

VERIFY® BOWIE-DICK TEST CARD

A Disposable Bowie-Dick Type Test for Air Removal Validation of Equivalent Performance to the AAMI-Described Bowie-Dick Test Pack

IDENTIFICATION OF TEST

Conventional AAMI Bowie and Dick Test Packs, Standard Commercial Paper Pack, and VERIFY Bowie Dick Test Cards (VERIFY Cards) were exposed to pre-vacuum steam autoclave cycles with exposure temperatures of 273°F ± 2°F (133°C ± 1.1°C). Vacuum levels and leak levels varied.

PURPOSE

The Bowie Dick Test is performed to assess air removal efficiency in steam sterilizers for use in pre-vacuum sterilization cycles. During vessel operation there are a number of factors which will affect proper function of the vessel. Important variables include vessel size, steam charge rate, steam mixing patterns, vacuum pump efficiency, and steam trap bleed rates. This set of studies was intended to span the potential sources of residual air in an operating sterilizer and compare the effectiveness of the VERIFY Card, standard commercial paper pack, and the conventional AAMI pack in detecting these residuals.

DEFINITIONS

VERIFY Card

A chemical indicator on a paper substrate laminated on all sides with plastic and provided with means to allow air removal and/or steam penetration. The card is used to verify steam penetration and absence of residual air pockets.

Standard Commercial Paper Pack

A disposable Bowie and Dick Type Test Pack marketed which consists of a chemical indicator on a paper substrate enclosed in a stack of paper and foam and wrapped with a nonwoven CSR (Central Supply Reprocessing) Wrap and closed with a steam autoclave tape.

Test Sheet

A chemical indicator sheet used to verify steam penetration and absence of residual air pockets. The chemical indicator turns from yellow to brown in the presence of adequate steam.

AAMI Bowie-Dick Test Pack

A test pack, as defined in AAMI recommended procedure titled "Good Hospital Practice; Steam Sterilization and Sterility Assurance" (approved November 1993), and prepared as per description in ST79.

Huck Towels

All cotton surgical towel with a tight knit weave to limit linting (ST 79).

Acceptable Appearance ("Pass")

An appearance of the chemical indicator showing complete conversion to brown.

Unacceptable Appearance ("Fail")

For conventional AAMI Bowie and Dick Test Pack and Paper Pack, an appearance of the chemical indicator sheet showing the presence of a spot (yellow, tan, or grey). The indicating area outside the spot has changed completely to brown and inside the spot is the lighter color. An unacceptable color change for VERIFY Card will also be an uneven color change. The indicating area near the access port has changed to brown, and the area further away is of a lighter color.

Marginal Appearance ("Borderline")

An appearance which might be deemed acceptable by some and deemed unacceptable by others.

EQUIPMENT

Multicycle Steam Sterilizer

A standard design steam sterilizer (22" x 22" x 36" [559 x 559 x 914 mm] chamber) was used for the studies. The unit features a System 20 microcomputer control system which can be programmed to duplicate the pre-set operating cycle parameters of hospital steam sterilizers. This unit can also be programmed to create fault conditions such as reduced vacuums and air leaks. All pressure, temperature, timing controls, and monitoring devices are calibrated against National Institute of Standards and Technology (NIST) traceable standards.

**System 20-Steritrol 20 by Scientific Industries*

Ancillary Laboratory Supplies and Equipment

SPECIFIC TEST METHODS

Sample Preparations

1. AAMI Bowie and Dick Test Packs were prepared as follows:
 - a. Huck towels were folded to dimensions of 9" x 12" (229 x 305 mm).
 - b. Towels were folded and stacked in piles approximately 10" (254 mm) high with the test sheet in the middle of the stack.
 - c. Stacks were wrapped with a nonwoven CSR Wrap. Wrap was taped with steam autoclave tape.
 - d. After each exposure, all towels were machine laundered in commercial machines, using two wash cycles, the first with soap and the second without. These were then machine dried and allowed to equilibrate to ambient humidity for at least 24 hours before use.
2. Paper packs were used according to manufacturer's instructions for use.
3. VERIFY Cards were used according to manufacturer's instructions for use.

