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The Science of Speed

How those rapid readout BIs actually work

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LEARNING OBJECTIVES

1. *Review how biological indicators work.*
2. *Understand how rapid readout biological indicators work.*
3. *Discuss the recommended practices for use of biological indicators.*

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Biological indicators (BIs) are an important part of a quality control system for hospital sterilization processes. The information on the quality of the sterilization process supplied by biological indicators, when combined with the information from physical monitors and chemical indicators, provides the basis for the decision on whether or not to release the medical devices for use on patients.

Biological indicator basics

Biological indicators are defined as a test system containing viable microorganisms that provide a defined resistance to a specified sterilization process[1]. The key part of this definition is "viable microorganisms," as biological indicators are the only sterilization monitoring device that directly tests the effect of the sterilization process on microorganisms.

The primary biological indicator design used in health care facilities is the self-contained biological indicator, or SCBI. (SEE FIGURE 1) Self-contained biological indicators contain the critical elements of a biological indicator: the bacterial spores on a carrier, and the growth media required to culture the test organisms to determine if the BI is positive or negative. The self-contained design eliminates the need for a microbiological laboratory to complete the BI test.

To better understand biological indicators, we need to take a minute and review a little bit of basic microbiology. The term "spores" is short for bacterial endospores. There are a few types of bacteria that have developed the ability to change from an active, growing cell (or vegetative cell) to a highly protected, dormant cell (endospore), and back again depending on their environment. These bacteria will change to a spore when faced with a shortage of food or other conditions that are harmful to the cell. The spore itself is like a plant seed or hard nut – it is biologically dormant (or "sleeping"), it has a highly protective dry shell, and it is capable of withstanding extreme conditions for prolonged periods of time without ill effect. If the spore senses that conditions have improved and will support life, it goes through a series of biological steps called activation and germination, to shed the hard coat and become a regular, active bacterial cell once again.(SEE FIGURE 2). Biological indicators use the spore form of *Bacillus* bacteria because of the toughness of these spores and the challenge they present to the sterilization process. Each sterilization process requires a specific *Bacillus* species proven to be the most resistant to that process.

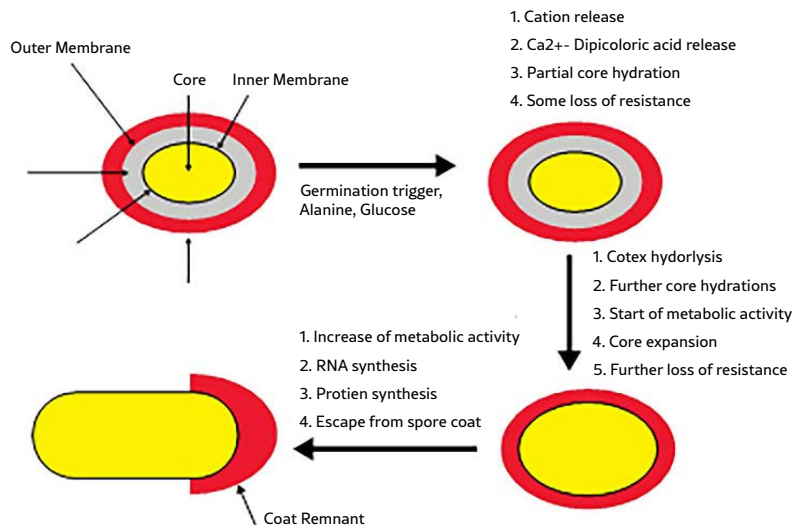
Spores require a source of nutrients and optimized temperature and pH to begin the activation, germination, and outgrowth processes. Self-contained biological indicators contain growth media that has been optimized to support outgrowth of the spores used in that BI. All biological indicators require incubation, during which the spores are exposed to the growth media and the biological indicator is heated to the optimum temperature for spore outgrowth. Any surviving spores will first activate and germinate to become vegetative cells, and then these cells will begin to "grow," which means they will replicate (one becomes two, two become four, and so on). (SEE FIGURE 3)

Incubation time

The incubation time for a biological indicator is the amount of time that the BI must be incubated before a decision can be made that the BI is negative (i.e., the spores are all dead) and the test is complete. This concept takes a little more explanation . . . if a biological indicator turns positive, it has completed its "task" of providing information on the quality of the biological indicator system (in the case of a positive control) or of the

FIGURE 1 – Components of a self-contained rapid readout biological indicator.
Photo courtesy of 3M.

FIGURE 2 – Activation and germination of a bacterial spore



sterilization process itself (a positive test BI indicates a sterilization process failure). If a biological indicator turns positive you will end the BI test at that point and take appropriate action. But how long must you incubate a BI before you can decide that it is truly negative and end the test? This time frame is called the incubation time.

The international biological indicator performance standards state that the reference incubation time for a biological indicator is 7 days.[2] This incubation time was established in the early days of biological indicators and was based on the technology available at that time. An incubation period of seven days is not at all practical or useful in today's healthcare environment. So, for biological indicators, there was a need for speed.

