STERIS

Life Sciences

TECHNICAL MONOGRAPH

Steraffirm® [VH2O2] Process Indicator

(PCC051)

Science & Solutions for Life

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1. Introduction

This Technical Monograph (TM) illustrates the principles of operation of Steraffirm [VH2O2] Process Indicator (PI) (PCC051) and guidance as to its effective use.

Steraffirm [VH2O2] PIs are intended for use with STERIS VHP Biodecontamination Units in biodecontamination[1] of clean, dry, sealed Enclosures[2].

[1] In this document, when referring to the use of VHP Biodecontamination Systems with Vaprox® Hydrogen Peroxide Sterilant or Vaprox 59 Hydrogen Peroxide Sterilant in the United States of America (USA), the term Biodecontamination is defined as sterilization of exposed porous and non-porous surfaces in a pre-cleaned, dry, sealed Enclosure. Any reference to Biodecontamination pertaining to the use of this equipment in the United States does not, and is not intended to convey additional claims of effectiveness beyond those contained in the USA Environmental Protection Agency (EPA) registered labeling of Vaprox Hydrogen Peroxide Sterilant (EPA Reg. No. 58779-4) or Vaprox 59 Hydrogen Peroxide Sterilant (EPA Reg. No. 1043-123).

[2] Contained area to be Biodecontaminated (e.g., rooms, facilities and equipment).

2. Description

Steraffirm [VH2O2] PI (PCC051) consists of a PVC strip with a magenta ink circle and a yellow endpoint color standard circle.

The magenta indicator ink circle is specially formulated to be responsive to hydrogen peroxide vapor during the Biodecontamination Cycle and exhibits a gradient color change from magenta to orange to yellow. The yellow endpoint color standard circle is used as a visual comparison to the indicator ink.

Other characteristics are as follows:

- Packaged in sealed, foil re-sealable pouch
- Package includes Instructions for Use (IFU)
- Package label and indicator strip includes lot number, expiration date, and reorder number
- Produced under controlled conditions to assure effectiveness through expiration date
- Declaration of Conformity available upon request or online at www.sterislifesciences.com.
- Complies with ISO11140-1:2005 for Class 1 Chemical Indicator

[3] *Tyvek is a registered trademark of E. I. du Pont de Nemours and Company.*

3. Principles of Operation

Steraffirm [VH2O2] PIs comply with ISO11140-1:2005 Sterilization of health care products - Chemical indicators for Class 1 chemical indicators.

Class 1 PIs are intended for use with individual units (e.g. packs, containers) to indicate that the unit has been directly exposed to the sterilization process and to distinguish between processed and unprocessed units. They shall be designed to react to one or more of the critical process variables.[4]

The critical process variables are time, temperature, and hydrogen peroxide vapor concentration.

Table 1. Class 1 Chemical Process Indicator Test Conditions & Performance Criteria[4]

Test Condition	Time	Temperature	H_2O_2 Concentration	Visible Change Specified by Manufacturer
Absence of VH_2O_2	45 min ± 5 min	50 °C ± 0.5 °C	None	None
		27 °C ± 0.5 °C		
VH_2O_2	7 sec ± 1 sec	50 °C ± 0.5 °C	2.3 mg/L ± 0.4 mg/L	None
	10 sec ± 1 sec	27 °C ± 0.5 °C		
	6 min ± 1 sec	50 °C ± 0.5 °C		Acceptable Change
	10 min ± 1 sec	27 °C ± 0.5 °C		

PIs are placed within the Enclosure per the Fumigation Management Plan (FMP). The PIs are then exposed to hydrogen peroxide vapor during the Biodecontamination Cycle. After Biodecontamination Cycle completion, PIs are collected and PI indicator ink color change is observed as follows:

- If the indicator ink has changed from magenta to orange to yellow, the process indicator was exposed to hydrogen peroxide vapor
- If the indicator ink has remained magenta, the indicator may not have been exposed to hydrogen peroxide vapor

Results are recorded per the FMP.

NOTE: STERIS Biodecontamination Units are only to be operated by Trained and Certified Applicators who have successfully completed both the STERIS Training and Certification Course for Applicators of Vaprox Hydrogen Peroxide Sterilant and Vaprox 59 Hydrogen Peroxide Sterilant and the pertinent VHP Biodecontamination Unit Operator Course. Certification must be active and in force for all Applicators of Vaprox Hydrogen Peroxide Sterilant and/or Vaprox 59 Hydrogen Peroxide Sterilant.

[4] *ISO11140-1:2005 Sterilization of health care products - Chemical indicators for Class 1 chemical indicators*

4. Consumables

Vaprox® Hydrogen Peroxide Sterilant

35% stabilized aqueous solution of hydrogen peroxide designed for use with VHP Biodecontamination Units and Accessories (EPA Reg. No. 58779-4).

Steraffirm® [VH2O2] Process Indicator (PCC051)

Chemical indicator designed for use with STERIS's VHP process technology at low to intermediate hydrogen peroxide vapor concentrations.

5. Performance Evaluation

Procedure

PIs were tested inside an isolator under atmospheric conditions at four different concentrations. Time, temperature, relative humidity, and hydrogen peroxide vapor concentration were recorded. The PIs were observed at regular time intervals to determine color change progression.

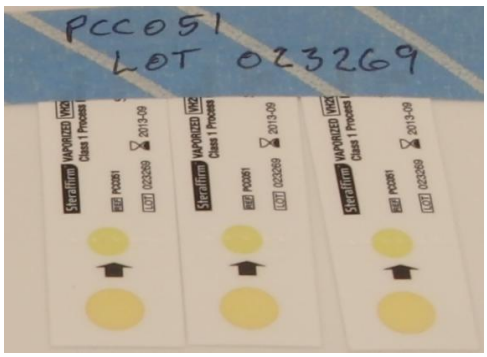
Note: The results presented are for guidance purposes ONLY as actual Customer conditions will vary.

