The Mystery of Bowie & Dick

Alterations in the Vacuum on Your Sterilizer Throughout the Year

BY WILLIAM LEIVA, SENIOR PROGRAM MANAGER FOR STERILE REPROCESSING, MEDTRONIC

Intro and first learning objective: Understand the rationale of the porous load test pack.

If you were to read about one John Herbertston Bowie or one James Dick, most of us would never connect their names to steam sterilization. However, if you were to read about Bowie & Dick, your thoughts would lean toward one of the most commonly used tools by SPD Professionals. Doctor Bowie, a British Bacteriologist, conducted many studies in the United Kingdom between 1949 and 1955, and concluded that most hospital sterilization systems (steam was the only method used in the United Kingdom at that time) "did not ensure adequate sterilization due to faulty construction, faulty installation, or sterilizers were not used correctly". Doctor Bowie, with one of his team members, Mr. James Dick, developed the "high-vacuum autoclave" (Figure 1). This autoclave heralded a plethora of changes that led to what we know as vacuum-assisted steam sterilizers, or simply prevac sterilizers.

Shortly after this development, they noticed that while the 'high vacuum' autoclave was better than conventional gravity units, to evaluate air removal, a new tool needed to be devised. This was first described in 1963 as a way to assess air removal from a test device to ensure that the vacuum successfully removed air before the steam entered the chamber at the end of the conditioning phase and during exposure. It was initially developed as a cross made of indicator tape, protected by multiple layers of cotton towels. The vast majority of the Bowie & Dick type test packs are based on this reliable design, with a handful of exceptions used abroad and not currently FDA-cleared to be used on US hospitals.

The use of a porous load to assess air removal had two reasons: first, back in the 1950s and 1960s, most of the sterile barrier used was made of natural fibers coming primarily from cotton (100% cotton, muslin). Second, these natural wrapping materials

Learning Objectives

1. **Understand the rationale of the porous load test pack.**
2. **Describe the current Bowie & Dick test package technologies and the information they provide.**
3. **Understand air removal systems and performance changes over the year.**

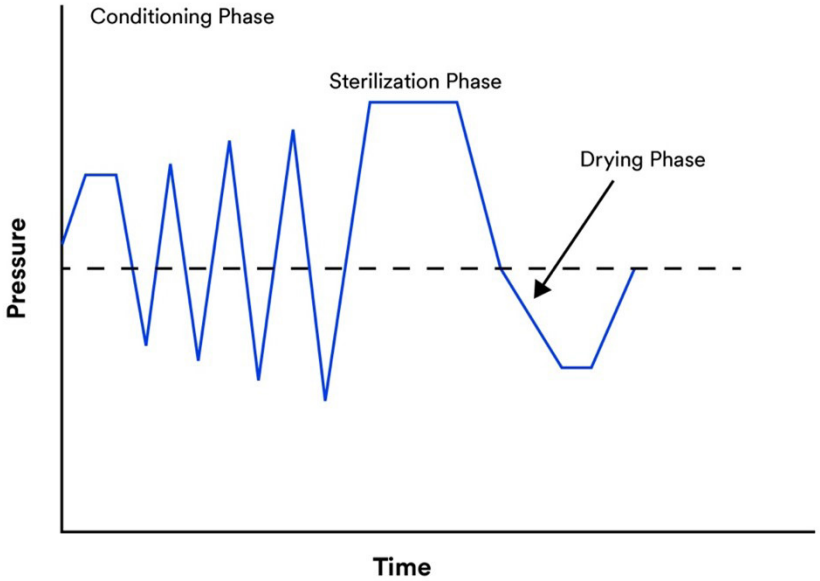

Figure 1: A general cycle profile of a pre-vacuum steam sterilization cycle, with four negative pressure pulses before the exposure phase.

allowed air to become trapped within the fibers, making air removal difficult during the air removal test; therefore, if the Bowie & Dick test was successful, a significant amount of residual air within the chamber was removed, making the sterilizer suitable for that day of work.

From a conceptual perspective, today's Bowie & Dick test packs include a sheet printed with an ink designed to react by changing color when exposed to specific conditions: presence of steam, temperature of 273 ° F (134 °C), for 3.5 minutes. As steam can only effectively diffuse onto the test pack and the test sheet in the absence of residual air, the Bowie & Dick test pack will show effective air removal during the sterilizer conditioning phase (Figure 2).

Second learning objective: Describe the current Bowie & Dick test package technologies and the information they provide.

We are used to a variety of devices called Bowie & Dick "type" test packs, which, with the exception of the ink pattern on the test sheet and small differences on the pack size, are rather similar.

