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Learning Objectives

1. Explain the differences between Class 5 integrating indicators and Class 6 emulating indicators and understand how each should be used according to the Association for the Advancement of Medical Instrumentation (AAMI) guidelines.
2. Describe the AAMI guidelines for routine biological indicator (BI) testing of flash steam sterilization cycles.
3. Describe the proper procedure for qualification testing and understand when this testing is required.

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SELF-STUDY SERIES

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Frequently asked questions: 3M Sterilization Assurance Techline

by Sandra Velte, B.A.

For the past two years it has been my job to answer the 3M Sterilization Assurance Techline. In that time I have responded to thousands of telephone and email inquiries from customers and sales representatives from across the country. In addition to answering questions about 3M Sterilization Assurance products, I provide information related to sterilization standards and recommended practices as well as troubleshooting of sterilization process failures. Answers to three of the most frequently asked questions are discussed in this self-study lesson.

What are the differences between Class 5 and Class 6 chemical indicators?

There are six classes of chemical indicators (CIs) defined in the AAMI guidelines that are classified according to intended use and certain performance requirements. These classifications are *not* ranked in order of importance or performance but rather are based on the type of information the CI results provide.

Class 5 integrating indicators are the most accurate of the internal chemical indicators. Only Class 5 integrating indicators are designed to react to all critical variables of a steam sterilization cycle (time, temperature, and saturated steam) and have stated values equivalent to or exceeding the performance requirements of BIs in ideal steam sterilization conditions. Therefore, Class 5 integrating indicator results in most situations will be similar to those of a BI and this monitoring device can detect failures when the selected temperature isn't reached.

The most recent AAMI standard for manufacturers of chemical indicators, *Sterilization of health care products-Chemical indicators-Part 1: General requirements*, ANSI/AAMI/ISO 11140-1:2005, added new testing requirements for Class 5 integrating indicators.¹ In this standard, Class 5 integrating indicators are the only class of CIs that must have a response correlated to a BI.

Additionally, the response of a Class 5 integrating indicator must now correlate to a BI at three stated values (i.e., time/temperature relationships) including 250°F/121°C, 275°F/134°C, and one or more in between. The previous standard, *Chemical indicators-Guidance for selection, use and interpretation of results*, ANSI/AAMI ST60:1996, required only one stated value.² Class 5 integrating in-

dicators must now also have a stated value at 250°F/121°C that is greater than 16.5 minutes. This ensures that the Class 5 CI does not change inappropriately or too quickly at significantly lower temperatures.

Class 5 CIs that meet the previous standard (i.e., ANSI/AAMI ST60:1996), rather than the current standard (i.e., ANSI/AAMI/ISO 11140-1:2005), may change inappropriately at significantly lower temperatures. Lower temperatures occur during the come-up time of the cycle or during a sterilization process failure which could be the result of incorrect packaging or loading, poor steam quality or quantity, choosing the incorrect cycle for the load, or equipment malfunction resulting in inadequate air removal and steam penetration.

If a Class 5 CI has no stated value at 250°F/121°C, or that stated value is not greater than 16.5 minutes, then it is not a Class 5 integrating indicator by the current standard requirements. The current standard also requires a dry heat test showing that the CI does not reach its endpoint in 30 minutes at 280°F/137°C.

Keep in mind that all testing performed by manufacturers is conducted in a research vessel (called a resistometer) with no come-up time, unlike a hospital sterilizer. It is also important to know that CI performance is tested by manufacturers in ideal saturated steam sterilization conditions and failure modes, such as superheating of steam and inadequate air removal, are not required tests.

Class 6 emulating indicators react to the three critical variables for a specified steam sterilization cycle. Class 6 CIs are sometimes referred to as *cycle specific indicators*. Therefore, if you run multiple steam sterilization cycles, you must use a distinct Class 6 CI to monitor each cycle time and temperature. And because Class 6 CIs are not required to correlate to a BI throughout the full range of steam sterilization temperatures, a Class 6 indicator could reveal a pass where a BI would indicate a failure.

