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LEARNING OBJECTIVES

1. *Examine the science behind and the information provided by BIs.*
2. *Review current recommended practices for the use of BIs.*
3. *Discuss positive BI troubleshooting success stories.*

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SELF-STUDY SERIES

Sterile processing mysteries:

The story of the positive BI

by Craig Wallace

Has this happened in your sterile processing department? It's a busy day, lots of surgeries scheduled, the department is humming and everything's great until . . . you get a positive BI (BI) in one of your sterilizers. Why is it positive? What does it mean? BIs are complex devices that measure the lethality (killing power) of the sterilization process. If the BI is positive, there was a problem in the cycle. Today, we'll take a closer look at how BIs work, and how you should use them to make sure your sterilization processes are working correctly. We'll finish with some stories about real-life BI positives and how the sterile processing team solved these sterile processing mysteries.

BI basics

International standards define a BI as a "test system containing viable microorganisms providing a defined resistance to a specified sterilization process"[1] The key part of this definition are the words "viable microorganisms." BIs contain a large number of viable (living) microorganisms. The microorganisms used in BIs are bacterial spores. A few kinds of bacteria can change themselves into spores as a sort of self-preservation tool, to allow the bacteria to survive when conditions are toxic or not favorable for growth. Spores are like hard, dry seeds that are biologically dormant, and they are very stable and hard to kill. BIscontain a large number of these highly resistant spores to create a significant challenge for the sterilization process.

BIs used in healthcare today are called self-contained BIs (SCBIs). Self-contained means that all the components required for the BI test are held within the indicator so there is no need for a microbiology lab to read the results. The basic components of a typical SCBI are shown in Figure 1.

BIs require incubation, which means exposure to heat over a defined period of time. During incubation, any surviving spores turn back into regular bacterial cells, and then start to grow. You incubate a BI to find out if the sterilization process operated correctly and all the spores are dead, or if there was a sterilization process failure and some of the spores survived. But how can you tell if any spores survived or not? You need a signal from the BI that tells you what is happening.

Manufacturers design their BIs to produce a signal that you can easily recognize to indicate if the BI is positive or negative. The simplest design has a pH indicator in the growth medium that will change color if bacteria are growing (positive BI). Today's rapid readout BIs leverage early biochemical activity from surviving spores coupled with specialized fluorescent indicators in the growth medium to produce a fluorescence. This fluorescence is measured by an incubator/reader device that then indicates a positive or negative BI result on the reader.

A simple explanation of the value of BIs and the basic assumption for BI testing is clearly stated by the Centers for Disease Control and Prevention (CDC) in their Guideline for Disinfection and Sterilization in Health Care Facilities: "BIsare recognized by most authorities as being closest to the ideal monitors of the sterilization process because they measure the sterilization process directly by using the most resistant microorganisms (i.e., *Bacillus* spores), and not by merely testing the physical and chemical conditions necessary for sterilization. Since the *Bacillus* spores used in BIs are more resistant and present in greater numbers than the common microbial contaminants found on patient-care equipment, the demonstration that the

Figure 1 – Self-contained BI Photo courtesy: 3M

BI has been inactivated strongly implies that other potential pathogens in the load have been killed."[2] So, sterilization processes are intended to kill microorganisms, and BIs are the only monitoring device that directly measures the success of the process.

While the large numbers of highly resistant spores do present a significant challenge to the sterilization process, it is important to remember that the sterilization cycles validated by the sterilizer manufacturers and cleared by the Food and Drug Administration (FDA) are required to be very robust with a significant amount of overkill, or safety factor, built into the cycle. Sterilization processes that are operating correctly have enough overkill to easily inactivate all BIs. If a BI is positive, it means something went wrong in the process resulting in the sterilization process failure.

So, how do you know if the BI is creating the correct challenge to the process? BI performance requirements for most sterilization processes are defined in international standards.[3] Compliance with these standards should be noted on the BI's instructions for use (IFU) or quality certificates. In addition, regulators like the FDA will require BI manufacturers to define and control the challenge presented by their BIs, especially for processes not covered by the international standards [e.g., vaporized hydrogen peroxide (VH_2O_2)].

Recommended practices for use of BIs

Steam and vaporized hydrogen peroxide (VH_2O_2) are the most common sterilization processes used in healthcare facilities today. The Association for the Advancement of Medical Instrumentation (AAMI) publishes standards that specify best practices for all aspects of medical device reprocessing using these sterilization methods. These practice standards are AAMI ST79[4] for steam and AAMI ST58[5] for VH_2O_2 sterilization. We will review the BI monitoring recommendations from these standards in a moment. But first, we'll take a minute to review a couple of terms used in the recommendations.

