

Infection Control Division | **Biological Indicators**

## BT110 Self-Contained Biological Indicator Rapid Readout Fluorescence System



### Usage

#### United States

Monitoring the efficacy of ethylene oxide sterilization processes.  
Conditions: 600 mg/l, HR 60 %, 55 °C, 240 minutes.

#### Outside the United States

Monitoring Ethylene Oxide Sterilization Processes.

### Applicable regulation

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

ISO 11138-1:2017 and ISO 11138-2:2017; IRAM 37102-1:1999 and  
IRAM 37102-2:1999.

### 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: 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, blue color.

Polypropylene microfibers on spore carrier, 17.0 mm diameter.

Spore carrier: filter paper, 16.0 mm diameter.

$\geq 10^6$  *Bacillus atrophaeus* ATCC®\* 9372 spores per vial.

Final fluorescence reading is performed after 4 hour-incubation at  
37 °C (sensitivity:  $\geq 97$  %).

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 37 °C, thus showing the  
presence of living spores. If sterilization process is successful culture  
medium will remain blue after the incubation process.

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

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7-day readout for visual confirmation by color change is optional and not intended to be routinely performed; it is an initial validation of the 4 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 dry out.

### Environmental conditions during manufacture

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

### Storage conditions

T= 10-30 °C, RH 30-80 %, keep in the 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. Chemical indicator line, printed with EO 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.

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

### Possible target markets

Healthcare and Industry.

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### Other important information

Incubation at 37 °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 Steam, Dry Heat, Radiation or any sterilization process other than EO.