



Propper BI-O.K.® Self-Contained Biological Indicator for Vaporized Hydrogen Peroxide (VHP)

November 19, 2014

Composition of product and intended use:

Intended use: The BI-O.K.® self-contained biological indicator is used for routine monitoring and validation of vaporized hydrogen peroxide (VHP) sterilization processes.

Product description: the self-contained biological indicator for Vaporized Hydrogen Peroxide consist of the following components:

1. Plastic vial with soft walls;
2. Orange cap with 3 holes on top for sterilant admission;
3. Filter paper (Tyvek) inside the cap;
4. Glass ampoule with growth incubation medium and pH indicator changing color from orange-red to yellow;
5. Glass fiber carrier inoculated with spores;
6. External vial label with VHP process indicator and Lot number and expiration date. A generic pen can be used to write necessary additional information on the label, and after processing the writing will be visible.
7. The indicators are supplied inside a zip-loc pouch with external label containing all necessary information about the product, lot number and expiration date.

Microorganisms used in the indicator: The indicator contains $1.5 \times 10^6 - 5.0 \times 10^6$ *Geobacillus stearothermophilus* spores (ATCC 7953 or ATCC 12980).

Typical use of the indicator: The BI-O.K.® VHP self-contained biological indicator is placed inside a Tyvek pouch or alone; the SCBI is then placed in a loaded chamber at the most challenging area for sterliant penetration, typically the middle of the top shelf. A sterilization cycle is initiated based on manufacturers' recommendations. Upon cycle completion, the BI-O.K.® VHP vial is retrieved and activated by crushing the media ampoule to facilitate contact between media and spore strip. The vial is incubated at 55-60°C for 24 hours to observe spore growth. If a particular healthcare facility protocol require one week incubation, the BI-O.K.® VHP self-contained biological indicator can be observed for up to seven (7) days. If the spores have been killed during the cycle, the media will remain red-orange, indicating a successful

sterilization. If spores survive after a sterilization cycle, growth will occur, as indicated by a media color change from red-orange to yellow, indicative of a failed sterilization cycle.

Performance parameters of the biological indicator:

Spore population range: $1.5 \times 10^6 - 5.0 \times 10^6$ spores/strip

Survival*: 30 seconds

Kill*: 6 minutes

Incubation Time: 24 hours, up to 7 days

Incubation temperature range: 55 – 60°C

Organism: *Geobacillus stearothermophilus* ATCC 7953 or ATCC 12980

* Survival and Kill are tested in J&J Sterrad¹ NX sterilizer. If other types of sterilizers are used, Survival and Kill times may be different.

Storage conditions: Temperature +15 °C +30°C, Relative Humidity 20-70%. Short excursions of temperature in the range of +10 °C + 35 °C during transportation is allowed. Do not freeze!

Expiration: 18 months after manufacturing date if stored in recommended temperature and humidity.

Utilization of indicators: unused indicators after expiration date and indicators that demonstrated growth need to be inactivated. The suitable methods are: in a gravity steam sterilizer at 121°C for at least 30 minutes or in pre-vacuum sterilizers at 132°C for at least 5 minutes. Healthcare facilities can use their own validated methods of de-activation suitable for *Geobacillus stearothermophilus*.

1. Sterrad is a registered trademark of Johnson & Johnson Corp., USA.