Process challenge devices (PCDs)

In an ideal world, BIs would be placed inside of packs next to the instruments, so they could measure the lethality of the process precisely where the instruments are located. This, of course, is impossible from both a logistics and a cost standpoint. Instead, BIs are placed inside of PCDs. The intent of the PCD is to create a physical barrier that will slow down access of the sterilant to the BI, as if the BI were inside a pack. PCDs are easily retrieved by the sterile processing team and the BI testing can be started immediately.

Implant loads

Improperly sterilized implantable devices can present a greater risk of infection than other devices that are only in contact with the patient for short periods of time during the surgical procedure. For this reason, recommended practices specify more frequent use of BIs (for a higher level of quality control) for sterilization loads that contain implants than for loads that do not contain implants.

Steam sterilization - practices for using BIs for load release

Best practices for sterilization quality control recommend using physical monitoring, chemical indicators, and BIs and consolidating the information from all three to help decide if the sterilization process was successful and the instruments are safe for patient use. Table 1 reviews the recommended testing plan for load release for steam sterilization:

Table 1 – Load release testing – steam sterilization

	Loads containing implants	Loads without implants
Physical monitoring	Every cycle	Every cycle
External (process) CI	On the outside of every package	On the outside of every package
Internal (pack) CI	Inside every package	Inside every package
PCD Testing	PCD with BI and Type 5 CI: In every load	Optional use: PCD with BI, BI + Type 5 CI, Type 5 CI, or Type 6 CI

Reference: ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities.*2017.

The BI testing recommendation for loads containing implants is to test every cycle with a PCD containing a BI and a Type 5 chemical integrator. This is considered the highest level of quality control as every cycle is tested with a BI, and the Type 5 chemical integrator is present as an option for immediate release of the instruments if there is an emergency (the BI result must still be obtained, however). Testing recommendations for loads without implants are not as rigorous as those for implant loads, with optional use of a PCD that may or may not contain a BI. Many healthcare facilities have chosen to monitor all steam loads (with and without implants) with a BI PCD to achieve a uniform standard of care, to reduce the costs of a recall, and to reduce monitoring errors.

VH_2O_2 sterilization - practices for using BIs for load release

VH_2O_2 sterilization processes are more complex than steam sterilization processes, but the quality control testing recommendations are similar. Table 2 reviews the recommended testing plan for load release for VH_2O_2 sterilization:

Table 2 – Load release testing – vaporized hydrogen peroxide sterilization

	Loads containing implants	Loads without implants
Physical monitoring	Every cycle	Every cycle
External (process) CI	On the outside of every package	On the outside of every package
Internal (pack) CI	Inside every package	Inside every package
PCD (load challenge)	BI/PCD in every load	BI/PCD daily, preferably every load

Reference: ANSI/AAMI ST58, *Chemical sterilization and high-level disinfection in healthcare facilities.* 2013.

The recommendations for VH_2O_2 testing also differentiate between implant and non-implant loads. However, there is no Type 5 chemical integrator requirement for VH_2O_2, as Type 5 integrators are not defined for VH_2O_2 sterilization. Again, many healthcare facilities test every VH_2O_2 load with a BI.

Positive BIs – sterile processing mysteries

A positive BI means there has been a sterilization process failure. Facility policies and procedures should specify all of the actions

Self-Study Test Answers: 1. B, 2. A, 3. A, 4. B, 5. A, 6. A, 7. B, 8. A, 9. B, 10. A

Page 34

to be taken in these situations, but an investigation into the cause of the failure will always be required. Where do you start? AAMI ST79 provides excellent guidance on how to conduct an investigation (see Figure 10 and Table 4 in the 2017 edition)[4]. While this information is specific to steam sterilization process failures, the principles can be applied to VH_2O_2 sterilization failure investigations as well.

Now let's hear about a couple of real-life positive BI mysteries, and how they were solved . . .

Story 1: BI positives in steam sterilization

This story starts with a hospital's call to a BI manufacturer's technical support team reporting a single positive BI from one of their four sterilizers. Their SPD is very busy with all four sterilizers running multiple cycles each day, and they only experienced this single positive BI. Their facility monitors every steam load with a BI/PCD. The hospital reported that the cycle printout from the failed process looked fine, and all the chemical indicators in the load showed 'pass' results. They had called their sterilizer sales representative to ask for help, but the sales rep simply referred them to the BI manufacturer, suggesting that perhaps this was a defective BI.

The BI manufacturer's technical team reviewed some history. This hospital had experienced several positive BIs from multiple sterilizers two years earlier that had been traced to poor steam quality supplied to the department. The hospital had invested in a dedicated steam supply for the sterilizers, which solved the problem. The tech team confirmed that the BI was not defective and felt the BI had detected a problem with that cycle, but it was not possible at that point to determine the exact cause of the failure.

