STERIS®

SYSTEM 1E™ LIQUID CHEMICAL STERILANT PROCESSING SYSTEM

APPLICATION

For rapid, safe, standardized low-temperature liquid chemical sterilization of **heat-sensitive** critical and semi-critical devices.

DESCRIPTION

The **SYSTEM 1E Liquid Chemical Sterilant Processing System** consists of the **SYSTEM 1E™ Processor, A&B Pre-Filters, Ultraviolet Light Water Treatment System** and **S40™ Sterilant Concentrate**.

The **SYSTEM 1E 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 less than 25* 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** devices. At the completion of each cycle, a comprehensive printout 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 exclusively for use in the SYSTEM 1E 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.

NOTE: Contact STERIS Customer Service for S40 Sterilant Concentrate ordering information (20 single-use containers per case).

STANDARDS

Each SYSTEM 1E Processor 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.

(Typical only - some details may vary.)

LIQUID CHEMICAL STERILIZATION MONITORING

NOTE: As with any processing method, effective liquid chemical sterilization in the SYSTEM 1E Processor requires proper cleaning, preparation and placement of devices. Prior to processing any device in the SYSTEM 1E Processor, 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 Cycle ensures that all devices are processed in exactly the same manner. Each cycle printout provides documentation on whether the parameters for liquid chemical sterilization have been met.

The Diagnostic Cycle and MaxPure™ Filter integrity test provide validation of system integrity.

FEATURES

System chamber holds the Processing Trays and Containers for the devices to be liquid chemically sterilized. The chamber door is opened manually by a release latch/handle. A window in the chamber lid allows the operator to observe the liquid chemical sterilization process. Preparation of the S40 Sterilant Concentrate use dilution occurs automatically within the sealed processing chamber. When the lid is closed and latched, water flows into the chamber, and the active ingredient

The Selections Checked Below Apply To This Equipment

VOLTAGE

☐ 115 VAC, 60 Hz, 20 amp, 1-Phase, 3-Wire

LANGUAGE/TOUCH PADS

☐ English/English

ACCESSORIES

☐ Workstation Cart
☐ GFCI Outlet (20 amp, hospital grade, duplex)
☐ Temperature Control Valve
☐ Temperature Booster (240 V, 1-Phase or 3-Phase)
☐ Temperature Booster (208 V, 1-Phase)
☐ Temperature Booster (208 V, 3-Phase)
☐ Thermometer Assembly (use with Temperature Control Valve)
☐ UV System Cover
☐ UV System Under-counter Bracket

☐ **S40 STERILANT CONCENTRATE**

☐ **PROCESSING CONTAINERS/TRAYS**

☐ **QUICK CONNECTS**

Item _____

Location(s)_____

_____

is aspirated from the sterilant container in the sterilant compartment.

Control panel includes a display window, touch-sensitive keypads and an impact printer to allow easy initiation, option setting and monitoring of cycles.

- **Display window** – the 2-line x 16-character, easy-to-read vacuum fluorescent display shows cycle information and option selections.
- **Touch pads** – by pressing the control panel touch pads, the operator can start or cancel a cycle, check the cycle phase while the unit is in-cycle, change or set option selections and advance the printer paper. Control touch pads are available in English language.
- **Printer** – ink-on-paper, impact-type printer with a take up motor records all cycle data on 2-1/4" (57 mm) wide, single-ply paper.

Printouts provide key cycle data, consisting of date, time the cycle was started, Load ID (manually entered by the operator or processor-printed), remarks section (for manually entering any comments), Operator ID number (manually entered or processor-printed), Processor serial number and cycle count. Liquid Chemical Sterilization Cycle also includes outcome of MaxPure Filter integrity test, process temperature, concentration of sterilant, exposure time, fill time and inlet temperature of water. Any cycle faults are listed and warn the operator of incomplete liquid chemical sterilization, should a fault occur. Diagnostic cycles also include whether the Processor passed or failed (and if so, the reason for the failure). The printout also lists codes for options that can be programmed, including Operator ID, Patient ID, Device ID, Procedure ID and Physician ID. Any or all of these can be utilized.

