

V-PRO[®] Low Temperature Sterilization System

Environmental H₂O₂ Safety Profile

V-PRO[®] Sterilizer Environmental H₂O₂ Safety Testing

No matter where you work, we all expect to go home at the end of each day safe and sound. At STERIS, we believe this is of the utmost importance for our Customers and employees. Safety is our most important activity at work, whether in sterile processing, manufacturing or servicing equipment, and with over 124 years of practice, STERIS is a world class expert on safety with the record to prove it.

Sterile processing department (SPD) managers are required to be knowledgeable on a vast array of standards. With something as important as employee safety, it is imperative to seek out current government standards, occupational health organizations, certified industrial hygiene experts or other similarly educated professionals for guidance and support. This is a summary of how STERIS uses these resources when testing the safety of the V-PRO[®] Sterilizers, and the results, which validate the environmental safety of the V-PRO Sterilizers for healthcare employees.

Background

To protect healthcare employees, the Occupational Safety and Health Administration (OSHA) has established a Permissible Exposure Limit (PEL) for hydrogen peroxide exposure of 1 ppm over an 8-hour Time Weighted Average (TWA). For many departments, an 8-hour TWA correlates to the exposure an employee may encounter during an 8-hour shift. A different evaluation for transient exposures is the short-term exposure limit (STEL), which is the maximum amount of a chemical that an employee can safely be exposed to over a 15-minute period. Where established, this short-term limit can ensure that large chemical exposure is not minimized when averaged over 8 hours. While STELs exist for many chemicals, OSHA has not established a STEL for hydrogen peroxide. In countries outside the United States, different occupational health organizations have established their own PELs and STELs for hydrogen peroxide. See Table 1 for a few examples.

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Table 1. Examples of Global Hydrogen Peroxide Exposure Limits

Country	PEL 8-hour TWA (ppm)	STEL/ 15-min TWA (ppm)	Reference
USA	1	Not established	OSHA, 29 CFR 1910.1000, Table Z-1
Australia	1	Not established	Safe Work Australia, Workplace-exposure-standards-airborne-contaminants, 2013
France	1	Not established	INRS, H ₂ O ₂ Base de données FICHES TOXICOLOGIQUES, 2016
Germany	0.5	0.5	MAK-Werte Liste, 2012
Mexico	1	2	NORMA Oficial Mexicana NOM-010-STPS-1999
Poland	1.5	4	Ministra Pracy i Polityki Społecznej, 2005
Spain	1	Not established	INSHT LÍMITES DE EXPOSICIÓN PROFESIONAL PARA AGENTES QUÍMICOS EN ESPAÑA, 2008
UK	1	2	HSE EH40, 2011

Test Methodology

Since OSHA is the organization responsible for workplace safety standards in the United States, the hydrogen peroxide monitoring was conducted in accordance with the fully validated OSHA test method, 1019². An independent industrial hygienist (Certified Industrial Hygienist and Certified Safety Professional) conducted the testing in accordance with practices outlined in 21 CFR § 58 Good Laboratory Practices (GLP) for Non Clinical Laboratory Studies¹. The V-PRO Sterilizers used for the testing were installed and maintained according to STERIS's recommendations.

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There are two approaches for monitoring workers' chemical exposure in the workplace:

- Employee breathing zone measurements, which are critical as they evaluate the actual exposure for the employee.
- Monitoring the area near chemical source, which may identify unsafe levels prior to an exposure.

STERIS included both approaches in this testing.

In accordance with the OSHA method 1019, a calibrated pump was used to draw air across a coated filter. The measurements were collected at three (3) locations: above the door of the V-PRO maX Sterilizer (Figure 1), above the door of the V-PRO 60 Sterilizer (Figure 2), and in the employee's breathing zone (Figure 3). On each sterilizer, the filters used to collect the samples (for both the PEL and 15-minute exposure) were placed directly above the sterilizer door, flush with the front of the sterilizer.



Figure 1: V-PRO maX Sterilizer with filters



Figure 1: V-PRO 60 Sterilizer with filters

On the employee, the devices used to collect the samples (for both PEL and 15-minute exposure) were placed within the employee's breathing zone.



Figure 2: Employee with filters in breathing zone

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How the Testing was Performed

The two sterilizers processed loads continuously during the test, as is typical in many sterile processing departments. The Non Lumen Cycle for both the V-PRO maX and V-PRO 60 Sterilizers was used since it is the shortest duration cycle (28 minutes), and therefore created the most potential exposures during a workday. Use of other longer V-PRO Sterilizer cycles would reduce the number of times the employee approached the sterilizer and would reduce the exposure to the chemical source. The 2-sterilizer, shortest cycle method creates a realistic but challenging scenario to evaluate environmental employee safety.

