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Learning Objectives

1. Define the classes of chemical indicators and how each class should be used to monitor the sterilization process.
2. Define the term "endpoint" as it relates to chemical indicators.
3. Define the term "stated value" as it relates to chemical indicators.
4. Describe how manufacturers test chemical indicators.

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Front of the class – An update on chemical indicator classifications

by Susan Flynn, BESC, CSPDT

International Standards are prepared by International Organization for Standardization (ISO) technical committees. These committees include representatives from countries that have national standards bodies. For example, delegates from the Association for the Advancement of Medical Instrumentation's (AAMI's) Sterilization Standards Committee represent the United States on the ISO Technical Committee responsible for standards related to the sterilization of health care products. Published ISO standards can be adopted by AAMI as is or with technical variations. Most AAMI standards and recommended practices are approved by the American National Standards Institute (ANSI) as American National Standards as they represent a national consensus.

This self-study discusses ANSI/AAMI/ISO 11140-1:2005 *Sterilization of health care products - Chemical indicators - Part 1: General requirements*. In this case, AAMI adopted the ISO standard without technical variations and it was approved by ANSI as an American National Standard, hence the triple acronym, ANSI/AAMI/ISO, in the document title. The 2005 document replaced ANSI/AAMI ST60-1996 *Sterilization of health care products - Chemical indicators - Part 1: General requirements*, which was based on the 1995 edition of the ISO standard but had significant deviations from the international document.

Background

Understanding some of the terms used in the Chemical Indicator document will help us delve into the content.

- **Critical variable:** "parameters identified as being essential to the sterilization process (and requiring monitoring)."¹
- **Endpoint:** "point of the observed change as defined by the manufacturer occurring after the indicator has been exposed to specified stated values."¹ For example, the endpoint of a color change chemical indicator would be the post-sterilization color of a successful cycle while the endpoint for a moving-front style chemical indicator would be the color change bar moving into the "accept" or "safe" area.
- **Resistometer:** a specialized test vessel capable of reproducible cycles and used by manufacturers to characterize the performance of chemical indicators.
- **Stated value (SV):** "value or values of a critical variable at which the indicator is designed to reach its endpoint as defined by the manufacturer."¹ For example, a Class 5 Integrating Indicator with a stated value of 3.5 minutes at 134°C should reach its endpoint when tested at 134°C for 3.5 minutes in a resistometer.

In addition to these terms, reviewing the critical variables for the sterilization processes used in healthcare facilities in the United States is a good refresher. Refer to Table 1 for the Critical Variables

Table 1: Critical Variables for Common Sterilization Processes

Sterilization Process and ANSI/AAMI/ISO Symbol	Critical Variables per ANSI/AAMI/ISO 11140-1:2005(1)
Steam STEAM	Time, temperature and water (as delivered by saturated steam)
Dry Heat DRY	Time and temperature
Ethylene Oxide EO	Time, temperature, relative humidity and ethylene oxide (EO) concentration
Vaporized Hydrogen Peroxide VH2O2	Time, temperature, hydrogen peroxide concentration, and, if applicable, plasma

and Symbol for selected sterilization processes.

Now that we're on common ground with a few key terms and the critical parameters, let's look at the six classes of Chemical Indicators defined in the ANSI/AAMI/ISO 11140-1:2005 standard. Table 2 provides AAMI definitions for each of these classes and examples of typical applications for each class.

So what's new?

ANSI/AAMI/ISO 11140-1, 2005 classifies chemical indicators by their intended use and provides performance requirements for each classification. Note that the document states that "this classification has no hierarchical significance".¹ This means a Class 4 indicator is not better than a Class 2 indicator, they simply each have different characteristics and intended uses. The major changes in the updated AAMI document are: the addition of performance requirements for chemical indicators for the vaporized hydrogen peroxide sterilization process; the increased performance requirements for Class 5 Integrating Indicators; and the addition of Class 6 Emulating Indicators to the standard.

