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Efficacy of Aerus Medical Guardian Air System against Various Bioaerosols

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Background: This in-vitro study characterized the decontamination efficacy of the Aerus Medical Guardian against various aerosolized biologicals. Aerus Medical LLC's (Bristol, VA) Medical Guardian unit is an indoor air purification system that is designed to neutralize airborne microorganisms. The effectiveness of the system was assessed for six (6) aerosolized biologicals: two vegetative bacteria: *Staphylococcus epidermidis (Gram +)* and *Erwinia herbicola (Gram -);* two viruses: MS2 (RNA bacteriophage) and Phi X174 (DNA bacteriophage); a bacterial endospore; *Bacillus globigii*, and a mold spore; *Aspergillus niger*. The testing consisted of a single control trial plus triplicate decontamination trials for each organism tested.

Methods: Each of the six (6) organisms used for testing were nebulized into a sealed environmental bioaerosol chamber containing the Aerus Medical Guardian air system. AGI impingers were used to capture chamber bioaerosol concentrations at set sampling times. Viable cascade impactors were utilized with some organisms for higher resolution sample collection. All impinger samples were serially diluted, plated and enumerated in triplicate to yield viable bioaerosol concentration at each sampling point and time. Chamber control trial data was subtracted from Medical Guardian trial data to yield net LOG reduction in the chamber for each tested bioaerosol challenge.

Results: *Staph* had an average Net LOG reduction of 5.46 +/- 0.34 for the triplicate trials. *Erwinia's* average Net LOG reduction was 5.36 +/- 0.37. The Medical Guardian's efficacy against the MS2 virus was 5.58 +/- 0.43. The performance against Phi X174 showed 4.05 +/- 0.27 net LOG reduction. The endospores, *Bacillus*, had an average net LOG reduction of 4.23 +/- 0.31, and the mold spores, *A. niger*, had a net LOG reduction of 4.12 +/- 0.10. The two test viruses, MS2 and Phi X174, organisms showed no viability after t=75minute (MS2) and T=60minutes (PhiX174), in order to calculate the net LOG kill for these organisms a fictitious single colony count was used to calculate the limits of detection for each trial and to show the minimum Net LOG reduction achieved for the Medical Guardian.

Summary: Overall, the Medical Guardian showed an average Net LOG reduction for all organisms tested of 4.80 +/- 0.74. The unit seemed most effective at removing vegetative bacteria from an environment, with an average net LOG reduction of the two vegetative bacteria tested of 5.41 +/- 0.07. However both viruses were below detectable limits due there being zero plaques observed on plates after a certain time point, meaning that the net LOG reduction for those organisms only represents a minimum value. Spores are known to be tough and highly resilient, and therefore it is not unexpected that their net LOG reductions, average 4.18 LOG, are not quite as high as the other organisms. Overall the Medical Guardian showed a high efficacy against of a broad range of viable bioaerosol.

This study was conducted in compliance with FDA Good Laboratory Practices (GLP) as defined in 21 CFR, Part 58.

Overview

This study was conducted to evaluate the efficacy of the Aerus Medical Guardian produced by Aerus Medical LLC's (Bristol, VA), to decontaminate viable airborne bioaerosols. Testing was conducted in a controlled stainless steel aerosol chamber designed to simulate a small room environment. The Medical Guardian's effectiveness was tested against six (6) Bio-safety level 1 (BSL1) organisms in order to evaluate the system's Net LOG reduction of the viable bioaerosols.

All Bioaerosol challenge testing for this study used an Aerus Medical Guardian (Model # F170A) developed by Aerus Medical LLC (Bristol, VA). A picture and details of the Medical Guardian air system is shown in **Figure 1.**

The effectiveness of the Medical Guardian was evaluated against vegetative bacterium, endospores, viruses, and mold spores. Testing with each of the six distinct organisms was completed in triplicate trials plus a control trial to demonstrate the capability of reducing viable bioaerosol concentrations. There were a total of twenty-four (24) independent trials in this study.

Each organism was examined during a set process involving a control trial and three test trials. During the control trials the Medical Guardian would remain inside the testing chamber, but would never be activated. The organisms were aerosolized into the controlled chamber, and air samples were collected at set time points throughout each trial. Comparisons of the number of living organisms between the control trials and the test trials allowed for determination of the Medical Guardian's efficacy at removing viable bioaerosols from an enclosed room environment.

	Aerus Medical Guardian
Picture:	
Device Features	
Manufacturer:	Aerus Medical LLC
Model:	F170A
Notes:	Ion Generator, Photocatalytic Oxidizer

Figure 1: *Aerus Medical Guardian air system*

Bioaerosol Testing Chamber

A large sealed aerosol test chamber was used to replicate a potentially contaminated room environment and to contain any potential release of aerosols into the surrounding environment.

The aerosol test chamber is constructed of 304 stainless steel and is equipped with three viewing windows and an air-tight lockable chamber door for system setup and general ingress and egress. The test chamber internal dimensions are 9.1ft x 9.1ft x 6.8ft, with a displacement volume of 562 cubic feet, or 15,914 liters. **Figure 2** shows a diagram of the testing chamber configuration. Testing conditions inside the chamber were consistently 72.0 F with 50% relative humidity.

The chamber is equipped with filtered HEPA inlets, digital internal temperature and humidity monitor, external humidifiers (for humidity control), lighting system, multiple sampling ports, aerosol mixing fans, and a HEPA filtered exhaust system that are operated with wireless remote control. For testing, the chamber was equipped with four 3/8 inch diameter stainless steel probes for aerosol sampling each sampling about 18" from the nearest sidewall. A stainless 1 inch diameter port was used for bio-aerosol dissemination into the chamber using a Collison 24-jet nebulizer for the bacteriophages, vegetative cells and bacterial spores, or a dry powder eductor for the fungal spores.

A ¼ inch diameter probe was used for continuous aerosol particle size monitoring via a TSI Aerodynamic Particle Sizer (APS) model 3321. All sample and dissemination ports were inserted approximately 18 inches from the interior walls of the chamber to avoid wall effects and at a height of approximately 40 inches from the floor.

The aerosol sampling and aerosol dissemination probes are stainless steel and bulk headed through the chamber walls to provide external remote access to the aerosol generator and samplers during testing.

The test chamber is equipped with two high-flow HEPA filters for the introduction of filtered purified air into the test chamber during aerosol evacuation/purging of the system between test trials and a HEPA filtered exhaust blower with a 500 ft^3/min rated flow capability for rapid evacuation of remaining bioaerosols.

A magnehelic gauge with a range of 0.0 +/- 0.5 inch H_2O (Dwyer instruments, Michigan City IN) was used to monitor and balance the system pressure during aerosol generation, aerosol purge and testing cycles.

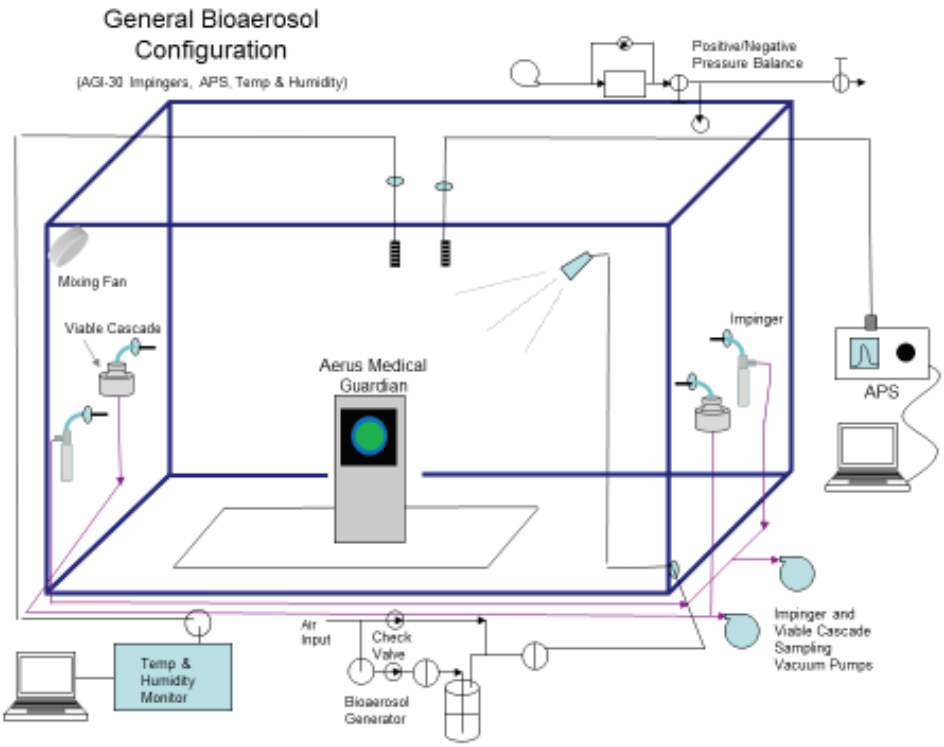

Figure 2: *Bio-Aerosol Test Chamber Flow Diagram.*

Test Location and Conditions

Testing was conducted at Aerosol Research and Engineering labs located at 15320 S. Cornice Street in Olathe, Kansas 66062. Laboratory conditions were approximately 70.6 F with 36% relative humidity.

Bioaerosol Sampling and Monitoring System

Two AGI-30 impingers (Ace Glass Inc., Vineland NJ) were used for bio-aerosol collection of biological aerosols to determine the chamber concentration. These impingers were connected to the bioaerosol chamber via sample ports located at opposite corners of the chamber.

The AGI-30 impinger vacuum source was maintained at a negative pressure of 18 inches of Hg during all characterization and test sampling to assure critical flow conditions. The AGI-30 sample impingers were flow characterized using a calibrated TSI model 4040 mass flow meter.

Aerosol particle size distributions and count concentrations were measured in real-time through the duration of all control and Aerus trial runs using a model 3321 Aerodynamic Particle Sizer (APS) (TSI Inc., St Paul, MN). The APS sampled for the entire duration of all trials (90 minutes) with 1 minute sampling intervals.

The impingers were filled with 20 mL of sterilized PBS (addition of 0.005% v/v Tween 80) for bioaerosol collection. The addition of Tween 80 was shown to increase the impinger collection efficiency and de-agglomeration of all microorganisms.

During testing with some organisms, sample collections were also obtained using a pair of viable cascade impactors. A viable cascade impactor (SKC Inc., Valley View, PA) comprises an inlet cone, precision-drilled 400-hole impactor stage, and a base that holds a standard-size agar plate (**Figure 3**). A high flow pump pulls microorganisms in air through the holes (jets) where they are collected on the agar surface.

Figure 3: SKC BioStage Viable Cascade Impactor.

Trial	Run	Species (gram, description)	ATCC Ref	Target Monodispersed Particle Size	Challenge Conc. (#/L)	Total Trial Time (min)	Impinger Sample Time (min)	Sampling	Plating and Enumeration
1 2	Control Challenge	*Stapilococcuss epidermidis* (+, vegetative)	12228	2.5-3.0µm	10^4-10^6	90	0, 15, 30, 45, 60, 75, 90	APS, Impingers & Viable Cascade	all samples in triplicate
3 4	Control Challenge	*Erwinia herbicola* (-, vegetative)	27155	2.5-3.0µm	10^4-10^6	90	0, 15, 30, 45, 60, 75, 90	APS, Impingers & Viable Cascade	all samples in triplicate
5 6	Control Challenge	*MS2 bacteriophage* (E. coli phage)	15597-B1	<50 nm	10^4-10^6	90	0, 15, 30, 45, 60, 75, 90	APS, Impingers	all samples in triplicate
7 8	Control Challenge	*Aspergillus niger* (mold, spore forming)	13835	<5.0µm	10^4-10^6	90	0, 15, 30, 45, 60, 75, 90	APS, Impingers	all samples in triplicate
9 10	Control Challenge	*Bacillus globigii* endospore *(Bacillus* Spores)	16404	<3.5 µm	10^4-10^6	90	0, 15, 30, 45, 60, 75, 90	APS, Impingers & Viable Cascade	all samples in triplicate
11 12	Control Challenge	Phi X174 bacteriophage (E. coli *phage)*	13706-B1	<50 nm	10^3-10^5	90	0, 15, 30, 45, 60, 75, 90	APS, Impingers & Viable Cascade	all samples in triplicate

Table 1: *Bioaerosol Test Matrices for all trials.*

This method of bioaerosol collection was chosen as the most sensitive and accurate sampling process for the quantification of bioaerosols with this testing configuration. With viable collection enumeration detection at one colony forming unit (cfu), direct collection onto nutrient agar, and immediate incubation after sample collection, it provides the highest sensitivity for low concentration viable aerosol collection and measurement. This method of collection was not a feasible option for all organisms due to the plating methods of viruses and growth patterns of mold spores. **Table 1** shows the complete test matrix for this study.

Bioaerosol Generation System

Test bioaerosols were disseminated using a Collison 24-jet nebulizer (BGI Inc. Waltham MA) driven by purified filtered house air supply. A pressure regulator allowed for control of disseminated particle size, use rate and sheer force generated within the Collison nebulizer. The mold spore organisms were disseminated using a dry powder aerosolization unit.

Prior to testing, the Collison nebulizer flow rate and use rate were characterized using an air supply pressure of approximately 60 psi, which obtained an output volumetric flow rate of 50-80 lpm with a fluid dissemination rate of approximately 1-2 ml/min. The Collison nebulizer was flow characterized using a calibrated TSI model 4040 mass flow meter (TSI Inc., St Paul MN).

Species Selection

Species selection is based on Biological Safety Level 1 (BSL1) surrogates for a wide range of BSL3 pathogenic organisms. It is routine in the bioaerosol field to use surrogate species to test performance against BSL3 organism decontamination due to the high cost and limited lab space associated with aerosol BSL3 testing. For this reason a broad range of viable bioaerosol surrogates were selected to specifically test the Guardian's efficacy against various types of pathogenic bioaerosols encounter in hospital and other environments.

Staphylococcus epidermidis (Gram +, ATCC 12228) acts as a surrogate for its cousin, *Staph aureus,* which has developed multi drug resistance (MRSA) and is one of the major leading causes of hospital-acquired infections.

Erwinia Herbicola (Gram -, ATCC 27155) is a Gram-negative bacterium and has been used historically as a surrogate for black plague causing bacterium, *Yersinia pestis*.

MS2 (ATCC 15597-B1) is a viral RNA bacteriophage that is commonly used as a surrogate for the influenza virus and the norovirus.

PhiX-174 (ATCC 13706-B1) is a small, single-stranded DNA virus that is often used as a surrogate for HCV, HCB, and HIV in research studies.

Aspergillus niger (ATCC 13835) endospores are used as a surrogate for several toxic black mold species such as *Stachybotrys chartarumand*.

Bacillus globigii (now named *Bacillus subtillis*) endospores (ATCC 16404) are routinely used as a surrogate for weaponized anthrax, *Bacillus anthracis*. Phi X174

Vegetative Cells Culture & Preparation

Pure strain seed stocks were purchased from ATCC (American Type Culture Collection, Manassas VA). Working stock cultures were prepared using sterile techniques in a class 2 biological safety cabinet and followed standard preparation methodologies. Approximately 100ml of *Staph* and *Erwinia Herbicola* stock was prepared in tryptic soy liquid broth media, and incubated for 24 hours with oxygen infusion (1cc/min) at 37°C. Biological stock concentrations were greater than 1 x 10^9 cfu/ml for *Staph* and *Erwinia* using this method.

Stock cultures were centrifuged for 12 minutes at 4000 rpm in sterile 50mL conical tubes, growth media was decanted, and the cells re-suspended in sterile PBS buffer for aerosolization. Aliquots of these suspensions were enumerated on tryptic soy agar plates (Hardy Diagnostics, Cincinnati OH) for viable counts and stock concentration calculations. For each organism, test working stocks were grown in sufficient volume to satisfy use quantities for all tests conducted using the same culture stock material.

Viral Culture & Preparation

Pure strain viral seed stock and host bacterium were obtained from ATCC. Host bacterium was grown in a similar fashion to the vegetative cells in an appropriate liquid media. The liquid media was infected during the logarithmic growth cycle with the specific bacteriophage. After an appropriate incubation time the cells were lysed and the cellular debris discharged by centrifugation. MS2 stock yields were greater than 1 x 10^9 plaque forming units per milliliter (pfu/ml) with a single amplification procedure. Phi X174 stock yields were less than MS2 yields, and ranged between 1 x 10^8 to 1 x 10^9 pfu/ml after two amplifications.

Endospore Culture & Preparation

Bacillus globigii spores were growth, sporelated, spray dried and stored in a pure dry powder (2.41 x 10^{11} cfu/gr.) form ahead of time. Master stocks were prepared using the pure spore and were kept stored in a 30% ethanol : 70% PBS + tween solution to maintain their endospore state and to prevent contamination by other vegetative cells. Nebulization proceed directly using this master stock.