These B&D tests work on the basis of a vapor-sensitive ink. When air is removed and steam is diffused into the pack, the inks change color in a way that is easy to determine by the user who performs the evaluation. Given the susceptibility of variation in color perception among different observers, the standard for Bowie & Dick Test Packs[3], accompanying instructions define the requirements for the color change and explain how to determine whether the test shows acceptable air removal. This is done under specific light conditions (e.g., intensity, wavelength, angle of incidence), and with properly calibrated equipment (i.e., spectrophotometers). However, despite the standardization on the B&D sheet, there are still situations where two observers perceive a different color change on the sheet. This speaks of a technology that is intrinsically qualitative, that is, it does not provide specific

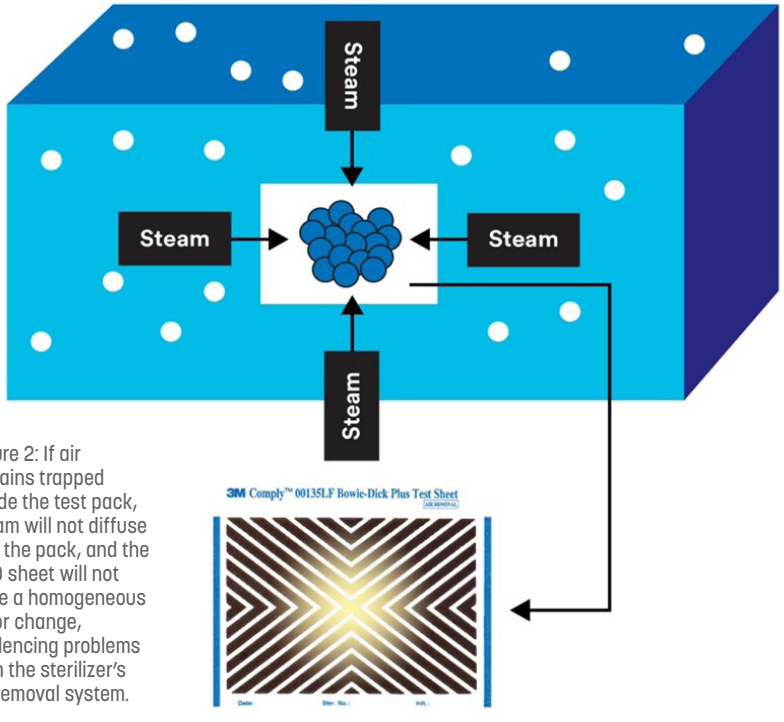

Figure 2: If air remains trapped inside the test pack, steam will not diffuse into the pack, and the B&D sheet will not have a homogeneous color change, evidencing problems with the sterilizer's air removal system.

Lesson:

The Mystery of Bowie & Dick

October 2024

This lesson was developed by Solventum. Lessons are administered by Endeavor Business Media.

Earn CEUs

After careful study of the lesson, complete the examination online at **educationhub.hpnonline.com**. You must have a passing score of 80% or higher to receive a certificate of completion.

Certification

The **Certification Board for Sterile Processing and Distribution** has pre-approved this in-service unit for one (1) contact hour for a period of five (5) years from the date of original publication. Successful completion of the lesson and post-test must be documented by facility management and those records maintained by the individual until recertification is required. DO NOT SEND LESSON OR TEST TO CBSPD. **www.cbspd.net**.

Healthcare Sterile Processing Association, **myhspa.org**, has pre-approved this in-service for 1.0 Continuing Education Credits for a period of three years, until August 24, 2027.

For more information, direct any questions to *Healthcare Purchasing News* editor@hpnonline.com.

Quiz Answers:
1. A, 2. C, 3. B, 4. A, 5. D, 6. B, 7. A, 8. D

information on the intensity of the color change or on the residual air or noncondensable gases.

A newer technology was recently approved by the FDA in their De-Novo4 program, which was identified as a digital physical and chemical sterilization process sensor. This new technology offers the ability to detect air removal and steam penetration while delivering the result in an unequivocal way by the use of an autoreader. This technology may have the ability to address issues of B&D sheet interpretation with the potential to deliver quantitative results for residual air.

Third learning objective: Understand air removal systems and performance changes over the year.

We know that steam sterilization is achieved through the condensation of saturated steam on medical devices, which enables energy transfer and delivers sterility. However, to cause this condensation of steam, the sterilizer chamber must be free of residual air. Now, where is this air coming from? And what do we really mean when we talk about air removal?

As air is everywhere, it can be found inside packs, trapped within lumen devices, and inside the sterilizer chamber before closing the door. However, air is part of a broader group of gases called non-condensable gases (NCGs). The NCG can enter the sterilizer chamber through the steam supply from door seals and from faulty valves through the multiple systems operating the sterilizer. When coming from the steam supply, it is often generated during the water treatment process, where CO2 can be generated during reverse osmosis and carried through the steam supply. When these NCGs reach the chamber, they lead to negative consequences because, as their name implies, they do not condensate under the normal operating conditions of a steam sterilizer. Due to the complex behavior of gases under pressure, these gases move to the colder spots within the chamber, which often is next to the instruments and inside containers, and act as thermal insulation, preventing steam from reaching every spot within the sterilizer, containers, and instruments. Even smaller amounts of NCG can lead to sterilization failure, leading to positive biological indicators or internal chemical indicators without adequate change. This emphasizes the importance of the daily air removal test, which will ensure that the sterilizer is effectively removing air from the chamber.

