AVIDICARE

TECHNICAL REPORT

Stress Testing the Opragon

Temperature-controlled Air Flow Ventilation System

INTRODUCTION

In 2018, Maximuse BV was engaged by a large teaching hospital in the Netherlands to conduct a comprehensive performance evaluation of the Opragon, Temperature-controlled Air Flow (TcAF) ventilation system. Maximuse is an engineering consultancy specializing in the design of state-of-the-art operating rooms with a focus on integration of patient safety and workflow efficiency.
The Netherlands has one of the most rigorous standards for operating room air quality in the world. In rooms where infection sensitive surgery is performed, 10 CFU/m^3 is the maximum allowable level of airborne microbial contamination during a surgical procedure. Moreover, a mean value of ≤5 CFU/m3 must be maintained to ensure that the air quality remains below the maximum allowable level. Regular measurement is required to demonstrate compliance.

As a part of the design process for a new surgical center, the planners commissioned the independent study to determine whether the Opragon ventilation system could meet the new standard. The goal was to measure the performance of the Opragon under both routine and extreme conditions. The study[1] was undertaken at Art Clinic, in Gothenberg, Sweden. (Fig. 1)

Figure 1 Gothenberg clinic operating room

"This procedure was an extreme example in which maximum efforts were made to provoke the system."

Remko Noor, Chief Executive Officer, Maximuse.

"The Opragon gives the surgical team peace of mind and allows them to focus on their important tasks."

Dr Koen Defoort, head of surgery at the Sint Maartens Kliniek (ranked #6 globally in orthopedics).

- Over 300 Opragon systems have been installed in Europe, Asia and the US.
- The Opragon is designed and manufactured by Avidicare AB.
- For more information visit www.avidicare.com.

OPERATING ROOM CONFIGURATON

The operating room used in this study was 54m2 (540sqft). The Avidicare Opragon 8 TcAF ventilation system consists of 8 air showers over the surgical field and 10 air showers in the periphery of the room (Fig. 2).

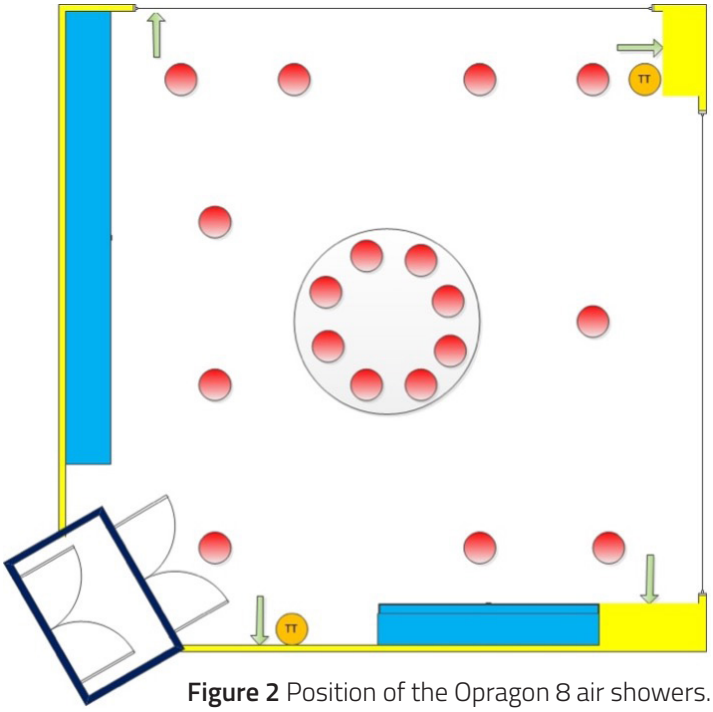


Figure 2 Position of the Opragon 8 air showers.

METHODS

The study consisted of three simulated surgical procedures beginning with a routine knee arthroplasty. Each subsequent procedure was designed to raise the level of stress on the Opragon system by increasing the factors known to influence airborne contamination such as the number of personnel; number of door openings; movement of personnel and equipment; and thermal heat load. The final procedure, a leg trauma, was designed to put maximum pressure on the system.

