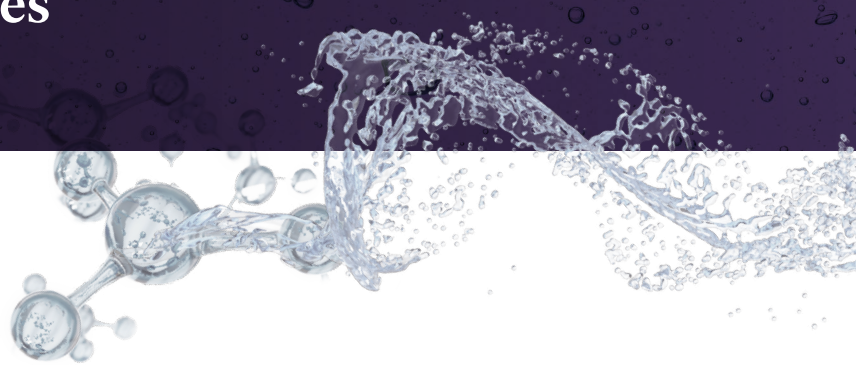
COMPARISON STUDY

# of Environmental Hydrogen Peroxide Levels of STERRAD™ Systems and Other Low-Temperature Hydrogen Peroxide Sterilizers Reveals Striking Differences



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 offer shorter sterilization cycles and use hydrogen peroxide (H_2O_2), a sterilant with a better safety profile than ethylene oxide (EtO) sterilizers. Consequently, STERRAD™ Systems and other low-temperature hydrogen peroxide 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.

AT NO TIME SHOULD SHORT-TERM EXPOSURE EXCEED 5 PPM.

Alternative low-temperature hydrogen peroxide sterilizers from other manufacturers 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 alternative hydrogen peroxide sterilizers from another manufacturer available in the market.

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

ALTERNATIVE STERILIZING SYSTEMS

Model 1

Model 2

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 alternative sterilizers' chamber doors were opened following the completion of each cycle.

For the STERRAD™ 100NX System, regardless of the cycle type, results from both the top and the front sensors showed that hydrogen peroxide concentrations were well below the ACGIH® short-term peak exposure of 5 ppm.

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.

One of the alternative sterilizing systems (model 1) showed concentration peaks ranging from 7 ppm to as high as 20 ppm after its chamber door was opened (Graphs 2 and 4).

Spikes ranging from 5 ppm to as high as 17 ppm occurred after the chamber door was opened for the other alternative sterilizer (model 2).

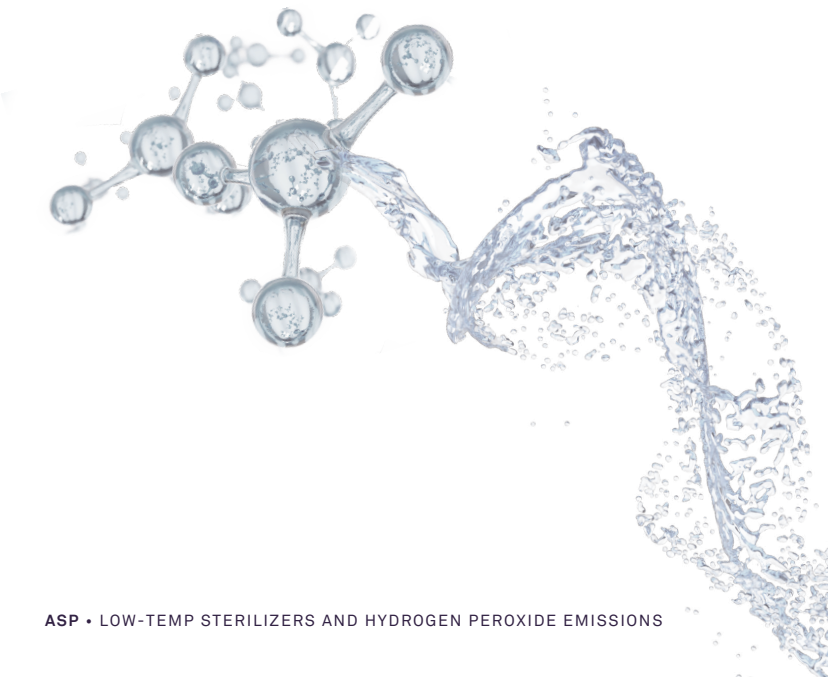
There was no variance noted between cycle types or when the chamber was full or empty.

