

# Responses to Questions for SYSTEM 1E Process Monitoring and Validation Webinar

## MONITORING THE SYSTEM 1E™ PROCESSOR

**Q:** I want to confirm that there is no need for a Biological Indicator (BI) and that use of a Chemical Indicator (CI) along with physical monitoring is sufficient to ensure liquid chemical sterilization.

**A:** A biological indicator is not required in order to use the SYSTEM 1E Liquid Chemical Sterilant Processing System. The SYSTEM 1E processor has a validated cycle and automatically monitors the critical parameters of liquid chemical sterilization including time, temperature and presence of sterilant. Specifically, when used as directed, the processor monitors these parameters to determine if the necessary conditions for liquid chemical sterilization have been achieved. This information is printed on the tape at the end of the cycle as part of the permanent record keeping for the system. If any of the critical parameters are not met, the processor aborts and the user is alerted.

**Q:** Does the SYSTEM 1E internally monitor for a biological indicator?

**A:** There is not an internal monitor for a biological indicator.

**Q:** Is a CI required?

**A:** A chemical indicator is not required per FDA Guidance for Liquid Chemical Sterilants, nor is it required by the FDA's clearance of SYSTEM 1E. S40 Sterilant Concentrate is a single use sterilant. If the S40 sterilant is properly stored and used within shelf life, the sterilant will not lose potency as can occur with a reusable germicide. The sterilant is sealed and weighed prior to shipment to assure that the proper dose of sterilant will be delivered during the cycle. Stability testing is also performed to validate that S40 is effective throughout its shelf life when stored properly and used prior to the expiration date.

## BIOLOGICAL INDICATOR CLEARANCE:

**Q:** Will there be a Biological Indicator available for SYSTEM 1E? If clearance is provided, do I need to use it?

**A:** STERIS cannot provide any assurance that the FDA will clear a biological indicator for use with the SYSTEM 1E Liquid Chemical Sterilant Processing System. STERIS continues to discuss the BI 510k submission with the FDA. If the product receives clearance, a healthcare facility can choose to use the biological indicator as part of a quality assurance program. There is not a requirement to use the biological indicator if it becomes available.

**Q:** Did FDA put their position in writing regarding the use of a BI or CI with Liquid Chemical Sterilants?

**A:** The FDA 510(k) Guidance for Liquid Chemical Sterilants/High Level Disinfectants is publicly available on the FDA website. A link is provided for your convenience.

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073773.htm>

**Q:** If BI is required for steam and hydrogen peroxide, why not liquid chemical sterilants?

**A:** The 510k submission requirements for Steam sterilizers and Vaporized Hydrogen peroxide sterilizers are regulated by the FDA's 1993 Guidance on Pre-Market Notification Submissions for Sterilizers Intended for Use in Healthcare Facilities. In that guidance, FDA requires that a "functional system" is in place in order to clear a sterilizer for use in the United States. That functional system includes a biological indicator. Liquid chemical sterilants are explicitly excluded from the scope of this guidance and are regulated by the FDA 2000 Guidance document referenced above.

**Q:** Why was a biological indicator required with SYSTEM 1?

**A:** SYSTEM 1 was initially cleared for sale with the use of a commercial spore strip. A dedicated biological indicator was not introduced until 1996. FDA Guidance at the time of the clearance of SYSTEM 1 was different than the guidance currently in place for the clearance of liquid chemical sterilants.

**Q:** If it is not required, why did STERIS seek clearance?

**A:** STERIS filed a 510k for a biological indicator for SYSTEM 1E recognizing that some healthcare facilities may have a quality program that includes the use of a biological indicator. STERIS is trying to minimize the changes associated with a transition from SYSTEM 1 to SYSTEM 1E for those Customers who choose to transition to SYSTEM 1E.

## **VALIDATION:**

**Q:** Is there an independent study showing the efficacy of the CI?

**A:** All validation studies on the Verify chemical indicator have been conducted by STERIS for use in the 510k submission for the product. Additionally, as part of the 510(k) submission independent clinical staff from hospitals verified the functional use of SYSTEM 1E CI's.

