Evaluation of the 3M™ Attest™ eBowie-Dick Test Card Performance Requirements for ISO 11140-4 Type 2 Indicators

Kayla Ostrander
BS, MS, CRCST, CHL, CER

Kayla Ostrander is a Technical Applications Engineer with Solventum Medical Surgical Business (formerly 3M Medical Solutions Division) in St. Paul, MN. Her role at Solventum includes providing education for customers and sales personnel on improving the performance of the sterilisation process and implementing best practices. Prior to working for Solventum, Kayla worked in sterile processing as both a Technician and a Supervisor for various hospitals in the Twin Cities. Kayla holds both a MS and BS in Communication Studies, and a Certificate in Nonprofit Leadership from Minnesota State University, Mankato. Kayla is a Certified Registered Central Service Technician (CRCST), Certified Healthcare Leader (CHL), Certified Endoscope Reprocessor (CER), and a member of HSPA.

Abstract

Background

Sterilisation is an integral component of the overall infection control program. The sterilisation process needs to be monitored with indicators to ensure that the required conditions are adequately achieved. The 3M™ Attest™ eBowie-Dick Test Card evaluates the performance of prevacuum sterilisers by confirming adequate air removal from the steriliser chamber. ISO 11140-4:2007 specifies performance requirements for Type 2 indicators as an alternative to the Bowie and Dick type test for detection of steam penetration. This study evaluated the 3M™ Attest™ eBowie-Dick Test Card 10135 according to the performance requirements specified in ISO 11140-4:2007.

Method

Three lots containing at least 96 cards each of the 3M™ Attest™ eBowie-Dick Test Card 10135 were tested on PASS and FAIL test cycles (12 cards for each cycle) as defined by ANSI/AAMI/ISO 11140-4:2007/(R)2012.

Results

The results from testing 12 samples from different lots of the eBD test card in the B1, B2 and B3 PASS cycles, showed that a total of 108 cards out of 108 cards passed. In addition, when testing 12 samples from different lots in the B1 FAIL cycles (three conditions: modified air removal stage, induced leak and air injection) as well as the B2 FAIL cycle (one condition: modified air removal stage) and the B3 FAIL cycle (one condition: air injection), 108 cards out of 108 cards failed for the B1 cycles and 36 out of 36 cards failed for the B2 and B3 cycles. The eBD test card meets AAMI and ISO standards defining performance requirements for a Bowie-Dick test type test for detection of steam penetration.

Introduction

Today, the Bowie-Dick test is widely used and recognised as a valuable means of monitoring the performance of vacuum-assisted steam sterilisers. However, several aspects have changed since the original work was done in Britain in the early 1960s. Most of today's sterilisers operate differently from those used by Bowie and Dick, which drew a single deep vacuum before beginning the sterilisation cycle. Prevacuum sterilisers today typically have a series of steam injections and vacuum excursions before beginning the sterilisation phase, and the vacuum depth is not as great as in the older high vacuum sterilisers. The new 3M™ Attest™ eBowie-Dick Test Card 10135 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 Bowie-Dick test pack should be done daily, prior to running the first full load of the day. If a steriliser has an inadequate vacuum, air leak, or poor steam quality, air pockets may form inside the steriliser and compromise sterility by preventing steam penetration into some of the packs in the load. The indicator sheet inside the Bowie-Dick test pack will not develop properly if air remains trapped inside the steriliser chamber. If a Bowie-Dick test indicates a problem, the steriliser should be taken out of service until the malfunction is identified and corrected.

The Bowie-Dick test is run at 132–134ºC (270–273ºF) for 3-1/2–4 minutes. The purpose of the conditioning phase is to remove all the air from the steriliser chamber. This allows the steam to contact 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 steriliser chamber include inadequate vacuum (i.e., incomplete air removal), air leaks, or the presence of non-condensable gases in the steam. The Bowie-Dick 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 Bowie-Dick test pack. The test pack should be placed on the bottom shelf of the steriliser rack, over the drain, because this is the coldest spot in the steriliser chamber.

