Sterilization quality control in the clinic setting

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To provide the best possible patient outcomes and because accreditation bodies are paying closer attention to the processing of reusable medical devices, it is important that clinics reprocessing medical devices, whether in an independent practice or an office affiliated with a larger healthcare system, are familiar with current recommended practices. ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities, is the ‘go to’ document for steam sterilization, including table-top sterilizers often used in clinics.

A table-top sterilizer is defined in AAMI ST79 as a “Compact steam sterilizer that has a chamber volume of less than or equal to 2 cubic feet and that generates its own steam when distilled or deionized water is added by the user.”1 It is an essential piece of equipment in many office-based medical and dental practices and small ambulatory-care clinics. Across the country, many health care systems have initiatives to standardize reprocessing of medical devices throughout their system. As part of this standardization effort, Sterile Processing Managers and/or Infection Preventionists typically identify all the various locations that perform device reprocessing in their system and work to ensure that common policies and procedures are adopted system-wide. The 3M Sterilization Tech Line often hears from systems which have recently identified or acquired clinics using table-top steam sterilizers. We also have frequent discussions with clinics determined to implement best practices. Both groups have questions about appropriate sterilization quality control procedures. This article will review the quality control practices specific to table-top sterilizers provided in the recently published AAMI ST79:2017.

The Joint Commission
One of the drivers for health care systems to standardize device reprocessing system-wide is The Joint Commission’s Standard IC 02.02.01 which states, “The hospital reduces the risk of infections associated with medical equipment, devices, and supplies.”2 The rationale for this standard is based on the infection risk posed to patients if medical devices are improperly cleaned and sterilized. The standard recommends implementation of standard processes which address:

• “Orientation, training, and competency of health care workers who are processing medical equipment, devices and supplies
• Level of staffing and supervision of the health care workers who are processing medical equipment, devices, and supplies
• Standardization of process regardless of whether it is centralized or decentralized
• Reinforcing the process (for example, the use of placards which list the steps to be followed, according to the manufacturer’s guidelines)
• Ongoing quality monitoring”2

Centers for Disease Control
Recognizing the opportunity for improved infection prevention practices in the non-hospital setting, in 2016 the CDC published Version 2.3 of their summary guide entitled, “Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care.”3 A companion Infection Prevention Checklist for Outpatient Settings (included in the document as Appendix A) reminds the reader that:

• “Critical items (e.g., surgical instruments) are objects that enter sterile tissue or the vascular system and must be sterile prior to use.”
• “Cleaning must always be performed prior to sterilization and/or disinfection.”
• “Single-use devices (SUDs) are labeled with the manufacturer for a single use and do not have reprocessing instructions. They may not be reprocessed for reuse except by entities which have complied with FDA regulatory requirements and have received FDA clearance to reprocess specific SUDs.”3

The checklist can be used by office-based practices to conduct a self-audit on their reusable device reprocessing. In addition to the checklist items specific to sterilizer quality control, broader questions about device reprocessing include:

• “Policies, procedures, and manufacturer reprocessing instructions for reusable medical devices used in the facility are available in the reprocessing area(s)
• HCP [Healthcare Personnel] responsible for reprocessing reusable medical devices receive hands-on training on proper selection and use of PPE and recommended steps for reprocessing assigned devices: i. Upon hire, prior to being allowed to reprocess devices ii. Annually iii. When new devices are introduced or policies/procedures change.

• After cleaning, instruments are appropriately wrapped/packaged for sterilization (e.g., package system selected is compatible with the sterilization process being performed, items are placed correctly into the basket, shelf or cart of the sterilizer so as not to impede the penetration of the sterilant, hinged instruments are open, and instruments are disassembled if indicated by the manufacturer).

• Sterile packs are labeled with a load number that indicates the sterilizer used, cycle or load number, date of sterilization, and, if applicable, the expiration date.

• After sterilization, medical devices and instruments are stored so that sterility is not compromised.

