

Sterile U Network

TUTORIALS

Quality Control for Table-top Steam Sterilizers

Introduction:

Many health care professionals in office-based settings are not aware that they are subject to the same standards and guidelines as hospitals and surgery centers. The AAMI *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* (ANSI/AAMI ST79:2006/A1:2008/A2:2009)¹ covers all health care facilities that perform steam sterilization including clinics and dental offices that use a table-top sterilizer. ST79 is a consolidation of five previous standards, including ANSI/AAMI ST42 *Steam sterilization and sterility assurance using table-top sterilizers in office-based, ambulatory-care medical, surgical, and dental facilities*.

What is a table-top steam sterilizer?

AAMI ST79 defines a table-top steam sterilizer as a compact steam sterilizer with a chamber volume of not more than 2 cubic feet. Most table-top sterilizers generate their own steam within the chamber; distilled or deionized water is added by the user. For steam of acceptable quality the sterilizer manufacturer's instructions must be followed regarding water purity requirements, filling and draining the reservoir, and general equipment cleaning and maintenance. Manufacturers generally "recommend distilled or deionized water to help prevent mineral buildup in the steam generating system and to ensure the purity of the steam generated for sterilization."¹

How do they work?

The majority of table-top sterilizers are gravity-displacement units but at least one model has dynamic-air-removal functions.² During the fill cycle of a gravity-displacement table-top sterilizer, water is released from the reservoir into the sterilizer chamber where it is electrically heated and vaporized into steam. After the sterilization cycle is completed, a condensation coil converts steam back into water. Some models are fully automatic and cycle through 'fill, sterilize, exhaust and dry cycles' but many require manual operation to move through the cycles. After the sterilizing cycle is completed, the door is opened slightly to allow moisture to escape and the dry cycle starts. Automated sterilizers have self-diagnostic software and use display codes to assist in troubleshooting. Trays and racks hold peel packs, cassettes and instruments away from the sterilizer sides and bottom.³ Manufacturers Pelton & Crane, Tuttnauer, Midmark/Ritter and SciCan have the majority of units in operation in the US.⁴

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Frequently Asked Questions:

1. What monitoring tools should be used for table-top steam sterilization cycles?

All steam sterilizers used for reprocessing 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).

Physical Monitors

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.

Some table-top sterilizers in office-based settings show the measurements from the physical monitors on a digital display but do not have recording devices (e.g., printout) that provide a permanent record. “Sterilizers that do not have recording devices should not be used,” according to section 10.5.1 of AAMI ST79.¹ Physical monitoring is needed to detect malfunctions as soon as possible, so that corrective actions can be taken. This is the first step in stopping the use of medical devices that may not be sterile.

External and Internal Chemical Indicators

External CIs are Class 1 process indicators used for Exposure Control to distinguish processed from unprocessed medical devices at a glance. Indicator tape is an example of an external CI. AAMI ST79 recommends that an external CI should 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 are used for Pack Control and verify that steam penetrated to the location of the instruments inside each package. AAMI ST79 recommends that a Class 3, 4 or 5 internal CI be placed in each package in the area least accessible to steam penetration, which may or may not be the center of the package.¹ 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.

Paper-plastic peel pouches are a common packaging material used in table-top steam sterilizers. If the internal CI in a paper-plastic peel pouch is visible, then an external CI is not needed. However, if a paper-plastic peel pouch is pre-printed with a Class 1 external CI, a Class 3, 4 or 5 internal CI is still needed.

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Biological Indicators

Biological indicators (BIs) contain live spores that are highly resistant to the sterilization process and provide information about the lethality of the sterilization cycle. They are used in PCDs (i.e., test packs or challenge packs) for the purpose of Load Control. The BI PCD is placed in the most challenging location in the sterilizer with a full load and provides information about the efficacy of the sterilization cycle. Routine sterilizer efficacy testing with a BI PCD is recommended weekly, preferably daily, and with all implant loads. Implants should be quarantined until the result of the BI is known.

2. How is routine BI testing conducted in a table-top steam sterilizer?

Biological indicator testing of a table-top sterilizer is conducted in a fully loaded chamber. The BI PCD should be representative of the load contents and placed in the “cold point” or area least favorable to steam sterilization. This area is typically the center of the load toward the front of the chamber but varies with sterilizer design; therefore, the manufacturer of the sterilizer should be consulted about placement of the BI PCD. All different cycle types used should be tested. For example, if a table-top sterilizer is used to run cycles at both 250°F and 270°F, then both of these cycles should be routinely tested with a BI PCD.

3. Can a pre-made commercially available FDA-cleared BI test pack be used to monitor a table-top steam sterilizer?

Since there are no commercially available BI PCDs designed for table-top sterilizers, the user must make his or her own BI PCD that represents the most challenging package configuration in the load. The BI PCD should also contain one or more CIs and items normally present during routine sterilization. For example, if routine loads contain instruments in peel pouches, then the appropriate BI PCD is a BI and a CI along with a representative instrument in a peel pouch. However, if wrapped sets are also routinely processed, then a “dummy” wrapped set that contains a BI and one or more CIs and representative instruments should be used as the BI PCD. This is because wrapped sets provide a greater challenge to steam penetration and air removal than peel pouches.

4. Which 3M™ Attest™ Biological Indicator should be used to monitor a table-top steam sterilizer?

When determining which 3M Attest Biological Indicator to use to monitor a table-top steam sterilizer, it is important to first identify the method of air removal and the cycle temperature. Most table-top steam sterilizers are gravity-displacement units that generate steam from water that the operator pours into a reservoir. Prevacuum table-top steam sterilizers that are connected to a boiler system are not as common.

