

Infection Control Division | Accessories

BPH Bionova® Photon Auto-Reader Incubator

For incubation and readout of Instant Self-Contained Biological Indicators.



Usage

Terragene® Bionova® Photon Auto-reader Incubator (BPH) incubates at 60 °C and reads the Terragene® Bionova® Photon SCBIs at the times prescribed in the User Manual.

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 De Novo

DEN220042

Characteristics

2 readout positions (38 mm deep, 9 mm diameter) for incubation of Instant (7 s readout) 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.

Terragene® Bionova® Photon Auto-reader (BPH) is intended to be marketed as Over-the-Counter (OTC) device.

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

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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, 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.