OPERATOR MANUAL

X10™ Biodecontamination Unit

(TEAM) **10087252**

A WORD FROM STERIS CORPORATION

IMPORTANT: A listing of the *SAFETY PRECAUTIONS* to be observed when operating and servicing this equipment and/or handling Vaprox 59 Hydrogen Peroxide Sterilant can be found in *SECTION 1* of this manual. Do not operate or service the equipment or handle the Sterilant until you have been trained and certified on this information as well as the information on the Vaprox 59 Hydrogen Peroxide Sterilant product label and package insert.

IMPORTANT: Please refer to *SECTION 2.1, TERMS AND DEFINITIONS*, for a list of terminology used in this document. This manual describes the STERIS Biodecontamination Process using Vaprox 59 Hydrogen Peroxide Sterilant. The U.S. EPA has registered Vaprox 59 Hydrogen Peroxide Sterilant (EPA Reg. No. 1043-123) and its use. Refer to either the Vaprox 59 Hydrogen Peroxide Sterilant label and package insert for detailed Safety Precautions and application instructions.

Thank you for choosing this fine STERIS Life Sciences product. STERIS is committed to ensuring your continued satisfaction. This manual contains important information on proper use and maintenance of the X10™ Biodecontamination Unit. **All personnel involved in the use and maintenance of this equipment must carefully review and comply with the *SAFETY PRECAUTIONS* and instructions contained in this manual and the Vaprox® 59 Hydrogen Peroxide Sterilant Safety Data Sheet (SDS), product label and package insert.** These instructions are important to protect the health and safety of personnel operating the X10 Biodecontamination Unit and should be retained in a conveniently accessible area for quick reference.

Complete instructions for uncrating and installing this unit, as well as equipment drawings, have been furnished. If missing, contact STERIS Life Sciences for replacement copies, giving the serial, equipment and model numbers of the Biodecontamination Unit.

*NOTE: Refer to **SECTION 2** of this manual for a listing of Terms, Definitions and Symbols that may appear in this manual or on your equipment.*

Advisory

A listing of the ***SAFETY PRECAUTIONS*** to be observed when operating and servicing this X10 Biodecontamination Unit and/or handling the Sterilant is found in ***SECTION 1*** of this manual or on the container label. Do not operate or service the equipment or handle the Sterilant until you have become familiar with this information.

Any alteration of the unit not authorized or performed by STERIS Life Sciences voids the warranty, could adversely affect Biodecontamination efficacy, and could violate national, state and local regulations.

Vaprox 59 Hydrogen Peroxide Sterilant have been EPA registered by STERIS in accordance with Federal Regulations for the specific uses described in this manual. The X10 Biodecontamination Unit must be used only on Enclosures (refer to ***SECTION 2.1, TERMS AND DEFINITIONS***) that have been pre-cleaned and dried per facility process and current protocols. Please refer to the Vaprox 59 Hydrogen Peroxide Sterilant package insert for additional information and application instructions.

Printed in U.S.A.

Intended Use

DANGER – FIRE AND EXPLOSION HAZARD:

- **Verify all materials coming in contact with hydrogen peroxide are compatible with oxidizers. Contact STERIS Life Sciences or the material manufacturer for information on material compatibility.**
- **This Biodecontamination Unit is not designed to process flammable liquids. Do not process liquids, linens, powders or any cellulose materials. Process only those materials compatible with hydrogen peroxide.**

NOTE: The X10 Biodecontamination Unit is to be used by Trained and Certified Applicators who have successfully completed both the STERIS Training and Certification Course for Applicators of Vaprox Hydrogen Peroxide Sterilant and the X10 Biodecontamination Unit Operator Course. Certification must be active and in force for all Applicators of Vaprox 59 Hydrogen Peroxide Sterilant.

The X10 Biodecontamination Unit is designed for mobile Biodecontamination of clean, dry, sealed Enclosures (refer to ***SECTION 2.1, TERMS AND DEFINITIONS***) of three, four, five and six foot widths with corresponding internal volumes from 15.6 - 31.2 ft^3 (.44 - .88 m^3) using STERIS's patented VHP® Process Technology and using Vaprox 59 Hydrogen Peroxide Sterilant.

Uses other than as specified and described in this manual are not recommended and may not be effective or safe in operating the Biodecontamination Unit. Consult this manual or STERIS Life Sciences for further information.

The Biodecontamination Unit utilizes specially designed disposable 70 mL Cups* of Vaprox 59 Hydrogen Peroxide Sterilant.

**Available separately for purchase.*

Introduction

The STERIS X10 Biodecontamination Unit offers fast, economical Biodecontamination of Enclosures (refer to ***SECTION 2.1, TERMS AND DEFINITIONS***).

The Biodecontamination Unit uses STERIS's patented VHP Process Technology. This process utilizes hydrogen peroxide vapor as a broad spectrum anti-microbial without condensation of the active ingredient onto surfaces with good material compatibility.

The Biodecontamination Unit comes with two programmed cycles designed to achieve a minimum of a 6-log bioburden reduction in a Class II Type A2 Biological Safety Cabinet:

1. Cycle 1 for 3 - 4' (0.9 - 1.2 m)
2. Cycle 2 for 5 - 6' (1.5 - 1.8 m)

The X10 features *X-Phase* hardware technology and *VaproxLink* software technology. *X-Phase* hardware technology features a rotating cylinder design that enables heating, dehumidification, conditioning, Biodecontamination and aeration for an All-In-One unit design while *VaproxLink* software technology automatically identifies Vaprox 59 Hydrogen Peroxide Sterilant Cup and verifies expiration date.

With 0.5-2.5 g/min of Sterilant injection, the Biodecontamination Unit is capable of Biodecontaminating a single Class II Type A2 cabinet from 3 - 6' (0.9 - 1.8 m) with internal cabinet volume up to 31.2 ft^3 (.88 m^3).

The *X10* Biodecontamination Unit is multi-lingual (English, French, Spanish, Italian and German) and available in either 120 or 230 Vac, single phase, electrical service.

Service Information

A thorough preventive maintenance program is essential to safe and proper equipment operation. Comprehensive instructions for monthly, quarterly and semi-annual preventive maintenance can be found in the Maintenance Manual (available from STERIS Life Sciences).

Only STERIS-trained personnel should attempt to perform maintenance on the X10 Biodecontamination Unit to avoid personal injury, improper equipment performance, invalidation of the warranty or other costly damage.

Customers are encouraged to contact STERIS Life Sciences concerning our annual maintenance program. Under the terms of the program, preventive maintenance, adjustments and replacement of worn parts are provided on a scheduled basis to help ensure optimal equipment performance and to help minimize untimely or costly schedule interruptions. STERIS Life Sciences maintains a worldwide staff of well-equipped, factory-trained technicians to provide these services, as well as on-site installation, training and expert repair services. Contact STERIS Life Sciences** for details.

***1 (800) 440-9009 or www.sterislifesciences.com.*

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The base language of this document is ENGLISH. Any translations must be made from the base language document.

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SAFETY PRECAUTIONS

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NOTE: Refer to SECTION 2 of this manual for a listing of Terms, Definitions and Symbols that may appear in this manual or on your equipment.

The following *Safety Precautions* **must** be observed when operating or servicing this STERIS X10™ Biodecontamination Unit and when handling Vaprox® 59 Hydrogen Peroxide Sterilant Cups. *Safety Precautions* are divided as follows:

- **DANGER** indicates personal injury or substantial property damage results if proper precautions are not taken.
- **WARNING** indicates the potential for personal injury and/or potential for property damage may result if proper precautions are not taken.
- **CAUTION** indicates the potential for damage to equipment may result if proper precautions are not taken.

For emphasis, certain *Safety Precautions* are repeated throughout the manual. **It is important to review ALL *Safety Precautions* before operating or servicing the unit.** Also read the Vaprox 59 Hydrogen Peroxide Sterilant SDS for additional information on the proper use and handling of hydrogen peroxide.

STERIS recommends that all operators should be regularly trained in the operation and safe usage of the equipment, including emergency procedures for any harmful material released into the environment. Records of attendance at training shall be maintained and evidence of understanding shall be demonstrated.

NOTE: Disregarding the presented safety information is considered **ABNORMAL USE** *of this product. If the equipment is used in a manner not specified by STERIS, the protection provided by the equipment may be impaired.*

DANGER – SLIPPING HAZARD:

Water or hydrogen peroxide spilled on the floor presents a slipping hazard – promptly clean up the spill. If in doubt whether the liquid is water or hydrogen peroxide, test the liquid using a Liquid Hydrogen Peroxide Test Strip (follow manufacturer's instructions), before wiping up. If the liquid is hydrogen peroxide, contain the spill and dilute with water (at least 20 parts water to one part H_2O_2) prior to wiping up. Observe all hydrogen peroxide handling precautions. Refer to the Vaprox 59 Hydrogen Peroxide Sterilant SDS for spill containment and cleanup.

DANGER – FIRE AND EXPLOSION HAZARD:

Liquid hydrogen peroxide is a strong oxidant and poses a FIRE, EXPLOSION OR CONTAINER RUPTURE HAZARD. Avoid excessive heat, contamination or contact with combustible materials. Clothing, shoes or other combustible materials that have come in contact with hydrogen peroxide must be immediately and thoroughly washed with water. Discard shoes contaminated with Vaprox 59 Hydrogen Peroxide Sterilant in a fireproof container. If Vaprox Sterilant is allowed to dry in the materials, a fire may result. **IN CASE OF FIRE**, use water only. **CONTAIN SPILLS** and dilute with water (at least 20 parts water to one part H_2O_2). After diluting the spill, sodium metabisulfide or sodium sulfite (1.9 lb of SO2 equivalent per 500 mL of H_2O_2) may be used to destroy the peroxide. SEE SDS FOR ADDITIONAL INFORMATION. EFFECTS MAY BE DELAYED.

Verify all materials coming in contact with hydrogen peroxide, especially the concentrated liquid, are compatible with oxidizers. Contact STERIS Life Sciences or the material manufacturer for information on material compatibility.

This Biodecontamination Unit is not designed to process flammable liquids. Do not process liquids, linens, powders or any cellulose materials. Process only those materials compatible with hydrogen peroxide.

DANGER – PERSONAL INJURY, CONTAMINATED ENCLOSURE AND/OR EQUIPMENT DAMAGE HAZARD:

- Use only Vaprox 59 Hydrogen Peroxide Sterilant Containers, containing STERIS-registered hydrogen peroxide which has been specially formulated, tested and approved for use in this X10 Biodecontamination Unit. Vaprox 59 Hydrogen Peroxide Sterilant has been registered by STERIS in accordance with U.S. Federal Regulations for the specific uses described in this manual. Use of other materials and/or H_2O_2 other than Vaprox 59 Hydrogen Peroxide Sterilant could impair equipment operation, result in costly repairs, result in an ineffective Biodecontamination Cycle, violate federal law and void the equipment warranty.
- Before using Vaprox 59 Hydrogen Peroxide Sterilant, check the expiration date. Do not use a Sterilant if it is beyond its expiration date, or if it will not be fully used before its expiration date.
- When using a Vaprox 59 Hydrogen Peroxide Sterilant Cup, always wear appropriate Personal Protective Equipment (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE), keep the Cup upright and do not squeeze.
- Before disposing of a Vaprox 59 Hydrogen Peroxide Sterilant Cup, empty all remaining Cup contents into a sink with running water (at least 20 parts water to one part Vaprox H_2O_2), then carefully triple rinse the Cup with tap water.
- Before starting a cycle, check Sterilant to ensure it is not expired.
- No one may open a sealed Enclosure during or after an aborted cycle without PPE (refer to Sterilant SDS for PPE) if Sterilant levels within the treated Enclosure are above one PPM. Refer to Sterilant label and package insert for instructions.

