

**GENERAL DESCRIPTION**

The VERIFYSTEAM Integrating Indicator is a type 5 integrating indicator as defined by the Association for the American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization (ANSI/AAMI/ISO) in ANSI/AAMI/ISO 11140-1 standard for chemical indicators. The indicator requires all critical parameters necessary for steam sterilization (time, temperature and saturated steam) and has been correlated to biological indicator death.

**APPLICATION**

The VERIFYSTEAM Integrating Indicator is designed to monitor 250°F/121°C gravity, 270°F/132°C gravity and 275°F/135°C steam sterilization cycles. See **Table 1** for a complete list of validated steam sterilization cycles. Integrator strips are placed into each pack to be steam sterilized in the area deemed to be the most resistant to steam penetration. During the steam sterilization process, steam penetrates the indicator strip causing the steam sensitive dark colored chemical to melt and migrate across the window. When the dark bar reaches the accept window the conditions for sterilization were met. If the dark bar does not appear in the accept window, the conditions for sterilization were not met.

**Table 1: List of Validated Steam Sterilization Cycles**

<b>Sterilization Cycle Type</b>	<b>Sterilization Temperature and Time</b>
Gravity	250°F/121°C for 30 minutes
	270°F/132°C for 15 minutes
	275°F/135°C for 10 minutes
Dynamic Air Removal (prevacuum and steam-flush pressure-pulse)	270°F/132°C for 4 minutes
	275°F/135°C 3 minutes
Immediate Use Steam Sterilization	270°F/132°C 3 and 10 minute gravity
	270°F/132°C 4 minute dynamic air removal
	275°F/135°C 3 and 10 minute gravity
	275°F/135°C 3 minute dynamic air removal

**FEATURES**

- Type 5 integrating indicator (ANSI/AAMI/ISO 11140-1:2014)
- Correlated to the performance of a biological indicator as specified in ANSI/AAMI/ISO 11138
- Dark color bar migrates along a paper wick to reach the ACCEPT area
- Made in the absence of lead-based or heavy metal-based indicator ink and is latex free
- Stable results
- Indicator length of 4"

**BENEFITS**

- Internationally recognized performance
- May be utilized across several sterilization cycles
- Endpoint result is clear and unambiguous
- Eliminates exposure to lead, other heavy metals and latex
- The indicator may be kept as part of your records
- Increases ease of locating indicators in pouches and instrument sets

## TECHNICAL PROPERTIES

---

**Size:** Approximately 4 in x 3/4 in / 10 cm x 2 cm

**Components:**

Aluminum Foil

Steam sensitive chemical containing color dye

Filter paper

Label face stock laminated with cast polypropylene film

**Shelf life:** Five years from the date of manufacture, when stored at recommended conditions.

Test data demonstrates that the integrating indicator meets the requirements for a Type 5 integrating indicator as defined in ANSI/AAMI/ISO 11140-1:2014. **Tables 2 through 4** show results for the ANSI/AAMI/ISO 11140 Type 5 integrating indicator Pass and Fail tests for the product's stated values.

**Table 5** indicates the temperature coefficient for each lot tested.

**Table 2: Pass/Fail Testing From three (3) lots of VERIFY STEAM Integrating Indicators  
With a Stated Value of 250°F/121°C and 23.00 Minutes**

<b>Lot</b>	<b>Pass Test 121°C for 23.00 Minutes # Accept/# Tested</b>	<b>Fail Test 120°C for 19.55 Minutes # Accept/# Tested</b>
Lot 1	9/9	0/9
Lot 2	9/9	0/9
Lot 3	9/9	0/9

**Table 3: Pass/Fail Testing From four (4) Lots of VERIFY STEAM Integrating Indicators  
With a Stated Value of 270°F / 132°C and 2.00 Minutes**

<b>Lot</b>	<b>Pass Test 132°C for 2.00 Minutes # Accept/# Tested</b>	<b>Fail Test 131°C for 1.70 Minutes # Accept/# Tested</b>
Lot 1	9/9	0/9
Lot 2	9/9	0/9
Lot 3	9/9	0/9

**Table 4: Pass/Fail Testing from four (4) lots of VERIFY STEAM Integrating Indicators  
with a Stated Value of 275°F / 135°C and 1.2 Minutes**

<b>Lot</b>	<b>Pass Test 135°C for 1.20 minutes # Accept/# Tested</b>	<b>Fail Test 134°C for 1.02 minutes # Accept/# Tested</b>
Lot 1	9/9	0/9
Lot 2	9/9	0/9
Lot 3	9/9	0/9

**Table 5: Calculated Correlation Coefficient for three (3) Lots of VERIFY **STEAM** Integrating Indicators**

<b>Lot</b>	<b>Temperature Coefficient</b>	<b>Regression Coefficient</b>
Lot 1	11.1	0.9985
Lot 2	11.1	0.9985
Lot 3	11.1	0.9985

## **DIRECTION FOR USE**

---

Place a VERIFY **STEAM** Integrating Indicator into each pack to be sterilized. Position the integrator in that area judged to be the most resistant to steam penetration. Upon completion of the sterilization cycle, release the sterilized items using departmental procedures.

When the pack is to be used, open the pack and aseptically remove the indicator. Examine the indicator to determine that the dark bar has entered the ACCEPT window, assuring the sterilization conditions have been met.

If the dark bar has not entered the Accept window, it is an indication that the sterilizing conditions have not been met. The entire pack must be reprocessed per standard hospital procedures for reprocessing packs.

After opening the indicator's foil package, utilize zippered seal mechanism to reseal pouch. Always store unused integrators in the foil pouch.

## **STORAGE CONDITIONS**

---

VERIFY **STEAM** Integrating Indicators should be stored at room temperature.

## **SERVICE**

---

### **Sales**

Service is one of the most important ways to verify consistent quality of the facility's performance and operation. A tailored service program by STERIS provides effective, trouble-free operations.

### **Technical**

STERIS is pleased to provide a completely staffed and equipped technical service laboratory capable of performing needed tests and providing both telephone and on-site assistance when needed. More details on how this service can benefit a facility's particular situation can be provided upon request.

## **ORDERING INFORMATION**

---

<b>Description</b>	<b>Quantity</b>	<b>Reorder Number</b>
VERIFY <b>STEAM</b> Integrating Indicator	250 strips per pack	PCC064
VERIFY <b>STEAM</b> Integrating Indicator	8 packs per box/250 strips per pack	PCC064B
VERIFY <b>STEAM</b> Integrating Indicator	1000 strips per pack	PCC065
VERIFY <b>STEAM</b> Integrating Indicator	2 packs per box/1000 strips per pack	PCC065B
VERIFY <b>STEAM</b> Integrating Indicator	200 strips per pack	PCC066

---

**For further information, please contact:**



STERIS Corporation  
5960 Heisley Road  
Mentor, OH 44060-1834 • USA  
440-354-2600 • 800-548-4873  
[www.steris.com](http://www.steris.com)