



STERIS SYSTEM 1<sup>®</sup> Sterile Processing System:  
Transition Guidance

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## BACKGROUND

STERIS Corporation was notified on December 3, 2009 that the U.S Food and Drug Administration (FDA) had issued a notice to healthcare facility administrators regarding the regulatory status of the STERIS SYSTEM 1® Sterile Processing System (hereafter SYSTEM 1). The notice outlined actions to be taken by healthcare facilities using the SYSTEM 1 device. The FDA has stated that healthcare administrators should transition to acceptable alternatives for device reprocessing.

STERIS is providing this Transition Guidance document to help our Customers evaluate acceptable alternatives to SYSTEM 1. The document offers recommendations for working through the evaluation and transition process; a list of alternative reprocessing methodologies for critical and semi-critical devices; plus observations regarding the potential impact of these alternatives on Customers' operations. We have included links to additional information resources such as professional organizations and other companies that offer alternative sterilization and decontamination technologies.

STERIS has established a dedicated hotline at 800-548-4873 to support Customers through this transition. We will also continue providing the latest information via our website at [www.steris.com](http://www.steris.com).

## PURPOSE OF THIS DOCUMENT

This document is intended to support healthcare facilities and their assigned working committees in making informed decisions about the transition to acceptable reprocessing alternatives. At a high level, the decision-making process should include the following considerations:

- Identify all current low temperature re-usable medical devices currently processed in the SYSTEM 1 sterilizer.
- Obtain and review all original equipment manufacturer's instructions for use for these devices. In particular, make sure you understand which sterilization/high level disinfection modalities are currently cleared by FDA to process these devices.
- Identify all current modalities available in your healthcare facility and the devices that can be moved away from SYSTEM 1 to an acceptable alternative process.
- Compile a list of re-usable medical devices you can process given the healthcare facility's current capabilities.
- Determine whether there is another healthcare facility in your system with the appropriate sterilization/high level disinfection modalities and the operational capacity to process these devices.
- If yes, can temporary arrangements be made for transportation and processing?
- If no, is there a 3rd party low temperature service available in the area?

After considering the factors listed above, if no alternatives exist within your facility or system, the following steps will guide you through the decision-making process.

These are merely our suggestions to help you through the transition decision-making process. Of course, you should defer to your own healthcare facility/system's policies and procedures.

## DEVICE REPROCESSING TRANSITION PROCEDURE

### I. OBJECTIVE:

To establish a clear, comprehensive and consistent procedure for transitioning to acceptable alternative device reprocessing methodologies other than SYSTEM 1 in perioperative, endoscopy and sterile processing settings.

### II. SCOPE:

All perioperative, endoscopy and sterile processing areas of your facility.

### III. EXCEPTIONS:

None

### IV. DEFINITIONS:

- A. Qualified Personnel** – Members of staff who have the requisite product, process and quality knowledge and training in the operation of equipment used during the verification process: typically, instrument technicians or instrument specialists.
- B. User Verification** – Documented procedures, performed in the user environment, for obtaining, recording and interpreting results data establishing that pre-determined specifications have been met.
- C. Validation** – Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

#### NOTE 1:

Validation covers three activities:

- i. Installation qualification
- ii. Operational qualification
- iii. Performance qualification

#### NOTE 2:

Validation is performed by the device manufacturer. For example STERIS Corporation validates the AMSCO V-PRO™ 1 Low Temperature Sterilization System.

### V. POLICY:

Capital equipment and medical device procurement are collaborative processes requiring clinical, legal, and financial acumen. Patient care, product standardization and value analysis goals drive the selection of functional and reliable products that are safe; cost-effective; environmentally friendly; consistent with the mission of quality care; and that avoid duplication or rapid obsolescence.

## DEVICE REPROCESSING TRANSITION PROCEDURE

*(continued...)*

### VI. PROCEDURE:

- A. Establish a multidisciplinary committee with representation from everyone affected by the new technology/product. For example, for a product related to low-temperature sterilization, representation includes (but is not limited to) infection prevention and control; the OR; endoscopy; sterile processing; risk management; general counsel; and staff development/training/education.**

*Rationale:* The selection of new sterilization/high-level disinfection modalities and/or products can be complex, requiring a systematic, thoughtful process to help facilitate the evaluation, procurement and implementation process.

