

June 2006

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Learning objectives

1. Know the What, Why, When, Where and How Bowie-Dick testing is performed and interpretation of test results.
2. List the three reasons for using a "Control" Biological Indicator.
3. Describe how to monitor extended steam sterilization cycles using biological and chemical indicators.
4. Describe some potential causes for sterilization process failures and where to begin investigating.

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SELF-STUDY Series

Important questions about steam sterilization monitoring

by Dorothy Larson, CSPDT

Each day I speak with many people at various levels and in many different functions within hospitals, surgery centers and office-based facilities. However large or small a facility may be, the questions and issues being raised tend to be similar in nature. The purpose of this article is to share some of the important questions and concerns raised by you, the users of sterilization monitoring products!

The Bowie-Dick Test

What

Let's start with a review of Bowie-Dick testing, which is a common topic for discussion, and sometimes I hear that interpretation of the results can be tricky! First, what is a Bowie-Dick test, why do you use and how is it used?

The Bowie-Dick test is used daily to evaluate the efficacy of air removal and/or detect air leaks in dynamic-air-removal steam sterilizers also called pre-vacuum or vacuum-assisted sterilizers. The Bowie-Dick test does not determine if the parameters of sterilization have been met; it only assesses the efficiency of the air removal system (in most sterilizers this is the vacuum pump) and the presence of air leaks and/or gases in the steam.^{1,2}

Why

If the Bowie-Dick test is not a sterility assurance test then why use it at all? Because effective air removal is critical for predictable steam penetration and effective sterilization. Steam and air do not easily mix. Therefore, if air is not removed from the chamber, the sterilizing conditions may not be attained. Steam is the sterilant and steam needs to contact the surfaces of each instrument and item inside every pack and tray within a load. Insufficient air removal and/or leaks can defeat proper sterilization and result in a large volume of nonsterile supplies if this condition is undetected.

When

The Bowie-Dick test is run every day before the first processed load. (However, a warm-up cycle should be run first to properly heat the sterilizer and flush the steam lines.)¹ The time required to run the BD cycle may be shortened by omitting the drying phase.

The Bowie-Dick test should also be carried out during initial sterilizer installation and af-

ter relocation, sterilizer malfunction, sterilization process failures and major repairs of the steam sterilizer. For this testing three consecutive empty cycles are run, each containing one Bowie-Dick test pack.¹

Where and How

The test pack should be placed horizontally in the front, bottom section of the sterilizer rack near the door and over the drain in an otherwise empty chamber.¹ (Note: Do not place the Bowie-Dick test pack directly on the floor of a chamber or on anything other than the sterilizer shelf or cart itself.) The Bowie-Dick test pack should be the only item in the sterilizer! Anything else in the chamber could entrain a certain percentage of air and interfere with the ability of the Bowie-Dick test pack to detect that air. A cycle is run as specified by the sterilizer manufacturer. The recommended exposure time is 3.5 minutes and the exposure time should never exceed 4 minutes at 273°F (134°C).¹ Specific instructions of the sterilizer and/or indicator manufacturer should be followed.¹

Sometimes interpreting the test results can be tricky! To keep things simple let's picture it like this: If at the end of the cycle there is any remaining air in the chamber, that air will be forced by the steam into the center of the Bowie-Dick test pack. The presence of air in the Bowie-Dick test pack will affect the color change of the chemical indicator test sheet. If there is a non-uniform color change, such as the center of the test sheet being paler or a different color than the edges, that is an indication that an air pocket was present during the cycle due to a sterilizer malfunction or steam quality problem.¹

Now might be a good time to review your sterilizer(s) to see if you should be running a Bowie-Dick type test and to verify that the test is being performed properly.

Biological Indicator Controls

The question about using Biological Indicator (BI) controls is also common. Biological Indicators are intended to demonstrate whether the conditions were adequate to achieve sterilization.¹ A "control" is a BI that has not been exposed to the sterilant; therefore, the control BI is not processed in the sterilizer. The "test"

BI on the other hand is processed in the sterilizer and is exposed to the sterilant.

It may be worthwhile to state reasons for using a control and the benefits from its use as the control provides a good quality assurance check. "Each day that a test BI is incubated, at least one BI that is from the same lot and has not been exposed to the sterilant should be incubated as a control to verify the presterilization viability of the test spores, the ability of the media to promote growth of the test spores, and the proper incubation temperature."¹

If the spores in the control were not able to grow or be detected, there are several possible reasons why, including:

- improper storage conditions
- exposure to chemical vapors (i.e., during shipping or storage)
- incubation at wrong temperature
- a problem with the recovery media, or
- improper handling of the BI by user (i.e., not crushing a BI prior to placing in incubation well)

Without the use of a control BI you would not be aware of any of these problems with the biological indicator system that is being used. Consequently, you would assume that a negative test BI result demonstrated the sterilization process destroyed the spores when actually it may have been due to one of the reasons listed above.

If the control BI from a lot fails to grow, it should be assumed that the test BIs from that lot are either not viable or that faulty incubation and detection occurred. The results from the test BIs then would need to be considered invalid and that test repeated.¹ Only one control BI from a lot needs to be used per day in each incubator.

Using a control BI every day that you incubate a test BI gives assurance that the BI and the incubation system are doing the job that they are intended to do which provides you with an effective quality assurance check for your BI monitoring system.

Do the Biological and Chemical Indicators on the market today effectively test extended sterilization cycles?

