

September 2006

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Learning objectives

1. Discuss the history of the Bowie-Dick Test Pack
2. Describe the frequency of use and application of the Bowie-Dick Test Pack for steam sterilization
3. Discuss what to look for when selecting a Bowie-Dick test

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SELF-STUDY Series

Bowie-Dick testing, then and now

by Arthur Henderson, RN, BA, CNOR; Michael Russell, RN, MSN, CNS; Richard Bancroft; and Heide Ames

Definition

The Bowie-Dick test verifies the performance of a dynamic air-removal steam sterilizer. The test only verifies the ability of the sterilizer to remove air and replace it with steam (tests steam penetration).

Origins and history

The first Bowie-Dick Test was created by Dr. J. Bowie and Mr. J. Dick and was first published in the 'Lancet' journal in 1963¹. All sterilizer mechanisms were manual and prone to errors. The original test pack consisted of a stack of towels. In the center of the towels, a sheet of paper with steam indicator tape made in the pattern of St. Andrew's cross was placed. The test was adopted by many facilities as a means to evaluate the efficacy of air removal. This was the original reference test, but several adaptations were made in the industry that resulted in a variety of test components and procedures.

In 1980 the Association for the Advancement of Medical Instrumentation (AAMI) published the first standard method for performing this critical test and then revised the method in 1988 to specify the materials, constructions and test cycle to be used when performing this test.

Even with these very specific instructions, the air removal test proved to be highly variable depending upon who constructed the pack, the age and storage conditions of the materials used, and other factors. The solution came in the form of commercially available disposable test packs. Disposable test packs provided highly reproducible results and an economical alternative to user-constructed packs. Because of their reproducibility, new standards were created to describe the performance characteristics of these testing tools, and they were formally named Air Removal Tests.

In 1999 AAMI adopted new perfor-

mance standards and test methodologies for commercially available test packs that took into consideration many of the international requirements for these types of tests². However, fundamental differences still exist between the international standards and the United States standards.

Is the Bowie-Dick Test Pack relevant to steam sterilization today?

Air Removal Tests were designed to be challenging to the steam sterilization process of their time, but are they still applicable to today's modern, more efficient machines and today's typical sterilization loads? (For example, towels such as those once used for the Bowie-Dick Test are not commonly sterilized today.) To answer this question it is necessary to understand the mechanics of steam sterilization.

Steam sterilization can only occur when steam touches a cooler surface and condenses onto that surface. As the steam condenses, the energy that was stored in the steam as heat is transferred to the object and the condensed water flows away from the object. The transfer of heat energy in this fashion is much more effective and faster than heat transfer by convection. This condensed steam occupies more than 500 times less volume than the steam it came from. This reduction in volume upon condensation creates a continuous steam attraction to the surface until the object is at the same temperature as the steam. The amount of steam required to heat an object is dependent on the object's size and thermal prop-

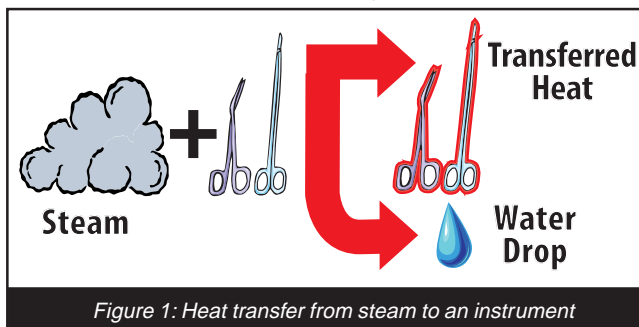


Figure 1: Heat transfer from steam to an instrument

erties. The larger an object's mass, the more steam is required (see Figure 1).

Air within a steam sterilizer is often referred to as a non-condensable gas (NCG). As the name indicates, non-condensable gases cannot condense into a liquid when touching a colder item. The nature of steam condensing and reducing in volume upon condensation causes NCG to be drawn to and held against cold surfaces, concentrating the NCG. This gas will block the steam from contacting the item and shield any bacteria that are present at that spot. Heat transfer can only happen in the slower, less effective convection method. **NCG acts like a shield between the steam and the item. The gas prevents the steam from touching the item, condensing, and transferring heat to the item.**

Wrapped packs, containers or pouches in a load are sometimes referred to as 'porous' items. Any NCG attracted to the load will be entrained within these packs, pouches or containers, and will not easily be displaced. A single unwrapped item would not have this same problem.