The entire checklist is available for free at the link provided in reference 3 at the end of this article. Why not schedule sometime during the week to perform a self-audit?

Routine load release
All steam sterilizers used for processing of patient-care items, including table-top steam sterilizers in office-based locations, should be routinely monitored with a variety of monitoring tools including physical monitors, chemical indicators (CIs), biological indicators (BIs), and process challenge devices (PCDs). Personnel operating table-top steam sterilizers should be consciously deciding whether to release each load based on the results of these monitoring tools.

Physical monitors are the charts, gauges and printouts on the equipment that provide real-time measurements of time, temperature, and pressure. Physical monitors verify that the correct parameters of the sterilization cycle were delivered and tell the operator whether or not the correct sterilization cycle was selected. After each cycle, a trained and knowledgeable operator should read and initial the cycle printout to verify that the correct cycle was selected and the cycle ran properly. AAMI ST79, Section 13.5.1 states: “Sterilizers that do not have recording devices should not be used, with the exception of sterilizers used together with accessory recording devices or printouts.”

Self-assessment
Is your sterilizer equipped with a printer? If not, can one be purchased as an accessory?

External CIs are used to distinguish processed from unprocessed medical devices at a glance. Steam sterilization indicator tape is an example of an external chemical indicator. AAMI ST79 Section 13.5.2.2.1 recommends that all packages should have a Type 1 external CI unless the internal CI is visible. If the external CI is not changed, the package should not be used. Internal CIs verify that steam penetrated to the location of the instruments inside each package. AAMI ST79 Section 13.5.2.2.2 recommends, “One or more internal chemical indicators should be placed within each package, tray, or rigid container. These indicators can be any type (Type 3, 4, 5, or 6) but preferably a Type 5 or Type 6 indicator because these types of CIs provide the user with more information on the critical steam sterilization parameters.” The results of internal CIs should be interpreted by trained and knowledgeable health care professionals at the point of use before the items are used for patient care. If the internal CI does not show an acceptable result, the items in the package should not be used.

Biological indicators (BIs) contain a large population of live spores that are highly resistant to the sterilization process. In the case of steam sterilizers, the use of BIs containing Geobacillus stearothermophilus spores is recommended. AAMI ST79 Section 13.5.3.1 states, “Biological indicators are the only sterilization process monitoring device that provide a direct measure of the lethality of the sterilization process.” Self-contained BIs consist of spores on a carrier and an ampoule of growth media both enclosed in an outer sleeve. After sterilization, the BI is activated (exposing the spores to the growth media) and incubated. If the microorganisms fail to grow in the specified incubation period, a negative result is recorded and it is concluded that the sterilization process was successful. Consult with the sterilizer and BI manufacturers to ensure that you are using a suitable BI for the table-top sterilizer cycle(s) being tested. The use of rapid readout biological indicators facilitates completion of biological testing and documentation right in the clinic within hours.

Routine sterilizer efficacy testing
To ensure they are able to effectively sterilize medical devices, all sterilizers should be routinely tested with a BI PCD. AAMI ST79 recommends that a BI PCD be used weekly and preferably each day the sterilizer is used. While the frequency of routine BI PCD testing is an element large systems may try to standardize, the BI PCD itself cannot be standardized. For table-top sterilizers, the user constructs a PCD that is representative of the type of package or tray that is routinely processed (see AAMI ST79, Section 13.7.5). The PCD should contain both a BI, a CI, and the items normally present in the package or tray. Each type of cycle used should be tested. For example, if the sterilizer is used to run small wrapped packs at 250°C (121°F) and pouched items at 270-275°C (132-135°C), each cycle should be tested with a representative BI PCD. The PCD is placed in a full load in the ‘cold point’, typically the center of the load. AAMI ST79, Section 13.7.3.2, recommends the PCD be placed, “on its edge if it is a small pack or flat if it is a tray or large pack.” In addition to routine efficacy testing, a BI PCD should be used in each load containing implants, and the implants should be quarantined until the result of the BI is known.