Samples were collected for the PEL evaluation (which included loading, unloading and in-cycle processing time for the sterilizers) as the sterilizers continuously processed loads. Within the same test period, two separate 15-minute exposure samples were collected for each sterilizer individually as well as for the employee operating both sterilizers.

The employee 15-minute evaluations were coordinated to align with the time that, for both sterilizers, the employee unloaded the sterilizer at the end of cycle, transported the load, and placed a new load into the sterilizer. This method maximized the number of times there was interaction with the sterilizers during the 15-minute periods, making this an ideal test to evaluate the employee's short term exposure.

In addition, loads consisted of double-wrapped sterilization trays for which all materials were labelled for use in V-PRO Sterilizers. All cycles completed normally during the test.

All samples were analyzed by an accredited Industrial Hygiene laboratory in accordance with the OSHA test method 1019.

Results

Breathing zone measurements are the most relevant to understand employee safety as these measurements evaluate actual employee exposure. **Measurements taken at the breathing zone of the employee and above both sterilizers were below the OSHA PEL of 1 ppm over an 8-hour TWA as well as below PELs established outside the United States** (Table 1). Note that the employee exposure (Table 2) while loading, unloading and operating two sterilizers is less than the sum of the two sterilizer measurements.

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Table 2. Test Results

Collection Site	8-hour TWA (ppm)	15-min TWA (ppm)	
		#1	#2
V-PRO maX Sterilizer	0.26	0.43	0.40
V-PRO 60 Sterilizer	0.11	*	0.23
Employee Breathing Zone	0.12	*	*

* Less than the analytical test method detection limit.

There is no OSHA short term exposure limit (STEL) for hydrogen peroxide; however occupational health organizations outside the United States (Table 1) have established STELs for hydrogen peroxide. **The employee breathing zone results for the 15-minute exposures evaluated in this testing are less than the test detection limit and are all below STEL limits set outside the United States.**

The American Conference of Governmental Industrial Hygienists (ACGIH®) is a member-based organization that advances occupational and environmental health, to include publication of annual editions of the TLVs® and BEIs® book. TLVs® and BEIs® are not standards, but provide guidelines for those trained in the practice of industrial hygiene. With regards to short term exposure limits, ACGIH suggests that:

Transient increases in workers' exposure levels may exceed 3 times the value of the TLV-TWA level for no more than 15 minutes at a time, on no more than 4 occasions spaced 1 hour apart during a workday, and under no circumstances should they exceed 5 times the value of the TLV-TWA level. In addition, the 8-hour TWA is not to be exceeded for an 8-hour work period. This guidance on limiting peak exposures above the value of the TLV-TWA is analogous to that for the TLV-STEL, and both represent 15-minute exposure limits.³

Test results from 15-minute exposure monitoring in Table 2, which takes into account the air volume, sampling time, and sampling rate requirements of OSHA occupational monitoring, are well beneath actionable levels recommended by the ACGIH to industrial hygiene professionals (5 x 1ppm = 5ppm as a 15-minute TWA). Therefore, testing in accordance with the OSHA test method supports the overall safety of V-PRO Sterilizers.

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Conclusions

This testing demonstrates that the V-PRO Sterilizers are safe for healthcare employees and the environment. Hydrogen peroxide emissions from the V-PRO Sterilizer process are well below the OSHA established PEL for hydrogen peroxide (1 ppm 8-hour TWA).

The 15-minute exposure monitoring of the V-PRO Sterilizers further demonstrates the safety of these units for the workplace environment.

When performing independent environmental testing, STERIS recommends following a validated protocol such as the OSHA test method 1019 with the guidance of an industrial hygienist or other qualified personnel with experience evaluating such test systems. If using another test method to evaluate environmental emissions, a clear understanding of the monitor characteristics (which may include response time, accuracy, precision, etc.) and the impact of those characteristics on the observed values is needed to correctly interpret the data and understand how the monitor results relate to employee safety.

References

1. OSHA Occupational Safety and Health Standards, 29 CFR 1910.1000, TABLE Z-1 Limits for Air Contaminants
2. OSHA Test Method 1019 for Hydrogen Peroxide, version 1, January 2016
<https://www.osha.gov/dts/sltc/methods/validated/1019/1019.pdf>
3. ACGIH 2016 TLVs[®] and BEIs[®], ISBN 978-1-607260-84-4

Disclosures and Acknowledgements

The industrial hygienist used in this study was paid a fee for the work performed. No additional compensation was provided for participation in this testing and neither the industrial hygienist nor the associated company has a vested financial interest in STERIS or its subsidiaries.

ⁱ Compliance was not mandatory since the testing was not subject to a review and did not require Part 58 compliance. The best practices outlined were followed to help ensure the quality and integrity of the data.