A couple of weeks passed, and the hospital called again. They were now getting more positive BIs from the same sterilizer. The BI manufacturer suggested that the hospital request a service call by the sterilizer manufacturer. During the service visit, the service representative noted that this sterilizer was due for maintenance, and he had also seen signs of minor cracks in the door gasket during an earlier visit. He replaced the door gasket, and the positive BI problem was solved.

What are some of the learnings here? Steam quality is the most common cause of steam sterilization process failures, and BIs are uniquely able to detect these problems. Steam quality problems can start slowly and produce intermittent failures, making it appear that the BI is inconsistent instead of the process itself. In this case, the fact that only one of four sterilizers had a problem meant that the steam supply was not the root cause. The sterilizer with the positives did, however, had a maintenance issue specific to that one sterilizer. The faulty door gasket allowed air into the chamber, compromising the steam quality inside the chamber, resulting in positive BIs. Finally, every load monitoring provided more data and made it much easier to understand and define the scope of the problem. Now, let's move on to a VH_2O_2 story.

Story 2: BI positives in VH_2O_2 sterilization

This time the call to the BI manufacturer's technical support team was about intermittent BI positives in a hospital's ASP STERRAD 100NX sterilizer. This sterilizer can run four different sterilization cycles (Standard, EXPRESS, Flex, and DUO), however, the positive BIs only occurred in DUO cycles. The BI tech support team traveled to the hospital to work with the sterile processing team on the investigation.

Maintenance records showed that the preventive maintenance work was current and there were no other reported issues with the sterilizer. The investigation then focused on the cycle records for the DUO cycles, including load records and cycle printouts. The cycle printouts and chemical indicators did not show any evidence of a problem in the failed cycles. It became evident, however, that the positive BIs were always associated with a particular load consisting of two cystoscopes in large trays containing silicone mats and wrapped with heavy duty disposable wrap. The total weight of this load was 14.8 lbs.

After considering this information, a decision was made to reduce the load weight by only processing 1 cystoscope at a time. The manufacturer's maximum load for the DUO cycle was 13.2 lbs. so this change brought the load weight into alignment with the sterilizer and tray IFU. The silicone mats were also removed, as they were not part of the IFU. No additional BI positives occurred after these changes were implemented.

BIs once again demonstrated that they are the best method for detecting problems with the quantity or quality of the sterilant. Hydrogen peroxide is a very unstable and reactive chemical, so it is prone to situations, such as condensation, absorption, or chemical breakdown, that can reduce its concentration in the chamber - therefore reducing the killing power of the sterilization process. In this case, the oversized load likely absorbed, and possibly condensed, too much hydrogen peroxide during the process. It is also likely that the tray liner mats were absorbing hydrogen peroxide. The net result was too little VH_2O_2 remaining in the process, which was detected by the BIs. It is also worth noting that it is extremely important to read and follow all manufacturers' IFU associated with VH_2O_2 sterilization to help prevent sterilization process failures.

Summary

BIs are the only indicators that contain viable microorganisms and directly measure the effectiveness of the sterilization process. They are intended to be used with physical monitors and chemical indicators as part of a comprehensive sterilization quality control testing program. A positive BI is evidence that a sterilization process failure has occurred. These failures should be carefully investigated to determine the root cause and correct the problem. HPN

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3. International Organization for Standardization. Sterilization of healthcare products — BIs. . ISO 11138 Parts 1-5:2017. Geneva, Switzerland. ISO, 2017

4. ANSI/AAMI ST79, Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities. Association for the Advancement of Medical Instrumentation. 2017.

5. ANSI/AAMI ST58, Chemical sterilization and high-level disinfection in healthcare facilities. Association for the Advancement of Medical Instrumentation. 2013.

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CONTINUING EDUCATION TEST • APRIL 2021

Sterile processing mysteries: The story of the positive BI

Circle the one correct answer:

1. **Bacterial spores are growing cells and are quite easy to kill.**
   A. True
   B. False
2. **BI (BIs) provide the only direct measurement of the effectiveness of the sterilization process.**
   A. True
   B. False
3. **BIs signals can include a color change or a fluorescent response.**
   A. True
   B. False
4. **Self-contained BIs require a microbiology lab to complete the test.**
   A. True
   B. False
5. **Process-challenge devices are intended to imitate the effects of the packaging and load.**
   A. True
   B. False
6. **BI incubation is necessary to allow time for the organism's biological processes to occur.**
   A. True
   B. False
7. **BIs inside PCDs are not required for every sterilizer load containing an implant.**
   A. True
   B. False
8. **Standards recommend the use of physical monitors, chemical indicators, and BIs for sterilization quality control.**
   A. True
   B. False
9. **Air entering a steam sterilizer is helpful and can never cause a sterilization process failure.**
   A. True
   B. False
10. **Improper loading can affect the concentration of vaporized hydrogen peroxide and cause a sterilization process failure.**
    A. True
    B. False

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