Sterilization process failures
A sterilization process failure can be indicated by a failed physical monitor, a failed CI from a PCD, or a positive result for a test BI. AAMI ST79 provides guidance on actions to take when investigating a sterilization process failure in Section 13.7.5. This section states, “If the cause of the failure is not immediately identified, the load should be quarantined, and all loads back to the last negative BI should be recalled. Items in these loads should be retrieved, if possible, and reprocessed (see 13.7.5.2). The sterilizer in question should be taken out of service until the cause of the failure is identified and corrected.” Many clinics consider the impact of executing a recall when establishing their BI monitoring frequency.

Documentation
The sterilizer quality control process includes documentation tasks. Each package should be traceable to the load in which it was sterilized. This is usually accomplished by labeling each package with a lot control number including the sterilization date, the sterilizer number, and the load number. AAMI ST79 recommends that the
following information be recorded and maintained for each sterilization cycle:

a. the lot number;

b. the specific contents of the lot or load;

c. the exposure time and temperature, if not provided on the sterilizer recording chart;

d. the name or initials of the operator;

e. the results of biological testing, if applicable;

f. the results of Bowie-Dick testing, if applicable;

g. the response of the CI placed in the BI PCD, if applicable; and

h. any reports of inconclusive or nonresponsive CIs found later in the load.1

As mentioned earlier, the sterilizer printer tape should be reviewed and signed by the operator.

In addition to sterilization cycle records, AAMI ST79 recommends keeping a maintenance record for each sterilizer. The sterilizer instruction manual should provide guidance on routine care, preventive maintenance and calibration of the sterilizer. The maintenance record may be in paper or electronic format and should provide a continuous history of all scheduled and unscheduled service. (Section 12.7)

### Summary

Critical devices must be sterilized before use. Table-top steam sterilizers play a key role in device sterilization in office-based medical and dental clinics. Quality control practices for table-top sterilizers in clinics therefore deserves the same attention to detail applied in hospital and ambulatory surgery center sterile processing departments. Fortunately, AAMI ST79 provides guidance on testing and documenting the test results for steam sterilizers used in clinic settings. A comprehensive quality control program includes routine sterilizer efficacy testing, routine load release (using physical monitors, CIs, and BI PCDs), qualification testing, and proper documentation. Accreditation bodies continue to pay close attention to device reproprocessing, wherever it is being done. To get a head start on preparing for your next accreditation survey, take advantage of the CDC’s free “Infection Prevention Checklist for Outpatient Settings: Minimum Expectations for Safe Care”3 to assess your facility’s compliance to recommended device reproprocessing practices. HPN

### Common sterilization quality control questions from the clinic setting

**Q. Should we use a commercial BI test pack, like the main hospital does, to test our table-top sterilizer?**

**A.** No, commercially available pre-assembled BI Process Challenge Devices (BI PCDs) are equivalent in challenge to the 16-towel PCD and are used to monitor sterilizers larger than 2 cubic feet. There is not a standardized pre-assembled PCD for table-top sterilizers. AAMI ST79 Section 13.7.3 recommends the use of a representative PCD i.e., that the user construct a PCD of the same type of package or tray that is routinely processed through the sterilizer. For example, if a clinic’s typical loads consist of instruments packaged in peel pouches, then the appropriate BI PCD would consist of a BI, a CI, and a representative instrument placed in a peel pouch.

**Q. How often should we test the sterilizer with a biological indicator?**

**A.** AAMI ST79 recommends routine sterilizer efficacy monitoring with a BI PCD be conducted weekly, but preferably each day that the sterilizer is used. Most table-top sterilizers have several cycle options and AAMI ST79 recommends testing each cycle type that is used. Any loads containing implants should also be monitored with a BI PCD and the implant should be quarantined until the BI result is available. If there is a sterilization process failure, AAMI recommends the recall of all loads back to the last negative biological indicator. Many facilities elect to monitor more frequently than AAMI recommends to ensure uniform patient care, and avoid difficult and costly recalls that can include physician and patient notifications.