Class 6 CIs must pass the same dry heat test described above. However, there is no requirement for testing at three or more time/temperature relationships and no requirement for a stated value at 250°F/121°C that is greater than 16.5 minutes.

When graphed, the three stated values for the Class 5 integrating indicator will form a line that is above the BI death curve (see Figure 1). This means that under ideal steam ster-

ilization conditions, the Class 5 CI would not give a passing result unless a BI would be killed. The graph illustrates that the response of the Class 5 integrating indicator parallels the biological response over the full range of sterilization temperatures.

A Class 6 emulating indicator can be comparable to the biological response at one sterilization time/temperature condition (i.e., the cycle for which the Class 6 CI is labeled). But, the response of a Class 6 emulating indicator could fall below that of a BI at lower temperatures (see Figure 2). Therefore, you could get a passing result from a Class 6 CI when a BI would not be killed, indicating that items are sterile when they may not be. As I mentioned earlier, lower temperatures occur during the come-up time of the cycle or during a sterilization process failure.

According to ANSI/AAMI ST79: 2008, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, Class 5 integrating indicators may be used as internal chemical indicators; or in a process challenge device (PCD), or test pack, as an option for load release of non-implant loads. AAMI ST79 also recommends that a Class 5 integrating indicator should be in the BI PCD for implant loads. In the case of an emergency, when the implant needs to be released before the BI result is known, the Class 5 integrating indicator provides additional information about the adequacy of the cycle.³

ANSI/AAMI ST79:2008, the first recommended practice document for users that discusses Class 6 emulating indicators, says: "NOTE-This edition of ANSI/AAMI ST79 does not cover the use and application of Class 6 emulating indicators. Refer to the manufacturer's written instructions for use."³

Class 6 emulating indicators are appropriate for use as internal chemical indicators in the specific cycles for which they are designed and labeled. Class 6 emulating indicators are not recommended to be used in the place of biological indicators for routine sterilizer testing, qualification testing, or load release for implants.

What are the recommended practices for BI monitoring for flash sterilization?

First, we need to establish what is considered a flash sterilization cycle. AAMI ST79 defines flash sterilization as a process designed for the steam sterilization of patient care items for immediate use. A flash steam sterilization cycle:

- Can be 270°F/132°C gravity or dynamic-air-removal;
- Can contain an unwrapped open perforated tray, rigid container system, protec-

tive organizing case, or single-wrapped surgical tray;

- Has little or no dry time (i.e., items come out wet);
- Produces items that must be used immediately or reprocessed (i.e., items cannot be stored for later use).

According to AAMI ST79, routine sterilizer efficacy monitoring of flash sterilizers is done with one or more BIs and one or more CIs in a BI challenge test tray (i.e., PCD) placed on the bottom shelf over the drain in an otherwise empty chamber. In addition, if you are running prevacuum flash cycles you also need to test your sterilizer daily with a Bowie-Dick test.

To test your sterilizer's performance, the open perforated tray configuration must always be tested. However, if you run a three minute open tray cycle and a ten minute open tray cycle, then it would be appropriate to only test the shorter, more challenging, three minute cycle for that particular configuration. AAMI ST79 also recommends testing all tray configurations, such as rigid containers, protective organizing cases, and single-wrapped surgical trays, because they create more of a barrier to air removal and steam penetration than the open perforated trays.

Flash sterilization process failures can result from not running the correct cycle for the type of tray used. You can make sure you are

able to detect flash sterilization problems by running a BI PCD that is representative of each type of tray used, at the right sterilization time and temperature.

The term "express cycle" refers to a dynamic-air-removal (i.e., vacuum-assisted or prevacuum) flash cycle for single-wrapped hard goods. The sterilizer manufacturer can provide you with written instructions for proper use of the express cycle. For example, it is inappropriate for instruments with lumens or porous items to be processed in an express cycle. In addition, only a single-layer wrapper can be used.

An express cycle is an option for sterilization of instruments for immediate patient use and should not be used for terminal sterilization. In an express cycle, fewer vacuum pulls are drawn during the conditioning or come-up time than in a regular prevacuum cycle. For example, one manufacturer's express cycle has two vacuum pulls instead of four during the come-up time.