Aspergillus niger fungal spores were also cultured, purified and stored in purified bulk powder form with a concentration of 3.4 x 10^9 cfu/gr. Due to the size of the spore (5µm diameter) nebulization was not used for dissemination of the bioaerosol, instead a custom dry eductor and feeder was used dispersed into the chamber using a ARE Labs dry powder aerosolization unit.

Plating and Enumeration

Impinger and stock biological cultures were serially diluted and plated in triplicate (multiple serial dilutions) using a standard spread plate assay technique onto tryptic soy agar plates. The plated cultures were incubated for 24-48 hours (species dependent) and enumerated and recorded.

Inert Particle Characterization

In order to calculate the dissemination efficiency, stability and to pinpoint impinger/viable cascade sample times pre-testing was conducted using polystyrene latex beads (PSL miscrospheres) prior to bioaerosol testing. PSL microspheres were used to characterize the various aspects of the chamber and Aerus system.

Polydispersed PSL beads with aerodynamic diameters of 1.0µm were nebulized and chamber concentrations were recorded using the APS. The control trials were used to calculate nebulization efficiencies, particle stability and AGI-30 collection efficiencies were used to estimate generation efficiencies, dissemination times, sample times and aerosol persistence prior to bioaerosol testing. Live trials with the Medical Guardian system were also performed to measure particle removal rates of the system.

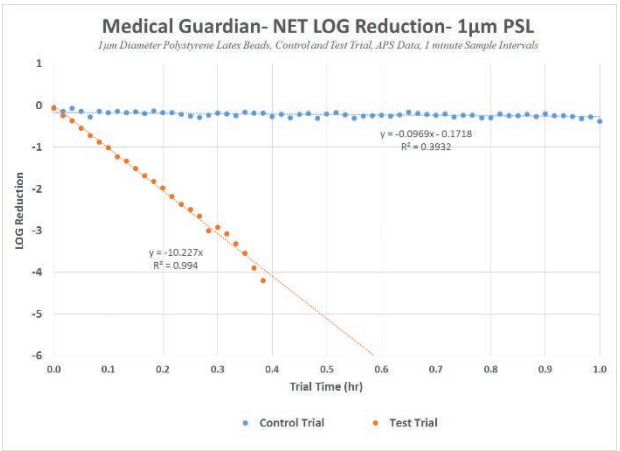

Figure 4: *LOG Reduction of 1.0um PSL Beads*

Figure 4 shows the LOG reduction of 1.0um PSL beads both with the Medical Guardian unit on (Test Trial) and off (Control Trial). The figure shows the

General Timeline for Bioaerosol Chamber Testing

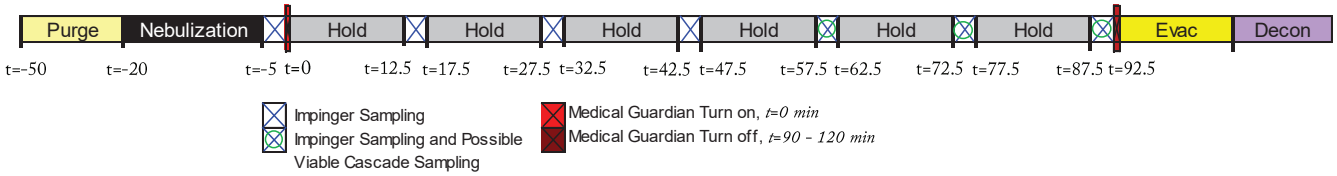

Table 2*:* General *Trial Timeline for Aerus Medical Guardian Decontamination Trials.*

comparison between the reduction with and without the Medical Guardian. When the Guardian is turned on the LOG reduction of 1.0um PSL beads follows a precise logarithmic function. It is notable that this size (1um) is smaller than the vegetative bacteria, bacterial endospores, and mold spores, but larger than the two viruses.

Control Testing

To accurately assess the Aerus Medical Guardian unit, test chamber pilot control trials were performed with all Bioaerosols from 90 to 120 minute periods without the Medical Guardian in operation to characterize the biological challenge aerosol for particle size distribution, aerosol delivery/collection efficiency, decay rate and viable concentration over time. Control testing was performed to provide baseline comparative data in order to assess the actual reduction from Medical Guardian challenge testing and verify that viable bioaerosol concentrations persisted above the required concentrations over the entire pilot control test period.

During control runs, a single low velocity fan located in the corner of the bioaerosol test chamber was turned on for the duration of trial to ensure a homogenous aerosol concentration within the aerosol chamber. The mixing fan was used for all control runs and was turned off during Medical Guardian decontamination trials. The two impingers used for bacteriophage, vegetative, fungal and bacterial endospore test sampling were pooled and mixed prior to plating and enumeration.

Medical Guardian Testing

For each control and challenge test, the Collison nebulizer was filled with approximately 50 mL of biological stock and operated at 50 psi for a period of 20 or 25 minutes (organism dependent). For control and Medical Guardian trials, the impingers were filled with 20 mL of sterilized PBS (addition of 0.005% v/v Tween 80) for bioaerosol collection. The addition of Tween 80 was shown to increase the impinger collection efficiency and de-agglomeration of all microorganisms.

The chamber mixing fan was turned on during bioaerosol dissemination to assure a homogeneous bioaerosol concentration in the test chamber prior to the first impinger sample.

Following bioaerosol generation, baseline bioaerosol concentrations were established for each pilot control and Guardian test by sampling simultaneously with two AGI-30 impingers located at opposite corners of the chamber. AGI samples were collected for 2, 5, or 10 minutes (organism dependent) at intervals of 15 minutes throughout the entire period. **Table 2** above shows the general timeline for each Medical Guardian live bioaerosol challenge trial.

Collected impinger chamber samples were pooled and mixed at each sample interval for each test. Aliquots of impinger samples were collected and then used for plating. Impingers were rinsed 6x with sterile filtered water between each sampling interval, and re-filled with sterile PBS using sterile graduated pipettes for sample collection.

For Medical Guardian biological testing, the unit was turned on immediately following a time 0 baseline sample and operated for the entirety of the test (up to 90 minutes). Subsequent impinger samples were taken at intervals of 15 minutes and samples enumerated for viable concentration to measure the effective viable bioaerosol reduction during operation of the Medical Guardian system over time. **Table 2** outlines the general timeline for the testing procedure with the Medical Guardian.

Test chamber temperature and humidity were recorded at the initiation and completion of each test.

All samples were plated in triplicate on tryptic soy agar media over a minimum of a 2 log dilution range.

Plates were incubated for viable plaque forming units (pfu) formation for the viral phase of the study, and colony forming units (cfu) for fungal spore, and bacterial endospore phases of the study. Plates were incubated and enumerated for viable counts to calculate aerosol challenge concentrations in the chamber and reduction of viable microorganisms.

Post-Testing Decontamination and Prep

Following each test, the chamber was air flow evacuated/purged for a minimum of twenty minutes between tests and analyzed with the APS for particle concentration decrease to baseline levels between each test. The chamber was decontaminated between live microorganism trials with aerosol/vaporous hydrogen peroxide (35%). The Collison nebulizer and impingers were cleaned at the conclusion of each day of testing by soaking in a 5% bleach bath for 20 minutes. The nebulizer and impingers were then submerged in a DI water bath, removed, and spray rinsed 6x with filtered DI water until use.

Data Analysis

Shows the results of the quadruplicate trials for each biological tested for this study. All results indicate the calculated viable bioaerosol concentration both upstream and downstream of the Clean Air System and the Net LOG reduction provided by the system.

All trials show individual and group average +/- standard deviations for Net LOG reduction on a per challenge organism basis.

Results by Organism

Staphylococcus epidermidis

The *S. epidermidis* are a gram positive, aerobic bacteria that grow in trypticase soy at 37°C and were chosen to act as surrogates for *Staph aurus.* Infections from *S. aurus* are a leading cause of hospital-acquired infections and are linked to 50,000 deaths in the USA per year.

Staph cultures were initiated the day prior to their testing, and grew to a concentration greater than $1e^{10}$ cfu/ml. After nebulization, initial concentrations of *Staph* averaged $2.6e^{5}$ cfu/L of atmosphere inside the testing chamber. The control trial experienced only a 0.62 LOG reduction of *Staph* after 90 minutes of sample collections using the AGI-30 impingers.

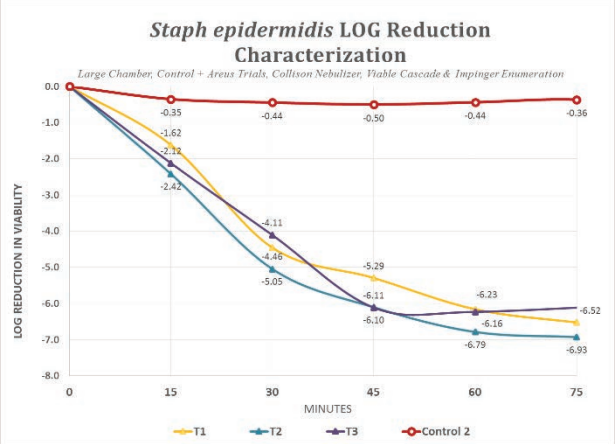

Figure 5: LOG Reduction of *S. epidermidis* in control and Medical Guardian test trials.

The Medical Guardian trials saw a drastic increase in reduction with the unit activated. In 15 minutes, over the three test trials, an average of only 1.183% of the viable *Staph* still remained inside the testing chamber. **Figure** 5 shows the LOG reduction of *Staph* for the control and test trials over the 90 minute testing periods. At 60 minutes there was an average net LOG reduction of *Staph* of 5.95 +/- 0.34 with a limit of detection of 8.15. **Figure 6** shows the LOG reductions for each *Staph* trial and their average +/- standard deviation.

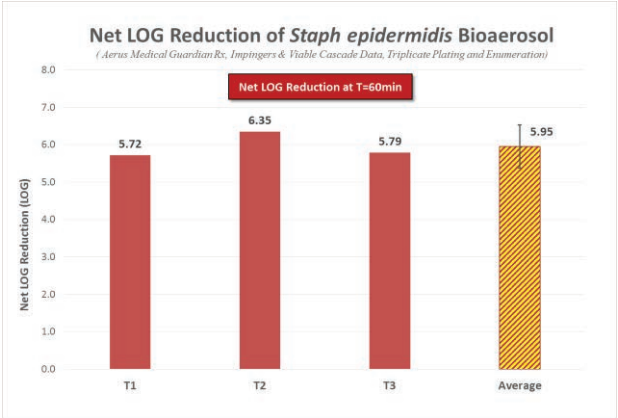

Figure 6 Net LOG Reduction of *Staphylococcus epidermidis*

Erwinia herbicola

The black plague surrogate, *Erwinia herbicola,* was the second and final vegetative bacterium tested in this study. The gram-negative bacterium were grown overnight to an average concentration of $8.4e^{9}$ cfu/ml,

and after nebulization had an average concentration of 1.9e^5 cfu/L of atmosphere inside the testing chamber.

The *Erwinia* control trial saw a 0.70 LOG reduction after 90 minutes of sample collection. After 15 minutes of being activated, the Medical Guardian removed an average of 99.992% of the viable *Erwinia* from the chamber atmosphere. The average net LOG reduction of *Erwinia* by the Medical Guardian at 75 minutes was 5.36 +/- 0.37 with a limits of detection of 7.64.

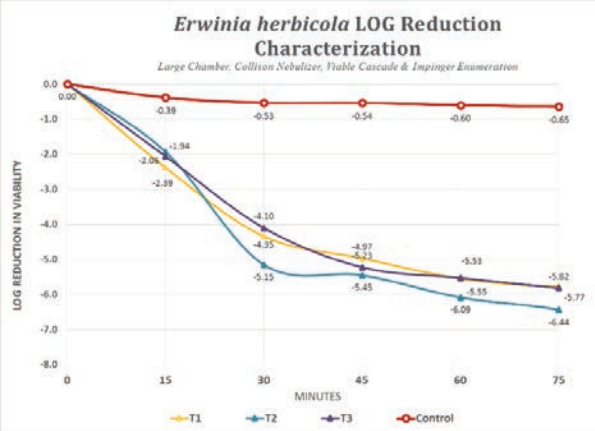

Figure 7: LOG Reduction of *Erwinia herbicola* in control and Medical Guardian test trials.

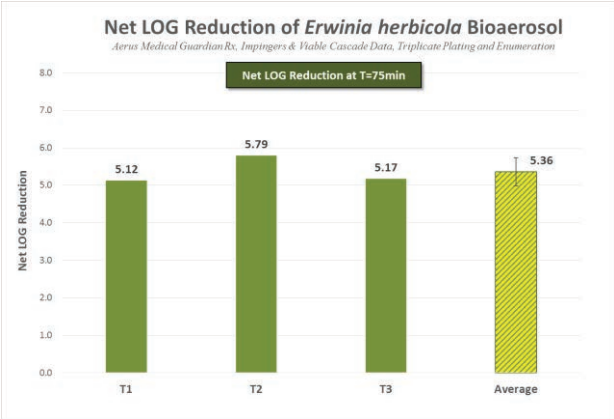

Figure 8: Net LOG *Reduction of Erwinia herbicola.*

MS2 Virus

The bacteriophage MS2 is a single stranded RNA virus that often serves as a surrogate for noroviruses in studies of disease transmission. MS2 infects *E. coli*, which was used as its mechanism of reproduction for this study. Average concentrations of MS2 reached 5.4e^9 pfu/mL in culture pre testing, and chamber concentrations after nebulization averaged 8.1e^5 pfu/L of atmosphere.

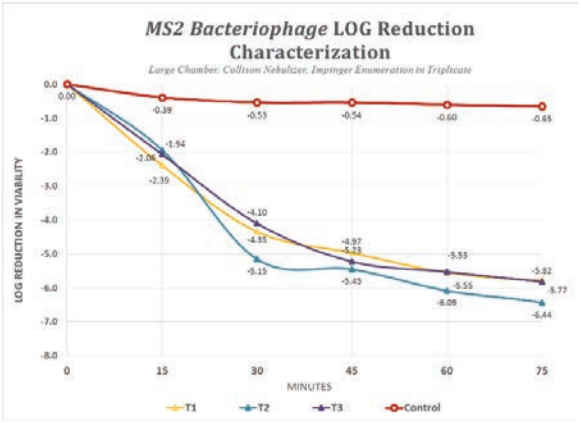

Figure 9: LOG Reduction of MS2 bacteriophage in control and Medical Guardian test trials.

The single control trial saw a slightly increased reduction in viable organisms overtime compared with the vegetative bacterium, reaching a LOG reduction of 0.94 in 90 minutes. With the Medical Guardian activated, an average of 99.999% of the virus had been removed from the chambers atmosphere in 15 minutes. At 60 minutes, there was an average net LOG reduction of MS2 of 5.58 +/- 0.43 with a limits of detection of 6.37. The Net LOG reduction is considered a minimum value because a single pfu was artificially added at 60 minutes in order to show detection limits. There were in reality, no observed viable growth collected at 60 minutes. However, if zeros were to be marked for the plates the logarithmic math does not calculate.

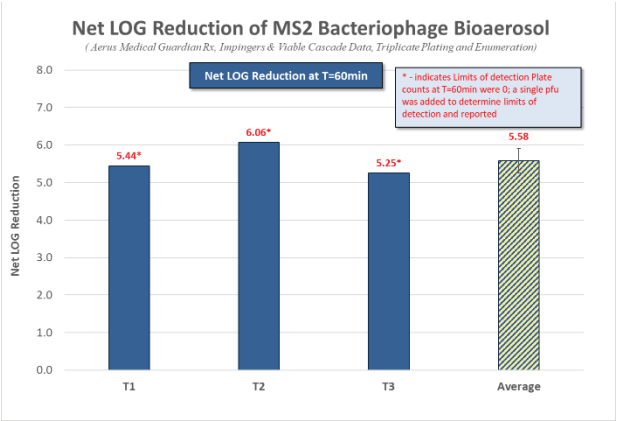

Figure 10: Net LOG Reduction of MS2 bacteriophage

***Bacillus globigii* endospores**

Endospores are an extremely resilient structure formed by some bacteria under unfavorable conditions that are resistant to UV radiation, desiccation, chemical disinfectants and severe temperatures. The *Bacillus*

globigii spores tested served as surrogates for a similar species that causes Anthrax.

Unlike the vegetative bacterium and viruses, the spores did not need to be cultured before testing. Large quantities of spores stored in alcohol can be purchased and are ready for immediate testing. Pre nebulization stock of *B. globigii* was at a concentration of $2.7e^9$ cfu/mL, and chamber concentration post nebulization had an average concentration of $7.95e^5$ cfu/L.

