HOSPITAL SURGICAL AND CARDIO ICUS TESTING REPORT

EFFICACY OF BEYOND MEDICAL GUARDIAN AIR WITH AERUS ACTIVEPURE TECHNOLOGY
IN CANADIAN MEDICAL ICU SETTINGS
AUGUST2, 2019



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

Date of Report

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Contents	
Executive Summary	3
Materials and Methods	
Results and Graphs	
Total Bacteria and Fungi; Results (Swab)	7 - 8
Methicillin Resistant Staphylococcus (MRSA) (Swab)	9 - 10
Blood and Potato Agar Plate Results (Air)	11 - 12
Airborne Particulates	13 - 14
Noteworthy Unusual Observations	15
Conclusion	16
Contact Information	17

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."

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.

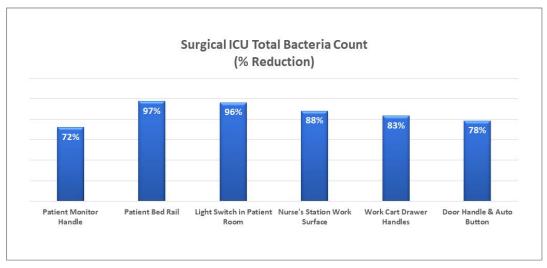
The difference between the before samples and the samples after running the Beyond Medical Guardian Air units for seven days was very substantial and significant.

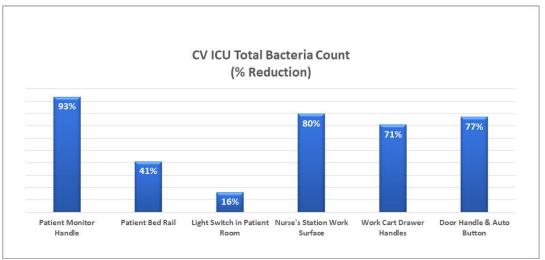
TOTAL BACTERIA AND FUNGI RESULTS (SWAB)

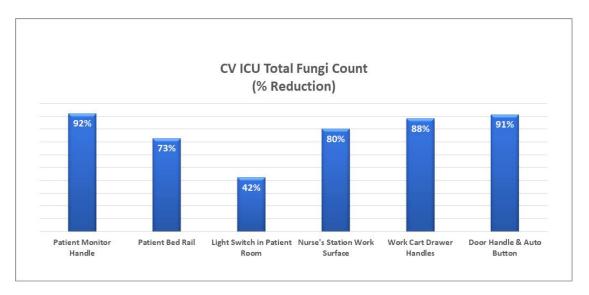
During the surface sampling periods on May 30, 2019, a combined total of 15,430 Colony Forming Units (CFUs) of bacteria were discovered in the Surgical Intensive Care Unit (SICU) and 2,956 CFUs of bacteria were measured in the Cardiovascular Intensive Care Unit (CV-ICU) as a result of the surface sampling. 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.

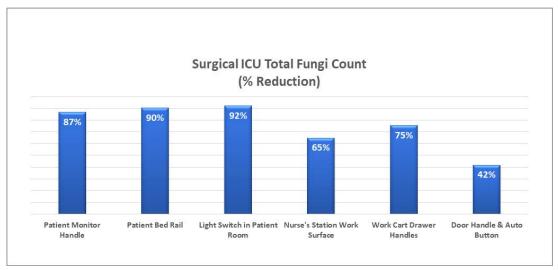
During the same test period time on June 5, 2019, seven days after installing the Beyond Medical Guardian Air units, the combined total bacteria count was reduced to 867 CFUs of bacteria in the SICU and 784 CFUs of bacteria in the CV-ICU. Testing results for Fungi in these same areas were 313 CFUs in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