CFU measurements were undertaken according to the Swedish Standard SIS-TS 39:2015 which requires measurement at both the wound and the instrument tables. Equipment consisted of agar plates and 2 rotating slit samplers. Samples were incubated aerobically for 48 hrs. at 35°C.

Particle measurements using particle counters were also taken in the center and periphery of the room to determine whether the Opragon was capable of maintaining the required conditions throughout the entire space.

Each procedure lasted a minimum of 50 minutes. During each procedure, microbial samples were taken at two locations: 1) a maximum distance of 2 feet from the patient wound area (with a sterile tube/ hose),and 2) at the instrument table(s). Three samples were taken at each location. To demonstrate ultraclean conditions, the maximum level of airborne microbial contamiantion must be below 10CFU/m^3.

PROCEDURES AND RESULTS

Procedure 1: Knee Arthroplasty

During this procedure, in addition to the patient, there were 5 surgical personnel performing the simulated procedure.
Two instrument tables, routine surgical equipment and anesthesia equipment were in place with all equipment turned on.
There were 6 door openings during the procedure.
Figure 3 depicts the placement of agar plates and air samplers.

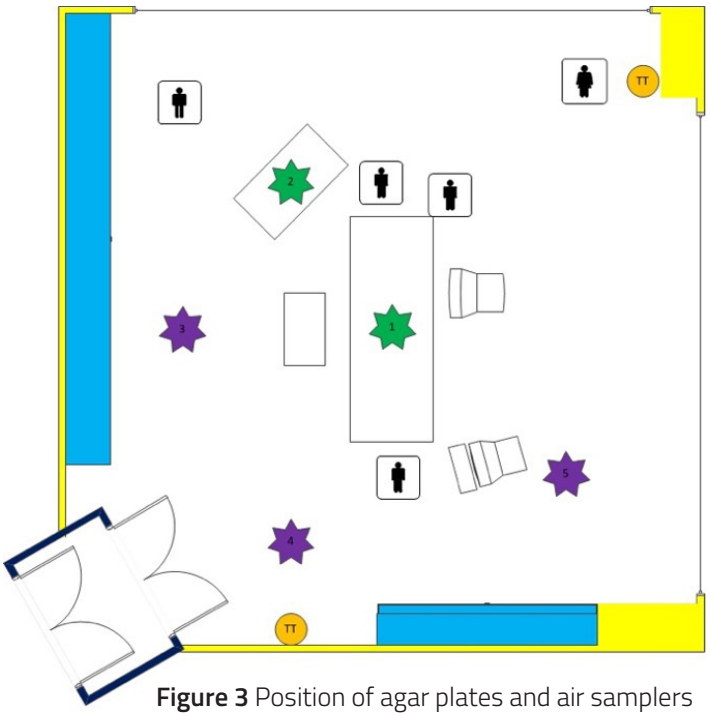


Figure 3 Position of agar plates and air samplers indicated by the green and purple stars.

During this procedure the Opragon maintained the wound area at an average of 0.6 CFUs and the instrument tables at 1.2 CFUs. (Table 1)

Area	1	2	3	4	5	Average
Wound	3	0	0	0	0	0,6
Instruments	1	1	1	2	1	1,2

Table 1 CFU-measurements during Knee Arthoplasty

No particles were recorded at the wound area (location 1). At the instrument table (location 2) maximum values of 14,125 (>0.5µm) and 2,407 (>5µm) were recorded. In the periphery locations (3-5) the number of particles observed was similar to those at the instrument table. (Table 2)

0,5 µm	Sterile zone		Periphery		
Level	1	2	3	4	5
High	0	14.125	15.538	15.891	1.059
Low	0	1.765	0	0	0
Average	0	5.841	3.391	3.009	37

5,0 µm	Sterile zone		Periphery		
Level	1	2	3	4	5
High	0	2.407	1.412	1.765	353
Low	0	0	0	0	0
Average	0	360	360	507	7

Table 2 Particle-measurements during Knee Arthroplasty

Procedure 2: Caesarean section

In addition to the patient, in this simulated procedure there were 9 medical staff, 2 instrument tables, routine surgical equipment, anaesthesia equipment and a Bair Hugger.
All equipment was turned on.
During this procedure there were 8 door openings. (Fig. 4)

