Learning Objectives

1. Review the importance of device reprocessing in the non-hospital setting.

2. Discuss the recommended quality control practices for table-top sterilizers provided in AAMI ST79.

3. Describe the appropriate biological indicator process challenge device (BI PCD) for table-top sterilizers.

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Table-top steam sterilizers: quality control considerations

by Susan Flynn, 3M Health Care

A table-top sterilizer, defined in ANSI/AAMI ST79 as a “Compact steam sterilizer that has a chamber volume of not more than 2 cubic feet and that generates its own steam when distilled or deionized water is added by the user,” is an essential piece of equipment in many office-based medical and dental practices and small ambulatory-care clinics. Some of these facilities are independent and others are affiliated with large health care systems. Across the country, many health care systems have initiatives to standardize reprocessing of medical devices throughout their system. As part of this effort, Sterile Processing managers and/or Infection Preventionists are determining the various locations that perform device reprocessing and working to ensure common policies and procedures are adopted system-wide. In many cases, clinics using table-top steam sterilizers are part of the mix and questions arise about appropriate quality control practices.

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 users of table-top sterilizers, whether in an independent practice or a clinic affiliated with an Integrated Delivery Network, are current on recommended practices associated with the use of this critical tool. AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities, is the ‘go to’ document for steam sterilization, including that done in table-top sterilizers. This article will review the quality control practices specific to table-top sterilizers discussed in AAMI ST79.

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.” The rationale for this standard discusses the risk posed to patients if medical devices are improperly cleaned and sterilized and recommends implementing standard processes which take into consideration:

- “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.”

Centers for Disease Control

Recognizing the opportunity for improved infection prevention practices in the non-hospital setting, in 2011 the CDC published a summary guide entitled, “Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care”2. A companion checklist3 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;
- Pre-cleaning must always be performed prior to sterilization and/or disinfection;
• Single-use devices (SUDs) are labeled by 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.”

The checklist can be used by office-based practices to conduct a self-audit on their reusable device reprocessing. In addition to 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 are appropriately trained and competencies are regularly documented (at least annually and when new equipment is introduced);
• Training and equipment are available to ensure that HCP wear appropriate PPE to prevent exposure to infectious agents or chemicals (PPE can include gloves, gowns, masks, and eye protection);
• After pre-cleaning, instruments are appropriately wrapped/packaged for sterilization (e.g., package system selected is compatible with the sterilization process being performed, hinged instruments are open, instruments are disassembled if indicated by the manufacturer);
• Sterile packs are labeled with the sterilizer used, the cycle or load number, and the date of sterilization;
• 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 the references at the end of this article.

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). Operators of table-top steam sterilizers should be consciously making a decision 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 parameters of the sterilization cycle have been met and tell the operator whether or not the sterilizer is doing its job properly. After each cycle, a trained and knowledgeable operator should read and initial the cycle printout to verify that all cycle parameters were met.

Figure 2: Typical BI PCDs for table-top steam sterilizers

AAMI ST79, Section 10.5.1 states: “Sterilizers that do not have recording devices should not be used.”

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 recommends that an external CI be used on the outside of each package 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 recommends that an external CI be used on the outside of each package containing implants, and the implants should be quarantined until the result of the BI is known.

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 tabletop sterilizers, the user constructs a PCD that is representative of the type of package or tray that is routinely processed. See Figure 2 for examples of the BI PCDs usually in table-top steam sterilizers. Each type of cycle mode used should be tested. For example, if the sterilizer is used to run small wrapped packs at 250°C (121°F) and pouches at 270-275°F (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.

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:

1. the lot number;

See SELF-STUDY SERIES on page 56
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 ap- 
plicable;  
f) the results of Bowie-Dick testing, if ap- 
plicable;  
g) the response of the CI placed in the BI 
PCD, if applicable; and  
h) any reports of inconclusive or nonre- 
sponsive CIs found later in the load.1  

As mentioned earlier, the sterilizer print- 
er tape should be reviewed and signed by 
the operator.  

