



Product Technical Data Sheet

Form No.: FTP-010 Rev.: F

Product Name: Instant Readout Chemical Integrator Challenge Test Pack - Steam

Product Type: Chemical Integrator

Reorder Number: LT 101

Description: The SteriTec Instant Readout Chemical Integrator Challenge Test Pack was designed specifically for load testing of steam sterilizers. The Test Pack verifies sterilization conditions in each load instantly with accuracy equal to a biological test pack, thus providing instant results for load release assurance. The Test Pack consists of a chemical integrator test sheet placed inside a package of porous and non-porous materials. The pack provides resistance to the penetration of steam during the sterilization cycle.

Performance Characteristics:

When exposed to steam, the indicator, "PASS", changes color.

Color Change: Purple to Green

Critical Parameters: (in a hospital standard steam pre-vacuum sterilizer – color change end points)
3.5 +/- .5 minutes at 132° C (270° F)

Stated Value: (as determined in a steam sterilizer resistometer – color change end points)
5 minutes (+0/-45sec.) at 132° C (+0/-1°C) (270° F)

Indicator Stability: Excellent Before and After Sterilization

Physical Characteristics:

Dimensions: 2.47" W X 3.97" L

Substrate Material: Indicator Card = Print Blotter
Pack Sheets = 80 lb Cover

Quantity / Box: 1

Boxes / Case: 40

Selling Unit: Case

Environmental Limitations:

Storage: 32° - 104° F (0° – 40° C) at 10 – 60% humidity.

Shelf Life: 3 years from date of manufacture.

FDA 510(k) Release to Market Date: April 23, 1998, K965212

Standards Classification:

Integrator Card

AAMI ST60, Class 5

EN ISO 11140-1:1996, Class 5

Test Pack

AAMI ST60, Class 2

EN ISO 11140-1: 1996, Class 2