DANGER – CHEMICAL INJURY HAZARD:

- When handling hydrogen peroxide, wear appropriate PPE (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE) and observe all Safety Precautions. See Vaprox 59 Hydrogen Peroxide Sterilant SDS, product label and package insert for additional handling information.
- CORROSIVE. Causes irreversible eye damage or skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. User should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. User should remove contaminated clothing and wash before reuse. Applicators and all other handlers must wear PPE (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE). See Vaprox 59 Hydrogen Peroxide Sterilant product label and package insert for additional handling information.
- When handling the Biodecontamination System hoses, wear appropriate PPE (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE). Any visible liquid in the hoses must be treated as concentrated hydrogen peroxide and all hydrogen peroxide handling precautions must be observed.
- If power has been interrupted, do not attempt to access the Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*). Hydrogen peroxide may be present in the Enclosure.
- Read the manufacturer operating instructions before attempting to use the low level hydrogen peroxide monitor.

DANGER – CHEMICAL INJURY HAZARD (Cont'd):

When handling Vaprox 59 Hydrogen Peroxide Sterilant Cups, note the following:

- Use extreme caution when handling a damaged, leaking or expired hydrogen peroxide Cup. Always wear appropriate PPE (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE) when handling damaged, leaking or expired Cups, or when wiping up hydrogen peroxide spills.
- When handling a Cup under water, do not allow your glove openings to go below the surface of the water permitting liquid to enter the gloves.
- A Vaprox 59 Hydrogen Peroxide Sterilant Cup must be in the Cup holder at all times. When no Cup is in place, concentrated liquid hydrogen peroxide may drip from the Cup connector.

Before running a Biodecontamination Cycle, always verify that the Biodecontamination Unit is properly connected to the sealed Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*) to ensure complete containment of the hydrogen peroxide vapors (check hose connections and ensure all Enclosure vents/ports are sealed). Post warning signs on and around the treated Enclosure to prevent accidental entry during the Biodecontamination Cycle. Refer to the Vaprox 59 Hydrogen Peroxide Sterilant label and package insert for specific detailed instructions.

When the control panel warning light is ON, harmful Sterilant vapors are present within the Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*). Do not access the Enclosure. If it is necessary to access the Enclosure being processed under these conditions before the end of the Aeration phase or after an aborted Cycle, wear appropriate PPE (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE). Ensure no skin is exposed. Follow all re-entry protocols listed on the Vaprox 59 Hydrogen Peroxide Sterilant label and package insert.

At the end of the Aeration phase, use a low level hydrogen peroxide monitor to check and periodically monitor the hydrogen peroxide vapor concentration within the Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*). The hydrogen peroxide vapor concentration should be at or below established levels before the Enclosure is accessed by Trained and Certified Applicators. The Vaprox 59 Hydrogen Peroxide Sterilant label and package insert contain required hydrogen peroxide limits for re-entry and releasing of the Enclosure after Biodecontamination.

Any visible liquids in the Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*) must be treated as concentrated hydrogen peroxide. Always test residual liquids, using a Liquid Hydrogen Peroxide test strip (follow manufacturer's instructions), before diluting and wiping up. Observe all hydrogen peroxide handling precautions presented in the Vaprox 59 Hydrogen Peroxide Sterilant SDS, product label and package insert.

The Biodecontamination Unit generates harmful hydrogen peroxide vapor and discharges it from the Outlet port. Always ensure all connections are vapor tight and that the Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*) is properly sealed, secured and placarded as described on the Vaprox 59 Hydrogen Peroxide Sterilant label and package insert. Heed this Safety Precaution to ensure, under normal conditions, the Biodecontamination Unit and Enclosure do not leak H_2O_2 vapor.

WARNING – PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD:

Repairs and adjustments to this equipment must be made only by STERIS Life Sciences or STERIS-trained service personnel. Maintenance performed by unqualified personnel or installation of unauthorized parts could cause personal injury, impair equipment protection design, result in improper equipment performance, invalidate the warranty or result in costly damage. Contact STERIS Life Sciences regarding service options.

Regularly scheduled preventive maintenance is required for safe and reliable operation of this equipment. Contact STERIS Life Sciences to schedule preventive maintenance.

Lifting the Biodecontamination Unit requires more than one person. The unit weighs approximately 68 lb (31 kg).

Place the Biodecontamination Unit only on flat surfaces. Various internal components are designed for operation when Unit is placed on a level, flat surface.

Ensure the Biodecontamination Unit is positioned so access to power switch and facility outlet are not restricted. To disconnect Biodecontamination Unit, pull cord from facility outlet. The power switch is NOT intended to be used as a means of disconnect.

Integrated (temperature and humidity) sensors are fragile. Do not bang, twist or crush. Biodecontamination Unit does not operate properly with a damaged sensor.

WARNING – ELECTRIC SHOCK HAZARD:

Disconnect electrical power source to equipment (pull plug from facility outlet) before attempting to access the Biodecontamination Unit. The power switch is NOT intended to be used as a means of disconnect.

CAUTION – POSSIBLE EQUIPMENT DAMAGE:

Use nonabrasive cleaners when cleaning unit. If you need technical assistance or additional instructions, call STERIS Life Sciences.

- Follow all directions on container.
- Do not use abrasive cleaners on plastic surfaces.
- Avoid detergents with bases, aromatics, ketones, esters and chlorinated hydrocarbons.
- Avoid contacting plastic surfaces with greases and oils.

Keep connecting hoses off the floor. If supply connecting hoses rest on cool floors or other cool surfaces, hydrogen peroxide may condense in the hoses. Place a support under the hoses (e.g., lash hoses to plastic easel or plastic tripod) to prevent kinks and undue strain on the hose connections.

Use only Distilled Water for the hydrogen peroxide piping purge. Use of tap water will damage the vaporizer.

REMEMBER – POSSIBLE TIME DELAY:

Insufficient clearance space will make repairs more difficult and time-consuming. Refer to the equipment drawing for minimum clearance for service/maintenance access requirements.

TERMS, DEFINITIONS AND SYMBOLS

2

2.1 Terms and Definitions

Aeration – Final phase of a Biodecontamination Cycle. Allows for re-entry into treated, sealed Enclosures once the Sterilant concentration levels are at or below permissible levels. Typical H_2O_2 concentration ≤1 PPM.

BI – Biological Indicator used for Biodecontamination Cycle evaluation. Typically E6 *Geobacillus stearothermophilus* is used.

Biodecontamination[1] **–** Third phase of the Biodecontamination Cycle or the obtaining of bioburden reduction targets in a sealed Enclosure.

Biodecontamination Cycle[1] **–** Represents the complete process (Biodecontamination) from start to finish which may include Dehumidify, Condition, Biodecontamination and Aeration phases.

Biodecontamination Unit – STERIS X10™ Biodecontamination Unit.

Catalytic Converter – A component of the Biodecontamination Unit utilizing a catalyst to degrade H_2O_2 into water vapor and oxygen.

CI – Chemical Indicator used for Biodecontamination Cycle validation and Sterilant mapping.

Condition – Second phase of the Biodecontamination Cycle. Sterilant is added to the sealed Enclosure to reach the target concentration needed for the Biodecontamination phase.

Cup – Vaprox® 59 Hydrogen Peroxide Sterilant container, 70 mL.

Dehumidify – First phase of the Biodecontamination Cycle. Achieves temperature and humidity conditions necessary for subsequent Biodecontamination phases.

Enclosure – Contained area to be Biodecontaminated (e.g., Class II Type A2 Biosafety Cabinet).

FMP – Fumigation Management Plan.[2]

HMI – Human Machine Interface (such as the control display).

H2O2 or H_2O_2 – Hydrogen peroxide.

I/O – Input/Output.

PLC – Programmable Logic Controller.

[1] *When using STERIS X10 Biodecontamination Units with Vaprox 59 Hydrogen Peroxide Sterilant in the United States, the term Biodecontamination referred to in this Operator Manual is defined as Sterilization of exposed porous and non-porous surfaces in a precleaned, dry, sealed Enclosure. Any reference to Biodecontamination as it relates to the use of this equipment in the United States does not impart additional claims of effectiveness beyond that approved in the EPA registered labeling of Vaprox 59 Hydrogen Peroxide Sterilant for use on precleaned, dry, exposed porous and non-porous surfaces in a sealed Enclosure.*

[2] *Guidance for developing a suitable Fumigation Management Plan can be found in STERIS publication (P129383-938) or searching EPA website (epa.gov) for the key words 'Vaprox Package Insert.'*

Continued ...

Terms and Definitions (Cont'd)

PPE – Personal Protective Equipment including goggles or face shield, chemical-resistant gloves (barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, polyvinyl chloride, or Viton®[3]) and SCBA (Self-Contained Breathing Apparatus) if hydrogen peroxide concentrations exceed one ppm during handling/or application of Sterilant. Refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for appropriate PPE.

RH – Relative Humidity.

SCBA – Self-Contained Breathing Apparatus.

scfm – Standard Cubic Feet per Minute.

scmh – Standard Cubic Meters per Hour.

SDS – Material Data Sheet.

Sporicidal – Antimicrobial activity which destroys or eliminates all forms of microbial life including hard-to-kill microbial spores.

SSR – Solid State Relay.

Sterilant – Vaprox 59 Hydrogen Peroxide Sterilant (STERIS EPA-registered, 1043-123, 59%). Sterilant contains stabilizers and other additives making it suitable for STERIS VHP Biodecontamination Units.

Sterilization – Complete killing of all microbial life including spores.

Unit – Biodecontamination Unit.

USB – Universal Serial Bus. Industry standard defining cables, connectors and communication protocols used in a bus for connection, communication and power supply between computers and electronic devices.

Vac – Volts Alternating Current.

Vdc – Volts Direct Current.

VHP – STERIS proprietary process technology utilizing H_2O_2 vapor as a broad spectrum anti-microbial without condensation of the active ingredient on the surfaces.

[3] *Viton is a registered trademark of DuPont Performance Elastomers.*

2.2 Symbols

Table 2-1 contains symbols which may appear on your STERIS *X10* Biodecontamination Unit components.

Table 2-1. Definition of Symbols

Symbol	Definition
	Protective Earth (Ground)
	Electrostatic Sensitive Device
	Electric Shock Hazard
	Attention, Consult Manual for Further Instructions
	This Product Has Been Tested To The Requirements Of CAN/CSA-C22.2 No. 61010-1, Second Edition, Including Amendment 1, Or A Later Version Of The Same Standard Incorporating The Same Level Of Testing Requirements
	Inlet Sterilant Hose Connection (From Enclosure Exhaust Into Biodecontamination Unit)
	Outlet Sterilant Hose Connection (From Biodecontamination Unit Into Enclosure Work Area)
SN	Serial Number of Unit
V~	Voltage Rating of Unit, Alternating Current
A	Amperage Rating of Unit
Hz	Frequency Rating of Unit
ϕ	Phase of Unit

OPERATING INSTRUCTIONS

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IMPORTANT: A listing of the *SAFETY PRECAUTIONS* to be observed when operating and servicing this equipment and/or handling Vaprox® 59 Hydrogen Peroxide Sterilant can be found in *SECTION 1* of this manual. Do not operate or service the equipment or handle the Sterilant until you have been trained and certified on this information as well as the information on the Vaprox 59 Hydrogen Peroxide Sterilant product label and package insert.

IMPORTANT: Please refer to *SECTION 2.1, TERMS AND DEFINITIONS*, for a list of terminology used in this document. This manual describes the STERIS Biodecontamination Process using Vaprox 59 Hydrogen Peroxide Sterilant. The U.S. EPA has registered Vaprox 59 Hydrogen Peroxide Sterilant (EPA Reg. No. 1043-123) and its use. Refer to either the Vaprox 59 Hydrogen Peroxide Sterilant label and package insert for detailed Safety Precautions and application instructions.

NOTE: Uses other than as specified and described in this section, on the Sterilant label and/or package insert are not recommended, may not be effective in Biodecontamination, and may not be safe. Please contact STERIS Life Sciences for appropriate guidance, in-service and training.

