

Background

Study Method

The study was a simple comparison between four low-temperature sterilization systems – two from each manufacturer. The sterilizers from both brands are clinical in-use sterilizers.

Systems tested:

- STERRAD® 100NX® System
- STERRAD® NX® System
- V-PRO® maX
- V-PRO® 1 Plus

Continuous Environmental Testing

Continuous monitoring sensors were set up on the tops and fronts of the sterilizers to measure hydrogen peroxide concentrations near the sterilizers. The testing was performed using ChemDAQ® Steri-Trac® sensors, which are connected to a laptop computer to record the data. The sensors are specifically designed to measure very small concentrations of hydrogen peroxide and produce a linear response to increasing hydrogen peroxide concentrations.

The data was recorded beginning at the start of each cycle and ending ten minutes after the completion of the cycle. When the cycle was complete, the sterilizer door was opened.

A series of cycles were run on each of the sterilizers using different cycles and chamber loads to determine if these variables affect the environmental hydrogen peroxide concentration levels during and after the operation of the cycles. In addition, the runs were performed throughout a full day to simulate the potential effects of continual use on environmental hydrogen peroxide concentrations.

Sterilizer Cycles

Each sterilizer was run twice with a full or empty chamber through the combinations listed below in Table 1.

STANDARD, Lumen, Non-Lumen cycles are typically used to sterilize general instrumentation. FLEX and Flexible cycles are reserved for sterilizing flexible endoscopes.

Sterilizer	Cycle Types	Number of Runs
STERRAD® 100NX® System	STANDARD, FLEX	2
STERRAD® NX® System	STANDARD, ADVANCED	2
V-PRO® maX	Flexible, Lumen	2
V-PRO® 1 Plus	Non-Lumen, Lumen	2

Table 1.

FULL CHAMBER LOADS

Standard loads contain instruments which would typically be reprocessed using the appropriate cycle:

Standard Load	Flexible Scope Load
<ul style="list-style-type: none">• Sterilization tray• A silicone mat – 9"x 22"• Assorted stainless steel and plastic components	<ul style="list-style-type: none">• Sterilization tray• A silicone mat – 9"x 22"• 1 flexible endoscope
<ul style="list-style-type: none">• Used for STANDARD, Lumen, non-Lumen cycles	<ul style="list-style-type: none">• Used for FLEX and Flexible cycles

Conclusion

In a continuous hydrogen peroxide emissions monitoring test of four low-temperature sterilizers, the STERRAD® 100NX® System, STERRAD® NX® System, V-PRO® 1 Plus, and V-PRO® maX, monitors were placed on the tops and fronts of the sterilizers. Both STERRAD® System sterilizers ignite a gas plasma phase resulting in fewer measurable hydrogen peroxide emissions – none greater than 0.3 ppm. In contrast, the STERIS V-PRO® 1 Plus and V-PRO® maX sterilizers both produced significant hydrogen peroxide emissions, ranging between 5 and 20 ppm each time the chamber door was opened. The location of the sensor which made these measurements implies hydrogen peroxide clouds were emitted directly into the potential breathing zone of the operator who opens the sterilizer door to remove the load. The test results indicate that when the sterilizer doors were opened at the end of their cycles, STERIS V-PRO® sterilizers' hydrogen peroxide emissions were as much as 27 to 67 times more concentrated than those of STERRAD® System sterilizers.

The results of the study demonstrate that the STERRAD® System, which uses a gas plasma phase to dissociate hydrogen peroxide during the sterilization cycle, is more effective in limiting hydrogen peroxide emissions compared to STERIS V-PRO® sterilizers, which only passes hydrogen peroxide through a catalytic converter.

Therefore, STERRAD® Systems contribute to a safe working environment.

References

1. Occupational Safety & Health Administration website - https://www.osha.gov/dts/chemicalsampling/data/CH_246600.html
2. ACGIH® website - <http://www.acgih.org/tlv-bei-guidelines/tlv-chemical-substances-introduction> - <http://www.dir.ca.gov/title8/ac1.pdf>
3. Amsco® V-PRO® maX Low Temperature Sterilization System, Technical Data Monograph, STERIS Corporation 2013, M3635EN.2013-01, Rev. B
4. STERRAD® 100NX®, STERRAD® NX®, V-PRO® 1 Plus and V-PRO® maX Hydrogen Peroxide Emissions Testing report dated May 2016.

