



EU AirView™ BOWIE-DICK TEST PACK For Monitoring Air Removal/Steam Penetration

Crosstex Code: MBD030E

Product Description

Crosstex EU AirView™ Bowie-Dick Test Packs contain no lead or other toxic heavy metals. The indicators are manufactured to evaluate the efficacy of air removal and steam penetration in pre-vacuum sterilizers. A Bowie-Dick Test passing result indicates that the sterilizer has successfully removed air and can allow steam to penetrate a load placed in the chamber. The indicators are designed for use in pre-vacuum steam sterilizers operating at 134°C. The EU AirView™ Bowie-Dick Test Packs are designed for simulating a 7 kg cotton pack according to ISO 11140-4 Type 2.

Physical Properties

Process	Steam
Test Pack Dimensions	L: 13 cm x W: 9.5 cm x H: 1.5 cm
Packaging	30 Test Packs/Case
Chemical Indicator	Initial Color : Blue Signal Color : Dark Brown/Black Chemical Indicator Inks contain no lead or other toxic heavy metals

Intended Use

The EU AirView™ Bowie-Dick Test Pack is designed to detect the presence of residual air in pre-vacuum steam sterilizers operating at 134°C for 3.5 minutes. The indicator sheet within the EU AirView™ Bowie-Dick Test Pack will demonstrate a uniform color change from blue to dark brown/black when proper sterilization conditions are met as identified in ISO 11140-4 for Sub-atmospheric pulsing. If insufficient steam penetration occurs during the exposure cycle, the EU AirView™ Bowie-Dick Test Pack will demonstrate a non-uniform color change.

The EU AirView™ Bowie-Dick Test Packs are labeled “NOT FOR RESALE IN THE U.S.”

Instructions for Use

- 1) Daily, place the test pack on the bottom shelf, over the drain closest to the door, in an otherwise empty chamber.
- 2) Process in a prevacuum cycle of 134°C for 3.5 minutes exposure time.
- 3) After processing, carefully remove the test pack and allow to cool.
- 4) Confirm that the indicator label on the test pack box has changed color from blue to dark brown/black and then remove the indicator test sheet from the center of the test pack.
- 5) The indicator test sheet should show a uniform dark brown/black color change. Any non-uniform color change may indicate sterilizer malfunction and should be immediately reported.
- 6) Complete the information on the test sheet and retain as permanent record.

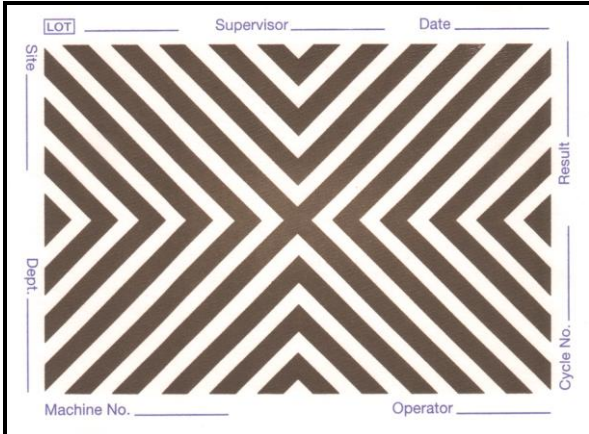
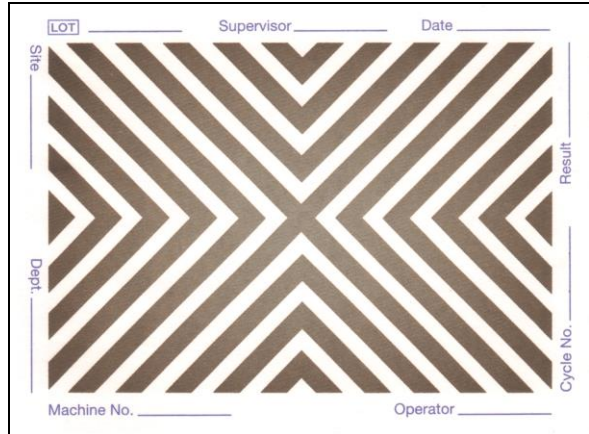
Crosstex International, Inc.

6789 W. Henrietta Road, Rush, NY 14543 | T 800.860.1888 | F 419.666.1715 | E productorders@crosstex.com | www.crosstex.com

Performance Characteristics

Result Availability	Immediately following exposure to high temperature steam processes
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Unexposed*	Exposed to Steam 134°C, 3.5 minutes*
 <p>The unexposed indicator card features a blue 'X' pattern formed by multiple parallel lines. The card includes fields for: LOT, Supervisor, Date, Site, Dept., Machine No., Operator, Result, and Cycle No.</p>	 <p>The indicator card after exposure to steam shows a dark brown 'X' pattern. The card includes fields for: LOT, Supervisor, Date, Site, Dept., Machine No., Operator, Result, and Cycle No.</p>

Failure Example 1*	Failure Example 2*
 <p>Failure Example 1 shows a dark brown 'X' pattern, similar to the exposed card but with a different color.</p>	 <p>Failure Example 2 shows a dark brown 'X' pattern, similar to the exposed card but with a different color.</p>

*Colors shown are representations of printed ink initial and signal colors but may vary from actual use.

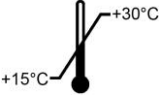

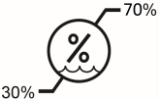





The signal color achieved from exposure to steam may vary from the example above due to differences in processing parameters (i.e., cycle time, temperature, brand of sterilizer, etc.).

Compliance

ISO 11140-4:2007, Sterilization of health care products - Chemical indicators - Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration

Storage and Shelf Life

	<p>15°C to 30°C</p>		<p>Keep away from sunlight</p>
	<p>30% to 70% relative humidity</p>		<p>Keep dry</p>
<p>Shelf Life</p>	<p>3 years from the date of manufacture The date of manufacture is based on the day the indicating ink is applied to the substrate. The remaining shelf life upon receipt will be shorter than 3 years</p>		<p>Do not reuse</p>
	<p>Keep away from sterilants. Do not use after expiration date.</p>		

Disposal

Discard as general waste.