

The Bowie and Dick Test

Historical Background and Relevance Today

Introduction

Sterile service department (SSD) practitioners will be aware of a daily test carried out on their sterilizers called the Bowie and Dick Test (BDT). This article provides insight into the background of the BDT, its purpose, and why it remains a fundamental step in assuring sterilizer performance.

Saturated steam sterilization processes (SSSP)

In SSDs, most reusable surgical instruments and other medical devices (RMeDs) are sterilized in SSSPs.¹ Saturated steam sterilization is achieved by maintaining surfaces at a specified temperature for sufficient time in the presence of moisture to achieve microbial inactivation. For an SSSP to be effective, air must first be removed from the chamber and load; otherwise, air pockets will form within RMeD load items,

preventing the ingress of saturated steam and thereby causing process failures. SSSPs are therefore carried out in three stages.

Stage 1: Air is removed from the chamber and load.

Stage 2: To achieve sterilization, the load is heated with saturated steam to a specified temperature (e.g. 132°C) and held for a prescribed time (e.g. 4 min).

Stage 3: The load is dried by evaporating the water condensed during the two preceding stages.

Two types of SSSP are used

1: The differences in the density of steam and air are employed to achieve passive displacement of air from the chamber and load by steam. Steam enters the top of the chamber and permeates through the chamber and load, forcing air out of a drain valve in the base of the chamber. This is termed “gravity displacement sterilization” and, because of its passive nature, is slow and can be inefficient.

2: Air is actively removed from the chamber and load by employing vacuum pumps or air ejectors. These types of processes have various synonyms, such as active air removal, vacuum-assisted or pre-vacuum sterilization. Such processes are quicker, provided the active air removal stage remains effective.

Objective 1: The advent of the BDT

In 1961, Dr. J. H. Bowie and co-workers carried out studies on recently installed pre-vacuum sterilizers in hospitals in and around Edinburgh.² His tests employed a stack of folded surgical towels, measuring about 22

x 30 x 25 cm. The stack presented a challenge to the air removal and steam penetration characteristics of the process. Temperature measurements from the center of the stack assessed the adequacy of air removal and steam penetration. If adequate air was removed, steam would rapidly penetrate the stack, and the temperature at the center would be equal to that in the coldest part of the chamber, the active chamber drain. If there was any air remaining, it would be driven towards the center of the stack, causing the temperature at the center to be lower than that in the chamber drain.

Bowie recognized that a routine test for assessing the adequacy of air removal and steam penetration was needed to ensure sterilizers remained effective given the unreliability of the vacuum systems then in use. He also recognized that it would be impractical and expensive to have temperature sensors permanently installed in the sterilizer so that the thermal characteristics of the challenge pack could be routinely assessed. Bowie recognized that the autoclave tape commonly used to secure the wraps of sterilization packs would only change to black when exposed to saturated steam during a sterilization cycle. Exposure to the dry conditions found in the center of an air pocket within a challenge pack would prevent the indicator ink from darkening.

With this insight Bowie and co-workers were able to specify a challenge pack made of a stack of folded huckaback towels into the center of which was placed a piece of paper, A4 in size, onto which was fixed two strips of autoclave tape in the form of a St. Andrew cross. The test pack, with

Learning Objectives

1. The advent of the Bowie and Dick Test
2. How to carry out the Bowie and Dick Test
3. Why does a Bowie and Dick Test fail?
4. The Relevance of the BDT Today

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a simplistic chemical indicator, could be easily made up in any SSD and be used at the beginning of each day. The result of the test could be readily interpreted by autoclave operators: a complete dark color on the tape indicating a satisfactory result, a light area in the center of the tape cross indicative of residual air, and a process failure. The BDT was thus born.³ For SSD technicians, the BDT remains an essential part of daily sterilizer monitoring. Understanding why the test was developed helps reinforce its role in detecting air removal and steam penetration problems before instruments are processed for patient care.

Further Advances

Because of its simplicity, low cost, and value as a routine control measure any SSD could implement, the BDT was adopted by many countries. The BDT as specified was used for many years. As SSDs became busier, the preparation of the BDT pack became inconvenient, and so the world of commerce stepped in and started to supply ready-to-use, disposable test packs based on a similar construction to the standard textile pack such as using a stack of porous material, often card, into the center of which was placed an indicator sheet pre-printed with a moisture- and temperature-sensitive ink. Today the practitioner is faced with an overwhelming choice of BDT products, not all of which have the same performance characteristics.⁴ Technological advances have also taken place, and re-usable and electronic versions of the BDT have become commercially available.^{5,6} As new test systems become available, SSD technicians must understand how to correctly select, use, and interpret these products to ensure reliable sterilizer monitoring.

