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VH202

Evaluation of a number of chemical indicators for monitoring vaporized hydrogen peroxide (VH2O2) sterilization processes

Zentralsterilization | Volume 28 | 4/2020, Dr. Brian Kirk.

Study objective

The study evaluated the characteristics and performance of eight chemical indicators (CIs) for monitoring VH2O2 sterilization processes of Type 1 and Type 4 CIs according to EN ISO 11140-1.

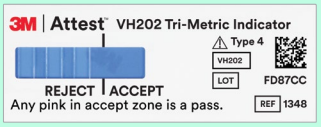
Methods

CIs were exposed to processes in which VH2O2 concentration ([c]), temperature (T) and time (t) were changed to give Type 1 and Type 4 pass and fail conditions as described in EN ISO 11140-1. Changes to individual variables then explored the performance of the CIs similar to the approach taken for steam and ethylene oxide Type 5 CIs. Colour change was evaluated visually, according to manufacturer's instructions, by comparison to a colour reference when supplied and by reflectance colourimetry.

Solventum key take aways

3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348 more accurately measures failures in the critical process variables of temperature, exposure time, and VH2O2 concentration as compared to all Type 1 and Type 4 VH2O2 CIs tested.

Attest tri-metric CI 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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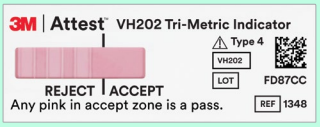

Processed accept

Results

Definitions of test conditions in the table provided by Solventum	Test Conditions	Type 1 Chemical Indicators				Type 4 Chemical Indicators			
		A ASP Sterrad	B Shinva	C Steris Celerity[1]	D Steris Verify[2]	E 3M Tri-Metric	F Gke steri rec[3]	G SPS	H Terragene Chemdye[4]
	Unexposed					REJECT ACCEPT	blue → green	BLUE when exposed	Turns to or lighter
ISO 11140-1 Pass Condition	Pass Condition					REJECT ACCEPT	blue → green	BLUE when exposed	Turns to or lighter
ISO 11140-1 Fail Condition	Fail Condition					REJECT ACCEPT	blue → green	BLUE when exposed	Turns to or lighter
20% Reduction in VH2O2 Concentration	SV [c] – 20% [c]					REJECT ACCEPT	blue → green	BLUE when exposed	Turns to or lighter
20% Reduction in Time	SV t – 20% t					REJECT ACCEPT	blue → green	BLUE when exposed	Turns to or lighter
20% Reduction in Time 10% Reduction in Temp	SV T – 10% SV t – 20% T+t					REJECT ACCEPT	blue → green	BLUE when exposed	Turns to or lighter
Control Condition #1 Double Exposure Time	T1 Pass (t x 2)		NT[5]			REJECT ACCEPT	blue → green	BLUE when exposed	Turns to or lighter
Control Condition #2 Full Hospital Cycle	ASP Sterrad NX100 standard cycle[6]					REJECT ACCEPT	blue → green	BLUE when exposed	Turns to or lighter

Table reproduced from: Kirk B. Evaluation of a number of chemical indicators for monitoring vaporized hydrogen peroxide (VH2O2) sterilization processes. Zentralsterilization 2020; 28 (4): 214–223. Footnotes to the above table are on the back of this paper.

Conclusions

This study examined the performance of eight Type 1 and Type 4 CIs for VH2O2 sterilization processes. A mixture of responses was observed. Some indicators gave appropriate pass and fail results, others gave all passes and some all fails. Performance was also examined when exposure to process variables was individually reduced ([c], t -20%) and where a combination of T+t were both reduced together (10% and 20%). Some indicators were unable to detect these decreases, some were able to detect some of the changes and **one was able to detect all three of the changes made**.

Footnotes

a: When the Steris Celerity CI was exposed to 3.7mg/L VH2O2 peak concentration, (2.8mg average, range 3.7 to 2.1) at 50°C for 720 seconds the indicator ink matched the reference orange colour.

b: The Verify indicator appeared yellow by visual observation however the pictures shown in the table show this as a light pink colour which can only be assumed an anomaly of reproduction.

c: The gke IfU shows pale green endpoint and the CI is printed with green as an endpoint. The observed colours which are annotated Pass appeared aquamarine (light blue/green) rather than a pure green.

d: The Terragene Chemdye IfU indicates an aquamarine (light blue/green) endpoint colour. The indicator itself has a green reference dot. All samples tested changed to aquamarine not green.

e: The CI was not tested (NT) in this condition having turned Yellow (endpoint) at the Type 1 Pass condition.

f: The ASP Sterrad CI turned a very pale yellow, almost white colour when eposed to this test condition resulting in poor photographic reproduction.

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EN_GL_70-2-11-8072-9