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## Learning Objectives

- 1) Explain the different chemical indicator designs and mechanisms of action
- 2) Identify steps to take when Class 6 chemical indicators fail
- 3) Explain how to handle conflicting results when multiple indicators are used in the same load

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# Class 6 emulating indicators: Use failure to your advantage

by Pamela Carter RN, BSN, CNOR, and Heide Ames

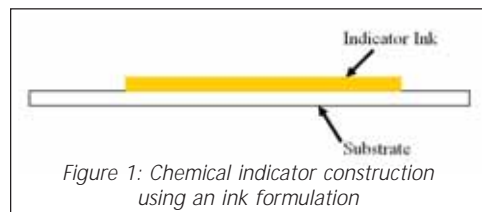
Chemical indicators have been around as long as life itself. For example, in nature, hydrangeas bloom blue in acidic soil and pink in basic soil, so they are an excellent indicator of soil conditions.

In reality, what seems like a simple color change is a complex series of reactions that must happen in just the right way. Some chemical indicators, including Class 6 emulating indicators, use color changes to signal that the conditions for sterilization have been met. These seemingly simple color changes tell a huge story about what is really happening behind closed sterilizer doors.

### Indicator design

Chemical indicators are either physical or chemical devices used to monitor one or more of the process parameters of the sterilization cycle. They are organized into six classifications. Each classification has specific performance requirements and expectations. In general, indicator performance becomes more tied to the sterilizer cycle as the indicator's classification number increases.

Indicators used in today's sterile processing departments and perioperative suites are based on two basic design types. The first type uses an indicator ink printed on a substrate. The ink contains one or more chemicals that react with the critical variables of sterilization (time, temperature, steam quality) to change color. The more variables that are measured, the more complicated the chemical reactions are.



The second type uses a material that changes its physical state when exposed to the variables of sterilization. The most widely used physical indicators are the "moving front" integrating indicators for steam. These types of indicators use a solid

pellet that melts when exposed to the temperatures of sterilization. The molten material is absorbed and advances along a paper wick that is visible through a window.

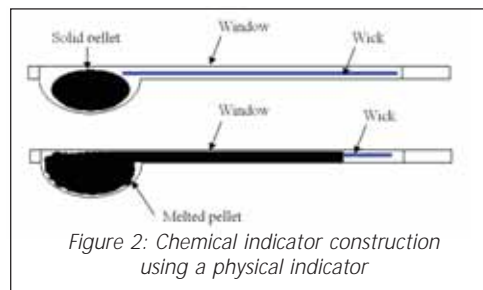


Figure 2: Chemical indicator construction using a physical indicator

Current Class 6 emulating indicators use an indicator ink design. The formulation for each cycle-specific indicator controls a color change with two or more chemical reactions. The most common Class 6 emulating indicators are composed of a two-part chemical indicator reaction. The first reaction collects steam energy. It must be exposed to steam at a temperature and time appropriate to achieve sterilization. Once enough of the sterilization conditions have been delivered, the second reaction occurs, changing the color of the indicator to a completely different color in a very short time. This is called a "total" color change. In comparison, other chemical indicator classifications are often formulated to show a "tonal" color change in which the indicators go through a gradual color change over time until they reach a specific color shade. (Figure 3.)

Class 6 emulating indicators are available as indicator strips used for internal pack monitoring, flash indicator strips used to monitor flash sterilization cycles, and challenge packs used to monitor steam sterilization cycles for wrapped goods. The manufacturer's instructions for use as cleared by the Food and Drug Administration (FDA) state that the flash indicator strips and indicator challenge packs may be used to monitor all loads and all items within the load. However, Class 6 emulating indicators may not be used for weekly efficacy testing or sterilizer qualification after installation, repair or relocation.

### Performance specifications

Class 6 emulating indicators have defined performance specifications: *passing* conditions; *failing* conditions; and *dry heat* conditions for steam emulating indicators. The passing and failing conditions are defined by the sterilization process and its critical parameters (270° F for 4 minutes, for example). They're also specific to each sterilization cycle.

The only Class 6 indicators currently available in the United States are for steam sterilization. Steam sterilizers have several preprogrammed cycles. A specifically formulated emulating indicator must be used for each of these cycles. The dry heat test for steam indicators specifies that the chemical indicator *will not show passing conditions* when exposed to dry heat conditions of 137°C for 30 minutes. Testing of the Class 6 indicators demonstrates that, because they are cycle-specific, Class 6 emulating indicators can provide more sterility assurance for the majority of specific sterilization cycles (Figure 4).

