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Time Saving Advantages of a New Electronic Bowie and Dick Test System

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Introduction

The Bowie and Dick (BD) test has been an important part of healthcare sterilization quality control programs for many years. The traditional BD test pack design, comprised of a paper sheet printed with a pattern of reactive ink embedded within a porous pack, was developed in the 1950s. Today's industry standards for sterile processing recommend a daily BD test for all pre-vacuum steam sterilizers. The Bowie-Dick test results are maintained as part of the batch record and quality control system. Recent technological advancements have resulted in a new electronic BD test that eliminates the need for human interpretation of the printed paper sheet and also provides automatic digital record keeping capability. This paper will describe this new electronic BD test and compare the technician time required for record keeping for the traditional design to the time required for the electronic BD test.

The Traditional Bowie and Dick Test

Saturated steam sterilization processes rely on energy released when the steam condenses on the surfaces of the instruments and packaging. This energy kills microorganisms by disrupting cellular macromolecules such as proteins and nucleic acids. Air is a non-condensable gas that, when mixed with steam, reduces the amount of condensation and thus the amount of energy released during the sterilization process. Thus, air must be removed from the steam sterilizer chamber and instrument load to achieve a successful steam sterilization process.

The original method of air removal from steam sterilizers was gravity displacement. In this process steam is introduced into the top of the chamber, and as pressure builds the residual air is forced out of the bottom of the chamber through the drain. Dynamic air removal processes were then developed to increase efficiency and reduce cycle time. Pre-vacuum sterilization processes utilize a vacuum pump to actively pull air out of the chamber and load. Today, pre-vacuum processes are the predominant type of steam sterilization process used in hospitals.

Air removal is critical for successful steam sterilization, but for many years there was no method available to test the efficiency of the air removal process. In the 1950s in England Dr. J.H. Bowie and J. Dick invented a test to challenge the air removal capability of the steam sterilizer.[1] The test device was comprised of two elements. The first element was a challenge pack comprised of a stack of surgical towels. The towels were porous and therefore retained air, and the stack of these porous towels presented a significant challenge to the sterilizer's vacuum system. The second element of the test was a detector system designed to determine if the air had been removed from the challenge pack. The original BD test used a paper sheet with a crossing pattern of indicator tape strips, placed in the center of the towel pack. The stripes on the indicator tape were printed with a reactive ink that changed color from light to dark upon exposure to steam. If the residual air was removed from the challenge pack, the indicator ink stripes would be a uniform dark color across the entire test sheet. However, if the air had not been completely removed, the residual air formed an air pocket within the challenge pack. The portions of the indicator tape strips that were in contact with the air pocket did not turn color as completely as the sections that were not in contact with the air pocket. This is because the residual air interfered with the steam condensation process and resulted in a cooler area, so the indicator ink in this area did not achieve a complete color change. After the BD test cycle, the technician removed the test sheet from the challenge pack and looked for non-uniformity in the color of the tape strips. A uniform dark color meant the air was removed. Lighter areas indicated an air removal failure (**Figure 1**).

The early BD test packs were assembled in the sterile processing department. Today, many manufacturers provide pre-made disposable BD test packs. These pre-made packs are comprised of a stack of heavy paper index cards, with a pre-printed indicator sheet in the center of the pack. The stack is overwrapped with a disposable wrap. The indicator sheet is printed with a reactive ink pattern that makes inconsistent color change due to an air pocket easier to visualize. **Figure 2** shows an example of a disposable BD pack indicator sheet, with uniform color sheets indicating a pass and non-uniform sheets that have detected an air pocket indicating a fail.

Bowie and Dick tests are expected to present a rigorous challenge to the air removal process, regardless of their construction. The International Organization of Standardization (ISO) has published global standards that specify the performance requirements for BD tests. This series of three standards (ISO standards 11140-3, 11140-4, and 11140-5)[2,3,4] establishes the requirements for individual test sheets, and for two different challenge pack configurations. Use of BD products that comply with the performance requirements specified in these standards will provide a level of assurance that the BD test will provide the correct challenge to the air removal system.

Regulatory agencies may also specify BD performance requirements, and these requirements may differ from those provided by ISO. The United States Food and Drug Administration (FDA) has established performance requirements for air removal indicators that manufacturers must meet as part of the regulatory approval process.[5]

Figure 1. Bowie and Dick Test — Residual Air Detection.

An illustration of the formation of an air pocket within a standardized stack of textiles and the effect the presence of such an air pocket would have on a CI sheet placed in the center of the stack. The light area on the CI sheet is where an air pocket is preventing the printed ink changing to the black endpoint after exposure to moist heat.

