



Instructions for Use: Biological Indicator-Steam

Brand Name of Product	EZTest® Biological Indicator-Steam
Generic Name of Product	Biological Indicator- Steam
Product Code Number(s)	6005500537
Intended Use	A self-contained biological indicator (BI) for monitoring steam sterilization cycles.
Range of Applications for Product	N/A
Key Specifications of Product	<ul style="list-style-type: none"> • BI Growth Medium: purple to yellow with growth. • Biological vial size: 1.79 inches.

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions	<ul style="list-style-type: none"> • Store at room temperature 15- to 30 °C (59 °F to 86 °F). • Do not store near sterilants or other chemicals.
Packaging Contents	Box of 100 biological indicators.
Shelf Life	Please refer to the expiration date printed on the product packaging.

Instructions for Using Product	
Description of Use(s)	N/A
Preparation for Use	N/A
Diagrams (drawings, pictures)	N/A
Steps for Use of Product	<p>Exposure</p> <ol style="list-style-type: none"> 1. Load the sterilizer as normal. 2. Identify the indicators by labeling pertinent process information. 3. Place an EZTest® Biological Indicator in the load to be sterilized. <ol style="list-style-type: none"> a. Position horizontally and located in the most difficult to sterilize area of the sterilizer (e.g., over the drain) or in accordance with the sterilizer manufacturer’s instructions for use. b. Use with representative materials to be sterilized. 4. Select the appropriate cycle and expose the load to the sterilization cycle. <ol style="list-style-type: none"> a. If an IUSS cycle (formerly known as FLASH) is selected, the items should be unwrapped. b. If come-up time is less than 1-minute, the use of a 3-minute exposure cycle may have to be extended to 4 minutes to ensure the BI is inactivated. 5. After the cycle is complete, remove the EZTest® Biological Indicator from the sterilizer and allow it to cool for at least 10 minutes. 6. Retrieve the EZTest® Biological Indicator(s) from the load. 7. A chemical indicator on the label will change from blue to black when sterilization exposure occurs. This distinguishes exposed from unexposed units. <i>(Note: A black color does not indicate acceptable sterilization.)</i> <p>Incubation</p> <ol style="list-style-type: none"> 1. To activate the media, place the indicator using a “crushing” device in an upright position and gently squeeze the crusher tube to break the glass ampoule to allow the medium to mix with the spores. 2. Place the activated indicator in the rack of an appropriate incubator adjusted at 55- to 60 °C (131- to 140 °F) and incubate immediately. <p>Use of Controls</p> <p>As a positive growth control, place an activated, un-sterilized EZTest® Biological Indicator (with the same lot number as those to be used in loads) in each incubator daily. Examine the positive indicator at regular intervals (i.e., 4-, 8-, 12-, and 24 hours).</p>

	<ol style="list-style-type: none"> 1. The yellow color is evidence of bacterial growth. 2. Record the results. 3. Remove all positive indicators as the yellow color is noticed. 4. Dispose of as mentioned below in the "Interpretation of Test Results" section.) <p><i>(Note: If the positive control does not grow, do not use the units from this box.)</i></p>
Interpretation of Test Results	<p>Biological Indicator:</p> <ol style="list-style-type: none"> 1. Examine the EZTest® Biological Indicator for signs of color change during incubation (i.e., 8-, 12-, 18-, and 24 hours). <ol style="list-style-type: none"> a. The appearance of a yellow color indicates bacterial growth. b. No color change indicates adequate sterilization. 2. Act on a positive test (yellow color) as soon as the color change is noted. <ol style="list-style-type: none"> a. Recall all loads back to the most recent negative BI. <ol style="list-style-type: none"> i. Follow your facility's recall policy and procedures. ii. Do not process any other loads until the root cause has been remedied and three consecutive negative BIs are accomplished. b. Always retest the sterilizer with an EZTest® Biological Indicator in another load. <ol style="list-style-type: none"> i. The incubation time is 24 hours. ii. This meets the US FDA, CDRJ, RIT protocol). 3. Record the results.
Contraindications of Test Results	N/A
Documentation	N/A
Special Warnings and Cautions	<ul style="list-style-type: none"> • ⚠ CAUTION: After sterilization, the contents of the EZTest® Biological Indicator are hot and under pressure <ul style="list-style-type: none"> ○ Always allow for cooling for at least 10 minutes. ○ Failure to cool may cause the glass ampule to burst and may result in injury from hot liquid and sharp debris. • ⚠ CAUTION: Wear safety goggles while crushing vial after cooling. <p><i>(Note: If yellow media in the EZTest® Biological Indicator is observed upon removal from the product box, this unit should be autoclaved then discarded.)</i></p>
Disposal	<ul style="list-style-type: none"> • Incinerate or autoclave any positive cultures at 121 °C (250 °F) for no less than 30 minutes. • Dispose of in accordance with your institution's policy. • Dispose of expired indicators by autoclaving at 121 °C (250 °F) for no less than 30 minutes.

Reprocessing Instructions	
Point of Use	N/A
Preparation for Decontamination	N/A
Disassembly Instructions	N/A
Cleaning – Manual	N/A
Cleaning – Automated	N/A
Disinfection	N/A
Drying	N/A
Maintenance, Inspection, and Testing	N/A
Reassembly Instructions	N/A
Packaging	N/A
Sterilization	N/A
Storage	N/A
Additional Information	N/A
Related Healthmark Products	N/A
Other Product Support Documents	Sterilization Brochure, Sterilization Price List
Reference Documents	N/A
Customer Service Contact	Healthmark Industries Company, Inc.

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