# Operating Room Ventilation

## A View From Different Perspectives

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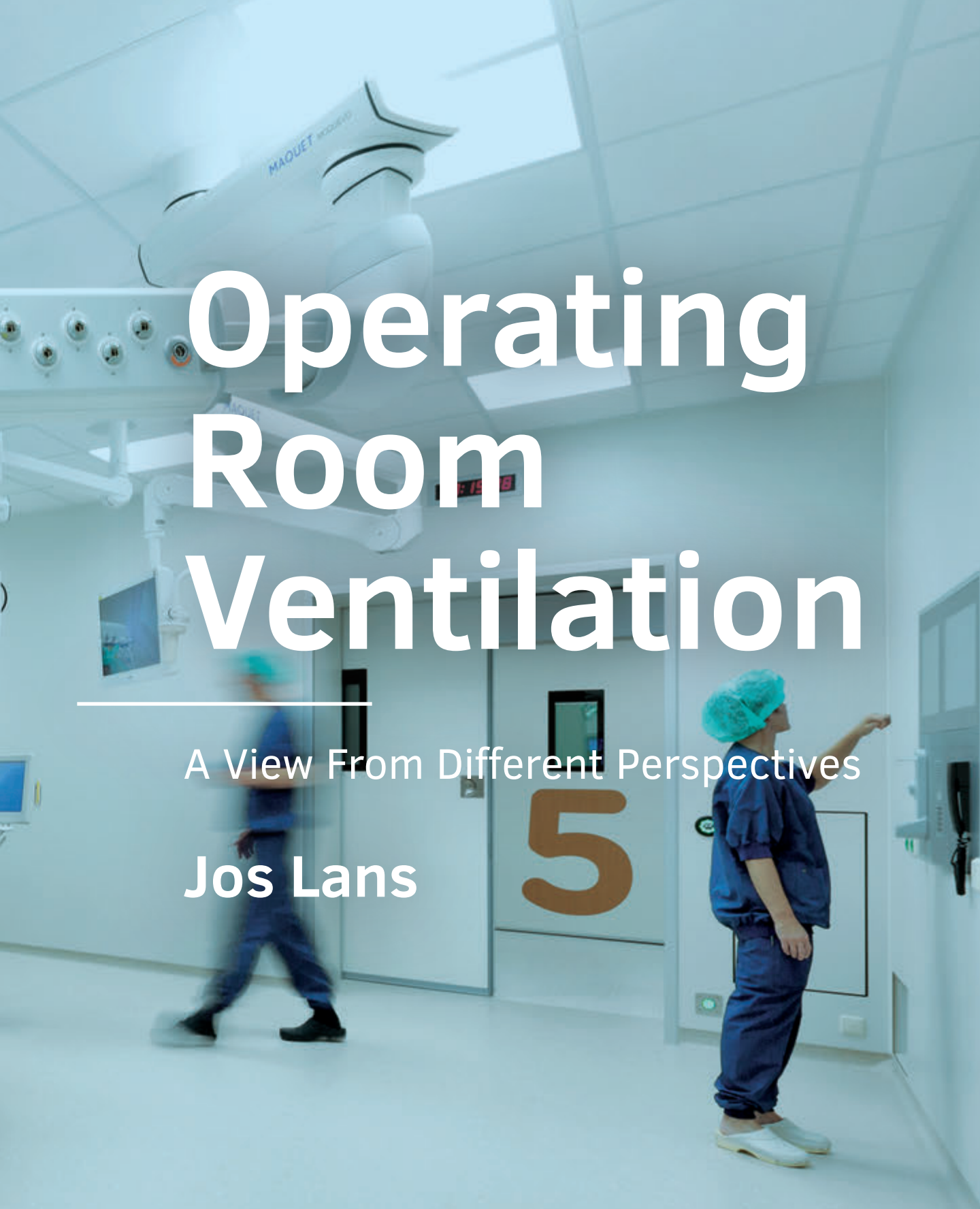
**DOI**
10.71690/abe.2024.21

**Publication date**
2024

**Document Version**
Final published version

**Citation (APA)**
Lans, J. L. A. (2024). *Operating Room Ventilation: A View From Different Perspectives*. [Dissertation (TU Delft), Delft University of Technology]. https://doi.org/10.71690/abe.2024.21

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A+BE | Architecture and the Built Environment | TU Delft BK