### Steps to take when an indicator fails

Class 6 emulating indicators can fail within instrument packs or within challenge packs used to monitor loads. When an indicator fails, it's important to investigate *all* potential sources: equipment failure, processing error, environmental error, technician error and sterility assurance monitor failure. Only through investigation can the root cause of the failure be identified and corrected before it occurs again.

#### If an internal pack indicator fails

When an indicator inside a pack shows a failing result, it indicates that the internal confines of a pack did not meet the minimum required sterilization conditions. What to do:

- Retrieve all the packs from the sterilization load and check for other failed indicator strips.
- Review the cycle printout and challenge packs (if used) to ensure passing conditions.
- If that is the only pack demonstrating a failure, retrieve all similar packs from the cycles before and after. If these also show failing indicators, the problem is with that type of pack. Determine the reason for the failure and recall all the similar packs that have been processed.
- When multiple packs demonstrate failures within the same load, or a load monitoring device or cycle printout indicates that another identified problem

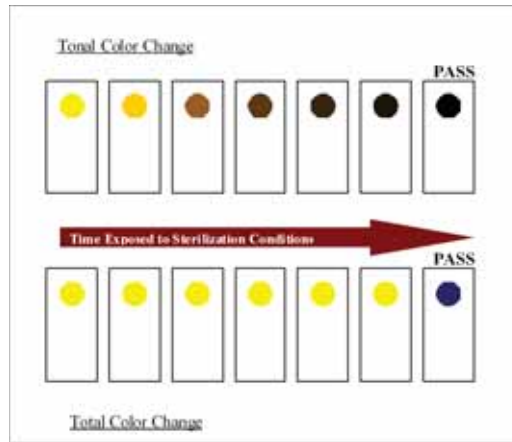


Figure 3. Tonal vs. total color

exists, recall the load and investigate how many loads have been affected. All affected loads must be recalled.

#### If a challenge pack fails

When a Class 6 challenge pack fails it indicates that the sterilizer was unable to remove air and penetrate the challenge pack with steam (Table 1, next page). What to do:

- The entire load must be reprocessed.
- Investigate the reason for the failure. Review previous cycles to determine the extent of the failure.
- Recall all loads processed between the failed Class 6 challenge pack and the last passing challenge pack (Class 6 or biological challenge pack, whichever is first).

#### What to do with conflicting results

Discrepant results may occur when more than one type of challenge pack or indicator is used within the same load. Whenever a

pack or indicator has failed, always reject the load, even when some indicators within the same load show passing conditions. When challenge packs do not agree (Class 6 challenge pack and biological indicator challenge pack give different results, for example), rule out false positives. False positives are sterility assurance indicator results that show a bad sterilization process even though it was a successfully completed sterilization cycle. If the failing result is a true positive (either a growing BI or a failing Class 6), then the failing challenge pack has detected a sterilization failure that the other challenge pack did not (Table 2, next page). Recall all loads processed since the last passing challenge pack of that type.

Class 6 emulating indicators perform complex reactive processes designed to monitor all the critical variables of sterilization. As a sterility assurance tool, they measure more of the sterile processing cycle than other classifications of indicators. Class 6 flash indicators and challenge packs for steam sterilization are used to monitor the conditions within containers, pouches and wrapped items, and allow the release of all loads and all items within the load. Knowing how to make the most of the information provided by a Class 6 indicator's "fail" result will help sterile processing departments resolve sterilization problems effectively. **HPN**

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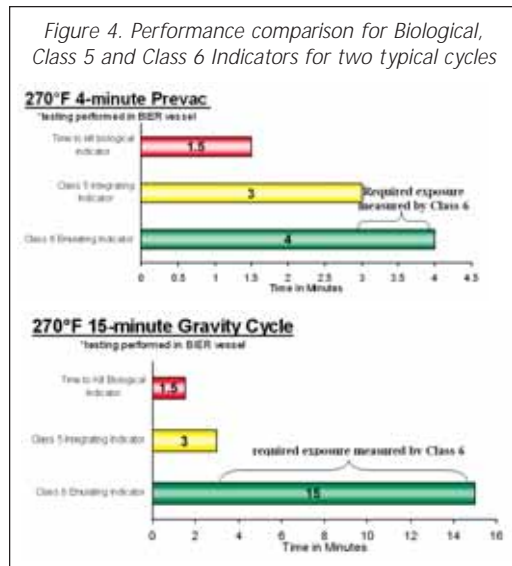


