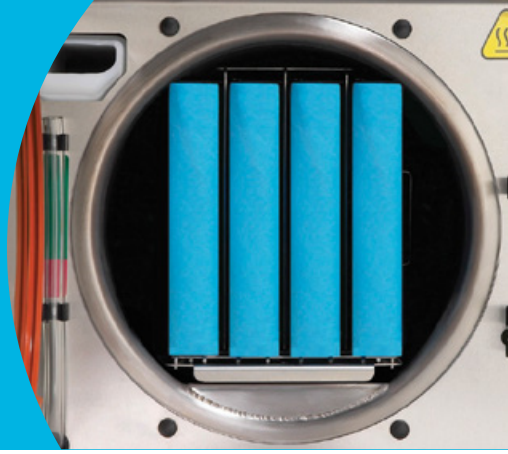
Best Practice for Routine Sterilizer Efficacy Monitoring

Dental table-top dynamic air removal and SFPP table-top steam sterilizers



RECOMMENDED STERILITY ASSURANCE PRODUCTS NEEDED:

Sure-Check™ Self-Seal Sterilization Pouches or Duo-Check™ Self-Seal Sterilization Pouches

- For creating a biological monitoring test pack

SteamPlus™ Type 5 Integrating Indicator

- For immediate release of non-implant sterilization loads or packs

ConFirm™ In-Office Biological Monitoring System

- Provides 10 or 24-hour BI monitoring results

ConFirm™ Premium or Value Mail-in Service

- Supports 3rd party validation of sterilizer monitoring

AirView™ II Bowie-Dick Test

- Air removal test for pre-vacuum dynamic air removal sterilizers

Testing procedure for table-top sterilizers:[1]

1 Select your sterilization packaging material (self-seal pouch or blue CSR wrap) to create an in-office biological monitoring test pack. Pick the pack type that best represents what is routinely processed.

- Record on the test BI vial label the sterilizer number, load number and processing date.
- BI test pack when using a **self-seal pouch**
  - Place BI and Type 5 integrating indicator in an empty pouch and seal it following the pouch's instructions for use.
- BI test pack when using a **cassette with a pouch or CSR wrap**
  - Place BI and Type 5 integrating indicator in a cassette that is typically used
  - Place cassette in the pouch and seal it following the pouch's instructions for use.
  - Or, wrap cassette with blue sterilization CSR wrap and secure with sterilization indicator tape following the instructions for use.
- **Including a Type 5 integrating indicator provides immediate feedback that all critical variables were met for proper instrument sterilization (time, temperature and saturated steam), allowing safe load release (implants always require a BI test to release them).**

Rational for BI test pack: "Best Practices" suggests that the self-seal pouch and pouched or wrapped instrument cassette that is routinely processed through the sterilizer should also be used for BI testing. This allows for a true representation of how patient instruments are safely packaged and exposed to the steam sterilization process.[2]

CONTINUED •••▸

Best Practice for Routine Sterilizer Efficacy Monitoring

Dental table-top dynamic air removal and SFPP table-top steam sterilizers

Testing procedure for table-top sterilizers (continued):[1]

2 The BI test pack procedure should include the following steps:

a. **Once the BI test pack is assembled**, label it with the sterilizer number, the date, load number and "TEST" (to identify it post sterilization) before being exposed to the sterilization cycle. For pouches label on the plastic film side. For a wrapped cassette, write only on the indicator tape.

b. Place BI test pack in a fully loaded chamber. It should be positioned in the location of the sterilizer chamber that is least favorable to sterilization. This area, known as the "cold point," is normally in the center of the load toward the front of the chamber. Always check the sterilizer's operator manual for details on correct BI test pack loading and placement.

c. Run a normal instrument cycle according to the sterilizer's operator manual.

d. Upon completion of the sterilization cycle and cooling of the BI test pack to room temperature, remove the test BI and Type 5 integrating indicator, visually inspect the indicators, and incubate the test BI.

- The BI test vial should be examined to confirm that the chemical indicator strip on the label has turned from blue to brown as proof of exposure to heated steam. Incubate the BI within 8 hours.
- Carefully crush the BI's inner media tube and incubate it at the correct time and temperature (see IFU).
- The Crosstex SteamPlus™ Type 5 integrating indicator provides immediate sterilization feedback with its moving blue bar indicating a pass (in SAFE zone) or fail (outside SAFE zone) of the process and load release.

e. Each day that test BIs are run, one BI from the **same lot number** that has not been exposed to the sterilization cycle should also be labeled, crushed and incubated at the same time as the test BI. This additional BI acts as a control to verify the viability of the test spores and proper BI incubation.

f. Upon completion of incubation, the test BI and control BI results should be observed.