24#21

**Design** | Sirene Ontwerpers, Véro Crickx

**Cover photo** | Hanne van der Woude / Courtesy Wiegerinck

**Keywords** | Operating Room Ventilation Systems, Computational Fluid Dynamics, Ventilation Effectiveness, Energy Consumption, Capital Expenditures, Surgical Site Infections, (Ultra Clean) Air Quality, Recovery Degree, Cleanliness Recovery Rate, Air Change Effectiveness

ISBN 978-94-6366-967-2
ISSN 2212-3202



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# Operating Room Ventilation

## A View From Different Perspectives

Dissertation

for the purpose of obtaining the degree of doctor
at Delft University of Technology
by the authority of the Rector Magnificus, prof.dr.ir. T.H.J.J. van der Hagen
chair of the Board for Doctorates
to be defended publicly on
Thursday 19 December 2024 at 15:00 o'clock

by

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This dissertation has been approved by the promotors.

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This study was supported by:

**Chapter 2 –** This study supported by the Swedish Research Council - Formas (Grant No. 2021-01422) and the China Scholarship Council (CSC) (No. 202108310037). Computational support was facilitated by the Swedish National Infrastructure for Computing (SNIC) at PDC Center for High-Performance Computing, KTH Royal Institute of Technology, under the auspices of the Swedish Research Council (Grant No. 2018-05973).

**Chapter 6 –** The Dutch Ministry of Health, Welfare and Sport (VWS) under the Urgenda Agenda Measure 51.

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# Summary

## Introduction

In recent years, operating rooms in the Netherlands have been built to the highest standards for operating room ventilation requirements. These high standards are associated with high investment costs, high operational costs, and high energy consumption. These standards have been upheld despite the fact that current guidelines provide room for varying the classification of operating rooms. New insights enabled hospitals to implement rational energy-saving measures such as reducing the amount of fresh air introduced or setting the air handling installation on standby at nights or on the weekends. Energy-saving measures have been implemented in air handling installations, but there is room for improvement regarding the reduction of the energy consumption of air handling installations.

This reduction can be achieved in several ways:

- lowering the classification of the operating room.
- switching the installation only on full capacity when the OR is in use.
- reducing the amount of outdoor air (ODA) or the total supply air (SUP).
- if possible, increasing the range (lower and upper setpoint) of the relative humidity.

A 2024 survey (see chapter 6) showed that 94% of the operating rooms in the Netherlands have an ultra-clean air supply system. Also, 80% of the ORs are classified according to the highest OR classification. However, 60% of the hospitals are using half or even fewer of the ORs on the complex for major (orthopedic) implant surgery.

One of the opportunities to reduce the energy consumption of a HVAC system for operating rooms is to reduce the number of air changes (air volume) of the OR air handling installation and air supply system when the type of surgery does not require an ultra-clean OR. This reduction can be realized by switching the ventilation system from an ultra-clean to a generic operating room level. Before the settings of an air handling installation are changed from an ultra-clean to a generic operating room level, it is important to analyze in advance (e.g. with Computational Fluid Dynamics (CFD)) how the air supply system will behave when the air change rate is reduced. It is imperative to know the costs of the different air handling installations

and air supply systems, the energy-saving potential and the effect on the surgical (ultra-clean) area after reducing the air change rate per hour. Before making any modifications to the OR air handling system, it is advisable to investigate whether the existing air handling installation and OR air supply system can be technically modified to implement the energy-saving measures.

The chapters indicated below report on the research that has been conducted to answer these questions.

## Chapter 2

### Ventilation performance evaluation of an operating room with temperature-controlled airflow system in contaminant control: Numerical study

This chapter explains the efficacy of temperature-controlled airflow systems in modern operating rooms for contaminant control, a critical factor in preventing surgical site infections. Experimental measurements were conducted in an operating room equipped with temperature-controlled ventilation to map the airflow field and contaminant dispersion (airborne particles with diameters ranging from 0.5 to 1 µm). The results of the experimental measurements were used to validate a Computational Fluid Dynamics (CFD) code. This code was then employed to simulate and examine different conditions, including different contaminant release locations and air supply rates.

For each simulated condition, the airflow distribution and contaminant dispersion were assessed, utilizing indices such as ventilation and air change efficiency scales. The results showed that contamination was effectively reduced when contaminants were released near exhaust outlets or under central unidirectional inlets. The presence of the operating table caused a major distortion of the central downward airflow, forming a horizontal air barrier at the periphery. Under this unique interior configuration, an appropriate air supply ratio between central and peripheral zones was required to achieve optimal overall ventilation performance.