**Q:** Can the SYSTEM 1E processor be tested independently?

**A:** Independent analyses would require multiple protocols using aseptic techniques in a controlled environment to permit independent verification of the performance of the SYSTEM 1E processor. STERIS conducted thorough validation of the performance of the chemistry and the system for the 510k submission of the processor. This data is available from your STERIS Account Manager. STERIS would recommend that any testing simply be performed using clinical microbiological procedures of the endoscope consistent with CDC\* suggestions.

\* See Guidelines for Disinfection & Sterilization in Healthcare Facilities, 2008, CDC, p 17.

**Q:** Is there a recommended policy or procedure for use of SYSTEM 1E without a BI?

**A:** STERIS has developed a detailed sample procedure to assist with a Customer's use of SYSTEM 1E without a biological indicator. It is important that the healthcare facility develop procedures specific to

their own needs and have those procedures documented, and that the staff are trained and following the established procedure.

**Q:** Did AAMI ST79 separate LCS out of the requirements for internal verification?

**A:** Liquid chemical sterilants are completely excluded from ST 79.

## **SYSTEM 1E Clearance:**

There were several questions about the clearance of the SYSTEM 1E processor and the April 9, 2010 posting from the FDA. Healthcare providers should be aware that this posting was revised on February 11, 2011 to provide more accurate information.

SYSTEM 1E Liquid Chemical Sterilant Processing System was cleared for liquid chemical sterilization of cleaned, immersible, reusable, critical and semi-critical heat sensitive medical devices. A link to the clearance is provided below. According to FDA guidance, critical devices are required to be sterilized prior to re-use.\* All of the data that STERIS provided to the FDA in the 510k submission for SYSTEM 1E demonstrate that the processed devices are free from microorganisms, which is the FDA's definition of sterile.

On April 9, 2010 FDA posted a statement regarding SYSTEM 1E and liquid chemical sterilization on its website. On February 11, 2011, that posting was revised. This revised posting provided several clarifications including reference to the SYSTEM 1E water treatment system, stating "The treatment method eliminates bacteria/fungi/protozoa from the water. Studies with the test virus MS2 (EPA recommended surrogate for waterborne viruses) showed a 6 log reduction." The FDA's clearance letter, and not a website statement, defines the lawful use of SYSTEM 1E through an attached indications for use page. The cleared indications for use statement (identified below\*) tells healthcare facilities how they can legally use the SYSTEM 1E. SYSTEM 1E may be used in both the OR for reprocessing of validated, heat-sensitive devices in both the OR (for critical devices) as well as Endoscopy (for semi-critical devices).

\*[http://www.steris.com/SS1/PDF/510K\\_12to14.pdf](http://www.steris.com/SS1/PDF/510K_12to14.pdf)

**Q:** Can you explain the extensively treated potable water?

**A:** The extensively treated potable water encompasses several enhancements in comparison to the water that is currently utilized with SYSTEM 1. The filtration system eliminates all bacteria, fungi and protozoa >0.1 micron and the internal MaxPure filter is tested at the completion of every cycle to make sure that the filter has not been compromised. The addition of the UV light provides irradiation sufficient to achieve a 6-log reduction of MS-2 virus to the potable water, in the unlikely event that viruses are present. MS-2 virus is a surrogate for waterborne pathogenic viruses recommended by US EPA since it is the most resistant organism to UV irradiation, linear kinetics, grows rapidly and finally is not a human pathogen. For detailed information on the water treatment process for SYSTEM 1E, please contact your STERIS Account Manager.

**Q:** Is it a high-level disinfectant?

**A:** SYSTEM 1E was cleared as a Liquid Chemical Sterilant Processing System. It is **NOT** a high-level disinfectant.

**Q:** Can I use autoclavable devices in SYSTEM 1E? What if the device can be processed in EtO?

**A:** The clearance for SYSTEM 1E is only for heat sensitive devices. Those devices that are heat stable or can be autoclaved cannot be run in SYSTEM 1E. If a healthcare facility has an Ethylene Oxide sterilizer **and** certain devices have been validated for a specific EtO cycle, then FDA is recommending that those devices be processed by EtO.

