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

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 in each of the sterilizers using different cycles and chamber loads to determine if these variables affect the environmental safety in a compliant workplace.

V-PRO® sterilizers
H₂O₂ emissions ranged from 27 to 67 times higher from STERRAD® Systems sterilizers.

STERILIZATION CYCLES
Each sterilizer was run twice with a full or empty chamber, with 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. Cycle Types

<table>
<thead>
<tr>
<th>Sterilizer Type</th>
<th>Cycle Types</th>
<th>Number of Runs</th>
</tr>
</thead>
<tbody>
<tr>
<td>STERRAD® 100NX®</td>
<td>Standard, Flex</td>
<td>2</td>
</tr>
<tr>
<td>STERRAD® NX®</td>
<td>Advanced</td>
<td>2</td>
</tr>
<tr>
<td>V-PRO® 1 Plus</td>
<td>Flexible, Lumen</td>
<td>2</td>
</tr>
<tr>
<td>V-PRO® 1 Plus</td>
<td>FLEX</td>
<td>2</td>
</tr>
</tbody>
</table>

FULL CHAMBER LOADS
Standard loads contain instruments which would typically be represented using the appropriate cycle types.

- Sterilization load
- Sterilization load + Flex Path
- Absorbed dosimeters and plastic components
- Low-temperature sterilizable components
- Used for FLEX and Flexible endoscopes

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® Flex nail, monitoring hydrogen peroxide emissions placed on the tops and fronts of the sterilizers. Both STERRAD® System sterilizers ignite a gas plasma phase resulting in lower measurable hydrogen peroxide emissions, more than 90% lower than STERIS V-PRO® 1 Plus and V-PRO® Flex nail sterilizers both produced significant hydrogen peroxide emissions, ranging between 5 and 20 ppm each time the chamber door was opened. The location of the chamber door made these measurements imply 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 are opened at the end of their cycles, STERRAD® System sterilizers ignite a gas plasma phase resulting in fewer measurable hydrogen peroxide emissions – none greater than 0.3 ppm. In contrast, those of STERRAD® System sterilizers 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 gas during the sterilization cycle, is more effective in limiting hydrogen peroxide emissions compared to STERIS V-PRO® sterilizers, which only pass hydrogen peroxide through a catalytic converter. Therefore, STERRAD® Systems contribute to a safer working environment.

Comparison Study of Environmental Hydrogen Peroxide Levels of STERRAD® Systems and STERIS V-PRO® Low Temperature 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 and V-PRO® sterilizers offer shorter sterilization cycles and use hydrogen peroxide (H₂O₂), a sterilant with a better safety profile than ethylene oxide (ETO) sterilants. Consequently, these sterilizers have become widely utilized for temperature- and moisture-sensitive medical devices.

There are safety standards in place to ensure that environmental concentrations of the hydrogen peroxide remain at safe levels. The OSHA Permissible Exposure Limit (PEL) for hydrogen peroxide is currently 1 ppm, 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. These limits are very strict, and intended to ensure worker safety in a compliant workplace.

LIKELIHOOD OF EXPOSURE: A TECHNICAL 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 produces unreacted hydrogen peroxide, which is converted to 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.

At no time should short term exposure exceed 5 ppm.

References
4. Continuous cycle, flex i.e. a 1 flexible endoscope + 1 plus and PRP® nail hydrogen Peroxide Emissions Testing report dated 2014.

Disclosures and Acknowledgments
The research was designed and executed by Noli Institute, a noncommercial independent research firm in cooperation with ChemDAQ Inc., a manufacturer of global safety monitoring systems. The manufacturers were not compensated for this study. The research was conducted under the guidance of the ChemDAQ staff.

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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 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® 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.

The V-PRO maX and STERRAD NX® Systems never registered a value above 0.3 ppm.

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