VHP® *MD140X* Biodecontamination Unit

In-Service Checklist

To help ensure a successful In-Service, please reference the following materials prior to and/or during the In-Service:

- *MD140X* Biodecontamination Unit Operator Manual
- *MD140X* Biodecontamination Unit Technical Data Sheet
- Vaprox® 59 Hydrogen Peroxide Sterilant Material Safety Data Sheet (MSDS), package label and package insert.
- Extended Printout Evaluation Form

Prior to the In-Service, determine the instruments to be processed. This will ensure a shorter setup time.

Review with your Customer the time allocation needed for In-Service and the necessary personnel to attend.

General

- ❑ Discuss the In-Service objectives / agenda (discuss what you will be covering)
- ❑ Review cautions or warnings which appear in the Operator Manual (Sec. 1) at the appropriate time during the In-Service
- ❑ Allow time for your Customers to ask questions and get them engaged throughout the In-Service with hands on demonstrations

Chemistry

Vaprox® 59 Hydrogen Peroxide Sterilant

Review and/or demonstrate the following features of Vaprox 59 Hydrogen Peroxide Sterilant (EPA Reg. No. 1043-123):

- ❑ Instructions on the cup for proper use
- ❑ Expiration Date – data matrix code assures use within date
- ❑ Cartridge design – 15 cycles per cartridge
- ❑ Use of PPE
- ❑ Sterilant level indicator
- ❑ Contents - 59% hydrogen peroxide (14 - day expiration after loading in *MD140X* Biodecontamination Unit)
- ❑ Proper disposal of cup

Biodecontamination Cycle Operation[1]

Review and/or demonstrate the following features:

- ❑ Review intended use per Operator Manual
- ❑ Review Introduction, sec 6.2 for proper use
- ❑ Unit is in **STANDBY** when first turned on (requires ~ 40 minutes to reach operating temperature)
- ❑ Ensure sterilant cup is installed. Refer to Sec. 4.2, Sterilant Cup Installation and Removal
- ❑ Verify printer is supplied with paper. Refer to Sec. 8.5, Change Paper Roll
- ❑ Review the **Options** touch screen
- ❑ Verify that the load is properly prepared, refer to Appendix A in Operator Manual
- ❑ Chemical Indicator (CI) – Use only STERIS recommended CI for *MD140X* Biodecontamination Unit
- ❑ Ensure that all trays and shelves are completely inside before closing the door
- ❑ Push chamber door closed
- ❑ **Lumen Cycle: 55 minutes—Total load must NOT exceed 19.65 lbs (8.9 kg) or 20 lumens**
- ❑ **Non-Lumen Cycle: 28 minutes—Total load must NOT exceed 19.65 lbs (8.9 kg)**
- ❑ **Flexible Cycle: 35 minutes—Process 2 flexible instruments or 1 flexible instrument and non-lumened load up to 24 lbs (10.9 kg) total weight**

Note: Chamber door must stay closed when unit is not in use.

- ❑ Press the correct validated cycle on the touch pad to begin a biodecontamination cycle (Lumen Cycle, Non-Lumen Cycle, or Flexible Cycle). Cycle will begin.
- ❑ Review cycle phases – Condition, Biodecontaminate, Aerate
- ❑ Review **Abort Cycle** information
- ❑ At cycle completion, ensure the proper unloading of the biodecontamination unit
- ❑ Review the cycle printout
- ❑ Read, record and discard CI
- ❑ Continue with BI test procedure (if applicable)
- ❑ Remove instruments
- ❑ Average cycle times may vary due to load size, wetness or absorbency

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[1]Not for use to reprocess reusable instruments for human use.

Leak Test (Weekly)

Review and/or demonstrate the following features leak test cycle:

- ❑ A leak test is recommended to be performed weekly (test will last ~ 14 minutes) on the unit to ensure the chamber is leak proof

The leak rate must be less than 0.3 Torr / minute (will appear on printout)

- ❑ Cycle completion – review printout
- ❑ Contact STERIS Life Sciences in the event of leak test failure

Troubleshooting / Routine Maintenance

Review and/or demonstrate the following related to troubleshooting and routine maintenance:

- ❑ Review **Alarm** screen information and how to respond
- ❑ Review typical **Alarm** printout
- ❑ Review Table 7.1 in the Operator Manual
- ❑ Review oil maintenance icon
- ❑ Daily – clean, check paper supply
- ❑ Weekly – leak test, check ink cartridge
- ❑ Quarterly – inspect door gasket

Chemical Indicator

Instructions for Chemical Indicators (CI) are found within the CI packaging.

Review and/or demonstrate the following:

- ❑ Locate and review the expiration date
- ❑ Internal: Place CI in tray or packaging for each cycle
- ❑ External: Place CI on each wrapped tray, interpret results upon removal of tray
- ❑ Remove internal CI at point of use and interpret the indicator color

Biological Indicator

Instructions for Biological Indicators (BI) are found within the BI packaging.

Review and/or demonstrate the following:

- ❑ Locate and review the expiration date of BI
- ❑ Review steps for Control BI
- ❑ Place BI (test) pouch to verify the cycle on top shelf (center, if possible) within loaded chamber
- ❑ Remove the BI from the unit at the end of the cycle
- ❑ Incubate the BI and read the results
- ❑ Review control / test results interpretation

About STERIS Corporation

STERIS Corporation is a leading provider of infection prevention and surgical products and services, focused primarily on critical healthcare, pharmaceutical and research markets around the world. The Company supplies a broad array of equipment, consumable and service solutions that help assure productivity and quality. The Company is listed on the New York Stock Exchange under the symbol STE. For more information, visit www.steris.com.

STERIS has a comprehensive offering of detergents, disinfectants, skin care products and sterility assurance products that support your needs. We also have world class technical support to design the most effective cleaning program for your facility.

STERIS Life Sciences Service

Delivering world-class support where you operate, STERIS Life Sciences Service offers the following services:

- Biodecontamination
- Preventative maintenance programs
- Replacement parts
- Calibration
- IQ/OQ
- Cycle development

and other services upon request.

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