

Infection Control Division | Accessories

## MiniBio Auto-reader Incubator

For incubation and readout of Rapid, Super Rapid or Ultra Rapid Biological Indicators



### Usage

#### United States

Terragene® Bionova® Reader Incubators MiniBio incubate at 60 °C and 37 °C and read the Terragene® Bionova® SCBI for fluorescent results at the times prescribed in the User Manuals.

#### Outside the United States

For incubation and readout of:

Bionova® Rapid Fluorescence Readout Biological Indicators: BT220 (steam): 3 h at 60 °C, BT110 (EO): 4 h at 37 °C, BT102 (formaldehyde): 2 h at 60 °C and BT95 (VH<sub>2</sub>O<sub>2</sub>): 2 h at 60 °C.

Bionova® Super Rapid Fluorescence Readout Biological Indicators: BT222 (steam): 1 h at 60 °C and BT96 (VH<sub>2</sub>O<sub>2</sub>): 30 min. at 60 °C.

Bionova® Ultra Rapid Fluorescence Readout Biological Indicators: BT224 (steam): 20 min. at 60 °C.

### Applicable regulation

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

Low Voltage Directive 2014/35/EU.

Electromagnetic Compatibility Directive 2014/30/EU.

RoHS Directive 2011/65/EU.

WEEE Directive 2012/19/EU.

### FDA 510(k)

K191021.

### Characteristics

3 positions (38 mm deep, 9 mm diameter) to incubate Rapid, Super Rapid and Ultra Rapid Fluorescence Readout Self-contained Biological Indicators.

1 ampoule crusher.

Special hole for external thermometer.

Incorporated top cap.

Dual Temperature System: allows selection between two different incubation temperatures (37 °C and 60 °C).

USB connection for registering results in a PC through Bionova® Cloud Web Application.

Allows incubating 3 SCBIs simultaneously, in different incubation times, at the same temperature.

Thermal printer to record results.

Sound alarm for event indication.

Automatic detection and cancellation of biological indicator fluorescence reading.

Firmware update by the user.

Fluorescence reading wavelength: ~ 460 nm.

Dimensions: 105 mm high, 156 mm wide and 145 mm deep.

Voltage range: 100- 240 VAC.

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Power: 28 W.  
Frequency: 50-60 Hz.  
Operating temperature: 10-30 °C.

### **Environmental conditions during manufacture**

T = 15-30 °C, RH = 35-85 %.

### **Storage conditions**

T = 5-40 °C, RH = 30-80 %, keep in a dark place.

### **Transport conditions**

It is recommended to respect the storage conditions during transport.

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 = 2-5 °C and T = 40-65 °C for no longer than seven days. No restrictions for relative humidity.

### **Shelf life**

5 years.

### **Packing**

1 unit per box.

Packing information: product code and description, storage conditions and manufacturer information.

### **Labelling**

On product: product code and description, operating conditions, manufacturing date, batch number, serial number, datamatrix code and manufacturer information.

On product's box: product code and description, storage conditions, manufacturing date, batch number, serial number, datamatrix code and manufacturer information.

### **Possible target markets**

Healthcare, Food, Pharmaceutical and medical devices industries.

### **Other important information**

Bionova® MiniBio Auto-reader has a button located on the incubator panel to select temperatures at 37 °C or 60 °C. It also has a button for each of the positions of readout to set up a different time for each position.

Bionova® MiniBio Auto-reader has an automatic readout system and a printer to record the results.

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### Precautions

Do not pour any liquid inside.

Do not immerse into any liquid.

Only for indoor use.

Disconnect the power cord before cleaning.

Do not use abrasive or corrosive cleaners or disinfectants.

Make sure that the incubator is connected to a properly rated power cord.