Test Method

1. Prior to each test series at least one empty chamber cycle was run to assure that the predetermined parameters were being met and the vessel was operating as expected.

The time required to reach vacuum level, the time to reach exposure start, and the time to complete the cycle were monitored for each cycle. These phases of the exposure cycles were timed to verify the reproducibility of exposure conditions for the test series.
2. A single AAMI Test Pack, a single paper pack, and two VERIFY Cards were exposed in each autoclave cycle. The Test Packs were placed on the bottom rack centered directly over the drain.
3. Triplicate exposures for each cycle were made. The test sheets and VERIFY Cards were observed and labeled immediately after exposure. The conventional AAMI Pack, Paper Pack, and VERIFY Cards were compared for each test series.

Test Series Parameters

All exposures were for 3.5 minutes exposure at 273°F ± 2°F (133°C ± 1.1°C). The vessel was allowed to stand open for 2 minutes between cycles for cooling and removal of residual humidity, Vacuum levels listed were determined by pressure transducer which was calibrated to NIST traceable standard both before and after test series.

- 1. Test 1 - Baseline Study:** A single vacuum was pulled to 28" (711 mm) Hg, steam was applied to 273°F (133°C) immediately after obtaining the vacuum level.
- 2. Test 2 - Reduced Vacuum Efficiency with One Pre-Vacuum:** Vacuum levels used were 27" (686 mm), 26" (660 mm), and 25.3" (643 mm) Hg. Each level had one vacuum pulse prior to steam charge to 273°F (133°C).
- 3. Test 3 - Air leak Malfunction:** Air leaks of 0.1" (2.5 mm), 0.2" (5 mm), 0.5" (12.7 mm), and 1.0" (25 mm) Hg were used. A one pulse vacuum was pulled to 28" (711 mm) Hg with the simulated leak cycles. The simulated air leak was set using a flow meter.

RESULTS

Reactions for all observed indicator sheets were described as acceptable, unacceptable, or marginal. These terms are defined under Definitions.

Test 1 - Baseline

Six samples of the VERIFY Cards, three samples of the paper packs, and three samples of the conventional AAMI packs were exposed. All samples indicated acceptable cycles.

Test 2 - Reduced Vacuum Efficiency, 1 Pre-vacuum Pulse

Multiple samples of three tests were exposed at pre-vacuum levels of 27" (686 mm), 26" (660 mm), and 25.3" (643 mm) Hg. All three - VERIFY Cards, paper packs, and AAMI packs - were acceptable at 27" (686 mm) Hg. They showed marginal results at 26" (660 mm) Hg and unacceptable results at levels 25.3" (643 mm) Hg.

Test 3 - Air Leak Malfunction, 1 Pre-vacuum Pulse

Multiple samples of three test packs were exposed to an air leak of 0.1" (2.5 mm), 0.2" (5 mm), 0.5" (12.7 mm), and 1.0" (25 mm) Hg. All three - VERIFY Cards, paper packs, and AAMI packs - showed marginal to unacceptable results at 0.1" (2.5 mm) air leak. They had unacceptable results at 0.2" (5 mm) and higher air leak cycles.

DISCUSSION

It should be noted that values describing the sensitivity of the test packs, such as leak rate or absolute pressure detection levels, are vessel specific rather than absolute values. That is, a Bowie-Dick Test Pack may detect a leak of 0.1" (2.5 mm) Hg in one vessel while only detecting a 0.2" (5 mm) Hg leak in a second vessel. The Bowie-Dick Test is a qualitative test intended to be interpreted by trained personnel.

CONCLUSIONS

The VERIFY Bowie-Dick Test Card was compared to the conventional AAMI Bowie and Dick Test Pack and the paper pack under a variety of simulated malfunctions for pre-vacuum steam sterilizers. The VERIFY Card was essentially equivalent to the conventional AAMI Bowie and Dick Test Pack and paper pack.

Table 1: Ordering Information

Catalog Number	Description	Quantity
S3095	Verify Bowie-Dick Test Card (Multi-Pulse)	31/Box
S3096	Verify Bowie-Dick Test Card Holder	1/Each

For further information, please contact:

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