MIC-EDU Single Isolator and Steris M-10 OWNER'S MANUAL

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Index

Page

1.0 Introduction……..3
1.1 Isolator……..……...3
1.2 Features……....3

2.0 Description……...4

3.0 Getting Started……..4
3.1 Site Selection……4
3.2 Assembly……..4

4.0 Set Up…….....5
4.1 Initial Cleaning…….....5

5.0 VHP Sanitization……..5
5.1 Valve Configuration for Decontamination Cycle……..5-6
Image 1.1 Input Valve....…….……7
Image 1.2 Exhaust Valve..……...……8

6.0 M-10 Information…….…….…..…..9

7.0 Operation Isolator……..9
7.1 Routine Checks……..9
7.2 Glove and Sleeve Replacement……..9
7.3 Inspection……...9
7.4 Modular Panels……..9-10

8.0 M-10 Operations (Figure 8.1)……...11
8.1 Bio-decontamination Process...……12
8.2 Cycle Description……..13
8.3 Operations M-10……..13-14

9.0 Safety……14

10.0 Troubleshooting……14
10.1 Isolator……..14
10.2 General……14-15
10.3 Tables 10.1 through 10.4…….16-18

11.0 Integrity Testing……18
11.1 HEPA Filters…….....18
11.2 Ammonia Leak Testing…….19
12.0 Replacement Parts and Sources……...20-21
Warranty……22

1.0 Introduction

Containment Technologies isolators allow for totally contained processing. Each enclosure design is based on customer input supported by Containment Technologies experience in aseptic processing. The designs are ergonomically integrated with the process equipment to provide an aseptic environment. The Containment Technologies approach reduces total process time and increases flexibility, allowing efficient processing of products.

1.1 Isolator

The isolator chamber is intended to provide ISO class 5 conditions. The isolator is made up of one chamber. The chamber is configured with a polycarbonate door on the inside and outside of the antechamber.

The chamber can be decontaminated with the Steris M-10 VHP generator. Engineering studies have been conducted to determine a six log reduction of Geobacillius stearothermophilus based on the program parameters of the M-10. Verification studies should be conducted with "loads" in the chamber if the intent is to use the VHP to achieve an aseptic condition of six log reduction.

The operating pressures should range between +0.20 and +0.50 inches water column. Target pressure is recommended to be +0.30 inches water column.

1.2 Features

The shell of the isolator is constructed of 316L stainless steel. Viewing areas and access doors are constructed of polycarbonate providing a safe, clear view of internal operations.

Components enter and exit through doors located on the end chamber maintaining the integrity of the inside of the chamber.

Individual interaction is through glove ports using a one-piece glove sleeve.

Airflow is unidirectional with air entering through a HEPA filter and exhausted through another HEPA filter.

The air handling system is designed to function as a recirculating system.

The lighting and air handling systems are external to the chamber. This provides for smooth, easily cleaned surfaces inside the chamber.

2.0 Description

The isolator system is made up of one chamber.

The chamber can be sanitized with VHP (Vapor Phase Hydrogen Peroxide). During a VHP sanitization cycle, the gloves and sleeves should be extended. This assures a full contact area for the VHP.

The isolator is operated with push button on/ off switches located on the fascia panel of the unit. These push buttons control the light and blower. The M-10 decontamination system is operated from the touch screen control panel located on the M-10.

3.0 Getting Started

3.1 Site Selection

The isolator is designed with cleanable surfaces to facilitate use in cGMP areas. Specific needs such as electrical classification based on the surrounding area should have been addressed in the specifications for the isolator. Always check the areas electrical classification against the capability of the isolator system before operation.

Environmental conditions such as temperature or humidity in the area of operation should be checked for process impact. The isolator uses ambient air that is passed through HEPA filters. The isolator air handling system is designed to add minimal heat load. The process equipment may generate heat and the system should be reviewed to determine the impact on temperature requirements. A temperature mapping of the isolator should be conducted to verify internal conditions.