The performance requirements for Class 5 integrating indicators were increased in the new version of the document. Integrating Indicators are the most accurate of the internal chemical indicators. Only Class 5 integrating indicators are designed to react to all critical variables and have stated values equivalent to or exceeding the performance requirements for BIs given in ISO 11138, *Sterilization of health care products – Biological indicator systems*. Steam Class 5 integrating indicators must now have three SVs, one each at 121°C/250°F and 135°C/276°F, and at one temperature in between (see Figure 1). Additionally, Class 5 steam integrating indicators **MUST** have a SV at 121°C of not less than 16.5 minutes to ensure performance is comparable to that of BIs in saturated steam.

This time correlates to inactivation of a biological indicator with a population of 1×10^5 microorganisms. This means "a direct relationship is established between the integrator endpoint and a satisfactory inactivation level in an equivalent BI and therefore the objective of a terminal sterilization process."¹

Class 6 Emulating Indicators are new to the AAMI document. Class 6 emulating indicators do NOT share the requirements outlined above for Class 5 integrating indicators. Class 6 emulating indicators are cycle specific, i.e. they are designed to react to all critical variables for a specified sterilization cycle. Therefore, if a Sterile Processing Department runs multiple exposure times (e.g. 4, 10 and 18 minutes at 272°F), a unique Class 6 emulating indicator would be required to monitor each type of cycle. The response of Class 6 emulating indicators does not necessarily correlate to that of a biological indicator so they cannot be used as an additional monitoring tool to release loads that do not contain implants or in a BI PCD to monitor implant loads.

At this time, the use of Class 6 emulating indicators is not covered in any AAMI end-user document. Appropriate use of Class 6 emulating indicators would be as an internal chemical indicator at the pack/tray level in cycles for which it is labeled.

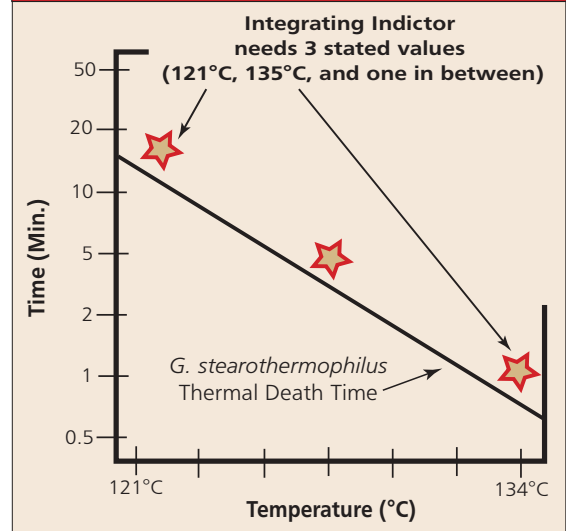
Class 5 and 6 steam indicators share a requirement that they must pass a dry heat test. The products must NOT reach their endpoints when exposed to dry heat at 137°C/280°F for 30 minutes.

How are chemical indicators tested?

It's important to understand that manufacturers do not characterize the performance of chemical indicators in hospital sterilizers. Rather, they use resistometers, specialized vessels that are capable of doing reproducible test cycles. "Resistometers allow for precise variation of the specific test conditions and cycle sequences in order to produce controlled physical studies. Resistometers differ from conventional sterilizers; therefore, if conventional sterilizers are used to attempt to duplicate resistometer conditions, erroneous and/or misleading results may occur."¹

Steam resistometers must reach the temperature set-point in < 10 seconds

Figure 1: Performance of Class 5 Steam Integrating Indicators



(see Figure 2) while hospital sterilizers may have up to 10 minutes of pre-conditioning or come-up time (see Figure 3). Because BI inactivation and CI progression toward endpoint begin to occur during this pre-conditioning or come-up time in hospital sterilizers, hospital sterilizers cannot be used to replicate manufacturers' stated values.

The cycle specific data for Class 6 emulating indicators is generated in a resistometer, not in a hospital sterilizer. Why is this significant? In use in a hospital sterilizer, Class 6 indicators could have significant progression towards endpoint during the come-up time.

What about low temperature sterilization monitors?

