



Product Technical Data Sheet

Form No.: FTP-073 Rev.: E

Product Name: Steri-Pak LF Bowie-Dick Test Sheet

Product Type: Bowie-Dick Indicator

Product Code: BD 110

Description: Steri-Pak LF Bowie-Dick Test Sheets are designed for daily monitoring of pre-vacuum steam sterilizers to detect air leaks, inadequate steam penetration and vacuum pump failures. The Test Sheet is designed to meet the ISO 11140-3 and ANSI/AAMI/ISO 11140-5 test methods for evaluating the sterilizer's effectiveness at steam penetration and air removal. The Test Sheet is placed inside a towel pack in the sterilizer at the most difficult to sterilize location and run through a sterilization cycle for 3.5 minutes at 134°C.

Performance Characteristics:

If no appreciable air is present in the sterilizer chamber after vacuums are drawn, the steam will penetrate to the middle of the test pack and turn the indicator sheet a uniform black color. If a small amount of air is present, sufficient to cause a two-degree temperature drop, the air will migrate to the middle of the test pack turning the center of the sheet a bluish color rather than a uniform black.

Color Change: Blue to Black for complete change and no air leak
Blue area in center with the presence of air.

Critical Parameters: (in a standard hospital pre-vacuum steam sterilizer)
3.5 minutes at 134°C with no air leaks

Stated Values: (as determined in a steam resistometer.
Not Applicable for Bowie-Dick test.

Indicator Stability: Excellent Before and After Exposure

Physical Characteristics:

Dimensions: 8-1/2" X 11"
Substrate Material: 70-pound Text
Quantity / Bundle: 100
Bundles / Case: 6
Selling Unit: Case

Environmental Limitations:

Storage: 50° -100°F (10° - 38°C) at 10 - 70% humidity

Shelf Life: The expiry date is printed on the product packaging.

FDA 510(k) Release to Market Date: Same as BD 111 with justification letter.

Standards Classifications:

ANSI/AAMI/ISO 11140-5
ISO 11140-1, Class 2 ISO 11140-3

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