The appropriate method for monitoring an express cycle is to make a representative BI PCD or challenge test tray (e.g., representative single-wrapped surgical tray) with a BI and one or more CIs. As with other flash cycles, for routine testing, the BI challenge test tray should be run on the bottom shelf over the drain in an otherwise empty chamber. [Note: The reduced number of vacuum pulls during the come-up time make an AAMI 16-towel BI test pack or a commercially prepared BI PCD too challenging for monitoring an express cycle.]

What testing do I need to do before I can start using a newly installed steam sterilizer?

Perform qualification testing upon sterilizer installation or relocation. This ensures the sterilizer is installed correctly and that the utilities are properly connected. Qualification testing determines if a sterilizer is operating at the specified conditions of time, temperature, pressure, air removal, moisture conditioning, and sterilant exposure. This testing verifies the sterilizer is performing properly before it is put into routine use.

Qualification testing is also done after major repairs, malfunctions, and sterilization process failures, such as positive BI results. The testing is performed to ensure that the sterilizer is performing correctly within specifications after repairs are made to the sterilizer and/or utilities.

In section 10.6.4 of AAMI ST79 a major repair of a steam sterilizer is defined as the following:

"A major repair is a repair outside the scope of normal maintenance, such as weld repairs of the pressure vessels, replacement of the

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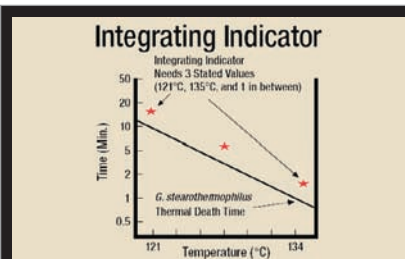


Figure 1:
Time/Temperature Response for Class 5 Integrating Indicator Compared to Biological Indicator Response (Source: 3M internal test result)

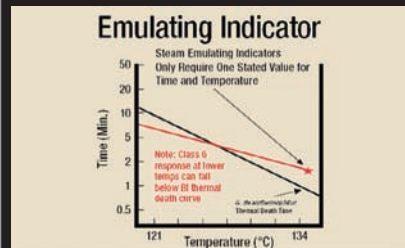


Figure 2:
Time-Temperature Response for Class 6 Emulating Indicator Compared to Biological Indicator Response (Source: 3M internal test result)

SELF-STUDY from page 31

chamber door or a major piping assembly, or rebuilds or upgrades on controls. Normal preventive maintenance, such as the rebuilding of solenoid valves, is not considered major repair.”³

In section 10.8.1, AAMI ST79 also provides a definition of a major repair of the utilities to a steam sterilizer:

“Significant changes to the utilities connected to the sterilizer (e.g., changes necessitated by water-main breaks, annual boiler maintenance, or additional equipment loads) could affect sterilizer performance. Major repairs of or changes to the utilities (e.g., the installation of new boilers) should be treated as major repairs.”³

All these events could affect the performance of the sterilization process, so it is important to maintain documentation of these events to ensure that qualification testing is performed at the appropriate times.

Now let’s discuss the proper procedure for conducting qualification testing. In sterilizers > 2 cubic feet and in flash sterilizers, a BI PCD is run in *three consecutive empty cycles*. In table-top sterilizers, the BI PCD is run in three consecutive full loads. All the biological indicators must be negative, and the chemical indicators must show an acceptable response for the sterilizer to be put into routine use.

In a sterilizer with a removable cart, it is important to cool the transfer cart to room temperature between cycles or use a new cart to avoid superheating, which can affect the test results. Using a cool cart also more closely duplicates normal processing procedures.

For qualification testing of all steam sterilizers, each type of cycle that is used should be tested with a BI PCD. Think of a sterilizer with four different cycles as four sterilizers in one. Each cycle has a different time, temperature, and type of air removal, that create a different challenge to air removal and steam penetration. Therefore, all the different cycles that are used should be tested. But if a sterilizer will run the same type of cycle (e.g., prevacuum at 132°C/270°F) for different exposure times (e.g., 4 minutes and 10 minutes), only the shortest cycle time needs to be tested.

