



Technical Data Sheet

Chemical Process Indicators (CPIs) For Monitoring Vaporized Hydrogen Peroxide (VH₂O₂) Processes ISO 11140-1 TYPE 1

True Indicating Code: CPYB-1



Product Description

True Indicating VH₂O₂ process indicator labels contain no lead or other toxic heavy metals. The Indicators are manufactured for use with individual units (e.g. Packs, containers) to indicate that the unit has been directly exposed to a VH₂O₂ processes and to distinguish between processed and unprocessed units. The Indicator color transitions from Yellow to Blue.

Physical Properties

Process	VH ₂ O ₂ / Plasma
Dimensions	12.7 mm (1/2") diameter circle
Imprinted Label Text	"Blue is H ₂ O ₂ Exposed"
Packaging	5,000 Indicators/Roll
Chemical Indicator	Initial Color: Yellow Signal Color: Blue

Indications for Use

The Indicators are intended for use in monitoring VH₂O₂ sterilization processes utilizing ≥ 2.3 mg/L of VH₂O₂. The indicators may not be suitable for monitoring disinfection processes.

Type 1 Process Indicator requirements:

- 2.3 mg/L at 50°C for 6 minutes

Instructions for Use

Use an Indicator on each item, pack, peel pouch, or tray intended for VH₂O₂ exposure. Place at a location considered most challenging for VH₂O₂ to reach. Process the packages/items as instructed in the sterilizer validation or manual.

Upon exposure to VH₂O₂, the Indicator will transition from Yellow to Blue. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from Yellow to a shade of Blue provides indication of exposure to VH₂O₂. If signal color is not achieved, this suggests ideal conditions were not met.

The chemical reaction which causes the color transition is a VH₂O₂ specific reaction and is irreversible. With prolonged exposure to VH₂O₂ or sunlight, the Blue signal color may fade to colorless.



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Performance Characteristics

Result Availability	Immediately following exposure to VH_2O_2 processes
Unexposed	Exposed to 50°C, 6 minutes, 2.3 mg/L VH_2O_2
	

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.). For a Type 1 Process Indicator, a color change to a shade of Blue produced during exposure to VH_2O_2 which is different from the initial color is considered acceptable.

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical indicators- Part 1:General requirements for Type 1 Chemical Process Indicators

Storage and Shelf Life

	15°C to 30°C		Keep away from Sunlight
	20% to 80% relative humidity		Keep Dry
Shelf Life	3 years from the date of manufacture. 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 3 years		
	Do not store near sterilants. Do not use after expiration date. DO not use the product if the indicator has transitioned to Blue prior to use.		

Disposal

Discard as general waste.

