



# Product Technical Data Sheet

Form No.: FTP-001 Rev.: F

**Product Name:** SteriTec Integrgraph Integrator

**Product Type:** Chemical Integrator

**Reorder Number:** CI 101

**Description:** The SteriTec Integrgraph provides an integrated response to steam sterilization at 132°-134° C for pre-vacuum sterilizers operating for 3 minutes or longer. The Integrgraph integrator gives a visible confirmation of the attainment of sterilization conditions at the location within the sterilizer chamber.

**Performance Characteristics:**

The Integrgraph has three different timing indicator inks printed on each indicator. The user can determine:

1. If only the first indicator bar turns green, the integrator has been subjected an insufficient steam sterilization process.
2. If the first and second bars turn green, sterilization conditions were met.
3. If the first two bars turn green as well as the short bar steam sterilization conditions occurred for an extended period.

**Color Change:** Purple to Green.

**Critical Parameters :** (in a standard hospital steam pre-vacuum sterilizer)

	<u>134° C</u>	<u>132° C</u>	<u>121° C</u>
Check Mark	1 min. (-10/+0sec.)	1.5 min. (-15/+0 sec.)	5 min. (-45/+0 sec.)
Long Bar	3 min (-30/+0 sec.)	3.5 min. (-30/+0 sec.)	12 min. (-2/+0 min.)
Short Bar	10 min (-1.5/+0 min.)	11 min. (-100/+0 sec.)	35 min. (-5.5/+0 min.)

**Stated Value:** (as determined in a steam resistometer)

	<u>134° C</u>	<u>132° C</u>	<u>121° C</u>
Check Mark	3 min. (-18/+0 sec.)	4 min. (-45/+0 sec.)	6.5 min. (-2.1/+0 min.)
Long Bar	5 min. (-23/+0 sec.)	7 min. (-.9/+0 min.)	16 min. (-2.4/+0 min.)
Short Bar	13 min. (-1/+0 min.)	17 min. (-2.1/+0 min.)	36 min. (-5.4/+0 min.)

**Indicator Stability:** Before and After Sterilization: Excellent

**Physical Characteristics:**

**Lamination:** Top and Bottom

**Dimensions:** 3" L X .75" W

**Indicator Substrate Material:** Blotter Paper

**Quantity / Bag:** 250

**Bags / Case:** 20

**Selling Unit:** Case

**Environmental Limitations:**

**Storage:** 32° - 104° F (0° – 40° C) at 10-60% humidity. Indicator strips are packaged in tamper evident moisture barrier foil bags. After removing indicators for use, reseal ziplock to protect remaining indicators from exposure to high humidity environmental conditions.

**Shelf Life:** 3 years from date of manufacture

**FDA 510(k) Release to Market Date:** May 8, 1997, K960441

**Standard Classification:**

AAMI ST60, Class 5

ISO 11140-1: 2005, Class 5