Control system includes pre-programmed Liquid Chemical Sterilization and Diagnostic Cycles.

A **main power ON/OFF switch**, in the back of the unit, can be used to shut off power to the unit.

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 36.5 psi (252 kPa).

An **ultraviolet light water treatment system** deactivates viruses in incoming potable water. This system has been tested to a 6-log MS2 virus inactivation level.

MaxPure filter is a triple-layer absolute filter (with 0.8-, 0.1- and 0.1-micron individual filters).

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.

CYCLE DESCRIPTION

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

Refer to the SYSTEM 1E Processor Operator Manual for full processing instructions:

Liquid Chemical Sterilization 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** devices are placed in the processing chamber. If applicable, the appropriate Quick Connect is attached to the device and the Processor is then sealed. Filtered, UV-treated 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 environmentally safe use dilution then drains from the chamber, and the device and chamber are rinsed with UV treated and filtered water two times. Upon successful completion of the Liquid Chemical Sterilization Cycle (less than 25* minutes duration), devices are ready for immediate use.

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

Diagnostic Cycle is run to ensure that the MaxPure Filter and all electro-mechanical systems of the SYSTEM 1E Processor 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 tells 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 14 minutes, and should be run once every 24 hours.

CONTROL VALUE SETTINGS

Cycle values (time, temperature) cannot be adjusted by the operator; however, certain control settings are operator-adjustable:

- **Language** – for displays and printouts. Default language is English.
- **Time set** – for setting/adjusting current time of day for displays and printouts.
- **Date set** – for setting/adjusting current date for displays, printouts.
- **Access code** – for limiting access to certain options to authorized operators.
- **Operator ID** – for assigning a 5-digit numeric code to an operator's name, to appear on cycle printouts.
- **Patient ID** – for assigning 16-digit numeric codes to specific patients, to appear on cycle printouts.
- **Device ID** – for assigning 5-digit numeric codes linked to specific devices, to appear on printouts.

- **Procedure ID** – for assigning 2-digit numeric codes linked to specific procedures, to appear on printouts.
- **Physician ID** – for assigning 5-digit numeric code to operator-selected physician names, to appear on printouts.
- **Informative option** – to have a series of quality assurance cycle-related questions appear on the display, to be answered by the operator before a cycle can be initiated.
- **Automatic duplicate print** – to have a duplicate printout print at the end of each cycle.
- **End-of-cycle tone** – to have a tone sound at the end of each cycle.
- **Time format** – for setting the sequence for time displays and printouts in AM/PM or 24-hour format.
- **Date format** – for setting the sequence for date displays and printouts (month/day/year, day/month/year, year/month/day).
- **Filter Changed?** – for resetting the MaxPure Filter 90-day countdown.

PROCESSING TRAYS AND CONTAINERS

Specialized Trays and Containers are designed to enable the operator to position devices appropriately for liquid chemical sterilization; ensure a continuous exchange of sterilant use dilution and rinse water on exposed surfaces of the devices (including internal structures and lumens) and protect certain types of devices during transportation following liquid chemical sterilization.

Contact STERIS Customer Service at 1-800-548-4873 for more information on device-specific trays and containers.

QUICK CONNECTS

Quick Connects facilitate liquid chemical sterilization of **heat-sensitive** devices with internal channels. Each Quick Connect contains processing instructions and an integrated assembly required to direct flow from the SYSTEM 1E Processor 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 to www.steris.com to identify which Quick Connects are required to process your specific devices.

ACCESSORIES

Accessories are available to enhance productivity or to meet specific Customer requirements, such as:

- **Workstation cart** (refer to M1013EN)
- **GFCI duplex receptacle outlet** (20 amps, hospital grade, duplex)
- **Temperature control valve**
- **Temperature booster** (240 V, 42 amps; 208 V, 1-Phase, 48 amps; or 208 V, 3-Phase, 48 amps)
- **Thermometer assembly** (use with Temperature Control Valve)
- **UV System Cover**
- **UV System Under-counter Bracket**

CONSTRUCTION

The SYSTEM 1E Processor frame is stainless steel, and the lid is an aluminum casting with a see-through viewing window. Processor trays are ABS or PVC plastic.