Steraffirm® [VH2O2] Process Indicator (PCC051)

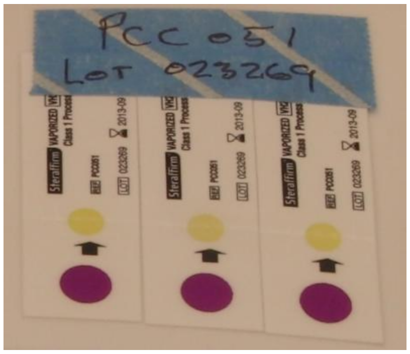
	Avg Time (mins)			
	250 ppm	500 ppm	750 ppm	1000 ppm
Start Indicator Ink Begins to Change	12	7	6	4
End Indicator Ink Reaches Yellow End Point	245	41	28	28

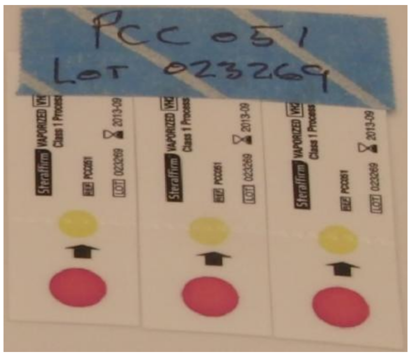
250PPM (30 minute intervals)

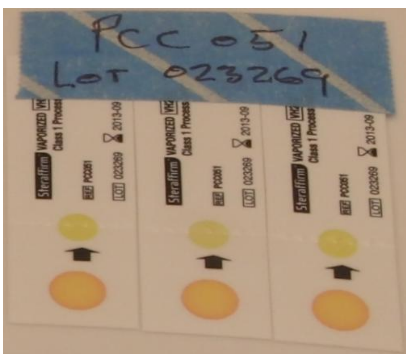
500PPM (10 min intervals)

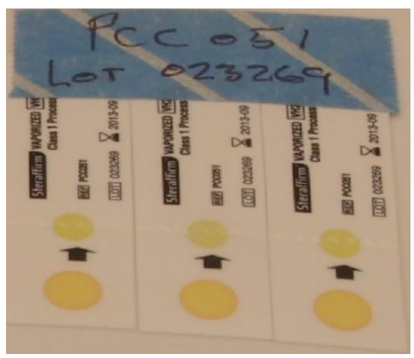


750ppm (5 minute intervals)

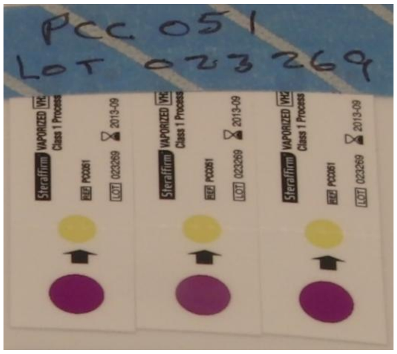


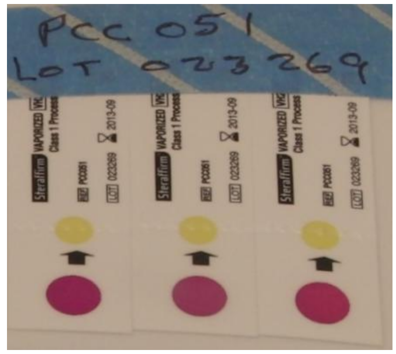


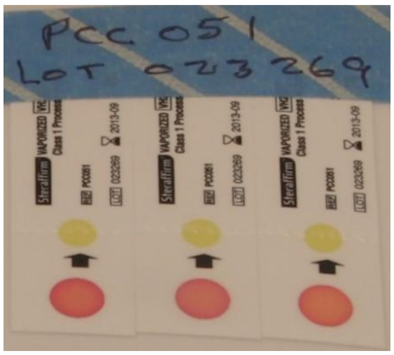


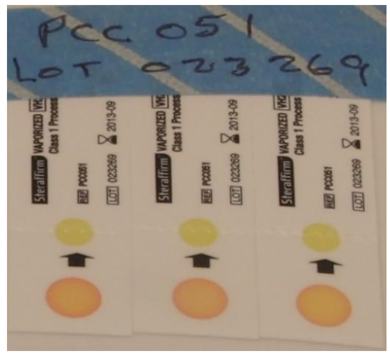


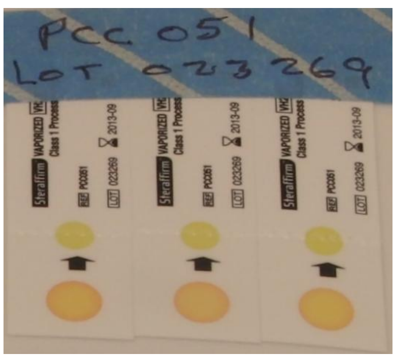
1000 ppm (5 minute intervals)

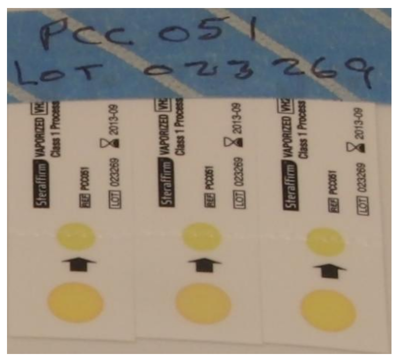












5. Conclusion

Steraffirm [VH2O2] Process Indicator (PCC051) complies with ISO11140-1:2005 for Class 1 Chemical Indicators.