Water quality  
While large steam sterilizers used in hos- 
pitals normally rely on steam generated 
by a remote boiler, table-top sterilizers 
typically generate their own steam and are 
therefore less subject to the variations in 
steam quality that can present challenges 
to those operating larger sterilizers. Input 
water quality, however, is important and 
AAMI ST79 therefore includes the follow- 
ing important reminder: “Table-top steam 
sterilizers generate their own steam. The 
user should carefully follow the sterilizer 
manufacturer’s written IFU regarding wa- 
ter purity requirements, filling, draining, 
and general maintenance of the system. 
Distilled or deionized water is generally 
recommended to help prevent the buildup 
of minerals in the sterilizing system and to 
ensure the purity of the steam generated 
for sterilization.”1  

Summary  
Accreditation bodies are paying atten- 
tion to device reprocessing, wherever it 
is being done. Critical devices must be 
sterilized before use. Table-top steam ster- 
ilizers play a key role in medical device 
sterilization in office-based medical and 
dental clinics. Quality control for table- 

top sterilizers therefore deserves the same 
attention to detail applied in hospital and 
ambulatory surgery center sterile process- 
ing departments. A comprehensive qual- 
ity control program for table-top steam 
sterilizers includes routine sterilizer ef- 
cy testing, routine load release (using 
physical monitors, CIs, and BI PCDs), 
qualification testing, and proper docu- 
mentation. Take advantage of the CDC’s 
free “Infection Prevention Checklist for 
Outpatient Settings: Minimum Expecta- 
tions for Safe Care”5 to assess your facil- 
ity’s compliance to recommended device 
reprocessing practices. 

References  
1. Association for the Advancement of Medical Instrumenta- 
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5. Centers for Disease Control and Prevention. Infection Preven- 
tion Checklist for Outpatient Settings: Minimum Expectations 

Susan Flynn is a Tech- 

nical Service Special- 

ist with 3M’s Infection 

Prevention Division in 

St. Paul, MN. Her role 
at 3M includes providing 
education for customers 

and sales personnel on 

improving the perfor- 

mance of the sterilization process and imple- 

menting best practices. In addition, she is a 

member of several AAMI working groups and 

writes sterilization related self-study articles. Flynn is a 

Certified Sterile Processing and 

Distribution Technician (CSPDT). 

Practical Application: A minimum of two bio-

logical 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 incu-

bated. The other ‘test’ BI is placed in a representa-

tive PCDs are selected and assembled. 

A representative 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 steril-
izers, 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

Common quality control questions for table-top sterilizers

Q. Should we use a pre-assembled 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 AAMI ST79 
recommends they be used to monitor sterilizers 
larger than 2 cubic feet. There is not a standard-
dized pre-assembled PCD for table-top sterilizers. 
AAMI ST79 Section 10.7.3 recommends each 
facility use 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 facility’s typical loads 
consist of instruments packaged in peel pouches, 
then the appropriate BI PCD would be a BI and 
a chemical indicator along with a representative 
instrument 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. Any loads containing implants should also be 
monitored with a BI PCD and the implant should be 
quarantined until the BI result is available. Consult 
with the sterilizer and BI manufacturers to ensure 
that you are using the correct BI for the cycle(s) 
being tested. 

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-entrain- 
ment. Daily Bowie-Dick testing is therefore not 
required for gravity-displacement table-top steam 
sterilizers. Some table-top sterilizers do feature dy-
amic-air removal and utilize either the steam-flush 
pressure-pulse (SFPP) or the pre-vacuum method 
of air removal. In this case, AAMI ST79 suggests 
consulting the sterilizer manufacturer to determine 
if a daily Bowie-Dick test is recommended. 

Q. What is a control BI?  

A. A control BI is a biological indicator from the 
same lot used for testing the sterilizer that is left 
exposed to the sterilant, and then incubated to 
verify the presterilization 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.

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Circle the one correct answer:

1. The Joint Commission has an expectation that sterilization processes be standardized throughout a facility.
   a. True    b. False

2. Table-top sterilizer manufacturers generally do not specify the type of water to be used.
   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. Improperly cleaned and sterilized medical devices can pose a risk to patient safety.
   a. True    b. False

5. According to the CDC, the competency of healthcare personnel responsible for reprocessing medical devices should be assessed 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 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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