After completing the BIPCD testing, the next step in qualification testing of prevacuum steam sterilizers is to run a Bowie-Dick test in three consecutive empty cycles. This test ensures your steam sterilizer is removing air efficiently before routine use. If the sterilizer has an air leak, inadequate vacuum, or non-condensable gases in the steam line, air pockets may form inside the sterilizer and prevent proper steam penetration of some packs in the load. A Bowie-Dick test is used to detect these types of malfunctions. Again, a cool transfer cart should be used to avoid superheating that will adversely affect the test results.

All results from qualification testing should be maintained in a record keeping system. If all biological indicators are negative, all chemical indicator and Bowie-Dick test results are acceptable, and the physical monitors indicate that the sterilizer is working as expected, then the sterilizer can be put into routine use. **HPN**

Editor’s note: A Class 6 indicator is not designed to match the performance of a biological indicator, but to exceed it and to monitor the specific cycle it is used for. Class 6 indicators are deliberately designed to be cycle-specific. Use of a Class 6 indicator in a different cycle is not intended by the manufacturer. FDA requires that all chemical and biological indicators are tested (and hence are appropriate) for all of the cycles for which they are claimed suitable. Only a Class 5 indicator is claimed to be comparable to a biological indicator.

Sandra Velte, B.A., is the voice at the end of the 1-800-441-1922 3M Healthcare Techline for Sterilization Assurance products (option 2). She spends her day answering technical questions about 3M products, troubleshooting sterilization process failures, and providing information related to sterilization best practices. Velte is a member of the Minnesota Healthcare Central Service Members Association and is a certified Central Sterile Processing and Distribution Technician.

References:

1. Association for the Advancement of Medical Instrumentation. Sterilization of health care products-Chemical indicators-Part 1: General requirements. ANSI/AAMI/ISO 11140-1:2005.
2. Association for the Advancement of Medical Instrumentation. Chemical indicators-Guidance for selection, use and interpretation of results. ANSI/AAMI ST60:1996.
3. Association for the Advancement of Medical Instrumentation. Comprehensive guide to steam sterilization and sterility assurance in health care facilities. ANSI/AAMI ST79:2008 (in progress).

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FAQ: 3M Sterilization Assurance Techline

Circle the one correct answer:

1. According to ANSI/AAMI/ISO 11140-1:2005, Class 5 integrating indicators must correlate to the performance of a BI at three stated values (time/temperature relationships), whereas Class 6 emulating indicators do not have this requirement.
A. True B. False
2. If you use four different cycles in your department (e.g., 270°F/132°C prevacuum 4, 8, and 10 minutes and 250°F/121°C gravity 30 minutes) you would need to stock four distinct Class 6 emulating indicators because Class 6 CIs are cycle specific.
A. True B. False
3. According to ANSI/AAMI/ISO 11140-1:2005, Class 6 emulating indicators must have a stated value at 250°F/121°C greater than 16.5 minutes.
A. True B. False
4. A Class 6 emulating indicator can be used to release an implant load.
A. True B. False
5. If you use 3 and 10 minute flash cycles for unwrapped instruments in an open perforated tray, you must test both cycles routinely with a BI challenge tray.
A. True B. False
6. Testing your flash sterilizer routinely with a BI in an open perforated tray at 3 minutes is sufficient if you use rigid containers to process all items at 10 minutes.
A. True B. False
7. An express cycle is a shortened prevacuum cycle that is used for terminal sterilization of wrapped items.
A. True B. False
8. Qualification testing is required after routine preventative maintenance is performed before the sterilizer can be put back into routine use.
A. True B. False
9. Qualification testing of a table top sterilizer is conducted with a full load.
A. True B. False
10. Qualification testing of a newly installed prevacuum sterilizer includes three consecutive cycles with a BI PCD followed by three consecutive cycles with a Bowie-Dick test in an otherwise empty chamber.
A. True B. False

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