

Infection Control Division | **Biological Indicators**

BT224 Self-Contained Biological Indicator

Ultra rapid readout fluorescence system



Usage

United States

Monitoring the efficacy of steam sterilization processes.

Outside the United States

Monitoring vacuum assisted and gravity air-displacement Steam sterilization cycles at 132-135 °C.

Applicable regulation

Designed under Quality Management System standards ISO 13485:2016/NS-EN, ISO 13485:2016.

ISO 11138-1:2017 and ISO 11138-3:2017; IRAM 37102-1:1999 and IRAM 37102-3:1999.

Authorization

ANMAT (Argentinean National Administration of Drugs, Food and Medical Devices) PM 1614-1.

Classification

Class 1, according to risk (ANMAT).

FDA 510(k)

K191021.

Characteristics

Polypropylene tube: 50.7 mm high x 8.5 mm external diameter. Wall thickness: 0.5 mm.

Polypropylene cap: 16.4 mm high x 10.5 mm external diameter. Wall thickness: 0.9 mm.

Cap filter: medical grade paper, 17.0 mm diameter.

Glass ampoule: 35.0 - 40.0 mm high. External diameter: 6.8 mm. Wall thickness: 0.2 - 0.3 mm.

Culture medium 0.5 - 0.7 ml, purple color.

Polypropylene microfiber on spore carrier, 17.0 mm diameter.

Spores carrier: filter paper, 16.0 mm diameter.

$\geq 10^6$ *Geobacillus stearothermophilus* ATCC® 7953 spores per vial.

Final fluorescence reading is performed after 20 minute-incubation at 60 °C (sensitivity ≥ 97 %).

An optional visual pH color change confirmation could be made after 48 hours of incubation. If sterilization process has not been successful, culture medium will change to a greenish color first, and then to yellow during incubation at 60 °C, thus showing the presence of living spores. If sterilization process is successful culture medium will remain purple after the incubation process.

7-day readout is optional and not intended to be routinely performed; it is an initial validation of the 20 minute-reading. Fluorescence results may be compared to the 7-day visual reading.

*ATCC® is a registered trademark of American Type Culture Collection.

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NOTE: if 7-day readout is performed, a humidified environment will be required to avoid medium to dry out.

D-Value: Not lower than 1.5 minutes at 121 °C. Another D-value is informed at 132 °C and at 135 °C.

Z-Value is informed.

Environmental conditions during manufacture

T = 15-30 °C, RH = 30-80 %. Sterility conditions are only necessary during the inoculation and manufacturing process, which is performed in laminar flow.

Storage conditions

T = 10 - 30 °C, RH 30-80 %, keep in a dark place in its original box.

Transport conditions

It is recommended to store it away from sunlight and at a temperature between 10 - 30 °C.

Products should be transported in closed and reinforced boxes in order to avoid damages.

The transport of this product does not represent any risk for human health.

Acceptable excursions during transport are as follows:

T = 2-10 °C and T = 30-37 °C for no longer than seven days. No restrictions for relative humidity.

Shelf life

2 years.

Packing

50 units per box.

Packing information: product code and description, process for intended use, presentation, regulation, bacterial strain, storage conditions, manufacturer information and data on pack's label.

Labelling

On product: 17.0 mm x 33.0 mm polypropylene label. Chemical indicator line printed with Steam reactive ink (color change to brown). Graph showing final fluorescence reading time, product code, batch number, expiration date, process for intended use and name of organism printed in black.

On product's pack: product code and description, batch number, bacterial load, manufacture and expiration date, barcode and datamatrix code.

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Possible target markets

Healthcare and Industry.

Other important information

Incubation at 60 °C must be performed in Bionova® Auto-Reader incubators.

Read product's instructions for use thoroughly before use.

Precautions

Do not store the product near sterilizing agents.

Do not expose this product to Ethylene Oxide, Dry Heat, Radiation or any sterilization process other than Steam.