Disclosures and Acknowledgments

The research was designed and executed by Actionable Research, an independent third party research firm in conjunction with ChemDAQ® Inc., a manufacturer of environmental safety monitoring systems. The research sponsor was Advanced Sterilization Products. All data were collected by the ChemDAQ® staff.



Case Study Comparison Study of Environmental Hydrogen Peroxide Levels of STERRAD® Systems and STERIS V-PRO® Low Temperature Sterilizers Reveals Striking Differences

This article was prepared by Advanced Sterilization Products, and has not undergone any scientific peer review.

Introduction

The increased use of terminal sterilization for critical and temperature-sensitive medical devices has given rise to higher usage of low-temperature sterilization methods. STERRAD® Systems and V-PRO® sterilizers offer shorter sterilization cycles and use hydrogen peroxide (H₂O₂), a sterilant with a better safety profile than ethylene oxide (EtO) sterilizers. Consequently, these sterilizers have become widely used for temperature- and moisture-sensitive instrument reprocessing.

There are safety standards in place to ensure that environmental concentrations of the hydrogen peroxide remain at safe levels. The OSHA Permissible Exposure Limit (OSHA PEL) for hydrogen peroxide is currently 1 ppm,¹ which is equal to the American Conference of Governmental Industrial Hygienists (ACGIH®) Threshold Limit Value (TLV). While this concentration limit is a time-weighted average (calculated over an 8-hour period), the ACGIH® also has a short-term peak exposure, which states that at no time should the exposure exceed 5 ppm.² These limits are very low, and intended to ensure worker safety in a compliant workplace.

Likelihood of Exposure: A Technological Perspective

Manufacturers design their systems to ensure environmental hydrogen peroxide exposures are kept to a minimum. Advanced Sterilization Products claims that use of a gas plasma phase in the STERRAD® System sterilizer process dissociates unreacted hydrogen peroxide into oxygen and water, eliminating the need for aeration. Alternately, the STERIS V-PRO® sterilizers pass hydrogen peroxide through a catalytic converter where it is reduced to water and oxygen.³

In line with environmental standards regulating exposure of hydrogen peroxide, a comparison study was conducted to determine the differences in hydrogen peroxide emissions for both STERRAD® Systems and STERIS V-PRO® sterilizers.

At no time should short term exposure exceed 5 ppm.



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Background

Sensor Placement

The sensors were placed in similar positions for all sterilizers: on top of the sterilizer (on top) and directly over the sterilizer door (on front).

STERRAD® SYSTEMS



STERRAD® 100NX® System



STERRAD® NX® System

V-PRO® STERILIZERS



V-PRO® maX



V-PRO® 1 Plus

Results

In all cases, there were no notable emissions from the sterilizers during the active cycle (the time between the start and finish of each cycle). However, there were significant hydrogen peroxide emissions measured when the STERIS V-PRO® sterilizers' chamber doors were opened following the completion of each cycle.

Spikes ranging from 5 ppm to as high as 17 ppm occurred after the chamber door was opened for the V-PRO® 1 Plus sterilizer. There was no variance noted between cycle types or when the chamber was full or empty.

The V-PRO® maX system showed concentration peaks ranging from 7 ppm to as high as 20 ppm after its chamber door was opened (Graphs 2 and 4).

These spikes in concentration are indicative of a cloud of vaporous hydrogen peroxide rising up from the open chamber of each V-PRO® sterilizer. Each spike in concentration was well above the maximum ACGIH® exposure limits of 5 ppm for short-term exposure. Sensors directly above the doors of the V-PRO® sterilizers measured these concentrations for 10 minutes following a completed cycle. Moreover, this area is in proximity to where an operator would stand to remove the chamber load.

The V-PRO® maX showed concentration peaks ranging from 7 ppm to as high as 20 ppm.

The STERRAD® 100NX® and STERRAD® NX® Systems never registered a value above 0.3 ppm.

