3M™ Attest™ eBowie-Dick Test Card Performance for ISO Type 2 Indicators

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Abstract

Background

Healthcare facilities have sterilization guidance and recommended practices as critical components of their overall infection prevention and control programs. The sterilization process must be monitored with indicators that demonstrate the required conditions are adequately achieved. The 3M™ Attest™ eBowie-Dick Test System evaluates the performance of pre-vacuum sterilizers by confirming adequate air removal from the sterilizer chamber. ISO 11140-5:2007 specifies performance requirements for Bowie and Dick air removal test sheets and packs. This study evaluated the 3M™ Attest™ eBowie-Dick (eBD) Test Card 10135 according to the performance requirements specified in ISO 11140-5:2007.

Method

Four lots containing 30 cards each of the 3M™ Attest™ eBowie-Dick Test Card 10135 were tested on PASS and FAIL test cycles (15 cards for each cycle) as defined by ANSI/AAMI/ISO 11140-5:2007/(R)2012.

Results

The results from testing 15 samples from each of four different lots of the eBD test card in the PASS cycle showed that a total of 60 cards out of 60 cards passed. In addition, when testing 15 samples from each of four different lots in the FAIL cycle, 60 cards out of 60 cards failed. The eBD test card meets AAMI and ISO standards defining performance requirements for a Bowie-Dick test.

Introduction

Today, the Bowie-Dick (BD) test is widely used and recognized as a valuable means of monitoring the performance of vacuum-assisted steam sterilizers. However, several aspects have changed since the original work was done in Britain in the early 1960s.[1] Most of today's sterilizers operate differently from those used by Bowie and Dick, which drew a single deep vacuum before beginning the sterilization cycle. Pre-vacuum sterilizers today typically have a series of steam injections and vacuum excursions before beginning the sterilization phase. In addition, the vacuum depth is not as great as in the older high vacuum sterilizers. The new 3M™ Attest™ eBowie-Dick Test System (eBD) replaces the towel packs initially described by Bowie and Dick and disposable test packs developed since, while removing subjectivity in the interpretation of the results.

What is the purpose of a Bowie-Dick cycle?

Monitoring with a BD test pack should be done daily, prior to running the first full load of the day. If a sterilizer has an inadequate vacuum, air leak, or poor steam quality, air pockets may form inside the sterilizer and compromise sterility by preventing steam penetration into some of the packs in the load. The indicator sheet inside the BD test pack will not develop properly if air remains trapped inside the sterilizer chamber. If a BD test indicates a problem, the sterilizer should be taken out of service until the malfunction is identified and corrected.

In the U.S., the BD test is run at 132–134°C (270–273°F) for 3.5–4 minutes. The purpose of the prevacuum phase is to remove all the air from the sterilizer chamber. This allows the steam to make contact with all the surfaces in the load. If air is present, steam penetration to all the surfaces in the load will be impeded. Causes of air remaining in the sterilizer chamber include inadequate vacuum (i.e., incomplete air removal), air leaks, or the presence of non-condensable gases in the steam. The BD test is run in an otherwise empty chamber because this is a more rigorous test than if the chamber was full with a normal load. If there were other packs in the chamber, any air present would be distributed throughout all the packs and thus fail to be detected by the indicator sheet in the BD test pack. The test pack should be placed on the bottom shelf of the sterilizer rack, over the drain, because this is the coldest spot in the sterilizer chamber.

AAMI 11140 Parts 1 and 5

The Association for the Advancement of Medical Instrumentation (AAMI) defines ISO Type 2 chemical indicators as intended for use in specific test procedures as defined in relevant sterilizer/sterilization standards.[2] Further requirements for specific test indicators and indicator systems (Type 2 indicators) are provided in ISO 11140-3, ISO 11140-4, and ISO 11140-5. In North America, the Food and Drug Administration (FDA) recognizes ISO 11140-5.

ISO 11140-5 defines the performance requirements for Type 2 indicators for BD-type air removal tests used to evaluate the effectiveness of air removal during the pre-vacuum phase of prevacuum steam sterilization cycles.[3] Additionally, this part of ISO 11140 includes information on test methods and equipment to be used to meet these performance requirements.