Modern sterilizers used in hospital and healthcare settings use dynamic air removal, which is usually composed of an air removal system and multiple valves and electronic or electromechanical components that control operation. Air removal itself occurs through either the use of water ejectors, also known as Venturi systems, or the use of a liquid ring pump.

Since both systems use water to enable or create vacuum, looking into the characteristics of water is not only important but imperative. More specifically, the temperature of the water affects its density, which in turn affects the performance of the air removal systems. In very broad terms, the higher the water temperature, the lower the air removal effectiveness; however, we do not often account for the seasonal changes that affect the water temperature. Although this has been known for years in the scientific community, it has been overlooked in many SPDs. To address this, under the leadership of AAMI, the standards development community works on the development of the standard ANSI/AAMI ST 108: 2023 'Water for the Processing of Medical Devices'. This standard, in its Annex B.2., includes a reference on the temperature of the water and its impact on pump performance (Table 1), which provides great information for SPD and support personnel to understand the implications of the temperature of the source water and the efficiency of the vacuum system.

With many health care facilities located in areas with significant temperature variations, the temperature of the water changes throughout the year. These changes in water

Table 1: water temperature and pump performance.

Water Temperature	Pump Performance
Cold (<16 °C / 60 ° F)	Optimal
Tepid (16 - 38 ° C / 60 - 100 ° F)	Decreased pumping speed
Warm (38 - 45 ° C / 100 - 113 ° F)	Greatly decreased pumping speed.
Hot (45 - 49 ° C / 100 - 113 ° F)	Not recommended
Above 49 ° C / 120 ° F	Not recommended

Source: ANSI/AAMI ST 108:2023.

temperature may occur due to water distribution systems, water storage, and exposure of the piping system throughout the health facility infrastructure. In turn, this may affect the water temperature enough to create alterations in the performance of the vacuum system.

Conclusions

Although we have seen significant improvements in vacuum system technology and in the configuration of prevacuum cycles, the concept of a porous pack is simple and effective: the Bowie & Dick test pack remains a critical tool for SPD professionals in their daily routine, providing reliable information, assessing the sterilizer, and evidencing problems with air removal, steam diffusion, or vacuum system failures.

There are two downsides to this technology: the need to interpret the color change of the ink sheet that may lead to the need for a 'second opinion', and the lack of data to help assess the cause of a failure of a B&D test.

A failure on the B&D test does help SPD professionals to prevent the use of the sterilizer with air-removal problems, which in turn enhance patient safety; however, there is a need to acquire additional data from this test, specifically quantitative data, to ascertain the amount of residual noncondensable gases on the vessel. This would greatly benefit the assessment of the equipment, enable trend analysis, and provide better predictive and preventive maintenance on vacuum systems. **HPN**

References:

1. EN 285 Sterilization - Steam sterilizers - large sterilizers. 2015. Revised in 2021.
2. ANSI/AAMI ST 108:2023 *'Water for the processing of medical devices'*.
3. ANSI/AAMI/ISO 11140-5:2007 Sterilization of Health Care Products - Chemical Indicators - Part 5: Class 2 Indicators for Bowie and Dick-Type Air Removal Tests
4. FDA de novo program. https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request

William Leiva is currently a Subject Matter Expert on Medical Devices Sterilization and Reprocessing and is currently the Senior Program Manager for Sterile Reprocessing with Medtronic.

He holds undergraduate degrees in physics and engineering and master's degrees in business administration and public health, where he focused his research on infection prevention strategies involving medical device reprocessing. He is currently a candidate for a Ph.D. in Cybernetics and Econometrics, researching around the economic impact of the burden of premature mortality. He has published peer review articles on the application of 3D printing technologies for medical devices and for austere environments.

The Mystery of Bowie & Dick - Practice Quiz

Alterations in the Vacuum on Your Sterilizer Throughout the Year

1. **The Bowie & Dick test was developed to assess the effectiveness of the _____ system.**
   A. Air removal
   B. Steam penetration
   C. High-vacuum
   D. Gravity
2. **The Bowie & Dick test is usually conducted at:**
   A. 250 ° F (121 °C), for 15 minutes.
   B. 250 ° F (121 °C), for 6 minutes.
   C. 273 ° F (134 °C), for 3.5 minutes
   D. 270 ° F (132 °C), for 5 minutes
3. **Current Bowie & Dick packs detect air removal by:**
   A. Air detection
   B. Steam diffusion
4. **Current Bowie & Dick packs provide:**
   A. Qualitative information
   B. Quantitative information
5. **Residual air can be present as a result of the following:**
   A. Water treatment
   B. Air present in lumens
   C. Air trapped in the packs
   D. All of the above
6. **A critical input for vacuum systems is:**
   A. Water ejectors
   B. Water
   C. Liquid ring pumps
   D. Electrical valves
7. **Vacuum performance improves with lower water temperature.**
   A. True
   B. False
8. **Water temperature may change due to the following:**
   A. Seasonal effects
   B. Storage
   C. Distribution
   D. All of the above

Healthcare Purchasing News Education Hub

All CEU quizzes must be taken online at: **educationhub.hpnonline.com.** The cost to take the quiz is $10.

HSPA Healthcare Sterile Processing Association | CBSPD