

Infection Control Division | Accessories

## BHY Bionova® Hyper Auto-Reader Incubator

For incubation and readout of Hyper Rapid Self-Contained Biological Indicators



### Usage

For incubation and readout of Bionova® Hyper Rapid Biological indicators BT98 (VH2O2): readout fluorescence system after 5 minutes of incubation at 60 °C.

### Applicable regulation

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

Electrical Safety: IEC 61010-1; IEC 61010-2-010.

Electromagnetic Immunity: IEC 60601-1-2; EN 60601-1-2.

Electromagnetic Compatibility: EN 61326-1; EN 62311;

RED Directive 2014/53/EU; 47 CFR Part 15.

RoHS Directive 2011/65/EU.

WEEE Directive 2012/19/EU.

### FDA 510(k)

K221641.

### Characteristics

2 readout positions (38 mm deep, 9 mm diameter) for incubation of Hyper Rapid Biological indicators.

Simultaneous incubation on both readout positions at 60°C.

1 ampoule crusher.

Dedicated hole for external thermometer.

Audible alarms for event notification.

Automatic detection of placed indicators. Automatic readout cancelation if indicators are removed before time.

Unique ID number for each carried out result for audit purposes.

Easy access to the last 50 results.

USB connectivity.

Wi-Fi connectivity.

Bluetooth® wireless technology connectivity.

Fully compatible with Bionova® Cloud Web Application.

Fully compatible with Terragene® Wireless Assistant App for mobile devices.

Firmware can be easily updated by the user.

Fluorescence reading wavelength: ~ 460 nm.

Dimensions: 107 mm high, 97 mm wide and 103 mm deep.

Voltage range: 100 - 240 V AC.

Power: 18 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

Infection Control Division | Accessories

## BHY Bionova® Hyper Auto-Reader Incubator

For incubation and readout of Hyper Rapid Self-Contained Biological Indicators



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, batch and serial number, manufacture firmware, manufacture date, datamatrix code and manufacturer information.

On product's box: product code and description, storage conditions, batch and serial number, manufacture firmware, manufacture date and datamatrix code.

### Possible target markets

Healthcare, Food, Pharmaceutical and Medical Devices Industries.

### 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.

Use only the included power supply (AC power adapter), power supply's AC plug, power supply cords, and USB cable.

This product contains dry natural rubber.