AAMI also provides specific recommendations on the make-up of a BD towel pack.[4] These include type of towels, type of wrap material, dimensions of the pack, and placement of the test sheet within the test pack. However, variability in these components can contribute to nonuniform test results. Manufacturers eliminated many of these variables by introducing disposable BD test packs. These disposable packs have been shown to be as effective as towel packs. Disposable test packs are small and eliminate the costly labor involved in making towel packs. They are an effective, inexpensive way to assure that a prevacuum sterilizer is operating properly. However, further improvements are needed. For example, current BD test packs rely on determination of the result through a visual interpretation of a color changing indicator ink. In some cases, this visual interpretation is not always straightforward. Since potentially marginally failing results may be misinterpreted as a pass, the design of current BD test packs leaves room for improvement.

For the eBD test system, the user does not need to visually interpret the test to obtain a result. Pass or Fail results are determined by an Auto-reader, which displays the results, thus eliminating the need for visual interpretation. Another improvement over current test packs of the eBD test system is the ability to provide the results in a digital format, voiding the need to scan in the paper indicator sheets, which can potentially increase workflow efficiency. Lastly, the eBD test system employs a lumen-based challenge rather than a porous challenge, which improves the robustness of the product. This will be discussed in more detail below.

3M™ Attest™ eBowie-Dick Test System

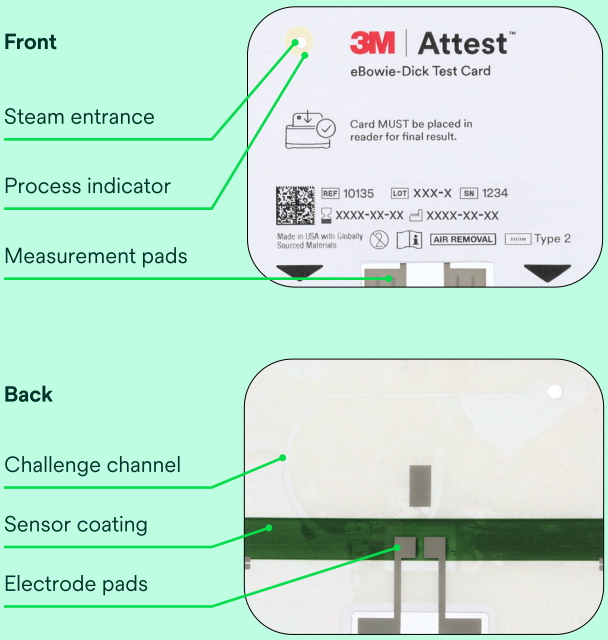
The new eBD Test system consists of the 3M™ Attest™ eBowie-Dick Test Card 10135, the 3M™ Attest™ eBowie-Dick Card Holder 10135H in which the test card is placed, and the 3M™ Attest™ eBowie-Dick Auto-reader 1190.

The Attest eBowie-Dick Test Card 10135 consists of a laminated card with a lead-free steam-sensitive chemical indicator positioned at the end of a lumen challenge designed to restrict air removal and steam penetration. The test card is sensitive to inadequate air removal from the chamber during the conditioning phase of a dynamic air removal cycle, as well as the presence of non-condensable gasses during saturated steam sterilization exposure.

The test card uses an engineered channel sized to precise dimensions to create a resistance to air removal and steam penetration. The channel begins at an inlet opening with a well-defined diameter and terminates in a rectangular opening located over the sensor of the test card (**Figure 1**). The test card includes an exterior process indicator.

The Attest Bowie-Dick Test Card 10135 undergoes a change in electrical resistance upon exposure to saturated steam. After completion of a Bowie-Dick test cycle, the electrical resistance of the test card is read using the Attest eBowie-Dick Auto-reader 1190. The Attest eBowie-Dick Test Card 10135 will reach a PASS value when adequate air removal and steam penetration is achieved. An air removal failure and or a steam penetration failure is indicated by a FAIL result.

Figure 1. Front and back views of the 3M™ Attest™ eBowie-Dick Test Card 10135.



Differences between a channel-based challenge and a porous-based challenge

Currently used Bowie Dick packs: porous-based challenge

In the case of a porous media challenge, a permeable paper can be used. The permeability of the paper allows air to flow through it under a pressure difference across the sheet. The air permeability through an individual blotter paper card making up the construction of a paper-based test pack indirectly depends on the thickness of the paper card and is directly dependent on the area and the permeability constant of the paper card. A paper test pack is designed to provide a challenge to air removal and steam penetration by stacking cards of a given property until an adequate challenge is achieved. This challenge is variable in nature because it is based in part on a property of the paper (the permeability constant) which results from the manufacturing process for making the paper and cannot be predetermined.

