

Closure and Opening Protocols for Medical Facilities

Table-top sterilizers and sterility assurance monitors

Please contact your sterilizer manufacturer for questions related to extended storage/periods of inactivity and start-up recommendations, and follow individual state agency guidance where applicable.

Recommended sterility assurance products needed:

- Passport™ Plus Sterilizer Monitoring Mail-in Service (PP-012 / PP-052) or, SporView™ 10 In-Office BI System (SVT-050 – box of 50 BIs / NDB-060 BI incubator kit)
- STEAMPlus™ Type 5 Integrator (SSI-100)
- Sure-Check™ Self-Seal Sterilization Pouch (multiple sizes available)
- AirView™ II Bowie-Dick Test (MBD030) for Class/Type B dynamic air removal sterilizers

Prior to office closure:

- Clean and declutter all clinical and instrument reprocessing areas.
- Clean sterilizer(s) including loading equipment, and check gaskets and other parts for needed maintenance, per manufacturer's instructions for use (IFU). Replace worn or damaged parts if needed.
- Monitor sterilizers at least weekly by using a biological indicator. This should still be completed during times of limited treatment (medical emergencies).
- Steam sterilizers: Clean and descale the chamber, and close the unit following manufacturer's instructions for use. Drain the water reservoir.
- Conduct an inventory of all sterility assurance products you currently use. Be sure to factor for extra supplies to cover potential periods of unexpected shipment delays and higher than normal patient volume when re-opening.

Prior to re-opening:

Simplified approach

- Follow sterilizer manufacturer recommendations for returning unit to service following periods of inactivity, if applicable.
- If the weekly sterilizer biological indicator testing has not been conducted:
 - Run a biological indicator (BI) in all office sterilizers and mail-in for analysis or process in the office, depending on the system that the practice uses.
 - **Mail-in service**
This should be done a week or more prior to reopening. Please factor in the time required to obtain test results to determine when you must run the test.
 - **In-office BI system**
Most common medical practice in-office BI testing systems can be achieved in 10 to 24 hours and provide your facility, employees and patients with a piece of mind that a BI test has passed.
 - Run a type 5 integrator strip placed in a sterilization pouch in each sterilizer as an immediate assessment of sterilizer function. Type 5 integrators are equivalent in performance to a biological indicator and offer the highest level of sterility assurance of a chemical indicator. Note: this should not replace the need to run weekly use of BIs.

Prior to re-opening:

Best practice approach

- Follow sterilizer manufacturer recommendations for returning unit to service following periods of inactivity, if applicable.
- If the weekly BI sterilizer testing has not been conducted, it is strongly recommended to conduct a qualification testing of your sterilizer.
 - To get your steam table-top sterilizer(s) up running is to follow what is outlined in ANSI/AAMI ST79:2017 section 13.8.3 Qualification testing of table-top sterilizers (sterilizers having a chamber volume less than or equal to 2 cubic feet).
 - ST79 outlines that a process challenge device (PCD) should be representative of the items routinely processed in the sterilizer and contain a BI and chemical indicator (CI) (13.7.3.1). For medical practices this is typically a sterilization pouch or a tray wrapped in sterilization wrap.

Rationale: There currently are no standardized PCDs for table-top sterilizers. Therefore, a representative package that is routinely processed in the sterilizer is used as the PCD.

- Suggested examples and a product selection lists for composing a PCD using a sterilization pouch or a tray wrapped in sterilization wrap:
 - For dynamic-air-removal sterilizers (Class/Type B) using prevacuum technology**, monitoring of three consecutive cycles in an empty chamber with a Bowie-Dick test pack, if applicable (see 13.7.6).
Note: This does not apply to gravity steam sterilizers.
 - For all steam table-top sterilizers**, monitoring of three consecutive cycles in a fully loaded chamber with a PCD containing a biological indicator and a Type 5 Integrator.

Note: Due to the processing time of mail-in BI testing it is recommended to use a standard in-office BI system which will process BI results in 10 or 24 hours.