- B. Collect and distribute to the committee information related to the product. Such data includes (but is not limited to) the following:**

1. FDA clearance documentation
2. Relevant research articles published in peer-reviewed journals
3. Manufacturers' literature and instructions for use
4. Expert opinions
5. Reports from peers who are using or have trialed the technology/product

- C. In addition to evaluating the product's intended application, consider the following:**

1. Impact on patient safety
2. Any legal implications associated with use of the technology/product
3. Cost/value analysis (return on investment)
4. Staff training and education
5. Ease-of-use of technology/product
6. Related safety issues
7. Compatibility of product with existing equipment
8. Environmental impact
9. Availability of ongoing support from vendor for such services as maintenance
10. Impact on standardization of product inventory

- D. If a product trial is indicated, the following guidelines apply:**

1. Establish a timeline for the trial
2. Identify the personnel and departments that should trial the product
3. Establish the amount of product that should be evaluated
4. Develop evaluation tools through the multidisciplinary committee identified above
5. Determine and implement the education and demonstrations needed for the trial
6. Define the desired outcome
7. Analyze the data and compare actual outcomes with desired outcomes

## DEVICE REPROCESSING TRANSITION PROCEDURE

*(continued...)*

### **VII. THIRD PARTY REFERENCES FOR HIGH-LEVEL DISINFECTION AND STERILIZATION:**

- A.** ANSI/AAMI ST79:2008. "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities." Arlington, VA: AAMI.
- B.** ANSI/AAMI ST58:2005. "Chemical Sterilization and High Level Disinfection in Health Care Facilities."
- C.** The Association of periOperative Registered Nurses (AORN), "Recommended Practices for Product Selection in Preoperative Practice Settings." Denver, CO: AORN. (2009).
- D.** Association for Professionals in Infection Control and Epidemiology (APIC) "Guideline for Disinfection and Sterilization in Health Care Facilities." Washington, D.C. APIC (2008).
- E.** Society of Gastroenterology Nurses and Associates, Inc (SGNA) "Guidelines for Use of High-Level Disinfectants and Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes." Chicago, IL: SGNA. (2009).
- F.** CDC "Guideline for Disinfection and Sterilization in Health Care Facilities, 2008", available on the CDC website.

### **VIII. RESPONSIBILITY:**

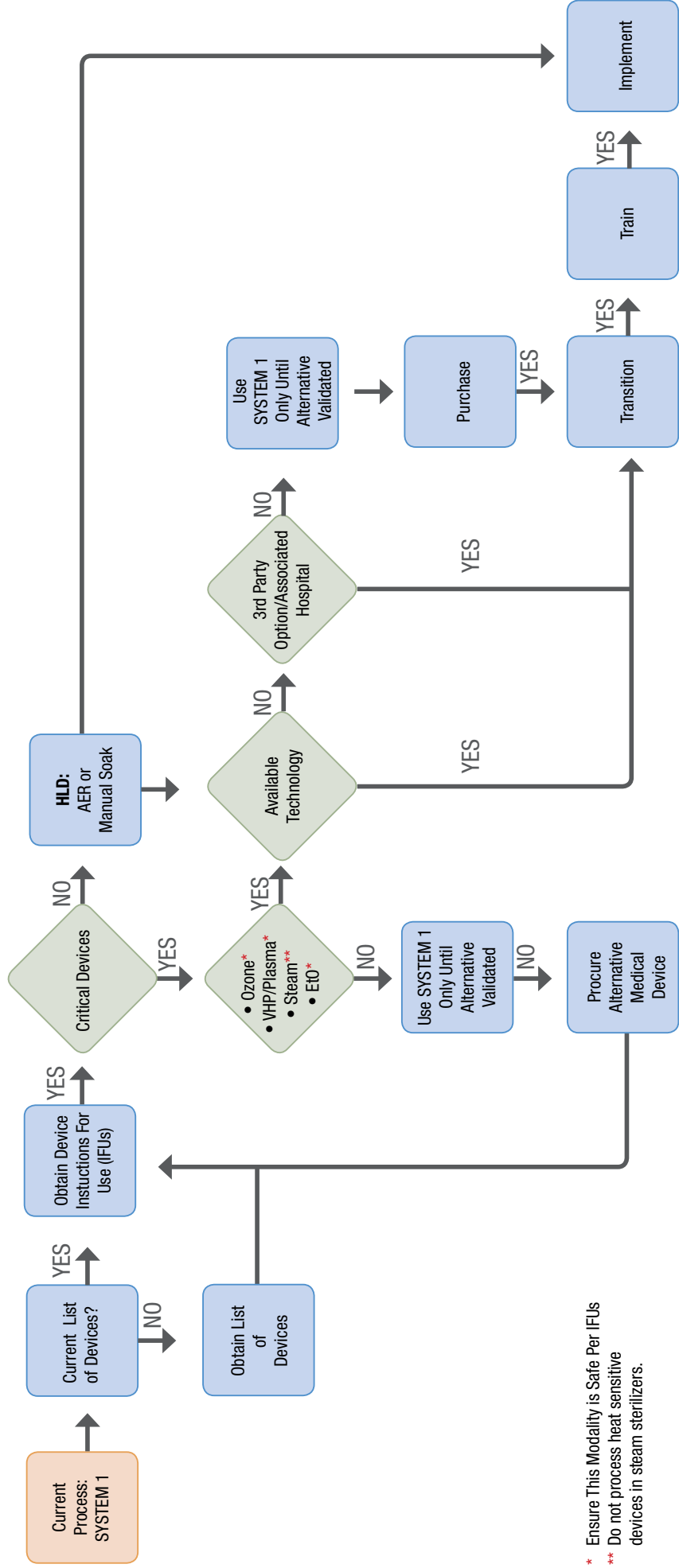
OR, endoscopy and sterile processing educators should be responsible for assuring that proper training is conducted with all employees responsible for the processing and sterilization of instruments and supplies in accordance with this work instruction.