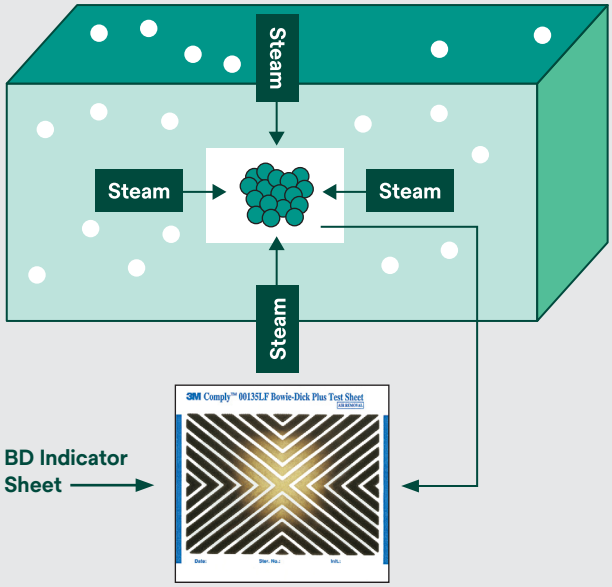
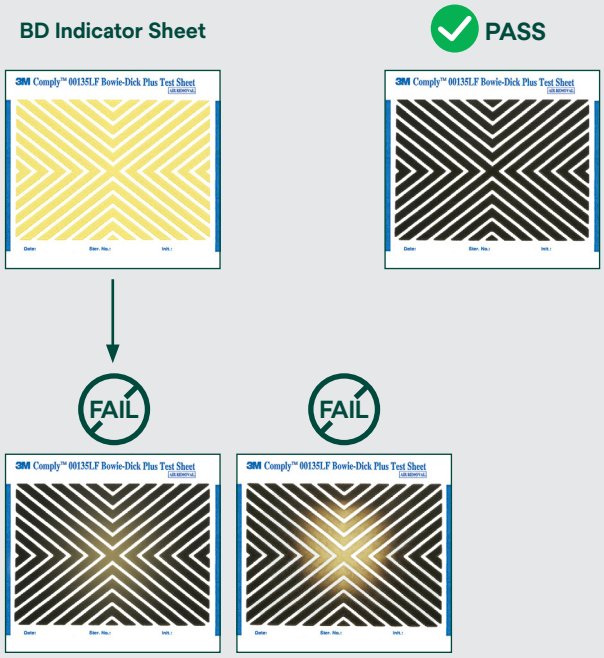


Figure 2. Disposable BD Test Sheets Pass and Fail.



Bowie and Dick Testing in Hospitals

BD testing of pre-vacuum sterilizers is an important part of sterilization quality control programs for hospital steam sterilizers. The test is intended to routinely demonstrate that the sterilizer's air removal system is working properly. The generally accepted testing frequency is once per day per sterilizer.[6,7] For example, the Association for the Advancement of Medical Instrumentation's (AAMI) guide to steam sterilization in hospitals states that "A Bowie-Dick (Type 2 CI) test should be performed each day the sterilizer is used, before the first processed load".[6] BD tests are also used to verify pre-vacuum sterilizer performance during requalification after a sterilization process failure. BD tests are run after three successful empty chamber tests using a biological indicator (BI) in a process challenge device (PCD). From AAMI ST79 ..."For dynamic-air-removal sterilizers, a Bowie-Dick test pack should then be run in three consecutive empty-chamber cycles".[6]

The hospital BD test is run in an empty chamber to provide the greatest challenge to the air removal process as it maximizes the volume of air that must be removed. The BD test pack is placed in the most challenging location in the sterilizer chamber, typically over the drain. The sterilizer should be pre-heated, either by a regular loaded cycle run before the test, or by running a warmup cycle, depending on the facilities' operating schedule.

The requirements for creating and retaining records of sterilization quality control test results are often facility or network specific, and are driven by government regulations, accrediting agency requirements, and/or the management policies of the facilities themselves. Records can be in paper or electronic form, though electronic records are preferred to reduce the storage space required and simplify the search for old records. **From AAMI ST79... "Information may be recorded in a paper or electronic log or filed as individual documentation records. Electronic records of sterilization process monitoring results, including specific load item identification, are recommended."**[6] Many hospitals utilize instrument tracking systems that integrate quality control testing records with the load and instrument tracking information. The method for entering BD test results will vary by facility, but many enter the result in their computer system manually, then scan the BD test sheet into the electronic records, and some hospitals also file the BD test sheet.

New Electronic Bowie and Dick Test

A new electronic Bowie and Dick (eBD) test system has entered the healthcare market. The 3M™ Attest™ eBowie-Dick Test System uses a small test card with electronic sensors instead of a traditional BD test pack with a chemical indicator sheet (**Figure 3**).

