3M | Attest™
Sterilization Solutions

VH2O2

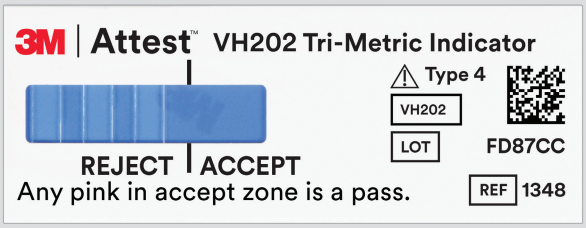
Color Stability of Chemical Indicators (CIs) for Vaporized Hydrogen Peroxide (VH2O2) Sterilization in Pack Storage

Background

Internal pack monitors, i.e., internal CIs, for monitoring VH2O2 sterilization have been found to change color during storage inside the pack.[1] The industry accepted theory for this effect is a result of residual VH2O2 off-gassing from packaging materials or devices. CIs for monitoring VH2O2 sterilization that change color from residual off-gassing inside the pack may not be a reliable internal pack monitor. If the VH2O2 sterilization process had failed to deliver adequate conditions to the inside of the pack but the CI inside continued to change colors towards an ACCEPT or PASS result due to the residual off-gassing, this CI would not be a dependable internal pack monitor.

Purpose

The purpose of this study was to evaluate and compare the performance of the 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348/1348E (Type 4) to six other VH2O2 CIs (Type 1 and Type 4) with respect to stability of the CIs initial color change during storage of the CI inside a pack after exposure to a fractional VH2O2 cycle (e.g., a failed VH2O2 cycle).



3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348 (Type 4) — Unprocessed

Objective

The study objective was to quantitatively measure the reactive chemistry color change of the 3M™ Attest™ Tri-Metric CI in comparison to six other Type 1 and Type 4 VH2O2 CIs during storage in a pack after exposure to a fractional VH2O2 cycle (e.g., a failed VH2O2 cycle). A camera placed inside the pack along with the CIs and instruments was used to capture the reactions of the CIs during and after the exposure to a fractional VH2O2 cycle (e.g., a failed VH2O2 cycle) and during subsequent storage inside the exposed pack.

This condition simulates a use case where the amount of sterilant (or the sterilizing conditions) delivered by the sterilizer was inadequate or the packaging or the load was prepared incorrectly where the sterilant (or the sterilizing conditions) did not fully encompass the inside of the pack. This scenario reflects a user condition where the failing conditions inside the pack resulted initially in a REJECT or FAIL CI response but, over time during storage inside the pack, the REJECT or FAIL CI color continues to react and change towards an ACCEPT or PASS result due to the reaction of the residual off-gassing from the packaging and the instruments. A high-level outline of the study procedure is contained in the four steps below.

1. **CIs and camera placed in pack with instruments. Pack is wrapped**
2. **Wrapped pack exposed to fractional VH2O2 sterilization process. Camera records CI color during processing.**
3. **Wrapped pack removed from sterilizer. Camera records CI color immediately post exposure.**
4. **Wrapped pack placed in storage. Camera records CI color during 6 weeks in storage.**

A high-level diagram of the study procedure is also shown in Figure 1.

Color Stability of Chemical Indicators (CIs) for Vaporized Hydrogen Peroxide (VH2O2) Sterilization in Pack Storage

Figure 1: High-level diagram of the study procedure steps.

Method and Materials

The pack with the test CIs and camera was a standard VH2O2 compatible tray with representative surgical devices / instrument load (~8 lbs / ~3.6 kg) wrapped with disposable sterilization medium weight wrap. Five CIs from each CI type were placed in the pack. Two different fractional VH2O2 cycles (e.g., a failed VH2O2 cycle) were used in this study.

VH2O2 Fractional Exposure Condition A

VH2O2 cycle is aborted 2 minutes and 30 seconds after starting the cycle.

VH2O2 Fractional Exposure Condition B

VH2O2 cycle is aborted 9 minutes after starting the cycle.

Two different exposure conditions were necessary in this study because the CIs tested have differing sensitivity to the sterilizing conditions. The abort times for each condition were chosen to reflect the difference in sensitivity. The 3M™ Attest™ Tri-Metric CI 1348/1348E was included in both conditions to allow a direct comparison.

After exposure to the fractional VH2O2 cycle, the pack with CIs and camera were removed from the sterilizer and placed into storage for six weeks. During the six weeks of storage at specified time intervals of 0 weeks (initial color of the CI at the abort time specified for condition A or B), 1 week, 2 weeks, 4 weeks, and 6 weeks, images of the CI were recorded with the camera.

All color changes from the CIs were recorded using a camera residing in the pack with the CIs and instruments. The camera had a field of view sufficiently large enough to encompass the set of CIs placed in the instrument tray along with the instruments. The camera was turned on remotely allowing video footage to be taken of the CIs in the tray without having to unwrap the tray. This configuration allowed for the instrument tray housing the CIs for a given exposure condition to be kept wrapped throughout the course the storage of the pack.