MOUNTING ARRANGEMENT

The SYSTEM 1E Liquid Chemical Sterilant Processing System can be installed in a variety of locations, with a minimum counter width of 40" (1016 mm), depth of 24" (610 mm), and minimum height of 38" (965 mm) measured from the top of the counter surface, to ensure proper overhead clearance (UV System not wall mounted).

If the Processor is installed on a hard-surface counter or permanently mounted shelf, the surface must be able to safely support 165 lbs (75 kg). A 2" (51 mm) diameter hole is required to allow passage of the plug and hoses through the mounting surface.

Adequate clearance for installing dual pre-filter and ultraviolet light treatment system must be provided above, below or to the side of the processor. Please study the Site Preparation Guide (T6540) for full information.

Installation site selection must be within 5' (1.5 m) of electrical, water and drain inlet. Must be *more than* 5' (1.5 m) from patient.

Also available is a workstation cart, designed to organize SYSTEM 1E Processor accessories and supplies for easy access and use (see Accessories).

PREVENTIVE MAINTENANCE

A global network of skilled service specialists can provide periodic inspections and adjustments to help ensure low-cost, peak performance. Contact your STERIS Representative for information on annual maintenance agreements.

ENGINEERING DATA

Shipping Weight: 178 lbs (81 kg)

Dry Weight: 140 lbs (64 kg)

Operating Weight: 165 lbs (75 kg)

Water Consumption: 8.7 U.S. gal (33L) per cycle

Sterilant Consumption: 1 single-use cup per liquid chemical sterilization cycle.

Environmental Factors: 60-90°F (16-32°C) room temperature;10-90% relative humidity, non-condensing.

UV System: Width 30" (76 cm), Depth 9" (23 cm), Height 28" (71 cm), Weight 44 lb (20 kg).

Dry weight: 44 lb (20 kg); Operational weight: 49 lb (22 kg); Wall bracket weight: 9 lb (4 kg); On-Cart dry weight: 35 lb (16 kg); On-cart operational weight: 40 lb (18 kg)

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.
3. Customer must be sure mounting surface can safely support 165 lbs (75 kg).
4. Processor space requirements (UV System not wall-mounted):
   - Width: 40" (102 cm) minimum
   - Depth: 24" (61 cm) minimum
   - Height: 38" (97 cm) minimum
5. UV System space requirements:
   - Width: 30" (76 cm)
   - Depth: On Cart – 9" (23 cm); On Wall – 10" (24 cm)
   - Height: Wall-mounted – 28" (71 cm); Under-counter Cabinet – 17" (43 cm)"

UTILITY REQUIREMENTS

Water

Water Consumption:

8.7 U.S. gal (33L) per cycle; peak: 2.5 U.S. gal/min (9.5 L/min) at 36.5 psig (252 kPa).

Water Specifications:

Tap or other potable water, 3/4" (1.9 cm) I.D. male hose connection. Pressure: 40-50 PSIG (276 - 345 kPa); 109 - 140°F (43 - 60°C); Optimum temp: 115 - 118°F (46 - 48°C); $\leq$ 140 ppm hardness as $CaCO_3$; transmittance $\geq$ 88% at 254 nm

Drain

1-1/4" (3.18 cm) minimum, sink or other sanitary, non-backpressuring.