**Q. Should we run a Bowie-Dick test in our table-top sterilizer?**

**A.** A Bowie-Dick type test is used to test the ability of a dynamic-air-removal steam sterilizer to remove air from the chamber and prevent air re-entrainment. Daily Bowie-Dick testing is therefore not required for gravity-displacement table-top steam sterilizers. Many table-top sterilizers do feature dynamic-air removal and utilize either the steam-flush pressure-pulse (SFP) or the pre-vacuum method of air removal. In this case of SFP cycles, AAMI ST79 suggests consulting the sterilizer manufacturer to determine if a daily Bowie-Dick test is recommended.

**Q. What is a control BI? Where do I get the control BI?**

**A.** A control BI is a biological indicator from the same lot used for testing the sterilizer that is left unexposed to the sterilant, and incubated to verify the viability of the spores, the proper incubation temperature of the incubator, and the ability of the growth media to support growth of the spores. A positive control should be incubated each day that a test BI is incubated. The control BI should give a positive result in order for the result from the test BI to be considered valid.

Practical application: A minimum of two biological indicators will be used each day a table-top sterilizer is tested. One BI serves as the control and is taken straight from the box, activated and incubated. The other ‘test’ BI is placed in a representative PCD, processed with a full load, then activated and incubated following the BI manufacturer’s instructions. Acceptance criteria for this routine testing include a positive result for the positive control BI and a negative result for the test BI.

**Q. How do we qualify our new table-top sterilizer?**

**A.** Qualification testing of table-top sterilizers should be conducted after sterilizer installation, relocation, malfunctions, major repairs, and sterilization process failures. As with routine testing, representative BI PCDs are selected and assembled. The BI PCD is placed in the ‘cold spot’ in the chamber and run in three consecutive full loads. Load items from the three qualification runs should be quarantined until the BI results are negative. For dynamic-air-removal table-top sterilizers, check with the manufacturer to see whether they recommend that qualification testing also include three consecutive cycles with a Bowie-Dick test pack. Acceptance criteria include sterilizer printouts indicating complete cycles, appropriate chemical indicator results, and negative results from the test BIs.1

**Q. How do we achieve traceability of load items?**

**A.** AAMI ST79 recommends that each item be labeled with a lot control identifier prior to sterilization. A load sticker can be used to document the sterilizer ID number, date of sterilization, and cycle number.
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Circle the one correct answer:

1. Improperly cleaned and sterilized medical devices can pose a risk to patient safety.
   A. True  B. False

2. It is not necessary to keep a maintenance record for table-top sterilizers.
   A. True  B. False

3. A positive control BI having the same lot # as the test BI should be incubated each day that the sterilizer is tested.
   A. True  B. False

4. The Joint Commission has an expectation that sterilization processes be standardized throughout a facility.
   A. True  B. False

5. According to the CDC, healthcare personnel responsible for reprocessing medical devices should receive hands-on training annually.
   A. True  B. False

6. Qualification testing of table-top sterilizers includes running three consecutive full loads with a representative BI PCD.
   A. True  B. False

7. Any sterilization loads containing implants should be monitored with a BI PCD.
   A. True  B. False

8. Bowie-Dick testing should be done daily in gravity-displacement table-top steam sterilizers.
   A. True  B. False

9. Commercially available pre-assembled BI PCDs, equivalent in challenge to the AAMI 16 towel PCD, are used for routine monitoring of table-top sterilizers.
   A. True  B. False

10. Sterile packs should be labeled with the sterilizer, the cycle or load number, and the date of sterilization.
    A. True  B. False

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References
2. The Joint Commission. 2018 Hospital Accreditation Standards.

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