When an inert gas is used in the isolator, proper safety devices should be in place to assure both operator safety and desired conditions. A monitor should be provided both to determine the level of inert gas in the enclosed environment and external area.

3.2 Assembly

Shipment of the isolator and Steris M-10 may require removal of components. If any component is removed and requires installation at the owner's site, the installation is to be under the supervision of a CTG representative or per written procedure that is conducted and verified by qualified owner representatives.

Communication between CTG and the owner should always occur to assure that the integrity of the system is not compromised. Proper testing should take place after installation. If there are any questions, contact CTG.

4.0 Set-up

4.1 Initial Cleaning

The isolator system should be thoroughly cleaned inside and out to remove any dust, dirt or debris that may have accumulated during shipping and storage. Use a mild detergent and a soft cloth to wipe down all surfaces. After the surfaces have been cleaned, they should be rinsed with clean water. Surfaces should be dried with a lint free cloth.

Procedures are required to assure that contamination is not spread. The following operating procedures will help to minimize the spread of contamination.

1. A procedure for operation of any external door.
2. Procedure for visual checks to insure that end doors are closed, sealed and locked.
3. Procedure for verification of pressure differential of the chamber before opening the airlock doors.
4. Visual check of all gloves and sleeves to assure integrity.

5.0 VHP Sanitization

Vapor Phase Hydrogen Peroxide is a surface sanitizing agent. Its use in isolator has been documented in a number of studies. The Steris VHP M10 provides an effective means of sanitizing the CTG isolator chamber. There is a supply and return hose connection from the VHP unit to the isolator that allows the unit to be attached to the chamber. To begin the sanitizing, the valves controlling the airflow must be placed in the proper position. The valves for the VHP cycle are opened. There is a cycle program of VHP operation for the chamber.

The cycle is programmed into the Steris unit and begins with a pressure check to assure no leaks that would allow VHP to escape into the surrounding environment. The decontamination by the VHP unit is based on four phases. The first phase is the dehumidification phase where the environmental conditions inside the chamber are adjusted to maximize the effectiveness of the VHP. The second phase is the conditioning phase, followed by a decontamination phase in which the hydrogen peroxide is introduced into the chamber. The last phase is an aeration phase to remove the VHP from the chamber.

5.1 Valve Configuration for Decontamination Cycle

The design of this single chamber unit is for recirculating airflow. Valve manipulation for VHP cycles is a simple process. Just follow the steps below. See images 1.1-1.2 for reference.

Valve configuration for running VHP cycles:

1. Open the gate valve labeled **IN** on the M10 underneath the left chamber
2. Open the gate valve labeled **OUT** on the M10 underneath the left chamber

**Remember to close both valves once VHP cycle has been completed to avoid saturation of desiccant cartridge.

Image 1.1

Image 1.2

6.0 M-10 Information

M-10 Serial number with program application number:

M-10 Serial #: 5717-05-17-01

Program Application: 175x02 HMI

7.0 Operations Isolator

7.1 Routine Checks

The items listed in this section will require routine inspection and maintenance during operation of the isolator.

Door Gaskets – To be visually checked daily for signs of wear or abrasion that could lead to leaks.

Gloves/Sleeves – Gloves and sleeves should be visually inspected at the beginning of each work shift for wear or potential holes. Proper change out procedures are included in the operations section of this manual

Gauges – individual pressure differential gauge for the chamber should be inspected at the beginning of each shift to assure that they are functioning.

7.2 Gloves and Sleeves Replacement

If a breach in a glove or sleeve occurs during operations the operation should stop immediately and all open containers be segregated. The chamber should be cleared. The glove or sleeve then should be changed and the isolator re-sanitized by running a VHP cycle.

7.3 Inspection (Daily)

After starting up the isolator, it is good practice to do a visual inspection. The pressure gauge is located on the front fascia of the isolator.

Pressure Gauge – The gauge has high/low non-audible alarms but the visual inspection will verify that the gauge is operating in the desired ranges.

