

## CHEMICAL PROCESS INDICATORS (CPIs)

### For Monitoring Vaporized Hydrogen Peroxide Sterilization Processes (CLASS 1/TYPE 1)

Crosstex Code: CPI-P03

#### Product Description

CPI-P03 are intended for use with individual units (e.g. packs, containers) to indicate that the unit has been directly exposed to a H<sub>2</sub>O<sub>2</sub> process and to distinguish between processed and unprocessed units. The indicator color transitions from yellow to blue.

#### Physical Properties

Process	Vaporized H <sub>2</sub> O <sub>2</sub>
Dimensions	Diameter: 12.7 mm (0.5") circle Thickness: 0.20 mm (indicator); 0.26 mm (indicator and liner)
Imprinted Label Text	"BLUE IS H <sub>2</sub> O <sub>2</sub> EXPOSED"
Packaging	5,000 Indicators/Roll
Chemical Indicator	Initial Color: Yellow Signal Color: Blue

#### Intended Use

The indicators are intended to monitor H<sub>2</sub>O<sub>2</sub> sterilization processes utilizing  $\geq 2.3$  mg/L of H<sub>2</sub>O<sub>2</sub>. The indicators may not be suitable for monitoring disinfection processes.

Class 1/Type 1 Process Indicator Requirements:

- 2.3 mg/L  $\pm$  0.4mg/L at 50°C  $\pm$  0.5°C

#### Instructions for Use

Use an indicator on each item, pack, peel pouch, or tray intended for H<sub>2</sub>O<sub>2</sub> sterilization. Place at a location considered most challenging for H<sub>2</sub>O<sub>2</sub> to reach. Process the packages/items as instructed in the sterilizer validation or manual.

Upon exposure to H<sub>2</sub>O<sub>2</sub>, 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 H<sub>2</sub>O<sub>2</sub>. If the signal color is not achieved, this suggests ideal sterilization conditions may not have been met. Determine if the load was successfully sterilized by examining a biological indicator, or re-sterilize the load using a new chemical indicator.

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## Performance Characteristics

Result Availability	Immediately following exposure to H <sub>2</sub> O <sub>2</sub> processes
Unexposed*	Exposed to 50°C, 6 minutes, 2.3 mg/L H <sub>2</sub> O <sub>2</sub> *
	

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

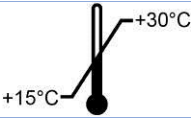

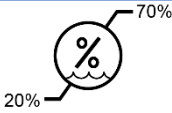




The signal color achieved from exposure to H<sub>2</sub>O<sub>2</sub> may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature, etc.). For a Type 1 Process Indicator, any color change produced during exposure to H<sub>2</sub>O<sub>2</sub> 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

## Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 70% relative humidity		Keep dry
<b>Shelf life</b>	2 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 2 years		
	Keep away from sterilants. Do not use damaged Indicators or Indicators which have transitioned to blue. Do not use after expiration date		

## Disposal

Discard as general waste.