Standardization of the BDT

Over the years, different countries adopted slightly different approaches

to conducting the BDT. In the UK, a stack of Huckaback Towels was specified as the test pack.⁷ In many European countries, a stack of about 30 cotton sheets folded to an A4 size and weighing 7kg, was employed; this later becoming the test pack specified in EN285.⁸ In the USA, a stack of Huck towels approximately the same size as the Bowie textile pack, weighing 4 kg, was described by the Association for the Advancement of Medical Instrumentation (AAMI) in AAMI ST79 and subsequently adopted in ISO11140-5.⁹ Each of these test packs provides slightly different challenges to air removal and steam penetration of the sterilization cycle. Also, commercial packs required standardization. For this reason, standardization was begun, firstly by the European standards committee, resulting in the publication of EN867-4 (now obsolete) and then by the International Standards Committee (ISO) resulting in the publication of three standards. ISO11140-3 specifies the requirements for an indicator sheet which is placed at the center of the textile pack specified in EN285.¹⁰ ISO11140-4 specifies the performance requirements for commercial alternative BDTs. These test packs are intended for use in sterilizers that meet EN285. Their performance is compared to test packs described in ISO 11140-5 and the American National Standards Institute (ANSI) and AAMI standard ANSI/AAMI ST 8.¹¹⁻¹³

The performance characteristics of commercial BDTs are required to have equivalent performance to the thermometric performance of the standard textile pack when exposed to a pre-vacuum sterilization cycle. This equivalency is established by positioning temperature sensors in the center of the standard textile pack and in the chamber drain. The test pack is then exposed to a sterilization cycle, and the temperature is measured in the drain and center

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Quiz Answers:

1. A, 2. B, 3. B, 4. A, 5. C, 6. C, 7. B, 8. A, 9. C, 10. C, 11. B, 12. C, 13. C, 14. A, B, C, 15. B

of the pack. In a successful cycle all sensors will measure equal temperatures, indicating satisfactory air removal and steam penetration. An alternative BDT is then subjected to the same test cycle, and this should show a pass result, however judged. The sterilization cycle is then adulterated by changing the process conditions so air remains in the chamber. The textile pack is then exposed to the adulterated cycle and the temperature in the center of the pack compared to that measured in the drain. If the center of the pack is more than 2°C lower than that in the drain at a specified time in the holding stage, the process is regarded as a failure. The alternative BDT is then exposed to the same test conditions, and this should show a fail result. Understanding the principles behind BDT standardization helps SSD technicians recognize the importance of using approved test devices and accurately evaluating daily test results before processing medical devices.

Objective 2: How to carry out the BDT

The BDT is a test for air removal and steam penetration for a sterilization process used to process RMeD loads. It does not assess the sterilization performance. We need to know the production cycle is working correctly, so this should be tested, not a special BDT cycle. However, there are two exceptions. Firstly, the holding time and temperature of the cycle can be adjusted to those specified for the commercially produced BDT. Secondly, the drying stage can be reduced sufficiently to just dry the pack.

The BDT is carried out after a warm-up cycle, so the sterilizer has reached its optimum operating conditions. Testing a sterilizer which has remained on standby for several hours can result in a failed BDT, a result unrepresentative of normal operating conditions. The BDT pack

is placed on a trivet at a specified height above the drain of the empty sterilizer chamber. An empty chamber is the most challenging condition for air removal, and any cold air, having a greater density than hot steam, will migrate to the base of the chamber as the process proceeds, optimizing detection by the BDT.

The BDT should be removed immediately after the cycle is complete, and the indicator sheet inspected following the instructions. If left in the chamber, it will heat up, potentially giving rise to aberrant color changes on the indicator sheet, leading to misinterpretation of the result. Generally, a uniform color change across the printed ink surface indicates a pass. Any differences in color between the edge and center of the printed surface should be regarded as a failure. Indicator sheets should be viewed using a standardized protocol in good light. Differences in visual acuity between operators should be considered when developing the protocol. Test results should be recorded as part of the quality assurance records for the department. Standards require the test result to remain stable for at least six months, but if filing the sheet, manufacturers' storage instructions must be followed, otherwise, changes to the appearance of the ink can occur. Some modern BDTs evaluate results electronically and store results automatically.⁶

Objective 3: Why does a Bowie and Dick Test Fail?

The sterilization process will be designed to pass a BDT once an effective process has been established, a routine daily test will ensure ongoing performance. There are a number of process failures that will give rise to a BDT failure.

Incorrect Processing

BDT products are calibrated to perform optimally when exposed to specified processing conditions. These will

be stated on the product label and in the instructions. Exposure to a lower temperature or a shorter time will result in an incomplete color change on the indicator sheet, leading to misinterpretation of the result. Exposure to conditions greater than those specified will reduce the sensitivity of the product, resulting in a failed BDT being interpreted as a pass.

