3M | Attest™
Sterilization Solutions

VH2O2

Detecting vaporised hydrogen peroxide sterilization (VH2O2) process failures in clinical settings using chemical indicators

Zentralsterilization | Volume 28 | 6/2020, Dr. Brian Kirk.

Study Objective

Determine the ability of VH2O2 CIs to indicate when sterilizers were operated according to recommendations (pass) and when operated with unsuitable loads or processing cycles (fails).

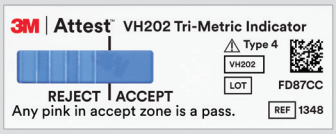
Methods

Studies were conducted in sterile processing departments (SPD) in USA. Visual interpretation and reflectance colourimetry were used to assess CI colour change when placed inside loads (reference Figure 1) which were within or exceeded the weight limit for a STERRAD® NX100 EXPRESS process (SPD1) and then a different load in EXPRESS or STANDARD NX100 processes (SPD2).

3M Key Take Aways

3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348 has the highest accuracy and precision in terms of correctly detecting failures in comparison to all competitive Type 1 and Type 4 VH2O2 CIs tested including all current VH2O2 CIs available from Steris and ASP.

3M Attest Tri-Metric indicator provides a higher level of quality assurance for monitoring VH2O2 sterilization processes as compared to all Type 1 and Type 4 VH2O2 CIs tested.



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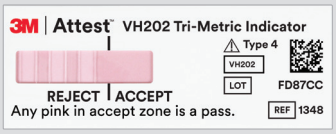
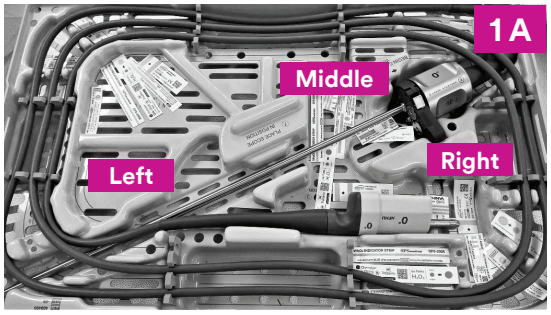
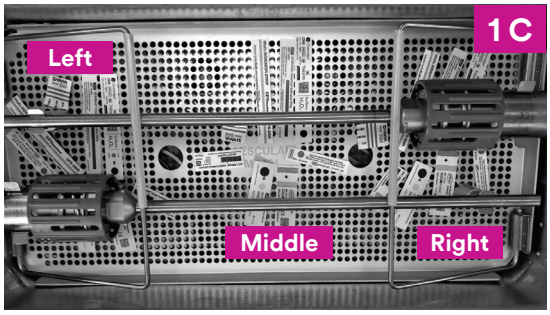
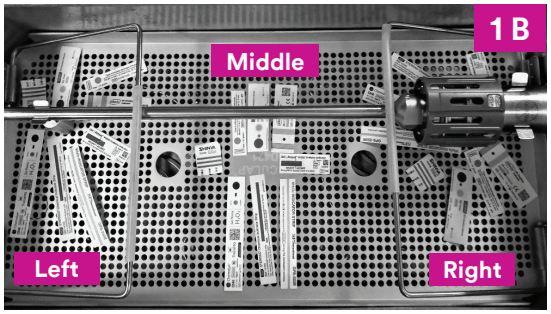


Processed accept

Figure 1 A to D: Showing the Position of CIs Placed Within Different Load Configurations







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Results

Table 1: Visual interpretation of the colour change indicated by CIs exposed to the test conditions shown. Results are expressed as the number of Fail results within each replicate group when interpreted accordingto the manufacturer's instructions (i.e., comparison with a colour reference printed on the CI or in IFUs or as instructed by IFUs). The accuracy and precision, expressed as a percentage, of each set of indicators expresses a value related to the proportion of false and true pass and fails (see text).

