

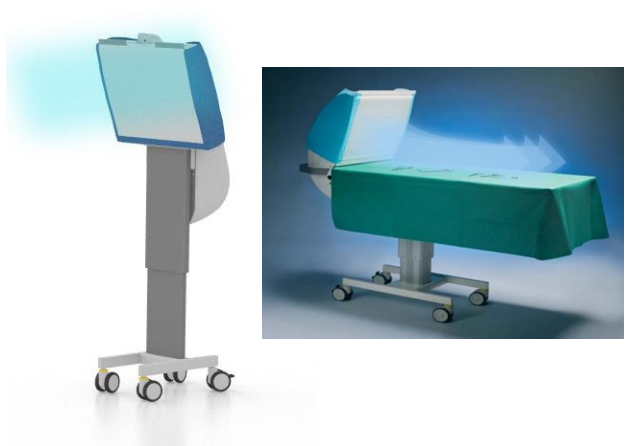
Design of Cardiac Surgery Operating Rooms

Operating Room Ventilation System for heart surgery ISO 5

The operio mobile laminar air flow system makes it possible to upgrade existing operating theatres from ISO 7 to ISO 5



Operio Sterile Air Flow units are a state-of-the-art laminar flow technology that creates sterile, ultraclean conditions for operating rooms to protect patients from infections. The Operio laminar air flow technology enables cost-effective upgrading of existing operating rooms from ISO 7 to ISO 5. **Operio creates an asepsis for the instruments and operating area (and that's what matters!) that is up to 100 times higher than in a conventional operating room ISO 7** because the sterile air flow protects directly the instruments and the operating area without obstructions – such as operating lights, microscopes or the operating team.



The Operio Sterile Air Flow unit filters the ambient air through a highly purifying H 14 Hepa filter with an efficiency of over 99.9%, which eliminates bacteria and micro-organisms (including coronavirus covid 19) by over 99.9%! These units can be positioned to produce a “bacteria-free zone” that offers the greatest possible protection for both the surgical team and the patient, in that they filter 400 m3 of air per hour, thus reducing microorganisms in the entire room.

Portable laminar air flow for heart surgery



The focus-oriented, mobile laminar air flow devices generate an ultraclean, germ-free air flow by filtering the air with a Hepa H14 filter, which can be aimed precisely at the desired operating field area. The "sterile air flow" is not hindered neither by the operating theater lights nor by the operating microscope. In this way, extremely low-germ air can be created in the area of the operating wound and the instruments, which makes it possible to operate under perfectly hygienic conditions



In cardiac surgery two mobile laminar air flow units are often used to protect both the instruments and the operating area. This technology can be used in any existing operating rooms without costly reconstruction work. This laminar air flow is perceived by the staff as very pleasant, as it does not generate cold air.

Sterile instrument table



The instruments and implants (especially in trauma surgery) are protected by ultraclean air during both preparation and surgery.

Focussed laminar air flow



The "sterile air flow" protects the instruments and the OR field even with large OR lights. Due to the horizontal flow without any obstacles, an extremely low level of germs is achieved in the critical area of the instruments and the surgical field

The Operio OR ventilation system has a proven ability to reduce airborne bacteria levels. Less bacteria in the operating room air leads to lower risk for SSIs. The key factor in reducing surgical site infection is to minimize the contamination of the sterile (clean) zone where the surgical procedures are performed. One main source of infection in the OR is squames, which are skin scales shed from the exposed skin of O.R. people in the operating room.

The sterile Air Flow device Operio filters the ambient air through a highly cleaning H 14 Hepa filter with has an efficiency of over 99.995% eliminating bacteria, microorganisms and even coronavirus Covid-19 to over 99.9%! The devices can be positioned in such a way that a "germ-free zone" is set up that offers the greatest possible protection for both the surgical team and the patient. The devices filters 400 m3 of air per hour so that the microorganisms are reduced in the entire room.