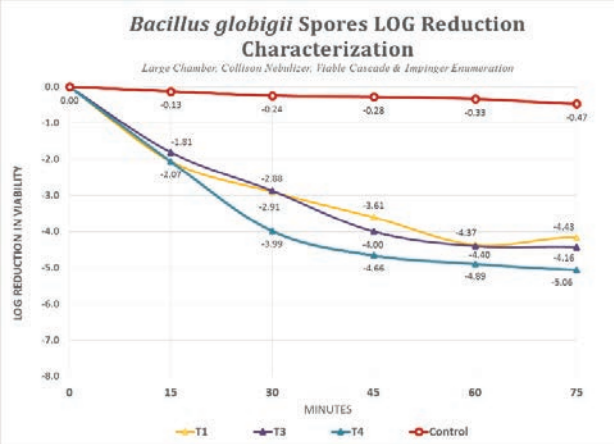

Figure 11: LOG Reduction of *Bacillus globigii* endospores in control and Medical Guardian test trials.

With the Medical Guardian off, the control trial saw a LOG reduction after 90 minutes of 0.49. After 15 minutes with the Medical Guardian activated during the test trials, 1.09% of the spores remained in the chambers atmosphere. After 90 minutes there was a net LOG reduction of 4.23 +/- 0.31 with a limits of detection of 5.70.

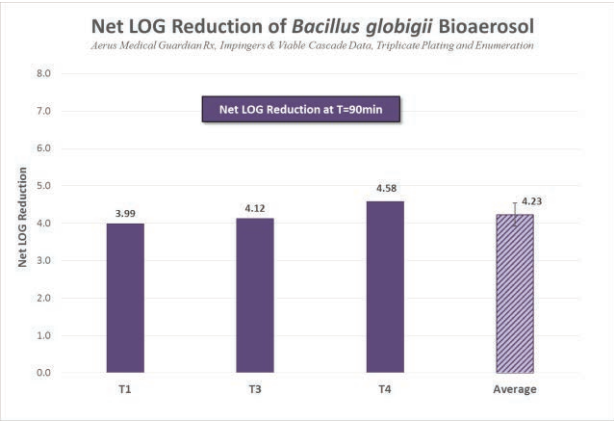

Figure 12: Net LOG Reduction of *Bacillus globigii* endospores

***Aspergillus niger* Mold Spores**

Aspergillus niger, the second spore based organism tested is a fungus rather than bacterial species. It is known for causing black mold disease in fruits and vegetables and is closely related to *Aspergillus fumigatus,* the most common airborne fungal pathogen. Like *B. globigii*, the *A. niger* spores did not require cultivation, but were commercially acquired ready for testing.

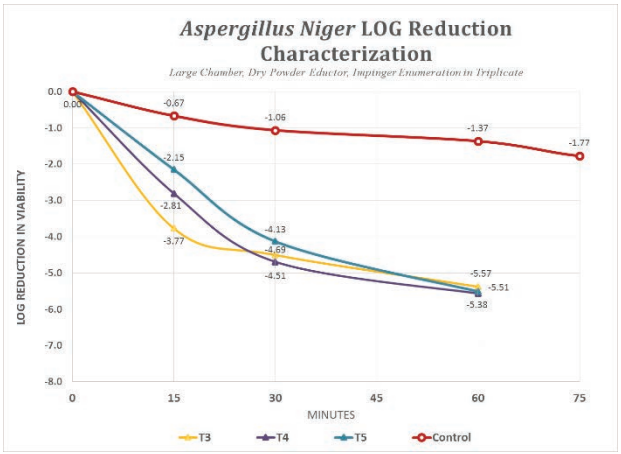

Figure 13: LOG Reduction of *Aspergillus niger* spores in control and Medical Guardian test trials.

Concentrations of *A. niger* inside the chamber after nebulization was less than previous organisms, with an average of $2.61e^4$ cfu/L. The control trial revealed a LOG reduction after 90 minutes of 1.77, which was higher than had been observed previously. With the Medical Guardian activated for 15 minutes during testing trials, an average of only 0.29% of *A. niger* remained inside the chamber. After 60 minutes there was an average net LOG reduction of 4.12 +/- 0.10 with a limits of detection of 5.59.

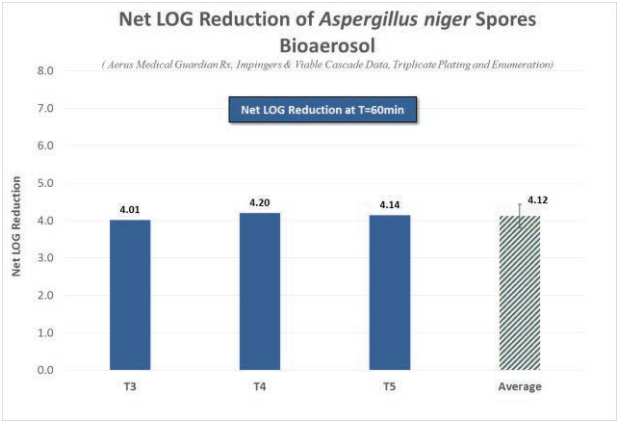

Figure 14: Net LOG Reduction of *Aspergillus niger* spores.

Phi X174 Virus

The Phi X174 bacteriophage testing was planned immediately following MS2 testing, however obstacles arose with culturing the virus to desirable concentrations. The testing was pushed back to the end of the study to give time to develop slight alterations to the growth protocols. Like MS2, Phi X174 infects *E. coli,* however it is a DNA virus with a small genome.

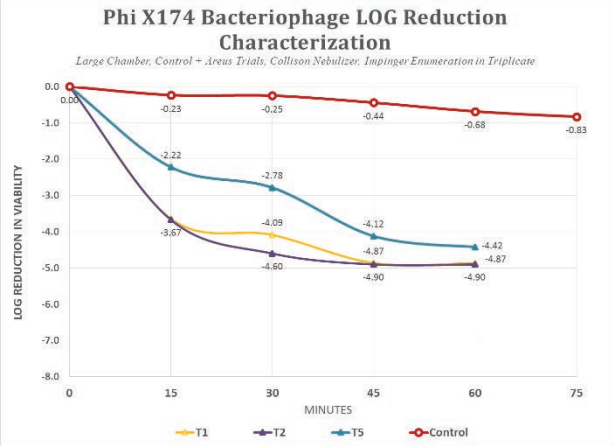

Figure 15: LOG Reduction of Phi X174 bacteriophage in control and Medical Guardian test trials.

Pre-testing cultures of Phi X174 had an average concentration of $4.4e^8$ pfu/mL, which was significantly lower than any other organisms tested. Once nebulized, the concentration of the atmosphere inside the testing chamber averaged $7.63e^3$ pfu/L. There was a LOG reduction of Phi X174 of 0.89 at 90 minutes during the control trial, and an average net LOG reduction of 4.05 +/- 0.27 with limits of detection of 4.73 during testing trials. There were no plaques observed beyond 30 minutes and a single pfu was added to determine detection limits.

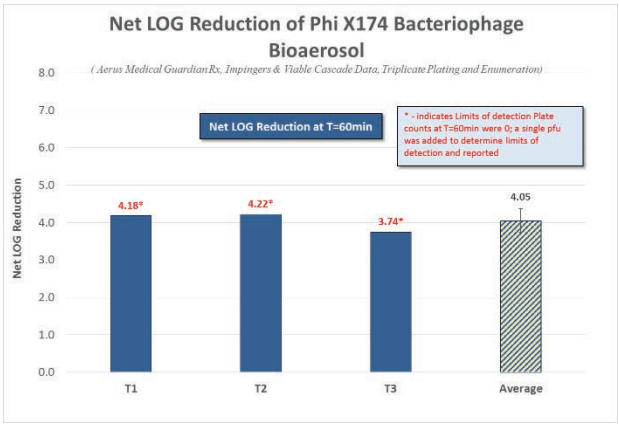

Figure 16: Net LOG Reduction of Phi X174 bacteriophage.

Aerus Medical Guardian Bioaerosol Challenge Summary					Net LOG Reduction Results						Limits of Detection
	Challenge Organism	Surrogate for	ATCC #	Gram	Time (min)	T1	T2	T3	Avg Net LOG Reduction	Standard Deviation	
1	*Staphylococcus epidermidis*	Methicillin Resistant *Staph aureus* (MRSA)	12228	pos	60	*5.72*	*6.35*	*5.79*	*5.95*	*0.34*	*8.15*
2	*Erwinia herbicola*	*Yersinia pestis* (Black Plague)	27155	neg	75	*5.12*	*5.79*	*5.17*	*5.36*	*0.37*	*7.64*
3	MS2 virus	Influenza, Norovirus	15597-B1	NA	60	*5.44*	*6.06*	*5.25*	*5.58*	*0.43*	*6.37*
4	Phi X174 virus	HCV, HBV, HIV	13706-B1	NA	60	*4.18*	*4.22*	*3.74*	*4.05*	*0.27*	*4.73*
5	*Bacillus globigii* endospore	*C. difficile* (spore) & Anthrax (spore)	16404	pos	90	*3.99*	*4.12*	*4.58*	*4.23*	*0.31*	*5.70*
6	*Aspergillis niger* mold spore	Black Mold	13835	NA	60	*4.01*	*4.20*	*4.14*	*4.12*	*0.10*	*5.59*

*Red text = at detection limits, Calculated LOG Reduction values represent a minimum

Table 3: *Net LOG reduction summary for the Medical Guardian air system.*

Summary of Results

Overall, the Medical Guardian's showed an average Net LOG reduction for all organisms tested of 4.80 +/- 0.74. The unit was more effective at removing vegetative bacterium from the testing chambers atmosphere than either the viruses or spores, with an average net LOG reduction for just the two vegetative bacteria of 5.41 +/- 0.07. However testing of both viruses were below detectable limits due there being zero plaques observed on plates after a certain point, meaning that the net LOG reduction for those organisms only represents a minimum value. Spores are known to be tough and highly resilient, and therefore it is not unexpected that their net LOG reductions are not quite as high as the other organisms.

The **Figure 17** below shows each average net LOG reduction for the organisms tested +/- their standard deviations. **Table 3** shows a final summary table of the net LOG reduction results for each organism tested in this study.

The Medical Guardian had an overall Clean Air Delivery Rate of 94.63 cubic feet per minute (cfm), which is explained in detail in **Appendix A.**

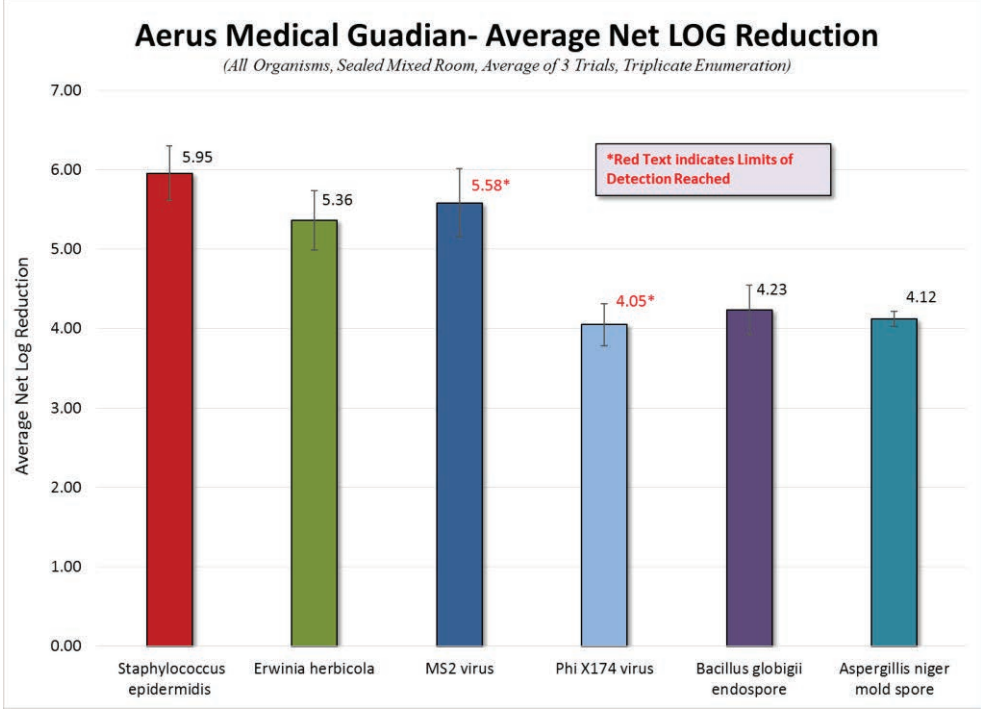

Figure 17: *Average net LOG reduction for each bioaerosol organism tested, average +/- standard deviation for the triplicate trials.*

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J.F. Heildelberg et al. *Effects of Aerosolization on Culturabilty and Viability of Gram-Negative Bacteria*. Applied and Environmental Microbiology. Sept 1997, p 3585-3588.

P Hyman et al. *Practical Methods for Determining Phage Growth Parameters*. Bacteriophages: Methods and Protocols, Vol. 1*: Isolation, Characterization and Interactions.* vol. 501. 2009. pp. 175-201.

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Study Director

Jamie Balarashti
Aerosol Research and Engineering Laboratories

GLP Statement

We, the undersigned, herby certify that the work described herein was conducted by Aerosol Research and Engineering Laboratories in compliance with FDA Good Laboratory Practices (GLP) as defined in 21 CFR, Part 58.

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Study Director
ARE Labs, Inc.

3/1/2019
Date

Principal Investigator:

Dan J. Merchant
Principal Investigator
ARE Labs, Inc.

3/1/2019
Date

MRIGlobal

The science you expect.
The people you know.

Verification of the Effectiveness of ActivePure® Technology in Decontamination of SARS-CoV-2

Final Report

FOR

Aerus, LLC

14841 Dallas Parkway
Aberdeen Bldg., Suite 500
Dallas, Texas 75254

MRIGlobal Project No. 311624.01.001

August 13, 2020

Preface

This final report was prepared at MRIGlobal (MRIGlobal) for the work performed under MRIGlobal Task No. 311624.01.001, "Verification of the Effectiveness of ActivePure® Technology in Decontamination of SARS-CoV-2"

Test devices were supplied to MRIGlobal by Aerus, LLC for the conduct of the program. The experimental phase of this task was initiated by MRIGlobal on May 18, 2020 and ended on August 2, 2020.

The Study Director of the program was Rick Tuttle. Execution of the study was assisted by Carl Gelhaus, Ph.D., Luca Popescu, Ph.D., Kristen Solocinski, Ph.D., Sam Humphries, and managed by William Sosna.

The studies were performed in compliance with MRIGlobal QA procedures. All operations pertaining to this study, unless specifically defined in this protocol, were performed according to the Standard Operating Procedures of MRIGlobal or approved laboratory procedures, and any deviations were documented.

MRIGLOBAL

Richard Tuttle

Rick Tuttle
Study Director

Approved by:

Claire L Cantrell

for Ed Sistrunk
Division Director
Medical Countermeasures

August 13, 2020

Contents

Figures

Tables

Section 1.
Objective

The emergent threat of COVID-19 infection originating from SARS-CoV-2 and the high rate of transmission associated severe illness and fatalities, has created a needed response for rapid development and evaluation of effective countermeasures. In response to testing for Aerus, LLC, MRIGlobal conducted testing and evaluation of Aerus, LLC's whole room air disinfection system with ActivePure® Technology. The ActivePure® room disinfection system uses free oxygen and water molecules in the air that are pulled through a honeycomb matrix. The technology creates powerful oxidizers that are released back into the room which destroy biological bacterial and viral contaminants. The ActivePure® whole room disinfection system was evaluated in independent surface destruction tests of SARS-CoV-2 (Washington Isolate Strain) in laboratory trials at MRIGlobal.

Section 2.
Sponsor, Testing Laboratory, and Personnel Responsibilities

2.1 Sponsor

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14841 Dallas Parkway
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Dallas, TX 75254

2.2 Sponsor's Representative

Andrew Eide
Vice President, Product Development and Manufacturing

2.3 Testing Laboratories

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Kansas City, MO 64110
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2.4 Personnel Responsibilities

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Section 3.
Test Systems and Methods

3.1 Equipment

Test Equipment

The ActivePure whole room disinfection system uses ActivePure® Technology and is a portable air purification system with dimensions of approximately 13" D × 13" W × 22" H. The system generates powerful oxidants that destroy bacteria, virus and odors without the use of chemicals. The system recirculates air in room environments at desired volumetric flow settings of 300 cfm using fan forced air flow. The system is designed to purify air and surfaces in rooms up to 3000 ft^3. As air enters the system, oxygen and water molecules in the air enter the unit through a honeycomb matrix which converts the molecules to powerful oxidizers that are released back into the room which destroy biological bacterial and viral contaminants. The ActivePure® unit was provided to MRIGlobal by Aerus, LLC and was set for single speed air recirculation flow operation (300 cfm). The unit was also equipped with an on/off power switch and an ActivePure® on/off switch for selection between blower only operation, or combined blower and ActivePure® operation for testing.

