STERIS®

SYSTEM 1® endo LIQUID CHEMICAL STERILANT PROCESSING SYSTEM

APPLICATION

For rapid, safe, standardized low-temperature liquid chemical sterilization of cleaned, immersible, and reusable semi-critical, heat-sensitive medical devices and their accessories in healthcare facilities.

DESCRIPTION

The **SYSTEM 1® endo Liquid Chemical Sterilant Processing System** consists of the **SYSTEM 1® endo Processor, A&B Pre-filters,** and **S40® Sterilant Concentrate**.

The **SYSTEM 1 endo Liquid Chemical Sterilant Processing System** is an automated, tabletop, microcomputer-controlled device which maintains the process parameters necessary to ensure standardized and effective liquid chemical sterilization. The entire process takes place within the system's environmentally sealed chamber at or near the site of the patient procedure. Devices can be processed in approximately 18* minutes, minimizing device downtime between patient procedures. Processing temperatures do not exceed the safe temperature limits that most manufacturers recommend to ensure protection of heat-sensitive medical devices. At the completion of each cycle, a comprehensive electronic cycle record documents the process and load information.

* *Actual cycle time may vary due to water pressure, incoming water temperature or filter status.*

S40 Sterilant Concentrate is a single-use chemistry labeled for use in the SYSTEM 1 endo Liquid Chemical Sterilant Processing System. Its active ingredient is peracetic acid, an effective liquid chemical sterilant. The chemicals also minimize corrosion or degradation of the devices being processed.

(Typical – details may vary)

STANDARDS

Each SYSTEM 1 endo Liquid Chemical Sterilant Processing System meets applicable requirements of the following standards, and carries the appropriate symbols:

- **Underwriters Laboratories (UL) Standard** UL-61010-1 as certified by ETL Testing Laboratories, Inc.
- **FCC CFR 47**, Part 15, subpart B:2017
- **CISPR** 11:215+A1:2016

The Selections Checked Below Apply To This Equipment

VOLTAGE
- ❑ 115 VAC, 60 Hz, 20 amp, 1-Phase, 3-Wire (P6900)

CONSUMABLES
- ❑ S40® Sterilant Concentrate - 20 Single Use Containers/Case (S4000)
- ❑ VERIFY® Chemical Indicators for S40® Sterilant - 120 Indicators (LCC016)
- ❑ VERDOC® Automated Liquid Chemical Processing Systems - 100 Cycle Log Forms (RK036)
- ❑ VERDOC® Automated Liquid Chemical Processing Systems - 100 Cycle Envelopes (RK037)

QUICK CONNECTS
- ❑ Based on facility endoscope inventory. Please contact STERIS Account Manager or the Device Matrix on www.steris.com

FILTERS
- ❑ Dual Pre-filter Replacement Kit (A1567)
- ❑ "A" Pre-filter Replacement (A1501E)
- ❑ "B" Pre-filter Replacement (A1562)
- ❑ Sterile Air Filter (A1503E)
- ❑ MaxLife® Bacterial Retentive Water Filter (A1530)

DATA MANAGEMENT
- ❑ ConnectAssure Data Export (JM3030)

CONTAINERS AND TRAYS
- ❑ Flexible Endoscope Processing Container and Tray (C1140E)
- ❑ Flexible Endoscope Processing Container (C1141E)
- ❑ Flexible Endoscope Processing Tray (C1142E)
- ❑ Flexible Endoscope Lid (C1602E)
- ❑ General Processing Container and Tray (C1200E)
- ❑ General Processing Container (C1201E)
- ❑ General Processing Tray (C1202E)
- ❑ General Processing Lid (C1601E)
- ❑ Directed Flow Processing Container and Tray (C1220E)
- ❑ Directed Flow Processing Container (C1221E)
- ❑ Directed Flow Processing Tray (C1222E)
- ❑ Directed Flow Processing Lid (C1600E)
- ❑ Universal Flexible Processing Tray (C1160E)
- ❑ Ultrasound Tray (C3000XL)