The V-PRO® maX is designed with extraction fans above the door, which are intended to reduce operator exposure to vapor. Despite this, the sensor placed on the front of the V-PRO® maX still registered concentrations following the opening of the chamber door at or above the ACGIH® a short-term peak exposure of 5 ppm in every measured case.

In comparison, for the STERRAD® 100NX® System, regardless of the cycle type, results from both sensors showed that hydrogen peroxide concentrations were well below the ACGIH® a short-term peak exposure. **The highest reading measured for the STERRAD® 100NX® System was 0.3 ppm (Graphs 1 and 3).** Results for the STERRAD® NX® System were very similar to the STERRAD® 100NX® System, never registering a value above 0.2 ppm.

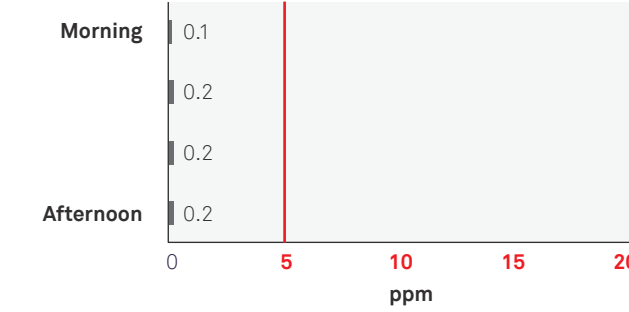
Analysis Of Measurement

The gray bars indicate measured peak concentration (ppm) levels. Red bars indicate concentration (ppm) levels above the ACGIH® permissible limit of 5 ppm.

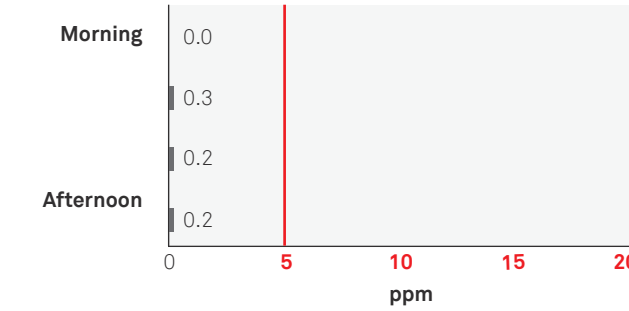
STERRAD® 100NX® SYSTEM



Graph 1.
STERRAD® 100NX® System FLEX Cycles



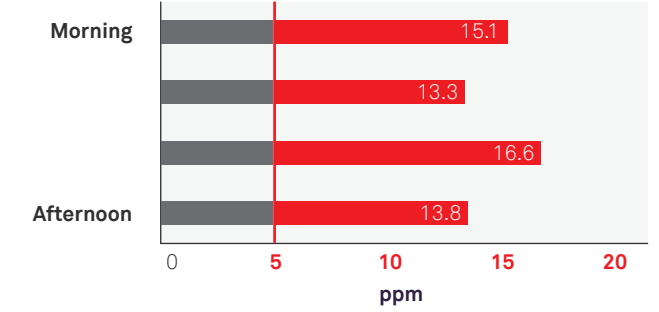
Graph 3.
STERRAD® 100NX® System STANDARD Cycles



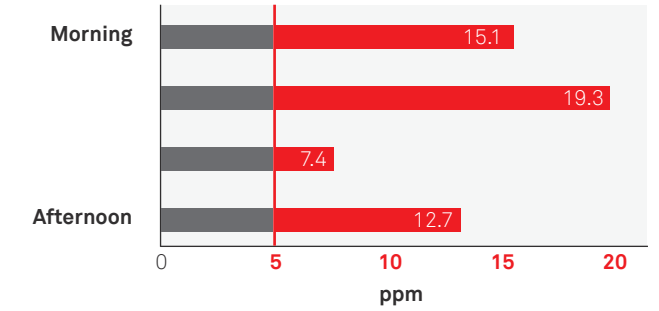
V-PRO® maX Sterilizer



Graph 2.
V-PRO® maX Flexible Cycles



Graph 4.
V-PRO® maX Lumen Cycles



Key
■ Above ACGIH® permissible limits (5 ppm)
■ Peak concentration (ppm)