3.1 Introduction

NOTE: Refer to SECTION 2 of this manual for a listing of Terms, Definitions and Symbols that may appear in this manual or on your equipment.

The STERIS VHP X10™ Biodecontamination Unit, using STERIS's patented VHP Process Technology, offers fast, economical biodecontamination of Enclosures.

This process utilizes H_2O_2 vapor as a broad spectrum anti-microbial. There is no condensation of the active ingredient onto surfaces and Sterilant has good material compatibility.

The Biodecontamination Unit comes with two programmed cycles designed to achieve a minimum of a 6-log bioburden reduction in an Enclosure (Class II Type A2 Biological Safety Cabinet):

- Cycle 1 - 3 - 4' (0.9 - 1.2 m)
- Cycle 2 - 5 - 6' (1.5 - 1.8 m)

The STERIS X10 Biodecontamination Unit features X-Phase hardware technology and VaproxLink software technology. X-Phase hardware technology features a rotating cylinder design that enables heating and Biodecontamination Cycle phases (Dehumidification, Conditioning, Biodecontamination and Aeration) for an All-In-One unit design while VaproxLink software technology automatically identifies Vaprox® 59 Hydrogen Peroxide Sterilant Cup and verifies expiration date.

Other X10 Biodecontamination Unit features:

- With 0.5 - 2.5 g/min of Sterilant injection, the Biodecontamination Unit is capable of Biodecontaminating a single Class II Type A2 cabinet from 3 - 6' (0.9 - 1.8 m) with an internal cabinet volume of up to 31.2 ft^3 (.88 m^3).
- Biodecontamination Unit operates outside (with the addition of Sash Support Plate and Exhaust Plenum Adapter) the Enclosure and can operate as a stand alone Biodecontamination Unit.

- All Biodecontamination Cycle data is output to a USB interface in encrypted format for data storage.
- Biodecontamination Unit is easily transported in a light weight and IP20 rated case (with retractable handle and wheels).
- A separate AR60™ Aerator is available for catalyzing sterilant for applications requiring faster aeration time.
- The X10 Biodecontamination Unit is multi-lingual (English, French, Spanish, Italian and German) and available in either 120 or 230 Vac, single phase electrical service.
- To minimize exposure to liquid Sterilant during handling, the system uses specially designed disposable Cups containing approximately 70 mL of Vaprox 59 Hydrogen Peroxide Sterilant.

3.2 Operation

NOTE: The STERIS X10 Biodecontamination Unit is to be used by Trained and Certified Applicators who have successfully completed both the STERIS Training and Certification Course for applicators of Vaprox 59 Hydrogen Peroxide Sterilant and the STERIS X10 Biodecontamination Unit Operator Course. Certification must be active and in force for all Applicators of Vaprox 59 Hydrogen Peroxide Sterilant.

WARNING – PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD:

- **Lifting Biodecontamination Unit requires more than one person. The unit weighs approximately 68 lb (31 kg).**
- **Place the Biodecontamination Unit only on flat surfaces. Various internal components are designed for operation when Unit is placed on a level, flat surface.**
- **Ensure the Biodecontamination Unit is positioned so access to power switch and facility outlet are not restricted.**
- **Integrated (temperature and humidity) sensors are fragile. Do not bang, twist or crush. Biodecontamination Unit does not operate properly with a damaged sensor.**

3.2.1 Attach to Enclosure

The following information is intended to enable a Trained and Certified Applicator to properly attach the Biodecontamination Unit to an Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*):

1. Review site-specific FMP* and verify all accessories are present (if applicable) and proper location of Biodecontamination Unit.
2. Consult with facility officials on Safety Precautions, security, warning placards and other facility requirements.
3. Position Biodecontamination Unit and any needed accessories cases near Enclosure (see Figure 3-1).

   NOTE: Ensure Biodecontamination Unit is within 10' (3 m) of the facility power outlet. Use of extension cords is not recommended.

**Guidance for developing a suitable Fumigation Management Plan can be found in STERIS publication (P129383-938) or searching EPA website (epa.gov) for the key words 'Vaprox Package Insert.'*

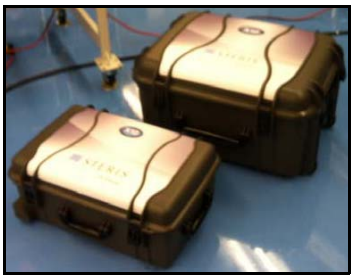


Figure 3-1. VHP X10 Biodecontamination Unit in Cases

4. Unlatch (all six) Biodecontamination Unit case cover and lift cover (see Figure 3-2).

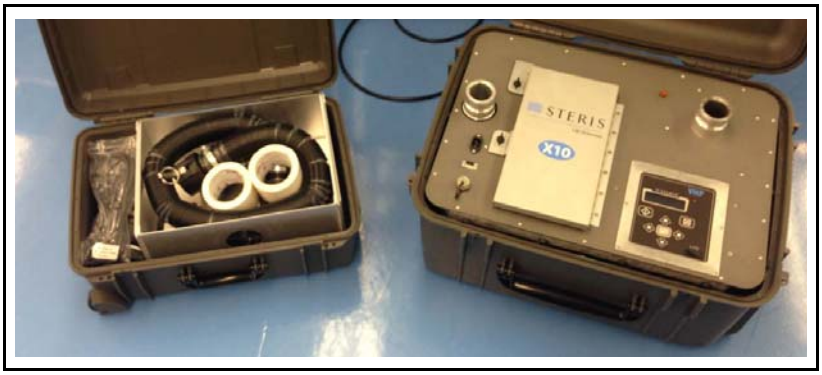


Figure 3-2. Open Biodecontamination Unit Case

5. Open Accessories Case (see Figure 3-3) and unpack accessories:
   - Inlet Hose Assembly
   - Outlet Hose Assembly
   - Sash Support Plate Assembly
   - Exhaust Plenum Adapter
   - Power Cord (Either 120V or 230V).

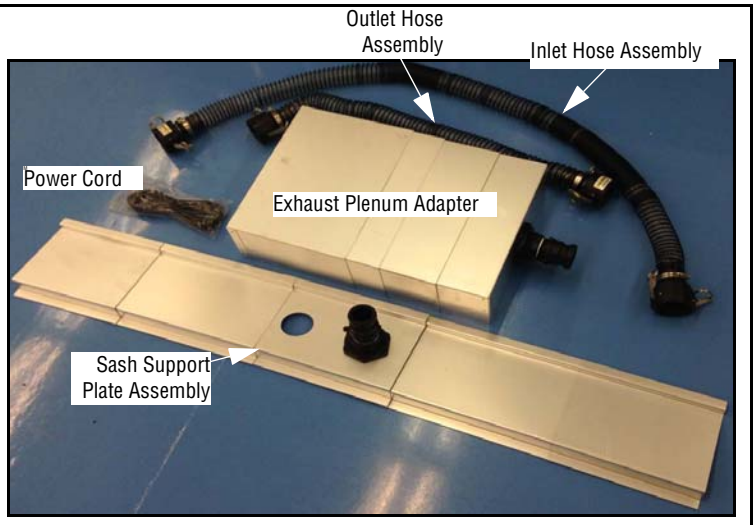


Figure 3-3. Accessory Case Components

6. Attach Sash Plate Assembly to Enclosure.
7. Attach Exhaust Plenum Adapter to Enclosure.
8. Connect hoses from VHP X10 Biodecontamination Unit to Enclosure (see Figure 3-4). Follow labels on Biodecontamination Unit.

Figure 3-4. Connect Biodecontamination Unit to Enclosure

3.2.2 Prepare Enclosure and Biodecontamination Unit

The following information is intended to enable a Trained and Certified Applicator to properly set-up the Biodecontamination Unit and prepare the Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*):

1. Per FMP*, make all necessary preparations to Enclosure. Verify CIs and BIs are placed inside Enclosure as required.
2. Wearing proper PPE, unpack desiccant cartridge and Vaprox 59 Sterilant Cup from packaging (see Figure 3-5).
3. Ensure Sterilant Cup is not expired.
4. Plug Biodecontamination Unit power cord into proper facility outlet (120 Vac, 20A or 230 Vac, 10A; single source circuit).
5. Turn Biodecontamination Unit power ON,
6. Use **Arrow Keys** to highlight **SELECT CYCLE** on display. Press **Start** button to continue.
7. Use **Arrow Keys** to highlight desired cycle on display. Press **Start** button to continue.
8. If cycle option asks, set date and time.
9. If cycle option asks, select language.
10. Follow screen prompt, open door and insert Sterilant Cup and desiccant cartridge into unit (see Figure 3-5).

    NOTE: Refer to SECTION 6.6, STERILANT CUP INSTALLATION AND REMOVAL, and SECTION 6.7, DESICCANT INSTALLATION AND REMOVAL, for more information of desiccant cartridge and Sterilant Cup insertion.
11. Follow screen prompt, press **Start**.

**Guidance for developing a suitable Fumigation Management Plan can be found in STERIS publication (P129383-938) or searching EPA website (epa.gov) for the key words 'Vaprox Package Insert.'*

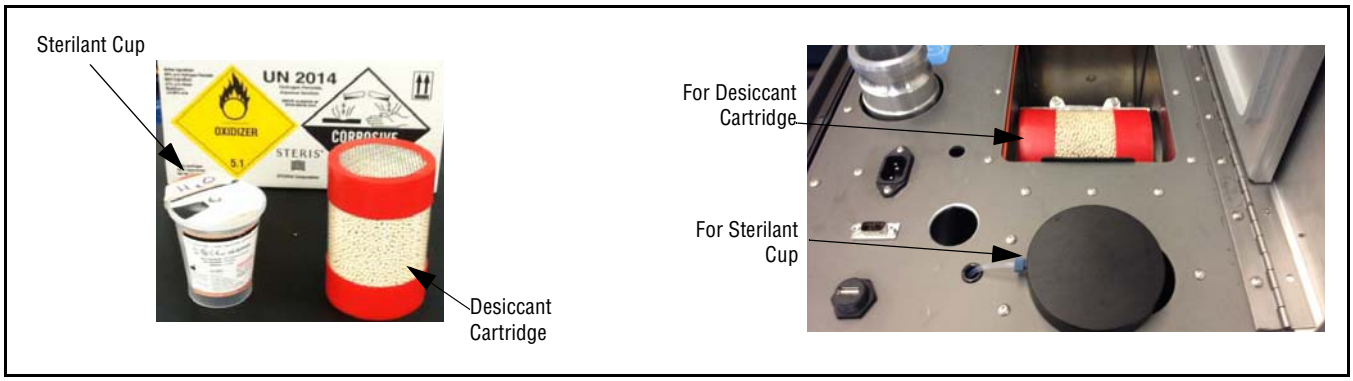


Figure 3-5. Open Supply Door

DANGER – CHEMICAL INJURY HAZARD:

- **When handling the Biodecontamination System hoses, wear appropriate PPE (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE). Any visible liquid in the hoses must be treated as concentrated hydrogen peroxide and all hydrogen peroxide handling precautions must be observed.**
- **The Biodecontamination Unit generates harmful hydrogen peroxide vapor and discharges it from the Outlet port. Always ensure all connections are vapor tight and that the Enclosure (refer to *SECTION 2, TERMS AND DEFINITIONS*) is properly sealed, secured and placarded as described on the Vaprox 59 Hydrogen Peroxide Sterilant label and package insert. Heed this Safety Precaution to ensure, under normal conditions, the Biodecontamination Unit and Enclosure do not leak H_2O_2 vapor.**

12. Follow screen prompt, insert USB device or press **Start**.
13. Follow display commands as cycle proceeds (refer to *SECTION 6.4, BIODECONTAMINATION CYCLE*).
14. At completion of HOLD phase, MANDATORY AERATION (5 minutes) phase starts.
15. At completion of MANDATORY AERATION, if optional aeration is desired, press **Cancel**. Proceed as follows:
    a. Control asks, **USE EXTERNAL AERATOR?**
    b. Turn Enclosure fan OFF.
    c. Position VHP AR60™ Aerator near Enclosure.
    d. Disconnect Outlet and Inlet Hose Assemblies from Biodecontamination Unit and connect to AR60 Aerator (see *Figure 3-6*).
    e. Plug AR60 Aerator into applicable wall outlet (120 or 230 Vac).
    f. Turn AR60 Aerator ON by pressing power switch.
    g. Turn Enclosure fan ON.
    h. Press **Check** button.
    i. Allow AR60 Aerator to operate until H_2O_2 is reduced to a safe level of less than or equal to 1 PPM.
16. At completion of MANDATORY AERATION, if optional aeration is not desired, control continues with AERATION phase.
17. Cycle completes, alarm sounds and control displays **COMPLETE - PRESS KEY**. Press **Check** button.
18. Proceed to next section.