The Attest eBowie-Dick Test Card: channel-based challenge

In the Attest eBowie-Dick Test Card, the challenge to air removal and steam penetration is provided by an engineered channel. Air flow in this channel is inversely dependent on the length of the channel and directly dependent on its cross section. Every dimension of the channel used in the eBD Test Card is engineered (i.e., predetermined) and can be replicated with high precision from card to card. The physics of air removal embodied by the channel challenge of the eBD test card is very similar to the challenge of air removal from a lumened instrument. For example, rigid endoscopes and laparoscopic instruments have narrow internal channels requiring air removal to ensure that adequate steam sterilization can occur. Any air remaining in the lumens of these instruments would compromise the sterilization of those internal surfaces. The eBD Test Card, by virtue of its engineered channel configuration, therefore, offers a configuration that better simulates lumened devices.

The following section demonstrates that the performance of the eBD test card meets the requirements of ISO 11140-5.

Method for demonstrating ISO equivalence

PASS and FAIL cycles definition

PASS and FAIL test cycles were first defined according to ANSI/AAMI/ISO 11140-5:2007/(R)2015, by using two temperature sensors (Data Trace from Mesa Labs), one placed in the center of an AAMI Standard Towel Test Pack and one placed at the drain of the sterilizer. **Figure 2** identifies the location of the temperature sensors in the chamber for this testing as it was originally performed.

The PASS cycle was defined such that at the beginning of the final 1 minute of the 3.5 minutes of a 134°C sterilization exposure, the average temperature differential between the center of the test pack and the drain of the sterilizer was 0.4°C ± 0.1°C. This is within the permitted tolerance specified in ANSI/AAMI/ISO 11140-5:2007/(R)2015; Section 5.2, Section 6.2 and Annex B[3] for a no-fault condition that will be used to test the PASS performance of a BD indicator.

Similarly, the FAIL cycle was defined such that, at the beginning of the final 1 minute of the 3.5 minutes of a 134°C sterilization exposure, the average temperature differential between the center of the towel pack and the drain of the sterilizer was 2.5°C ± 0.4°C. This is within the permitted tolerance specified in ANSI/AAMI/ISO 11140-5:2007/(R)2015; Section 5.2, Section 6.2 and Annex B[3] for the standard fault condition that will be used to test the FAIL performance of a BD indicator.

To test the performance of the new eBD test card, an AMSCO Lab 110 Sterilizer was used. The test card result was measured using a calibrated multimeter. Three eBD test cards were inserted into three individual eBD card holders and aligned on the top of the support rack near the drain in one cycle as shown in **Figure 3**.

Four lots containing 30 cards each of the Attest eBowie-Dick Test Card 10135 were tested (15 cards per lot for the FAIL cycle, and 15 for the PASS cycle).

A given test cycle (PASS or FAIL) was then selected and run. After the cycle was completed, the eBD test cards were removed from the sterilizer and left to cool at room temperature for at least three minutes prior to recording the result.

Figure 2. Testing configuration with location of temperature sensors for PASS and FAIL test cycles.

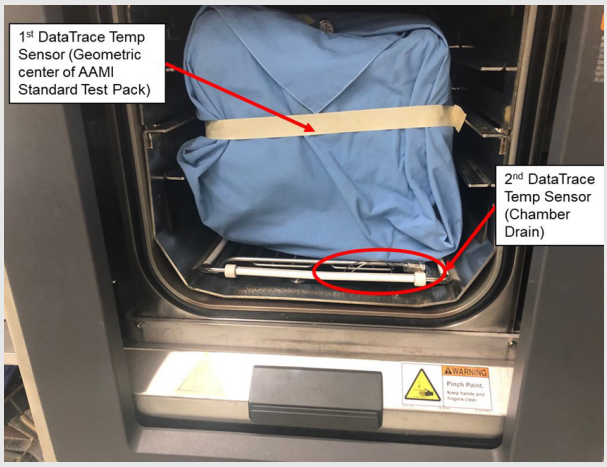


Figure 3. Testing configuration for eBD test card performance.

Results

Table 1 below summarizes the results of this testing for the PASS Cycle.