These spikes in concentration are indicative of a cloud of vaporous hydrogen peroxide rising up from the open chamber of each sterilizer. Each spike in concentration was well above the maximum ACGIH® peak exposure limits of 5 ppm. Sensors directly above the doors of the sterilizers from the other manufacturer 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 STERRAD™ 100NX AND STERRAD NX™ SYSTEMS NEVER REGISTERED A VALUE ABOVE 0.3PPM.

The alternative sterilizer system 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 comparator sterilizer still registered concentrations following the opening of the chamber door at or above the ACGIH® short-term peak exposure of 5 ppm in every measured case.

ONE ALTERNATIVE MODEL FROM ANOTHER MANUFACTURER SHOWED CONCENTRATION PEAKS RANGING FROM 7 PPM TO AS HIGH AS 20 PPM.



ANALYSIS OF MEASUREMENT

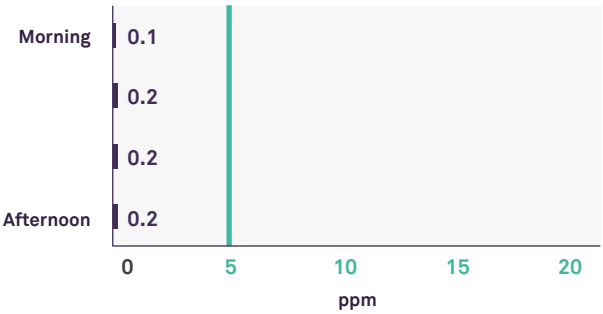
The dark violet bars indicate measured peak concentration (ppm) levels. Light green bars indicate concentration (ppm) levels above the ACGIH® permissible limit of 5 ppm.

STERRAD™ 100NX System

ALTERNATIVE STERILIZER **MODEL 1**

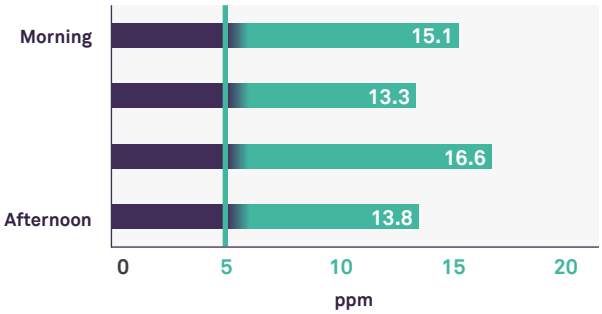
Graph 1.

STERRAD™ 100NX System FLEX Cycle



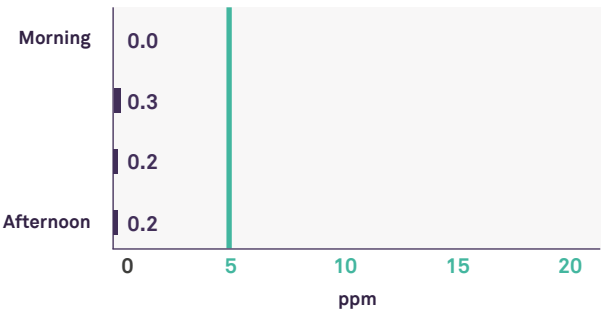
Graph 2.

Alternative Sterilizer Model 1 Flexible Cycles



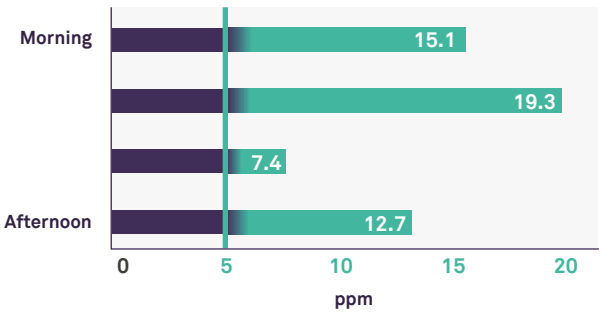
Graph 3.

STERRAD™ 100NX System STANDARD Cycles



Graph 4.

Alternative Sterilizer Model 1 Lumen Cycles



Key

- Above ACGIH® permissible limits (5 ppm)
- Peak concentration (ppm)

Background

STUDY METHOD

The study was a simple comparison between four low-temperature sterilization systems – two with STERRAD™ Technology and two from another manufacturer producing low-temperature hydrogen peroxide sterilizers using a catalytic converter. The sterilizers from both brands are clinical in-use sterilizers. The STERRAD™ 100NX and STERRAD NX™ Systems were tested against two comparable models from the alternative manufacturer.

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. Data recording began at the start of each cycle and ended 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.

Table 1.