Residual NCG comes predominantly from two sources:

1. NCG that was never effectively removed from the item: During the preconditioning phase of a prevacuum sterilizer, a vacuum is drawn in the chamber. This 'sucks' out the air trapped within the packs and items that were placed within the sterilizer. After the vacuum set point has been reached, steam is allowed to enter the chamber and reach a set pressure point. This forces steam into the packs. A series of vacuum and steam pulses are required to ensure that all the air is removed and that steam has replaced it. The ability to remove the steam from the pack can be altered when an air leak is present. The air leak allows air to enter the chamber during the vacuum phase. This prevents a sufficient vacuum from occurring within the pack, trapping air within it. The trapped air acts as a barrier to steam and prevents its penetration into the pack.

2. From NCG that is reintroduced following an effective initial removal from the item: Air leaks into the sterilizer chamber tend to be easier to locate than NCG re-entrainment is. Re-entrainment occurs when NCG is brought into the steam sterilizer's chamber with the steam. The sterilizer is able to draw a sufficient vacuum, but because there is NCG in the steam itself, NCG is re-introduced into the pack as the steam enters (re-entrainment). The difficulty is that re-entrainment is hard to detect. When there

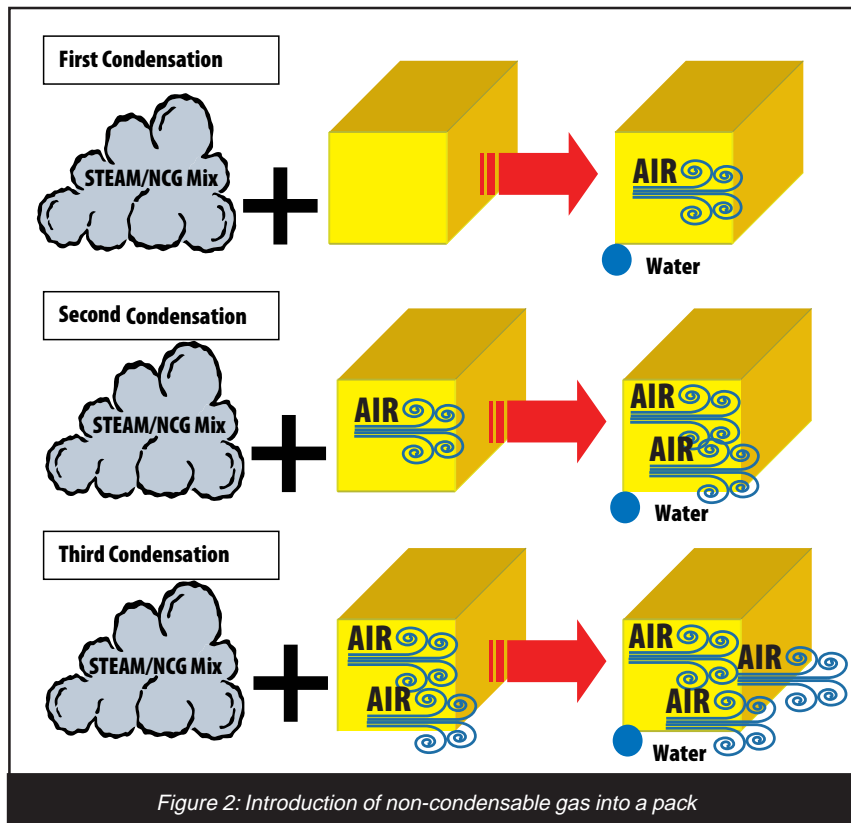


Figure 2: Introduction of non-condensable gas into a pack

is NCG mixed in with the steam, the steam will condense but the NCG will not, leaving a water droplet, a bubble of non-condensable gases and a partial vacuum. More steam/NCG mix is drawn in and the water condenses, resulting in additional NCG and another partial vacuum. This cycle continues until the pack is heated. (See Figure 2.)

