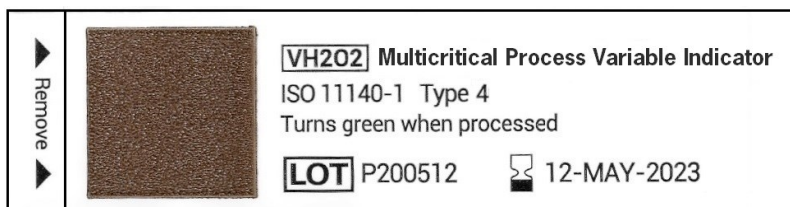


MULTICRITICAL PROCESS VARIABLE INDICATOR STRIP

For Monitoring Hydrogen Peroxide Sterilisation (Plasma) Processes (ISO-11140-1CLASS / TYPE 4)

Excelsior Code: HVG-250E



Product Description

Excelsior 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 sterilisation process to distinguish between processed and unprocessed units. The indicator colour transitions from Violet to Green when exposed to sterilisation process.

Physical Properties

Process	Plasma / VH_2O_2
Indicator Strip Dimensions	19 mm x 70 mm (0.75" x 2.75")
Packaging	250 Strips / Package
Chemical Indicator	Initial Colour: Violet Signal Colour: Green Chemical Indicator Inks contain no lead or other toxic heavy metals

Indications for Use

The indicators are intended to monitor VH_2O_2 sterilisation processes utilising ≥ 2.3 mg/L of VH_2O_2 . The Indicators may not be suitable for disinfection processes.

Class /Type 4 Process Indicator Requirements:

- 2.3mg/L at 50°C for 6 mins
- Complete Colour Change Time: 30 minutes \pm 5 minutes


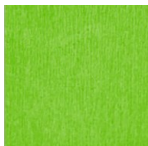
Instructions for Use

Use an indicator in each pack, peel pouch or tray to be sterilised. Process packages/items as instructed in the steriliser validation or manual.

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

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

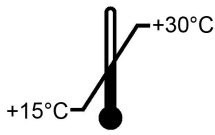





Performance Characteristics

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



The signal colour 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 Indicators, a colour change produced during exposure to VH_2O_2 which is different from the initial colour is considered acceptable.

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

	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 reuse
	Keep away from sterilants. Do not use after expiration date. Do not use the product if the indicator has transitioned prior to use.		

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

Disposal

Discard as general waste.

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



Excelsior
Scientific