SARS-CoV-2 (USA-WA1/2020) was obtained from The University of Texas Medical Branch (UTMB) from an isolate of a patient who traveled to an infected region of China and developed the clinical disease (COVID-19) January 2020 in Washington, USA. The complete genome of USA-WA1/2020 has been sequenced. The Isolate-GenBank: MN985325 and after one passage in in Vero cells GenBank: MT020880. The complete genome of SARS-CoV-2 strain USA-WA1/2020 has been sequenced after four passages in collaboration with Database for Reference Grade Microbial Sequence (FDA-ARGOS; GenBank: MT246667). Each vial used on study contains approximately 0.5 mL of cell lysate and supernatant from Cercopithecus aethiops kidney cells infected with SARS-CoV-2 isolate USA-WA1/2020.

3.2 Methods

Testing Description

MRIGlobal conducted testing characterization of a single ActivePure® portable air purification system in surface decontamination trials to evaluate the log reduction destructive kill effectiveness against an envelope virus (SARS-CoV-2) strain USA-WA1/2020. All tests were conducted in a biological class 3 facility at MRIGlobal, Kansas City, MO. The biological safety cabinet has internal dimensions of 6'W × 4'D × 4'H, with a displacement volume of approximately 96 ft^3. The cabinet is annually pressure decay tested for leak free integrity, and certified for safety. For testing of the ActivePure® unit, the cabinet was sealed with the exhaust, and filter air inlet vents capped with gasketed steel plates for isolation and testing under static conditions without cabinet flow. The ActivePure® unit was positioned in the center of the biosafety cabinet with position marks drawn on the bottom of the cabinet for proper placement and alignment preceding each test. The unit was tested for viral surface destruction efficacy using sterile 1" × 3" × 1 mm stainless steel test coupons inoculated with SARS-CoV-2. Test coupons were each inoculated with a 200 µL of SARS-CoV-2 stock suspension in a sterile class 2 biological safety cabinet. Individual test coupons were placed in test identification labeled

sterile petri dishes and inoculated from a standard stock viral suspension with 200 mL of SARS-CoV-2 virus using a calibrated micropipette. The viral suspension was then evenly coated over the test coupons surface using sterile cell spreaders. Coated test coupons were air dried at standard laboratory conditions in the biological level 2 safety cabinet prior to exposure tests. Additional positive control coupons were similarly prepared and were subjected to the same environmental conditions and time course as test coupons without being subjected to ActivePure® Technology exposure. The positive control coupons served as viral concentration standards to define the efficacy of the system in deactivating the SARS-CoV-2 virus from test coupons.

For each test, a set of three SARS-CoV-2 inoculated test coupons were placed on the floor of the biosafety cabinet at the exhaust outlet of the ActivePure® unit, and at a 45° offset angle from the outer housing of the blower to avoid direct air flow turbulence. A diagram of the test setup is shown in Figure 1.

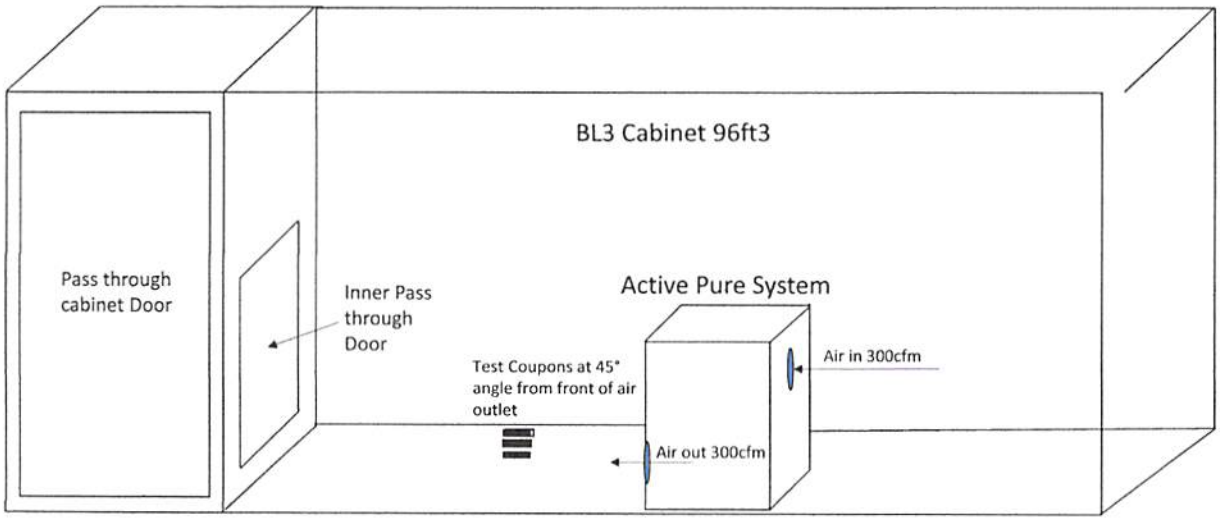

Figure 1. Diagram of ActivePure® Test System

Tests were conducted over four (4) exposure times of 1, 3, 6 and 7 hours. Test coupons were subjected to the ActivePure® technology operation during the exposure process. Positive control coupons were subjected to the same exposure time course with only the unit blower flow operational without ActivePure® technology operational. This provided a common and standardized test control for all system tests over each timecourse, and accurate assessment of the test units ActivePure® technology viral deactivation efficacy. A test matrix is shown in Table 1.

Table 1. ActivePure® Test Matrix

System operating condition	System Flow Volume (cfm)	Test virus	Exposure time (hours)	Number of coupons	Coupon viral inoculation volume (µl)	Coupon DMEM extraction vol (ml)	Total samples/ Test	Number of tests	Total Sample assays
With ActivePure	300	SARS - CoV – 2	1	3	200	2	3	1	3
Without ActivePure	300	SARS - CoV – 2	1	3	200	2	3	1	3
With ActivePure	300	SARS - CoV – 2	3	3	200	2	3	1	3
Without ActivePure	300	SARS - CoV – 2	3	3	200	2	3	1	3
With ActivePure	300	SARS - CoV – 2	6	3	200	2	3	1	3
Without ActivePure	300	SARS - CoV – 2	6	3	200	2	3	1	3
*Without ActivePure	300	SARS - CoV – 2	*7	3	200	2	3	1	3
*With ActivePure	300	SARS - CoV – 2	*7	3	200	2	3	1	3

* Added additional humidity above ambient lab humidity

Section 4.
Sample Analysis and Results

Stock virus used for test and control coupon inoculation (SARS-CoV-2, strain USA-WA1/2020) were concentration titered by serial dilution to obtain the 50% tissue culture infectious dose ($TCID_{50}$). This was conducted to ensure that sufficient concentration and quantity of virus were available for testing. For cell and virus cultures, sterile DMEM (Mediatech) supplemented with 7% fetal bovine serum (HyClone), GlutaMax (Gibco), and penicillin-streptomycin-neomycin antibiotic mixture (Gibco) were utilized. Vero E6 cells (monkey kidney cells obtained from ATCC (CRL-1586) were used for assays with ASFV. All cells were maintained at 36°-38°C and 5% CO_2 in a humidified atmosphere, and cells were seeded into flasks for propagation and expanded into 96 well plates for titration of SARS-CoV-2 virus. Cells were infected with viral coupon sample extractions at 70% confluence and observed for the presence of cytopathic effect (CPE) for four (4) to five (5) days post-infection. A 10X serial dilution of coupon sample viral extractions were applied to cell assay plates at up to an 8 log dilution factor for the presence of viral growth into the plate host cells. Plates were inoculated with 5 replicate samples at each dilution level, with each row of replicates 10x more dilute than that used in the preceding row for viral cell infectivity detection. Viral propagation plate readings were conducted under high intensity magnification of each plate cell for viral host cell infectivity and recorded on a sample test log for positive (+) or negative (-) viral propagation. Data was entered into a Reed Muench calculation for sample concentration measurement and determination of the $TCID_{50}$ (50% tissue culture infectious dose of a virus).

Test Results:

Coupon preparation including SARS-CoV-2 inoculation, drying, exposure testing, extractions, and cell assay plating were conducted in a sterile class 2 biological safety cabinet. Testing for 1, 3, and 6 hour tests with the ActivePure® technology were conducted in the BL3 cabinet without the addition of humidity. An additional test over a 7 hour ActivePure® technology exposure period was conducted on 8/2/2020, with the humidity maintained in the test cabinet using a Honeywell digital humidity monitor with humidity level setpoint control that provided a continuous and regulated humidity level of 63% RH (relative humidity) during the test. Following a 4 day plate assay viral incubation period, plates were read for viral infectivity and data recorded on $TCID_{50}$ test logs. Results were entered into a Reed Muench data analysis program for results and comparison of positive test control sample viral titer coupon concentrations to ActivePure®exposed test coupon results. A plot showing the averaged log reduction efficacy of the ActivePure® Technology in deactivating a set of three (3) SARS-CoV-2 infected stainless steel coupons. The log reduction data shows the averaged test coupon viral deactivation in relation to the averaged positive control coupons (non- ActivePure® exposured) over each exposure period, and is shown in Figure 2.

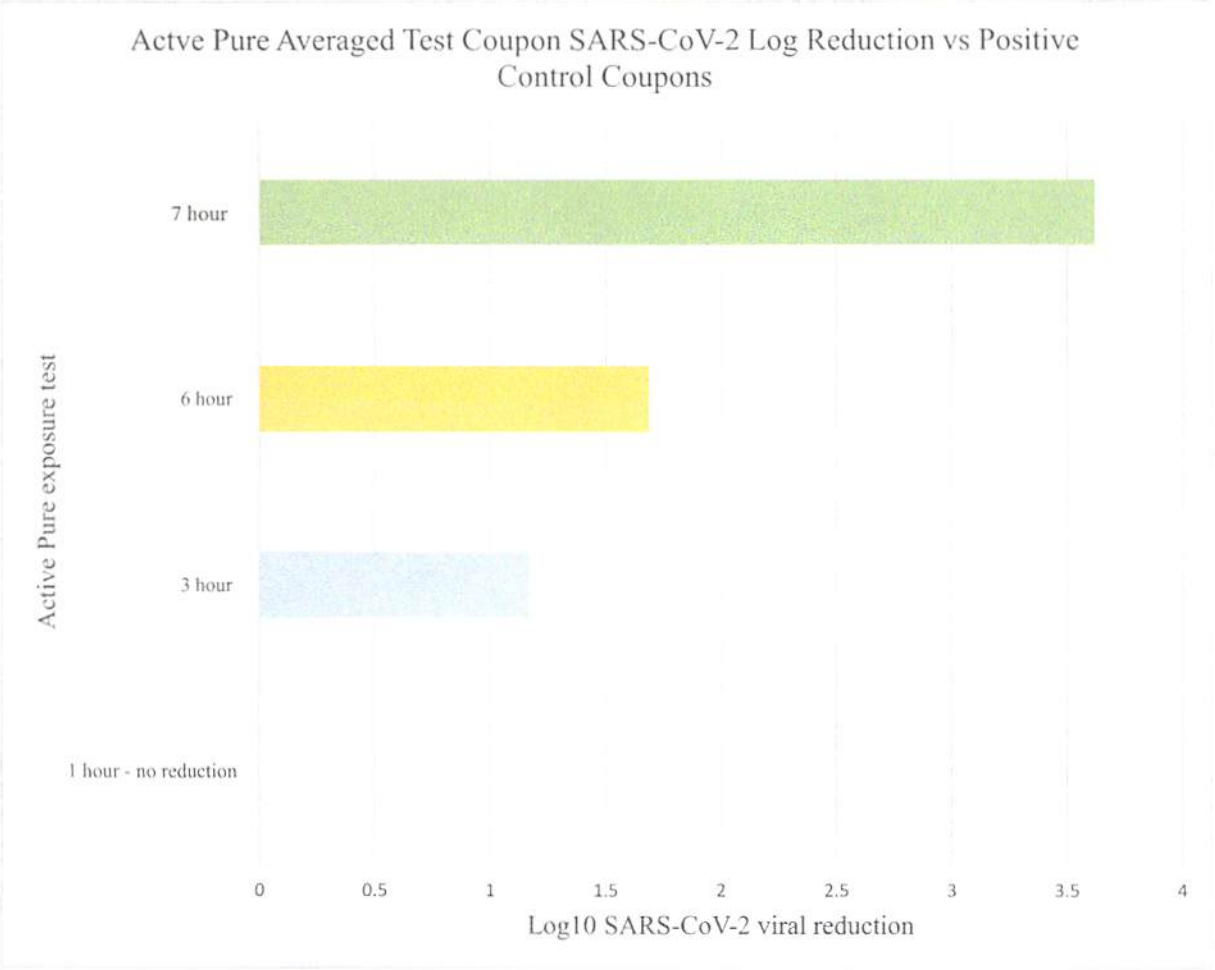

Figure 2. Test Results for ActivePure® SARS-CoV-2 log reduction Efficacy

Laboratory environmental conditions in MRIGlobals BSL3 laboratories are monitored continually and data logged using an Amegaview data capture system. The laboratory temperature and humidity conditions for each test, and test cabinet %RH (if applicable) as well as the log and percent reduction efficacy of the ActivePure® unit are shown in Table 2.

Table 2. Tabulated Test Results, Test Parameters and Environmental Conditions

Test Date	Active Pure exposure time (hr)	Lab Temperature (°F)	Lab Humidity (%RH)	BL3 Test Cabinet Humidity (%RH)	Averaged SARS-CoV-2 Log viable reduction	Averaged SARS-CoV-2 viable reduction (%)
5/17/2020	1	72	47	NA	0	0
6/15/2020	3	71.5	55	NA	1.17	93.27
6/15/2020	6	71.5	55	NA	1.69	97.95
8/2/2020	7	72	52	63	3.62	99.98

Testing of the ActivePure® unit showed substantial viral reduction of SARS-CoV-2 on test coupons for the 3 and 6 hour tests with results of 93.27%, and 97.95% respectively. The 7 hour test included controlled humidification of the test cabinet at 63% RH throughout the test with a viable reduction of 99.98% of SARS-CoV-2 on test coupons. It is theorized that the humidity levels in the test cabinet (air tight seal), may have reduced over the ActivePure® operation and the ActivePure® production of powerful oxidizers may have reduced or depleted during 1, 3, and 6 hour testing, thus reducing effectiveness against SARS-CoV-2. The 7 hour test, with the addition of humidity control regulated at 63% showed almost a 2 log viral kill increase over the 6 hour test, and approximately a 2.5 log increased virus kill in relation to the 3 hour test. 1 hour exposure test showed no viral deactivation efficacy of the ActivePure® system in reducing test coupon viral concentrations in relation to positive control coupons.

Section 5.
Quality Assurance

5.1 Type of Study

This study was non-GLP, however all work was executed using established SOPs, at MRIGlobal in Kansas City, MO and all procedures utilized were technically valid in accordance with MRIGlobal Standard Operating Procedures and/or laboratory procedures.

5.2 Standard Operating Procedures

The study was performed according to the relevant standard operating procedures and/or laboratory procedures of MRIGlobal.

Section 6.
Location of Study Data

Exact copies of all raw data, correspondence, records, final protocol, amendments, and deviations, and any other study documentation necessary for reconstruction of the study will be archived at MRIGlobal. All raw data (including original study records, data sheets, work sheets, and computer printouts) will be archived by MRIGlobal.

Airborne Inactivation of the Novel Coronavirus SARS-CoV-2 by Aerus Technology

Aerus Medical, LLC contract

Final Report Date of 22 December 2020

To

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Objective

SARS-CoV-2, the virus responsible for the COVID-19 pandemic, has had a profound, detrimental effect across the globe. The disease is associated with flu-like symptoms, persistent chest pain, respiratory complications/distress, confusion, and death. To date, there has been over 68 million cases of COVID-19 and over 1.5 million COVID19-related deaths worldwide, while in the United States alone, there has been approximately 15 million COVID19 cases and 284,000 COVID19-related deaths. In attempts to prevent the spread of the virus, several countries have implemented mandatory shutdowns of businesses and schools. While these measures have proven effective in controlling the spread of infection, they unfortunately have crippled several economies and are therefore unsustainable.

SARS-CoV-2 is believed to be transmitted by various means which includes direct, indirect, or close contact with infected people; aerosol transmission; and fomite transmission. In the case of aerosol transmission, SARS-CoV-2 virions become suspended in respiratory secretions or droplets expelled into the air by infected individuals. These droplets, due to their extremely small sizes, remain aerosolized for extended periods of time and are potentially inhaled by other individuals in the vicinity. Due to this route of aerosol transmission, the need for air purification devices capable of inactivating the virus within indoor environments is paramount.

Aerus Medical, LLC, has developed technology that can eliminate microbial contaminants by creating powerful oxidizers that can inactivate microbes. Aerus technology has demonstrated in lab tests the ability to eliminate surface SARS-CoV-2 (coated in a bio-film) by 99.98% in just 7 hours. In tests resulting in FDA Class II Medical Device Clearance, Aerus technology demonstrated 99.999% reductions in airborne MS2 Bacteriophage in just 30 minutes. These findings suggest Aerus technology would also be effective at eliminating airborne SARS-CoV-2.

