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Material Compatibility with Hybrid Hydrogen Peroxide on Critical Laboratory Equipment and Sensors after 125 Cycles of Exposure

Synopsis

This study sought to support normal pharmaceutical laboratory operations by exposing commonly used sensitive laboratory equipment, a particle counter, to 100 hours of hybrid hydrogen peroxide (HHP) biodecontamination. Following 125 decontamination cycles, this work assessed the impacts on the particle counter. Material compatibility was proven by two methods—zero-count testing and quality testing performed by the manufacturer. All zero-count tests produced successful results demonstrating no introduction of contaminants that would instigate false counts. Quality testing and inspection showed the particle counter's calibration remained in tolerance, finding no detrimental effects to material compatibility, optic sensors, or electronic function. Further, efficacy testing employing *Geobacillus stearothermophilus* biological indicators (2.2×10^6 population) demonstrated sporicidal efficacy of the HHP cycle even within areas of limited access on the particle counter itself (tested at 20-100 mm). This work supports laboratory functions demonstrating that 100 hours of exposure to CURIS HHP decontamination is non-impactful on the operation of this important piece of equipment.

Background

Vaporous biodecontamination practices are an integral part of pharmaceutical and laboratory operations. Laboratories contain sensitive, calibrated equipment which must itself be periodically decontaminated either alone or within the laboratory. Examples of this are microscopes, particle counters, and incubators with sensitive sensors. Facilities require that common decontamination procedures are not only efficacious, but that they are also compatible with laboratory equipment.

Current studies show that some decontamination methods are challenged by small crevices,[1] such as those found on laboratory equipment. With potentially limited access to these small areas, gaseous decontamination methods may not be as effective as on more exposed surfaces. Research is needed to better understand this dynamic and ensure decontamination practices are thorough.

Many past and current decontamination methods can pose health risks to staff,[2] affect equipment functionality by burning out sensors or damaging lenses, and even reduce longevity by causing corrosion or brittleness. In contrast, some modern decontamination technology can achieve equivalent efficacy at greater safety margins for workers and equipment.[3] Biodecontamination processes that are fast, thorough, compatible with equipment, and safer for personnel continue to be of interest.

Introduction

To investigate the relationship between potentially sensitive equipment and decontamination practices, the Climet Instruments Company and CURIS System collaborated to study material compatibility, reach, and efficacy of decontamination with Hybrid Hydrogen Peroxide (HHP), 7% concentration.

This work exposed a particle counter, a commonly employed and highly sensitive piece of laboratory equipment, to 100 hours of decontamination. Particle counters are frequently used in cleanroom environments in which the presence and quantity of particles need to be monitored. Ensuring this equipment is properly decontaminated helps with contamination control within a facility and supports regular laboratory functions. Particle counters contain sensitive optic lenses and calibrated electronics which could pose a challenge to finding effective decontamination methods that are compatible with these sophisticated components.

The system used to decontaminate the particle counter was the CURIS 7000ei series vapor integration system which paired with CURoxide, a 7% hydrogen peroxide solution, produces hybrid hydrogen peroxide (HHP). This decontamination technology is commonly used to decontaminate larger laboratory equipment such as biological safety cabinets,[4] isolators,[5] pass-through chambers, and others, but has not yet been tested specifically on particle counters.

This study explores the compatibility dynamics of a quick and efficacious method to provide decontamination to sensitive devices with a low concentration HHP delivery system while maintaining a sporicidal kill.

Materials

- CI-170 Particle Counter (Climet; Redlands, CA)
- Zero-Count particle filter (Climet; Redlands, CA)
- CURIS 7000ei Series Vapor Integration System (CURIS; Oviedo, FL)
- CURIS Extraction Pod (CURIS; Oviedo, FL)
- CURoxide 7% Hydrogen Peroxide Solution (CURIS; Oviedo, FL)
- *Geobacillus stearothermophilus* biological indicators Lot#AH-118 2.0 x 10^6 (Mesa Labs; Lakewood, CO)
- Hydrogen Peroxide Chemical Indicators (3M; Saint Paul, MN)
- Amprobe THWD-3 (Amprobe; Everett, WA)
- ATAGO PAL-39S (Atago; Bellevue, WA)
- ATI Series F12/D Gas Transmitter (ATI; Dallas, TX)

Methods

The particle counter was tested in a small enclosure under environmental conditions similar to those within a climate-controlled facility (Figure 1). The particle counter was open (dust cap removed) during decontamination cycles to allow exposure of the sensors inside the unit. In addition, the back panel and battery compartment were loosened to enable a gap for HHP to access the recesses of the particle counter. To reach 100 hours of exposure, 125 decontamination cycles were completed at an average of 46 minutes per cycle.

Figure 1. Particle counter during HHP decontamination cycle.

Zero Count and Quality Testing

A zero-count test was performed following every set of 10 decontamination cycles. Also commonly referred to as a False Count Test, this procedure was used to verify that HHP decontamination did not instigate false counts.[6] In addition, standard quality checks were performed on the particle counter upon completion of 100 exposure hours. No contamination or damage to electronics was found by the manufacturer, Climet, and the calibration remained within tolerance.