Another common question is about using Biological Indicators (BIs) and Chemical Indicators (CIs) to monitor extended cycles. BIs and CIs available today are generally designed to test minimum sterilization cycle parameters recommended by the sterilizer manufacturer. Due to the many various cycle parameters that are being specified by medical device manufacturers today, it would be nearly impossible

to make BI and CI process challenge devices to monitor every different cycle. For items requiring extended sterilization cycles, in addition to the use of BIs and CIs, physical monitors, such as the computer generated sterilizer printouts for each cycle, should be reviewed carefully to ensure that (a) the correct cycle was selected for the items that were processed and (b) that the correct parameters for time, temperature and pressure were met.

To learn more information about each set or tray and how it performs within your sterilizer, first determine the appropriate extended cycle parameters based on manufacturer's written instructions for use for that specific set or tray. To verify that you can effectively process each set or tray in your facility, perform product testing.¹ Place BIs and CIs in the most challenging areas within each set or tray, run the cycle, and record both the sterilization parameters that were used and the BI and CI monitoring results.

By paying particular attention to the cycle setting that is selected on the sterilizer for the item(s) being processed and by performing testing of each set or tray with the use of BIs and CIs you will have a high level of assurance of having achieved sterility.

I have a Positive Biological Indicator yet all other parameters show good results.

You have a positive BI yet all the other parameters, including the sterilizer computer printout, look good – so what is the problem? Most likely the BI is doing the job it is supposed to do which is to alert you when there has been a sterilization process failure.⁴ This is a good thing because it alerts you to items that have been processed which may not be sterile – before they are used on patients!

There are many things to consider and to potentially investigate when you have a positive BI. This can be overwhelming so above all else remain calm. First, verify that all the other parameters of the sterilization cycle were met. Then, consider such things as incorrect packaging for the chosen cycle, the sterilizer being overloaded, steam quality issues, non-condensable gases from the boiler additives, building construction creating steam supply interruptions, inadequate water pressure.^{3,5} Remember that there usually is a very good reason as to why you have a positive BI and that is why you are using sterilization monitoring products. It's nice to know that everything is working fine but you also need to know when something is not working properly so that any potential problems can be corrected before they escalate into bigger issues.

Sometimes there can be very simple solutions, such as a rigid container valve not being properly loosened and tightened prior to it being used. Or maybe a sterilizer gasket or valve needs replacing. Or perhaps the wrong cycle was selected or the cycle wasn't even run at all! Whatever the problem may be, it is important to first acknowledge that the sterilization process failure is real and then take the appropriate action to resolve the situation.

Summary

Become more familiar with your sterilization procedures and processes and challenge these procedures and processes by asking questions to continue to learn more about your equipment and all the factors that can affect a successful sterilization process. Not only will you become a more valuable resource within your facility but you will also have the confidence and assurance of providing every patient with the best possible care. After all, this is what every person deserves!

So please keep those important questions coming. We all know that one of the best ways to learn is to ask. Learning the most that we can about our jobs will help us to do our part in providing the best patient care possible – which is why we do what we do. **HPN**

About the Author:

Dorothy Larson, senior technologist in 3M Medical Products, St. Paul, MN, is the voice on the end of the 1-800-441-1922 3M Health Care Tech Line for Sterilization products (option '2'). Ms. Larson spends her day solving sterilization process failures, answering technical questions, and providing technical information and documentation as requested. She has been working in this role for 9 years, and is a certified Sterile Processing and Distribution Technician. She is also a member of ASHCSP and IAHCSP.

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ANSWER
1. B 2. A 3. A 4. B 5. B 6. A 7. B 8. A 9. B 10. A

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CONTINUING EDUCATION TEST — June 2006

Important questions about steam sterilization monitoring

Circle the one correct answer

1. When running the daily Bowie-Dick test, the Bowie-Dick test pack is not the only item run in the load.
 - a. True
 - b. False
2. The Bowie-Dick test assesses the efficiency of the vacuum system and the presence of air leaks and/or gases in the steam.
 - a. True
 - b. False
3. The Biological Indicator control is a good test to ensure that the biological indicators and incubator are working properly.
 - a. True
 - b. False
4. The Biological Indicator control is the biological indicator that is exposed to the sterilant.
 - a. True
 - b. False
5. When running extended cycles, do not check with the manufacturer's written instructions for use when choosing appropriate sterilization parameters.
 - a. True
 - b. False
6. When running a Bowie-Dick test pack, always place horizontally in the front, bottom section of sterilizer rack, near the door and over the drain, in an otherwise empty chamber.
 - a. True
 - b. False
7. You had a positive biological indicator, but because all other sterilization parameters were met, there is no need to investigate the cause of the positive any further.
 - a. True
 - b. False
8. For items requiring extended sterilization times, place biological and chemical indicators in the most challenging areas within each set or tray, and record the sterilization parameters and the BI and CI monitoring results to verify effective sterilization before placing items into routine use.
 - a. True
 - b. False
9. For items requiring extended sterilization cycles, computer generated sterilizer printouts do not need to be reviewed to ensure the correct cycle was selected and that the correct parameters for time, temperature and pressure were met.
 - a. True
 - b. False
10. If the control BI from a lot fails to grow, it should be assumed that the test BIs from that lot are either not viable or that faulty incubation and detection occurred.
 - a. True
 - b. False

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June 2006

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