Best Practice for Routine Sterilizer Efficacy Monitoring

Table-top steam sterilizers and in-office monitoring

Recommended sterility assurance products needed:

- SporView™ In-Office Biological Monitoring System (10 or 24 hour)
- STEAMPlus™ Type 5 Chemical Integrator
- Duo-Check™ or Sure-Check™ Self-Seal Sterilization Pouch (multiple sizes available)
- AirView™ II Bowie-Dick Test for Class/Type B pre-vacuum air removal sterilizers

Testing procedure for dynamic air removal sterilizers:

1. For dynamic air removal sterilizers with pre-vacuum air removal, run a daily Bowie-Dick air removal test pack.
   - Select the air removal cycle and place the test pack in the empty chamber as specified by the sterilizer IFU.
   - At the conclusion of the cycle, open the test pack and remove the test sheet to interpret and record results.
2. 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.
3. Select your sterilization packaging material (pouch or sterilization wrap) to compose your process challenge device (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
4. 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.

Every Day

Bowie-Dick Test

(Pre-vacuum Sterilizers)

+

Best practice: Every Day

(Minimum: Every Week)

BI and Type 5 CI in PCD

+

Every Pack

Type 5 Chemical Integrator

(Continued on next page.)

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5. 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 AAMI ST79:2017 13.8.3.2., as noted in Step 3 above.
     - The cycle should be run according to the sterilizer manufacturer's written IFU.
   - Upon completion of the sterilization cycle and cooling of the PCD, the BI and CI should be removed from the PCD and their identification recorded. The BI should be handled, incubated and interpreted according to the BI manufacturer's IFU. Follow the CI IFU for interpretation of CI results as well.
   - 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.
6. 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 process is evidenced by negative results from all test BIs, positive (growth) results from all control BIs, and appropriate readings from physical monitors and CIs, showing that the sterilization cycle was correct and complete.

PCD system for in-office testing using a sterilization pouch

Ref. #	Description	Quantity
SVT-050	SporView™ 10 Self-Contained Steam Biological Indicators (10 Hour)	50/Box
SCS-025	SporView™ Self Contained Biological Indicator (24 hour)	25/Box
NDB-060	55-60 C Dry Block Incubator, 11mm *(Made outside of the USA.)*	1 Each
SCXS	Duo-Check™ Self-Seal Sterilization Pouches 3.5 in x 5.25 in (8.9 cm x 13.3 cm) (other sizes available)	200/Box
SCXS2	Sure-Check™ Self-Seal Sterilization Pouches 3.5 in x 5.25 in (8.9 cm x 13.3 cm) (other sizes available)	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 **STLF18MM**	Lead-Free Steam Indicator Tape 1 in x 60 yd (24 mm x 55 m) or 0.75 in x 60 yd (18 mm x 55 m)	 18 Rolls/Case 24 Rolls/Case
SVT-050	SporView™ 10 Self-Contained Steam Biological Indicators (10 Hour)	50/Box
SCS-025	SporView™ Self Contained Biological Indicator (24 hour)	25/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 *(Made outside of the USA.)*	1 Each

Bowie-Dick Test Pack

Ref. #	Description	Quantity
MBD030	AirView™ II Bowie-Dick Test Pack 5 in x 3.75 in x 0.625 in (12.7 cm x 9.5 cm x 1.6 cm)	30/Case

MADE IN USA *All products made in the USA unless otherwise noted.*