The objective of this study was to test the ability of a device manufactured by Aerus Medical, LLC, to inactivate airborne SARS-CoV-2.

Experimental Procedure

Virus
SARS-CoV-2, strain USA_WA1/2020, was provided by the World Reference Center for Emerging Viruses and Arboviruses.

Plaque assay
Vero E6 cells were seeded in 6-well or 12-well plates to a confluency of 90-100%. Samples were serially 10-fold diluted in PBS. Diluted samples were plated onto the cells and left to incubate at 37ºC with 5% CO2 for one hour. After incubation, samples were overlaid with a mixture of 2X MEM (supplemented the 8% FBS and 2% pen/strep) and1.6% LE agarose. The plates were incubated overnight at 37ºC at 5% CO2. Plaques

were visualized with neutral red stain and a light box. The lower limit of detection (LLD) for the assay was 40 pfu/ml.

Aerosol generation and sampling

The aerosolization was performed using a Biaera aerosol control platform (Aero3G, Biaera Technologies, LLC) fitted with a custom-made 150-liter chamber manufactured by Biaera Technologies, LLC (**Figure 1**). The viral aerosol was generated using a 6-jet Collison nebulizer (flowrate set to 14.0 LPM), and it was combined with a standard volume of air to deliver a given concentration of virus to the chamber. For each nebulization, 10 ml of the viral inoculum at concentrations of 1-5 x 10^7 pfu/ml was used. The duration of aerosolization was 15 minutes. Aerosol samples were collected at 12.5 LPM for 5 minutes immediately following aerosolization and at various testing time-points using BioSamplers (SKC, Inc.) containing 20 ml of collection medium to determine the chamber viral concentrations. The total airflow to the aerosol setup was 50.0 LPM. Temperature and humidity were monitored during nebulization and sampling.

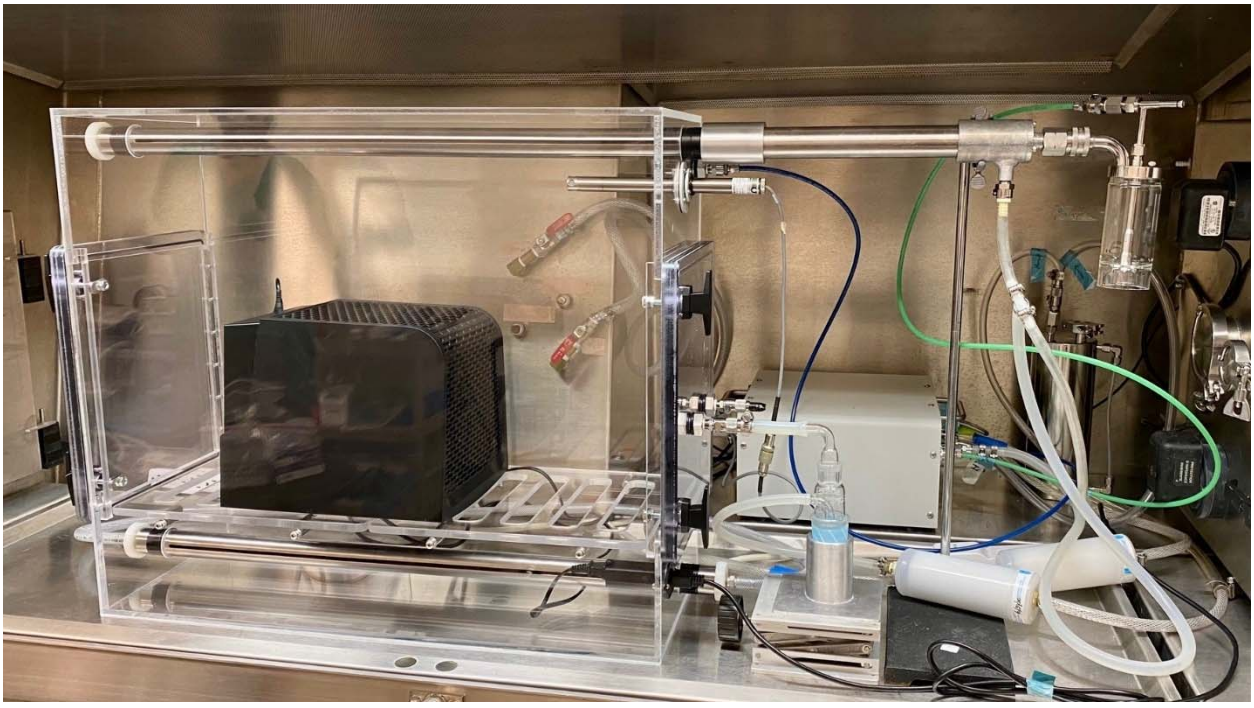


Figure 1. Aerosol testing setup

Aerus devices

Two devices manufactured by Aerus Medical were used in the study, an experimental device and a control device. These were the Aerus Pure & Clean and the Vollara Air & Surface Pro. The experimental device was equipped with the Aerus ActivePure technology capable of inactivating airborne viruses, as well as a fan used for air intake and output (all other technologies within the devices were either removed or deactivated). The control device was essentially identical to the experimental device, but the viral

inactivation ActivePure technology was removed from the control device. For operation, both devices were plugged into a 110V outlet within the chamber.

Aerosol testing timeline

The time and duration of aerosolization, device on-time, and sampling were performed according to **Figures 2A-C**. The device on-times tested were 3 and 10 minutes (**Figure 2A**), 15 and 30 minutes (**Figure 2B**), and 60 minutes (**Figure 2C**). These timelines were used for both the experimental (using the experimental device) and control (using the control device) runs. A test run with a timeline similar to **Figure 2A** was also performed wherein the control device was not turned on at t=0. This was done to ascertain the degree at which the aerosol droplets settle without air circulation being generated by the fan within the devices.

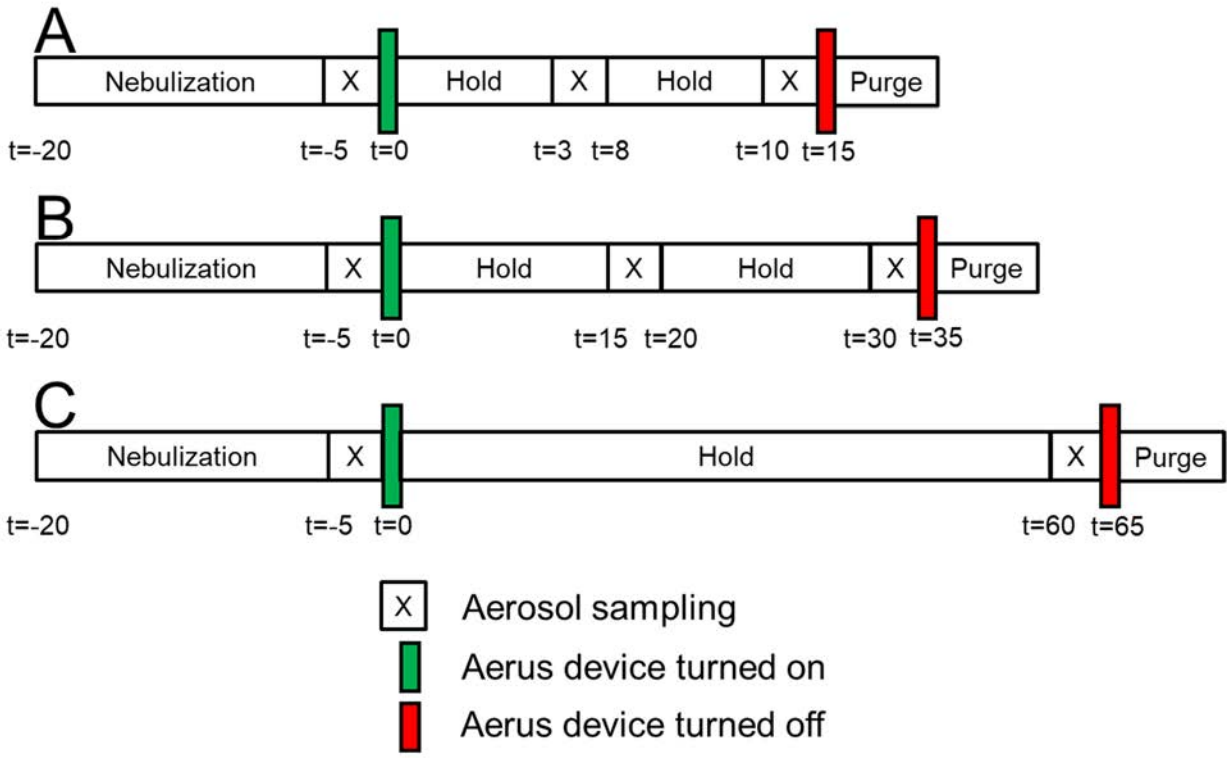


Figure 2. Testing timelines

Results

During the aerosol and sampling runs, the average humidity level was approximately 70%, and the temperature was approximately 22ºC. **Table 1** provides the log reductions (relative to the viral concentration at t=0) in viral concentration for the control and experimental devices with the various on-times. All device on-times were tested in triplicate except for the 3-minute (unit off) control, 10-minute (unit off) control, 30-minute control, and 60-minute control. In the case of the experimental device, the measured viral concentrations were below the plaque assay LLD (40 pfu/ml or 1.6 logs) for all but one

sample collection. Therefore, the range in log reduction was ≥2.87 to ≥3.38 which equates to ≥99.87 to ≥99.96%. However, since no plaque were detected in nearly every case, the percent inactivation could be ≥99.99% (≥4 logs). The log reductions in viral concentration for the control runs ranged from 0.61 to 2.91; however, the viral concentration of one sample collection (60-minute control) did fall below the assay LLD therein giving a log reduction of ≥3.18. The true net reduction in viral concentration could not be determined since the experimental device inactivated the virus to undetectable levels. Moreover, the true net log reduction for the runs over 3 minutes would be misleading since a greater portion of the virus settled in the test chamber as time passed. Because of this, it is likely that more of the virus was inactivated than could be measured. The study raw data is provided in the Appendix.

Table 1. Log reduction in viral concentration

Test unit	Device on-time	Log reduction from t=0	Test unit	Device on-time	Log reduction from t=0
Control device	3 minutes	0.84	Experimental device	3 minutes	3.38
		0.68			≥2.98
		0.61			≥2.87
	10 minutes	1.49		10 minutes	≥3.38
		1.27			≥2.98
		1.15			≥2.87
	15 minutes	1.49		15 minutes	≥3.38
		1.15			≥2.91
		1.18			≥2.92
	30 minutes	2.91		30 minutes	≥3.38
		1.91			≥2.91
		----			≥2.92
	60 minutes	2.42		60 minutes	≥3.22
		≥3.18			≥2.97
		----			≥2.87
	3 minutes (unit off)	0.61			
	10 minutes (unit off)	1.18			

Summary

The Aerus technology inactivated airborne SARS-CoV-2 to undetectable levels. The results show that, when accounting for the LLD, the percent reduction in virus was ≥99.87 to ≥99.96%; however, since no virus was detected after using the experimental device, the true percent reduction was likely greater than 99.99% in every case. The true net reduction could not be determined due to the LLD of the quantitation assay, but this too was likely greater than 99.99%.

Appendix

Raw data

Plate #	Sample	Sample Description	Run Date	Plaque Assay Date	Stain & Read Date	Dilution Read (10^{-x})	PFU Count	µl/Well	PFU/ml	Log_{10} PFU/ml
1	post-nebulization	Nebulizer #1	11/16/2020	11/16/2020	11/18/2020	4	442	250	1.77E+07	7.25
2	post-nebulization	Nebulizer #2	11/16/2020	11/16/2020	11/18/2020	4	389	250	1.56E+07	7.19
3	post-nebulization	Nebulizer #3	11/16/2020	11/16/2020	11/18/2020	4	402	250	1.61E+07	7.21
4	post-nebulization	Nebulizer #4	11/16/2020	11/16/2020	11/18/2020	4	370	250	1.48E+07	7.17
5	post-nebulization	Nebulizer #5	11/16/2020	11/16/2020	11/18/2020	4	270	250	1.08E+07	7.03
6	post-nebulization	Nebulizer #6	11/16/2020	11/16/2020	11/18/2020	4	297	250	1.19E+07	7.07
7	0-minute experimental	BioAnalyzer #1-1	11/16/2020	11/16/2020	11/18/2020	3	24	250	9.60E+04	4.98
8	3-minute experimental	BioAnalyzer #1-2	11/16/2020	11/16/2020	11/18/2020	1	1	250	4.00E+01	1.60
9	10-minute experimental	BioAnalyzer #1-3	11/16/2020	11/16/2020	11/18/2020	1	0	250	<4.00E+01	<1.60
10	0-minute experimental	BioAnalyzer #2-1	11/16/2020	11/16/2020	11/18/2020	3	24	250	9.60E+04	4.98
11	15-minute experimental	BioAnalyzer #2-2	11/16/2020	11/16/2020	11/18/2020	1	0	250	<4.00E+01	<1.60
12	30-minute experimental	BioAnalyzer #2-3	11/16/2020	11/16/2020	11/18/2020	1	0	250	<4.00E+01	<1.60
13	0-minute experimental	BioAnalyzer #3-1	11/16/2020	11/16/2020	11/18/2020	2	166	250	6.64E+04	4.82
14	60-minute experimental	BioAnalyzer #3-2	11/16/2020	11/16/2020	11/18/2020	1	0	250	<4.00E+01	<1.60
15	0-minute control	BioAnalyzer #4-1	11/16/2020	11/16/2020	11/18/2020	2	104	250	4.16E+04	4.62
16	3-minute control	BioAnalyzer #4-2	11/16/2020	11/16/2020	11/18/2020	1	151	250	6.04E+03	3.78
17	10-minute control	BioAnalyzer #4-3	11/16/2020	11/16/2020	11/18/2020	1	34	250	1.36E+03	3.13
18	0-minute control	BioAnalyzer #5-1	11/16/2020	11/16/2020	11/18/2020	2	80	250	3.20E+04	4.51
19	15-minute control	BioAnalyzer #5-2	11/16/2020	11/16/2020	11/18/2020	1	26	250	1.04E+03	3.02
20	30-minute control	BioAnalyzer #5-3	11/16/2020	11/16/2020	11/18/2020	1	1	250	4.00E+01	1.60
21	0-minute control	BioAnalyzer #6-1	11/16/2020	11/16/2020	11/18/2020	2	79	250	3.16E+04	4.50
22	60-minute control	BioAnalyzer #6-2	11/16/2020	11/16/2020	11/18/2020	1	3	250	1.20E+02	2.08
23	post-nebulization	Nebulizer #1	11/17/2020	11/17/2020	11/19/2020	5	70	250	2.80E+07	7.45
24	post-nebulization	Nebulizer #2	11/17/2020	11/17/2020	11/19/2020	5	62	250	2.48E+07	7.39
25	post-nebulization	Nebulizer #3	11/17/2020	11/17/2020	11/19/2020	5	68	250	2.72E+07	7.43
26	post-nebulization	Nebulizer #4	11/17/2020	11/17/2020	11/19/2020	5	37	250	1.48E+07	7.17