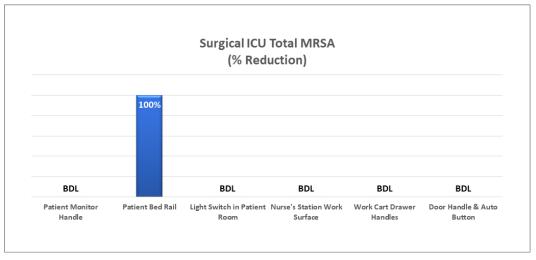


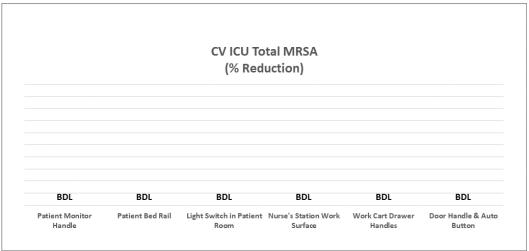
METHICILLIN RESISTANTSTAPHYLOCOCCUS(MRSA) (SWAB)

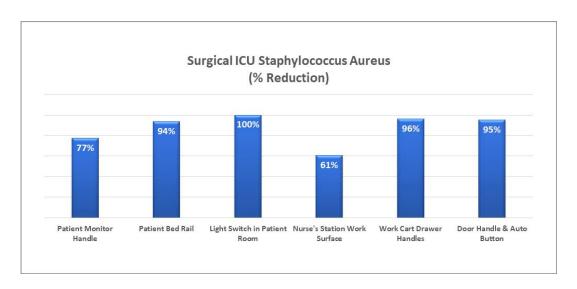
During the surface sampling periods on May 30, 2019, a total of 31 CFUs of Methicillin Resistant Staphylococcus Aureus (MRSA) were discovered in the Surgical Intensive Care Unit (SICU) and 0 CFUs of Methicillin Resistant Staphylococcus Aureus (MRSA) were found in the Cardiovascular Intensive Care Unit (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.

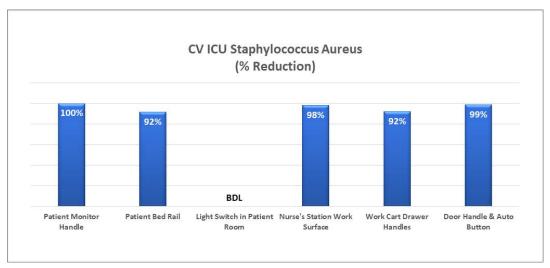
During the same test period time on June 5, 2019, seven days after installing the Beyond Medical Guardian Air units, the combined MRSA count was reduced to 0 in the SICU and 1 CFU was present in the CV-ICU. This equates to a reduction in MRSA bacteria in the SICU to 100% and the level in the CV-ICU was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









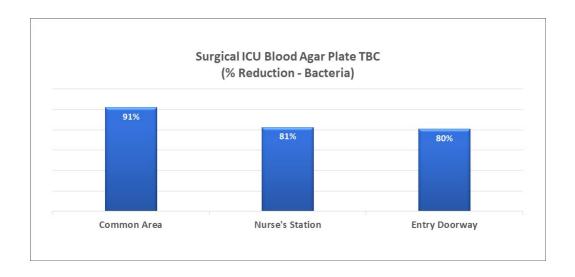
BLOOD AND POTATO AGAR PLATE RESULTS (AIR)

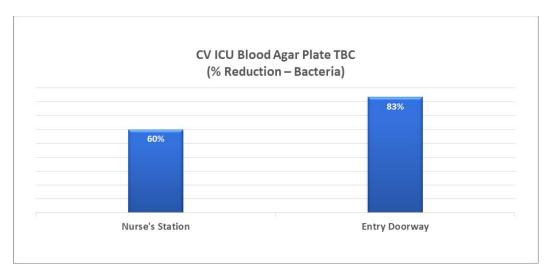
Agar plate samples collected on May 30, 2019 had a combined total bacteria count of 104 CFUs with **blood agar** and total fungi of 17 CFUs with **potato agar** in the Surgical Intensive Care Unit (SICU) and a total bacteria count of 24 CFUs with **blood agar** and total fungi of 7 CFUs with **potato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