ANSI/AAMI/ISO 11140 parts 1 and 4

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 steriliser/sterilisation standards.[1] 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. While most Health Care facilities in the United States use Type 2 indicators complying with ISO 11140-5, there are other countries where Type 2 indicators complying with ISO11140-4 are used as an alternative.

ISO 11140-4 defines the performance requirements for alternative Type 2 indicators for Bowie and Dick-type tests used to evaluate the effectiveness of steam penetration.[2] Additionally, this part of ISO 11140 includes information on test methods and equipment to be used to meet these performance requirements.

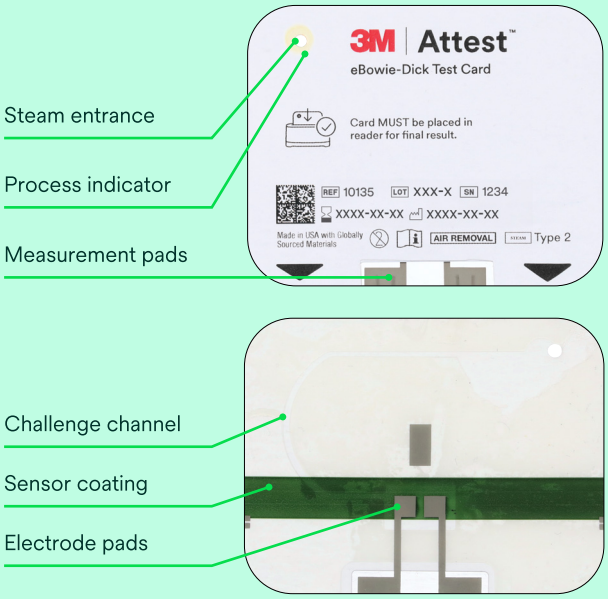
3M™ Attest™ eBowie-Dick Test system

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

The 3M™ Attest™ eBowie-Dick Test Card 10135 consists of a laminated construction 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 sterilisation exposure.

The test card uses an engineered channel sized to precise dimensions to create 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. See **Figure 1** for a diagram of the lumen channel and the openings along with the dimensions. The test card includes an exterior process indicator.

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



The 3M™ Attest™ eBowie-Dick Test Card 10135 undergoes a change in electrical resistance upon exposure to saturated steam. After the completion of a Bowie-Dick test cycle, the electrical resistance of the test card is read out using the 3M™ Attest™ eBowie-Dick Auto-reader 1190. 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, which is a critical benefit and improvement over the current test packs available.

The 3M™ 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.

Another improvement over current test packs of the eBD test system is the ability to provide the results in a digital format, avoiding the need to scan in the paper indicator sheets, which can potentially increase workflow efficiency.

Finally, 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.

Differences between a lumen based versus a porous based challenge

Although an equivalent challenge to air flow can be obtained using either a porous media or an engineered channel, the physics involved with these methods is different as described below.

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.

In the eBD 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 sterilisation can occur. Any air remaining in the lumens of these instruments would compromise the sterilisation of those internal surfaces. The eBD Test Card, by virtue of its engineered channel configuration, therefore, offers a configuration that better simulates lumened devices.

