

GENERAL DESCRIPTION

The Steraffirm™ Bowie-Dick Test pack consists of a series of steam penetration (air removal) barriers in the center of which is a chemical indicator sheet. The test pack is placed directly into an otherwise empty steam sterilizer chamber, with no retaining devices required. During processing, the cycle must remove or displace the air from the barrier material and replace it with steam throughout the pack. A uniform change from yellow to blue/purple indicates adequate steam penetration. The thermo-chromic ink formulation detects problems with steam quality and is free of lead and other heavy metals.

APPLICATION

Performed after a warm-up cycle at the beginning of every day the prevacuum steam sterilizer is in operation, the Bowie-Dick (Air Removal) Test verifies the prevacuum sterilizer effectively removes air. The test conforms to ANSI/AAMI/ISO 11140-4¹ Class 2/B. The Steraffirm Bowie-Dick Test Pack provides reliable performance and accurate results. The Steraffirm Bowie-Dick Test Packs are for Life Sciences applications and international use and are not approved for use in healthcare facilities in the United States.

FEATURES

Preassembled, single use pack

Abrupt and distinctive total color from yellow to blue/purple instead of a tonal color change of yellow or white to black

No lead or other heavy metals

Indicator sheet can be kept as a permanent record

Lot number and expiration on each pack

BENEFITS

Eliminates the need to construct test packs

Does not lead to misinterpretation as other test packs with black endpoints which must exhibit a uniform change over the entire indicator black endpoint pattern

No concerns over exposure to lead or other heavy metals

Documentation of the efficacy of the sterilizer to record removed air from the pack

Traceability and recognition of expired packs at time of use

TECHNICAL PROPERTIES

Test data demonstrates that, in a steam sterilizer in the presence of saturated steam at 121-124°C (250-255°F) for 8 to 8.3 minutes, the sensitivity of the pack is sufficient to detect a 2°C (3.6°F) temperature depression (between the center of the test pack and the drain temperature) at the start of exposure as specified in EN867-41 (see Figure 1).

The environmentally friendly Steraffirm Bowie-Dick Test Pack is made of 100% recycled paper. The integrator ink contains no lead or heavy metals known to be toxic to humans and the environment.

The Steraffirm Bowie-Dick Test Pack detects problems with steam quality and may serve as a diagnostic tool when reviewed by a STERIS service expert. It is recommended to obtain a digital image, photograph, or photocopy of the exposed indicator sheet if retained as part of a batch record.

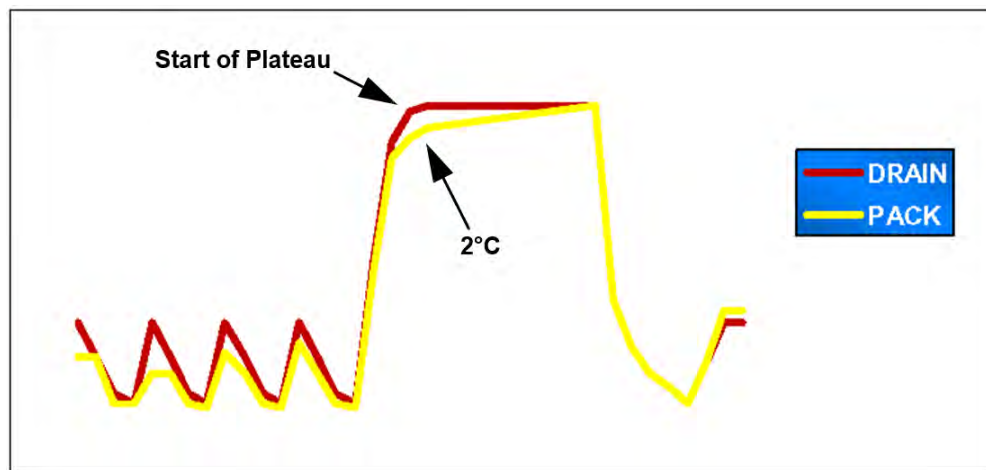


Figure 1: Cycle Temperature Profile Demonstrating 2°C (3.6°F) Temperature Depression as Specified in EN867-4

DIRECTIONS FOR USE

Preheat the sterilizer by running one complete cycle with an empty chamber. It is important to include all shelving and racks in the preheat cycle. After pre-heat cycle completion, place the Steraffirm Bowie-Dick Test Pack 4-8" (100-200 mm) above the chamber drain or as near as is practically possible, without obstructing the drain. Do not place on the chamber floor.

Perform a prevacuum exposure cycle at 121-124°C (250-255°F) for 8 to 8.3 minutes (longer than 8.3 minutes invalidates the test). Upon completion of the test cycle, remove and open the test pack. If air removal is sufficient to allow even steam penetration, the entire indicator ink figure on the indicator test sheet changes color from yellow to blue/purple.



Figure 2: Yellow - Unused



Figure 3: Blue/Purple - Pass

Colors are an approximation.

If residual air is present in the chamber and steam penetration is not achieved, the indicator ink color remains yellow toward the center (see Image 1 of Figure 4). Atypical failures may result from steam supply quality issues such as non-condensable gas in the steam supply, wet steam, or superheated steam. Some possible test sheet results due to steam quality problems are shown in Images 2-4 of Figure 4. See the instructions enclosed in the product packaging for detailed use directions.

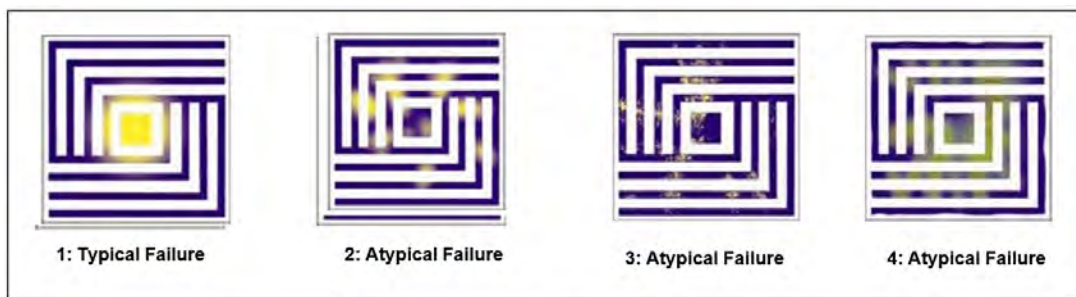


Figure 4: Typical and Atypical Failures

Colors are an approximation.

STORAGE CONDITIONS

Store unused integrators at 0-30°C (32-86°F) away from direct sunlight. Do not store the integrators near steam sterilizers or near strong alkaline or acidic products such as cleaning/disinfecting agents.

These storage conditions should be maintained after use, e.g., when the indicator strip is filed. It is recommended to obtain a digital image, photograph, or photocopy of the exposed indicator sheet if retained as part of a batch record.

SERVICE

Sales

Service is one of the most important ways to verify consistent quality of the facility's performance and operation. A tailored service program by STERIS provides effective, trouble-free operations.

Technical

STERIS is pleased to provide a completely staffed and equipped technical service laboratory capable of performing needed tests and providing both telephone and on-site assistance when needed. More details on how this service can benefit a facility's particular situation can be provided upon request.

ORDERING INFORMATION

Description	Quantity Per Box	Reorder Number
Steraffirm Bowie-Dick Test Pack	Box (20 tests)	EQC003

REFERENCES

1. American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization (ANSI/AAMI/ISO) 11140-4 (2007): Specifies performance for a Class 2 indicator to be used as an alternative to the Bowie and Dick test for steam sterilizers for wrapped health care goods (instruments, etc. and porous loads).

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