27	post-nebulization	Nebulizer #5	11/17/2020	11/17/2020	11/19/2020	5	91	250	3.64E+07	7.56
28	post-nebulization	Nebulizer #6	11/17/2020	11/17/2020	11/19/2020	5	79	250	3.16E+07	7.50
29	0-minute experimental	BioAnalyzer #1-1	11/17/2020	11/17/2020	11/19/2020	2	96	250	3.84E+04	4.58
30	3-minute experimental	BioAnalyzer #1-2	11/17/2020	11/17/2020	11/19/2020	1	0	250	<4.00E+01	<1.60
31	10-minute experimental	BioAnalyzer #1-3	11/17/2020	11/17/2020	11/19/2020	1	0	250	<4.00E+01	<1.60
32	0-minute experimental	BioAnalyzer #2-1	11/17/2020	11/17/2020	11/19/2020	2	81	250	3.24E+04	4.51
33	15-minute experimental	BioAnalyzer #2-2	11/17/2020	11/17/2020	11/19/2020	1	0	250	<4.00E+01	<1.60
34	30-minute experimental	BioAnalyzer #2-3	11/17/2020	11/17/2020	11/19/2020	1	0	250	<4.00E+01	<1.60
35	0-minute experimental	BioAnalyzer #3-1	11/17/2020	11/17/2020	11/19/2020	2	93	250	3.72E+04	4.57
36	60-minute experimental	BioAnalyzer #3-2	11/17/2020	11/17/2020	11/19/2020	1	0	250	<4.00E+01	<1.60
37	0-minute control	BioAnalyzer #4-1	11/17/2020	11/17/2020	11/19/2020	2	115	250	4.60E+04	4.66
38	3-minute control unit off	BioAnalyzer #4-2	11/17/2020	11/17/2020	11/19/2020	2	28	250	1.12E+04	4.05
39	10-minute control unit off	BioAnalyzer #4-3	11/17/2020	11/17/2020	11/19/2020	1	75	250	3.00E+03	3.48
40	0-minute control	BioAnalyzer #5-1	11/17/2020	11/17/2020	11/19/2020	2	155	250	6.20E+04	4.79
41	3-minute control	BioAnalyzer #5-2	11/17/2020	11/17/2020	11/19/2020	2	32	250	1.28E+04	4.11
42	10-minute control	BioAnalyzer #5-3	11/17/2020	11/17/2020	11/19/2020	1	83	250	3.32E+03	3.52
43	0-minute control	BioAnalyzer #6-1	11/17/2020	11/17/2020	11/19/2020	2	152	250	6.08E+04	4.78
44	60-minute control	BioAnalyzer #6-2	11/17/2020	11/17/2020	11/19/2020	1	0	250	<4.00E+01	<1.60
45	post-nebulization	Nebulizer #1	11/19/2020	11/19/2020	11/21/2020	4	232	250	9.28E+06	6.97
46	post-nebulization	Nebulizer #2	11/19/2020	11/19/2020	11/21/2020	4	192	250	7.68E+06	6.89
47	post-nebulization	Nebulizer #3	11/19/2020	11/19/2020	11/21/2020	4	202	250	8.08E+06	6.91
48	post-nebulization	Nebulizer #4	11/19/2020	11/19/2020	11/21/2020	4	236	250	9.44E+06	6.97
49	post-nebulization	Nebulizer #5	11/19/2020	11/19/2020	11/21/2020	5	18	250	7.20E+06	6.86
50	post-nebulization	Nebulizer #6	11/19/2020	11/19/2020	11/21/2020	4	141	250	5.64E+06	6.75
51	0-minute experimental	BioAnalyzer #1-1	11/19/2020	11/19/2020	11/21/2020	2	74	250	2.96E+04	4.47
52	3-minute experimental	BioAnalyzer #1-2	11/19/2020	11/19/2020	11/21/2020	0	0	250	<4.00E+01	<1.60
53	10-minute experimental	BioAnalyzer #1-3	11/19/2020	11/19/2020	11/21/2020	0	0	250	<4.00E+01	<1.60
54	0-minute experimental	BioAnalyzer #2-1	11/19/2020	11/19/2020	11/21/2020	2	82	250	3.28E+04	4.52
55	15-minute experimental	BioAnalyzer #2-2	11/19/2020	11/19/2020	11/21/2020	0	0	250	<4.00E+01	<1.60
56	30-minute experimental	BioAnalyzer #2-3	11/19/2020	11/19/2020	11/21/2020	0	0	250	<4.00E+01	<1.60
57	0-minute experimental	BioAnalyzer #3-1	11/19/2020	11/19/2020	11/21/2020	2	74	250	2.96E+04	4.47

58	60-minute experimental	BioAnalyzer #3-2	11/19/2020	11/19/2020	11/21/2020	0	0	250	<4.00E+01	<1.60
59	0-minute control	BioAnalyzer #4-1	11/19/2020	11/19/2020	11/21/2020	2	52	250	2.08E+04	4.32
60	3-minute control	BioAnalyzer #4-2	11/19/2020	11/19/2020	11/21/2020	1	128	250	5.12E+03	3.71
61	10-minute control	BioAnalyzer #4-3	11/19/2020	11/19/2020	11/21/2020	1	37	250	1.48E+03	3.17
62	0-minute control	BioAnalyzer #5-1	11/19/2020	11/19/2020	11/21/2020	2	71	250	2.84E+04	4.45
63	15-minute control	BioAnalyzer #5-2	11/19/2020	11/19/2020	11/21/2020	1	22	250	8.80E+02	2.94
64	0-minute control	BioAnalyzer #6-1	11/19/2020	11/19/2020	11/21/2020	2	49	250	1.96E+04	4.29
65	15-minute control	BioAnalyzer #6-2	11/19/2020	11/19/2020	11/21/2020	1	32	250	1.28E+03	3.11
66	30-minute control	BioAnalyzer #6-3	11/19/2020	11/19/2020	11/21/2020	1	6	250	2.40E+02	2.38

HOSPITAL SURGICAL AND CARDIO ICUs TESTING REPORT

EFFICACY OF BEYOND MEDICAL GUARDIAN AIR WITH AERUS ACTIVEPURE TECHNOLOGY

IN CANADIAN MEDICAL ICU SETTINGS

AUGUST 2, 2019

BEYOND®

BY AERUS

Testing of contaminants in the air and on surfaces inside ICUs at Canadian Hospital

Date of Report August 2, 2019

Contents

EXECUTIVE SUMMARY

Post-Surgical Site Infections (SSI) and Healthcare-Acquired Infections (HAI) are of major concern to hospitals, doctors and patients across North America.

The Public Health Agency of Canada reported a 17-fold increase in MRSA rates in Canadian hospitals between 1995 and 2010. [1] In a study published in 2003, "an estimated one in nine Canadian patients develops a healthcare-associated infection during his or her hospital stay — a total of 220,000 patients per year. Further, an estimated 8,000 Canadians will lose their lives from these infections every year." [2] Often, treatment is more costly than prevention: estimated costs in 2004 were $82 million. In 2010, costs were estimated at $129 million.[3]

In Canada, health spending was projected to reach $253.5 billion in 2018 (versus $207 billion in 2012). Statistics show that from 2017-2018, the average cost of a bed in Canada for acute care is $6,137/day.[4] A 2014 article in The Canadian Journal of Infectious Diseases & Medical Microbiology noted that "approximately 60% of total health spending is directed to hospitals and although it's difficult to estimate, the proportion of this spending attributed to the management of nosocomial infections, overuse and/or misuse of antimicrobials, and infections due to multidrug-resistant bacteria is significant."[5]

Statistics as somber as these make it clear that even a small reduction in SSI/HAI occurrences can translate into significantly improved overall patient care as well as lower medical costs for health providers.

This study was conducted to determine whether the Beyond by Aerus ActivePure® Technology could materially reduce or eliminate microorganisms and particulate matter from the air and on surfaces in an active hospital Surgical Intensive Care Unit (SICU) and a Cardiovascular Intensive Care Unit (CV-ICU) environment. Surface and airborne microorganisms are a major contributor of SSIs/HAIs, with bacteria Staphylococcus and Methicillin Resistant Staphylococcus as the most common. Specific analysis of bacteria (including MRSA, fungi and airborne particles) was performed before and after the installation of the Beyond Medical Guardian Air units.

The study results show material reduction in bacteria, MRSA, fungi and airborne particles after the installation of the Beyond Medical Guardian Air units – significantly reducing the exposure to infection from pathogens to those patients and healthcare providers in the SICU and CV-ICU environment.

- Bacteria and fungi reduction ranged from 73% to 94%.
- Methicillin-resistant Staphylococcus aureus (MRSA) was generally below detection levels (BDL) when first tested, but in one instance, it was very high and post installation showed a 100% reduction.
- Staphylococcus Aureus was reduced by 97%.
- Blood and potato agar plate samples showed reductions of 64% to 85% in bacteria, mold and yeast.
- Airborne particle reduction ranged from 41% to 95%.

MATERIALS AND METHODS

Sampling locations selected in the Surgical Intensive Care Unit (SICU) and the Cardiovascular Intensive Care Unit (CV-ICU) focused on areas most likely to have routine exposure or physical contact. These areas were active spaces, where cleaners are applied on a routine basis, which helps lower additional bacteria counts. In addition to surface testing, blood and potato agar plates were used to collect ambient air samples using a BioStage collection device attached to a vacuum pump. A laser particle counter was used to independently measure total airborne particulates 1.0 micron and smaller.

Pre-Treatment (Before) Protocols

On May 30, 2019, surface and air samples were collected in the Surgical Intensive Care Unit (SICU) and the Cardiovascular Intensive Care Unit (CV-ICU) of a Canadian hospital. Samples were taken to determine if and to what degree bacteria (including MRSA) and fungi exist within that environment, to establish a baseline for comparison. Normal ICU operating conditions were in place as were all other hospital protocols relating to the control of airborne and surface pathogens.

To determine levels of contaminants, five individual surface locations inside the SICU and CV-ICU areas were selected for sample collection. These areas were;

- patient monitor handle
- patient bed rail
- light switch in the patient area
- nurse's station work surface
- medical equipment cart drawer handles.

Surface samples were collected using the sampling methodology established by the Antimicrobial Testing Laboratory to ensure consistent sampling and prevent contamination during collection and handling. The Antimicrobial Testing Laboratory located in Round Rock, Texas is an independent and accredited FDA, EPA third-party test laboratory.

Each individual surface location was sampled using the 3M pre-moistened biocide-free cellulose sponge swab with a 10 mL neutralizing buffer. The swab was moved in an overlapping pattern over the surface area to fully expose the swab to any possible pathogens. The exposed swab was then placed in its sample container and sealed for transit to the lab. This process was performed for each of the selected surface sampling locations. The collected samples were packaged in containers with cold packs to keep the samples cool during transit to the Round Rock, Texas lab. Upon receipt to the lab, microbiologists unpacked and prepared the samples for plating. The prepared plates were then incubated at a temperature of 30°-36°±C for 2 – 5 days. Fully incubated plates were removed and the Colony Forming Unit (CFU) count was determined and recorded.

MATERIALS AND METHODS CONTINUED

Air samples were collected in real time at two locations within the SICU and two locations within CV-ICU areas. The air sample counts were collected using a laser particle counter specifically designed for counting airborne particles. The laser particle counter device is calibrated and NIST traceable. The laser counter measured in real time the number of total particles 1.0 micron and smaller per cubic meter of air. The particle counter does not differentiate the type of contaminants counted, only the number of particles.

Agar plates were used in the same locations the airborne particle counts were taken to collect air samples for specific analysis of bacteria, molds and yeast. Blood agar plates were used to collect air sample for analysis of bacteria while potato agar plates were used for the analysis of molds and yeast. Each agar plate was exposed to the air using a BioStage collection device attached to a vacuum pump, with an airflow rate of 30 liters per minute. Collected plates were sealed and shipped to the independent lab where they were incubated from 2 – 5 days at a temperature of 30°-36°±C.

Treatment (After) Protocols

Upon completion of the May 30, 2019 air and surface sampling, Beyond Medical Guardian Air units were placed into the SICU and CV-ICU areas. These units utilize several technologies, most notably our ActivePure Technology – which creates powerful and safe hydroxyls and super ions that travel through the air and onto surfaces remediating pathogens – and a better-than-HEPA filter media. ActivePure is in the Space Technology Hall of Fame and is the only technology in its class certified as Space Technology by the NASA sponsored Space Foundation. ActivePure is derived from technology initially developed for and used on the International Space Station. The Beyond Medical Guardian units were turned on and allowed to operate continuously for seven days while normal hospital protocols for control of air and surface pathogens also continued. The Beyond Medical Guardian Air Units were also used in conjunction with a few additional purification units engineered with the same, but a smaller version of, ActivePure Technology used in the Beyond Medical Guardian Air Units.

On June 5, 2019 surface and air samples were again collected in the Surgical Intensive Care Unit (SICU) and the Cardiovascular Intensive Care Unit (CV-ICU) following the same protocols established and used in before treatment. Samples and measurements were collected and analyzed to determine whether and to what degree use of the Beyond Medical Guardian Air units reduced bacteria (including MRSA) and fungi (mold, yeast and air particles) within the SICU and CV-ICU environment.

MATERIALS AND METHODS CONTINUED

ActivePure Technology utilizes a proprietary hydrophilic photo catalytic coating consisting of non-Nano titanium dioxide with a proprietary combination of additional transition elements to enhance efficacy. Activated by a specific wavelength of ultraviolet light, oxygen and humidity are extracted from the air to create powerful oxidizers that target air and surface pathogens. These oxidizers are extremely effective at destroying bacteria, viruses, fungi, volatile organic compounds (VOCs) and other environmental contaminants. Most significantly, they are not harmful to humans, pets or plants and are completely safe for indoor use in occupied spaces.

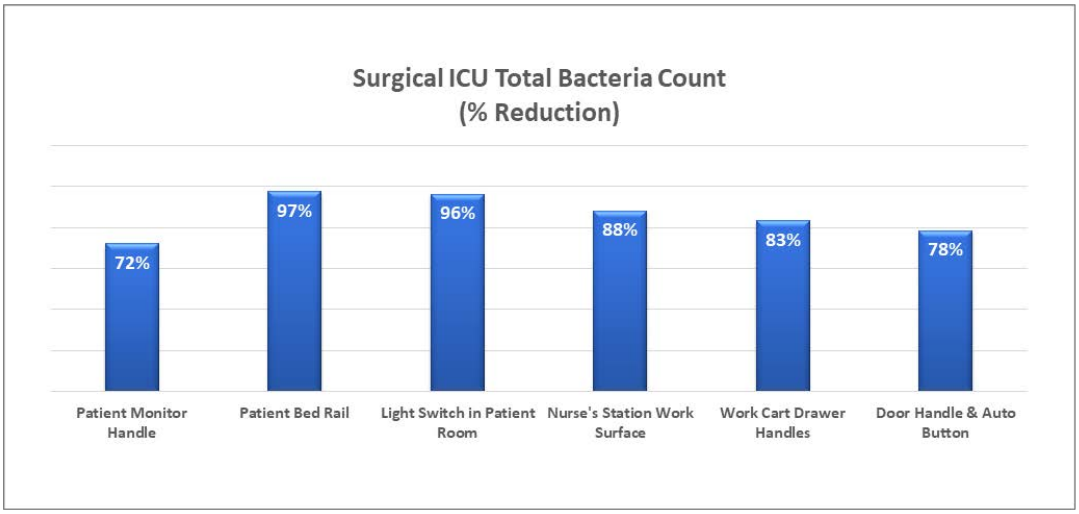
The difference between the before samples and the samples after running the Beyond Medical Guardian Air units for seven days was very substantial and significant.

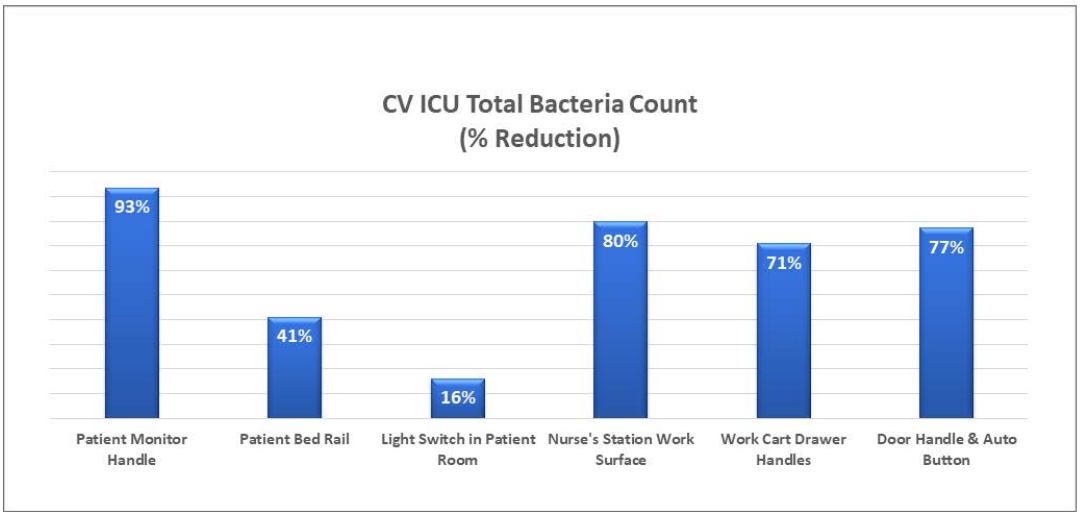
TOTAL BACTERIA AND FUNGI RESULTS (SWAB)

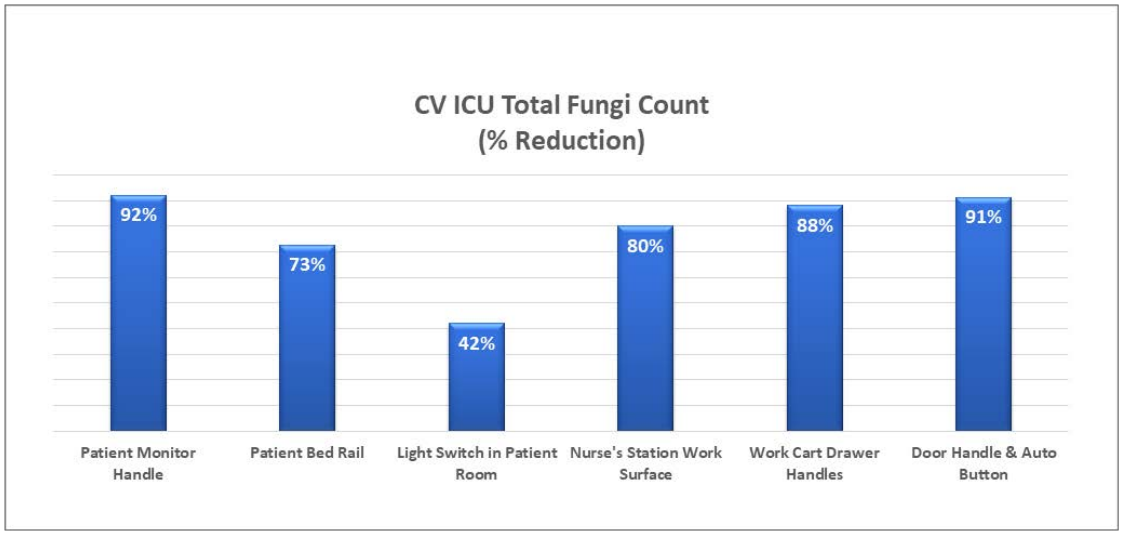
During the surface sampling periods on May 30, 2019, a combined total of 15,430 Colony Forming Units (CFUs) of bacteria were discovered in the Surgical Intensive Care Unit (SICU) and 2,956 CFUs of bacteria were measured in the Cardiovascular Intensive Care Unit (CV-ICU) as a result of the surface sampling. Testing results for Fungi (molds and yeast) in these same areas were 2,812 CFUs in the SICU and 480 CFUs in the CV-ICU.

