

ExpoSure™ Biological Indicator

Geobacillus stearothermophilus

TECHNICAL REPORT

Complies with:

USP

ISO 11138

And all appropriate subsections

Technical Data and Use of ExpoSure™ Biological Indicator

INTRODUCTION

The ExpoSure™ Biological Indicator is a self-contained biological indicator (SCBI) for use in monitoring the efficacy of the following STERRAD® sterilization cycles:

- STERRAD® 50
- STERRAD® 100S (Short & Long¹)
- STERRAD® 200 (Short & Long¹)
- STERRAD® NX® (Advanced & Standard)
- STERRAD® 100NX® (STANDARD, FLEX, DUO, and EXPRESS)

ExpoSure™ is easy to use and doesn't require sophisticated analysis or equipment.

ExpoSure™ units contain a 7mm Quartz fiber disc that is inoculated with spores of the bacteria *Geobacillus stearothermophilus* (ATCC 7953 or equivalent culture collection strains) and placed in a plastic vial that serves as a culture tube. A glass ampoule containing sterile culture medium and pH color indicator in the vial is crushed after exposure and absorbs into the inoculated disc to promote growth. A Tyvek® disc filter is placed over the top of the culture tube to prevent contamination, and a cap is set over the top with a gap to allow sterilant penetration through the two side holes. A label on the outside of the vial includes a chemical indicator that serves as a visual indicator of whether or not the unit has been run through a cycle.

STORAGE

ExpoSure™ Biological Indicators should be stored between 2-25°C and ≤60% RH. The SCBI should be stored away from sterilizers, light and sources of oxidation. ExpoSure™ Biological Indicators have a 12 month shelf life.

MEDIUM

The culture medium is a soybean casein digest derived medium manufactured to a proprietary formulation. The media is filled into glass ampoules, flame sealed, and then sterilized. The ampoule is an "onion skin" glass that allows it to be easily crushed through the plastic tube with a provided plastic crusher tool.

Bromocresol purple is added as a pH indicator to facilitate the detection of growth. When sterile, the medium is purple in color. After sterilization, if viable spores are present, bacterial growth will occur resulting in a change in the pH. The color of the medium will change from purple to yellow. If no viable spores are present, the medium will remain purple throughout incubation, indicating a successful sterilization cycle. If any SCBIs appear yellow or turbid prior to use, they should be sterilized and discarded.

¹ "Long" applies to industrial cycles only

USE

Exposure

1. Remove the desired number of ExpoSure™ Biological Indicators from the box.
 2. Ensure that each cap is in a raised position to allow the sterilant access to the interior of the vial.
 3. Place the SCBIs to be sterilized in a Tyvek® pouch and then place in the “worst case” (least lethal) location in the load.
 4. Process the load as usual.
 5. Remove from the sterilizer and retrieve the ExpoSure™ Biological Indicators from the load.
 6. Remove the SCBIs from the Tyvek® pouch as soon as it is removed from the load to eliminate the effects from potential residual sterilant inside the pouch. Press the cap down on the SCBIs to prevent media evaporation.
 7. The chemical indicator on the label of the SCBIs changes to blue and serves as indication that the SCBIs was exposed in a sterilization cycle.
- NOTE: A color change to blue on the label does not indicate acceptable sterilization.**
8. Insert the SCBI into the provided vial crusher and apply enough force to break the onion skin ampoule inside.
 9. Ensure that the disc is fully submerged in the media. Tap the bottom and/or side of the SCBI with a finger if needed to fully saturate the disc.

INCUBATION

ExpoSure™ Biological Indicators should be incubated for 24 hours at 55°C-60°C. Mesa Laboratories, Omaha Manufacturing Facility has performed the FDA protocol for determining the incubation read-out time and the data meets the FDA criteria after 24 hours of incubation.

The incubation time of the ExpoSure™ Biological Indicators was validated according to the Center for Devices and Radiological Health, FDA protocol entitled, “Guide for Validation of Biological Indicator Incubation Time”. Three lots of ExpoSure™ Biological Indicators were prepared according to Mesa’s standard operating procedures. For each lot, 100 SCBIs were exposed in an H₂O₂ resistometer. Exposure conditions were 2.5 mg/L ± 0.3 mg/L H₂O₂ at 50°C ± 1°C. The exposed SCBIs were activated, and incubated at 55°C-60°C for seven days. Table 1 shows the results where 30-80% of the tubes were positive for microbial growth.

Table 1: Results of the Reduced Incubation Time Study

BI Lot Number	# Positive 24 hours	# Positive 7 days	Percent Positive ⁽¹⁾
1159s test 5	30	30	100%
1161s test 4	35	35	100%
1176s test 5	66	66	100%

⁽¹⁾Acceptable protocol results require greater than 97% of the base number of biological indicators to test positive. This percentage is calculated by using the number of positive biological indicators on day 7 as the base number (denominator); and using the number of positive biological indicators at 24 hours as the numerator.

The data shows that the 24 hour incubation time claim was valid; with the ratio of positives at 24 hours being the same as the ratio of positives at 7 days. A 24 hour incubation time provides users with a rapid release of sterilized product. It should be noted that incubator performance is critical in achieving these incubation times, the temperature of the incubator should be constantly monitored to ensure a temperature range of 55°C-60°C at all times.

INTERPRETATION

After the incubation period, the ExpoSure™ Biological Indicators should be examined for color change or turbidity. **ANY** color change or turbidity not present in a negative control SCBI (a negative control is a sample from the same lot, but one that has not been processed in a sterilizer or crushed) indicates that conditions necessary to achieve sterilization were not met. In this event, follow your facility policies and procedures for a failed sterilization cycle. A positive test (any color or turbidity change when compared to the negative control) can be acted on as soon as the color change is noted.

If after 24 hours the media color remains purple and there is no turbidity in the sample, this indicates that conditions necessary to achieve sterilization were met.

A positive control (a unit from the lot that has been crushed, but not exposed to a sterilization cycle) should be incubated for each cycle tested, or at least once per week. As soon as a control turns yellow, it should be appropriately recorded and then autoclaved and discarded. The control serves as visual evidence that the lot being used contains viable spores on the carrier. Positive controls are not to be used as a “color standard” to compare test results. Incubating the positive controls for longer than 24 hours is not recommended. A positive control that does not change color and is truly a negative result due to lack of growth is a serious issue. Some potential situations that may cause this are: a malfunctioning incubator; inadvertent sterilization of the control sample; inadvertent sterilization of the box of indicators (due to improper storage).

RESISTANCE PERFORMANCE TESTING

D-value determination was performed by Stumbo Murphy Cochran analysis, and a population assay was performed on the SCBIs. ExpoSure™ Biological Indicators were exposed in H₂O₂ resistometer. Exposure conditions were 2.5 mg/L ± 0.3 mg/L H₂O₂ at 50°C ± 1°C. 50 units per exposure time were used. Following exposure, samples were activated and incubated at 55°C-60°C for 24 hours. Performance data is presented in Table 2.

Table 2: Results of the Stumbo Murphy Cochran Calculation and Population Assays
2.5 mg/L ± 0.3 mg/L H₂O₂ at 50°C ± 1°C

BI Lot #	Number Negative Out of 50			Population/Unit	D-value (sec)
	Exposure Time (sec)				
	10 sec	15 sec	20 sec		
1159s	16	36	34	1.8 x 10 ⁶	2.28
1161s	32	38	31	1.8 x 10 ⁶	2.25
1176s	40	49	49	2.1 x 10 ⁶	1.93