Class 6 Emulating Indicators and Class 5 Integrating Indicators—A comparison of their ability to detect temperature failures within a steam sterilization cycle

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Background: During steam sterilizer processing, the temperature inside packages may be lower than the sterilizer temperature due to both sterilizer come-up-time and excessive load lag. While lower temperatures occur in every steam sterilizer during come-up-time, other factors such as equipment malfunctions, utility problems or operator errors can lead to excessive load lag. In these conditions, some chemical indicators may incorrectly show a pass result instead of a fail result. Therefore, accurate monitoring to determine the occurrence of low temperatures is critical for identifying sterilization process failures.

Methods: This study evaluated the ability of a Class 5 Integrating Indicator and two Class 6 Emulating Indicators to correctly indicate failures to achieve temperatures in some steam sterilization conditions. The performance of the 3M™ Comply™ SteriGage™ 1243 Steam Chemical Integrator (a Class 5 Integrating Indicator), the Steris® Verify® SixCess™ Chemical Indicator (a Class 6 Emulating Indicator) and the TITEMS Diagnostic EMULATOR (a Class 6 Emulating Indicator) were compared in a dynamic-air-removal (prevacuum) steam sterilization cycle using a steam resistometer test vessel.

Results: The Steris Verify SixCess Chemical Indicator and the TITEMS Diagnostic EMULATOR showed a pass result at 115°C (240°F) for 15 minutes and 121°C (250°F) for 8 minutes. In contrast, the 3M Comply SteriGage 1243 Steam Chemical Integrator correctly indicated a fail result in these conditions. These times at these temperatures would be considered significant failure condition for achieving sterilization.

Conclusions: Reliable in-pack monitoring with chemical indicators is imperative to help ensure proper sterilization of instruments used in patient care. In this study, the Class 5 Integrating Indicator detected failure to achieve required sterilization process conditions. The Class 6 Emulating Indicators provided inaccurate responses since they revealed pass results at the lower temperatures. If a sterilizer could instantly achieve the desired exposure temperature of 132°C (270°F), these Class 6 Emulating Indicators may provide the correct response. However, virtually all steam sterilizers used by health care facilities have lengthy come-up-times and load lag when the sterilizer contents and associated indicators are exposed to lower temperatures for prolonged periods of time. In some cases, the temperature inside packages may never reach the desired 132°C (270°F) temperature during a full sterilization cycle. Therefore, the way chemical indicators perform, not only at 132°C (270°F), but at lower temperatures, is critical to detecting steam sterilization process failures.
may not be lethal enough to kill microorganisms, yielding devices that are unsafe for patient use. Therefore, in-pack monitoring with chemical indicators becomes critical.

In all dynamic-air-removal steam sterilizers prior to exposure time, steam flushes and pressure pulses remove air and inject steam into the sterilizer. This “come-up-time” for steam sterilizers used in health care facilities can often last more than 20 minutes, depending on the load contents, chamber size and steam pressure. This is shown in the come-up-time Phase 1 in Figure 1. Lower temperatures occur during sterilizer come-up-time, even when there are no equipment malfunctions, utility problems and operator errors.

During come-up-time, chemical indicators begin responding to increases in temperatures. However, if a failure occurs during the sterilization process and required conditions are not reached, a chemical indicator may incorrectly show a pass condition when a failure occurred because it responded to the lower temperatures in the come-up-time.

The following study compared the ability of Class 5 Integrating Indicators and Class 6 Emulating Indicators to correctly report failures to achieve acceptable temperatures used during steam sterilization.

Figure 1

Load lag occurs when the instrument pack temperature does not come up to temperature as quickly within the sterilizer as the temperature within the chamber, as indicated by the temperature sensor located in the drain.
MATERIALS AND METHODS

The following indicators were evaluated:

- **3M™ Comply™ SteriGage™ 1243 Steam Chemical Integrator** (3M Company, St. Paul, MN, USA)
  - Sample sets tested: 1) 2014-01 BC, 2) 2014-01 KC, 3) 2014-01 TC
  - Stated values of 20.9-21.7 minutes at 121°C (250°F), 5.3-5.7 minutes at 128°C (262°F) and 1.7–1.9 minutes at 135°C (275°F). The stated value time at 121°C (250°F) must be at least 16.5 minutes

- **Steris® Verify® SixCess™ Class 6 Chemical Indicator** (Steris Corporation, Mentor, OH, USA)
  - Sample sets tested: 1) 14888, 2) 15391, 3) 14889, 15390, 15392
  - Stated value of 4 minutes at 132°C (270°F) for prevacuum and steam flush pressure-pulse including the express cycle

- **TITEMS Diagnostic EMULATOR** (Austmel Pty., Nerang Queensland, Australia)
  - Sample set tested: 70301
  - Stated value of 3.5 minutes at 134°C (273°F)

ANSI/AAMI/ISO 11140-1:2006 requires testing of chemical indicators in a resistometer test vessel that meets the specifications of ANSI/AAMI/ISO 18472:2006. In this study, an H&W Resistometer (Model ILS20, H&W Technology LLC, Rochester NY, USA), meeting these criteria was used for all testing.

