

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 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

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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		

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

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