Chamber Leaks

Air leaking from the outside into the chamber can give rise to a BDT failure. Leaks can occur due to a defective door seal, easily damaged during loading and unloading, or loose fittings, caused by vibration. A leak rate test, often carried out automatically, can identify if the leak rate is above a specified level, e.g. 1.3mB/min.⁸

Inadequate Vacuum Levels

If the specified vacuum levels are not achieved during the pre-vacuum stages of the cycle, insufficient air will be removed, resulting in a BDT failure. A faulty or incorrectly calibrated pressure sensor providing incorrect information to the controller can cause this. Examination of the pressure readings on the process recording can identify this type of fault.

Air Mixed with the Steam Entering the Chamber

During steam generation, it is possible to introduce non-condensable atmospheric gases into the steam. If not removed, these can form air pockets within the load and cause process and BDT failures. The presence of non-condensable gases in the steam supply above a specified level, e.g. 3.5 ml gas/100 ml steam condensate, can be identified by carrying out a steam quality test.^{1,8}

Objective 4: The Relevance of the BDT Today

The BDT was invented to address a particular problem with pre-vacuum

sterilizer designs prevalent in the 1950s and 1960s. Today, sterilizers are far more reliable and better designed, employing modern engineering techniques to ensure process reproducibility and reliability. SSDs often operate 24/7, so overnight closures don't always occur. Load configurations have changed, with fewer textiles being processed and more complex RMeDs being used. Nevertheless, equipment can fail. The textile packs specified in international and national standards represent a standardized challenge to the air removal and steam penetration stage of a pre-vacuum sterilization cycle. These packs are commercially independent, have a long history of use, and their performance is well understood; no new alternative has been specified having similar sensitivity. Conducting a daily independent BDT test, usually using commercial equivalents, provides additional assurance: that the sterilization process continues to perform effectively.

Conclusions

If you don't get the air out, you cannot get the steam in. The BDT is an independent, fundamental test ensuring the adequacy of air removal and steam penetration into a standardized challenge pack. The test is widely recognized in national and international standards as a daily basic test of sterilizer performance, adding to the overall quality assurance programs of a modern SSD.

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The Bowie and Dick Test - Practice Quiz

1. **For a pre-vacuum type sterilization cycle a rule of thumb is:**
 - A. If you don't get the air out, you cannot get the steam in
 - B. You don't need to get the air out to get the steam in
 - C. Steam will always find its way into a load
2. **For a steam sterilization process to be effective you must expose the load to:**
 - A. A specified time and temperature
 - B. A specified time and temperature in the presence of moisture
 - C. Any chosen time and temperature
3. **Bowie worked with a co-worker called;**
 - A. Donaldson
 - B. Dick
 - C. Duggan
4. **The Bowie and Dick test was invented in**
 - A. United Kingdom
 - B. Australia
 - C. New Zealand
5. **Bowie described a standard test pack made up of;**
 - A. Cotton drapes
 - B. Cotton gowns
 - C. Surgical towels
6. **A pre-vacuum type sterilization consists of;**
 - A. 1 stage
 - B. 2 stages
 - C. 3 stages
7. **Bowie described a standard daily test using a stack of textiles and a**
 - A. Pre-printed temperature and moisture sensitive test sheet
 - B. A cross of autoclave tape
 - C. A biological indicator.
8. **The first step in the evolution of the Bowie and Dick Test was to ;**
 - A. supply disposable commercial test packs
 - B. supply electronic e-BDTs
 - C. supply reusable BDT test products
9. **The ISO standards describing the performance for Bowie and Dick products are numbered;**
 - A. 11138
 - B. 11139
 - C. 11140
10. **According to standards the performance of a BDT is established by comparing it against**
 - A. the performance of a textile pack with a pressure indicator in the center
 - B. The performance of a textile pack with a biological indicator in the center
 - C. The performance of a textile pack with temperature sensors inserted into the center
11. **When conducting a BDT, the test pack is placed;**
 - A. Along with a load of products
 - B. Above the drain in an empty chamber
 - C. In a chamber filled to its maximum capacity
12. **When conducting a BDT;**
 - A. A special BDT cycle should be used
 - B. The production cycle should be used
 - C. The production cycle should be used but with its holding time and temperature adjusted to those specified for the BDT pack
13. **The BDT tests for**
 - A. A satisfactory sterilization cycle
 - B. For satisfactory sterilization conditions
 - C. For satisfactory air removal and steam penetration
14. **The reason why a BDT can fail is: (select all that apply)**
 - A. Due to a chamber leak
 - B. Due to inadequate vacuum levels during the pre-vacuum stage
 - C. Due to non-condensable gases in the steam
15. **Which statement best describes the relevance of the BDT today**
 - A. The BDT is no longer relevant in modern practice
 - B. The BDT provides independent assurance that the air removal stage of the pre-vacuum cycle is performing satisfactorily allowing rapid and even penetration of steam.
 - C. Standards require the BDT to be carried out therefore we do it.