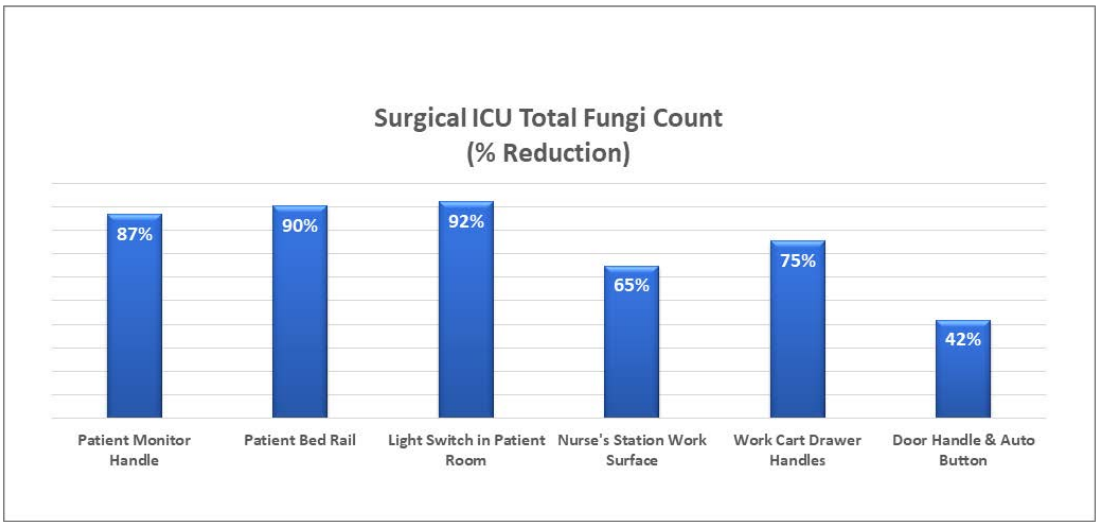
During the same test period time on June 5, 2019, seven days after installing the Beyond Medical Guardian Air units, the combined total bacteria count was reduced to 867 CFUs of bacteria in the SICU and 784 CFUs of bacteria in the CV-ICU. Testing results for Fungi in these same areas were 313 CFUs in the SICU and 70 CFUs in the CV-ICU.

This equates to a reduction in total bacteria by 94% in the SICU and 73% in the CV-ICU and a total reduction in Fungi by 89% in the SICU and 85% in the CV-ICU.







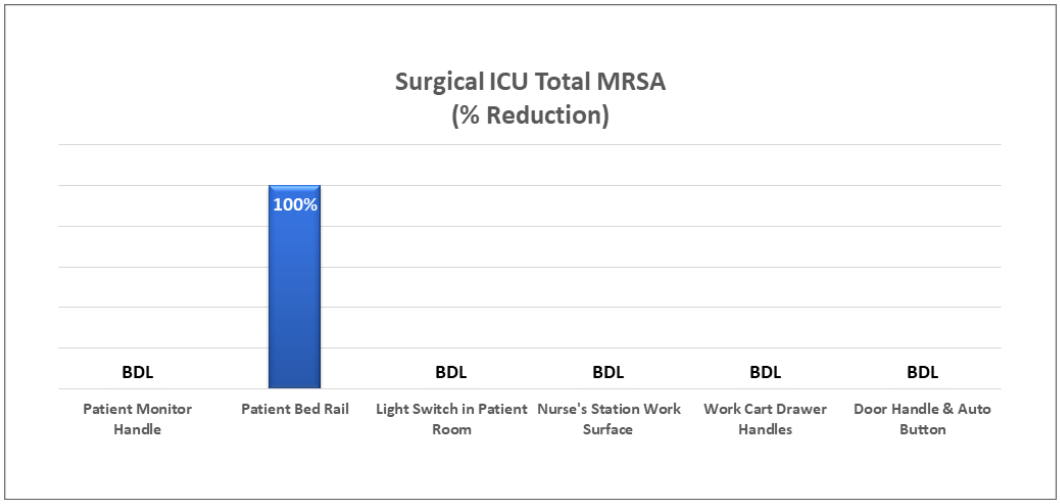


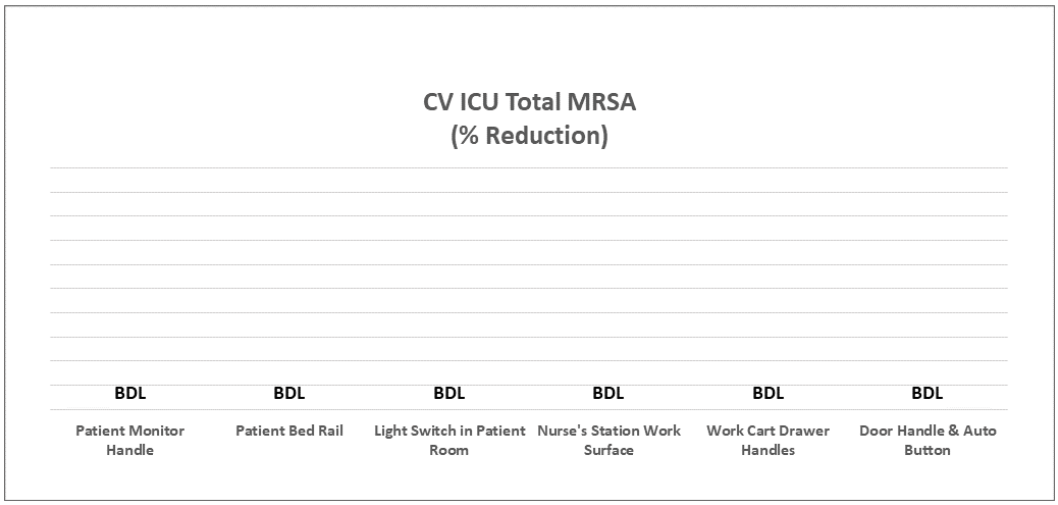
METHICILLIN RESISTANT STAPHYLOCOCCUS (MRSA) (SWAB)

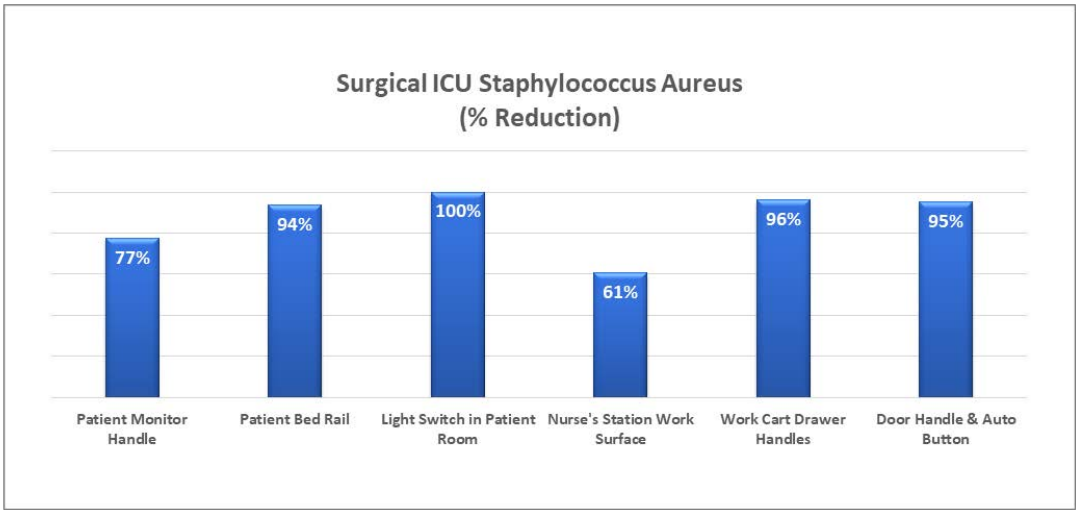
During the surface sampling periods on May 30, 2019, a total of 31 CFUs of Methicillin Resistant Staphylococcus Aureus (MRSA) were discovered in the Surgical Intensive Care Unit (SICU) and 0 CFUs of Methicillin Resistant Staphylococcus Aureus (MRSA) were found in the Cardiovascular Intensive Care Unit (CV-ICU) as a result of the surface sampling. Testing results for Staphylococcus, Aureus in these same areas were 6,314 CFUs in the SICU and 1,779 CFUs in the CV-ICU.

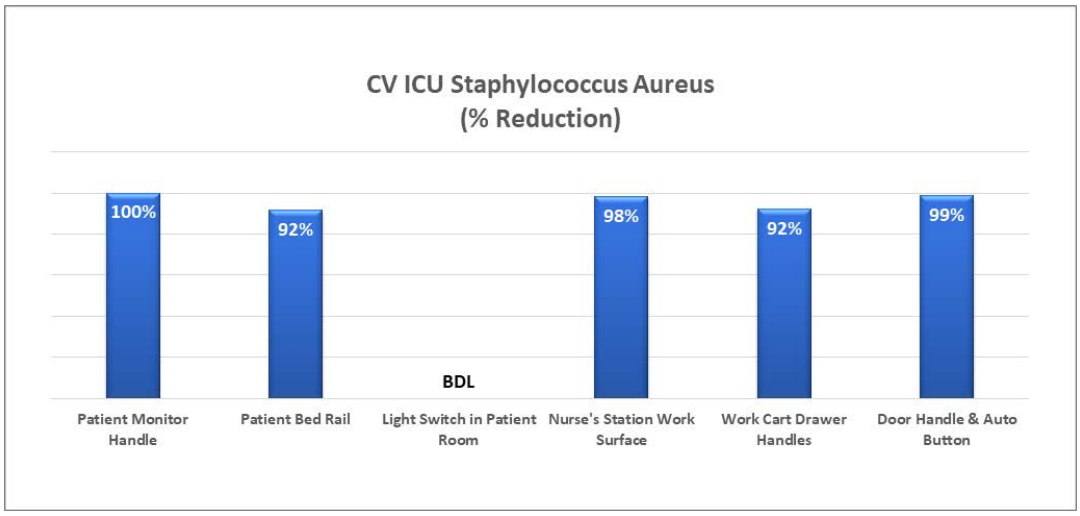
During the same test period time on June 5, 2019, seven days after installing the Beyond Medical Guardian Air units, the combined MRSA count was reduced to 0 in the SICU and 1 CFU was present in the CV-ICU. This equates to a reduction in MRSA bacteria in the SICU to 100% and the level in the CV-ICU was below detection limits (BDL).

Testing results for Staphylococcus Aureus in these same areas were 186 CFUs in the SICU and 57 CFUs in the CV-ICU. This equates to a reduction in Staphylococcus Aureus in the SICU by 97% and 97% in the CV-ICU.









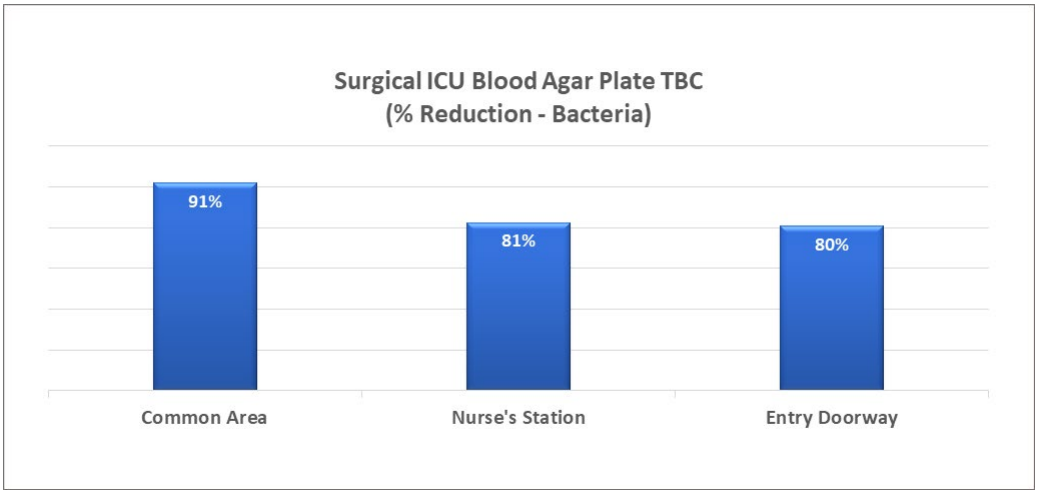
BLOOD AND POTATO AGAR PLATE RESULTS (AIR)

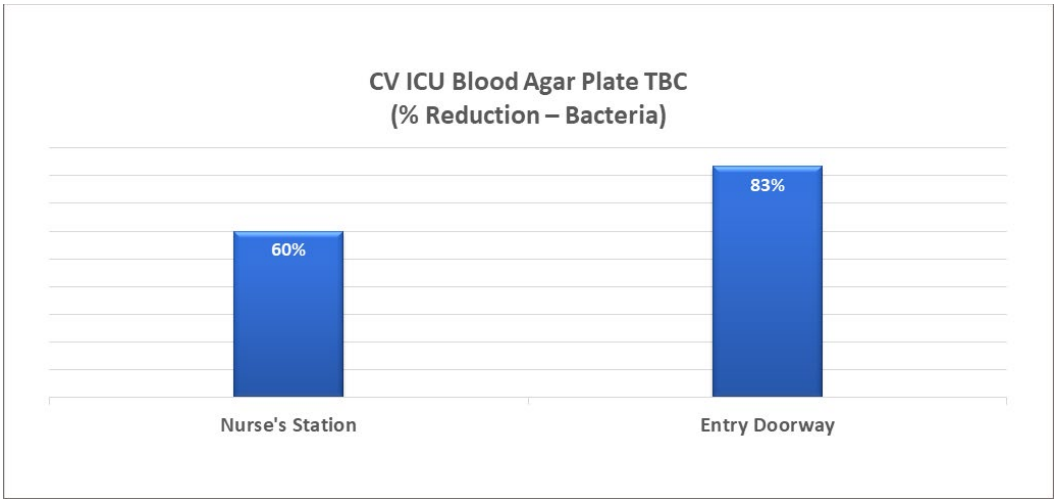
Agar plate samples collected on May 30, 2019 had a combined total bacteria count of 104 CFUs with **blood agar** and total fungi of 17 CFUs with **potato agar** in the Surgical Intensive Care Unit (SICU) and a total bacteria count of 24 CFUs with **blood agar** and total fungi of 7 CFUs with **potato agar** in the Cardiovascular Intensive Care Unit (CV-ICU), as a result of the sampling.

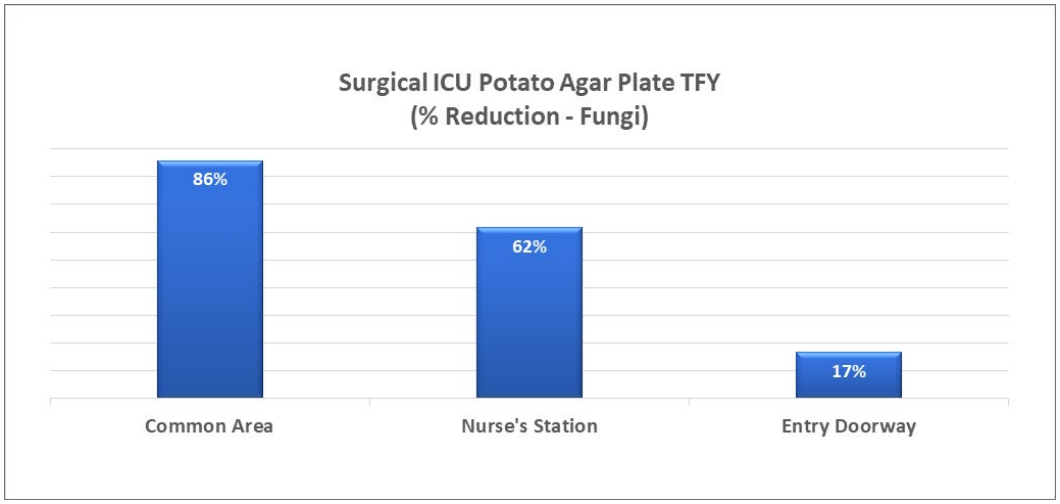
Agar plates collected on June 5, 2019, seven days after installing the Beyond Medical Guardian Air units, had a combined total bacteria count of 16 CFUs with **blood agar** and total fungi of 6 CFUs with **potato agar** in the SICU, and a total bacteria count of 11 CFUs with **blood agar** and a total fungi of 4 CFUs with **potato agar** in the CV-ICU as a result of the sampling.

