

SporeNews

biological indicators newsletter

Volume 12, No. 6



Introducing ExpoSure by Ryan McDonald

In the coming weeks, Mesa Labs will be launching ExpoSure™, a new self-contained biological indicator (SCBI) for monitoring the efficacy of hydrogen peroxide (H₂O₂) sterilization cycles. For those in the healthcare setting, ExpoSure has 510(k) clearance from U.S. FDA for use in the following STERRAD® cycles:

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

So, who would choose to use an H₂O₂ sterilization process over steam or ethylene oxide sterilization? Well, NASA, for one. One of NASA's primary concerns when exploring our solar system is Planetary Protection. An integral part of Planetary Protection is the reduction of bioburden on spacecraft and equipment. NASA, in cooperation with Jet Propulsion Laboratory (JPL), is currently¹ studying the benefits of using a hydrogen peroxide sterilization process for heat-sensitive electronics and sensors used on spacecraft that are headed for Mars, Jupiter and destinations beyond. After all, imagine the embarrassment if NASA found life on Mars...and it turned out to be an earth-originated organism that had inadvertently tagged along for the ride on a landing gear and subsequently contaminated the entire planet?

ExpoSure™ [510(k): K140589] is easy to use and doesn't require sophisticated analysis or equipment. The SCBIs consist of 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 of any viable spores. A Tyvek® disc filter is placed over the top of the culture tube which allows sterilant penetration into the SCBI and also prevents contamination. A specially designed cap allows for sterilant ingress and subsequent removal through the two side holes. A label on the outside of the vial includes a chemical indicator that serves as a visual indication of whether or not the SCBI unit has been exposed to the sterilant.

The ExpoSure™ SCBI has a shelf life of 12 months when stored between 2–25 °C and at ≤60% relative humidity (RH) away from sterilizers, light and sources of oxidation.

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. 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.

Reduced Incubation Testing Validates 24 Hour Incubation

An incubation time of 24 hours at 55–60 °C for 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 55–60 °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 ²
1159s test 5	30	30	100%
1161s test 4	35	35	100%
1176s test 5	66	66	100%

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.

Resistance Testing

D-value determination was performed by Stumbo Murphy Cochran analysis, and a population assay was performed on the SCBIs. The target population for this product is 1.0-4.0 x 10⁶, while the target D-value range is 0.75-6.00 seconds. ExpoSure™ Biological Indicators were exposed in the H₂O₂ resistometer with exposure conditions of 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 55–60 °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

While the ExpoSure SCBI has been extensively tested in hydrogen peroxide systems and has gained 510(k) clearance for use in the Sterrad sterilizers, it would likely work very well in any chemical sterilization process with pre and post vacuum capabilities. Mesa Labs would be happy to work with any firm in testing this SCBI in their particular sterilization processes.

Ryan McDonald has been with Mesa Labs since 2012 as an R&D Specialist. He graduated from the University of Nebraska-Lincoln with a B.S. in Biological Systems Engineering and an M.S. in Microbiology/Molecular Biology.

¹Chen, F., Mckay, T., Spry, J.A., Colozza, A., Distefano, S., & Cataldo, R. (2013). Planetary Protection Concerns During Pre-Launch Radioisotope Power System Final Integration Activities, Proceedings of Nuclear and Emerging Technologies for Space 2013, Albuquerque, NM, February 25-28, 2013.

²Acceptable 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.