For ethylene oxide (EO) sterilizers, ANSI/AAMI/ISO 11140-1:2005 provides guidance on testing Class 1, 3, 4, 5 and 6 indicators. The stated value for EO integrating (Class 5) indicators for a 'warm' cycle at a temperature of 54°C, EO concentration of 600 mg/l, and a relative humidity of 60% should be greater than 30 minutes.¹ This assures that the integrator will have an inactivation time equivalent to an appropriate biological indicator. Similarly for a 'cool' cycle, the stated value for a Class 5 indicator for a cycle at a temperature of 37°C, EO concentration of 600 mg/l, and a relative humidity of 60% should be at least 90 minutes.¹

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For the vaporized hydrogen peroxide sterilization process, ANSI/AAMI/ISO 11140-1:2005 provides test conditions only for Class 1

process indicators. At the specified hydrogen peroxide concentration, the process indicators should reach their endpoint after 6 minutes at 50°C or 10 minutes at 27°C. In the absence of hydrogen per-

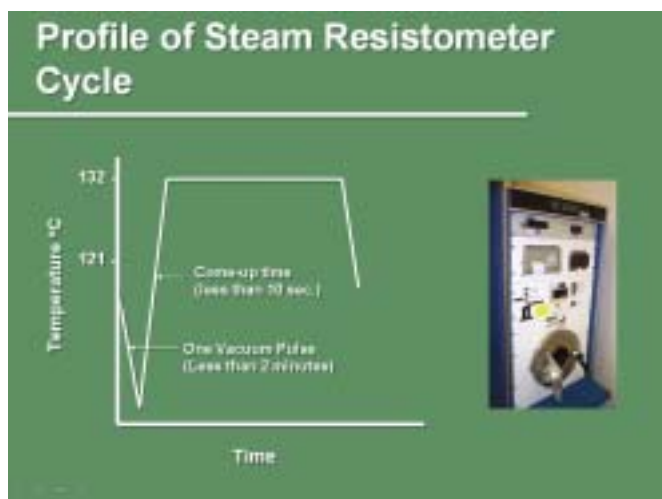


Figure 2: Steam Resistometer Temperature Profile

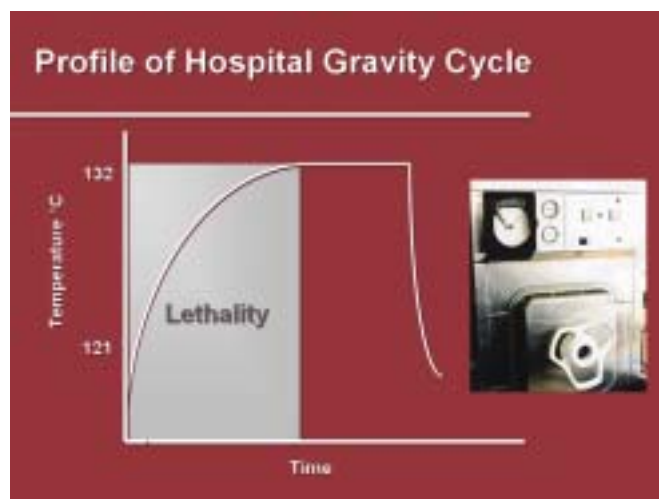


Figure 3: Hospital Sterilizer Temperature Profile

Table 2: Steam Chemical Indicator Classes Defined

Class	ANSI/AAMI/ISO 11140-1:2005 Definition*	Practical Application
Class 1: Process Indicators	"Process indicators are intended for use with individual units, (e.g., packs, containers) to indicate that the unit has been directly exposed to the sterilization process and to distinguish between processed and unprocessed units. They shall be designed to react to one or more of the critical process variables."	Indicator tapes, indicator labels, and load cards are examples of externally visible chemical indicators that should be on the outside of every package.
Class 2: Indicators for use in Specific Tests	"Class 2 indicators are intended for use in specific test procedures as defined in relevant sterilizer/ sterilization standards."	Bowie-Dick type tests are specific tests used for equipment control to evaluate the efficacy of air removal and steam penetration.
Class 3: Single Variable Indicators	"A single variable indicator shall be designed to react to one of the critical variables and is intended to indicate exposure to a sterilization process at a stated value (SV) of the chosen variable."	An example of a single variable indicator is a temperature tube that contains a chemical pellet that melts at a specific temperature. Single variable indicators may be used for pack control monitoring but would not provide as much information as a Class 4 or Class 5 chemical indicator when used as an internal chemical indicator. Internal chemical indicators should be used inside each pack.
Class 4: Multi-variable Indicators	"A multi-variable indicator shall be designed to react to two or more of the critical variables and is intended to indicate exposure to a sterilization cycle at SVs of the chosen variable."	Multi-variable chemical indicators are used for pack control monitoring. These internal chemical indicators are usually paper strips printed with a color change chemical indicator. Internal chemical indicators should be used inside each pack.
Class 5: Integrating Indicators	"Integrating indicators shall be designed to react to all critical variables. The SVs are generated to be equivalent to, or exceed the performance requirements given in the ISO 11138 series for BIs."	<ul style="list-style-type: none"> • May be used as an internal chemical indicator for pack control monitoring. Internal chemical indicators should be used inside each pack. • Can also be used as an additional monitoring tool to release loads that do not contain implants. For this application the Class 5 Integrating Indicator must be used in the appropriate Process Challenge Device (PCD).(2) • Should be used in a PCD to monitor implant loads. The PCD should also contain a BI. The implant should not be released until the BI result is known, except in emergencies.(2)
