

Infection Control Division | Biological Indicators

BT96 Self-Contained Biological Indicator

Super rapid readout fluorescence system



Usage

United States

Terragene Bionova® SCBI BT96 is a self-contained biological indicator inoculated with viable 10^6 *Geobacillus stearothermophilus* bacterial spores and is intended for monitoring the efficacy of vaporized hydrogen peroxide sterilization processes. BT96 is Super Rapid Readout. BT96 has Super Rapid readout at 30 minutes at 60 °C.

Intended use cycles: STERRAD 100S 54 minutes, STERRAD 100NX Standard and Express cycles and V-Pro Max and Sterizone VP4 cycles.

Outside the United States

Monitoring plasma or vaporized Hydrogen Peroxide sterilization processes (H_2O_2).

Applicable regulation

Designed under Quality Management System standards ISO 13485:2016/NS-EN, ISO 13485:2016, ISO 11138-1:2017 and IRAM 37102-1:1999.

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: 50.4 mm high x 8.5 mm external diameter. Wall thickness: 0.5 mm.

Polypropylene cap: 16.4 mm high x 10.7 mm external diameter. Wall thickness: 0.9 mm.

Cap filter: polyethylene fibers. 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 microfibers on spore carrier: 17.0 mm of diameter.

Spore carrier: polyethylene fibers, 17.0 mm of diameter.

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

Final fluorescence reading is performed after 30-minute incubation at 60 °C (sensitivity ≥ 97 %).

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

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An optional visual pH color change confirmation could be performed after 48 hours of incubation. If sterilization process has not been successful, culture medium will change 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 30-minute reading. Fluorescence results may be compared to the 7-day visual reading.

NOTE: If 7-day readout is performed, a humidified environment will be required to prevent medium from drying out.

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, 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. 1.5 mm chemical indicator line, printed with H₂O₂ reactive ink (color change to green). Graph showing final fluorescence reading time, product code, batch number, expiration date, process for intended use, name of organism and blank spaces for data entry.

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On product's packing: product code and description, batch number, bacterial population, manufacture and expiration date, presentation, bar code and datamatrix code.

Possible target markets

Healthcare and Industry.

Other important information

It is advisable to incubate at 60 °C in Bionova® IC10/20FR, IC10/20FRLCD o MiniBio 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 Hydrogen Peroxide.