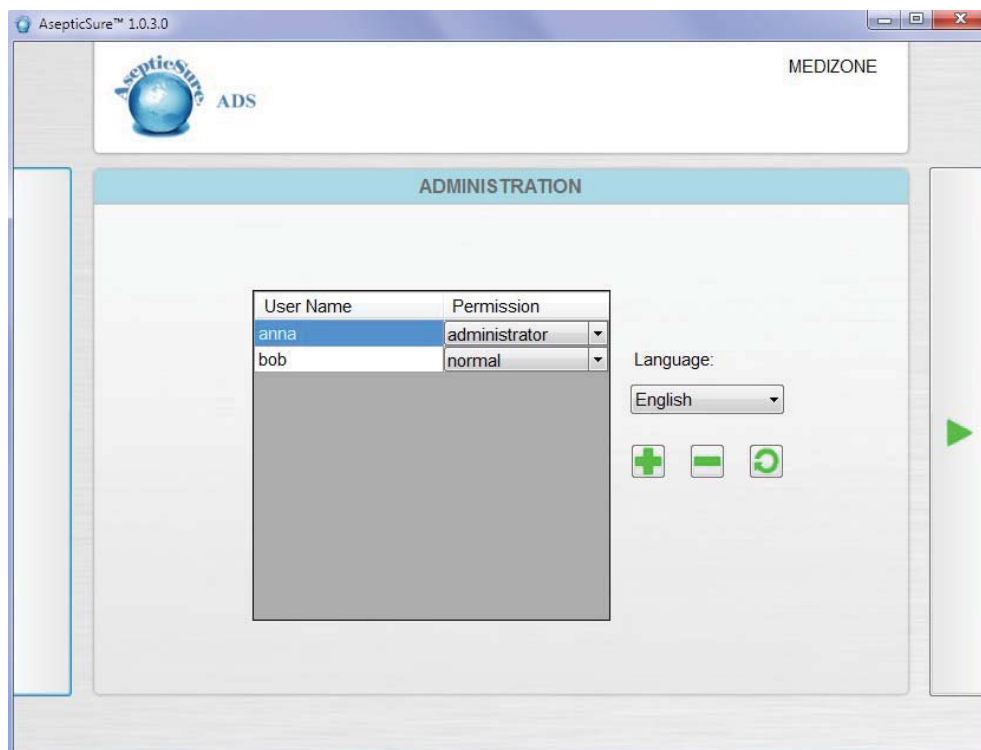


AsepticSure™ Administration

Description of the AsepticSure™ Administration function

The AsepticSure™ Administration function is used to

- Add a new user (“+”);
- Delete an existing user (“-”);
- Reset a user password (↻);
- Change the permission level of a user



Chapter 6

Maintenance / Troubleshooting

Guidelines

In order to operate the AsepticSure™ system, training by Medizone International Inc. personnel is required.

Upon completion of this training, a User ID and password will be provided to the user.

Inspection (every usage)

Prior to every use, The AsepticSure™ systems should be inspected for mechanical damage or breakage.



DO NOT USE THE SYSTEM IF IT HAS OR APPEARS TO HAVE SUSTAINED OR IS SUSPECTED TO HAVE SUSTAINED ANY DAMAGE. Contact your service representative immediately.

Preventive Maintenance



The AsepticSure™ Disinfection System requires preventive maintenance as defined in Service Manual. Please contact your authorized service representative for any additional information.

Special Care Requirements

Cleaning

The cleaning solutions in the following list are recommended for cleaning the Primary Station. Use a cotton cloth to clean the system.

Cleaning solutions not in this list should not be used as they may damage the system. Please contact your service representative if approval of additional cleaning solutions is required.

Table 7: Approved Cleaning Solutions



Solution	Comments
Warm water	Safe for all outer surface areas.
Commercial dishwashing liquid/water combination	Safe for all outer surface areas.

Troubleshooting

This section provides troubleshooting suggestions to solve common problems. If you cannot resolve a problem after trying these solutions, contact your service representative to arrange for service or repairs to the system.

Table 8: Troubleshooting Common Problems

Problem	Possible Solution(s)
Can't find available Primary Station(s)	<ul style="list-style-type: none"> Station has not been powered on Station is not in "Standby" mode The station is too far away from the Remote Station. Verify the unique ID of the station. Station is already being used.
After powering the Primary Station ON, it can't be placed into "Standby"	<ul style="list-style-type: none"> Failed self-test diagnostic, identify issue or contact service representative
Can't log into AsepticSure™ application	<ul style="list-style-type: none"> Wrong User ID and/or Password
Option to use AsepticSure™ Service or Administration mode not available	<ul style="list-style-type: none"> User privileges do not allow access to those modes
Signal strength not high enough	<ul style="list-style-type: none"> Move the Remote Station to a different area If problem persists connect via Ethernet cable.
Disinfection Cycle aborts	<ul style="list-style-type: none"> Communication is lost between the Remote Station and a Primary Station. Battery power of Remote Station has depleted. System is unable to maintain ozone concentration or humidity within specification



Problem	Possible Solution(s)
	<ul style="list-style-type: none"> ○ Dehumidifier might not be plugged into correct receptacle on Primary Station ○ Ozone destruct station(s) might not be plugged into correct receptacle on Primary Station ○ Primary Station is located in an inappropriate location ○ The room is not fully sealed ○ Not enough Primary Stations were employed for the specific room size. ● A component on the Primary Station has failed (e.g. hygrometer, ozone sensor, etc.) ● User has initiated an abort
Nothing is displayed on Remote Station screen	<ul style="list-style-type: none"> ● Remote Station has gone into sleep mode ● The battery of the Remote Station has fully depleted ● Remote Station has been powered off



Specifications

The equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is used in such an environment.