Class 6: Emulating Indicators	"Emulating indicators are cycle verification indicators which shall be designed to react to all critical variables for specified sterilization cycles. The SVs are generated from the critical variables of the specified sterilization process."	Could be used as internal chemical indicators for pack control monitoring for the cycle for which they are labeled. The use of Class 6 Emulating Indicators is presently not covered in any AAMI health-care facility user documents.

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Front of the class – An update on chemical indicator classifications

Circle the one correct answer:

- Indicator tape used to seal packs and distinguish between processed and unprocessed packs are an example of Class 1 Process Indicators.
A. True
B. False
- Only Class 5: Integrating Indicators are designed to react to all critical variables and have stated values (SVs) equivalent to or exceeding the performance requirements for BIs.
A. True
B. False
- The critical variables for the ethylene oxide sterilization process are: time, temperature and hydrogen peroxide concentration.
A. True
B. False
- Manufacturers use a test vessel called a resistometer to characterize chemical indicator performance.
A. True
B. False
- Unlike a hospital steam sterilizer, a steam resistometer has a very short (<10 second) come-up time.
A. True
B. False
- Class 5 integrating indicators in an appropriate Process Challenge Device (PCD) can be used to release loads that do not contain implants.
A. True
B. False
- Class 6 emulating indicators are cycle specific i.e., are designed to react to all critical variables for a specified sterilization cycle.
A. True
B. False
- For implant loads, it is acceptable to release the load based on the Class 5 integrating indicator result rather than waiting for the biological indicator result.
A. True
B. False
- Per ANSI/AAMI ST79:2006, an internal chemical indicator (Class 3, 4 or 5) should be used inside each package or tray.
A. True
B. False
- The use of Class 6 emulating indicators is presently not covered in any AAMI health-care facilities user document.
A. True
B. False

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oxide for test times of 45 minutes, or at the appropriate gas concentration for test times of 7 seconds at 50°C or 10 seconds at 27°C, the process indicators should fail to reach their endpoint.¹

How do I know the class of the product I'm using?

Either the chemical indicator packaging or the technical information supplied with the package should include a variety of information including: the class of chemical indicator; sterilization process; intended use for which the indicator is designed; the critical variable(s) to which the indicator will respond, and where applicable, their stated values.¹ You can expect to begin seeing this information as manufacturers update product packaging and package inserts to comply with the standard. Your choice of chemical indicator class should be based on the information you need about a particular sterilization process.

Summary

There are now six classes of chemical indicators. Only Class 5 integrating indicators are designed to react to all critical variables and have stated values (SVs) equivalent to or exceeding the performance requirements for BIs. Current AAMI user documents provide recommended practices for use of indicators labeled as Class 1 through 5. Chemical indicator classifications enable the end user to understand performance parameters of various chemical indicators. Understanding these classes will enable the user to select the appropriate chemical indicator for the application and the sterilization process being monitored. **HPN**

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References

- ANSI/AAMI/ISO 11140-1:2005 Sterilization of health care products – Chemical indicators – Part1: General requirements.
- ANSI/AAMI ST79:2006 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.