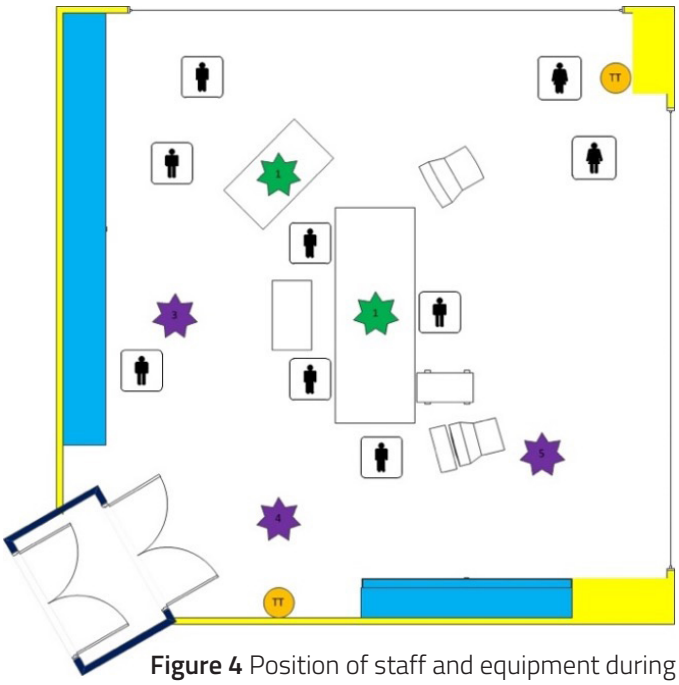


Figure 4 Position of staff and equipment during Caesarean section.

During the Caesarean procedure, the Opragon maintained the area at the wound at 0 CFUs throughout the duration of the procedure. The instrument table was maintained at an average of 1.6 CFUs. (Table 3)

Area	1	2	3	4	5	Average
Wound	0	0	0	0	0	0
Instruments	2	2	1	1	2	1,6

Table 3 CFU-measurements during Caesarean section

The particle measures show a maxium value of 706 (>0.5 um) and 353 (>5 um) particles at the wound area (location 1) and (>0.5 um) and 1412 (>5 um) at the instrument table. The periphery locations (3-5) show similar or just slightly higher levels of particles than levels recorded at the instrument table. (Table 4)

0,5 µm	Sterile zone		Periphery		
Level	1	2	3	4	5
High	706	9.535	12.007	19.423	5.297
Low	0	0	0	0	0
Average	21	1.681	3.905	6.427	974
5,0 µm	**Sterile zone**		**Periphery**		
Level	1	2	3	4	5
High	353	1.412	6.709	2.118	1.059
Low	0	0	0	0	0
Average	7	162	618	669	88

Table 4 Particle-measurements during Caesarean section

Procedure 3: Upper Leg Trauma

This procedure was designed to put maximum pressure on the Opragon system. In addition to the patient, in the room there were 13 surgical staff performing the simulated procedure, 2 instrument tables, 2 lamps, all routine surgical equipment, a suction unit, anesthesia equipment and a Bair Hugger. All equipment was turned to the highest level to create maximum heat loads. During the procedure an imaging C-arm was brought into the room and moved into place. The simulated procedure lasted 50 minutes during which there were 36 door openings.(Fig. 5 and 6)

Figure 5 Picture from Upper Leg Trauma procedure

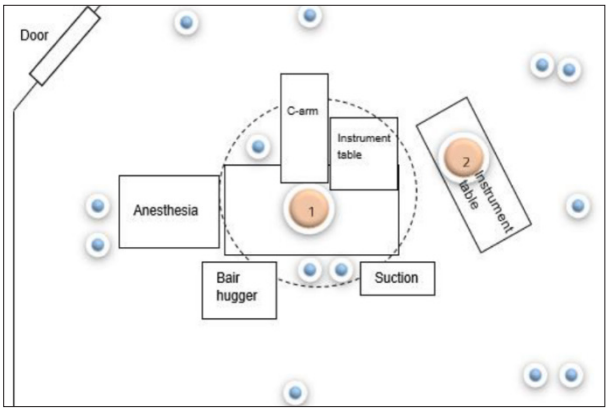


Figure 6 Location of staff, equipment, and placement of agar plates

Even under these extreme conditions, the Opragon maintained the area at the surgical wound at an average of 0.75 CFUs, at the instrument tables at an average of 6.8 CFUs. (Table 5)