Doors – Check that doors are closed and that the seals are intact. The pressure differential gauge will indicated leaks. An inspection helps to troubleshoot the potential damage to door seals.

Sleeves and Gloves – Inspect sleeves and gloves to be sure they have been correctly installed. Inspect for worn points or holes on sleeves and gloves.

7.4 Modular Panels

It may be necessary to remove the end panels. To remove or install the end panels, follow these instructions.

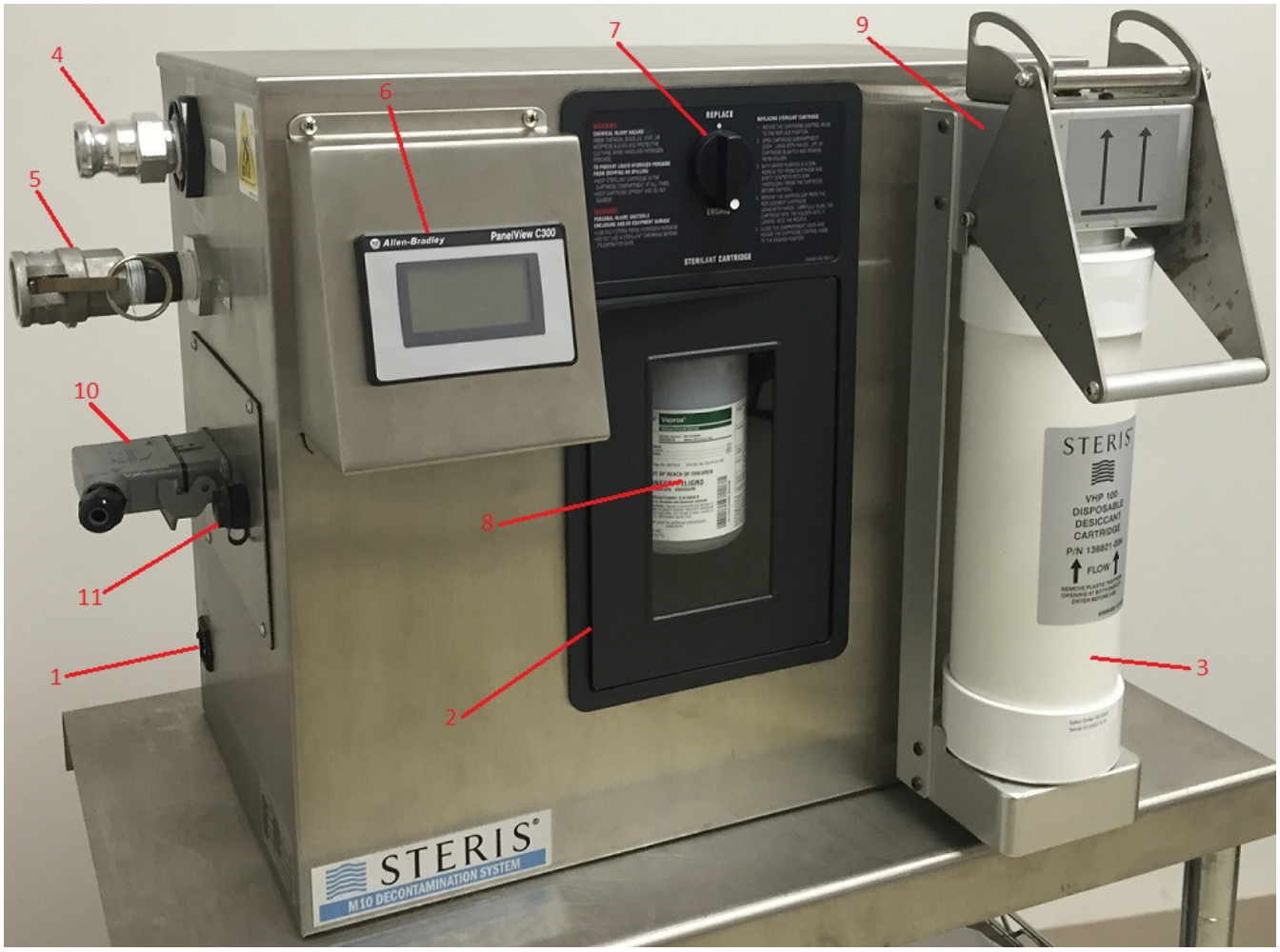
Installation

1. Carefully align the mounting holes in the modular panel with the studs on the isolator and slide the panel into place.
2. Install one washer and nut on the top row at both ends and hand tighten.
3. Install the rest of the washers and nuts and hand tighten.
4. Using a torque wrench, tighten the nuts to 26 inch pounds. Do not use excessive force or the studs can be twisted off.

Removal

1. Loosen the nuts being careful to not apply excessive force. Torque wrench set at 26 inch pounds is recommended.
2. Remove the nuts and washers. It is good practice to leave two on the top row attached until the operation is almost complete.
3. Remove the panel.

8.0 M10 Operation (Figure 8.1)



1. Main Power Switch
2. Vaprox Sterilant Cartridge Compartment
3. Desiccant Dryer Cartridge (disposable)
4. Return Port
5. Output Port
6. HMI Panel
7. Sterilant Engage Knob
8. Vaprox Sterilant Cartridge (disposable)
9. Desiccant Cartridge Holder
10. Remote Input/Output Interface
11. Ethernet Communications Port

8.1 Bio-decontamination Process

Introduction

The Bio-decontamination System (see Figure 8.1) provides a simple and reliable method for bio-decontamination isolators.

The VHP Process

The bio-decontamination cycle is a closed loop process utilizing dry, heated air as a carrier gas to deliver Vaprox® Hydrogen Peroxide Sterilant vapor (VHP) to the exposed surfaces inside the isolator. This closed loop process allows the bio-decontamination process to take place at, or near, atmospheric pressure.

