STERIS
Life Sciences

VHP® X10™ BIODECONTAMINATION UNIT

APPLICATION

The STERIS VHP *X10* Biodecontamination Unit is designed for mobile Biodecontamination[1] of clean, dry, sealed Class II Type A2 biological safety cabinets (Enclosures)[2] using STERIS's VHP® Process Technology, featuring *X-Phase™* hardware technology, *VaproxLink™* software technology and Vaprox® 59 Hydrogen Peroxide Sterilant.

[1] *In this document, when referring to the use of VHP® Biodecontamination Systems with Vaprox 59 Hydrogen Peroxide Sterilant in the United States of America (USA), the term Biodecontamination is defined as sterilization of exposed porous and non-porous surfaces in a precleaned, dry, sealed Enclosure. Any reference to Biodecontamination pertaining to the use of this equipment in the United States does not, and is not intended to convey additional claims of effectiveness beyond those contained in the USA Environmental Protection Agency (EPA) registered labeling of Vaprox 59 Hydrogen Peroxide Sterilant (EPA Reg. No. 1043-123).*

[2] *Contained area to be Biodecontaminated (e.g., rooms, facilities and equipment).*

DESCRIPTION

The VHP *X10* Biodecontamination Unit offers fast, economical Biodecontamination of biological safety cabinets. The Biodecontamination Unit uses STERIS's patented 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.

The Biodecontamination Unit is equipped with three factory-programmed cycles designed to give a minimum 6-log bioburden reduction in a Class II Type A2 biological safety cabinet:

- For 3-4' (0.9-1.2 m) Cabinet
- For 5-6' (1.5-1.8 m) Cabinet
- For Enclosures with a greater challenge, the XL Cycle (Non-Validated)

The *X10* Biodecontamination Unit features *X-Phase* hardware technology and *VaproxLink* software technology. *X-Phase* hardware technology enables Pre-Heat, Dehumidification, Condition, Biodecontamination and Aeration of the safety cabinet for an All-In-One unit design while *VaproxLink* software technology automatically identifies Vaprox 59 Hydrogen Peroxide Sterilant cup and verifies expiration date.

(Typical only - some details may vary.)

Other VHP *X10* Biodecontamination Unit features:

- Ability to operate outside (with addition of sash and plenum adapters) of the Enclosure and operate as a standalone unit. All Biodecontamination Cycle data is output to the USB interface in .CSV format for data storage.
- A separate *AR60™* Aerator is available for catalyzing Sterilant for increased workflow efficiency when multiple Enclosures are to be Biodecontaminated.
- A multi-lingual (English, French, Spanish, Italian and German) control is available in either 120 or 230 Vac, single phase, electrical service.
- Minimal exposure to liquid hydrogen peroxide during handling; the system uses specially designed disposable cups containing approximately 70 mL of Vaprox 59 Hydrogen Peroxide Sterilant.
- Light weight, IP67 rated transport case with retractable wheels and handle; this Biodecontamination Unit is easily transported.

The Selections Checked Below Apply To This Equipment

VOLTAGES
- ❑ 120 Vac, 50/60 Hz
- ❑ 230 Vac, 50/60 Hz

ACCESSORIES
- ❑ AR60 Aerator
- ❑ Accessory Case

CONSUMABLES
- ❑ Disposable Desiccant
- ❑ Vaprox 59 Hydrogen Peroxide Sterilant Cup (3 x 70 mL)

LANGUAGE OPTIONS
- ❑ English
- ❑ French
- ❑ German
- ❑ Spanish
- ❑ Italian

STERILITY ASSURANCE PRODUCTS
- ❑ Process Indicator
- ❑ Biological Indicator
- ❑ Biological Indicator Culture Media

Item _____

Location(s)_____

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The VHP *X10* Biodecontamination Unit is only to be operated 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 VHP *X10* Biodecontamination System Operator Course.Certification must be active and in force for all Applicators of Vaprox 59 Hydrogen Peroxide Sterilant.

STANDARDS

The VHP *X10* Biodecontamination Unit meets the applicable requirements of the following standards:

- **Underwriters Laboratories (UL): UL61010-1 Third Edition**.
- **Canadian Standards Association (CSA): Standard C22.2 No. 61010-1 Third Edition**.
- **Ingress Protection Rating (IP) 20** while in operation.
- Governing Directives for Affixing the CE Mark:
  - » **EMC Directive (2004/108/EC, 92/31/EEC, 93/68/EEC)**.
  - **» Low Voltage Directive (2006/95/EC, 93/68/EEC).**
  - **» RTTE Directive (1999/5/EC).**

CYCLE DESCRIPTION (Typical)

In practice, an atomized aqueous solution of 59% hydrogen peroxide (Vaprox 59 Hydrogen Peroxide Sterilant) is vaporized and a high velocity air stream disperses it throughout the Enclosure. Software automatically runs the selected Biodecontamination Cycle.