Test Condition	Position in Tray	AuC[d] (mean, range) (mg.s/l)	A ASP	B Shinva	C Celerity[c]	D Verify[c]	E Tri-Metric[c]	F Gke[a]	G SPS	H Terragene[b]
Recommended condition Xi. Xi Probe / ASP STERRAD EXPRESS cycle	Left	1237 (921–1453)	0/10	0/10	1/10	1/10	1/10	0/10	0/10	0/10
	Middle		0/10	0/10	2/10	1/10	2/10	0/10	1/10	0/10
	Right		0/10	0/10	1/10	4/10	2/10	0/10	0/10	0/10
Exceeds sterilizer manufacturer's cycle load weight limit DV1. One DaVinci probe / ASP STERRAD EXPRESS cycle	Left	874 (763–1146)	0/10	0/10	7/10	10/10	10/10	0/10	6/10	0/10
	Middle		0/10	0/10	7/10	10/10	10/10	0/10	7/10	2/10
	Right		0/10	0/10	5/10	10/10	10/10	0/10	6/10	0/10
Exceeds sterilizer manufacturer's cycle load weight limit DV2. Two DaVinci probes / ASP STERRAD EXPRESS cycle	Left	838 (695–965)	0/10	0/10	7/10	10/10	10/10	0/10	7/10	0/10
	Middle		0/10	0/10	8/10	10/10	10/10	0/10	7/10	0/10
	Right		0/10	0/10	7/10	10/10	10/10	0/10	8/10	0/10
Incorrect cycle type per device manufacturer StE. Stryker Camera probe / ASP STERRAD EXPRESS cycle	Centre	1760 (1597–1971)	0/10	0/10	2/10	10/10	10/10	0/10	8/10	0/10
	Outer Edges		4/20	0/20	17/20	6/20	20/20	0/20	20/20	0/20
Recommended condition StS. Stryker Camera probe / ASP STERRAD Standard cycle	Centre	6902 (6642–7371)	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10
	Outer Edges		0/20	0/20	0/20	0/10	0/20	0/20	0/20	0/20
Accuracy (%)			43	40	77	87	97	40	85	41
Precision (%)			41	40	65	79	100	40	74	41

a: Product F was extremely difficult to interpret with all CI colours being a similar turquoise / aquamarine / blue-green and therefore could be interpreted as a pass or fail.

b: The reference colour printed on CI H varied in depth of green some being much darker than others thereby giving rise to possible misinterpretation.

c: CIs C, D and E gave colour changes very close to their endpoint when exposed to test condition Xi making absolute interpretation of the result difficult. The following observations were interpreted as fails. Product D had a very slightly observable magenta ring around the central yellow portion. Product C was a red/yellow colour rather than the reference orange. Product E had a slightly mauve colour in the accept zone rather than the described pink.

d: AuC is the area under the VH2O2 concentration curve measured from within the chamber. Test condition Xi was significantly higher ($p \leq 0.05$) than test conditions DV1 and DV2 which were equal.

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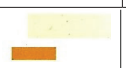
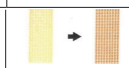
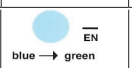
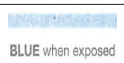
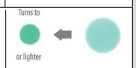
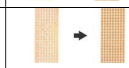
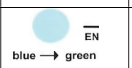
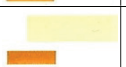
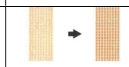
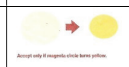
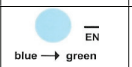
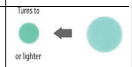
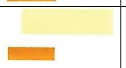
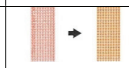
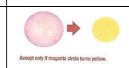
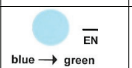
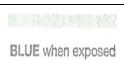
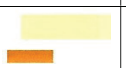
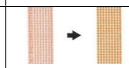
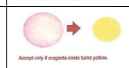
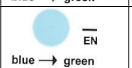
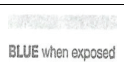
Table 2: Examples of the colour change indicated by CIs exposed to the test conditions shown (also see Table 1). For product A the indicator colour in the final two rows had changed to a very light yellow which photographic reproduction has not detected.

Test Condition	Position in Tray	A ASP	B Shinva	C Celerity[c]	D Verify[c]	E Tri-Metric[c]	F Gke[a]	G SPS	H Terragene[b]
Xi. Xi Probe / ASP STERRAD EXPRESS cycle	Left								
	Middle								
	Right								
DV1. One DaVinci probe / ASP STERRAD EXPRESS cycle	Left								
	Middle								
	Right								
DV2. Two DaVinci probes / ASP STERRAD EXPRESS cycle	Left								
	Middle								
	Right								
StE. Stryker Camera probe / ASP STERRAD EXPRESS cycle	Centre								
	Outer Edges								
StS. Stryker Camera probe / ASP STERRAD Standard cycle	Centre								
	Outer Edges								

For footnotes a to c see Table 1. Table and images reproduced from: Kirk B. Detecting vaporised hydrogen peroxide sterilization (VH2O2) process failures in clinical settings using chemical indicators. Zentr Steril 2020;28 (6): 334-343

Conclusions

Not all of the CIs examined were capable of indicating if a VH2O2 sterilization process had been used according to recommendations. Of the CIs exhibiting such capability, results showed that when placed within instrument sets, they were a valuable aid in detecting sterilization process failures. Products Steris Celerity, Steris Verify, 3M Tri-Metric and SPS were capable of indicating failures due to incorrect loading or use of an incorrect process. Products 3M Tri-Metric and SPS were also capable of indicating non-uniformity of sterilizing conditions within instrument sets and would prove useful in PQ studies in addition to routine use for detecting sterilization failures. Of the CIs tested, the 3M Tri-Metric had the highest accuracy and precision indices in terms of correctly detecting failures.

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