

Infection Control Division | **Biological Indicators**

BT220 Self-Contained Biological Indicator

Rapid readout fluorescence system



Usage

United States

Terragene® Bionova® BT220 is a self-contained biological indicator inoculated with viable *Geobacillus stearothermophilus* bacterial spores and is intended for monitoring the efficacy of steam sterilization processes.

Autoclave/Steam cycles		
Gravity displacement		
121 °C	132 °C	135 °C
30 min	15 min , 25 min	10 min
Dynamic air removal (vacuum assist)		
132 °C	135 °C	
4 min	3 min	
Fluorescence read time	pH color change	
3 hours	48 hours	

Outside the United States

Terragene® Bionova® BT220 Self-Contained Biological Indicators have been designed for quick and easy monitoring of vacuum assisted and gravity displacement steam sterilization cycles at 121-135 °C.

Applicable regulation

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

ISO 11138-1:2017, ISO 11138-3:2017, ISO 11138-8:2021 and ISO 11140-1:2014.

Authorization

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

Classification

Class 1, according to risk (ANMAT).

FDA 510(k)

K163646.

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 10.7 mm external diameter. Wall

thickness: 0.5 mm

Cap filter: medical grade paper, 17.0 mm diameter.

Glass ampoule: 35.0 - 40.0 mm high. External diameter: 6.5 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.

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$\geq 10^6$ *Geobacillus stearothermophilus* ATCC®* 7953 spores per vial.
Final fluorescence reading is performed after 3-hour incubation at 60 °C (sensitivity: ≥ 97 %).

A visual confirmation of the result is optional (color change of the medium caused by pH change) and can be made after incubation at 60°C for 48 hours and/or for 7 days. If sterilization process has not been successful, culture medium will change to a greenish color first, and then to yellow, 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 3-hour 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 avoid medium to dry out.

D-Value: Not lower than 1.5 minutes at 121 °C. Not lower than 10 seconds at 132 °C. Not lower than 8 seconds at 135 °C.

Z-Value: Not lower than 10 °C.

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 away from sunlight 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.

Shelf life

2 years.

Packing

50 units per box.

Packing information: Product code and description, process for intended use, regulatory and standards information, bacterial strain, storage conditions and manufacturer information.

Labelling

On product's packing: product code and description, batch number, bacterial load, manufacture and expiration date, bar code and Data Matrix.

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

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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 use this product to control ethylene oxide, hydrogen peroxide, dry heat, formaldehyde or any sterilization process other than steam.