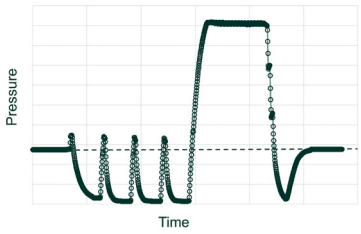
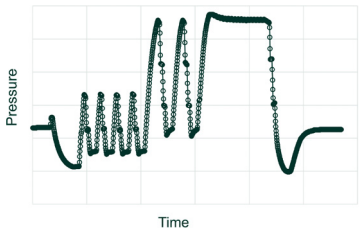
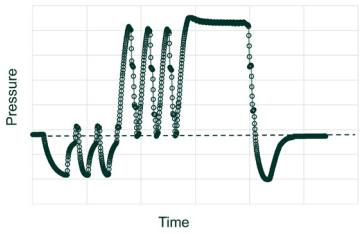
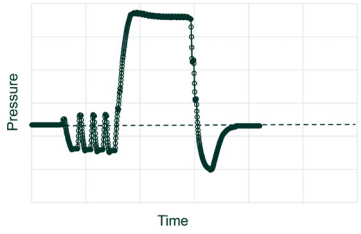
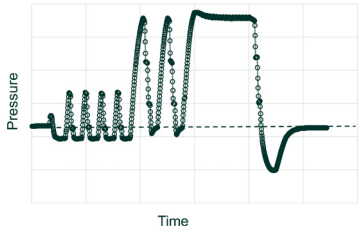
The following section demonstrates that the performance of the eBD test card meets the requirements of ISO 11140-4.

Method for demonstrating ISO equivalence

PASS and FAIL cycles definition

PASS and FAIL test cycles were first defined in accordance with ANSI/AAMI/ISO 11140-4:2007/(R)2015 using a programmable Getinge 666 Steriliser. **Figure 2** shows the experimental pressure profiles for the PASS and the modified air removal stage FAIL cycles used to test the eBD Test Card. In addition, **Figure 2** also lists the additional FAIL cycle conditions (induced air leak and air injection) that were also tested in accordance with ISO 11140-4. For the B3 cycle (super-atmospheric pulsing) there is no requirement to test a modified air removal stage failure mode or an induced air leak failure mode. Similarly, for the B2 cycle (trans-atmospheric pulsing) there is no requirement to test failure modes beyond a modified air removal stage. To create an induced air leak FAIL cycle, the Getinge 666 steriliser was fitted with a variable needle valve that could be precisely opened to create a controlled ambient to chamber air leak. To create an air injection FAIL cycle, an air injection apparatus constructed following directives in ANNEX L of ISO 11140-4 was connected to the chamber of the Getinge 666 steriliser.

Figure 2. Testing conditions defined in ISO11140-4. The plots show the experimental pressure profiles used for testing the PASS cycle conditions (top row of figure) and the modified air removal stage FAIL cycle conditions (B1 – Sub-atmospheric pulsing and B2 – Trans-atmospheric pulsing only). X's mark FAIL cycle conditions that do not require testing. Check marks identify additional FAIL cycle conditions that require testing.

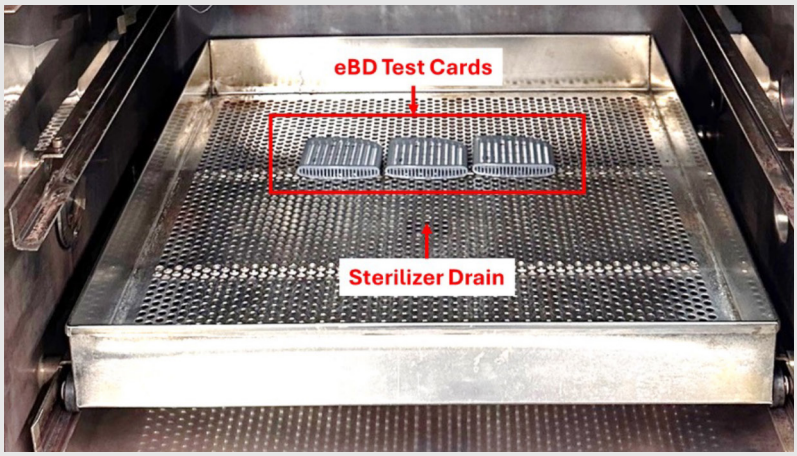
		Sub-atmospheric pulsing B1 cycle	Trans-atmospheric pulsing B2 cycle	Super-atmospheric pulsing B3 cycle
PASS cycles				
FAIL cycles	Modified air removal stage			X
	Air leak	✓	X	X
	Air injection	✓	X	✓

Three eBD 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**. The test card result was measured using a calibrated multimeter.