## **STERILANT CHEMISTRY:**

**Q:** Is the cup still designed with two compartments? Can I use STERIS 20 in SS1E?

**A:** The cup for S40 Sterilant Concentrate has two compartments: the acid capsule and the outer cup that contains the buffers. STERIS 20 is NOT interchangeable with S40. Only S40 Sterilant Concentrate can be used with the SYSTEM 1E processor. Only STERIS 20 sterilant can be used in SYSTEM 1.

**Q:** How are S40 and Peracetic Acid different? What is the effect on material compatibility of devices? Is there a concern about processing devices in SYSTEM 1 and then SYSTEM 1E?

**A:** S40 contains both peracetic acid and inert ingredients (buffers). STERIS has validated material compatibility to a minimum of 300 cycles. There is no concern about reprocessing a device in SYSTEM 1 with STERIS 20 and then reprocessing that same device in SYSTEM 1E with S40. Make sure all instructions for use and device cleaning and maintenance requirements are followed.

## **INDUSTRY ORGANIZATIONS:**

**Q:** What position have groups such as AAMI, AORN and TJC taken with respect to SYSTEM 1E and use without a biological indicator?

**A:** The use of SYSTEM 1E without a biological indicator is consistent with AAMI ST58, which is the appropriate standard for liquid chemical sterilization. STERIS has provided information to AORN to clarify the use of the processor with critical devices without a BI. AORN Recommended Practice references AAMI ST58. The Joint Commission does not prescribe policies for healthcare facilities. TJC seeks to verify that Quality Programs are in place and that healthcare facilities are adhering to their defined policies and procedures.

## **DEVICE VALIDATIONS:**

**Q:** Have manufacturer's validated their devices for SYSTEM 1E? How do I determine what heat sensitive devices have been validated?

**A:** STERIS conducts validation testing for both efficacy and material compatibility for devices for SYSTEM 1E. As part of the 510k submission for SYSTEM 1E, STERIS submitted data to the FDA for a representative set of devices that encompassed highly challenging test conditions to achieve liquid chemical sterilization. The labeling for the SYSTEM 1E Quick Connects identifies the specific device

models that have been validated for reprocessing in SYSTEM 1E. Based upon STERIS data, all of the heat sensitive devices that were validated for reprocessing in SYSTEM 1 can be reprocessed in SYSTEM 1E. STERIS has developed the appropriate data to substantiate the efficacy of the SYSTEM 1E process with specific devices identified in the labeling. Manufacturer validation is not required for devices to be included in the SYSTEM 1E labeling. STERIS has a complete matrix available that identifies all validated heat sensitive devices that may be liquid chemically sterilized in SYSTEM 1E.

## **SYSTEM 1 TRANSITION**

**Q:** How long will SYSTEM 1 be supported?

**A:** STERIS will support SYSTEM 1 until August 2, 2011 for those Customers that have provided required documentation to STERIS.

**Q:** Have you started shipping SYSTEM 1E processors and how can I purchase one?

**A:** STERIS has started shipping and installing SYSTEM 1E units in healthcare facilities. Please contact your STERIS Capital Account Manager at 1-800-548-4873 for details on pricing and delivery.

**Q:** Can I use my existing quick connects and trays?

**A:** STERIS proposed a plan to FDA that would allow us to relabel existing Quick Connects and perform a slight modification to trays. That proposal has not been accepted by FDA. STERIS is recommending that Customers purchase new SYSTEM 1E trays and quick connects. Please contact your STERIS representative for details on a promotional offer that is available to you.

## **PROCESSOR SPECIFICATIONS:**

Several questions were submitted requesting specifications and maintenance for the processor. A link to the Technical Data Sheet is provided.

[http://www.steris.com/media/PDF/system1/SD924\\_07-01-10TechData.pdf](http://www.steris.com/media/PDF/system1/SD924_07-01-10TechData.pdf)

**\*FDA Labeling Reusable Medical Devices for Reprocessing in Healthcare Facilities: FDA Reviewer Guidance, Office of Device Evaluation, April 1996**

This is a summary of the primary areas of questioning during the SYSTEM 1E webinar. Some questions and responses were condensed and edited for clarity or convenience. Product descriptions and operations herein are general information, for illustration only, and do not alter product warranties, labeling, instructions for use or other technical information. Follow the Operator's Manual and all user directions. If you have additional questions, please call STERIS at 1-800- 548-4873