H_2O_2 vapor is continuously injected for the required exposure time to achieve bio-decontamination. The VHP evacuated from the isolator in a closed loop operation is catalytically converted by the bio-decontamination unit into water vapor and oxygen.

The Bio-decontamination Cycle Phases

The bio-decontamination cycle consists of four phases: DEHUMIDIFY, CONDITION, BIO-DECONTAMINATION and AERATION.

• DEHUMIDIFY — Dry, filtered air is circulated through the chamber to reduce humidity to a preset level in the 10-60% relative humidity range. This permits the necessary target Vaprox H_2O_2 vapor concentration to be maintained below saturation (dew point) levels during the condition and bio-decontamination phases. The return air is dried as it passes through the dryer. The internal filter prevents contamination of internal machine components and prevents recontamination of the chamber. This filter also protects the vaporizer from dryer cartridge particles.

• CONDITION —The flow of dry, filtered air continues while Vaprox vapor is injected into the air stream just before it leaves the unit. The Vaprox injection rate is higher than that of the bio-decontamination phase, because the condition phase is intended to quickly reach the target bio-decontamination concentration. Condition time is affected by sterilant injection rate, chamber volume, contents and temperature, and is shorter that the bio-decontamination cycle time.

• BIO-DECONTAMINATION —The target VHP antimicrobial concentration is maintained by continuing Vaprox vapor injection for a specific period of time throughout the chamber.

• AERATION — Vaprox H_2O_2 vapor injection is stopped and the re-circulating flow of dry, filtered air continues through the catalytic converter to reduce the H_2O_2 vapor concentration within the chamber.

8.2 Cycle Description

The operator starts the bio-decontamination cycle from the Steris M10 Unit main menu display. An Operator Password is required to start the cycle.