Table 1. Results of eBD test card performance for PASS cycle.

eBD Test Card Sensor Lot	Cycle	Number Tested	Number of eBD Test Card Sensors resulting in a PASS	Number of eBD Test Card Sensors resulting in a FAIL	TOTAL (% PASS)
1	PASS Cycle: 134°C, 3.5 minutes	15	15	0	100
2	PASS Cycle: 134°C, 3.5 minutes	15	15	0	100
3	PASS Cycle: 134°C, 3.5 minutes	15	15	0	100
4	PASS Cycle: 134°C, 3.5 minutes	15	15	0	100

Table 2 below summarizes the results of this testing for the FAIL Cycle.

Table 2. Results of eBD Test Card performance for FAIL cycle.

eBD Test Card Sensor Lot	Cycle	Number Tested	Number of eBD Test Card Sensors resulting in a PASS	Number of eBD Test Card Sensors resulting in a FAIL	TOTAL (% PASS)
1	FAIL Cycle: 134°C, 3.5 minutes	15	0	15	100
2	FAIL Cycle: 134°C, 3.5 minutes	15	0	15	100
3	FAIL Cycle: 134°C, 3.5 minutes	15	0	15	100
4	FAIL Cycle: 134°C, 3.5 minutes	15	0	15	100

To verify that the sampling plan size of N=15 per lot and test condition was appropriate, a capability analysis was performed to determine process performance indices for the entire data set by lot and cycle tested. A process performance index or Ppk value is a statistical measure of how well a product is meeting performance specifications. For this testing, a Ppk value of 1.17 or greater was taken as an indication that the sample size was statistically adequate to demonstrate meeting performance criteria. Table 3 below summarizes this capability analysis.

Table 3. Results of capability analysis for eBD Test Card performance.

Temp/Test Condition	Test Cycle	Lot 1 Ppk	Lot 2 Ppk	Lot 3 Ppk	Lot 4 Ppk
134°C	PASS Cycle	No variance	3.57	4.65	4.31
134°C	FAIL Cycle	35.78	1.52	3.43	6.01

All Ppk indices are greater than 1.17 showing that the sampling size of N=15 per lot and test condition provides a result statistically representative of the test card's performance.

Summarizing the results of this testing: the PASS and FAIL conditions for this testing were determined in accordance with AAMI/ISO 11140-5 using the standard towel pack to achieve a ΔT of 2.5°C in the FAIL cycle and less than 0.4°C in the PASS cycle. The results from testing four different lots of the eBD test card in the PASS cycle showed that all 60 cards passed. Similarly, the results from testing four different lots of the eBD test card in the FAIL cycle showed that all 60 cards failed.

A capability analysis using the electrical resistance measured from tested cards demonstrates that the sampling size of 15 cards per lot was statistically appropriate to support the PASS and FAIL results to a 99% confidence level.

Discussion

The results presented above validate the performance of the new eBD test card by confirming that it meets the requirements of a Type 2 indicator according to ISO 11140-5.

This new Attest eBowie-Dick Test System affords the user many advantages over current products. First and foremost, it is an inherently digital test that makes use of a novel chemistry—an engineered channel-based challenge and an auto-reader instrument to provide an objective PASS/FAIL result. This overcomes a significant issue with almost all current BD tests: the user needs to visually interpret the color change of an indicator sheet. In some instances, there are occurrences of marginal test results where an accurate visual interpretation of the color change as either a PASS or FAIL result may be very difficult. Resolution of these occurrences take up valuable reprocessing time as it typically results in either retesting the sterilizer or securing additional consultation from other users to interpret the color change (i.e., a second opinion). In the worst of scenarios, these occurrences result in an inaccurate assessment of the test, possibly yielding a FALSE PASS interpretation that may create a patient risk. The new eBD test card eliminates the need for visual interpretation, providing a digital result with an accuracy meeting the requirement of AAMI/ISO standards governing the performance of these products.

In addition, the digital solution provided by the eBD test card can also improve the efficiency of the user's testing workflow because it eliminates the need to digitize the results of the color changing indicator sheet of current products through scanning or photographing. Furthermore, the connected solution of the eBD test card is designed to provide an automated means of creating, storing, and transferring the test result to instrument tracking systems, and may eliminate the need for manual data entry required for current products.

Conclusion

The new eBD test card provides a novel alternative with several advantages over current BD tests. By employing a new indicating chemistry in combination with a reader, the eBD test card provides a digital result which eliminates the need for a subjective visual interpretation and can improve the efficiency of the BD test workflow. The eBD test card also employs an engineered channel-based challenge which improves performance by reducing the variance inherent to a paper-based porous challenge. The results presented here validate the performance of the new eBD test card as meeting the requirements of a Type 2 indicator according to ISO 11140-5.

References

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