



Product Technical Data Sheet

Form No.: FTP-001 Rev.: H

Product Name: SteriTec Integrgraph Integrator

Product Type: Chemical Integrator

Reorder Number: CI 101

Description: The SteriTec Integrgraph provides an integrated response to steam sterilization in pre-vacuum sterilizers operating at 132°-134°C for 3 minutes or longer and at 121°C for 12 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)

Degrees	Check Mark Insufficient	Long Bar Correct	Short Bar Extended
134° C	1 minute	3 minutes	10 minutes
132° C	1.5 minutes	3.5 minutes	11 minutes
121° C	5 minutes	12 minutes	30 minutes

Stated Values: (as determined in a steam resistometer)

Degrees	Check Mark Insufficient	Long Bar Correct	Short Bar Extended
134° C	3.25 minutes	4.75 minutes	11 minutes
132° C	3.75 minutes	5.5 minutes	12 minutes
121° C	8 minutes	12.5 minutes	30 minutes

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: 50° - 100°F (10° - 38°C). 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: The expiry date is printed on the product packaging.

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

Standard Classification:

ISO 11140-1, Class 5

DISTRIBUTED BY:
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