The cycle is ready to run if:

- The outside airlock door is closed and locked using supplied key.
- Valves are manipulated allowing proper airflow. **IMPORTANT** – failure to properly manipulate valves will cause incorrect airflow.
- The Vaprox container is inserted and the knob is in the downward position.
- The desiccant cartridge is inserted and has a proper seal.
- The screen title, Run, will be displayed only when all of the conditions required for starting a cycle are satisfied. Otherwise, a banner indicating the unresolved condition will be displayed in its place:

    1. RESERVOIR NOT READY – the reservoir is currently being filled.
    2. ALARM ACTIVE (blinking text) – a system alarm is active.
    3. NO CYCLE SELECTED – a cycle has not been selected to run.
    4. DESICCANT LOW – insufficient desiccant for selected cycle.
    5. CART. NOT ENGAGED – a Vaprox Sterilant cartridge is not installed/engaged.
    6. The START (blinking text) button will be active and displayed only when none of the conditions listed above are true.
    7. The ALARMS button will be active and displayed only when a system alarm is active.

- The START (blinking text) button will be active and displayed only when <u>none</u> of the conditions listed above are true.

8.3 M-10 Starting a Cycle

Once your inspection of the Isolator unit is complete, you are ready to start the bio-decontamination process. Please be sure to read through all safety procedures (listed above) before operating the Steris M10 Bio-decontamination Unit. Below are listed the step-by step procedures for operating the unit through a bio-decontamination cycle.

Step-by-step preparation and entry of desired activity:

1. Check Isolator pressure.

2. Lock outside airlock door.

3. Turn on Drager H_2O_2 alarm sensor by pressing the **ON** button and holding until countdown is complete. Hang the sensor from the fascia panel.

4. Open both the **IN** and **OUT** gate valves (located next to the M10) by pulling on the handle.

5. From the mode selection screen on the M10 touch screen display – Press **RUN**

6. Touch in the black box and enter passcode – **aa**

7. Press the Enter button and a right arrow box should appear **>>**

8. Press the right arrow button >>

9. Select desired cycle (CYCLE 1 or CYCLE 2)

10. Press **START**

11. Once cycle is complete, the display will read "Out of Cycle". Press the left arrow until you return to the Mode Selection screen.

12. Turn off Drager H_2O_2 Alarm Sensor by pressing and holding both the **+** and **ON** buttons until it powers off. Place it back in the charger.

13. Close the **IN** and **OUT** gate valves by pushing the handle back in. **NOTE** - Failure to do so will saturate the desiccant cartridge.

*Dryer cartridge will run approximately **12** cycles – recommend marking the cartridge as to cycle usage. Vaprox cartridge is good for approximately **36** cycles.

9.0 Safety Precautions

The following Safety Precautions must be observed when operating or servicing this Steris M-10 VHP® unit and when handling the Vaprox® Hydrogen Peroxide sterilant cartridges. Also read the Vaprox sterilant Material Safety Data Sheet (MSDS) for additional information on the proper use and handling of hydrogen peroxide. Read the M-10 Manual for additional information.

10.0 Troubleshooting

10.1 Troubleshooting Isolator

If the Isolator doesn't work!!!!

Light – Check plug, if properly connected, then the possibilities are:

- Blown Bulb
- Faulty Switch

Air System – Check plug, if properly connected, then the possibilities are:

- Faulty Switch
- Faulty Blower Motor

No pressure indication on the gauge:

- Check all openings for proper seal
- Check polarity of plug if blower is running and gauge is showing zero (note: there is negative pressure but it will not show on the gauge)

10.2 GENERAL

Note: The troubleshooting section below will assist you in the case of any alarms.

This section of the manual describes possible alarm conditions or malfunctions that may occur during the operation of the Bio-decontamination Unit and indicates probable causes and actions to perform to correct the situation. Alarms occur as a result of component failures, utility failures, unexpected measurements from Resistive Temperature Detectors (RTDs) and/or pressure transducers, or as a warning indication that operator intervention is necessary to correct or acknowledge the current condition.