INSTALLATION
- ❑ Workstation Cart (A1965)
- ❑ GFCI Outlet (20 A, Hospital grade, Ivory) (A1001)
- ❑ Temperature Control Valve (A1002)
- ❑ Thermometer Assembly for use with A1002 (A1005)
- ❑ Temperature Booster - 240V, 1 Phase, 42 A (A1003)
- ❑ Temperature Booster - 208V, 1 Phase, 48 A (A1004)
- ❑ Temperature Booster - 208V, 3 Phase (A1017)
- ❑ Temperature Booster - 480V, 3 Phase (A1019)
- ❑ Water Softener Kit (A1593)
- ❑ Water Softener Cartridges - 4/Box (A1594)
- ❑ Incubator (C1392)
- ❑ Replacement Thermometer (S3033)

Item _____

Location(s)_____

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LIQUID CHEMICAL STERILIZATION MONITORING

NOTE: As with any processing method, effective liquid chemical sterilization in the SYSTEM 1 endo Liquid Chemical Sterilant Processing System requires proper cleaning, preparation and placement of devices. Prior to processing any device in the SYSTEM 1 endo Liquid Chemical Sterilant Processing System, the user must ensure that the reprocessing instructions provided by both the device manufacturer and STERIS are completely understood and followed.

Standardization of the Liquid Chemical Sterilization (LCS) Cycle ensures that all devices are processed in exactly the same manner. Each cycle provides documentation on whether the parameters for liquid chemical sterilization have been met.

The Diagnostic Cycle and the integrity test of the MaxLife Water Filter provide validation of system integrity.

FEATURES

Control panel is a color touch screen control to provide user with easy interaction with the unit.

ConnectAssure Technology is an electronic record management system that collects cycle information from STERIS equipment to be displayed in an SPD tracking system or in the ConnectAssure software interface.

ConnectAssure Data Export exports XML cycle records from equipment to your tracking system.

Data Management provides key cycle data, consisting of date, time the cycle was started, Processor serial number, cycle count, outcome of process temperature, exposure time, fill time, phases duration and inlet temperature of water. The cycle record can also list, optionally, the Load Operator ID, the Device ID, the Case ID, the Procedure ID and the Physician ID. Any or all of these can be utilized.

LCS Cycle record also includes any cycle faults and warns the operator of incomplete liquid chemical sterilization, should a fault occur.

Diagnostic cycle records also include whether the Processor passed or failed (and if so, the reason for the failure).

Control System includes pre-programmed LCS and Diagnostic Cycles.

Class 1 Protection against electric shock.

Dual Pre-filters for incoming potable water. Filter "A" is 2.5 micron; Filter "B" is 0.1 micron nominal. The pre-filter assembly includes a pressure regulator to reduce incoming water pressure to 50 psi (345 kPa).

MaxLife Filter is a dual-layer absolute filter (with 0.2/ 0.2-micron pore-size membranes).

Sterile Air Filter in the Processor housing is 0.2 micron absolute. It filters incoming air during the Drain phase of every processing cycle.

Electronic System monitors and maintains the parameters necessary to ensure liquid chemical sterilization.

Bar Code Reader allows User to scan information such as Operator ID, Device ID, Case ID, Procedure ID and Physician ID.

CYCLE DESCRIPTION

The SYSTEM 1 endo Liquid Chemical Sterilant Processing System features two standard cycles: LCS Cycle and Diagnostic Cycle.

Refer to the Operator Manual for SYSTEM 1 endo Liquid Chemical Sterilant Processing System for full processing instructions:

LCS Cycle is used to process devices that have been properly cleaned, then visually inspected and tested for proper working condition, according to the manufacturer's recommendations. Immersible, heat-sensitive, semi-critical medical devices are placed in the processing chamber. If applicable, the appropriate Quick Connect is attached to the device and the Processor is sealed when lid is closed. Filtered water enters the chamber and mixes with the sterilant to prepare the use-dilution. The use-dilution fills the chamber and is typically heated to 115 - 131°F (46 - 55°C) for liquid chemical sterilization. The device is exposed to heated use-dilution for six minutes. The environmentally safe use-dilution then drains from the chamber, and the device and chamber are rinsed twice with filtered water. Upon successful completion of the LCS Cycle (approximately 18* minutes duration), devices are ready for immediate use, or can be prepared for storage.

