

WellAir's Novaerus Defend 400 Air Cleaning Device Shows a Substantial Reduction in Airborne Bacterial Bioburden in Operating Room¹

Testing location:

Healthcare facility operating room located in Glen Echo, Maryland, Washington DC. The facility was running at normal capacity and actively treating patients. There were 25 cases in total; 13 cases were recorded on control days while there were 12 cases recorded on the test days.

The testing was performed over six days in December 2021, March 2022 and April 2022. There were three days for testing and three days for control sampling; with one day each on each month listed.



PRODUCT BACKGROUND

The Defend 400 air cleaner (WellAir) is an FDA cleared device that has previously been demonstrated to remove and inactivate micro-organisms using patented NanoStrike™ technology.² The NanoStrike technology is complemented with high-efficiency particulate arrestance (HEPA) filter. The device is compact and portable to allow for incorporation in any healthcare room.

Defend 400
Air Cleaning Device

 **FDA Cleared**
Class II Medical Device

OBJECTIVE

To test the hypothesis that the use of a portable stand-alone air cleaner in an operating room within a hospital/healthcare environment is effective in reducing airborne bioburden in the environment.

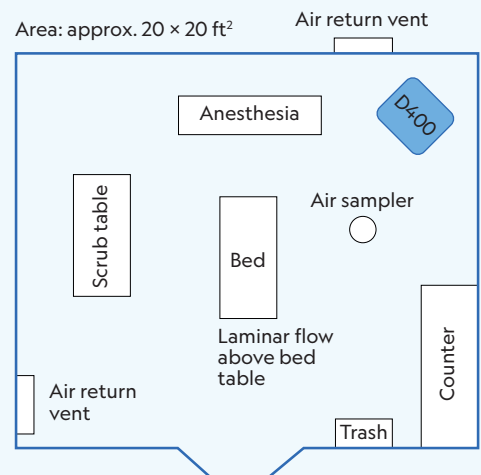


Fig. 1.

Layout diagram of the operating room. The stand-alone air cleaner is tagged as D400.

METHODOLOGY

- The levels of airborne bioburden were measured by collecting 100 litres of air samples on TSA agar plates using an impaction air sampler.
- An equal number of test and control samples were taken on the different days and samples were taken in duplicate.

- Test and control samples were collected over three days each, six in total. A total of 120 air samples were collected:
 - 60 during controls sampling, and 60 during test sampling
- The air samples were analysed by EMSL lab for bacterial counts and identification of three most prominent species present in each agar plate.
- The Defend 400 device was set at speed 5 (maximum speed), 210 CFM (356 m³/h) and was switched on for the duration of the test sampling periods.
- The device was turned off for the duration of the control sampling periods.

RESULTS

Post-operation total colony counts saw a reduction of 56.7% between control and test samples (p-value 0.003432).

A total of 41 different bacterial species were identified in the agar plates analysis that were collected throughout the trial. Identification of 1 bacterial pathogen and 19 bacterial opportunistic pathogens.

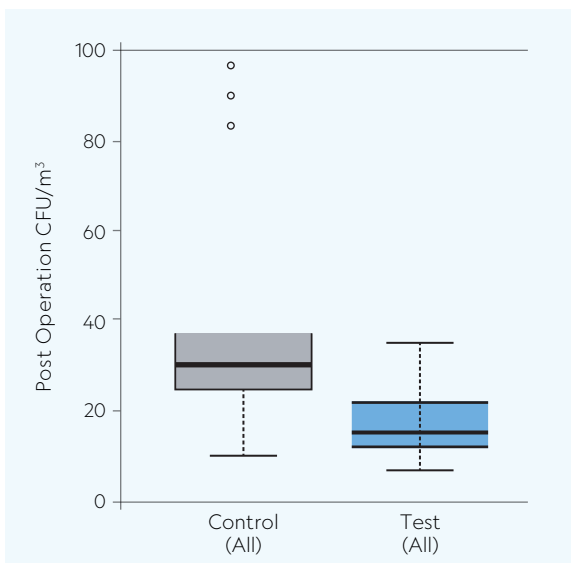


Fig. 2. Box-Whisker plot of colony counts from post-operation samples for all microorganisms.

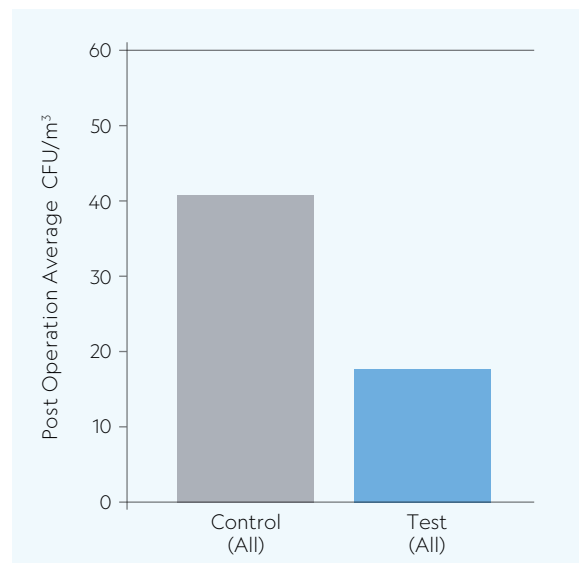


Fig. 3. Bar plot of average colony counts from post-operation sampling for all microorganisms.

CONCLUSIONS AND DISCUSSION

The use of a portable stand-alone air cleaner in an operating room has shown substantial reduction in airborne bacterial bioburden overall.

REFERENCES

1. F. Soberon & L. Lawlor, Evaluation of an air cleaner device in an operating room, September 2022
2. <https://wellairsolutions.com/research>