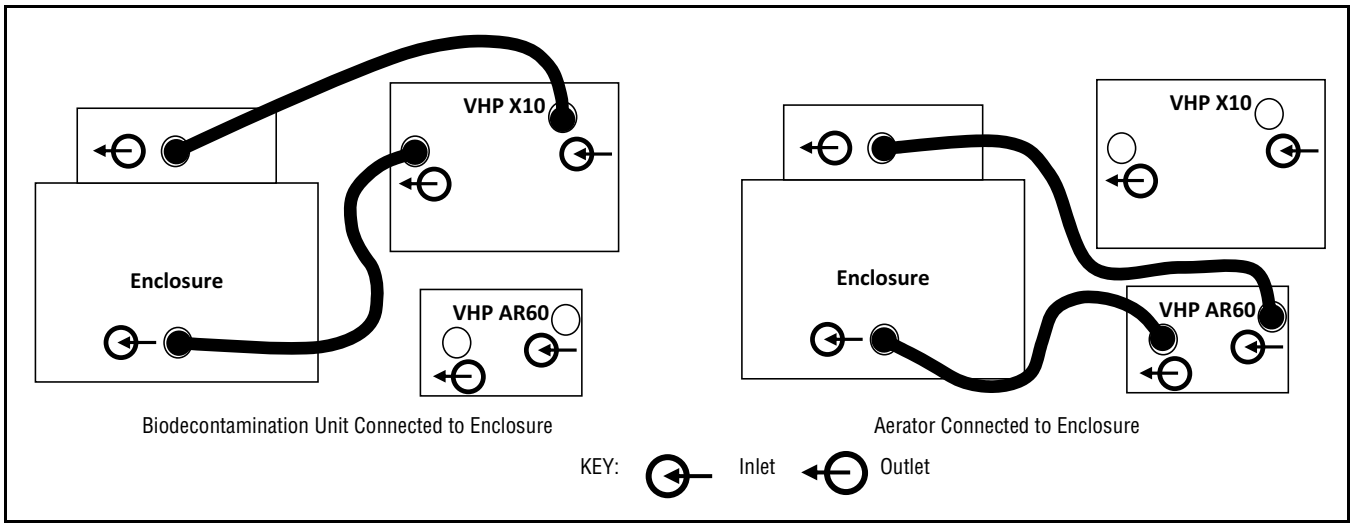


Figure 3-6. Connecting *X10* Biodecontamination Unit and AR60 Aerator to Enclosure

3.2.3 Cycle Completion

DANGER – CHEMICAL INJURY HAZARD:

- **Any visible liquids in the Enclosure (refer to *SECTION 2, TERMS AND DEFINITIONS*) must be treated as concentrated hydrogen peroxide. Always test residual liquids, using a Liquid Hydrogen Peroxide test strip (follow manufacturer's instructions), before diluting and wiping up. Observe all hydrogen peroxide handling precautions presented in the Vaprox 59 Hydrogen Peroxide Sterilant SDS, product label and package insert.**
- **At the end of the Aeration phase, use a low level hydrogen peroxide monitor to check and periodically monitor the hydrogen peroxide vapor concentration within the Enclosure (refer to *SECTION 2, TERMS AND DEFINITIONS*). The hydrogen peroxide vapor concentration should be at or below established levels before the Enclosure is accessed by Trained and Certified Applicators. The Vaprox 59 Hydrogen Peroxide Sterilant label and package insert contain required hydrogen peroxide limits for re-entry and releasing of the Enclosure after Biodecontamination**

The following information is intended to enable a Trained and Certified Applicator to properly disconnect a *X10* Biodecontamination Unit from an Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*) after Biodecontamination Cycle completion:

1. After CYCLE COMPLETE, Enclosure may be entered per FMP.
2. Remove and properly discard of used desiccant cartridge and Sterilant Cup from Biodecontamination Unit.
3. Disconnect hoses, move Biodecontamination Unit from Enclosure.

   NOTE: Do not transport Biodecontamination Unit with Sterilant Cup in the Unit.
4. Remove Sash Support and Exhaust Plenum Adapter from Enclosure.
5. Return Enclosure to operational status per FMP.

TROUBLESHOOTING

4

IMPORTANT: A listing of the *SAFETY PRECAUTIONS* to be observed when operating and servicing this equipment and/or handling Vaprox 59 Hydrogen Peroxide Sterilant can be found in *SECTION 1* of this manual. Do not operate or service the equipment or handle the Sterilant until you have been trained and certified on this information as well as the information on the Vaprox 59 Hydrogen Peroxide Sterilant product label and package insert.

4.1 Troubleshooting

DANGER – PERSONAL INJURY, CONTAMINATED ENCLOSURE AND/OR EQUIPMENT DAMAGE HAZARD: No one may enter a sealed Enclosure during or after an aborted cycle without SCBA and appropriate PPE (refer to Sterilant SDS for PPE) if Sterilant levels within the treated Enclosure are above one PPM. Refer to Sterilant label and package insert for instructions.

WARNING – PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD: Integrated (temperature and humidity) sensors are fragile. Do not bang, twist or crush. Biodecontamination Unit does not operate properly with a damaged sensor.

The VHP *X10*™ Biodecontamination Unit alerts the Trained and Certified Applicator of various alarm/abort situations. Alarms occur as a result of component failures, utility failures, unexpected measurements from sensors or as a warning indication that Applicator intervention is necessary (see **Table 4-1** and **Table 4-2**).

Refer to Troubleshooting Guide (**Table 4-3**) for description of Alarm Message Displays.

If a situation occurs that is not described in this manual, please call STERIS Life Sciences. Trained service personnel can promptly restore this *X10* Biodecontamination Unit to proper working order.

NOTE: Never permit unqualified persons to service this Biodecontamination Unit.

Table 4-1. Alarm/Abort Actions

Phase at Alarm-Abort	Action Following Alarm-Abort
Before start of Sterilant Injection phase (before Condition/Biodecontamination)	Advance to Cycle Complete
During Sterilant injection (Condition/Biodecontamination)	Advance to Aeration

Table 4-2. Power Interruption/Power-Up Actions

Active Cycle Phase	Action Upon Power Return
Heat Cabinet	Abort Cycle
Dehumidify	Abort Cycle
Re-Heat Cabinet	Abort Cycle
Heater Cap Warm-Up	Abort Cycle
Condition	Aeration
Biodecontamination	Aeration
Aeration	Restart Aeration
Cycle Complete	Return to Cycle Complete

Table 4-3. Troubleshooting Guide

Alarm Message Display	Description	Possible Causes and / or Corrections
1. Power Lost	Occurs after the X10 BU has experienced a loss of power	• System Initiated: NA
2. Door Open	Occurs when the safety interlock key is not inserted in the safety interlock switch	• Door not completely closed at beginning of cycle – Close Door • Safety interlock switch failure or wiring disconnected/shorted. • Contact STERIS.
3. Door Interlock Fail	Occurs at any time during a cycle and after the dehumidify phase, the safety door interlock coil remains energized	• Safety interlock switch failure or wiring disconnected/shorted. • Contact STERIS.
4. Datalog Save Fail	Occurs while attempting to save a datalog file to a USB Flash memory stick	• Verify that a USB Flash memory stick is inserted in the USB port. • Attempt the save operation while using a different USB Flash memory stick.
5. Heater Cap RTD Fail	Occurs when the heater cap RTD (RTD1) temperature reading indicates a break or short in the wiring or the reading is at an extreme high or low for 10 seconds continuously	• Sensor failure or wiring disconnected/ shorted. • Analog channel failure. • Contact STERIS.
6. Htr Cp Too Long Heat	Occurs during the heating (heater cap) phase (prior to Condition or Biodecontamination), the heater cap temperature fails to reach the setpoint temperature within 15 minutes	• Improper in-cycle heater cap temperature setpoint. • RTD1/Control board/Wiring failure. • RTD1 failure. • AC Control Board/Solid State relay (SSR2) failure. • Contact STERIS.
7. Heater Cap Temp Dev	Occurs during the Condition or Biodecontamination phase, the heater cap RTD1 temperature reading is 86°F (30°C) above or below the programmed setpoint temperature for two seconds continuously	• Pre-heater temperature too low. • RTD1/Control Board/Wiring failure. • Improper in-cycle heater cap temperature setpoint. • Contact STERIS.
8. Heater Cap Overtemp	Occurs at any time, the heater cap over-temperature switch (SW2) has tripped	• RTD1 failure. • Solid State relay (SSR2) failure. • RTD1/Control Board/Wiring failure when heater cap is cool. • Contact STERIS.

Table 4-3. Troubleshooting Guide (Cont'd)

Alarm Message Display	Description	Possible Causes and / or Corrections
9. Cabinet Temp RTD Fail	Occurs at any time, the Airflow RTD (RTD2) temperature reading indicates a break or short in the wiring or the reading is at an extreme high or low, for 10 seconds continuously	• Sensor failure or wiring disconnected/ shorted: Check RTD2 connector and connector on control board. Repair as needed or replace RTD. • Control Board failure: Replace control board.
10. Cabinet Too Long Heat	Occurs during the heating (cabinet) phase (prior to Condition or Biodecontamination), and after 15 minutes of operation, the Cabinet Temperature does not increase 0.1°C over a 5 minute period	• Improper cabinet heater temperature setpoint: Verify temperature setpoint. Setpoint should be approximately 31°C. • RTD2/Control Board/Wiring failure: Verify proper operation of cabinet heater control circuit. • RTD2 failure: Calibrate or replace. • Solid State relay (SSR2) failure: Replace.
11. RH Sensor Failure	Occurs at any time, the airflow RH (RH1) reading indicates a break or short in the wiring for 10 seconds continuously	• Sensor failure or wiring disconnected/ shorted: Check the RH1 connector and connector on the control board. Repair as needed or replace RH probe or board. • Control Board failure: Replace control board.
12. Dehumidify Timeout	Occurs during the dehumidify phase, the RH sensor fails to reach the setpoint within 80 minutes	• Desiccant is saturated: Replace desiccant. • Blower failure: Verify movement of air. **See Alarm Message 14**. • RH Sensor/Control Board/Wiring failure: Verify proper operation of RH control circuit. • RH Sensor failure: Calibrate or replace. • Enclosure too large for dryer type: Increase dryer capacity.
13. Blower Airflow Dev	Occurs during any cycle phase, the cycle flow blower (MTR-1) control output has exceeded its upper or lower limit for two minutes continuously	• Air inlet blocked: Verify proper air flow through X10 unit. • MTR-1/Control Board/wiring failure: Verify proper operation of blower control circuit. • Solid State Relay (SSR1) failure: Replace.
14. Circ Blower Failure	Occurs during any cycle phase where the circulation blower option is ON and the blower does not run	• MTR-1/Control Board/wiring failure: Verify proper operation of blower control circuit. • Solid State Relay (SSR1) failure: Replace.
15. Operator Abort	Occurs at any time, when the Operator requests an abort during a cycle	• Operator initiated: Not applicable