Area	1	2	3	4	5	Average
Wound	3	0	0	0	1	0,8
Instruments	6	7	5	7	9	6,8

Table 5 CFU-measurements during Upper Leg Trauma

A maximum value of 5,660 (0.5 um) and 706 (5 um) particles were recorded at the wound area (location 1) and 13 066 (0.5 um) and 2 825 (5 um) at the instrument table (location 2) Recorded levels of particles in the periphery locations (3-5) were similar to or just slightly lower than those recorded at the instrument tables.(Table 6)

0,5 µm	Sterile zone		Periphery		
Level	1	2	3	4	5
High	5.660	13.066	7.062	12.007	3.884
Low	0	353	0	0	0
Average	1.195	5.426	5.589	5.623	944

5,0 µm	Sterile zone		Periphery		
Level	1	2	3	4	5
High	706	2.825	1.765	2.118	1.412
Low	0	0	0	0	0
Average	28	590	821	645	135

Table 6 Particle-measurements during Upper Leg Trauma

DISCUSSION

Based on a growing body of evidence demonstrating that conventional Laminar Air Flow (LAF) ventilation is not effective in protecting patients from the risk of surgical site infection (SSI) and may even contribute to SSI, in 2017 both the CDC and the WHO revised recommendations for use of LAF systems for infection sensitive surgeries. The WHO issued a conditional recommendation that LAF should not be used for prosthetic joint infection while the CDC back-tracked on its previous recommendation and deemed LAF an "unresolved issue."[2,3] Despite the change in recommendations, US institutions have had little choice in ventilation systems and concepts. The design of these systems has changed little since their inception in the 1960s.

While there is no standard definition for LAF, these systems are consistent in design from the perspective that they focus on the surgical field only. Designed to maintain a clean zone in the immediate surgical field only, these systems can meet the ASHRAE 170 standard when the limited protected zone extends only 12 inches beyond the perimeter of the surgical table (Figure 7).[4] While these systems, when properly calibrated, typically maintain ultraclean air quality in the range of <10CFU/m^3 inside the protected zone, values outside of this zone have been found to be considerably higher. Benen, et al, observed a a 55-fold increase in the mean value of airborne CFUs outside the protected zone compared to the value inside this zone.[5] This is particularly concerning given that previously sterilized instruments and implants are most frequently opened and staged on the back tables which are well outside of the clean zone.

Harp observed that turbulent wakes from obstacles in the airflow, the movement of equipment, personnel and doors can transport microbial containing particles to non-protected zones such as back tables. These wakes can also transport particles to the free sheer mixing layer resulting in critical zone contamination.