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

Basic description of example Biodecontamination Cycles:

After starting Cycle at the Human Machine Interface (HMI), the blower initializes and *X-Phase* hardware technology is engaged. *VaproxLink* software technology verifies a Vaprox 59 Hydrogen Peroxide Sterilant cup[3] is placed in the unit and that cup has a valid expiration date. Cycle proceeds through the following phases:

1. **Preheat** – Enclosure is heated to > 88°F (31°C). Upon reaching the desired temperature, Cycle advances to Dehumidification phase.
2. **Dehumidification** – Enclosure is dehumidified to a Relative Humidity (RH) of ~15% using a disposable desiccant cartridge[4]. Upon reaching the desired relative humidity, the Cycle advances to Condition phase.
3. **Condition** – Sterilant is added to sealed Enclosure until target concentration needed for full Biodecontamination phase is reached.
4. **Biodecontamination** – Enclosure is filled with Hydrogen Peroxide Sterilant vapor. Cycle continues for a pre-determined amount of time based upon Operator selections to achieve a minimum of a 6-log bioburden reduction. Upon reaching desired time, Cycle advances to Aeration phase
5. **Aeration** – Hydrogen Peroxide Sterilant vapor is catalyzed into water vapor and oxygen. Cycle continues for pre-determined amount of time based upon the cycle selected to achieve a minimum concentration of $\leq$ 1ppm. Upon reaching desired time, Cycle advances to Cycle Complete.

Biodecontamination Cycle information is saved to the USB.

ACCESSORIES

AR60 Aerator (VD0033) – Portable, high capacity, Sterilant catalyzation unit designed to shorten Biodecontamination Cycles in Enclosures.

X10 Accessory Case (VD0032) – Contains sash adapter and plenum adapter with quick disconnects and interconnecting hoses.

Vaprox Cup Tool (VD0034) – Tool designed to assist in the disposal of X10 Vaprox cups.

OPTIONS

Dräger H_2O_2 Sensors – Hydrogen Peroxide sensors available for permanent installation and portable operation.

CONSUMABLES

X10 Desiccant (VD0031) – Enables dehumidification of Enclosure.

Vaprox 59 Hydrogen Peroxide Sterilant (PB034) – 59% stabilized aqueous solution of hydrogen peroxide designed for use with VHP Biodecontamination Units and Accessories (EPA Reg. No. 1043-123). *Refer to Tech Data SD992 for further information.*

STERILITY* ASSURANCE PRODUCTS

Steraffirm® VH2O2 Process Indicators (PCC051 and PCC060) – Chemical indicators designed for use with hydrogen peroxide vapor.

Spordex® VH2O2 Biological Indicator (NA333) – *E6 Geobacillus stearothermophilus* (12980) biological indicator designed for use with hydrogen peroxide vapor.

Spordex® Biological Indicator Media (NA117) – Tripticase Soy Bean broth (TSB) culture media designed for use with Spordex biological indicators.

* *See Footnote 1 on Page 1.*

[3] *Vaprox 59 Hydrogen Peroxide Sterilant cup sold separately.*

[4] *X10 Biodecontamination Unit desiccant cartridge sold separately.*

CONTROL SYSTEM

Provides precise control of VHP *X10* Biodecontamination Unit and uses a PLC driven control system featuring a 7" HMI touchscreen.

Control stores and displays such information as Cycle steps; Cycle time; and Enclosure parameters (RH% and temperature) in English/metric units.

Control comes preloaded with factory programmed cycles. Settings such as date, time and language can be changed using HMI touchscreen.

CONSTRUCTION

Frame – Constructed of welded aluminum.

Case – Scratch and crack resistant, molded in color, polypropylene plastic; IP67 rated; wheels mounted to case; retractable handle; locking capability.

Blower – Internal 30-50 scfm (51-85 m^3/h) recirculation blower.

Injection Pump – Positive displacement pump with injection rates from 0.5 - 3.0 grams/min.

Integrated RH Sensor – Measures RH%.

Integrated Temperature Sensor – Measures temperature.