The card's unique physical design presents a lumen-based challenge to the sterilizer's air removal system, and integrated electronic sensors inside the card detect whether the air has been removed from the chamber.

For protection and stability, the card is placed into a reusable holder before being placed in the sterilizer. The card and holder system eliminates the need for the paper index cards and the overwrap. The card features a 2D barcode containing manufacturing lot and expiry date information.

After the cycle, the eBD test card is placed in a specially designed reader that translates the electronic results into a Pass or Fail response provided to the technician as a green or red light (**see Figure 4**). The reader can operate as a standalone, or it can be connected to a computer via a USB or wireless (bluetooth) connection. A computer connection enables the use of the accompanying reader software that automates the record keeping process by capturing test results and eBD test card lot numbers and linking them with the sterilizer number and cycle records. The software can also be connected to the hospital's instrument tracking system to automatically integrate eBD test results into the department's instrument tracking records.

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

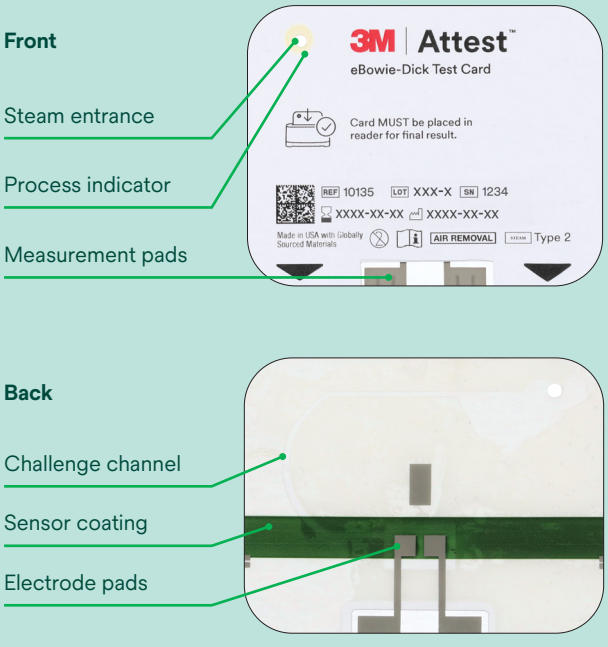
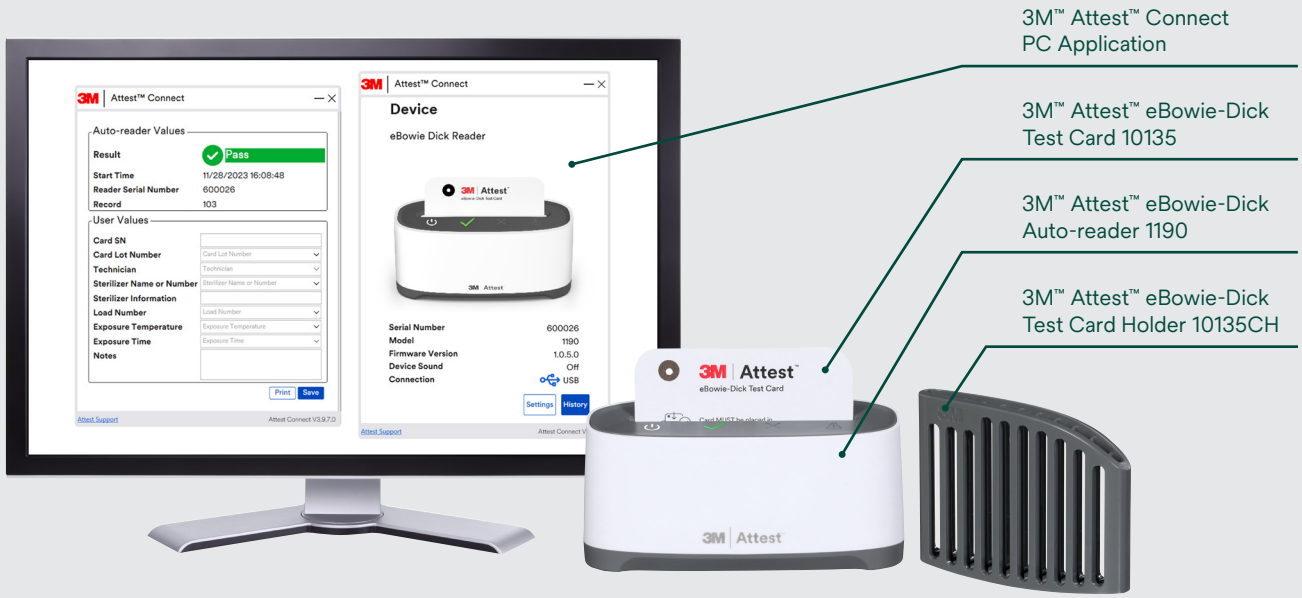


Figure 4. 3M™ Attest™ eBowie-Dick Test System



Bowie and Dick Record Keeping Time Study

One of the anticipated advantages of an eBD test is the potential for staff time savings by elimination of the manual reading and record keeping procedures required for conventional BD test packs. The purpose of this study was to compare the staff time required to read and record conventional BD test results to the time required to read and record electronic Bowie-Dick test results.

