

Steraffirm VH202 Indicator

For Chemical Indicator



APPLICATION

STERIS's Steraffirm VH202 Indicators (PCC051 and PCC060) are Type 1 or Type 4 hydrogen peroxide vapor chemical indicators developed for use with STERIS VHP® Biodecontamination Units using either Vaprox® Hydrogen Peroxide Sterilant or Vaprox® 59 Hydrogen Peroxide Sterilant.

DESCRIPTION

Steraffirm Indicator (PCC051) consists of a plastic strip with a magenta indicator ink circle and a yellow endpoint color standard circle. Steraffirm Indicator (PCC060) consists of a Tyvek®¹ strip with 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 Biodecontamination² 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 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.



STANDARDS

Steraffirm Indicator (PCC051) complies with the following standards:

- ISO11140-1:2014 for a Type 1 chemical indicator.

Steraffirm Indicator (PCC060) complies with the following standards:

- ISO11140-1:2014 for a Type 4 chemical indicator.

DIRECTIONS FOR USE

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

STERIS's VHP Process Technology produces hydrogen peroxide vapor from liquid Vaprox Hydrogen Peroxide

Sterilant or 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 either the Vaprox Hydrogen Peroxide Sterilant or Vaprox 59 Hydrogen Peroxide Sterilant package label and insert for additional information and application instructions.

After Biodecontamination Cycle completion, 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 indicator was exposed to hydrogen peroxide vapor
- Please note that a Type 4 indicator requires reaction to two or more critical parameters. Therefore, for a Type 4 indicator, exposure to hydrogen peroxide vapor should not alone be sufficient to change indicator.

1. Tyvek is a registered trademark of E.I. du Pont de Nemours and Company

2. When using STERIS VHP Biodecontamination Units with either Vaprox Hydrogen Peroxide Sterilant or 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.³ 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.

- 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 Hydrogen Peroxide Sterilant, Vaprox 59 Hydrogen Peroxide Sterilant and the pertinent 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.

NOTES

- Do not use after expiration date.
- STERIS Life Sciences recommends maintaining a digital record of Steraffirm Indicators.
- Users of Vaprox Hydrogen Peroxide Sterilant and Vaprox 59 Hydrogen Peroxide Sterilant are required to

take and pass the Vaprox Hydrogen Peroxide Sterilant Training and Certification Course (www.sterislifesciences.com). US ONLY

- Not for use in reprocessing of medical devices used for human applications.

ENGINEERING DATA

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%

Selections Checked Below Apply To This Equipment

- ☐ PCC051 - Steraffirm Indicator - 1 Package (200 Indicators)
- ☐ PCC060 - Steraffirm Indicator - 1 Package (200 Indicators)

Item:	
Locations:	

For Further Information, contact:



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

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