The healthcare facility should be responsible for developing and/or revising this Transition Guidance document in accordance with the infection control department; sterilization policy; current industry standards; regulatory requirements; and manufacturers' recommendations.

Service and maintenance of sterilizers should be the responsibility of the clinical engineering department. The cleaning of the outside surface should be the responsibility of sterile processing.

# SYSTEM 1 Transition Decision Tree

This flow design was developed to help facilitate a smooth transition to an alternative Sterilization or High Level Disinfection process for your current reusable medical devices being sterilized with your SYSTEM 1. Please use in accordance with the device manufacturer's instructions for use to include all cleaning and sterilization parameters.



\* Ensure This Modality is Safe Per IFUs  
 \*\* Do not process heat sensitive devices in steam sterilizers.

- **Current Process: SYSTEM 1** - Identify the total number of SYSTEM 1 units installed in your healthcare facility.
- **Current List of Devices?** - Do you have a complete list of reusable medical devices currently being processed through SYSTEM 1?
- **Obtain List of Devices** - Compile a list of all reusable medical devices currently being processed through SYSTEM 1 and obtain the necessary original equipment manufacturer's instructions for use (IFUs) for these devices.
- **Critical Devices or Hospital Policy** - Is the reusable medical device a critical device or does hospital policy dictate this device be sterilized prior-to-use?
- **EtO, Ozone, VHP/Plasma, Steam** - Based on the original equipment manufacturer's instructions for use is there an alternative modality of sterilization available?

- **Use SYSTEM 1 Only Until Alternative Validated** - The original equipment manufacturer for this device has specified SYSTEM 1 is the only sterilization method identified for sterilization.
- **Procure Alternative Medical Device** - Is there an alternative medical device available to support the medical procedure?
- **HLD: AER or Manual Soak** - If the device is identified as semi-critical and hospital policy will support High-Level Disinfection, you may then implement the use of an AER or manual soaking method.
- **Available Technology** - Does the alternative sterilization modality currently exist in your healthcare facility?
- **3rd Party Option/Associated Hospital** - Is there a 3rd party sterilization service in your area, or an associated healthcare facility currently using the alternative sterilization technology you seek?

- **Use SYSTEM 1 Only Until Alternative Validated** - Continue using SYSTEM 1 until an alternative sterilization method has been validated.
- **Purchase** - Once the alternative sterilization technology has been identified, pursue procurement options (once equipment specifications have been reviewed and can be satisfied given existing footprint).
- **Transition** - Install alternative sterilization technology.
- **Train** - Assure all staff and equipment operators are properly trained on the operation of said equipment, to include any accessories and new sterility assurance products supporting the alternative sterilization technology.
- **Implement** - Implement alternative sterilization technology.