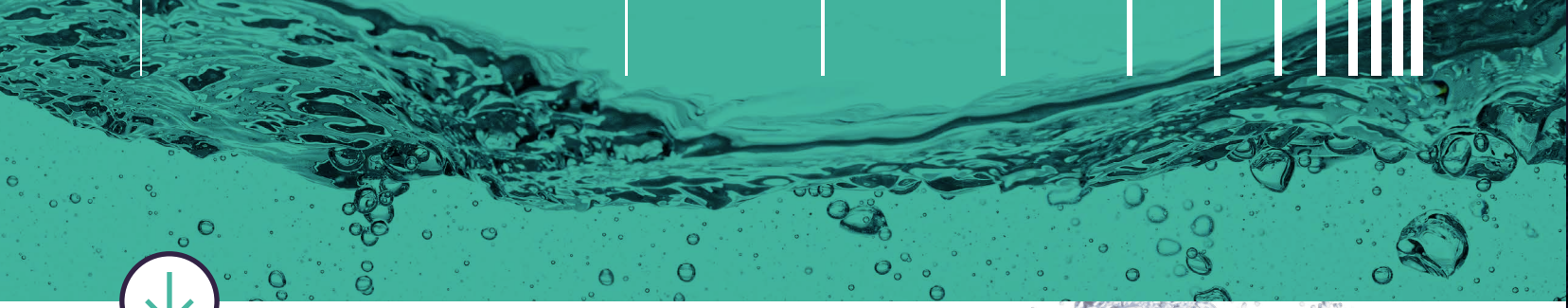
STERILIZER	CYCLE TYPES	NUMBER OF RUNS
STERRAD™ 100NX System	STANDARD, FLEX	2
STERRAD NX™ System	STANDARD, ADVANCED	2
ALTERNATIVE STERILIZER MODEL 1	Flexible, Lumen	2
ALTERNATIVE STERILIZER MODEL 2	Non-Lumen, Lumen	2

FULL CHAMBER LOADS

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

Table 2.

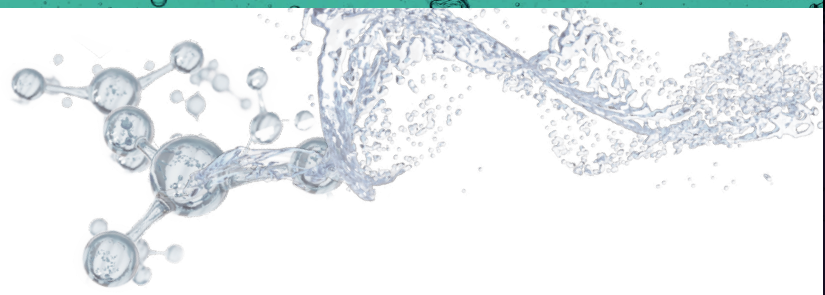
STANDARD LOAD	FLEXIBLE SCOPE LOAD
• Sterilization tray	• Sterilization tray
• A silicone mat ~ 9"x 22"	• A silicone mat ~ 9"x 22"
• Assorted stainless steel and plastic components	• 1 flexible endoscope
• Used for STANDARD, Lumen, non-Lumen cycles	• Used for FLEX and Flexible cycles



Conclusion

In a continuous hydrogen peroxide emissions monitoring test of four low-temperature sterilizers, the STERRAD™ 100NX and STERRAD NX™ Systems, along with two other sterilizer systems from another manufacturer, 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 comparator 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, the hydrogen peroxide emissions from STERRAD™ Sterilization Systems were up to 67 times less concentrated than those of other low-temperature hydrogen peroxide sterilizers from another manufacturer.

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 alternative models, which only pass hydrogen peroxide through a catalytic converter. Therefore, STERRAD™ Systems contribute to a safe working environment.



STERRAD™ STERILIZATION SYSTEMS H_2O_2 EMISSIONS WERE UP TO 67 TIMES LOWER THAN THOSE FROM ALTERNATIVE MODELS IN THE MARKET.

The ACGIH® states that at no time should short-term exposure of hydrogen peroxide exceed 5 ppm.[2] Although similar safety studies carried out by the manufacturer of the alternative sterilizers studied here indicated that their sterilizers did not breach the 8-hour PEL or the 15-minute short-term exposure level (STEL),[4] our results showed instantaneous peak measurements of hydrogen peroxide reached up to 20 ppm, breaching the guidelines set by the ACGIH®, and contributing to a more hazardous working environment.

Reference

1.Occupational Safety & Health Administration website. Available online at https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1000TABLEZ1
2.ACGIH® website. Available online at http://www.acgih.org/tlv-bei-guidelines/tlv-chemical-substances-introduction
3.Product information regarding the 3rd party product is available from ASP
4.Information regarding environmental testing of the 3rd party product is available from ASP

Disclosures and Acknowledgments

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