Table 4-3. Troubleshooting Guide (Cont'd)

Alarm Message Display	Description	Possible Causes and / or Corrections
16. External Aerator Fail	Occurs when the External Aerator option is ON and the External Aerator input is open.	• Auxillary Aerator Unit unplugged from Unit: Connect Auxillary Aerator Unit. • External Aerator option inadvertently selected: Deselect this option in the menu.
17. Sterilant Cup Expired	Occurs during the reading of the sterilant cup RFID tag, the sterilant cup expiration date is past the current calendar date	• Replace the sterilant cup with one that is not expired. • Check the sterilant cup's printed expiration date. • Check that the BU system date is correct.
18. Sterilant Cup Used	Occurs during the reading of the sterilant cup RFID tag, the sterilant cup serial number matches a previously used code	• Replace the sterilant cup with one that has not been used.
19. Sterilant Cup Bad SKU	Occurs during the reading of the sterilant cup RFID tag, the sterilant cup SKU code does not match the BSC system SKU code	• Replace the sterilant cup with one that has the correct SKU. • Check the sterilant cup's printed SKU code.
20. Sterilant Cup Bad Wrt	Occurs during the condition phase, the writing of the sterilant cup RFID tag, and subsequent verification reading, the RFID tag's serial number does not contain the used cup code	• Manually mark the cup as used. • Verify the proper operation of the RFID Reader/Writer.
21. RH Sensor Not Calib	Appears at any time the RH Sensor's Relative Humidity input is identified as not calibrated	• System initiated: Not applicable.
22. RH RTD Not Calib	Appears at any time the RH Sensor's RTD input is identified as not calibrated	• System initiated: Not applicable.
23. Machine Calib Due	Occurs any time calibration is due for the BSC Unit analog inputs or outputs	• System initiated: Not applicable.
24. Drum Assembly Index Fail	Occurs at any time the drum assembly does not encounter one of the three indexer sensors	• Check sensors on the drum position board. • Check the drum indexing motor (MTR-2). • Verify proper torque on rear drum assembly retaining bolt.
25. Control Board Fail	Occurs at any time a Control Board fault is issued by the Control Board	• TBD.
** STERIS Life Sciences*		

ROUTINE MAINTENANCE

5

5.1 Read Before Performing Routine Maintenance

WARNING – PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD:

- **Repairs and adjustments to this equipment must be made only by STERIS Life Sciences or STERIS-trained service personnel. Maintenance performed by unqualified personnel or installation of unauthorized parts could cause personal injury, result in improper equipment performance, invalidate the warranty or result in costly damage. Contact STERIS Life Sciences regarding service options.**
- **Regularly scheduled preventive maintenance is required for safe and reliable operation of this equipment. Contact STERIS Life Sciences to schedule preventive maintenance.**

The routine maintenance procedures described in this section of the manual should be performed whenever necessary. Any maintenance procedures not included in this section should be performed only by STERIS Life Sciences Service or STERIS-trained service personnel fully acquainted with the equipment.

In addition to the routine maintenance described in this section, regularly scheduled preventive maintenance is essential for safe and reliable operation of the equipment. Annual maintenance agreements are available to provide scheduled maintenance, adjustments and replacement of worn parts performed by a qualified technician, to help ensure peak equipment performance and help avoid unscheduled downtime. Contact STERIS Life Sciences for details.

Maintain a record of all maintenance procedures performed on the VHP *X10*™ Biodecontamination Unit. If a problem occurs, refer to *SECTION 4, TROUBLESHOOTING*, or contact STERIS Life Sciences.

NOTE: Never permit unqualified persons to service this equipment.

5.2 Clean Biodecontamination Unit

CAUTION – POSSIBLE EQUIPMENT DAMAGE: Use nonabrasive cleaners when cleaning Biodecontamination Unit. If you need technical assistance or additional instructions, call STERIS Life Sciences.

- **Follow all directions on container.**
- **Do not use abrasive cleaners on plastic surfaces.**
- **Avoid detergents with bases, aromatics, ketones, esters and chlorinated hydrocarbons.**
- **Avoid contacting plastic surfaces with greases and oils.**

STERIS Life Sciences recommends cleaning the outside surfaces of the VHP *X10* Biodecontamination Unit with a mild detergent solution (such as Liqui-Jet™ 2 Instrument Detergent).

Clean the Biodecontamination Unit as follows:

1. Unplug unit.
2. Apply cleaning solution with a damp cloth, rubbing in back and forth motion.

   NOTE: Avoid getting solution into the controls. Wring out cloth before wiping the control panel.
3. Rinse cloth and wipe off any detergent residue.
4. Dry surfaces with clean, lint-free cloth.

   NOTE: Should it become necessary to sterilize or disinfect the outside plastic VHP X10 Biodecontamination Unit surfaces before entering an Enclosure, STERIS Life Sciences recommends Spor-Klenz® Ready-To-Use Cold Sterilant. This sterilant is a liquid sporicide specifically formulated for sterilization and disinfection of hard surfaces.

5.3 Clean Hoses

*NOTE: Condensation inside the hoses must be assumed to be concentrated hydrogen peroxide (H_2O_2). **Review the DANGERS, WARNINGS and CAUTIONS located below and in** SECTION 1, SAFETY PRECAUTIONS**, of this manual before handling the hoses**. Also, read and comply with the Safety Precautions outlined on the Vaprox® 59 Hydrogen Peroxide Sterilant MSDS and the Vaprox 59 Hydrogen Peroxide Sterilant product label and package insert.*

DANGER – FIRE AND EXPLOSION HAZARD: Liquid hydrogen peroxide is a strong oxidant and poses a FIRE, EXPLOSION OR CONTAINER RUPTURE HAZARD. Avoid excessive heat, contamination or contact with combustible materials. Clothing, shoes or other combustible materials that have come in contact with hydrogen peroxide must be immediately and thoroughly washed with water. Discard shoes contaminated with Vaprox sterilant in a fireproof container. If Vaprox 59 Hydrogen Peroxide Sterilant is allowed to dry in the materials, a fire may result. IN CASE OF FIRE, use water only. CONTAIN SPILLS and dilute with water (at least 20 parts water to one part H_2O_2). After diluting the spill, sodium metabisulfide or sodium sulfite (1.9 lb of SO2 equivalent per 500 mL of H_2O_2) may be used to destroy the peroxide. SEE MSDS FOR ADDITIONAL INFORMATION. EFFECTS MAY BE DELAYED.

DANGER – SLIPPING HAZARD: Water or hydrogen peroxide spilled on the floor presents a slipping hazard – promptly clean up the spill. If in doubt whether the liquid is water or hydrogen peroxide, test the liquid using a Liquid Hydrogen Peroxide Test Strip (follow manufacturer's instructions), before wiping up. If the liquid is hydrogen peroxide, contain the spill and dilute with water (at least 20 parts water to one part H_2O_2) prior to wiping up. Observe all hydrogen peroxide handling precautions. Refer to the Vaprox 59 Hydrogen Peroxide Sterilant SDS for spill containment and cleanup.

DANGER – CHEMICAL INJURY HAZARD:

- **CORROSIVE. Causes irreversible eye damage or skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. User should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. User should remove contaminated clothing and wash before reuse. Applicators and all other handlers must wear PPE (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE). See Vaprox Hydrogen Peroxide Sterilant or Vaprox 59 Hydrogen Peroxide Sterilant product label and package insert for additional handling information.**
- **When handling the Biodecontamination System hoses, wear appropriate Personal Protective Equipment (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE). Any visible liquid in the hoses must be treated as concentrated hydrogen peroxide and all hydrogen peroxide handling precautions must be observed.**
- **When handling hydrogen peroxide, wear appropriate PPE (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE) and observe all Safety Precautions. See Vaprox 59 Hydrogen Peroxide Sterilant MSDS, product label and package insert for additional handling information.**

The Sterilant delivery hoses must be cleaned periodically to remove dust and other debris from the interior surfaces. Clean the hoses annually, or whenever the interior of the hoses becomes soiled or dusty.

Clean hose interiors as follows:

1. Put on PPE (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE).

2. Remove or disconnect hoses from Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*) and/or Biodecontamination Unit.

   NOTE: Sterilant delivery hoses should not be left lying around where they can be contaminated with dust or other particles which may catalyze the decomposition of the Sterilant. Hoses should be disconnected from the VHP X10 Biodecontamination Unit and stored when not connected to an Enclosure.
3. Submerge hoses in a **clean** sink or tub filled with water containing a mild detergent.
4. Soak hoses for 30 minutes, then drain the sink or tub.
5. Thoroughly rinse hoses with distilled water.
6. Dry hoses by blowing oil-free, filtered, compressed air through them, or allow hoses to air dry.
7. Return hoses to their original position when dry.

5.4 Cleaning Touch Screen

The *VHP X10* Biodecontamination Unit is controlled by a PLC. Clean the touch screen at regular intervals (at least once a week) as follows:

1. Ensure Biodecontamination Unit power is OFF.
2. Using water with detergent, screen cleaning agent or alcohol (Ethanol), dampen a clean cloth. Do NOT spray fluid directly on screen.
3. Gently wipe screen.
4. Dry with clean, lint-free cloth.

5.5 Replacement Parts and Supplies

Use only STERIS-authorized parts on this equipment. Use of unauthorized parts will void the warranty.

5.5.1 Ordering Information

WARNING – PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD: Repairs and adjustments to this equipment must be made only by STERIS Life Sciences or STERIS-trained service personnel. Maintenance performed by unqualified personnel or installation of unauthorized parts could cause personal injury, result in improper equipment performance, invalidate the warranty or result in costly damage. Contact STERIS Life Sciences regarding service options.

To order replacement parts and/or supply products, proceed as follows:

1. Include the part number and description as listed in *SECTION 5.5.2, SUPPLY PRODUCTS* and *SECTION 5.5.3, RECOMMENDED SPARE PARTS*.
2. Include the model and serial numbers of your equipment on your order.
3. Send your order directly to the STERIS Life Sciences Representative serving your area.

Contact STERIS Life Sciences* if you need parts that are not listed in this manual.

**1 (800) 440-9009 or www.sterislifesciences.com.*

5.5.2 Supply Products

DANGER – PERSONAL INJURY, CONTAMINATED ENCLOSURE AND/OR EQUIPMENT DAMAGE HAZARD: Use only Vaprox 59 Hydrogen Peroxide Sterilant Containers, containing STERIS-registered hydrogen peroxide which has been specially formulated, tested and approved for use in this *X10* Biodecontamination Unit. Vaprox 59 Hydrogen Peroxide Sterilant has been registered by STERIS in accordance with U.S. Federal Regulations for the specific uses described in this manual. Use of other materials and/or H_2O_2 other than Vaprox 59 H_2O_2 Sterilant could impair equipment operation, result in costly repairs, result in an ineffective Biodecontamination Cycle, violate federal law and void the equipment warranty.

NOTE: Use only STERIS U.S. EPA-registered Vaprox 59 Hydrogen Peroxide Sterilant in STERIS Containers. Vaprox Containers contain high purity 59% hydrogen peroxide and are filled under controlled conditions to ensure effectiveness through the expiration date stamped on the label. Federal law requires that the sterilant be registered with the U.S. EPA. Use of unregistered sterilant is prohibited and a violation of Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) federal law and will void the warranty.

Table 5-1. *VHP X10* Biodecontamination Unit Selected Supply Products

Description	Part Number
Vaprox 59 Hydrogen Peroxide Sterilant (EPA Reg. No. 1043-123); 4 x 70 mL	PB034US
VHP X10 Desiccant Cartridge)	10032310
Spor-Klenz Ready-To-Use Cold Sterilant (1 qt. - 4 per case)	6525M2
Liqui-Jet 2 Instrument Detergent (1 gal)	103708

5.5.3 Recommended Spare Parts

The parts listed in this section are those that are necessary to repair the *VHP X10* Biodecontamination Unit in most instances.