Electrical Requirements

Processor: 115 VAC, 60 Hz, 15 amp

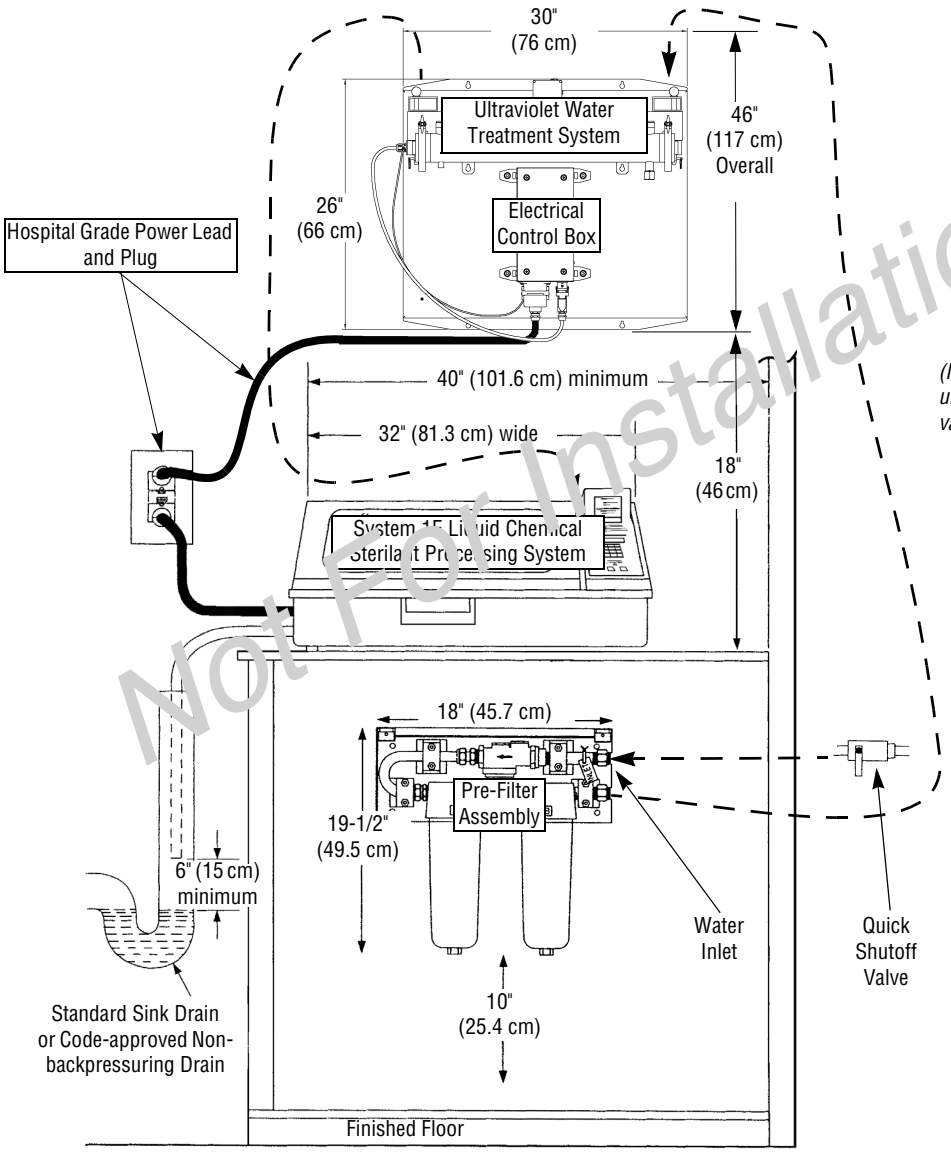
UV System: 115 VAC, 60 Hz, 1 amp

Service: 115 VAC, 60 Hz, 20 amp dedicated circuit terminated in a 20 amp hospital grade GFCI duplex receptacle.

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

Refer to the Following Information for Installation Details	
Document Number	**Document Title**
T6540	SITE PREPARATION and INSTALLATION GUIDE, SYSTEM 1E PROCESSOR

TYPICAL INSTALLATION - UV System Above SYSTEM 1E Processor
Not To Scale



TYPICAL INSTALLATION
Not To Scale

(Note that installation locations for ultraviolet light filter and pre-filter are variable)

For Further Information, contact:

STERIS®

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-548-4873
www.steris.com