Quick Disconnects – 2" (51 mm) aluminum cam and groove style fittings.

CALIBRATION

STERIS Life Sciences Service recommends that the VHP *X10* Biodecontamination Unit be calibrated at least once every year. STERIS Life Sciences Service representatives can provide this service to ensure valid operation of the unit. The control will alert operators of the need for calibration every 12 months.

PREVENTIVE MAINTENANCE

Customers are encouraged to contact STERIS Life Sciences Service concerning a 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 Service 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 Service* for details.

** 1 (800) 444-9009 or www.sterislifesciences.com.*

NOTES

1. STERIS Life Sciences Service recommends a dedicated, grounded electrical circuit be provided for each unit. Extension cord use is not recommended.
2. Unit should not be installed in an area not compatible with oxidizers. Consult the Safety Data Sheet (SDS) regarding hydrogen peroxide sterilant.
3. Access must be provided to power switch and hose connectors of unit.
4. Hose clearance must be adequate to prevent kinks and strains on the connectors.
5. Hoses must be supported to keep them from resting on the floor or other cold surfaces.
6. Unit weighs approximately 70 lb. (32 kg).
7. Unit Operating Dimensions: 15-1/8 x 28 x 22-3/8" (384 x 711 x 568 mm).
8. Enclosure size listed is recommended size. Connecting VHP *X10* Biodecontamination Unit to larger volumes may increase cycle time.
9. Airflow range is measured exiting VHP *X10* Biodecontamination Unit. Actual flow rates may vary from variations in local utility power output.

ENGINEERING DATA

***IMPORTANT:** Refer to equipment drawing 10105413 or installation details and specifications.*

Electricity
120 Vac, 60 Hz, 1 Phase, 12 Amp

230 Vac, 50 Hz, 1 Phase, 7 Amp

Airflow
30-50 scfm (51-85 scmh)

Temperature
60-104°F (16-40°C)

Sterilant Injection Rates
0.5 - 3.0 grams/min

Relative Humidity (RH)
Maximum 70%

CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LOCAL AND NATIONAL CODES AND REGULATIONS

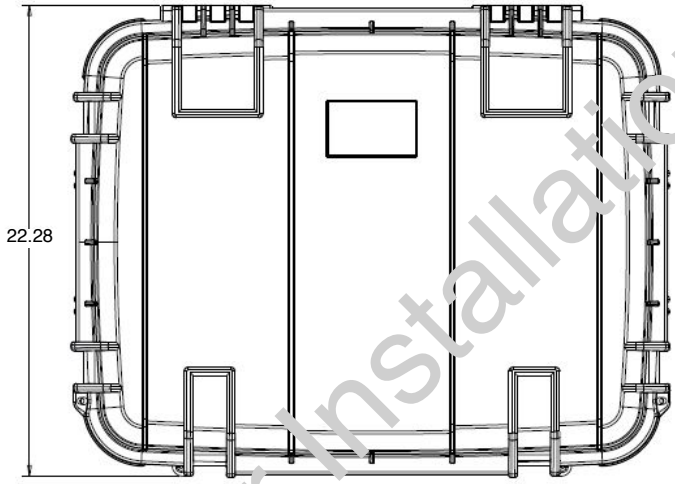
The base language of this document is ENGLISH. Any translations must be made from the base language.

Reference listed equipment drawing for detailed installation specifications. Obtain this drawing from your STERIS Representative.

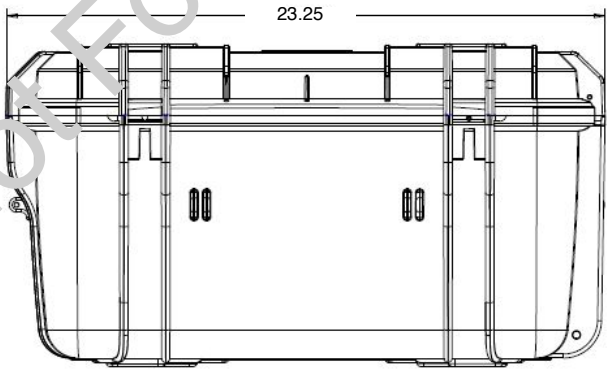
Equip. Dwg. No.	Equipment Drawing Title
10105413	Equipment Drawing - X10 Biodecontamination Unit

Dimensions are typical – drawing is not to scale.

Dimensions are inches (mm)



Top View



Front View

For Further Information, contact:

STERIS Life Sciences

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-444-9009
www.STERISLifeSciences.com