Table 5-2. Recommended Spare Parts

Description	Part Number	Quantity
BATTERY, Main Control Board, 3 V (CR2477)		2
CORD, Power, 230 Vac	10035152	1
CORD, Power, 120 Vac	10035151	1
CUP, Vaprox 59 Hydrogen Peroxide Sterilant (EPA Reg. No. 1043-123, 70 mL)	PB034	1
DESICCANT	TBD	1
FERRULE, Flangeless Tubing	P387349-031	10
FILTER, Injection	10015443	2
FUSE, Blower, 4 A	10037461	2
FUSE, Blower, 4 A ((For 120 Vac Unit)	10017002	2
FUSE, Blower, 2 A (For 230 Vac Unit)	10034820	2
FUSE, Heater, 10 A (For 120 Vac Unit)	10017003	2

Table 5-2. Recommended Spare Parts (Cont'd)

Description	Part Number	Quantity
FUSE, Heater, 5 A (For 230 Vac Unit)	10017003	2
HARNESS, Amber Light	10020036	1
HOSE ASSEMBLY, 2" Cam Lever	10038131	5 ft
HOSE ASSEMBLY, 2" Cam Lever	10038130	10 ft
NUT, Tubing	P387349-030	10
TUBE, Draw	10014998	1

5.6 Associated Publications

Publications listed in this section are those associated with the use and maintenance of this *VHP X10* Biodecontamination Unit.

When ordering, please include the part number (if applicable), description and quantity of each publication requested. Order directly from STERIS Life Sciences Representative.

Table 5-3. Associated Publications

Description	Part Number
Tech Data Sheet	SD997
Uncrating/Installation Instructions	10037273
Equipment Drawings	10105142
Maintenance Manual	P764335-550

SUPPLEMENTAL INFORMATION

6

6.1 Installation Verification

An equipment drawing, showing all utility and space requirements, is supplied when the *X10*™ Biodecontamination Unit is ordered. Any clearance space specified on the equipment drawing is necessary for proper operation, maintenance and repair of the system components. Uncrating/Installation Instructions were furnished with the *X10* Biodecontamination Unit. If these documents are missing or misplaced, contact STERIS Life Sciences, giving the serial, equipment and model numbers of the unit. Replacement copies will be sent to you promptly.

NOTE: Do not use Unit in an area not compatible with oxidizers.

6.1.1 Installation Checklist

After installing and connecting (refer to Figure 3-6) the *X10* Biodecontamination Unit on a hard level surface according to the instructions provided, complete the following checklist to ensure the installation is complete and correct. Contact STERIS Life Sciences to schedule a demonstration of proper equipment operation.

REMEMBER – POSSIBLE TIME DELAY: Insufficient clearance space will make repairs more difficult and time-consuming. Refer to the equipment drawing for minimum clearance for service/maintenance access requirements.

- ❑ Unplug system before servicing.
- ❑ Electric service to the system components must be as specified on the component data plates and equipment drawings.
- ❑ Electric service should be on a separate circuit, and not tied into circuits containing large reactive loads (e.g., motors).
- ❑ Electric service must provide a protective earth ground as specified by the local codes for an industrial circuit.
- ❑ Extension cord use is not recommended.

6.1.2 Pre-Operation Checklist

Read all *Safety Precautions* in *SECTION 1, SAFETY PRECAUTIONS*, before operating the equipment. Then complete the following checklist before operating the *X10* Biodecontamination Unit.

DANGER – CHEMICAL INJURY HAZARD: When handling hydrogen peroxide, wear appropriate PPE (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE) and observe all Safety Precautions. See Vaprox 59 Hydrogen Peroxide Sterilant SDS, product label and package insert for additional handling information.

WARNING – PERSONAL INJURY AND/OR EQUIPMENT DAMAGE HAZARD:

- **Lifting the Biodecontamination Unit requires more than one person. The unit weighs approximately 65 lb (30 kg).**
- **Park Biodecontamination Unit only on flat surfaces. The caster brakes are not designed to maintain the unit stationary on inclined surfaces. In addition, various internal components are designed for operation when unit is parked on a level, flat surface**.
- **Integrated (temperature and humidity) sensors are fragile. Do not bang, twist or crush. Biodecontamination Unit does not operate properly with a damaged sensor.**

Check that:

- ❑ The hoses (with appropriate connectors) properly connect the Biodecontamination Unit to the Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*) or other system components as described in *SECTION 3.2, OPERATION*.
- ❑ A hydrogen peroxide detection monitor or vapor tubes must be available to test for Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*) leakage.

- ❑ Biodecontamination Unit components are properly positioned in relation to Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*) being processed, as described in *SECTION 3.2, OPERATION*.
- ❑ The *X10* Biodecontamination Unit components are properly connected (refer to Figure 3-4 or Figure 3-6).
- ❑ A Vaprox® 59 Hydrogen Peroxide Sterilant Cup is in place; if a Cup is not in place or is empty, install a new Cup as described in *SECTION 6.6, STERILANT CUP INSTALLATION AND REMOVAL*.
- ❑ Desiccant cartridge assembly is properly inserted (see *SECTION 6.7, DESICCANT INSTALLATION AND REMOVAL*).

6.2 Technical Data

6.2.1 Overall Size (W x H x D)

28 x 22 x 15" (711 x 559 x 381 mm)

6.2.2 Weight

68 lb (31 kg)

6.2.3 Electric Requirements

120 Vac, 50/60 Hz, 12 A, 1 Ph
230 Vac, 50/60 Hz, 7 A, 1 Ph

6.2.4 Environmental Conditions

Temperature: 60 to 104°F (16 to 40°C)

Maximum Humidity: 70%

A-Weighted Sound Power Level: 73 dBA (mean) - 83 dBA (maximum); **use earplugs**.

Pollution Degree: 2

Installation Category (Overvoltage Category): II

IP67 Rating Closed; IP20 Rating Open

IC Number: IC:11700A-VHPX10

IC Statement:

> *This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.*

FCC Number: 2ABQIVHPX10.

FCC Statement:

> *This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.*

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct interference at his own expense.

6.3 Hydrogen Peroxide Biodecontamination

DANGER – PERSONAL INJURY, CONTAMINATED ENCLOSURE AND/OR EQUIPMENT DAMAGE HAZARD: Use only Vaprox 59 Hydrogen Peroxide Sterilant Cups, containing STERIS-registered hydrogen peroxide which has been specially formulated, tested and approved for use in this *X10* Biodecontamination Unit. Vaprox 59 Hydrogen Peroxide Sterilant has been registered by STERIS in accordance with U.S. Federal Regulations for the specific uses described in this manual. Use of other materials and/or H_2O_2 other than Vaprox 59 H_2O_2 could impair equipment operation, result in costly repairs, result in an ineffective Biodecontamination Cycle, violate federal law and void the equipment warranty.

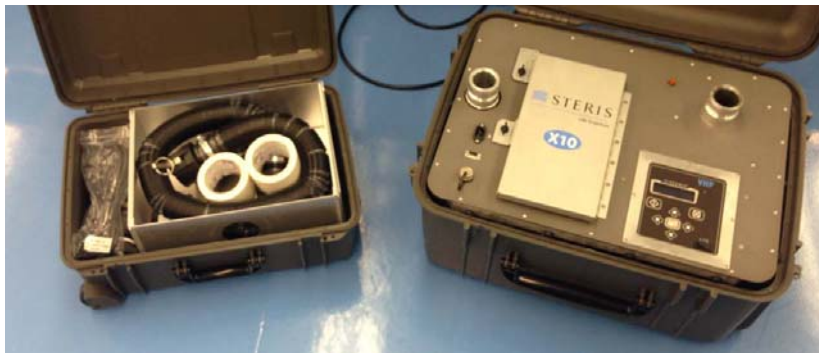


Figure 6-1. *X10* Biodecontamination Unit

The *X10* Biodecontamination Unit (see Figure 6-1) provides a simple and reliable method for Biodecontaminating pre-cleaned, dry sealable Enclosures (refer to *SECTION 2.1, TERMS AND DEFINITIONS*).

Effective use of H_2O_2 vapor for Biodecontamination requires adequate concentration and exposure time.

The *X10* Biodecontamination Unit typically uses a closed loop process (refer to *SECTION 3, OPERATING INSTRUCTIONS*) utilizing air as a carrier to deliver Vaprox 59 Hydrogen Peroxide Sterilant vapor to the exposed surfaces inside a pre-cleaned, dry, sealed Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*). This closed loop process allows the Biodecontamination process to take place at atmospheric conditions. Because Biodecontamination relies only on the contact of Sterilant with exposed surfaces, the transfer of heat and moisture required by steam processes is not necessary.

H_2O_2 vapor is continuously injected for the required exposure time to achieve Biodecontamination. The Sterilant evacuated from the Enclosure in a closed loop operation is catalytically converted into water vapor and oxygen. .

6.4 Biodecontamination Cycle

The properly installed *X10* Biodecontamination Unit outside the Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*) uses STERIS's VHP® process technology. This process uses hydrogen peroxide vapor as a broad-spectrum antimicrobial without condensation of active ingredient onto surfaces. This non-condensation feature provides additional benefit of a wide range of material compatibility.

In practice, an aqueous solution of 59% (Vaprox 59 Hydrogen Peroxide Sterilant) hydrogen peroxide vapor is atomized and a high velocity air stream disperses it throughout Enclosure. Relative humidity and temperature sensor measurements ensure the vapor does not condense on internal Enclosure surfaces.

NOTE: Refer to the Vaprox 59 Hydrogen Peroxide Sterilant package label for additional information and Application instructions.

The Biodecontamination Cycle (see Figure 6-2) proceeds as follows:

1. Biodecontamination Unit display prompts Trained and Certified Applicator to insert Vaprox 59 Hydrogen Peroxide Sterilant Cup and desiccant cartridge (see *SECTION 6.6, STERILANT CUP INSTALLATION AND REMOVAL* and *SECTION 6.7, DESICCANT INSTALLATION AND REMOVAL*).
2. Display prompts user to press **START**.

   NOTE: After starting the cycle, the Trained and Certified Applicator has time to safely finalize any sealing per FMP prior to Condition and Biodecontamination phases.
3. Biodecontamination Unit performs a system check on Sterilant Cup.
4. Upon successful check, Biodecontamination Unit begins Pre-Heat Cabinet phase.
5. After pre-heating cabinet to 88°F (31°C), Dehumidification phase starts and air circulates through desiccant to dehumidify Enclosure to 15% RH.

   NOTE: During this time the liquid Sterilant is primed into the injection lines (approximately two minutes for priming).
6. After 15% RH setpoint is reached, Enclosure is heated to 88°F (31°C).
7. Once setpoint is reached, heater cap is heated to set value.
8. Condition phase (Sterilant injection) begins. Biodecontamination Unit generates hydrogen peroxide vapor and circulates Sterilant throughout Enclosure at set injection rate to build concentration to > 400 PPM.
9. Biodecontamination phase follows for preset time. Biodecontamination Unit continues to circulate hydrogen peroxide vapor at a lower injection rate to achieve desired bioburden targets.