The amount of NCG re-introduced into the pack will depend on the quantity of steam that condenses on the pack and the concentration of non-condensable gas within the steam. Packs with increased thermal mass such as orthopedic sets will require more steam to heat up, resulting in a larger amount of NCG re-entrainment.

Even today's sterilizers are not capable of detecting NCG. To detect the presence of residual non-condensable gas, sensors would need to be placed within the packs exactly where the NCG would either be trapped or collect. In addition, these sensors would need to be able to tell the difference between steam and NCG at the same temperature.

So, is the air removal test pack designed 43 years ago still relevant to today's more complex instrumentation? Absolutely. The air removal test pack is still one of the most challenging tests of steam penetration. Its combination of relatively large mass and high porosity makes the Bowie-Dick Test a 'worst case'

situation. The air removal test is also a critical control for sterilizer performance and verification of the quality of steam produced by the unit. It ensures that the sterilizer is still able to provide the validated preconditioning required, and that the steam is free of NCG that could interfere with sterilization of complex instrumentation. Furthermore, removing this key element of a sterility assurance program lowers the vigilance and assurance level of the overall program.

What is the test procedure and how often should you do it?

AAMI (The Association for the Advancement of Medical Instrumentation) indicates that a Bowie-Dick test be performed every day that the prevacuum steam sterilizer is in operation.³ In addition, three consecutive Bowie-Dick tests must show a "pass" before a steam sterilizer is put back into use after installation or major repair. The standard describes a test pack consisting of several towels stacked one upon another. In the center of the stack, a large indicator sheet is placed. The stack is then secured within a 2-ply cotton sheet. To test, the

See SELF-STUDY SERIES on page 52

Answers	1. B
	2. D
	3. B
	4. A
	5. E
	6. B
	7. D
	8. A
	9. C
	10. E

SELF-STUDY SERIES from page 51

pack is placed on the bottom shelf over the drain. A prevacuum cycle with a 3½ - 4-minute exposure time is run. When the cycle is complete the indicator sheet is removed and evaluated for a failure to contact steam. Many commercially available air removal tests exist that can be used in place of a user-constructed pack. AAMI provides guidance to manufacturers and users regarding test pack performance in ANSI/AAMI/ISO 11140-1⁴ and ANSI/AAMI ST66⁵.

How do you select an air removal test from all the available products?

AAMI has prescribed minimum criteria for performance, but air removal tests are not all equal. It is important to review all of the technical data and the FDA clearance status, and to evaluate the pack's design features. When evaluating air removal tests, there are five key design features to assess:

1. Density refers to the actual compactness of the pack materials. The literal definition of density is the mass to volume ratio. Normally, during the exposure time, air and other NCG will diffuse out of items and mix with the steam in the chamber. A denser pack will retard this diffusion, keeping the air pocket in place over the indicator ink within the pack. This provides better detection of residual air. When comparing test packs, it is important to look for a pack made from dense materials.

2. Insulation refers to the ability of a material to retard heat. Something that has good isolative properties takes a long time to heat up. In addition, it will prevent the premature heating of the interior of the test pack by convection rather than by steam condensation.

3. Mass refers to the weight of the test pack. The more mass a pack has, the more material to heat up and the more steam required. Higher mass test packs will attract more steam, thereby increasing the ability to detect non-condensable gas.

4. Indicator ink specificity relates to the chemical reaction. The purpose of the test pack is to detect the presence of residual air. The indicator ink must be able to tell the difference between heated air and steam. An ink should require the presence of steam to change to its final color.

By combining these characteristics, test packs can be designed to mimic the performance of the traditional AAMI Bowie-Dick Test Pack. However, the performance among test packs can vary greatly. The AAMI Bowie-Dick Test Pack sets the bar of minimum performance characteristics. The variety of

commercially available test packs can be equivalent to or better than the AAMI Bowie-Dick Test Pack.

