- ❑ 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.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

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.

Changes or modifications not expressly approved by STERIS Life Sciences could void the user's authority to operate the equipment.

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.

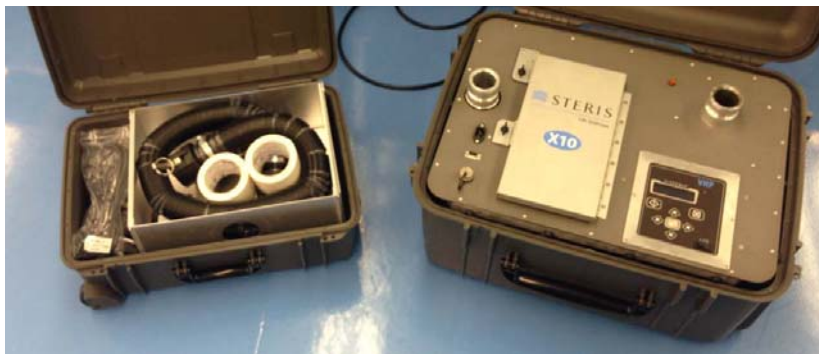

Figure 6-1. *X10* Biodecontamination Unit

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.