Still frame images were extracted from the video footage and a specialized software was used to split still frame images into L*, a*, and b* layers. Using the specialized software, in each layer image for each CI, an area was defined encompassing the CI reactive strip and the mean value of L*, a*, and b* was determined. For CIs with a reference color match, the mean values of L*, a*, and b* of the reference patch were also determined using the same process.

Color Stability of Chemical Indicators (CIs) for Vaporized Hydrogen Peroxide (VH2O2) Sterilization in Pack Storage

Results

Over the pack storage period of six weeks, significant color change was observed in all of the Type 1 and Type 4 VH2O2 CIs tested in this study except for the 3M™ Attest™ Tri-Metric CI 1348/1348E (Type 4). A table containing images of the actual test CIs, from each storage time interval is attached in document titled *Charts — Color Stability of Chemical Indicators (CIs) for Vaporized Hydrogen Peroxide (VH2O2) Sterilization in Pack Storage (70-2011-8117-2)*.[2]

The results of this study demonstrate that the 3M™ Attest™ Tri-Metric CI has the best stability post-exposure in a wrapped instrument tray (pack) stored at ambient conditions after a fractional (failed) VH2O2 sterilization cycle. All indicators in the study except for the 3M™ Attest™ Tri-Metric CI drifted to a color less than 10 units (delta E value or ΔE) away from the color of the indicator exposed to a complete cycle. This drift toward an ACCEPT / PASS color change occurred in less than 6 weeks. Apart from the 3M™ Attest™ Tri-Metric CI and the ASP indicator, by 6 weeks post-exposure storage, all remaining indicators drifted to a color that would be visually very difficult to perceive as different from the color of an indicator that had been exposed to a complete cycle (ΔE < 3 units).

ΔE is the change or drift in color of an indicator as compared to the fully exposed indicator from a complete cycle. ΔE < 10 units equates to a drift in color only 10 units away from a fully exposed indicator and ΔE < 3 units equates to a drift in color only 3 units away from a fully exposed indicator. The human eye cannot perceive a difference less than ΔE < 6 units.

In the summary table (Table 1), the '**ΔE_{Total}**' column represents the total drift of the color while stored in the pack. A larger value equates to a larger drift in color toward the fully exposed indicator.

'**Time for $\Delta E_{<10}$**' column in Table 1 represents the storage period when the indicator color drifted to only 10 units from the fully exposed indicator.

'**Time for $\Delta E_{6\ weeks}$**' column in Table 1 represents the number of units the color of the indicator was away from a fully exposed indicator at 6 weeks of storage. The smaller the value in this column represents an indicator that drifted in color very close to the fully exposed indicator.

Table 1: Summary of ΔE Characterization

Indicator	ΔE_{Total}	Time for $\Delta E_{<10}$	Time for $\Delta E_{<3}$	$\Delta E_{6\ weeks}$
Steris Verify (Type 1)	35.6	2 weeks	6 weeks	1.9
Steris Celerity (Type 1)	19.5	2 weeks	4 weeks	0.9
Terragene CD40 (Type 4)	13.7	2 weeks	2 weeks	1.3
ASP STERRAD (Type 1)	26.45	4 weeks	> 6 weeks	7.4
gke (Type 4)	3.7	0 weeks	0 weeks	1.7
SPS (Type 4)	16.2	2 weeks	6 weeks	2.6
3M™ Attest™ Tri-Metric CI (Type 4) *Condition A*	9.7	> 6 weeks	> 6 weeks	22.3
3M™ Attest™ Tri-Metric CI (Type 4) *Condition B*	9.9	> 6 weeks	> 6 weeks	17.1

Discussion

The results of this study showed the post-exposure color drift during storage within the wrapped tray observed in these indicators was sufficient to cause clear REJECT / FAIL result change to a potential ACCEPT / PASS result. CIs for monitoring VH2O2 sterilization that change color from residual off-gassing inside the pack may not be a reliable internal pack monitor.

Conclusion

The 3M™ Attest™ Tri-Metric CI is more color stable than all competitive VH2O2 CIs tested including ASP, Steris, and SPS. The 3M™ Attest™ Tri-Metric CI won't change color after sterilization from REJECT / FAIL to ACCEPT / PASS due to residual off-gassing inside the pack during storage for six weeks.

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References

1. Annual WFHSS and JSMI Conference 2012 — 13th World Sterilization Congress — *Problems on Hydrogen Peroxide Sterilisation — New Proposal for Safety and Effective Use* — Rika Yoshida, Hiroyoshi Kobayashi, Division of Infection Prevention and Control, Tokyo Healthcare University Postgraduate School; Slides 56–66.
2. Charts — Color Stability of Chemical Indicators (CIs) for Vaporized Hydrogen Peroxide (VH2O2) Sterilization in Pack Storage EN_GL_70-2011-8117-2.
3. Reference 3M Study EM- 05-692844.