



SPORVIEW[®] SELF-CONTAINED BIOLOGICAL INDICATOR For Monitoring Vaporized Hydrogen Peroxide (VH₂O₂)

Crosstex Code: VH50

Product Description

The SporView[®] Self-Contained Biological Indicators (SCBIs) for monitoring VH₂O₂ processes consist of:

- A thermoplastic vial and cap
- A crushable media ampule which contains modified Trypticase[®] (TSB) with a pH indicator. The modified TSB will transition from the initial purple color to yellow and/or demonstrate turbidity in the presence of bacterial growth
- An inoculated carrier (glass fiber disc) of *Geobacillus stearothermophilus* (Cell Line 7953) with a population level of 10⁶

Intended Use

The SCBIs may be utilized to monitor VH₂O₂ sterilization process efficacy. The SCBIs are For International Use Only.

Instructions for Use - Industrial Settings

Exposure: SCBIs may be placed inside representative materials or within the chamber directly. Package or wrap product as usual, if applicable. Locate SCBIs or product in areas most difficult to sterilize, as outlined in a sterilization validation protocol or according to standard operating procedure. Run the cycle.

After sterilization or exposure, remove SCBIs or product from sterilizer.

Activation: Activate the processed SCBIs within four (4) hours post-exposure. Squeeze the sides of the unit until the glass media ampule contained within is crushed. Ensure that the glass fiber disc is immersed in the growth medium. Activate one SCBI which has not been exposed in a sterilization process as a positive control.

Incubation: Place the processed, activated SCBIs and the positive control SCBI in a vertical position in an incubator at 55°C to 60°C for a minimum of 24 hours.

Monitoring: Examine the SCBIs daily during incubation. Record observations.

All positive SCBIs should be disposed of immediately. Do not continue to incubate a positive SCBI. Continued growth may result in metabolism of amino acids in the absence of sugars, causing the pH to rise and result in color reversion that is visibly darker than a sterile unit. These should be considered as positive for growth (turbidity will be present).

For unexpected positives, it is recommended that a Gram stain be performed. Gram positive rods are characteristic of the indicator organism.



Interpretation: Control SCBI: The Positive Control SCBI should exhibit a color change to yellow and/or demonstrate turbidity. If the control SCBI does not show signs of growth, consider the test invalid.

Test SCBI: A passing sterilization cycle is indicated by no signs of turbidity and the purple color not transitioning to yellow. A failed sterilization cycle is indicated by turbidity and/or a color change to yellow.

Chemical Indicator (CI): The chemical indicating strip should transition from pink/red to blue when exposed to a VH_2O_2 process. Lack of color change or a partial change in color of the CI does not necessarily indicate failure. The CI does not prove efficacy of sterilization; the biological result should be used to gauge efficacy of the sterilization cycle.

Physical Properties

Process	VH_2O_2
Dimensions	8.4 mm x 45.5 mm
Packaging	50/Box
Chemical Indicator	Each SCBI contains a CI strip on the vial labeling. The CI should transition from pink/red to blue when exposed to a VH_2O_2 process.

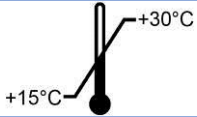






Monitoring Frequency

For greatest control of sterilized goods, it is recommended that one or more SCBIs be included with every load.

Performance Characteristics

Population	1.0 to 5.0 x 10 ⁶ per disc
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
VH_2O_2 Resistance	<i>D</i> value at 50°C, 2.5 mg/L using 59% H_2O_2 < 1 minute
Post-Market Criteria	Population: 50% to 300% of certified population

Storage and Shelf Life

	<p>20°C to 25°C average Excursions 15°C to 30°C allowed</p>		<p>Keep away from sunlight</p>
	<p>20% to 70% Relative Humidity</p>		<p>Keep dry</p>
	<p>Do not freeze</p>		<p>Protect from heat, radioactive sources, & sterilizing agents</p>
<p>Shelf Life</p>	<p>The shelf life of the SCBIs is based on the shorter of the two individual components (the media ampule and inoculated carrier), which have independent expiration periods.</p>		
	<p>Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the SCBIs. Do not use damaged SCBIs. Do not use after expiration date. Do not refrigerate. The SCBIs contain live cultures and should be handled with care.</p>		

Disposal

Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.

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