Test BI Visual Results

- If the processed test BI turns yellow (positive: spores have grown), the load has failed sterilization as the spores survived. Before running another load, the cause of the failure should be identified and corrected, and the load reprocessed. When this occurs, report results immediately to your supervisor.
- If the processed test BI from a lot remains purple (negative: spores were killed and failed to grow), that is evidence of a successful sterilization event.

Control BI Visual Results

- If the control BI from a lot remains purple (negative: spores fail to grow), the BIs from the lot are either nonviable, or improper BI incubation has occurred. The results from the test BIs should be considered invalid and the test repeated to confirm failure. When this occurs, report results immediately to your supervisor.
- If the control BI from a lot transitions to yellow (positive: spores have grown, proving they are viable), that is evidence of a properly responding BI and a correct incubation procedure.

CONTINUED •••▸

Best Practice for Routine Sterilizer Efficacy Monitoring

Dental table-top dynamic air removal and SFPP table-top steam sterilizers

Testing procedure for table-top sterilizers (continued):[1]

3 Record keeping:

- Record results into a record notebook and include the following; test date, sterilizer number, load number, incubation date, test BI results (- or +), control BI results (- or +), and operator initials.

4 Third party testing with ConFirm Premium or Value Mail-in Service:

- Supplement your in-office monitoring with third party spore strip testing and documentation for an unbiased independent test with record when proof of compliance must be provided. It is an effective way to ensure that your practice's sterility assurance system is beyond question. The combination of weekly in-office BI monitoring, combined with weekly or monthly third-party testing, ensures that layers of protection are in place for your practice and patients' safety and peace of mind.
- When a mail-in test fails, Crosstex customer care consultants will contact you immediately and assist your staff with determining what may have happened and how to prevent future failures.

5 For dynamic air removal sterilizers with pre-vacuum air removal:

- Run a daily Bowie-Dick air removal test pack every morning prior to the first load to confirm complete elimination of air from the chamber (the heavier air impedes steam from fully entering the chamber and sterilizing instruments).

EVERY LOAD

Type 5 Integrating Indicator

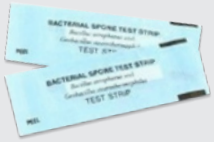
BEST PRACTICE: EVERY DAY

(Minimum Every Week)

In-Office BI + Type 5 Integrating Indicator Test Pack

BEST PRACTICE: EVERY MONTH

Mail-In 3rd Party Test



Ordering Information

REF. #	DESCRIPTION	QUANTITY
CBMS10	ConFirm™ 24 Starter Kit (24hr) (25 BIs, Incubator, Record Keeper)	Each
CSBI25	ConFirm™ 24 Biological Indicators (24hr)	25/Box
C10SK	ConFirm™ 10 Starter Kit (Incubator, Record Keeper)	Each
C10BI25	ConFirm™ 10 Biological Indicators (10hr)	25/Box
CST120	ConFirm™ Premium Test Service (12 tests, pre-paid postage)	Each
CVT120	ConFirm™ Value Test Service (12 tests, postage not included)	Each
CRK02	ConFirm™ Record Keeper	Each

REF. #	DESCRIPTION	QUANTITY
SSI-100	SteamPlus™ Type 5 Integrating Indicator 4 in x 0.75 in Strip (10.2 cm x 1.9 cm)	100/Pack
NDB-601	55º-60º C Dry Block Incubator w/Crusher* with Record Notebook	Each
SCS	Duo-Check™ Self-Seal Sterilization Pouches with Type 1 Process Indicators 3.5 in x 9 in (other sizes available)	200/Pack
SCS2	Sure-Check™ Self-Seal Sterilization Pouches with Type 4 Process Indicators 3.5 in x 9 in (other sizes available)	200/Pack
MBD030	AirView™ II Bowie-Dick Test Pack	30 Packs/Case

*Dry Block Incubator made in China

For more information, call us at (800) 722-1529, or visit us at HuFriedyGroup.com.

[1]Adapted from AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities, Section 13.7.3
[2]Adapted from AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities, Section 13.7.1