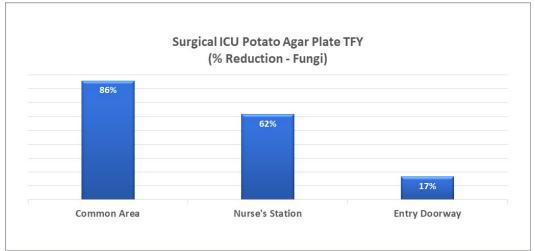
Agar plates collected on June 5, 2019, seven days after installing the Beyond Medical Guardian Air units, had a combined total bacteria count of 16 CFUs with **blood agar** and total fungi of 6 CFUs with **potato agar** in the SICU, and a total bacteria count of 11 CFUs with **blood agar** and a total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

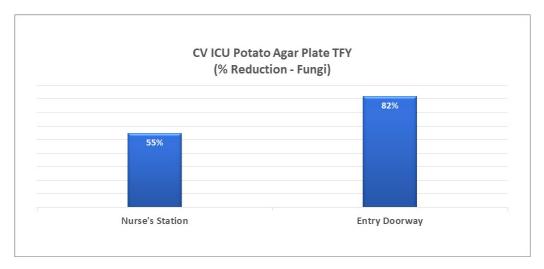
This equates to a reduction in total bacteria CFUs of 85% in the SICU and 72% in the CV-ICU. Total fungi CFUs were reduced by 64% in the SICU and 68% in the CV-ICU. The results indicate that the air was materially less contaminated with bacteria and fungi as a result of the Beyond Medical Guardian Air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





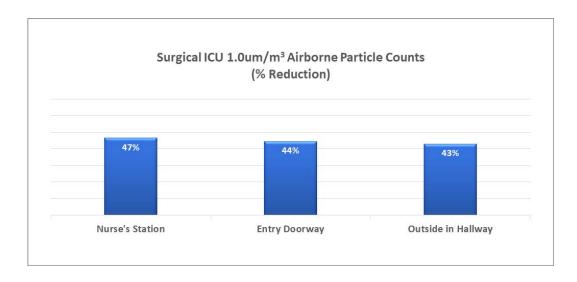


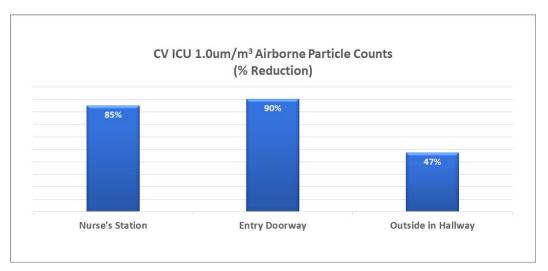


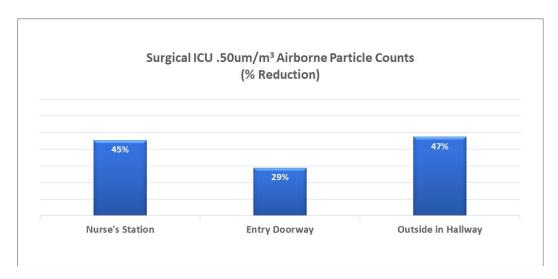
AIRBORNE PARTICUL ATES

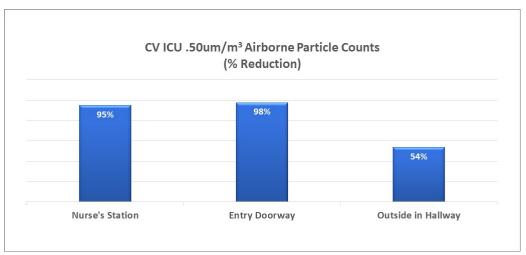
Prior to installing the Beyond Medical Guardian Air units, particle counts were collected three different times on May 30, 2019. The combined average particle counts measured 485,395 particles per cubic meter at 1.0 um and 958,580 particles per cubic meter at .5 um in the Surgical Intensive Care Unit (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%.









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

 $\underline{2.https://www.patientsafetyinstitute.ca/en/Topic/Pages/Healthcare-Associated-Infections-(HAI).aspx}\\$

3.Ibid

4. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4028670/

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