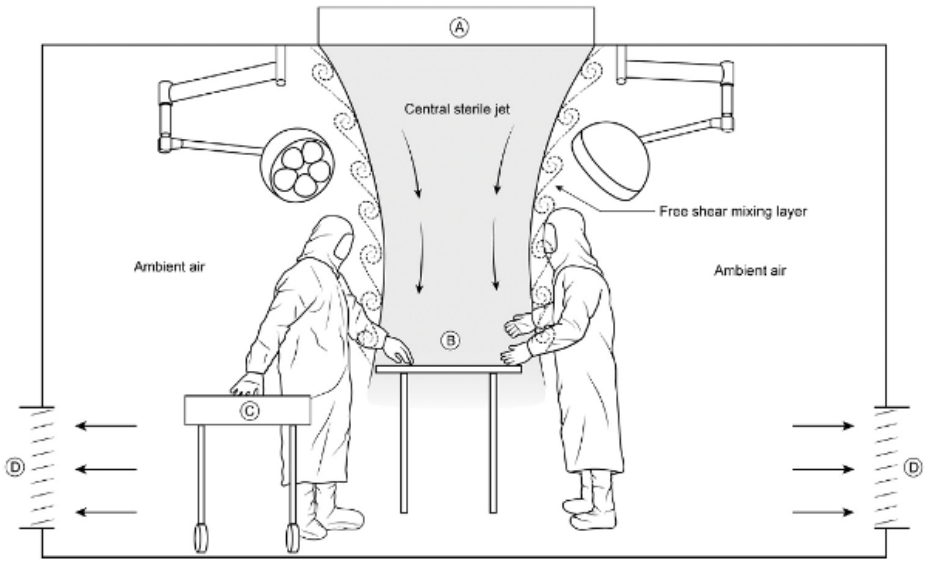


Fig 1. Schematic diagram of airflow in an operating room built to ASHRAE 170 – 2021 standards. (A) Ceiling diffusers supplying HEPA filtered air. (B) Surgical wound zone located in central jet of sterile air. (C) Back table zone for sterile instruments and supplies located in ambient air. (D) Near floor level exhaust grilles. Ambient air surrounds the central sterile jet and will contain variable amount of MCPs from personnel in room. The free shear mixing layer allows ambient room air to contaminate the central sterile jet.

Figure 7 Excerpted from Harp JH. Observational study of sterile field bioburden levels during orthopedic arthroplasty surgery in operating rooms complying with current United States ventilation specifications.[4]

Maintaining ultraclean conditions, even in the clean zone requires diligent application of infection prevention protocols, including AAMI Level 4 gowns and surgical helmets. In the simulated procedures outlined above, personnel wore standard surgical gowns, masks and bonnets.[4]

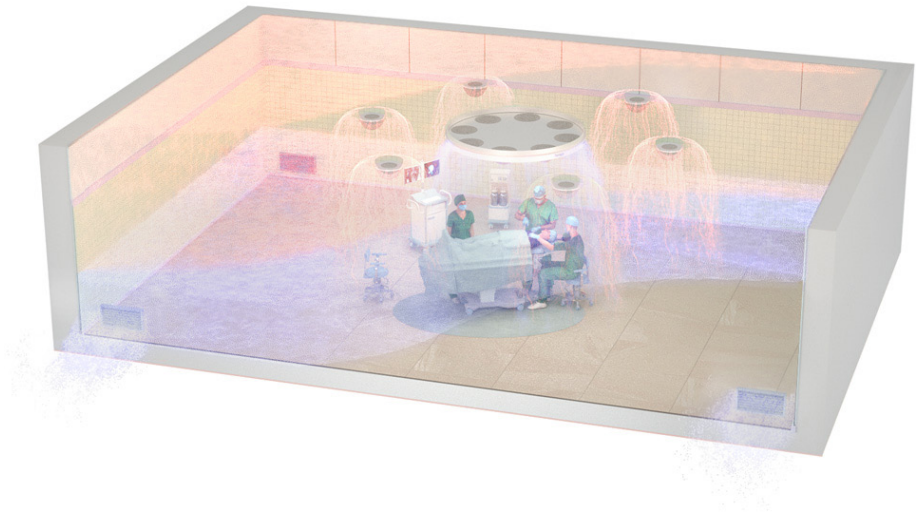
The Opragon was designed for the modern operating room with three goals in mind:

1) to maintain the entire room at ultraclean <10CFU/m3 conditions,

2) improve comfort for surgical personnel and

3) optimize energy consumption.

Through a patented combination of temperature differential and gravity the system is able to create a robust flow of air perpendicular to the floor. While velocity from the diffusers decreases with distance in a conventional LAF system, air velocity increases with distance from the diffusers in a TcAF system. This is one of the reasons why TcAF is more effective at sweeping the air downward in a consistent unidirectional manner.



CONCLUSION

This stress test demonstrates that even in the most challenging case with 13 staff, extreme movement and frequent door openings, the Opragon system was able to maintain ultraclean conditions throughout the whole room. It also shows that, in contrast to conventional laminar air flow systems, back tables where previously sterilized items are opened and staged are also maintained in ultraclean conditions. This robustness is valuable as it ensures conditions for safe surgery even when behavior and other conditions cannot be maintained at ideal levels.

ArtClinic, Sweden

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4. Harp JH. Observational study of sterile field bioburden levels during orthopedic arthroplasty surgery in operating rooms complying with current United States ventilation specifications,, Am J of Infect Con. 2023; 51(7):758-764.
5. Benen, T., Wille, F. & Clausdorff, L. Influence on different ventilations systems upon the contamination of medical devices. Hyg Med, 38(4), 142- 146.

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