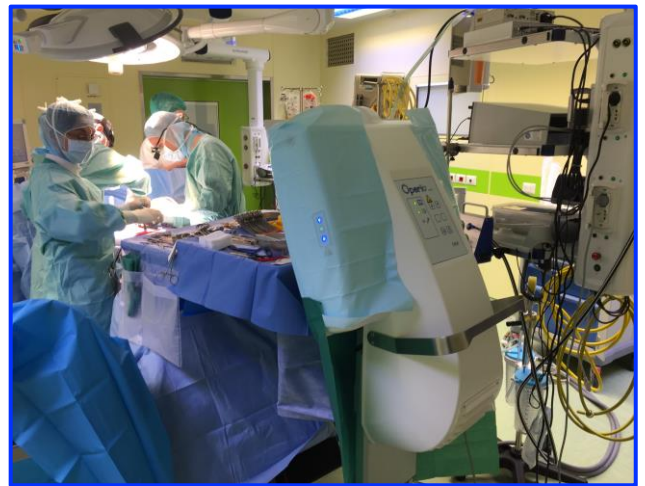
The mobility of the devices and the **inexpensive price** makes it possible to have high aseptic conditions in every existing operating theater.



Instruments prepared outside the air supply ceiling of a laminar air flow system (ISO 5) will become contaminated after a short time. The longer the operation lasts, the higher will be the risk of instrument contamination and thus of infection. (Thomas Benen¹, Frank Wille^{1*}, Lüder Clausdorff², The influence of different ventilation systems on microbiological instrument cleanliness Hyg Med 2013; 38-4).



Operio or Steristay, you can extend the protective zone into the operating theatre for instrument preparation. The Operio unit and Steristay Instrument Table ensure that instruments and implants remain sterile both during preparation and throughout the surgical procedure.



The Sterile Air Flow units enable upgrading an existing ISO 7 operating theatre to ISO 5 or extending the sterile zone in an existing operating theatre in order to prepare the instruments and implants under sterile conditions and to guarantee the best aseptic conditions during the operation.

Technical specifications



The Operio devices are extremely small and handy and can also be used in very small rooms. The removable instrument table from Operio is available in various lengths of 45 cm, 60 cm and 75 cm for operations that require more instruments. The detachable instrument table can also be attached to any existing instrument table in the O.R. The electrical height adjustment can be carried out by the sterile OR staff (using a sterile covered display) as well as by the other OR staff using a separate display. There is no need to purchase a separate instrument table for storing the instruments. By constantly cleaning the air with Hepa filters, the germ level in the entire OR can be reduced.

The devices have the CE mark and meet the requirements for medical devices 93/42 EEC / Class I, 2007/47 EEC, as well as the guidelines 2004/108 / CE, EN 60601-1-2: 2014, EN 60601-1: 2006, EN ISO 14971: 2012 and EN ISO 13485: 2012. The protective effect according to DIN 1946-4 is fulfilled

Studies und Experts opinion

Mobile ultra clean unidirectional airflow screen reduces air contamination in a simulated setting for intra vitreal injection Int Ophthalmol. 2017; 37(1): 131–137. Published 2016 Apr 30. doi: 10.1007/s10792-016-0236-1 PMID: 27138593
Ruth Lapid-Gortzak, 1,2 Roberto Traversari, 3 Jan Willem van der Linden, 2 Sarit Y. Lesnik Oberstein,1 Oren Lapid,4 and Reinier O. Schlingemann1

Infectiological significance of ventilation and air conditioning systems in operating and intervention rooms 2010

Kramer¹, R. Külpmann², F. Wille³, B. Christiansen⁴, M. Exner⁵, and Koll. Zentralbl Chir 2010; 135 (1): 11-17

A study by the University of Greifswald showed a 1000-fold reduction in the particles in the surgical field. The colony-forming units in the OR field were reduced by 250 times in simulated OR operations (Prof. Dr. med. Axel Kramer, Institute for Hygiene and Environmental Medicine, Greifswald).

Free State of Thuringia (Germany) from 1/7/2009:

Particle counts: the supply air corresponds to the conditions of the purity class ISO 5 and is accordingly low in germs (corresponding to less than 1 CFU / m³).

Sedimentation plates: Both in simulated surgery (0.2 CFU) and after surgery (0.3 CFU), very low bacterial counts were detected in the protection area. The exemplary guide values according to DIN 1946/4 for room class 1a (under 1 CFU) were thus complied with

Hybata 2014: The test tables with integrated TAV laminar Air Flow were positioned in the edge area of the OR.

Average values with TAV instrument table: 0.52 CFU / h * 50 cm² (adjustment of the average value to a standard area)

Limit value for room class 1A according to standard: $\leq 1 \text{ CFU} / \text{h} * 50 \text{ cm}^2$

Conformity to microbiological monitoring according to DIN 1946-4: 12-2008, Appendix F.) Many other studies (Journal of Hospital Infection 2002, 2003, 2010 and the journal of Orthopedics and Traumatology 2011 12: 207-211) confirm the protective effect according to DIN 1946-4.

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