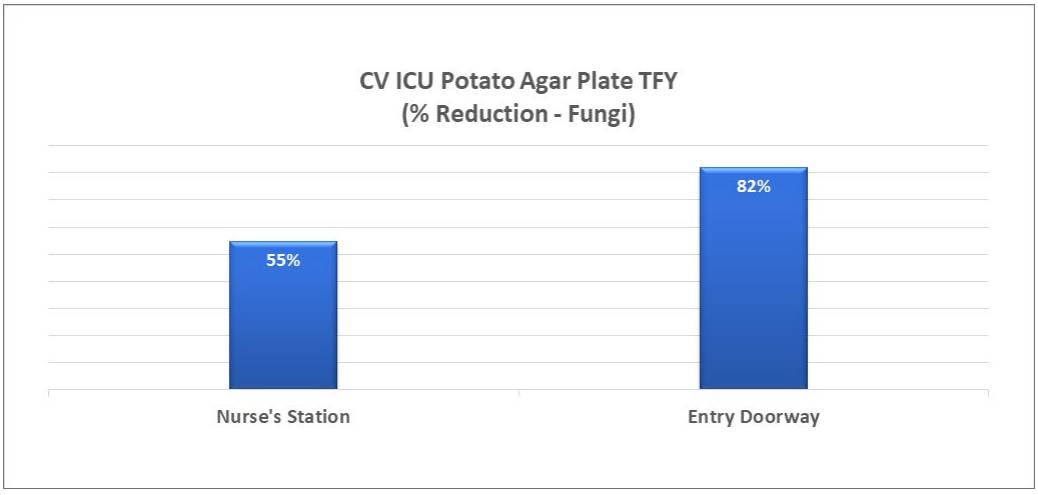
This equates to a reduction in total bacteria CFUs of 85% in the SICU and 72% in the CV-ICU. Total fungi CFUs were reduced by 64% in the SICU and 68% in the CV-ICU. The results indicate that the air was materially less contaminated with bacteria and fungi as a result of the Beyond Medical Guardian Air units.

All agar plate samples were collected using a BioStage Single-stage Impactor, coupled to a vacuum pump with an airflow rate of 30 liters per minute.





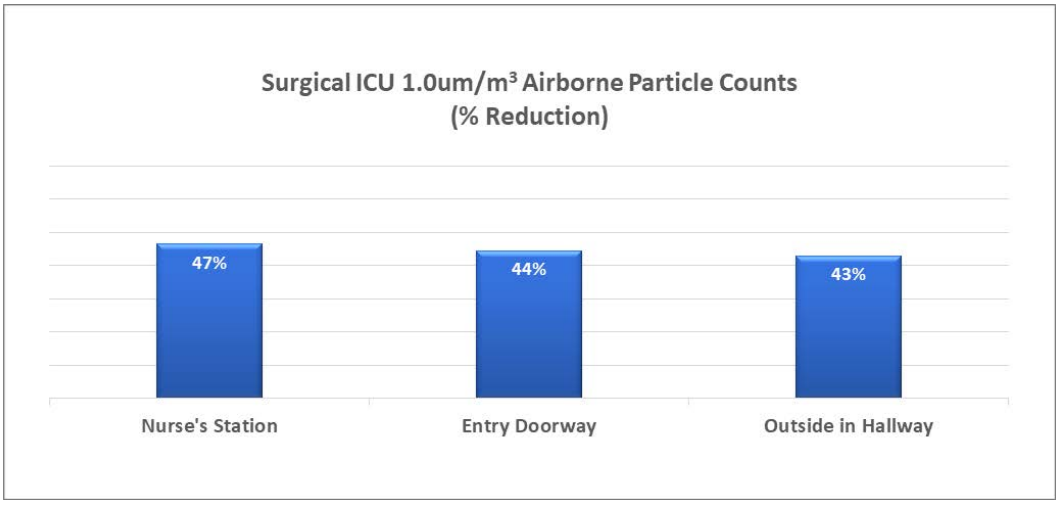


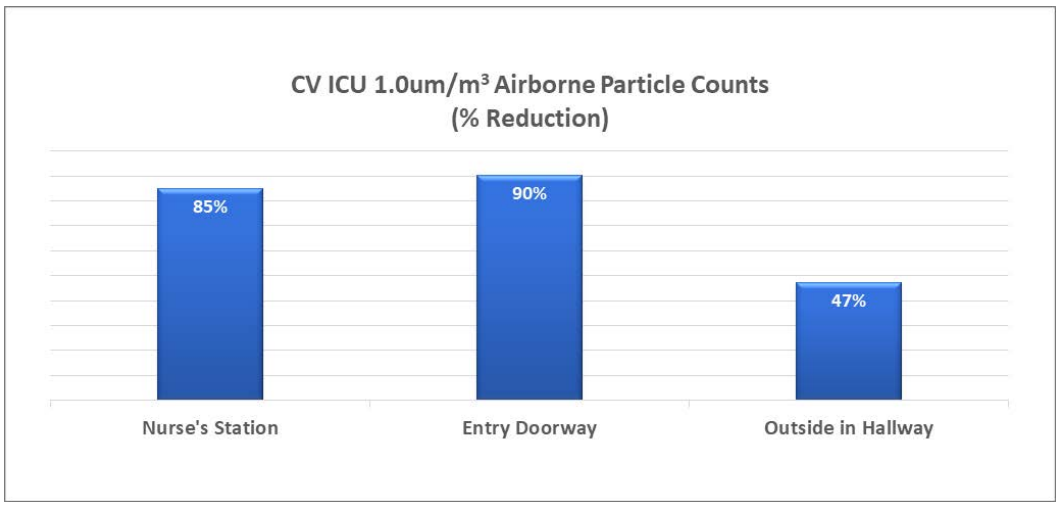


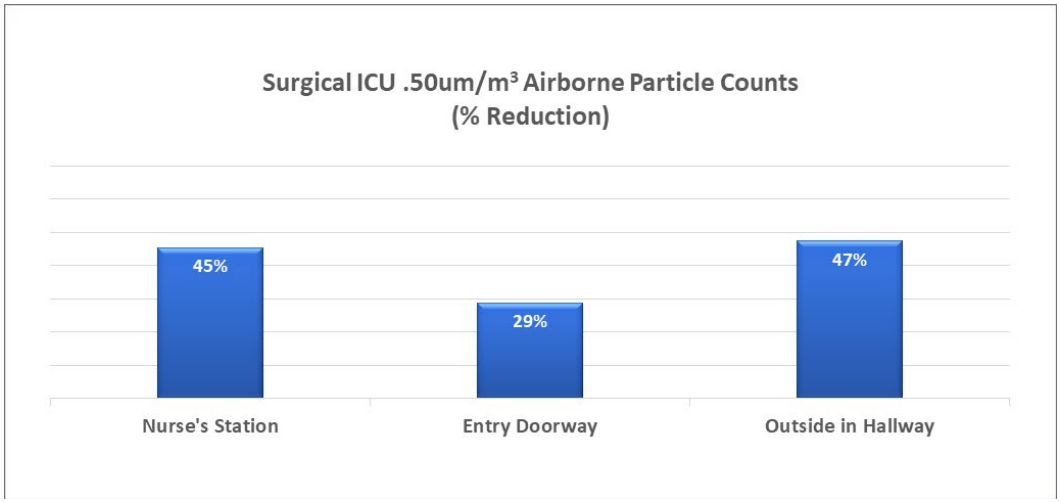
AIRBORNE PARTICULATES

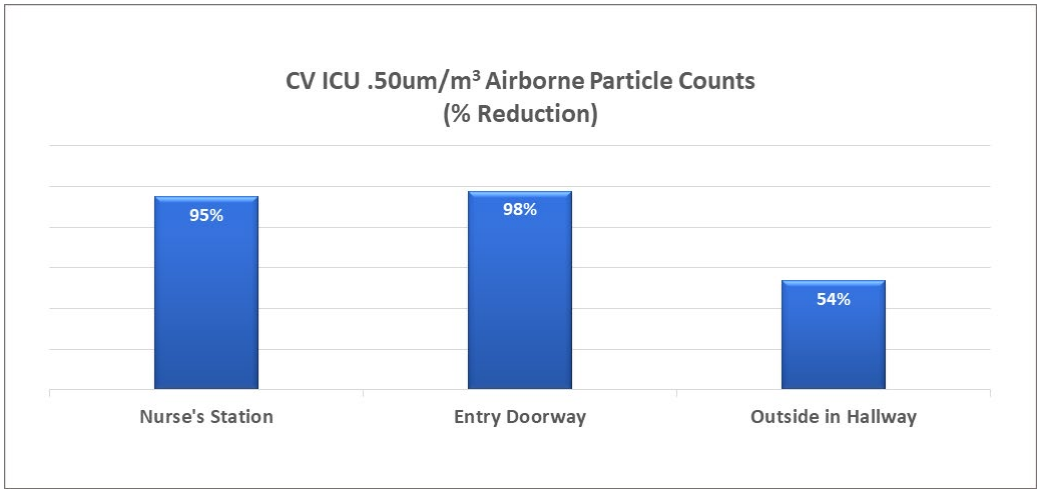
Prior to installing the Beyond Medical Guardian Air units, particle counts were collected three different times on May 30, 2019. The combined average particle counts measured 485,395 particles per cubic meter at 1.0 um and 958,580 particles per cubic meter at .5 um in the Surgical Intensive Care Unit (SICU). They measured 1,711,928 particles per cubic meter at 1.0 um and 12,145,965 particles per cubic meter at .5 um in the Cardiovascular Intensive Care Unit (CV-ICU).

During the same three test periods time on June 5, 2019, seven days after installing the Beyond Medical Guardian Air units, the combined average particle counts were reduced to 269,432 particles per cubic meter at 1.0 um and 569,315 particles per cubic meter at .5 um in the SICU and 269,061 particles per cubic meter at 1.0 um and 562,097 particles per cubic meter at .5 um in the CV-ICU. This equates to an overall reduction in airborne particulates in the SICU by 44% and in the CV-ICU by 84%.









NOTEWORTHY UNUSUAL OBSERVATIONS

None observed.

CONCLUSION

Testing results indicate that the Beyond Medical Guardian Air with Aerus ActivePure Technology materially reduces or eliminates microorganisms and particulate matter from the air and on surfaces in the Surgical ICU (SICU) and Cardiovascular ICU (CV-ICU) environments. Results showed that: Surface Bacteria counts were reduced over an average of 83%; Surface Fungi were reduced by 87%; Surface Methicillin Resistant Staphylococcus (MRSA) were (BDL) below detection levels with the exception of a single instance where it was reduced 100%; Surface Staphylococcus Aureus was reduced by 97% and Airborne Particulates were reduced over an average of 64% during the seven-day test period.

The Beyond Medical Guardian Air with Aerus ActivePure Technology was very effective in eliminating bacteria (including MRSA) and fungi on all surfaces, as well as providing ongoing protection of the surfaces and air against future contamination.

FOOTNOTES

1.https://sunnybrook.ca/media/item.asp?c=2&i=401&page=185
2.https://www.patientsafetyinstitute.ca/en/Topic/Pages/Healthcare-Associated-Infections-(HAI).aspx
3.Ibid
4. https://yourhealthsystem.cihi.ca/hsp/inbrief?lang=en#!/indicators/015/cost-of-a-standard-hospital-stay
5.https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4028670/

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Trial record **1 of 1** for: NCT04610294

Previous Study | Return to List | Next Study

Operating Room Air Filtration/Sterilization

ClinicalTrials.gov Identifier: NCT04610294

Recruitment Status : Not yet recruiting
First Posted : October 30, 2020
Last Update Posted : December 11, 2020

See **Contacts and Locations**

Sponsor:
The Cleveland Clinic

Information provided by (Responsible Party):
The Cleveland Clinic

Study Details | Tabular View | No Results Posted | Disclaimer | How to Read a Study Record

Study Description

Go to

Brief Summary:

Determine whether operating room air filtration and sterilization with the Aerus system reduces a composite of serious surgical site infections, infection-related complications, and death within 30 days after surgery.

Condition or disease	Intervention/treatment
Non-cardiac Surgery	Device: Functioning Aerus air filtration/sterilization Device: Deactivated Aerus air filtration/sterilization

Detailed Description:
The investigators primary goal is thus to determine whether filtering and sterilizing operating room air reduces a composite of serious surgical site infections, infection-related complications, and death within 30 days after surgery. The investigators will determine the effect of air filtration and sterilization on serious surgical site infections, and on the cost of care. infections, and on the cost of care.

Study Design

Go to

Study Type :
Observational

Estimated Enrollment :
86639 participants

Observational Model:
Case-Crossover

Time Perspective:
Prospective

Official Title:
Operating Room Air Filtration/Sterilization and Surgical Site Infection: A Randomized Multiple Cross-over Cluster Trial

Estimated Study Start Date :
January 2021

Estimated Primary Completion Date :
January 2024

Estimated Study Completion Date :
June 2024

Resource links provided by the National Library of Medicine

Genetic and Rare Diseases Information Center resources:
Oculocerebral Syndrome With Hypopigmentation

U.S. FDA Resources

Groups and Cohorts

Go to

Group/Cohort	Intervention/treatment
Aerus air sterilization Aerus air sterilization system will be used in an operating room, in addition to routine room air filtration	Device: Functioning Aerus air filtration/sterilization Two units of Aerus air sterilization system will be used in each operating room, and each will be set to "high." Units used for the trial will be modified internally to be active and will be sealed to prevent operating room personnel from opening the system and determining a unit's status.
Conventional air handling Only routine room air filtration will be used in an operation room.	Device: Deactivated Aerus air filtration/sterilization Two units of Aerus air sterilization system will be used in each operating room, and each will be set to "high." Units used for the trial will be modified internally to be inactivated and will be sealed to prevent operating room personnel from opening the system and determining a unit's status. Units will be inactivated by removing the activated carbon, high-efficiency particulate filter, and ionization chamber. However, the fan will remain active as will the "run" lights.

Outcome Measures

Go to

Primary Outcome Measures :

1. Composite outcome of postoperative complications [Time Frame: 30 days after surgery]

   A composite of mortality, major surgical site infection, and healing-related wound complications

Secondary Outcome Measures :

1. Serious surgical site infection [Time Frame: 30 days after surgery]

Deep or organ-space surgical site infection will be evaluated by analysis of International Classification of Disease revision 10 (ICD-10) diagnosis codes

2. Cost-of-care [Time Frame: 30 days after surgery]

   Our economic analysis will estimate the cost-effectiveness ratio, defined as the difference in average total hospital costs divided by the difference in the proportion with any of the components of the composite, and expressed as average cost per 1 percent improvement in the composite outcome.

Eligibility Criteria

Go to

Information from the National Library of Medicine

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study:

All

Accepts Healthy Volunteers:

No

Sampling Method:

Probability Sample

Study Population

The trial will take place in the adult operating rooms of the Cleveland Clinic Main Campus, specifically ORs 1-25 in E and 28-38 in H, 40-50 in G, and J operating rooms. Because of the cohort design, all patients who have surgery in these operating rooms will be included.

Criteria

Inclusion Criteria:

- All patients in designated adult operating rooms

- American Society of Anesthesiologists physical status 1-4.
- Surgery lasting at least 1 hour.

Exclusion Criteria:

- patients with present-on-admission infections

Contacts and Locations

Go to

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT04610294***

Contacts

Contact: Roberta Johnson 216-444-9950 johnsor13@ccf.org

Contact: Mauro Bravo, MD 216-636-9449 bravom2@ccf.org

Locations

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Cleveland Clinic

Cleveland, Ohio, United States, 44195

Contact: Roberta Johnson 216-444-9950 johnsor13@ccf.org

Contact: Mauro Bravo, MD 216-636-9449 bravom2@ccf.org

Principal Investigator: Daniel I Sessler, MD

Sponsors and Collaborators

The Cleveland Clinic

Investigators

Principal Investigator: Daniel I Sessler, MD The Cleveland Clinic

More Information

Go to

Responsible Party:

The Cleveland Clinic

ClinicalTrials.gov Identifier:

NCT04610294 History of Changes

Other Study ID Numbers:

20-656

First Posted:

October 30, 2020 Key Record Dates

Last Update Posted:

December 11, 2020

Last Verified:

December 2020

Studies a U.S. FDA-regulated Device Product:

No