



Product Technical Data Sheet

Form No.: FTP-073 Rev.: D

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 AAMI ST66 test methods for detecting the presence of air. 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: 32° - 104°F (0° – 40°C) at 10 - 70% humidity

Shelf Life: 36 months from date of manufacture

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

Standards Classifications:

AAMI ST66
EN ISO 11140-1, Class 2
ISO 11140-3

ITEM: SteriTec Steri-Pak LF Bowie-Dick Test Sheet, BD 110

PRODUCT TECHNICAL DATA SHEET, FTP-073

Change History

CO Number	Rev	Change Description	Date Released
479	A	New Document.	10/10/2001
964	B	Updated address.	08/04/2004
1206	C	Updated standards. Corrected storage temperatures.	04/03/2006
1460	D	Updated standards. Added stated values.	02/04/2008