Microbial Efficacy Validation

Decontamination cycles were periodically measured for efficacy using *Geobacillus stearothermophilus* bacterial spore indicators at a population of 2.0 x 10^6 spores within the tested enclosure. Biological indicators (BIs), placed within the battery compartment of the device, were also used to measure the penetration of HHP into crevices of the particle counter at depths ranging from 20 mm to 100 mm (Figures 2 and 3). Following each validation cycle, BIs were aseptically transferred to tryptic soy broth and incubated at 57°C, observed for 7 days, and results recorded.

HHP Exposure Validation

Hydrogen peroxide chemical indicators were also used to visualize the coverage of the HHP within the treatment space.

Figure 2. Photo of biological and chemical indicators placed within battery compartment of the particle counter.

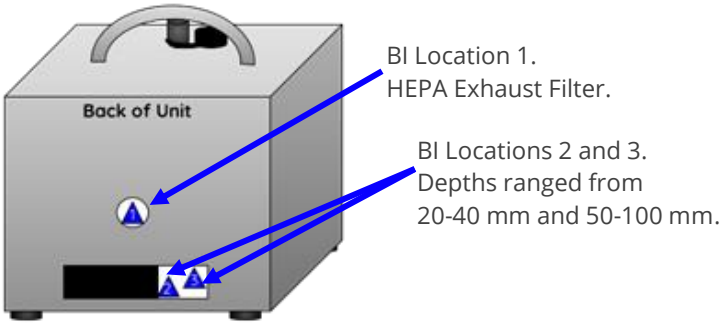

Figure 3. Biological indicator locations during HHP testing.

Results

Material & Electronic Compatibility

Optical Lens

An extensive quality check and examination by the manufacturer, Climet, found no discernable changes to the particle counter's optical lens, and the calibration remained in tolerance, proving 100 hours of HHP exposure did not affect these sensitive areas.

Electronics and Casing

The exterior of the particle counter is primarily fabricated with a stainless-steel casing framing and an electronic display screen. Following 100 exposure hours, there were no observed physical changes to the materials comprising the particle counter (see Figure 4). The electronic display was fully operational, and the stainless-steel casing was unchanged, as verified by the manufacturer of the particle counter, Climet.

Before HHP Exposure

After HHP Exposure

Figure 4. View of the particle counter before testing and following 100-hour testing.

Zero-Count Testing

All zero-count testing demonstrated no lingering residues or particles within the counter that would instigate false counts (Table 1). Normal operation of the particle counter for running zero-count testing also indicated no functional changes to the basic operation of the device.

Table 1. Summary of 100-hour hybrid hydrogen peroxide exposure testing.

Equipment Tested	Exposure Hours	# of Cycles	% H2O2	Biological Indicators (BI)	BI Passes	# of Zero Count Tests
Climet	100	125	7% (CURoxide)	2.2×10^6	41	12

In addition to zero-count testing, the particle counter was quality checked by a trained technician of the manufacturer, Climet. This quality check found that the particle counter was in good condition and the calibration remained in tolerance following 100 hours of HHP exposure. Climet confirmed that the optical lens and internal electronic components were not damaged.

Biodecontamination Efficacy

A total of 41 challenged biological indicators used throughout the 125 decontamination cycles of this study demonstrated a 6-log sporicidal efficacy both adjacent to and in areas of limited access within the battery compartment of the particle counter. These efficacious results additionally demonstrate the 100-hour exposure to HHP is equivalent to what would occur under normal laboratory practices (Figure 5).

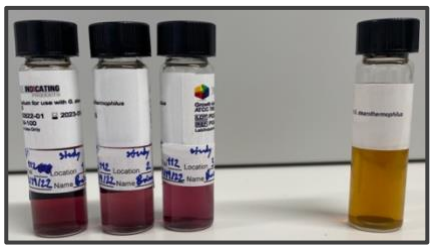

Figure 5. Biological indicators negative for growth post HHP treatment with one positive control.

Further, chemical indicators supported these results, showing a color change to indicate HHP exposure both in the tested compartment and within the battery compartment of the particle counter.

Discussion and Conclusion

In support of laboratory operations, this study investigated the efficacy and physical effects of 100 hours of exposure to HHP decontamination on a particle counter's sensitive components, simulating the real-world laboratory use of this equipment. There were no observed changes to materials, electronic functioning, or calibration of the particle counter at any point during testing or following 100 exposure hours.

At 7% H_2O_2, the lower concentration HHP cycle may provide increased material compatibility compared to that of more caustic methods,[7] helping make biodecontamination treatments safer for sensitive electronics.
Incorporation of BIs in this testing was designed to meet several purposes. First, demonstration of 6-log sporicidal efficacy confirms that the particle counter was not only exposed to HHP but, most importantly, was exposed to an equivalent level to what would take place during a standard decontamination cycle in a facility. Secondly, challenging BIs at varying depths in a limited access location helps build an understanding of the dynamics of decontaminating small crevices on equipment. The biological success observed here, ranging from 20 to 100 mm depth, shows promise that decontamination with the HHP system can migrate into and treat these challenging areas at a 6-Log sporicidal efficacy.

Quality control testing performed by the manufacturer, Climet, together with passing zero-count testing, demonstrates there was no impact to sensitive components of the particle counter. In addition, no change to calibration of the particle counter confirms the suitability of HHP decontamination for use as part of standard laboratory operations. In combination with the observed material compatibility, these results can provide facilities with peace of mind when decontaminating particle counters.

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