The hospitals that participated in this study ran Bowie-Dick tests once per day, either at the start of the next calendar day (midnight) or the next workday (for two shift operations). For their daily conventional BD test, hospitals created a BD test cycle record for each steam sterilizer in their computerized record system, and entered the specific BD test information (e.g., lot number) into the record. After completion of the BD test cycle, the test packs were opened and read, and the result entered via keyboard into the BD test record. The record keeping process was completed by scanning the BD test sheets and uploading the image into the BD test cycle record. In some instances, the BD sheet was also placed into a file or logbook.

For this study, the electronic BD test cards were placed into a reusable holder and run in each steam sterilizer immediately after completion of the daily conventional BD test. After the cycle, the eBD cards were removed from the sterilizer and holder and placed into the reader. The reader indicated a test result (green or red light), completing the process. The assumptions for the eBD test were that in actual use the reader would be fully connected to the hospital's record keeping system so the test result as well as the eBD test card batch number and expiry date would be automatically entered into the system, and that no scanning or photos of the eBD test card would be required. The assumptions for the eBD test were consistent with the manufacturer's design intent and instructions for use.

Five U.S. hospitals participated in this study. Timing measurements were conducted five separate times at each hospital over a maximum of two calendar weeks. A stopwatch was used to record the minutes and seconds required for the reading and record keeping processes for the conventional BD test pack and the eBD test card system. The observer maintained a discreet distance and remained out of the technician's line of sight to reduce any Hawthorne effect. For the conventional BD test, the timing of the record keeping process started with the opening of the conventional BD test pack and concluded with the scanning the BD test sheet image or placement of the BD sheet into the batch file, depending on the facilities' procedure. For the electronic BD test, the timing began with the removal of the eBD card from the holder and ended with the green or red light response from the reader.

Results

The five hospitals that participated in this study operated two to four pre-vacuum steam sterilizers in their sterile processing departments. Two hospitals operated two sterilizers, one operated three sterilizers, and two operated four sterilizers. The total time (minutes and seconds) required for the conventional BD and eBD record keeping processes for all sterilizers was measured and recorded each test day. The total time difference (time savings) between the conventional BD test and the eBD test was then calculated for each day. The calculated time savings for all 25 test days (5 hospitals x 5 test days/hospital) were aggregated and analyzed. The results are provided in (**Table 1**).

Table 1. eBD Time Savings.

Average Time Savings/Sterilizer/Day	Lower 95% Confidence Interval	Upper 95% Confidence Interval
1.31 minutes	1.15 minutes	1.37 minutes

Discussion

The electronic Bowie-Dick test system will provide several advantages over traditional BD packs. The system can reduce inventory storage space as compared to traditional 3M Bowie-Dick Test Packs and it can help eliminate the need for human interpretation for the pass/fail result. The reader and accompanying software will enable automatic integration of BD test results into instrument tracking system records.

Assessment of the seemingly moderate record keeping time savings of 1.3 minutes/sterilizer/day should consider the amplifying effect of multiple sterilizers in the facilities' sterile processing department. **A four-sterilizer department will see an additional 26 minutes of technician time become available each five-day work week, with 36 minutes/week for a seven-day operation. The potential impact becomes even more substantial when assessing the impact across an entire Integrated Delivery Network (IDN). Average time savings for a 10-hospital system could potentially free-up over four hours of technician time per week.**

1.3 minutes/sterilizer/day x 4 sterilizers x 5 days/week = 26 minutes/week time savings

26 minutes/week/SPD x 10 SPDs/IDN = 260 minutes/week = 4.3 hours/week/IDN time savings

Summary

Daily Bowie-Dick testing is an important part of a sterilization quality control program. Conventional Bowie-Dick test results are read and recorded, and then scanned or filed for future reference per the facilities' policy. A new electronic Bowie-Dick test system will automatically read and record the Bowie-Dick test results, and also incorporate the test results and lot identifying information into the hospital's record keeping and instrument tracking systems. Factoring in the average time savings found in this study, the automated reading and recording capability of this new system could potentially save 26 minutes of technician time each week in a four sterilizer department.

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