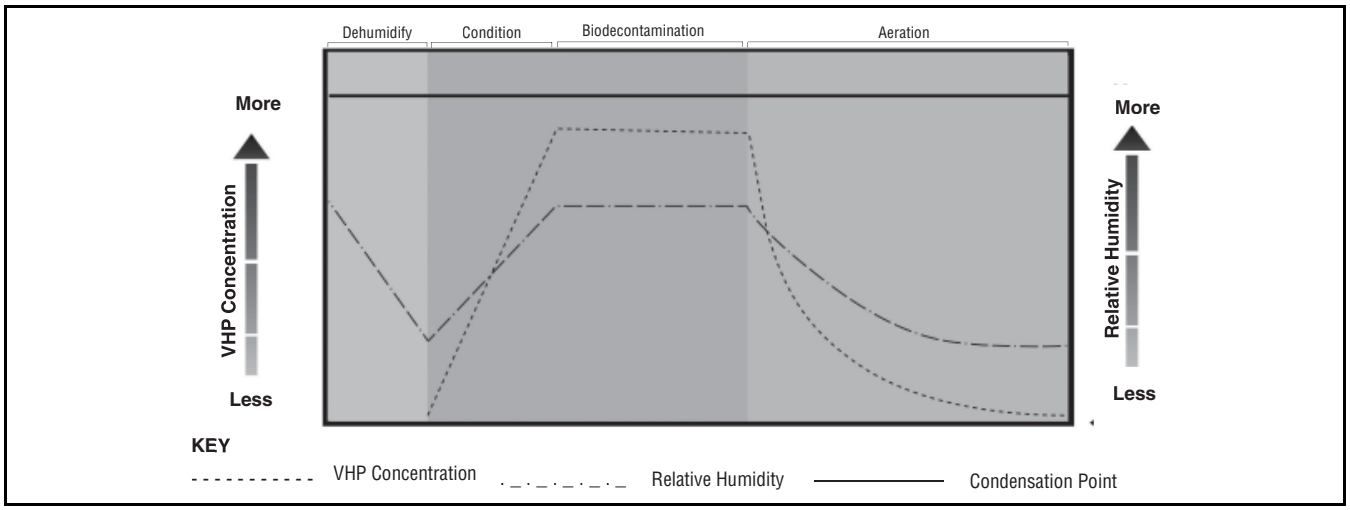


Figure 6-2. Typical Biodecontamination Cycle

10. At completion of Biodecontamination phase, Biodecontamination Unit enters a Hold phase to recirculate Sterilant vapor for set time (no injection or heat).
11. Injection lines are purged of any liquid back into Vaprox 59 Hydrogen Peroxide Sterilant Cup (approximately three minutes for purging).
12. At Hold phase completion, Biodecontamination Unit advances to Aeration phase for pre-determined time.
13. Air passes through catalyst until Sterilant concentration is reduced to 1 ppm.
14. Cycle Complete phase begins. Biodecontamination Unit turns blower OFF and saves cycle data to USB.

6.5 Hydrogen Peroxide Handling Precautions

Certain precautions **must** be observed when handling hydrogen peroxide (H_2O_2). **Review the *Safety Precautions* located in *SECTION 1* of this manual before handling the Vaprox 59 Hydrogen Peroxide Sterilant Cups**. Also, read, comply with and save the Sterilant SDS and Vaprox 59 Hydrogen Peroxide Sterilant Cups label and package insert.

DANGER – PERSONAL INJURY, CONTAMINATED ENCLOSURE AND/OR EQUIPMENT DAMAGE HAZARD:

- **Use only Vaprox 59 Hydrogen Peroxide Sterilant Containers, containing STERIS-registered hydrogen peroxide which has been specially formulated, tested and approved for use in this *X10* Biodecontamination Unit. Vaprox 59 Hydrogen Peroxide Sterilant has been registered by STERIS in accordance with U.S. Federal Regulations for the specific uses described in this manual. Use of other materials and/or H_2O_2 other than Vaprox 59 Hydrogen Peroxide Sterilant could impair equipment operation, result in costly repairs, result in an ineffective Biodecontamination Cycle, violate federal law and void the equipment warranty.**
- **Before using Vaprox 59 Hydrogen Peroxide Sterilant Cup, check the expiration date. Do not use Sterilant if it is beyond its expiration date, or if it will not be fully used before its expiration date.**
- **Before disposing of a Vaprox 59 Hydrogen Peroxide Sterilant Cup, empty all remaining Cup contents into a sink with running water (at least 20 parts water to one part Vaprox H_2O_2), then carefully triple rinse the Cup with tap water.**

DANGER – CHEMICAL INJURY HAZARD:

- **CORROSIVE. Causes irreversible eye damage or skin burns. May be fatal if inhaled. Harmful if swallowed or absorbed through the skin. Do not get in eyes, on skin or on clothing. Do not breathe spray mist. Prolonged or frequently repeated skin contact may cause allergic reaction in some individuals. User should wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. User should remove contaminated clothing and wash before reuse. Applicators and all other handlers must wear PPE (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE). See Vaprox 59 Hydrogen Peroxide Sterilant product label and package insert for additional handling information.**
- **When handling the Biodecontamination System hoses, wear appropriate PPE (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE). Any visible liquid in the hoses must be treated as concentrated hydrogen peroxide and all hydrogen peroxide handling precautions must be observed.**

DANGER – FIRE AND EXPLOSION HAZARD:

- **Liquid hydrogen peroxide is a strong oxidant and poses a FIRE, EXPLOSION OR CONTAINER RUPTURE HAZARD. Avoid excessive heat, contamination or contact with combustible materials. Clothing, shoes or other combustible materials that have come in contact with hydrogen peroxide must be immediately and thoroughly washed with water. Discard shoes contaminated with Vaprox 59 Hydrogen Peroxide Sterilant in a fireproof container. If Vaprox Sterilant is allowed to dry in the materials, a fire may result. IN CASE OF FIRE, use water only. CONTAIN SPILLS and dilute with water (at least 20 parts water to one part H_2O_2). After diluting the spill, sodium metabisulfide or sodium sulfite (1.9 lb of SO2 equivalent per 500 mL of H_2O_2) may be used to destroy the peroxide. SEE SAFETY DATA SHEET (SDS) FOR ADDITIONAL INFORMATION. EFFECTS MAY BE DELAYED.**

- **Verify all materials coming in contact with hydrogen peroxide, especially the concentrated liquid, are compatible with oxidizers. Contact STERIS Life Sciences or the material manufacturer for information on material compatibility.**

DANGER – SLIPPING HAZARD: Water or hydrogen peroxide spilled on the floor presents a slipping hazard – promptly clean up the spill. If in doubt whether the liquid is water or hydrogen peroxide, test the liquid using a Liquid Hydrogen Peroxide Test Strip (follow manufacturer's instructions), before wiping up. If the liquid is hydrogen peroxide, contain the spill and dilute with water (at least 20 parts water to one part H_2O_2) prior to wiping up. Observe all hydrogen peroxide handling precautions. Refer to the Vaprox 59 Hydrogen Peroxide Sterilant SDS for spill containment and cleanup.

6.6 Sterilant Cup Installation and Removal

DANGER – PERSONAL INJURY, CONTAMINATED ENCLOSURE AND/OR EQUIPMENT DAMAGE HAZARD: Before starting a cycle, check Sterilant to ensure it is not expired.

Review *SECTION 6.5, HYDROGEN PEROXIDE HANDLING PRECAUTIONS,* before proceeding. The *X10* Biodecontamination Unit uses Vaprox 59 Hydrogen Peroxide Sterilant in Cups (see *FIGURE 6-3*).

Figure 6-3. Typical Sterilant Cup

6.6.1 Cup Installation

Install Vaprox 59 Hydrogen Peroxide Sterilant Cup (see *FIGURE 6-3*) as follows:

1. Wearing proper PPE, unpack desiccant cartridge and Vaprox 59 Sterilant Cup from packaging (refer to *FIGURE 3-5*).
2. Check Cup expiration date. Do not use Cup if beyond expiration date listed on label (Figure 6-3).
3. Turn Biodecontamination Unit power ON, open supply door.
4. Gently grasp Cup and place in Biodecontamination Unit (see Figure 6-4).
5. Carefully insert Cup draw tube into Cup (see Figure 6-5).
6. Close supply door and lock.

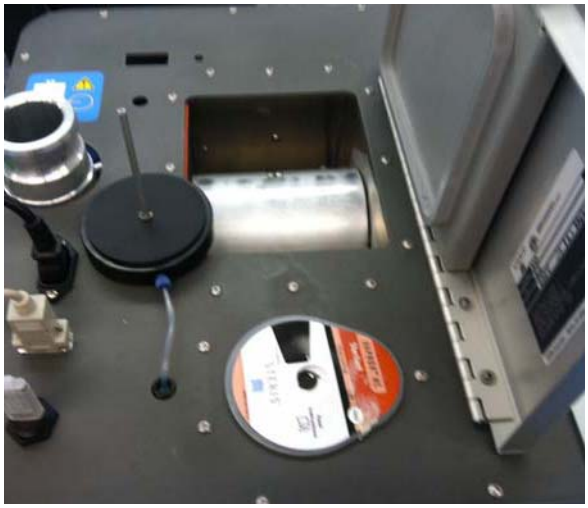


Figure 6-4. Sterilant Cup in Biodecontamination Unit (Typical)

Figure 6-5. Carefully Insert Draw Tube (Typical)

6.6.2 Cup Removal

When the Cycle is complete or if the *X10* Biodecontamination Unit is to be transported, the Cup must be removed. Proceed as follows:

1. Put on PPE (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE).

2. Gently grasp Cup and draw tube with both hands. Carefully lift Cup and draw tube from Biodecontamination Unit.
3. Dispose of Sterilant as directed in next section.

NOTE: For Cups, note the following:

1) If Cup in the Biodecontamination Unit is past the expiration date, remove the Cup, dispose of contents as instructed in the next Section (SECTION 6.6.3, DISPOSAL OF STERILANT FROM CUP).

2) Before transporting the Biodecontamination Unit, the Sterilant Cup must be removed from Biodecontamination Unit.

6.6.3 Disposal of Sterilant From Cup

If the Cup is empty, does not contain enough H_2O_2 for any further Biodecontamination Cycles or the Biodecontamination Unit needs transported, proceed as follows:

1. Put on PPE (refer to Vaprox 59 Hydrogen Peroxide Sterilant SDS for PPE). Refer also to Vaprox 59 Hydrogen Peroxide Sterilant label or package insert.
2. Empty all remaining Cup contents into a sink with running water (at least 20 parts water to one part H_2O_2).
3. When Cup is empty, carefully and thoroughly triple rinse Cup with tap water before disposal.
4. Properly dispose of empty Cup.
5. Rinse draw tube with water and set safely aside.

6.7 Desiccant Installation and Removal

The *X10* Biodecontamination Unit uses desiccant cartridges to convert the Sterilant into water vapor and oxygen. Install and remove desiccant cartridge as follows:

1. If not already unpacked, wearing proper PPE, unpack desiccant cartridge (see Figure 6-6) and Vaprox 59 Sterilant Cup from packaging (refer to Figure 3-5).
2. Turn Biodecontamination Unit power ON, open supply door by turning fastening screws (quarter turn).
3. Lift latch on desiccant door and place desiccant cartridge inside (see Figure 6-7).

Figure 6-6. Desiccant Cartridge (Typical)

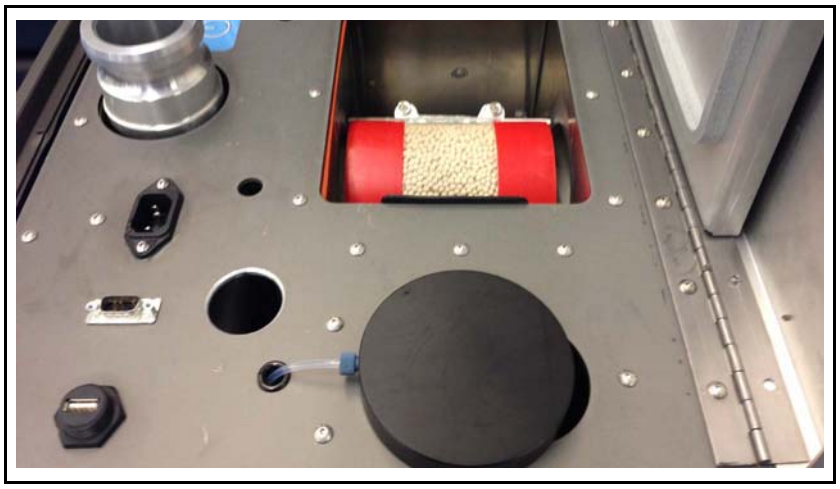


Figure 6-7. Place Desiccant Cartridge in Biodecontamination Unit

6.8 Sterilant Container Storage

Vaprox 59 Hydrogen Peroxide Sterilant Cups are warranted through the expiration date (see Figure 6-3) when the following storage practices are followed:

- Store Cups in an upright (vertical) position.
- Store Containers at room temperature, not to exceed 77°F (25°C). DO NOT FREEZE.