* *Actual cycle time may vary due to water pressure, incoming water temperature or filter status.*

Diagnostic Cycle is run to ensure that the MaxLife Filter and all electro-mechanical systems of the SYSTEM 1 endo Liquid Chemical Sterilant Processing System are functioning correctly. The cycle consists of a series of internal tests which are performed sequentially. A successful Diagnostic Cycle assures the operator that the system operates as designed for liquid chemical sterilization. Failure of a Diagnostic Cycle informs the operator that the processor must not be used until the problem is corrected and a successful Diagnostic Cycle is run. A Diagnostic Cycle takes approximately 19 minutes, and STERIS highly recommends the cycle be run every 24 hours of use or after a non-use period exceeding 24 hours.

SUPERVISOR SETTINGS

Cycle values (time, temperature) cannot be adjusted by the Supervisor; however, certain control settings are Supervisor adjustable.

General Settings: Set Date & Format, Set Time & Format, Set Language, Set Displayed units, Set Supervisor Password, view software information.

Functional Settings: Set audible alarm duration for end of cycle, Enable Operator ID input, Enable Case ID input, Enable Device ID input, Enable Procedure ID input, Enable Physician ID input, Enable Informative Option, set Time for Diagnostic Cycle Reminder (reminder to run Diagnostic cycle triggered

daily at set time), set Audio Volume, set Air Purge time, reset MaxLife filter 180 days countdown.

Printing Settings: Enable printer to print Supervisor Settings.

Manage Cycle Data: View/delete/export electronic cycle record

Operator Profiles Management: Create/edit/delete operator profiles

Physician Profiles Management: Create/edit/delete physician profiles

PROCESSING TRAYS AND CONTAINERS

Specialized Trays and Containers are designed to enable the operator to position devices appropriately for liquid chemical sterilization. Appropriate positioning in the chamber ensures a continuous exchange of sterilant use-dilution and rinse water on exposed surfaces of the devices (including internal structures and lumens). Trays and containers can help protect certain types of devices during transport following liquid chemical sterilization.

QUICK CONNECTS

Quick Connects facilitate liquid chemical sterilization of semi-critical medical devices with internal channels. Each Quick Connect contains processing instructions and an integrated assembly required to direct flow from the SYSTEM 1 endo Liquid Chemical Sterilant Processing System through the internal channels of devices. Each Quick Connect is designed to accommodate specific device and Processing Container/Tray combinations.

Contact your STERIS Account Manager, Customer Service Representative or go the Device Matrix on www.steris.com to identify which Quick Connects are required to process your specific devices.

CONSTRUCTION

The frame of the SYSTEM 1 endo Liquid Chemical Sterilant Processing System is stainless steel, and the lid is an aluminum casting with a see-through viewing window. Processor trays are ABS or PVC plastic.

A Workstation cart is available and is designed to provide a movable installation for SYSTEM 1 endo Liquid Chemical Sterilant Processing System. The cart also serves to help organize productivity aids and supplies for easy access and use.

Workstation cart can enhance productivity of the unit for when there is no available counter space at Customer site to place unit. The cart provides storage areas for containers, trays, and lids. A drawer is also included for additional storage for items such as Quick Connects, biological indicators, and log forms.

PREVENTIVE MAINTENANCE

Customers are encouraged to contact STERIS 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 help minimize untimely or costly schedule interruptions. STERIS 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 for details.

NOTES

1. Building service lines, provided by Customer, must supply the specified pressures and flow rates.
2. Backflow prevention device must be provided by Customer.

REQUIREMENTS

- Refer to Customer Site-Prep Guide - document T6840B
- ConnectAssure Data Export requires an ethernet drop and ethernet connection within 10 ft of the equipment. Customer must supply the network cable.

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

For Further Information, contact:

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