See **Tables 10.1-10.4**, *Troubleshooting Guide*, for the complete alarm listing (including *Screen* display), the condition(s) required to force the alarm, the possible causes of the alarm, the action taken by the bio-decontamination unit control upon occurrence of the alarm and instructions on correcting the situation.

If a situation occurs that is not described in or cannot be corrected by the ***Troubleshooting Guide***, please call CTG (317) 713-8200. Trained service personnel can promptly restore the bio-decontamination unit to proper working condition. **NOTE: Never attempt to service the bio-decontamination unit**

Table 10.1 Alarm/Abort Action

Phase at Alarm-Abort	**Action following Alarm-Abort**
Before start of injection (before Condition/Bio-decontamination)	Returns to Mode Selection screen
During Injection phase (Condition or Bio-decontamination)	Advances to Aeration
During Aeration	Remains in Aeration
Out of cycle (Cycle Complete or idle)	No change in cycle phase

Table 10.2 Troubleshooting Table for Alarms and Aborts

Alarm Description/Screen Display	**Possible Causes**	**Instructions**
Reservoir Fill Failure	Vaprox container empty	Check Vaprox container is installed correctly and not empty
Return Air Temp High	Air temperature exceeds set point	Call for service
Vap Temp Out of Range	Vaporizer unable to reach set point temperature	Call for service
Injection Rate Deviation	Injection pump hose restricted OR Unit out of calibration	Call for service Call for service
Dehumidify Timeout	Desiccant cartridge has reached its set point OR Cartridge may not be properly installed	Replace desiccant cartridge Check cartridge installation
Cycle Aborted	Alarm occurred during cycle OR	Check alarm and take corrective action

	Operator manually aborted cycle	
Liquid H_2O_2 Overfill/Leak	Leak in either fill hose or injection pump hose	Call for service
Vaporizer Over Temp	Vaporizer over temperature set point OR Vaporizer out of calibration	Call for service Call for service
VH (blinking) – Vaporizer heating indicator	Vaporizer hasn't reached temperature set point before Dehumidify phase completes	5 minutes automatically added to Dehumidification phase. No action necessary unless Alarm is triggered

Table 10.3 Troubleshooting Table for Miscellaneous Problems

Problem	Likely Cause(s)	Correction
Error message displayed on power up	PLC controller disconnected OR Program needs updating	Call for service
Condensation (fogging) on Isolator walls during cycle.	Calibration of air flow, injection pump or sterilant outlet tubing too cold.	Call for service

Table 10.4 Power Interruption/Power-Up Actions

Cycle Phase Active at Power Interruption	Biodecontamination Unit Action at Return of Power
Reservoir Fill	Aborts cycle, goes to Mode Selection screen
Dehumidify	Aborts cycle, goes to Mode Selection screen
Vaporizer Warm up	Aborts cycle, goes to Mode Selection screen
Condition	Aborts cycle, goes to aeration phase
Bio-decontamination	Aborts cycle, goes to aeration phase
Aeration	Restarts aeration
Cycle Complete	Returns to Complete phase

11.0 Integrity Testing

11.1 HEPA Filter

Filter integrity testing is routinely performed using the standard particulate challenge testing procedures. If a filter fails to pass the test, it should be repaired or replaced based on the recommendations of Containment Technologies Group. Testing for compliance to ISO class 5 conditions is based on taking counts in the multiple locations. A grid has been developed that defines locations for routine testing. A sample protocol has been provided in the documentation package.

11.2 Ammonia Leak Testing

The chamber is a gas tight enclosure and testing the integrity is most efficiently accomplished by using an “ammonia leak test”.

Procedure:
Verify integrity of the chamber by placing an ammonia source inside the chamber with test strips of pH sensitive cloth. Check each potential leak source by placing the pH sensitive cloth over the outside of the chamber junctures (such as the window gasket, panel gaskets, and the air handling system). Chamber is to be under positive pressure during testing with a target level of 0.30 inches of water column pressure shown on the differential pressure gauge.

An ammonia source inside the chamber with test strips of pH sensitive cloth outside of the isolator.