Shelf life of *UNOPENED* Vaprox 59 Hydrogen Peroxide Sterilant Cup is one year.

Shelf life of OPENED Cup installed in the *X10* Biodecontamination Unit is 45 days. However, Cup must not remain in Biodecontamination Unit when being transported.

6.9 General Component Identification

The X10 Biodecontamination Unit is designed for mobile Biodecontamination of clean, dry, sealed Enclosures (refer to *SECTION 2.1, TERMS AND DEFINITIONS*) of three, four, five and six foot widths with corresponding internal volumes from 15.6 - 31.2 ft^3 (.44 - .88 m^3) using STERIS's patented VHP® Process Technology and using Vaprox 59 Hydrogen Peroxide Sterilant.

NOTE: The X10 Biodecontamination Unit is to be used by Trained and Certified Applicators who have successfully completed both the STERIS Training and Certification Course for Applicators of Vaprox Hydrogen Peroxide Sterilant and the X10 Biodecontamination Unit Operator Course. Certification must be active and in force for all Applicators of Vaprox 59 Hydrogen Peroxide Sterilant.

Before operating the *X10* Biodecontamination Unit, become familiar with the location and function of all major components and controls presented in this section (see *FIGURE 6-8*). Refer to *SECTION 2.1, TERMS AND DEFINITIONS*.

1. Power Cord – Connects Biodecontamination Unit to Facility power.
2. Desiccant Cartridge – Converts Sterilant into water vapor and oxygen.

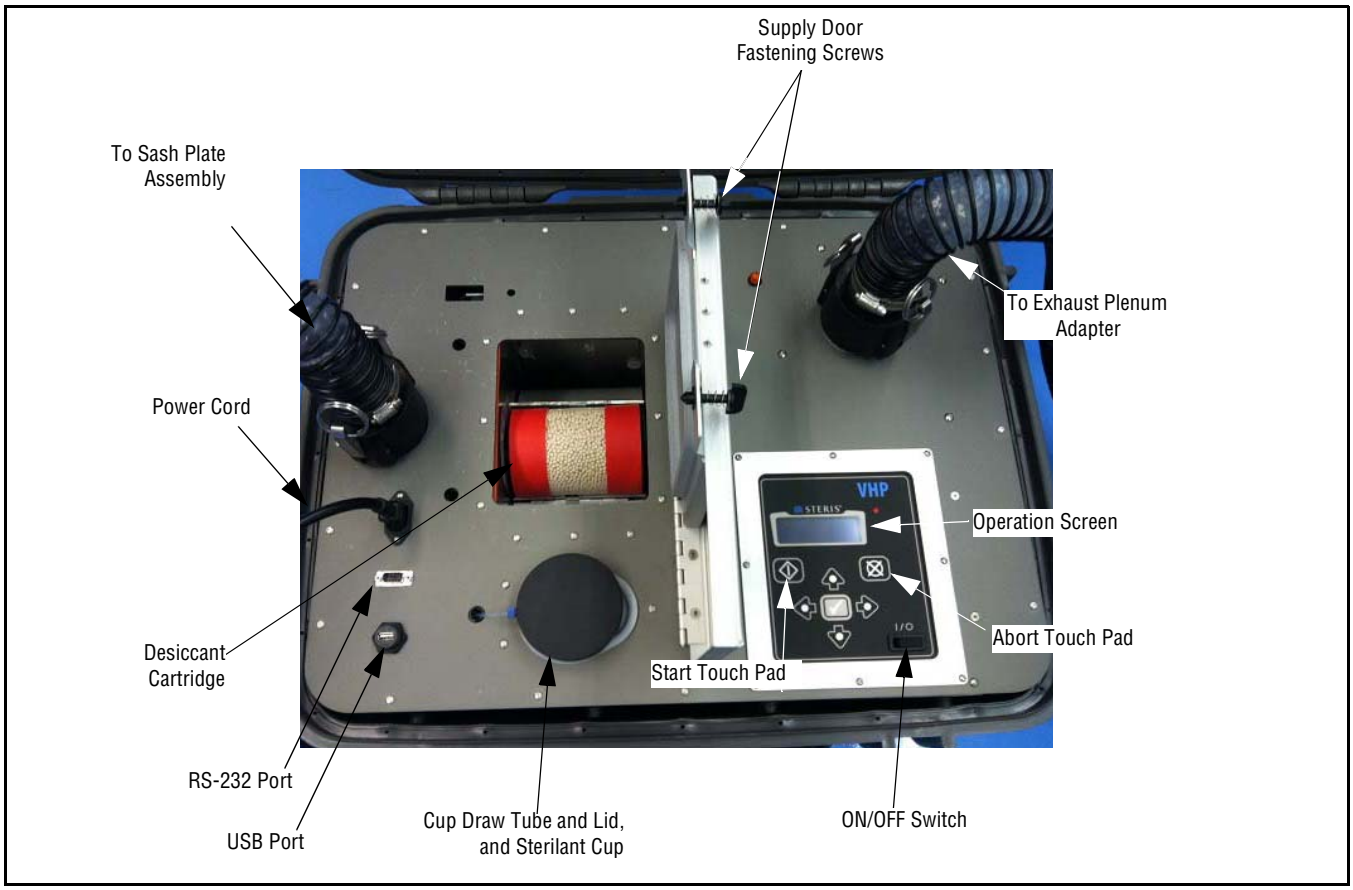


Figure 6-8. Component Identification

3. Cup Draw Tube – Draws Sterilant from Sterilant Cup.
4. Cup – Disposable Cup supplies Vaprox 59 Hydrogen Peroxide Sterilant.
5. USB Port – Biodecontamination Unit outputs cycle data in encrypted format for data storage through this port.
6. ON/OFF Switch – Enables power to controller.
7. Start Touch Pad – When pressed, starts cycle.
8. Abort Touch Pad - When pressed, aborts cycle.
9. Operation Screen – Can contain up to four lines of Operational text to enable operator to communicate with controller.

6.10 Operation

The following information is intended to enable a Trained and Certified Applicator to properly use the Biodecontamination Unit to Biodecontaminate an Enclosure (refer to *SECTION 2.1, TERMS AND DEFINITIONS*):

The STERIS X10 Biodecontamination Unit is to be used by Trained and Certified Applicators who have successfully completed both the STERIS Training and Certification Course for applicators of Vaprox 59 Hydrogen Peroxide Sterilant and the STERIS X10 Biodecontamination Unit Operator Course. Certification must be active and in force for all Applicators of Vaprox 59 Hydrogen Peroxide Sterilant.

1. Ensure Biodecontamination Unit is properly attached to Enclosure (refer to *SECTION 3.2.1, ATTACH TO ENCLOSURE*).

**Guidance for developing a suitable Fumigation Management Plan can be found in STERIS publication (P129383-938) or searching EPA website (epa.gov) for the key words 'Vaprox Package Insert.'*

2. Per FMP*, make all necessary preparations to Enclosure. Verify CIs and BIs are placed inside Enclosure as required.
3. Plug Biodecontamination Unit power cord into proper facility outlet (120 Vac, 20A or 230 Vac, 10A; single source circuit).
4. Turn Biodecontamination Unit power ON using ON/OFF switch.
5. Control tells operator to install Cup as follows:

```
OPEN DOOR
INSERT VAPROX CUP
```

   a. Open supply door by turning fastening screws (quarter turn). When door is opened, control panel reads:

```
INSERT VAPROX CUP
  AND DESICCANT
 THEN CLOSE DOOR
```

   b. Wearing proper PPE, unpack desiccant cartridge and Vaprox 59 Sterilant Cup from packaging.
   c. Ensure Sterilant Cup is not expired
   d. Place Sterilant Cup and desiccant cartridge into unit.

   NOTE: See SECTION 6.6, STERILANT CUP INSTALLATION AND REMOVAL, and Section 6.7, Desiccant Installation and Removal, for more information of desiccant cartridge and Sterilant Cup insertion.

   e. Carefully insert draw tube into Cup.
   f. Close supply door and lock using fastening screws.
6. Once door is closed and locked, control displays:

```
PRESS <START>
 TO CONTINUE
```

7. After pressing START, control displays:

```
INSERT USB LOGGING
FLASH MEMORY DRIVE
 OR PRESS <START>
    TO CONTINUE
```

8. Biodecontamination Unit drum assembly rotates and heating of Enclosure starts. Display shows:

```
3-4 FT CABINET CYCLE
PREHEATING CABINET
RH  = XX.X% CT =  XX.X °C
REM TIME xx:xx
```

9. When setpoint is reached, Dehumidify phase starts and display shows:

```
3-4 FT CABINET CYCLE
DEHUMIDIFYING
RH  = XX.X% CT = XX.X°C
REM TIME = XX:XX
```

10. When setpoint is reached, Warm-Up phase starts and display shows:

```
3-4 FT CABINET CYCLE
WARMING UP CABINET
RH  = XX.X% CT = XX.X°C
REM TIME = XX:XX
```

11. When setpoint is reached, heater cap is heated and display shows:

```
3-4 FT CABINET CYCLE
HEATING HEATER CAP
RH  = XX.X% CT = XX.X°C
REM TIME = XX:XX
```

12. When setpoint is reached, Condition phase starts and display shows:

```
3-4 FT CABINET CYCLE
CONDITION
RH  = XX.X% CT = XX.X°C
REM TIME = XX:XX
```

13. When setpoint is reached, Decontamination phase starts and display shows:

```
3-4 FT CABINET CYCLE
   DECONTAMINATION
RH  = XX.X% CT = XX.X°C
   REM TIME = XX:XX
```

14. When setpoint is reached, Biodecontamination Unit enters a Hold phase and display shows:

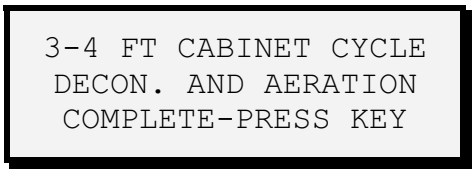
```
3-4 FT CABINET CYCLE
       HOLDING
RH  = XX.X% CT = XX.X°C
   REM TIME = XX:XX
```

15. At completion of Hold phase, drum rotates, Aeration phase starts and display shows:

```
3-4 FT CABINET CYCLE
  MANDATORY AERATION
RH  = XX.X% CT = XX.X°C
   REM TIME = XX:XX
```

16. If optional aeration is desired, proceed as follows:
    a. Verify Biodecontamination Unit has reached Aeration phase of Cycle. Press **Cancel** button.
    b. Display asks, **USE EXTERNAL AERATOR?** Press **Check** button.
    c. Turn Biodecontamination Unit OFF.
    d. Turn Enclosure fan OFF.
    e. Position VHP AR60™ Aerator near Enclosure.
    f. Disconnect Outlet and Inlet Hose Assemblies from Biodecontamination Unit and connect to AR60 Aerator (refer to *FIGURE 3-6*).
    g. Plug AR60 Aerator into applicable wall outlet (120 or 230 Vac).
    h. Turn AR60 Aerator ON by pressing power switch.
    i. Turn Enclosure fan ON.
    j. Allow AR60 Aerator to operate until H_2O_2 is reduced to a safe level of less than or equal to 1 PPM.

17. At completion of Aeration phase, drum rotates, door unlocks and display shows:



18. Alarm sounds, press **Check** pushbutton to silence. Screen returns to Home Screen and is ready for next cycle.