

Biological Indicator Incubator

REF 4145-CU-A

INTENDED USE

The Biological Indicator (BI) Incubator is intended to be used with self-contained biological indicators containing bacterial spores of *Geobacillus stearothermophilus* ATCC 7953.

SUMMARY AND EXPLANATION

The BI Incubator is designed for convenient and effective incubation of self-contained biological indicators containing *Geobacillus stearothermophilus* spores. The dry block incubator is pre-set to operate between 55°C and 60°C. The temperature is calibrated using a thermometer traceable to U.S. National Institute of Standards and Technology (NIST).

A self-contained biological indicator consists of a plastic vial housing a glass media ampoule and a paper carrier impregnated with bacterial spores. The self-contained BI is placed in the autoclave and processed. Upon removal from the sterilizer, the BI is activated by crushing the inner glass ampoule which allows the growth medium to contact the spore carrier. The activated BI is then incubated in the BI incubator for a specified length of time and observed for color change of the growth medium. If the medium turns yellow during incubation, the test is positive indicating growth and inadequate sterilization. If no change in the purple media, the test is negative, the spores are not viable, indicating successful sterilization.

Follow the BI manufacturer instructions with regards to incubation temperature and times for the BI.

The BI Incubator features fast warm-up time, 15 Incubation Wells, and an integrated activation cavity (Vial Crusher). The incubator design is intended to be plugged-in and left on. This insures that the temperature remains stable and eliminates variables with the BI results.

STORAGE AND STABILITY

1. Store and operate at controlled room temperature (2°C to 30°C), between 20 and 70% relative humidity.

PRECAUTION

1. For trained personnel use only.
2. Avoid touching the hot surface of the incubator.
3. For indoor use only.
4. Use with grounded AC power source. Electrical Rating: 120V, 60 Hz frequency, 0.75 A.
5. Main power supply voltage fluctuations not to exceed $\pm 10\%$ of the nominal voltage.
6. Do not place incubator in drafty areas, near open windows, air conditioning unit, heating vents, or heat-generating equipment since fluctuating temperatures may affect the incubator temperature.
7. Keep away from water sources.
8. Do not remove bottom cover.
9. Wear protective gloves, eyes and face protection when handling and activating the BI vials.
10. Do not use Vial Crusher with a glass tube or ampoule.
11. To clean the unit, unplug incubator, allow to cool, wipe with dampen cloth with water to remove residuals. Do not immerse incubator in liquid.

12. To clean the Incubation Wells and Vial Crusher, use a cotton-tipped applicator dampened with isopropyl alcohol.



ISO 7000 – 0434
Caution, risk of danger

Note: If the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

MATERIALS SUPPLIED

1. Biological Indicator Incubator with 15 Incubation Wells and integrated Vial Crusher, pre-set operation temperature between 55°C and 60°C only.
2. Instructions For Use.

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Calibrated thermometer (available separately from Innovatek Medical Inc.)
2. Timer
3. Sterilization monitoring result record log

INSTRUCTIONS FOR USE

1. Plug in incubator into a grounded AC power outlet, away from any heat or water sources.
2. The green indicator light will come on. (The green indicator light only indicates the power is on. It does **not** indicate correct temperature.)
3. Allow at least 15 minutes to heat up to temperature.
4. Check with a calibrated thermometer that the temperature of the incubator is between 55°C and 60°C before use.
5. Refer to the BI manufacturer instructions for information on processing, activation, incubation, and interpretation of results.
6. The incubator is intended to be plugged-in and left on.

QUALITY CONTROL

As a positive growth control, place an activated, unsterilized self-contained BI in the incubator each day of use and process. If the positive control does not grow, discontinue use and contact your local distributor.

LIMITATIONS

1. Monitor the temperature of the incubator before use and regularly while in use with a calibrated thermometer.
2. The calibrated thermometer must be re-calibrated, at a minimum once a year, or as per user facility's standard operating procedures.
3. Always follow the BI manufacturer instructions with regards to incubation temperature and times for the BI.
4. Contact Innovatek Medical Inc. for a list of brands of self-contained BI validated for use with the BI Incubator.

Distributed by:

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