

**APPLICATION**

STERIS's Steraffirm<sup>®</sup>VH2O2 Process Indicator (PCC063) is a Type 1 hydrogen peroxide vapor chemical indicator developed for use with STERIS MD140 Series and LS60 Series VHP<sup>®</sup> Biodecontamination Units using Vaprox<sup>®</sup> 59 Hydrogen Peroxide Sterilant.

**DESCRIPTION**

Steraffirm Process Indicator (PCC063) consists of a Tyvek<sup>®</sup> strip. The process indicator has a magenta indicator 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<sup>2</sup> 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:

- Package includes Instructions for Use (IFU)
- Package label, indicator strip and adhesive label include lot number, expiration date and reorder number
- Produced under controlled conditions to assure effectiveness through expiration date
- Certificate of Analysis available upon request.

<sup>1</sup> Tyvek is registered trademark of E. I. du Pont de Nemours and Company.

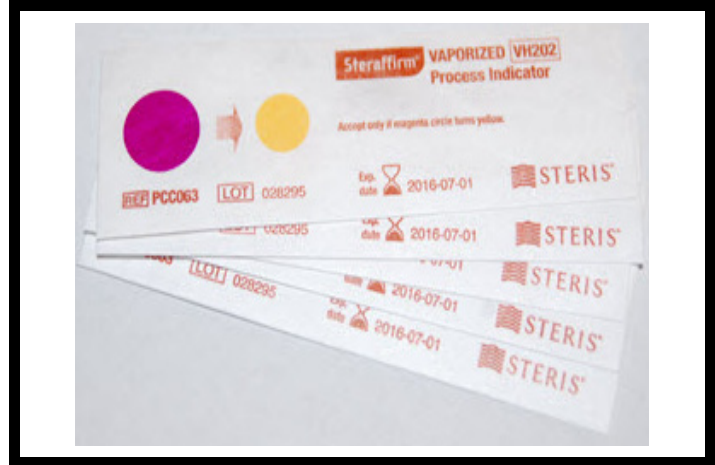
<sup>2</sup> When using STERIS VHP Biodecontamination Units with Vaprox 59 Hydrogen Peroxide Sterilant in the United States of America (USA), the term biodecontamination referred to in this document is defined as sterilization of exposed porous and non-porous surfaces in a pre-cleaned, dry, sealed enclosure.<sup>3</sup> Any reference to biodecontamination as it relates to the use of this equipment in the USA does not impart additional claims of effectiveness beyond that approved in the USA Environmental Protection Agency (EPA) registered labeling of Vaprox Hydrogen Peroxide Sterilant.

<sup>3</sup> Contained area to be biodecontaminated (e.g., rooms, facilities and equipment).

**STANDARDS**

Steraffirm Process Indicator complies with the following standards:

- **ISO11140-1:2014** process indicator.



(Typical - details may vary.)

**DIRECTIONS FOR USE**

Before using Steraffirm Process Indicator, check expiration date printed on both package label and indicator strip adhesive label. Do not use if it is beyond the expiration date. Follow Instructions For Use (IFU) shipped with product.

STERIS's VHP Process Technology produces hydrogen peroxide vapor from liquid Vaprox 59 Hydrogen Peroxide Sterilant and disperses this vapor throughout the Enclosure.

The Biodecontamination Cycle is conducted per the Fumigation Management Plan (FMP).

**NOTE: Refer to the Vaprox 59 Hydrogen Peroxide Sterilant package label and insert for additional information and application instructions.**

After Biodecontamination Cycle completion, process indicators are collected (refer to FMP for guidance) and 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 changed from magenta to any other color, the process indicator was exposed to some concentration of hydrogen peroxide vapor.
- If the indicator ink has remained magenta, the indicator may not have been exposed to hydrogen peroxide vapor.

Record the results 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 59 Hydrogen Peroxide Sterilant and the MD140 Series or LS60 Series Biodecontamination Unit Operator Course. Certification must be active and in force for all Applicators of Vaprox 59 Hydrogen Peroxide Sterilant.**

**Ordering Information**

- PCC063 - Steraffirm Process Indicator - 1 Box (200 Indicators)

Item \_\_\_\_\_  
Location(s) \_\_\_\_\_  
\_\_\_\_\_

## NOTES

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1. Do not use after expiration date.
2. STERIS Life Sciences recommends maintaining a digital record of Steraffirm Process Indicators.
3. Users of Vaprox 59 Hydrogen Peroxide Sterilant are required to take and pass the Vaprox Hydrogen Peroxide Sterilant Training and Certification Course ([www.sterislifesciences.com](http://www.sterislifesciences.com)). US ONLY
4. Not for use in reprocessing of medical devices used for human applications.

**CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LOCAL AND NATIONAL CODES AND REGULATIONS.**

**The base language of this document is ENGLISH. Any translations must be made from the base language document.**

## ENGINEERING DATA

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**Shelf Life (Unexposed Indicator):** 12 Months

**Color Change Stability (Exposed Indicator):** 12 Months

**Storage Conditions (Unexposed/Exposed Indicator):**

Do not store in direct sunlight, near heat, moisture, oxidizing agents, acids/alkalis or cleaning/disinfecting agents.

» Temperature: 43-86°F (6-30°C)

» Relative Humidity: 30-80%

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### For Further Information, contact:



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