## CONSIDERATIONS FOR REPLACING SYSTEM 1

In order to help Customers determine an appropriate alternative to SYSTEM 1, STERIS provides this summary of some of the available alternative technologies:

### CRITICAL DEVICES

- Ethylene Oxide Sterilization
- Steam Sterilization
- Ozone Sterilization
- Hydrogen Peroxide Gas or Plasma Sterilization

### SEMI-CRITICAL DEVICES

- Automated Endoscope Reprocessor: High-Level Disinfection
- Basin Soak: High-Level Disinfection

## ALTERNATIVE REPROCESSING TECHNOLOGIES

There are several relevant factors to evaluate in the transition decision-making process. The following matrix provides a high level comparison of the impact of selecting a particular technology. These factors include (but are not limited to): ability to re-process devices that are currently labeled for SYSTEM 1; time constraints; device inventory; labor issues (including worker safety); and relative cost.

Once it has been determined which appropriate alternative technology/product will meet the requirements of the task, Customers will need to implement a training plan. This will ensure consistency in performing all of the necessary steps to achieve a sterile or disinfected device.

**THE FOLLOWING TABLE INCLUDES OUR ASSESSMENT OF THE APPLICABILITY OF ALTERNATIVE MEANS OF STERILIZING DEVICES CURRENTLY PROCESSED IN SYSTEM 1. MOST ETO STERILIZERS HAVE NOT BEEN CLEARED FOR MARKETING WITH SPECIFIC LUMEN CLAIMS STATING THE LENGTH AND DIAMETER OF THE LUMEN DEVICES WHICH CAN BE EFFECTIVELY REPROCESSED IN AN ETO STERILIZER. IF THE INSTRUCTIONS FOR USE OF THE ETO STERILIZER DO NOT SPECIFY WHAT LUMEN DEVICE SPECIFICATIONS CAN BE EFFECTIVELY STERILIZED, THEN ETO SHOULD BE USED ONLY IF THE DEVICE MANUFACTURER CAN PROVIDE VALIDATED ETO REPROCESSING CYCLE PARAMETERS WHICH ARE COMPATIBLE WITH THE ETO STERILIZER AVAILABLE TO THE USER.**

## ALTERNATIVE REPROCESSING TECHNOLOGIES

(continued...)

ALTERNATIVE	ABILITY TO REPROCESS SYSTEM 1 LABELED DEVICES	CYCLE TIME	DEVICE INVENTORY	ADDITIONAL STEPS*	WORKER SAFETY	RELATIVE COST
<b>OZONE</b>	Medium	Approximately a 4 hour cycle time	Potential to require greater inventory investment	Devices must be wrapped, transported for processing and returned to the point-of-use	This is a safe technology	Operating cost is low. Acquisition cost is high. The technology requires installation of a source of oxygen. Facility modifications will be required for installation
<b>HYDROGEN PEROXIDE</b>	Low	30 - 60minutes	Potential to require greater inventory investment	Devices must be wrapped, transported for processing and returned to the point-of-use	This is a safe technology	Operating cost is moderate. Acquisition cost is high. Facility modifications may be required for installation
<b>ETHYLENE OXIDE (EtO)</b>	High**	Cycle times are 12 hours or greater. Ensure users have and understand the EtO manufacturer's parameters	Greater investment in device inventory to compensate for lengthy cycle-time	Devices must be wrapped, transported for processing and returned to the point-of-use	Ethylene oxide is a known carcinogen. OSHA has extensive monitoring and documentation requirements for use of this technology. EPA also has requirements for the use of this technology	Operating cost is relatively low. Acquisition cost is high. Indirect costs for additional inventory and monitoring are high. Facility modifications will be required for installation
<b>STEAM STERILIZATION</b>	Low	Cycle times are 45 minutes to 1 hour.	This will need to be carefully assessed by the facility	Devices must be wrapped, cooled, transported and returned to the point-of-use	This is a safe technology	Operating cost is relatively low
<b>HIGH LEVEL DISINFECTION: AER</b>	High for flexible endoscopes only	Times vary significantly by manufacturer and product	No impact	Devices must be cleaned and prepared according to manufacturer's instructions for reprocessing	This is a safe technology	Operating cost is low. Acquisition cost is high. Facility modification may be required for installation
<b>HIGH LEVEL DISINFECTION: BASIN SOAK</b>	High	10 - 20+ minutes	No impact	All aspects of this process are manual. Processing staff training, detailed written instructions and close supervision are advised to ensure consistent results	Product has to be appropriately ventilated. PPE must be employed to minimize risk of exposure to aldehyde based solutions	Operating cost is low

\* "For all sterilization and disinfection methods, flexible and rigid endoscopes must be pre-cleaned, inspected, leak tested and manually cleaned according to the recommendations of the manufacturer."