1	All door seals	No leak	☐ Pass ☐ Fail
2	Window seals	No leak	☐ Pass ☐ Fail
3	Panel seals	No leak	☐ Pass ☐ Fail
4	Filter housing seals	No leak	☐ Pass ☐ Fail
5	Duct work connections	No leak	☐ Pass ☐ Fail
6	Blower motor housing	No leak	☐ Pass ☐ Fail

Replacement Parts and Sources

Part	Source
Sensocon Pressure Gauge Model A 101	Containment Technologies Group 5460 Victory Drive Suite 300 Indianapolis, In 46203 Phone 317 713-8200 Fax 317 713-8201 e-mail: jrahe@mic4.com Stocked item
HEPA Filters Camfil Part Number - 855025866	Camfil 1 800 526-5148
Blower Motor Continental FAN AXC 100B	Containment Technologies Group 5460 Victory Drive Suite 300 Indianapolis, In 46203 Phone 317 713-8200 Fax 317 713-8201 e-mail: jrahe@mic4.com Stocked item
Door Replacements	Containment Technologies Group 5460 Victory Drive Suite 300 Indianapolis In 46203 Phone 317 713-8200 Fax 317 713-8201 e-mail: jrahe@mic4.com Two week lead time
Light Assembly	Containment Technologies Group 5460 Victory Drive Suite 300 Indianapolis In 46203 Phone 317 713-8200 Fax 317 713-8201 e-mail: jrahe@mic4.com Two week lead time

Part	Source
Push Buttons	Containment Technologies Group 5460 Victory Drive Suite 300 Indianapolis In 46203 Phone 317 713-8200 Fax 317 713-8201 e-mail: jrahe@mic4.com Stocked Item
Purple Pressure Control Filter Assembly 7580P100 - 7580P100 - PURPLE FILTER	Containment Technologies Group 5460 Victory Drive Suite 300 Indianapolis In 46203 Phone 317 713-8200 Fax 317 713-8201 e-mail: jrahe@mic4.com Stocked Item
Vaprox Sterilant Reorder Number PB006US Order Directly from Steris 35% Hydrogen Peroxide	Steris Corporation 5960 Heisley Road Mentor, Ohio 44060
Disposable Dryer Cartridge P/N 136821-004	Steris Corporation 5960 Heisley Road Mentor, Ohio 44060 (Can be ordered Direct from Steris)

LIMITED WARRANTY

For a period of one (1) year from initial installation, Containment Technologies Group, Inc. warrants that the Steris M-10 VHP generator will be free of defects in materials and workmanship. Containment Technologies Group, Inc. will support the correction of defects that may substantially affect the operation of the workstation. If the customer identifies any potential defects Containment Technologies Group, Inc. is to be informed immediately. This limited warranty does not cover damage caused by improper use or neglect. The proper protocol or standard operating procedure must be followed in operating the workstation and failure to do so negates the warranty. Containment Technologies Group, Inc. does not warrant factors beyond its control. These factors include but are not limited to: operation and maintenance by personnel improperly trained and certified in the use of the workstation, modifications, alterations, normal wear and tear, tampering, improper adjustments, accidents and Acts of Nature. This warranty does not cover equipment already covered under a manufacturer's warranty. Containment Technologies Group, Inc. shall not be liable under this limited warranty for incidental, special, indirect or consequential damages including without limitation loss of use, loss or delay of anticipated revenue, losses by reason of shut-down, cost of substitute facilities or service or other similar damages. Containment Technologies Group, Inc.'s sole liability, including liability arising out of contract, negligence, and strict liability in tort and warrant, shall not exceed amounts payable to Containment Technologies Group, Inc. for the equipment described herein.

The above is a limited warranty and is the only warranty made by Containment Technologies Group, Inc. No other warranty, expressed or implied is given. In consideration for this warranty all liabilities or obligations of Containment Technologies Group, Inc. for damages arising out of or in connection with this equipment or use thereof is absolved.