The following procedures were used:

- Chemical indicators from each of the product sets were taped across the top of a 7 inch by 22 inch rack of the H&W Resistometer and secured with 3M™ Comply™ 1222 Steam Chemical Indicator Tape for Steam Sterilization. The tape was applied at the opposite end from the indicator’s ink.

- Exposure times ranged from 2 minutes to 21 minutes in prevacuum steam sterilization cycles of 132°C (270°F), 121°C (250°F) and 115°C (240°F). (See Table 1.)

- At the end of each cycle, indicators were removed from the rack and cooled to room temperature.

- Results were recorded and then indicators were placed in envelopes for storage.

- All product/temperature/time combinations were tested three times.

Exposure time (Phase 2) for most dynamic-air-removal steam sterilization cycles is only 4 minutes. However, these indicators were tested for more than 20 minutes for the following reason. Steam is introduced into a sterilizer during come-up-time (Phase 1) and its temperature is generally lower than the steam temperature expected during exposure time (Phase 2). (See the solid red line in Figure 1.) Come-up-time can last for more than 20 minutes. When load lag occurs, a load is exposed to the additive time of the come-up phase and the exposure phase. Under these conditions, it is likely that steam is in the sterilizer for times approaching 30 minutes.

### Table 1: Steam Resistometer Exposure Times And Temperatures For All Chemical Indicators Tested

<table>
<thead>
<tr>
<th>Exposure Temperature</th>
<th>Exposure Times</th>
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<tbody>
<tr>
<td>132°C (270°F)</td>
<td>2 min. 3 min. 4 min.</td>
</tr>
<tr>
<td>121°C (250°F)</td>
<td>8 min. 10 min. 12 min. 14 min.</td>
</tr>
<tr>
<td>116°C (240°F)</td>
<td>15 min. 18 min. 21 min.</td>
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RESULTS

At 132°C (270°F) for 4 minutes in a dynamic-air-removal steam sterilizer cycle, the 3M Comply SteriGage 1243 Steam Chemical Integrator, the Steris Verify SixCess Chemical Indicator and the TITEMS Diagnostic EMULATOR provided pass results.

However, under inadequate sterilization process conditions, of 115°C (240°F) for 15 minutes and 121°C (250°F) for 8 minutes, both the Steris Verify SixCess Chemical Indicator and the TITEMS Diagnostic EMULATOR incorrectly provided pass results. The 3M Comply SteriGage 1243 Steam Chemical Integrator correctly identified these as temperature failure situations. Results are illustrated in Figures 2–4.
Figure 2
Summary: Comparison of Class 5 and Class 6 chemical indicators in a resistometer test vessel at 132°C (270°F). All indicators tested at 2 minutes responded appropriately and revealed the failure condition. Significant variation was witnessed between Class 5 and Class 6 types at 3 minutes. All of the TITEMS Diagnostic EMULATOR (Class 6) (15/15) and a large fraction of the Steris® Verify® SixCess™ Class 6 Chemical Indicator (17/39) show a pass, while only a small fraction of the 3M™ Comply™ SteriGage™ 1243 Steam Chemical Integrator show a Pass (2/45). NOTE: The 3M™ Comply™ SteriGage™ 1243 Steam Chemical Integrator Class 5 devices that showed a fail (2/45) at 4 minutes were at the pass-fail line.

Figure 3
Summary: Comparison of Class 5 and Class 6 chemical indicators in a resistometer test vessel at 121°C (250°F). At 8 minutes of steam exposure, 7% (1/15) of two different sets of the Steris® Verify® SixCess™ Class 6 Chemical Indicator and all (15/15) of the TITEMS Diagnostic EMULATOR (Class 6) provided a pass. At 10 minutes, all of Class 6 indicators show a pass, while only a small fraction of the 3M™ Comply™ SteriGage™ 1243 Steam Chemical Integrators (Class 5) indicated a fail result. NOTE: The 3M™ Comply™ SteriGage™ 1243 Steam Chemical Integrator (Class 5) have a Stated Values above 20 minutes and would not be expected to show a pass result before these times at 121°C (250°F) which provides an additional safety factor.
The purpose of sterilization monitors is to detect situations when sterilization process conditions are not achieved. Sterile processing departments rely on chemical indicators to provide the correct pass or fail result. If a temperature lower than 132°C (270°F) occurs and the elapsed time at the lower temperature is insufficient for sterilization, a chemical indicator should not provide a pass result.

This study revealed that the Steris® Verify® SixCess™ Class 6 Chemical Indicator and TITEMS Diagnostic EMULATOR (Class 6) provided pass results at 15, 18, and 21 minutes of steam exposure, while all of the 3M™ Comply™ SteriGage™ 1243 Steam Chemical Integrators (Class 5) indicated fail results at these same times. These times at 116°C (240°F) would be considered significant failure conditions.