Biological indicator signals

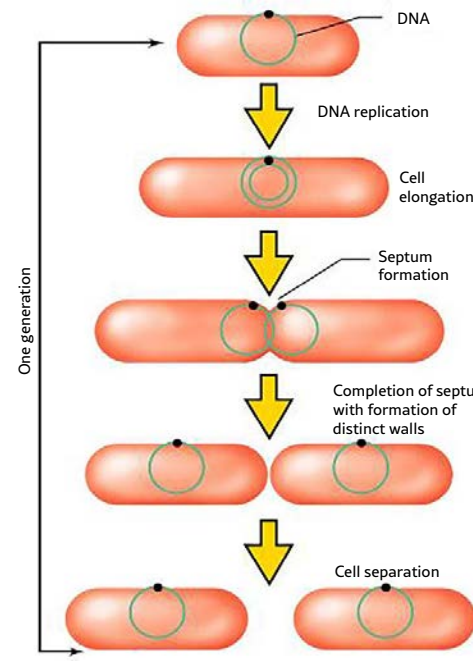
A biological indicator must produce a "signal" that it is positive or negative. This signal must be easily interpreted by the end user. Early BI spore strips used media "cloudiness" (turbidity) as a signal, but this was hard to interpret. A better signal was developed - a distinct color change in the growth media. The new SCBI designs put a color-based pH indicator into the growth media. A pH indicator is a chemical that responds to the acidity of the medium and will typically be one color at an alkaline pH and change to another color as the medium becomes more acidic. Biological indicators utilizing the pH color change system have growth media that is specially formulated so that bacteria growing in the medium will produce acidic by-products. As the bacteria grow continue to grow, the growth medium will continue to become more acidic until the pH indicator changes color. This technology was introduced in the 1970s. The optimization of the growth media and the improved color change signal reduced the incubation time from 7 days to 2-3 days. This was much faster and easier than spore strips, but still required incubation times that were not optimal for health care.

The next major leap in reduction of biological indicator incubation time came from new technology that enabled detection of biological signals from viable spores much earlier in their germination and outgrowth process. To understand this, we need to understand a little more microbiology. The spore activation and germination processes may sound simple, but they are complicated, multi-step processes.(SEE FIGURE 2) A good analogy is the steps that occur when a computer powers up. Once the power button is pushed the computer goes through a series of actions that turn on many programs and sub-systems in the computer in a specific order, until the computer is fully operational and ready for use. In the spore, the cell's "sub-systems" are created and activated by many biochemical reactions. Specialized proteins called enzymes act as catalysts that make these complicated reactions happen much more quickly. The first rapid readout biological indicators used the actions of some of these "boot up" enzymes to produce a signal that could be detected earlier in the spore outgrowth process, reducing the required BI incubation time from days to hours.

The enzymes used to produce a signal for rapid readout biological indicators are enzymes that become active early in the spore's activation and germination processes. Rapid readout biological indicator technology uses a special indicator in the growth medium that can interact with the enzyme. This chemical is like the pH indicator discussed earlier, except that instead of turning color based on a change in acidity this indicator changes from a non-fluorescent molecule to a fluorescent molecule when it is acted on by the enzyme. Fluorescence means that it will "glow" or emit light at a certain wavelength (say, Wavelength B), if it is first exposed to light of a different wavelength (Wavelength A). So, rapid readout BIs use a biological indicator reader that shines Wavelength A light onto the incubating biological indicators and has a detector that is sensitive to Wavelength B light and looks for a fluorescent signal. If the enzyme is active in the biological indicator (i.e., a positive control BI or a positive BI from a sterilization process failure), the sensors will detect the fluorescent signal and the reader analyzes this signal and indicates a positive BI result.

Rapid readout biological indicator technology has reduced incubation times from days to hours. Continued improvements of the physical design of these biological indicators concentrated the fluorescent signal to make it easier to detect. These changes, coupled with improved sensors and electronics in the readers, have now reduced biological indicator incubation times to less than 30 minutes. This dramatic improvement in incubation time, from 7 days to less than 30 minutes, means that this important quality control information regarding the efficacy of the sterilization process is now available in a timeframe that fits with the healthcare facilities' workflow.

FIGURE 3 – Bacterial growth



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

Quality control of sterilization processes

You can't see sterility. This basic fact drives the need for a quality control system that provides information on the quality of a sterilization process, so a decision can be made on whether or not the processed instruments are safe for patient use. The American National Standards for the key health care sterilization processes: steam, ethylene oxide, and vaporized hydrogen peroxide, all recommend the integrated use of three quality control monitoring tools: physical monitors, chemical indicators, and biological indicators.[3,4,5] The information provided by each tool is different. Physical monitors are electronic sensors inside the chamber that provide data on the environment inside the sterilizer chamber such as the temperature or pressure. This data is recorded on a printout that can also be used as a record of the cycle. Review of cycle printouts from the physical monitors can confirm that the proper cycle was selected. The second quality control tool, chemical indicators, utilize specially selected chemicals that respond to the effects of the sterilization process. Chemical indicators that are used on the outside of packages (Type 1 process indicators) can provide visual evidence that an item has gone through the sterilizer. Remember that process indicators are only designed to indicate exposure to the sterilant, and they *do not* provide evidence that the process was effective. The more sophisticated chemical indicators (Type 5 and Type 6 indicators) that are used inside of containers and packages are designed to respond to all the sterilization process variables. These chemical indicators provide more detailed information on whether the required process conditions were achieved inside of the packages.

