

CHEMICAL INDICATOR STRIP For Monitoring Vaporized Hydrogen Peroxide Sterilization Processes (CLASS 4 / TYPE 4)

Crosstex Code: GPS-250R

Product Image



Product Description

Crosstex Chemical Indicator Strips, GPS-250R, are intended for use with individual units (e.g. packs, containers) to indicate that the unit has been directly exposed to a VH₂O₂ process and to distinguish between processed and unprocessed units. The indicator color transitions from pink/red to blue.

Physical Properties

| | |
|----------------------------|---|
| Process | VH ₂ O ₂ |
| Indicator Strip Dimensions | 101 mm x 16 mm (4" x 0.625") |
| Packaging | 250 Strips/Box |
| Chemical Indicator | Initial Color : Pink/Red Signal Color : Blue |

Intended Use

The indicators are intended to monitor all cycles within the STERRAD[®] 100S, 200, NX, 100NX, and STERIS[®] V-PRO[®] vaporized hydrogen peroxide sterilizers. The VH₂O₂ Indicators are intended to be used with sterilization wraps, containers, cassettes, rails or pouches to distinguish between processed and unprocessed units for both Healthcare and Industrial applications.

Class 4/Type 4 Multi-critical Process Variable Indicator Stated Value:

- 2.3 mg/L ± 0.4 mg/L of VH₂O₂ at 50°C for 6 minutes

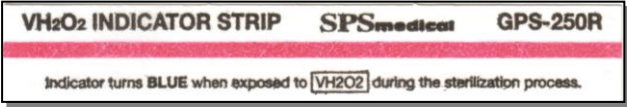
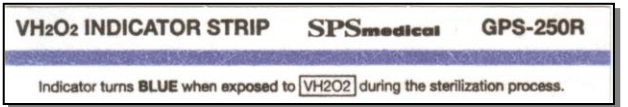
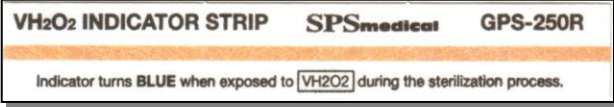
Instructions for Use

Use a strip in each pack, peel pouch, or tray to be VH_2O_2 sterilized. Process packages/items as instructed in the sterilizer validation or manual.

Upon exposure to VH_2O_2 , the chemical indicator will transition from pink/red to a shade of blue. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from pink/red to a shade of blue provides indication of exposure to VH_2O_2 . If signal color is not achieved, this suggests ideal sterilization conditions may not have been met. Colors other than blue such as yellow/green should be treated as a process failure. Determine if the load was successfully sterilized by examining the biological indicator, or re-sterilize the load using a new strip.

The endpoint color (blue) of the indicator will remain stable for a minimum of 45 days from the date of processing when stored according to the products labeled storage conditions.

Performance Characteristics

| | |
|---|--|
| Result Availability | Immediately following exposure to VH_2O_2 |
| Unexposed* | Exposed to $2.3 \text{ mg/L} \pm 0.4 \text{ mg/L}$ of VH_2O_2 at 50°C for 6 minutes* |
|  <p>VH₂O₂ INDICATOR STRIP SPS_{medical} GPS-250R Indicator turns BLUE when exposed to VH₂O₂ during the sterilization process.</p> |  <p>VH₂O₂ INDICATOR STRIP SPS_{medical} GPS-250R Indicator turns BLUE when exposed to VH₂O₂ during the sterilization process.</p> |
| Potential Fail Color | |
|  <p>VH₂O₂ INDICATOR STRIP SPS_{medical} GPS-250R Indicator turns BLUE when exposed to VH₂O₂ during the sterilization process.</p> | |

*Colors shown are representations of printed ink initial and signal colors but may vary from actual use.

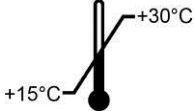







The signal color achieved from exposure to VH_2O_2 may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature, etc.).

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical Indicators- Part 1: General Requirements for Type 1 Chemical Process Indicators & Type 4 Multi critical Process Variable Indicators

Storage and Shelf Life

| | | | |
|---|--|---|------------------------------|
|  | 15°C to 30°C |  | Keep away from light sources |
|  | 20% to 70% Relative Humidity |  | Keep dry |
| <p>Shelf life</p> | <p>2 years from the date of manufacture</p> <p>The date of manufacture is based on the day the indicating ink is applied to the substrate. The remaining shelf life upon receipt will be shorter than 2 years.</p> |  | Do not reuse |
|  | <p>Keep away from sterilants, alkaline chemicals and acids. Do not use after expiration date. Do not use the product if the indicator has transitioned to a blue color prior to use.</p> | | |

Disposal

Discard as general waste.

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