PCD system for in-office testing using a sterilization pouch

Ref. #	Description	Quantity
SVT-050	SporView™ 10 Self-Contained Steam Biological Indicators	50/Box
NDB-060	55-60 C Dry Block Incubator, 11mm <i>(Made outside of the USA.)</i>	1 Each
SCXS2	Sure-Check™ Self-Seal Sterilization Pouches 3.5 in x 5.25 in (8.9 cm x 13.3 cm)	200/Box
SSI-100	STEAMPlus™ Type 5 Integrators 4 in x 0.75 in Strip (10.2 cm x 1.9 cm)	100/Pack

PCD system for in-office testing using a wrapped sterilization tray

Ref. #	Description	Quantity
SW36	CSR Sterilization Wrap 36 in x 36 in (91.4 cm x 91.4 cm) (other sizes available)	250/Case
STLF24MM	Lead-Free Steam Indicator Tape 1 in x 60 yd (24 mm x 55 m) or	18 Rolls/Case
STLF18MM	0.75 in x 60 yd (18 mm x 55 m)	24 Rolls/Case
SVT-050	SporView™ 10 Self-Contained Steam Biological Indicators	50/Box
SSI-100	STEAMPlus™ Type 5 Integrators 4 in x 0.75 in Strip (10.2 cm x 1.9 cm)	100/Pack
NDB-060	55-60 C Dry Block Incubator, 11mm <i>(Made outside of the USA.)</i>	1 Each

Detailed testing procedures:

1. Load your sterilizer with a full load. Be sure to include external and internal chemical indicators with all packs as you would normally use and process.
2. Select your sterilization packaging material (pouch or sterilization wrap) to compose your PCD. Pick the packaging that best represents the package that is routinely processed in your practice.
 - PCD system for in-office testing using a sterilization pouch
 - Place BI and Type 5 integrator in the pouch and seal it following the pouch IFU.
 - PCD system for in-office testing using a wrapped sterilization tray
 - Place BI and Type 5 in tray that is typically used (keep instruments in tray)
 - Wrap tray with CSR sterilization wrap
 - Secure with sterilization indicator tape following the IFU
3. Place PCD in a fully loaded chamber. The PCD should be placed on its edge if it is a small pack (pouch PCD) or flat if it is a large pack (PCD). It should be positioned in the area of the sterilizer chamber that is least favorable to sterilization (check IFU). This area, the "cold point," varies with sterilizer design but is normally in the center of the load toward the front of the chamber.
4. The test procedure should include the following steps:
 - The PCD should be labeled with the sterilizer, the date, load number and 'PCD' (in order to identify it post sterilization) before being exposed to the sterilization cycle.
 - The PCD should be positioned in the chamber according to 13.8.3.2., as noted in Step 3 above.
 - The cycle should be run according to the sterilizer manufacturer's written IFU.
 - After being exposed to the sterilization cycle, the BI should be removed from the PCD and the BI labeled with the sterilizer, the date, and the load number. All BIs used in challenging the sterilization cycle and as controls should be accounted for. The BIs should be handled and incubated according to the BI manufacturer's written IFU.
 - Consult the manufacturer's written IFU for the appropriate incubation instructions, time and temperature.
 - Each day that test BIs are run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control in each incubator to verify the pre-sterilization viability of the test spores and incubator function.
 - Note: If several test BIs from the same lot are run at the same time, only one control BI from that lot need be used.
 - The number of both test BIs and control BIs should be documented.
 - Upon completion of the incubation period, the test and control results should be read and recorded. If the control BI from a lot fails to grow, it should be assumed that the test BIs from that lot are nonviable or that improper incubation occurred. Therefore, the results from the test BIs should be considered invalid and the test repeated.
5. Acceptance criteria:
 - All monitoring results, including results from BI controls, should be interpreted by a qualified individual and included in the sterilizer records. An acceptable test is evidenced by negative results from the test BIs from all three consecutive test runs, positive (growth) results from all control BIs, and appropriate readings from physical monitors and CIs, showing that the sterilizer has been properly installed (or reinstalled after relocation) or repaired satisfactorily and that it will function effectively.
6. Ensure that you are monitoring three consecutive cycles following the above instructions.



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