

Plasma BI-OK® Self-Contained Biological Indicator

Product Profile

Product Description:

Plasma BI-OK® Self-Contained Biological Indicator is intended for use in routine monitoring and validation of vaporized hydrogen peroxide (VHP) sterilization processes. The indicator is suitable for different models of hydrogen peroxide sterilizers including sterilizers that use plasma stage.

Plasma BI-O.K.® self-contained biological indicator consist of the following components:

1. Plastic vial with soft walls;
2. Orange cap with 3 holes on top for sterilant admission;
3. Filter paper (Tyvek) inside the cap;
4. Glass ampoule with growth incubation medium and pH indicator changing color from orange-red to yellow;
5. Glass fiber carrier inoculated with spores of *Geobacillus stearothermophilus* (ATCC 7953 or ATCC 12980).
6. External vial label with VHP process chemical indicator that should turn to orange or yellow after the exposure to sterilant.
7. The indicators are supplied inside a zip-loc pouch with external label containing all necessary information about the product, lot number and expiration date.



Plasma BI-O.K.® Self-Contained Biological Indicator vial is activated by crushing the media ampoule to facilitate contact between media and spore strip. The vial is incubated at 55-60°C for 24 hours to observe spore growth. If a healthcare facility protocol requires one week incubation, the BI-O.K.® VHP self-contained biological indicator can be observed for up to seven (7) days.



If the spores have been killed during the cycle, the media will remain red-orange, indicating a successful sterilization. If spores survive after a sterilization cycle, growth will occur, as shown by a media color change from red-orange to yellow, indicative of a failed sterilization cycle.

Plasma BI-O.K.[®] Self-Contained Biological Indicator may be incubated in BI-O.K.[®] Biological Indicator Incubator specifically designed for Plasma BI-O.K.[®] Self-Contained Biological Indicator or any microbiological incubator providing the appropriate incubation temperature range of 55-60°C.

Plasma BI-O.K.[®] Self-Contained Biological Indicator has been validated only for vaporized hydrogen peroxide sterilization process. Plasma BI-O.K.[®] Self-Contained Biological Indicator is not for use in biological monitoring of steam, ethylene oxide or dry heat sterilizers.

Regulatory Status:

Plasma BI-O.K.[®] Self-Contained Biological Indicator meets the U.S. Pharmacopoeia <1035> performance criteria.

The performance characteristics of Plasma BI-O.K.[®] Self-Contained Biological Indicator are in accordance with currently accepted ISO 2859-1:1999.

Instructions for Use:

1. Package one or more Plasma BI-OK[®] indicators with items being sterilized.
2. Place the pack in the most difficult to sterilize area, typically the middle of the top shelf.
3. Run a normal hydrogen peroxide sterilization cycle.
4. Remove the pack from the sterilizer. Personnel should use appropriate gloves and safety glasses. Open pack and remove Plasma BI-OK[®] indicator.
5. Identify the vial by load, sterilizer and date.
6. Examine the chemical indicator on the vial label to verify exposure to sterilant. Chemical indicator should turn to orange or yellow color.
7. If the ampoule in the vial looks damaged, or there is a media leakage, dispose of the damaged vial and repeat the test with a new BI-OK[®] vial.
8. Activate the BI-OK[®] indicator by holding it in a vertical position. Compress the sides of the vial by using a manual crushing device to break the glass media ampule. The unit is properly activated when the media has been released from the ampule and the carrier inoculated with spores is in contact with the released media.
9. A positive (unprocessed) control from the same lot should be used each time a sterilization test is performed. A positive control must be performed a minimum of once a week.
10. Incubate the control (unprocessed) vial and the test (processed) vial(s) at 55-60°C for 24 hours.

Interpretation:

1. Appearance of a color change from red to yellow is evidence of bacterial growth. All control (unprocessed) vials should show this color change within 24 hours. All test (processed) vials should remain red.
2. If test vials show a yellow color change, the sterilization cycle was not successful. React to this sterilization failure immediately according to the policies of your institution.

Requirements:

1. Performance Information:

Determination of the viable population of Plasma BI-O.K.[®] Self-Contained Biological Indicator involves the following steps: separation of spores from the glass fiber carrier, serial dilutions, plating, colony counting, dilution calculations to determine the final population.

Table I *refers to USP/FDA Standards

<u>Sterilizing Agent</u>	<u>D-Value (minutes)</u>	<u>Survival</u>	<u>Kill</u>	<u>Test Organism</u>	<u>Population (heat shock spore/strip)</u>	<u>Incubation</u>
Vaporized hydrogen peroxide/plasma, 55°C (131°F)	N/A	4.5 to 30.0 sec.	5.5 to 32.0 min.	<i>Geobacillus stearothermophilus</i>	1.5-5.0 x 10 ⁶	55-60°C

2 Quality Assurance

The spore population on the carrier shall be of sufficient quantity and resistance to meet the performance requirements of **Table I** of this profile.

A certificate is required for each lot of Plasma BI-O.K.[®] Self-Contained Biological Indicators. The certificate states that the tests have been performed and all criteria and requirements have been met.

The certificate provides the heat shock spore population and the survival and kill time for *Geobacillus stearothermophilus*. These values conform to Table I listed above.

3 Lot Number

Each Plasma BI-O.K.[®] Self-Contained Biological Indicator has a lot number printed on the vial label. The lot number for each lot of Plasma BI-O.K.[®] Self-Contained Biological Indicator is unique and permits traceability to the components used in the manufacturing process. The expiration date of the final assembled product is based on which component (glass media ampoule, spore strip) expires first.

The lot number is **HYMMN** where “**H**” designates “Hydrogen Peroxide”, “**YYMM**” the last two digits of the year and the two digit month, and “**N**” is the serial number of the lot manufactured in any given month. [i.e., if Lot #1 was produced August 2014, the lot number would be H14081].

4. Shelf-Life

The spore carriers have a shelf life at room temperature of 24 months maximum from the date of manufacture.

5. Packaging, Labeling, and Storage

a. Packaging

Plasma BI-O.K.[®] biological indicator is available in boxes containing 20 or 40 vials.

b. Labeling

Each package shall contain a label with the following information:

- Lot Number
- Expiration Date
- Name/Product Reorder Number
- Quantity
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c. Storage

To ensure that the proper levels of resistance are maintained for the life of the indicators, the vials should be store in a cool, dry place at/or below 60°F.

6. Disposal

Unused Plasma BI-O.K.[®] self-contained biological indicators after expiration date and indicators that demonstrated growth need to ne inactivated. The suitable methods are: in gravity steam sterilizers at 121°C for at least 30 minutes or in pre-vacuum sterilizers at 132°C for at least 5 minutes.