\*\* Dependant on using a validated cycle, see page 7.

## ALTERNATIVE REPROCESSING TECHNOLOGY VENDORS

The sterilization and high-level disinfection tables below list industry leading companies that provide acceptable alternatives to SYSTEM 1\*. It is the responsibility of each healthcare institution to validate all devices that are to be processed in each one of these alternative technologies, according to manufacturer’s instructions for use. FDA has recommended that the healthcare provider also verify that alternative technologies have FDA clearance.

### STERILIZATION

TYPE	APPLICATION (CONSULT DEVICE MANUFACTURER'S INDICATIONS FOR USE)	AVAILABLE FROM STERIS WWW.STERIS.COM 1-800-548-4873	LEADING SUPPLIERS	WEBSITE
Eto (ETHYLENE OXIDE)	Heat-sensitive, immersible devices	Yes	STERIS 3M	steris.com 3m.com
VHP (Vaporous Hydrogen Peroxide)	Heat-sensitive, immersible devices	Yes	STERIS STERRAD	steris.com sterrad.com
Ozone	Heat-sensitive, immersible devices	No	TSO <sup>3</sup>	tso3.com
Steam Sterilization	Devices not sensitive to heat	Yes	STERIS Getinge Belimed	steris.com getinge.com belimedusa.com

### HIGH LEVEL DISINFECTION

TYPE	APPLICATION (CONSULT DEVICE MANUFACTURER'S INDICATIONS FOR USE)	AVAILABLE FROM STERIS WWW.STERIS.COM 1-800-548-4873	ALTERNATE SUPPLIERS	WEBSITE
<b>HLD CHEMISTRY</b>	Semi-Critical Devices			
<b>ALDEHYDE CHEMISTRIES</b>				
<b>GLUTARALDEHYDE</b>	Heat-sensitive, immersible devices	No	Medivators Metrex ASP	minntech.com metrex.com aspji.com
<b>ORTHO-PHTHALALDEHYDE</b>	Heat-sensitive, immersible devices	No	Metrex ASP	metrex.com aspji.com
<b>OXIDATIVE CHEMISTRIES</b>				
<b>HYDROGEN PEROXIDE</b>	Heat-sensitive, immersible devices	Yes – Resert HLD High Level Disinfectant	N/A	steris.com
<b>PERACETIC ACID</b>	Heat-sensitive, immersible devices	Yes – Reliance EPS as a validated system (see below)	Medivators	steris.com minntech.com
<b>AER</b>				
<b>MEDIVATORS</b>	Heat-sensitive, immersible devices	No	Medivators	minntech.com
<b>CUSTOM ULTRASONICS</b>	Heat-sensitive, immersible devices	No	Custom Ultrasonics	customultrasonics.com
<b>ASP</b>	Heat-sensitive, immersible devices	No	ASP	aspji.com
<b>STERIS RELIANCE EPS</b>	Heat-sensitive, immersible devices	Yes – Peracetic Acid	N/A	steris.com

\* “List of suppliers is not intended to be comprehensive. Per the December 10, 2009 FDA teleconference, additional information on available technologies will be forthcoming from FDA.”

## ADDITIONAL SOURCES OF INFORMATION

### STERILIZATION STANDARDS & GUIDELINES

Organization	Website
AAMI – Association for the Advancement of Medical Instrumentation (ANSI/AAMI ST79:2006)	<a href="http://www.aami.org">www.aami.org</a>
AORN – Association of Operating Room Nurses	<a href="http://www.aorn.org">www.aorn.org</a>
APIC – Association for Professionals in Infection Control	<a href="http://www.apic.org">www.apic.org</a>
SGNA – Society of Gastroenterology Nurses and Associates	<a href="http://www.sgna.org">www.sgna.org</a>

## STERIS SUPPORT DURING THE TRANSITION

STERIS Corporation is taking several steps to provide support during your transition from SYSTEM 1 to an acceptable alternative reprocessing method:

- We have established a **SYSTEM 1 Hotline** to address healthcare provider questions. Please call 1-800-548-4873.
- Your local STERIS representative can also answer your SYSTEM 1 inquiries.
- We are publishing constant updates on our website at [www.steris.com/SS1](http://www.steris.com/SS1).



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