- The AsepticSure™ Disinfection System complies with IEC 61326-1. See Chapter 1 “Additional Precautions (EMC)” for further information.

Operating Conditions

The following tables outline the environmental conditions for which the operation of the AsepticSure™ Disinfection System has been qualified.

Table 9: Operating Conditions

	Minimum	Maximum
Ambient Temperature (°C)	+18	+24
Relative Humidity (non-condensing)	35%	90%

Table 10: Optimal Initial Conditions

	Initial Conditions
Relative Humidity (non-condensing)	≤ 40%

Note that the AsepticSure™ alters the environmental conditions of the room during the Disinfection process.

Storage and Transportation Conditions

The following tables outline the environmental conditions for transporting or storing the AsepticSure™ Disinfection System

Table 11: Transportation and Storage Environment



	Minimum	Maximum
Ambient Temperature (°C)	+5	+45
Relative Humidity (non-condensing)	25%	95%

Specifications

AsepticSure™ System Specifications:

- Voltage Input:
 - 120V,/20A configuration: 120Vac, 20A maximum
 - 120V/15A configuration: 120 Vac, 15A maximum
 - 240V configuration: 230Vac, 12A maximum
 - RF: 902 MHz-928 MHz
 - Distance of remote station to primary station: ≤90 feet, indoor.
- Note that the distance specified to the primary station is under optimal conditions. This will vary depending on the indoor environment (obstructions, materials, etc.)*

- Weight: approximately 250 lb

Typical Disinfection Cycle Profile:

For a room up to 64m³ (or 2260 cu. ft.) and one (1) AsepticSure™ Disinfection System (120V/20A), a typical Disinfection Cycle profile is as follows:

Disinfection Cycle Stage	Duration
Pre-conditioning (if required)	No longer than 40 minutes
Conditioning	50 minutes
Treat	30 minutes
Purge	30 minutes



Glossary

Definitions and Acronyms

The following are the definitions and acronyms used in this User Manual:

AsepticSure™	A trademark of Medizone International for its disinfection system using its proprietary oxidative gas formula.
The system	For the purpose of this document, “the system” refers to one complete and functional AsepticSure™ device
Requirements	for the purpose of this document, “requirements’ is defined as a set of functions and performances that the device must meet in order to satisfy its intended use, including the needs of the user and patient. Requirements are the design input of the device design.
Disinfection	the process of destroying pathogenic organisms or rendering them inert ^{note 1} .
Disinfection Cycle	For the purpose of this document, disinfection “cycle” is defined as the duration which AsepticSure™ performs its disinfection function. It consists of the Conditioning stage, the Treatment stage, and the Purge stage.
Primary Station	For the purpose of this document, the ‘Primary Station’ is the principal component of the AsepticSure™ Disinfection System that will deliver the proprietary oxidative gas formula.
Peripherals	for the purpose of this document, ‘Peripherals` are components of the AsepticSure™ system that interact or communicate with the `Primary System`.



	These items are required components of the AsepticSure™ product, but are not integrated in the `Primary System
CISPR	Comité Internationale Spécial des Perturbations Radioelectrotechnique (International Special Committee on Radio Interference)
PPM	unit, parts per million
RH	relative humidity
ESD	electrostatic discharge
EMC	electromagnetic compatibility
HVAC	Heating, Ventilation and Air Conditioning



Appendix

A

Forms

Note: Items noted on the forms are only available directly from Medizone International Inc.



Medizone International, Inc.
 2330 Marinship Way, Suite 300
 Sausalito, CA
 94965
 Phone: (North America) 1-415-331-0303
 (International) +1 415-331-0303

AsepticSure™ Catalyst Order Form

www.medizoneint.com

The following number must appear on all related correspondence, shipping papers, and invoices:

P.O. NUMBER:

Purchaser:

Name:

Company:

Address:

City, State / Province:

Zip / Postal Code:

Phone:

Ship To:

Name:

Company:

Address:

City, State / Province:

Zip / Postal Code:

Phone:

P.O. DATE

QTY	Part Number	DESCRIPTION	UNIT PRICE	TOTAL
			SUBTOTAL	
			SALES TAX (GST in Canada)	
			SHIPPING & HANDLING	
			OTHER	
			TOTAL	

Send all correspondence to:

Authorized by _____

Date _____