Once you know the table-top sterilizer’s method of air-removal and the temperature of the cycles used, you can refer to the table below to identify which 3M Attest Biological Indicator products meet your needs.

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Air-removal method	Cycle Temp. °F	3M™ Attest™ BI Type	BI incubation time
Gravity	270 only	3M™ Attest™ 1261 Biological Indicator	24 hours
Gravity and Prevacuum	250 and 270	3M™ Attest™ 1262* Biological Indicator	48 hours
Gravity	270 only	3M™ Attest™ 1291** Rapid Readout Biological Indicator	1 hour
Gravity	250	3M™ Attest™ 1292** Rapid Readout Biological Indicator	3 hours
Prevacuum	270	3M™ Attest™ 1292** Rapid Readout Biological Indicator	3 hours

*3M™ Attest™ 1262 is universal for all table-top steam sterilization cycles

** Must be used in conjunction with 3M™ Attest™ 290 Auto-reader

5. How often do I need to incubate a positive control biological indicator?

AAMI ST79 recommends that a positive control BI be incubated every day a test BI is run. If several test BIs from the same lot are run on the same day, only one control BI from that lot needs to be incubated.

Incubating a positive control BI for a visual color-change result ensures that:

- the temperature of the incubator or Auto-reader is correct;
- the viability of the spores has not been altered due to improper storage temperature, humidity, or proximity to chemicals; and
- the culture media is capable of supporting growth.

The lot number of the control must match the lot number of the test BIs. If a new lot of BIs is opened during the day, a new positive control should be incubated. Keep in mind that if you use two types of BIs to monitor your table-top steam sterilizer, you need to incubate a positive control for each BI type used that day.

A positive control is a BI that is not sterilized; therefore, the spores should all be viable. When the control yields a positive result, this ensures that the processed or sterilized BI results are valid. This is important because you want to be sure that you are able to detect spores that survive the sterilization process. Running a positive control BI is good science – it is the quality assurance step that ensures the test BI results throughout the day are accurate.

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6. Are Bowie-Dick test packs used to monitor table-top steam sterilizers?

Bowie-Dick tests are a type of chemical indicator used in dynamic-air-removal (i.e., prevacuum) steam sterilizers for Equipment Control. The Bowie-Dick test monitors the efficacy of the vacuum system at removing residual air from the sterilizer chamber and it also detects air reentrainment. Inadequate air removal interferes with adequate sterilization. The Bowie-Dick test can detect inadequate air removal caused by inadequate vacuum, inadequate steam penetration, air leaks, and non-condensable gases in the steam. The Bowie-Dick test is conducted in an empty chamber and the recommended frequency for routine sterilizer efficacy monitoring is daily before the first processed load. If a table-top steam sterilizer is connected to the boiler system and has prevacuum capability, it should be tested daily with a Bowie-Dick test pack. If you are uncertain whether or not to run a Bowie-Dick test in your sterilizer, check with the sterilizer manufacturer.

7. When and how should qualification testing be done for table-top steam sterilizers?

As with other types of steam sterilizers used in a health care setting, qualification testing of table-top sterilizers should be conducted after sterilizer installation, relocation, major repairs, and malfunctions, and after sterilization process failures. For qualification testing of a table-top sterilizer, a representative BI PCD should be run in three consecutive full loads and the load items should be quarantined until the BI results are negative. If a table-top steam sterilizer is connected to the boiler system and has prevacuum capability, qualification testing would also include three consecutive cycles with a Bowie-Dick test pack. Remember to document when and why qualification testing was conducted as well as the results of the BIs, CIs, and physical monitors used during the qualification testing.

8. What information should be documented for each steam sterilization cycle?

Each package must be traceable to the load in which it was sterilized. This is usually accomplished by labeling each package in each load with a lot control number including the sterilization date, the sterilizer number, and the load number. If the sterility of a load is later called into question, it is important that all of the packages from that load can be identified and pulled from use or recalled.

AAMI ST79 recommends that the following information should be recorded and maintained for each sterilization cycle:

- a) the lot number;
- b) the specific contents of the lot or load, including quantity, department, and a specific description of the items (e.g., towels, type/name of instrument sets);
- c) the exposure time and temperature, if not provided on the sterilizer recording chart;

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- 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 PCD (BI challenge test pack, BI challenge test tray, or CI challenge test pack), if applicable; and
- h) any reports of inconclusive or nonresponsive CIs found later in the load.¹

The physical monitors (e.g., digital printout) for each cycle should be dated and signed by the operator and saved in the sterilizer records. Additionally, a log of repairs and preventive maintenance should be maintained for each sterilizer. Sterilizer and load information may be maintained in a paper or electronic record keeping system.

Summary:

Table-top sterilizers play a key role in medical device sterilization in office-based medical and dental clinics. Monitoring of table-top sterilizers in an office-based health care setting deserves the same attention to detail applied in hospital and surgical center sterile processing departments. A comprehensive quality control program for table-top steam sterilizers includes routine sterilizer efficacy testing (using physical monitors, CIs, and BIs), qualification testing, and proper documentation.

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For more information, call the 3M Help Line: 1-800-228-3957

1. Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities, Association for the Advancement of Medical Instrumentation, ANSI/AAMI ST79:2006/A1:2008/A2:2009
2. <http://www.statim-autoclave.com/statim-quantum-sterilizer.asp>
3. <http://www.rpiparts.com/techtalk0018.htm>
4. <https://decs.nhgl.med.navy.mil/4QTR05/Productevaluations/durvey/sst.htm>



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