Figure 4. Performance comparison for Biological, Class 5 and Class 6 Indicators for two typical cycles



*SELF-STUDY* from page 45  
member of the Association for the Advancement of Medical Instrumentation (AAMI), the International Association for Pharmaceutical Science and Technology (PDA), and the International Association of Healthcare Central Service Materiel Management (IAHCSMM).

References:  
1. ANSI/AAMI/ISO 11140-1:2005 Sterilization of healthcare products – Chemical Indicators – Part 1: General requirements;

Association for the Advancement of Sterilization: 2005, p. 16.  
2. ANSI/AAMI ST79:2008 Comprehensive guide to steam sterilization and sterility assurance in health care facilities; Association for the Advancement of Sterilization; 2008.  
3. Reduce Flash Sterilization Errors, Eliminate Blind Release and Increase Sterilization Productivity, Linda Clement et al, STERIS Corporation; www.verify-sixcess.com

Cycle Number	Result of Class 6 (C6) Challenge Pack	Result of Biological Indicator (BI) Challenge Pack
1	Passed	Passed
2	Passed	Not monitored
3	Not monitored	Not monitored
4	Not monitored	Passed
5	Not monitored	Not monitored
6	Failed	Failed

*Loads 5-6 are recalled since both the C6 and BI detected the problem.*

Table 1: Determining the extent of a recall when both load monitoring devices fail.

Cycle Number	Result of Class 6 Challenge Pack	Result of Biological Indicator Challenge Pack
1	Passed	Passed
2	Passed	Not monitored
3	Not monitored	Not monitored
4	Not monitored	Passed
5	Not monitored	Not monitored
6	Failed	Not monitored

*Loads 3-6 are recalled since the C6 in cycle 6 was the only pack able to detect the problem.*

Table 2: Determining the extent of a recall when one load monitoring device fails.

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# Class 6 emulating indicators: Use failure to your advantage

Circle the one correct answer:

- How many different designs exist for chemical indicators?
  - Two
  - Three
  - Ten
  - Six
- Which is an example of a physical change chemical indicator?
  - An indicator containing a pellet that melts when exposed to the conditions of sterilization
  - An indicator with a chemical reaction that changes from yellow to blue when exposed to the conditions of sterilization
  - A Self-Contained Biological Indicator that dies when exposed to the conditions of sterilization
- Emulating indicators are designed to do which of the following?
  - Measure two or more critical variables
  - Match the performance of a biological indicator
  - Show when all the critical variables of sterilization have been achieved that would have killed a biological indicator
  - Show when all the critical variables of sterilization have been achieved for a specific sterilization cycle
- Which is true about a total color change?
  - It's a fast final color change
  - Is created through multiple chemical reactions
  - It's a tonal process
  - a and b
  - None of the above
- For what applications are Class 6 emulating indicators used?
  - Qualification of steam sterilizers
  - Internal pack monitoring
  - Monitoring all sterilization loads and release of all items
  - a and b only
  - b and c only
- Class 6 emulating indicators eliminate the need for biological indicators.
  - True
  - False
- What should be investigated when an indicator strip or challenge pack shows failing results?
  - Equipment failure, processing error, environmental error, technician error and sterility assurance monitor failure
  - Equipment failure, hospital policies, processing error, environmental error, technician error and sterility assurance monitor failure
  - Equipment failure, processing error, lighting, environmental error, technician error and sterility assurance monitor failure
- A sterilized load may be released when a Class 6 challenge pack shows a failing result as long as the biological indicator is passing.
  - True
  - False
- If only one pack in a load demonstrates a failure, the next step(s) are:
  - Retrieve all similar packs from the cycles before and after.
  - If these also show failing indicators, the problem is with that type of pack.
  - Determine the reason for the failure and recall all the similar packs that have been processed.
  - a and c
  - a, b and c
- Class 6 emulating indicators have defined performance specifications. The passing and failing conditions are defined by each cycle's sterilization process and its critical parameters.
  - True
  - False

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