Three lots containing at least 96 cards each of the 3M™ Attest™ eBowie-Dick Test Card 10135 were tested (12 cards per lot for each of the FAIL cycle conditions, and 12 for each of the PASS cycle conditions).

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

Figure 3. Testing configuration for 3M™ Attest eBowie-Dick Test Card performance.



Results

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

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	B1 PASS cycle: 134°C, 3.5 minutes	12	12	0	100
2	B1 PASS cycle: 134°C, 3.5 minutes	12	12	0	100
3	B1 PASS cycle: 134°C, 3.5 minutes	12	12	0	100
1	B2 PASS cycle: 134°C, 3.5 minutes	12	12	0	100
2	B2 PASS cycle: 134°C, 3.5 minutes	12	12	0	100
3	B2 PASS cycle: 134°C, 3.5 minutes	12	12	0	100
1	B3 PASS cycle: 134°C, 3.5 minutes	12	12	0	100
3	B3 PASS cycle: 134°C, 3.5 minutes	12	12	0	100

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

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	B1 FAIL cycle: modified air removal stage	12	0	12	100
2	B1 FAIL cycle: modified air removal stage	12	0	12	100
3	B1 FAIL cycle: modified air removal stage	12	0	12	100
1	B1 FAIL cycle: induced air leak	12	0	12	100
2	B1 FAIL cycle: induced air leak	12	0	12	100
3	B1 FAIL cycle: induced air leak	12	0	12	100
1	B1 FAIL cycle: air injection	12	0	12	100
2	B1 FAIL cycle: air injection	12	0	12	100
3	B1 FAIL cycle: air injection	12	0	12	100
1	B2 FAIL cycle: modified air removal stage	12	0	12	100
2	B2 FAIL cycle: modified air removal stage	12	0	12	100
3	B2 FAIL cycle: modified air removal stage	12	0	12	100
1	B3 FAIL cycle: air injection	12	0	12	100
2	B3 FAIL cycle: air injection	12	0	12	100
3	B3 FAIL cycle: air injection	12	0	12	100

Summarizing the results of this testing: the PASS and FAIL conditions for this testing were determined in accordance with AAMI/ISO 11140-4. The results from testing three different lots of the eBD test card in all of the PASS cycles showed that all 108 cards passed. Similarly, the results from testing three different lots of the eBD test card in all of the FAIL cycles showed that all 180 cards failed.

The sample size for this performance testing (12 eBD Test Cards per lot and three distinct lots), is adequate and meets conventional industry standards when assessing an attribute-based response with the following quality levels: AQL = 0.4%, Alpha and Beta = 5%, and RQL = 8%.

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 11140-4.

This new Bowie-Dick test 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 Bowie-Dick 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 steriliser 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 significant 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 digitise the results of the color changing indicator sheet of current products through scanning or photographing. Furthermore, the connected solution of the eBD Test Card can also provide an automated means of creating, storing and transferring the test result to instrument tracking systems, and can 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 Bowie-Dick 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 improves the efficiency of the Bowie-Dick 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 11140-4.

References

1. ANSI/AAMI/ISO 11140-1:2004 *Sterilisation of health care products — Chemical indicators — Part 1: General Requirements*. International Organization for Standardization. (2014).
2. ANSI/AAMI/ISO 11140-4:2007 (R2012) *Sterilisation 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*. International Organization for Standardization. (R2012).

solventum

KCI Medical Limited
Charnwood Campus
10 Bakewell Road
Loughborough
England, LE11 5RB
01509 611 611

3M Healthcare EMEA Export Limited
2 Cumberland Place
Fenian Street,
Dublin 2,
D02 H0V5
1 800 320 500