

Chemical Process Indicators (CPIs) For monitoring Vaporised Hydrogen Peroxide (VH₂O₂) Sterilisation Processes (CLASS / TYPE 1)

Excelsior Code: CPI-P03E



Product Description

Excelsior Hydrogen Peroxide (H₂O₂) process indicator labels contain no lead or other toxic heavy metals. The indicators are manufactured for use with individual units (eg. Packs, containers) to indicate that the unit has been directly exposed to a H₂O₂ processes and to distinguish between processed and unprocessed units. The indicator colour transitions from yellow to blue.

Physical Properties

Process	Vaporised Hydrogen Peroxide (VH ₂ O ₂)
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 Colour: Yellow Signal Colour: Blue Chemical Indicators contain no lead or other toxic heavy metals

Indications for Use

The Indicators are intended for use in monitoring H₂O₂ sterilisation processes utilising ≥ 2.3 mg/L of H₂O₂. The indicators may not be suitable for monitoring disinfection processes.

Class 1 / Type 1 Process Indicator

- 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 H₂O₂ exposure. Place at a location considered most challenging for H₂O₂ to reach. Process the packages/items as instructed in the steriliser validation or manual.

Upon exposure to H₂O₂, the indicator will transition from yellow to blue. The transition colour may vary depending on the load configuration, length and conditions of exposure. A colour transition from yellow to a shade of blue provides indication of exposure to H₂O₂. If signal colour is not achieved, this suggests ideal conditions were not met.

The chemical reaction which causes the colour transition is a Hydrogen peroxide specific reaction and is irreversible. With prolonged exposure to H₂O₂ or light, the blue signal colour may fade to colourless.

Performance Characteristics

Result Availability	Immediately following exposure to H ₂ O ₂ processes
Unexposed*	Exposed to 50°C, 6 minutes, 2.3 mg/L H₂O₂ *
	

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

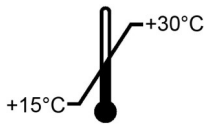
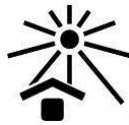





The signal colour achieved from exposure to H₂O₂ may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature etc.). For a type 1 process indicator, a colour change to a shade of blue produced during exposure to H₂O₂ which is different from the initial colour 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		
	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.

For additional product information:
Please visit us at
www.excelsiorscientific.com
Email us at sales@excelsiorscientific.com