



CHEMICAL PROCESS INDICATOR STRIP For Monitoring Vaporized Hydrogen Peroxide (VH₂O₂) or Ozone (O₃) Disinfection Processes ISO 11140-1 Type 1

True Indicating Code: CPVG-11

Product Description

True Indicating VH₂O₂ or O₃ Process Indicator strips contain no lead or other toxic heavy metals. For VH₂O₂ Type 1 processes, the Indicator strips are intended for use with individual units (i.e. packs, containers) to demonstrate that the unit has been exposed to the sterilant and to distinguish between processed and unprocessed units.

For use in disinfection and fogging processes of VH₂O₂, O₃, or a combination of the two, the Indicator strips are intended for use in confirmation that the disinfectant has effectively contacted the Chemical Indicator at a specific location or within a specific timeframe .

The Indicator will transition from Brown to Green when exposed to the sterilizing agent or disinfectant.

Physical Properties

Process	VH ₂ O ₂ / Plasma or O ₃
Indicator Strip Dimensions	19 mm x 70 mm (0.75" x 2.75")
Packaging	250 Indicator Strips / Package
Chemical Indicator	Initial Color: Violet/Brown Signal Color: Green

Indications for Use

Type 1 Process Indicator Requirements:

- 2.3mg/L at 50°C for 6 minutes

Instructions for Use

The Indicators are suitable for monitoring disinfection processes of VH₂O₂, O₃, or a combination of the two. ISO 11140-1 does not include guidance related to performance of Indicators for use in disinfection processes.

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

Disinfection: Locate Indicators in the most challenging areas within a room or disinfection chamber. Perform disinfection process as instructed by the equipment manual or internal procedures.

Upon exposure to VH₂O₂, O₃, or a combination of the two, the Chemical Indicator (CI) will transition from Violet/Brown to a shade of Green. The transition color may vary depending on the load configuration, location, length and conditions of exposure. A color transition from Brown to a shade of Green provides indication of exposure . If the signal color is not achieved this may suggest ideal exposure conditions were not met. Review the exposure conditions and investigate the sterilizer for malfunction, if applicable.

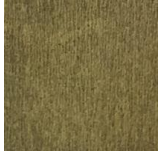
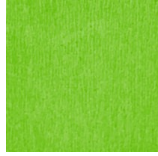

The chemical reaction which causes the color transition is a VH₂O₂ or O₃ specific reaction and is irreversible.





Technical Data Sheet

Performance Characteristics

Result Availability	Immediately following exposure to VH_2O_2 , O_3 , or a combination of the two	
Unexposed 	Exposed to VH_2O_2 50°C, 6 mins, 2.3mg/L (Sterilization Process) 	Exposed to VH_2O_2 under ambient conditions (Disinfection Process) 

Colors shown are representations and may vary from actual use.

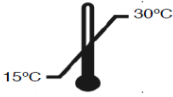






The signal color achieved from exposure may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature, etc.). For Type 1 Process Indicators, a color change produced during exposure which is different from the initial color is considered acceptable.

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 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.