To compare test packs, facilities can measure the *leak rate level*. The leak rate test mimics residual air introduced by a leak into the chamber during the vacuum pulses. Test packs are placed in the chamber and a leak is induced. The leak rate level is the rate at which air enters the chamber during the preconditioning phase of the test and causes the test pack to show a failing result (leak). It is often expressed as mm Hg/minute.

For proper comparison, all test packs need to be individually tested in the same sterilizer using the same test conditions. Factors such as position of the test pack within the chamber, chamber size, and location of the air leak will affect the results. To control for these variables, AAMI published ANSI/AAMI ST66. This document describes the standard test methods and test apparatus. In this test, the test methods are controlled so that they cannot bias the test.

Conclusion

The daily air removal test (Bowie-Dick Test) may have started as a means to evaluate steam sterilizers for leaks, but has evolved into a more comprehensive test for all sources of residual air. The test is still the most accurate means to determine steam penetration efficacy, and is a very important piece of any sterility assurance program. It must be performed regularly to ensure that the steam sterilizer can effectively remove air, and that the steam supply is also free of NCG that could affect the sterilization process. Only by evaluating the five key design features of a Bowie-Dick Test Pack can the most effective air removal test pack be selected. Ultimately, the user must decide how important each feature is to their facility and its sterility assurance program. **HPN**

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2. ANSI/AAMI ST66:1999 Sterilization of health care products – chemical indicators – Part 2: Class 2 indicators for air removal test sheets and packs
3. ANSI/AAMI ST46:2002 Steam sterilization and sterility assurance in healthcare facilities
4. ISO 11140-1 Sterilization of health care products- Part 1: General Requirements
5. Sterilization of health care products – Chemical Indicators – Part 2: Class 2 indicators for air removal test sheets and packs

Correction to the July CE Test

In HPN's July 2006 CE test, "The role of skin science in assuring hand hygiene compliance," on page 37, **transepidermal water loss** should be designated as **TEWL**. See www.hponline.com, July 2006, for the revised version.

CONTINUING EDUCATION TEST — September 2006

Bowie-Dick testing, then and now

Circle the one correct answer

- 1) Dr. J. Bowie and Mr. J. Dick developed the Bowie-Dick Test to evaluate the air removal properties of gravity steam sterilization cycles.
 - a. True
 - b. False
- 2) Residual non-condensable gases _____.
 - a. Shield bacteria from the steam
 - b. Take longer to heat an item
 - c. Enter through the steam supply or from the chamber
 - d. All of the above
 - e. None of the above
- 3) Residual non-condensable gases only come from the steam supply.
 - a. True
 - b. False
- 4) Items _____ attract more steam and thereby can be more affected by non-condensable gas in the steam supply.
 - a. With high mass
 - b. With small lumens
 - c. In an open tray
 - d. That heat quickly
- 5) An air removal test pack (Bowie-Dick test pack) must be able to ...
 - a. Detect residual air
 - b. Detect non-condensable gas in the steam
 - c. React to steam but not hot gases
 - d. A and B only
 - e. All of the above
 - f. None of the above
- 6) Density is critical because it _____.
 - a. Attracts more steam
 - b. Slows the diffusion of air out of the pack
 - c. Allows the steam to penetrate the pack faster
 - d. None of the above
- 7) Which characteristic of an air removal test ensures that only steam will heat the interior of the pack?
 - a. Porosity
 - b. Density
 - c. Indicator ink specificity
 - d. Insulation
- 8) The size of the sterilizer chamber, position of the test pack and location of the air leak can impact the ability of the air removal test to detect residual air.
 - a. True
 - b. False
- 9) The leak rate test mimics _____.
 - a. A faulty vacuum pump
 - b. Non-condensable gases being brought in with the steam supply
 - c. Residual air leaking into the chamber during the vacuum pulses
- 10) When comparing test pack performance it is important to ...
 - a. Talk to the sales person
 - b. Evaluate the porosity, density, mass, insulation and indicator ink specificity
 - c. Obtain the 510(k) number
 - d. A and B only
 - e. B and C only
 - f. All of the above

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