Routine Monitoring of the Steam Sterilization Process in Health Care Facilities


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This book chapter contains two studies, both sponsored by 3M Health Care, comparing the performance of Class 6 chemical indicators (CIs) with a Class 5 CI and three biological indicators (BIs) in detecting defined failure conditions in steam sterilization cycles.

STUDY #2 – Sterilization Indicator Detection of Temperature Differences in Steam Sterilization Cycles

Summary

Class 5 and Class 6 CIs are the only CIs that must react to all of the critical variables for the sterilization process that they are intended to monitor. They should both therefore have the capability to detect cycle temperatures lower than their stated value endpoint during the exposure phase of the sterilization process and subsequently alert the user to a potential failure condition.

This study was designed to compare the performance of a Class 5 integrating CI strip and two Class 6 emulating CI strips with two BI spore strips in response to three different temperatures in steam resistometer cycles. Cycle temperatures of 240°F, 250°F and 270°F were selected for the evaluation to provide a range of temperatures that would normally be experienced in steam sterilization cycles including those temperatures occurring in the come-up time or conditioning phases of 250°F and 270°F cycles.

Although the temperatures occurring during the come-up time are lower than the cycle set point temperature, there is still sufficient lethality to inactivate microorganisms and cause CI inks to undergo change. If the CI should reach its endpoint during the come-up or conditioning phase of the cycle, it would not be able to detect a temperature failure later in the exposure phase of the cycle.

Results

Below are the results in graphical form for the testing at the three temperatures.

Testing at 240°F

• The Class 5 CI indicated 100% FAIL results at all 240°F exposure times indicating inadequate sterilization conditions.
• The Class 6 CI strips showed a high percentage of PASS results at the 240°F exposure times indicating that significant color change of the indicators occurred at this temperature with these times.
• 100% of the BIs were POSITIVE for all of the 240°F exposure times indicating inadequate sterilization conditions.
Testing at 250°F

- The Class 5 CI indicated 100% FAIL results at all 250°F exposure times indicating inadequate sterilization conditions. These results are consistent with the 250°F stated value for this product which would require an exposure time greater than 16.5 minutes at 250°F to reach its endpoint and show a pass result.
- The Class 6 CI strips showed a high percentage of PASS results at the 250°F exposure times indicating that significant color change of the indicators occurred at this temperature with these times.
- The BIs showed a progressively higher rate of inactivation as the time was increased. These results are consistent with the labeled D_{250°F} values for these products.

Testing at 270°F

- The Class 5 CI showed 100% FAIL results at the 2 minute exposure time and showed 100% PASS results at the 3 and 4 minute times. These results are consistent with the 275°F stated value of 1.8–2.0 minutes for this product.
- The Class 6 CI strips showed FAIL results at the 2 and 3 minute exposures and PASS results at the 4 minute exposure at 270°F. These results are consistent with the label claims for these products at this temperature.
- All of the BIs tested were NEGATIVE for all three of the exposure times at 270°F.

Conclusions

Sterilization indicators should be designed such that they have minimal response to lower temperatures in order that they may monitor the cycle temperature for which they are indicated and detect failures if they occur. The Class 6 CIs evaluated in this study performed in accordance with their stated values when tested with minimal come-up time in a steam resistometer at 270°F. However, both of the Class 6 CIs showed predominately pass results in the lower temperature, shorter exposure time cycles indicating that these CIs may undergo significant color change at lower temperatures.

In contrast the Class 5 CI and the two BIs tested showed minimal response at the 240°F and 250°F temperatures demonstrating the capabilities to integrate the lower temperatures occurring during the conditioning phase, and, provide a more accurate indication of the overall cycle conditions than Class 6 CIs.

As come-up times in health care facility steam sterilization cycles can be up to 20 minutes, the Class 6 CIs may not be able to detect temperature failures in the exposure phase of the cycle to the same degree as a Class 5 CI or a BI.