The third quality control tool, biological indicators, are used to directly measure the effectiveness of the sterilization process by measuring its effect on live microorganisms. Let's take a closer look at the role of biological indicators in the quality control of sterilization processes.

The role of biological indicators in quality control

Biological indicators are placed with the load inside of the sterilizer chamber in the location determined to be the most difficult to sterilize. The typical biological indicator placement location for large steam sterilizers is over the drain, for ethylene oxide sterilizers, in the center of the load, and for hydrogen peroxide sterilizers at different chamber locations specific to the sterilizer, cycle, and load. The instructions of the manufacturer regarding the recommended placement location for the biological indicator in the sterilizer should be followed.

Biological indicators are typically used inside of process challenge devices (PCDs) or other items that can represent the sterilizer load. Placement of biological indicators inside of the containers or packages would give direct information on the lethality of the sterilization process inside the device packaging, but this placement is not practical as even today's rapid readout biological indicators require incubation time that would not be feasible in the OR. So, biological indicators are placed into PCDs or other devices that are intended to have the biological indicator perform as if it was placed inside of containers or packages in the load. Reference PCDs that can be constructed in health care facilities are described in the standards.[3,4] Commercially available PCDs that have been cleared by the US Food and Drug Administration (FDA) with performance equivalent to the reference PCDs are also available. These devices eliminate the need for staff time to assemble test packs and are typically more consistent because of automated assembly processes and quality control procedures required of medical device manufacturers.

The recommended frequency of use of biological indicators in health care facilities varies by the sterilization process. For steam, the recommendation from AAMI is weekly use, but preferably daily use, for routine efficacy monitoring. Also, a biological indicator should be used to release any load containing an implantable device. Implants loads should be quarantined until the biological indicator results are available.[3] Per AAMI, a biological indicator should be used to monitor every load for ethylene oxide sterilization processes. Again, any implants should be quarantined until the biological indicator results are available.[4] Finally, for vaporized hydrogen peroxide processes, the AAMI recommendation is that biological indicators be used daily, but preferably in every load. The same requirement of BI monitoring with load quarantine until the BI results are available applied for implants.[5]

As you can see, there is some variability in the current recommended practices regarding frequency of use of biological indicators. Many health care facilities are now leveraging the significant reductions in biological indicator incubation time to increase their frequency of use of this important QC tool, without negatively affecting their workflow. For example, rapid readout BIs make the quarantine of implantable devices until the biological indicator test result is available much more realistic. Many hospitals have moved to monitoring of every sterilization load with biological indicators even where the current health care standards do not require it, such as for steam and vaporized hydrogen peroxide. The criteria often cited for making this change include a desire to improve quality control to assure a uniform standard of care for all patients, avoidance of the extra work required in the event of a recall, as well as reduction of errors in the sterile processing department caused by varying requirements for biological indicator monitoring.

Summary

Biological indicator technology has continued to evolve with faster detection of the biological signals produced by the bacterial spores that provide the direct challenge to the sterilization process. These technologies have resulted in biological indicators with incubation times of less than 30 minutes for some sterilization processes. These short incubation times now make it possible to obtain biological test results in time for optimized instrument workflow, including shorter quarantine periods for implantable devices, and in many facilities, for all instruments. These indicators can facilitate improved quality control of sterilization processes by enabling increased frequency of biological monitoring. HPN

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Circle the one correct answer:

1. **Biological indicators utilize bacterial spores because spores are difficult to kill and present a significant challenge to the sterilization process.**
   A. True B. False
2. **Biological indicators with rapid readout technology rely on a biological signal from germinating and replicating spores.**
   A. True B. False
3. **The reference incubation time for a conventional biological indicator is seven days, but rapid readout technology has enabled biological indicators with incubation times of less than 30 minutes.**
   A. True B. False
4. **The most effective quality control system for healthcare sterilization uses a combination physical, chemical, and biological monitoring.**
   A. True B. False
5. **Sterilizer printouts from the electronic sensors in the chamber can prove that a sterilization cycle was effective**
   A. True B. False
6. **Chemical indicators on the outside of packages are used to test all the sterilization process parameters and prove that the process was effective.**
   A. True B. False
7. **Chemical indicators can provide a direct measurement of the lethality of the sterilization process.**
   A. True B. False
8. **Manufacturers' IFUs are the best reference for where biological indicators and PCDs should be placed in the sterilizer chamber.**
   A. True B. False
9. **Rapid readout biological indicators can make it easier to quarantine implantable devices until the BI test is complete.**
   A. True B. False
10. **For biological monitoring of steam sterilization, AAMI ST79 recommends weekly, but preferably daily testing as well as use of biological indicator PCDs with all implant loads.**
    A. True B. False

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