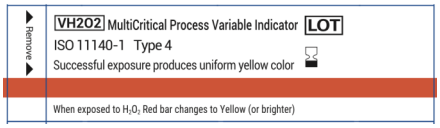
Technical Data Sheet

MULTICRITICAL PROCESS VARIABLE INDICATOR
For Monitoring Vaporized Hydrogen Peroxide Processes
ISO 11140-1 TYPE 4



True Indicating Code: CPRY-14

Product Description

True Indicating Vaporized Hydrogen Peroxide (VH_2O_2) Process Indicator strips contain no lead or other toxic heavy metals. The Indicator strips are intended for use with individual units (i.e. packs, containers) to demonstrate that the unit has been directly exposed to a VH_2O_2 process to distinguish between processed and unprocessed units. The indicator color transitions from Red to Yellow when exposed during a Sterrad® sterilization process.

Physical Properties

Process	VH_2O_2 / Plasma
Indicator Strip Dimensions	19 mm x 64 mm
Packaging	250 Strips / Package
Chemical Indicator	Initial Color: Red Signal Color: Yellow

Indications for Use

The indicators are intended to monitor VH_2O_2 processes utilizing ≥ 2.3 mg/L of VH_2O_2 equivalent to Sterrad® sterilization exposure. The Indicators may not be suitable for disinfection processes.

Type 4 Process Indicator Requirements:

- 2.3 mg/L at 50°C for 6 minutes

Instructions for Use

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

Upon exposure to VH_2O_2, the chemical indicator will transition from Red to a shade of Yellow. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from Red to a shade of Yellow provides assurance of effective exposure to VH_2O_2. If the signal color of Yellow is not achieved this may suggest ideal exposure conditions were not met. Review the exposure conditions and investigate the sterilizer for malfunction

The chemical reaction which causes the color transition is a VH_2O_2 specific reaction and is irreversible.

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Result Availability	Immediately following exposure to VH_2O_2

Unexposed	Exposed to VH_2O_2 50°C, 6 minutes, 2.3mg/L
	

Colors shown are representations and 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 Type 4 Process Indicator, a color change to Yellow produced during exposure to VH_2O_2 which is different from the initial color of Red is considered acceptable.

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical Indicators- Part 1:General Requirements for Type 4 Multicritical Process Variable 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 or disinfectants. Do not use after expiration date. Do not use the product if the indicator has transitioned prior to use.		

Disposal

Discard as general waste.

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