

Description, Features, Specifications

DESCRIPTION

The **SYSTEM 1 Processor** is an automated, tabletop, microcomputer-controlled device which maintains the process parameters necessary to ensure standardized and effective sterile processing.

The entire STERIS PROCESS takes place within the Processor's environmentally sealed chamber at or near the site of the patient procedure. Devices can be processed in less than 30 minutes, just in time for use, 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.*

STERILE PROCESS MONITORING

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

Sterile cycle standardization ensures that all devices are processed in exactly the same manner. Each cycle printout provides documentation on whether the parameters for sterilization have been met.

STERIS PROCESS Chemical Monitoring Strips are designed to detect the presence of the active ingredient in use during each processing cycle.

Biological Monitoring Kits for the STERIS PROCESS are also available. The Diagnostic cycle provides validation of Processor integrity.

NOTE: Contact your STERIS Representative to order STERIS Process Chemical Monitoring Strips and Biological Monitoring Kits.

For rapid, safe, standardized low temperature sterile processing of immersible surgical and diagnostic devices.

FEATURES

Processor chamber holds the Processing Trays and Containers for devices to be sterilized. The chamber door is opened manually by a release latch/handle. A window in the chamber lid allows the operator to observe the STERIS PROCESS. Preparation of the STERIS 20 dilution occurs automatically within the sealed processing chamber.

When the lid is closed and latched, water flows into the chamber, and the active ingredient is aspirated from the STERIS 20 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. The display and printer are factory-set to provide messages in the language of the destination country to which the Processor is shipped.

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 or International symbols, depending upon the destination country to which the unit is shipped.

Printer – ink-on-paper, impact-type printer with a take-up motor records all cycle data on two 1/4" (57 mm) wide, single ply paper.

Printouts include key cycle data, including date and time the cycle was started. Load ID (*manually entered by the operator or processor-printed*), remark sections (*for manually entering any comments*), Operator ID number (*manually entered or processor-printed*), Processor serial number, and cycle count. Sterile cycles also include 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 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 will also list 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 Sterile and Diagnostic cycles designed for typical load and processing requirements.

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

Dual pre-filters in the Processor piping filter potable water. "A" filter is 0.2 micron nominal; "B" filter is 0.2 micron absolute. The pre-filter assembly includes a pressure regulator to reduce incoming water pressure to 50 PSI (345 kPa).

Sterile water filter in the Processor housing is 0.2 micron, absolute.

Sterile air filter in the Processor housing is 0.2 micron absolute. It filters incoming air during the Rinse phase of the Sterile cycle.

Electronic system monitors and maintains the parameters necessary to ensure sterile processing.

CYCLE DESCRIPTION

The Processor features two standard cycles: Sterile Cycle and Diagnostic Cycle.

Sterile Cycle is used for devices that have been properly cleaned, then visually inspected and tested for proper working condition, according to the manufacturer's recommendations. Immersible surgical/diagnostic devices are placed in the processing chamber. If applicable, the device is adapted to the appropriate Quick Connect. A chemical monitoring strip is secured in the tray and the chamber is then sealed. Sterile water enters the chamber and mixes with the sterilant to prepare the used dilution. The use-dilution fills the chamber and is heated to 50-56°C for sterilization. The use-dilution is circulated around and through the device, processing chamber, and fluid pathway, including the sterile water filter, for 12 minutes. The environmentally safe use-dilution then drains from the chamber, and the device and chamber are rinsed with sterile water four times. Upon successful completion of the Sterile cycle (*less than 30* 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 sterile water filter and all electro-mechanical systems of the 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 processor will operate as designed for sterile processing. 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 runs. A Diagnostic cycle takes approximately 18 minutes, and should be ran once every 24 hours.

PROCESSING TRAYS AND CONTAINERS

Specialized Trays and Containers are designed to enable the operator to fix devices in the appropriate position for sterile processing and to ensure a continuous exchange of sterilant use-dilution and sterile rinse on exposed surfaces of the devices (*including internal structures and lumens*), and protect certain types of devices during transportation to a sterile field following sterile processing.

Contact STERIS Customer Service for more information on device-specific trays and containers.

QUICK CONNECTS

The purpose of the STERIS Quick Connects is to ensure sterilant use-dilution contact at all device sites. Each Quick Connect includes the flow unit and instructions required to properly connect and flow devices in the Processor. Quick Connects are available for most flexible and rigid devices with internal channels and include device-specific processing instructions.

Contact STERIS Customer Service for a list of available device specific Quick Connects.

CONSTRUCTION

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

MOUNTING ARRANGEMENT

SYSTEM 1 Processor 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. If the Processor is installed on a hard-surface counter or permanently mounted shelf, the surface must be able to safely support 200 lbs (91 kg). A 2" (51 mm) diameter hole is required to allow passage of the plug through the mounting surface. Installation site selection must be within 5' (1524 mm) of electrical, water, and drain inlet. Processor must be at least 18" (457 mm) away from open sink, to avoid water vapor being drawn into the unit by cooling fans. Also available is a workstation cart, designed to organize SYSTEM 1 accessories and supplies for easy access and use (*see Accessories*).

** If optional bar code reader is used, a minimum of 26" (660 mm) is required.*

Shipping Weight: 150 lbs (68 kg)

Operating Weight: 200 lbs (91 kg)

Water Consumption: 13.3 U.S. gal (50L) per cycle

Sterilant Consumption: 1 single-use cup per sterile process

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

NOTES

1. Building service lines, provided by Customer, must supply the specified pressures and flow rates.
2. Backflow prevented by others.
3. Customer must be sure mounting surface can safely support 200 lbs (91 kg).
4. Space requirements:

- Width: 40" (1016 mm) minimum
- Depth: 24" (610 mm) minimum*
- Height: 38" (965 mm) minimum

** If optional bar code reader is used, a minimum of 26" (660 mm) is required.*

UTILITY REQUIREMENTS

Water

Tap or other potable water, 3/4" I.D. male hose connection; 40-50 psig (276-345 kPa); 110-118°F (43-48°C). Max. flow rate: 4 U.S. gal/min (15 L/min).

Drain

1-1/4" (32 mm) minimum, sink or other sanitary, non-back pressuring.

Electricity†

120 VAC, 60 Hz, 20 Amps; or 230 VAC, 50 Hz, 10 Amps.

† Requires a 20 Amp, 120 V dedicated circuit terminated in a 20 Amp hospital grade GFCI double receptor.