These Class 6 Emulating Indicators may provide a correct response if a sterilizer were to instantly achieve the desired exposure temperature of 132°C (270°F). However, virtually all steam sterilizers used in health care facilities have lengthy come-up-times and experience load lag. In some situations, the temperature inside packages may never reach the desired 132°C (270°F).

Therefore, the way chemical indicators perform, not only at 132°C (270°F) but at lower temperatures, is critical. ANSI/AAMI/ISO 11140-1:2006 only requires that Class 6 Emulating Indicators be tested at 132°C (270°F) for a pass result and at 131°C (268°F) for a fail result. No testing is required at lower temperatures so a Class 6 Emulating Indicator can meet these ANSI/AAMI/ISO requirements, even though the product is never examined at reduced temperatures. However, the same standard requires that Class 5 Integrating Indicators be tested at 135°C (275°F), 121°C (250°F) and at least one temperature in between. In addition, the time to reveal a pass result at 121°C (250°F) must be at least 16.5 minutes.

Class 6 Emulating Indicators are intended to have a precise pass/fail window. Testing in this study revealed a considerable difference between the two types of Class 6 Emulating Indicators as witnessed in the pass/fail results displayed in the 132°C (270°F), 3 Minute and 121°C (250°F), 8 Minute results (See Figures 2 and 3). A precise pass/fail window for the Class 6 Emulating Indicators was not observed during this testing.

DISCUSSION

The purpose of sterilization monitors is to detect situations when sterilization process conditions are not achieved. Sterile processing departments rely on chemical indicators to provide the correct pass or fail result. If a temperature lower than 132°C (270°F) occurs and the elapsed time at the lower temperature is insufficient for sterilization, a chemical indicator should not provide a pass result.

This study revealed that the Steris Verify SixCess Chemical Indicator and the TITEMS Diagnostic EMULATOR can incorrectly show a pass result if 115°C (240°F) is achieved for 8 minutes. In contrast, the 3M™ Comply™ SteriGage™ 1243 Steam Chemical Integrator correctly indicated a fail result in these conditions.

These Class 6 Emulating Indicators may provide a correct response if a sterilizer were to instantly achieve the desired exposure temperature of 132°C (270°F). However, virtually all steam sterilizers used in health care facilities have lengthy come-up-times and experience load lag. In some situations, the temperature inside packages may never reach the desired 132°C (270°F).
CONCLUSION

Due to lower temperatures that can occur during sterilizer come-up-time or as a result of load lag, some chemical indicators may incorrectly show a pass condition instead of a failure. Therefore, reliable in-pack monitoring with chemical indicators is critical to help ensure proper sterilization of instruments used in patient care.

In this study, a Class 5 Integrating Indicator detected failure to achieve required sterilization process conditions while two types of Class 6 Emulating Indicators provided inaccurate responses since they revealed pass results at inadequate sterilization conditions.

Several industry and professional organizations, including AAMI and AORN, recognize the need for load and pack monitoring with a Class 5 Integrating Indicator.

GLOSSARY OF TERMS

Come-up-time: “Time elapsed from the introduction of the sterilizing agent to the attainment of the minimum specified exposure conditions.”

Dynamic-air-removal steam sterilizers: “Type of sterilization cycle in which “air is removed from the chamber and the load by means of a series of pressure and vacuum excursions (prevacuum cycle) or by means of a series of steam flushes and pressure pulses above atmospheric pressure (steam-flush pressure-pulse [SFPP] cycle).”

Load lag: “Difference between the temperatures in the free chamber space and the items of the load.”

Resistometer: “Test equipment designed to create defined combinations of the physical and/or chemical variables of a sterilization process.”

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.” For example, a Class 5 Integrating Indicator with a stated value of 2.1 minutes at 135°C (275°F) should reach its endpoint when tested at 135°C (275°F) for 2.1 minutes in a resistometer.

REFERENCES


BIOGRAPHIES

Steven Kirckof, BSCE Chemical Engineering, is an advanced product development specialist for 3M. He has more than 25 years experience in sterilization assurance practice and holds many patents and records of invention related to sterilization monitoring products. He participates in several AAMI Sterilization Standards Working Group committees and is the co-chair of the AAMI Chemical Indicator and Process Challenge Device Working Groups. He is also a United States delegate to the ISO (International Standards Organization) Chemical Indicator and Moist Heat Working Groups.

Tushar Kshirsagar, Ph.D. Chemistry, has more than 10 years industrial experience in FDA-regulated businessess. He has published 15 peer-reviewed articles, given numerous presentations and invited lectures and is the editor of the book “High Throughput Lead Optimization in Drug Discovery” (Taylor and Francis CRC Press Feb 2008). He is also the coauthor of several filed patents and is the recipient of an NIH SBIR grant.

Assumpta Bennaars-Eiden, Ph.D. Biochemistry, has five years of experience as a new product developer at 3M. She is an author of several 3M records of invention and has published in peer-reviewed journals. She also serves as an observer on the Molecular Methods Committee for the Clinical and Laboratory Standards Institute (CLSI).