The simulations demonstrated that obstacles significantly affect airflow patterns and contaminant control performance, with effects extending beyond their immediate vicinity. CFD simulation emerged as a potent tool in the design phase for assessing the impact of various obstacles and optimizing system configuration. Using CFD before selecting an ultra-clean ventilation system will provide valuable insights into the optimization of OR ventilation systems, emphasizing the relationship between airflow patterns, room layout, and contaminant control.

## Part A

### Chapter 3

#### Operating room ventilation systems: Recovery degree, cleanliness recovery rate and air change effectiveness in an ultra-clean area

Entrainment test methods are described in most European standards and guidelines to determine the protected area for Ultra-Clean Ventilation (UCV) systems. New UCV systems, such as temperature-controlled airflow (TcAF) and controlled-dilution ventilation (cDV) claim the whole Operating Room (OR) to be ultra-clean. Current test standards were not developed for assessing ventilation effectiveness outside the standard protected area. The aim of this study was to assess and compare the ventilation effectiveness of four types of OR ventilation systems in the ultra-clean area by using a uniform test grid. In this study, the ventilation effectiveness (VE) of the four ventilation systems was evaluated for three different ultra-clean protected areas: the standard protected area (A), the area outside the standard protected area (B), and the large protected area (AB). The VE was defined as the sum of the recovery degree (RD), the cleanliness recovery rate (CRR), and air change effectiveness (ACE).

RD, CRR, and ACE were significantly higher for the Uni-Directional Air Flow (UDAF) system when compared to the other systems in area A. In area B, UDAF and cDV were comparable regarding RD and CRR, and UDAF and Conventional Ventilation (CV) were comparable regarding ACE. In area AB, the UDAF and cDV were comparable regarding CRR and ACE but significantly different in RD. In area A, the ventilation effectiveness of the UDAF ventilation system outperformed the other ventilation systems. In area B, cDV performed the best, followed by UDAF, TcAF, and CV. In area AB, UDAF performed the best, followed by cDV, TcAF, and CV. See for overview results Chapter 3, Table 3.2, Descriptive examined OR ventilation systems, Area A, B and AB. Results are presented as median (interquartile range).

### Chapter 4

#### Air quality in the periphery of operating rooms during surgery

Most European ventilation standards and guidelines for infection-prone clean surgeries are developed to determine only the size and the air quality of the protected (ultra-clean) area. Nevertheless, the periphery, where non-sterile staff work, is sometimes used to partially position microbiologically sensitive instrument tables. This study aimed to determine the air quality in the periphery of the OR

by measuring the number of Colony Forming Units (CFU) during surgery. In an operating room equipped with a small uni-directional airflow system (UDAF), CFUs were measured in the periphery at the start incision, at several moments during surgery, and at the end of the surgery. The recovery time was measured in an at–rest situation. Measuring CFUs during 58 surgical procedures resulted in a mean number of CFU/$m^3$ of 7.0 (SD 10.7) at the start incision and 6.2 (SD 9.5) during closure of the wound. The number of CFUs in the periphery did not exceed the internationally accepted level of ≤10 CFU/$m^3$ in 82.4%. The mean CFU value in the periphery of all CFU measurements (between incision and closure) was 5.9/$m^3$ (SD 5.8). The mean 100-fold reduction was 6.0 (SD 1.2) minutes in an at-rest situation.

In conclusion, the number of CFUs did not exceed 10 CFU/$m^3$ in 82.4% of the measurements in the periphery. The air quality in the periphery is good enough to safely position instrument tables in case the protected area of the ultra-clean ventilation systems is not large enough.

## Part B

### Chapter 5

What is the effect of lowering the air change rate on the ventilation effectiveness in ultra-clean operating rooms?

The OR department is one of the most energy-intensive of a hospital. The majority of ORs in the Netherlands have an air handling installation with an ultra-clean ventilation (UCV) system. However, not all surgeries require an ultra-clean operating room. The aim of this study was to determine the effect of reducing the air change rate on the ventilation effectiveness in ultra-clean operating rooms. In this study, a 4x4 meter square measuring grid was used to measure and evaluate the lower air volume ventilation effectiveness ($VE_{Lv}$) of four systems: Conventional Ventilation (CV), controlled Dilution Ventilation (cDV), Temperature controlled Airflow (TcAF), and Uni-Directional Airflow (UDAF). The $VE_{Lv}$ consists of the recovery degree (RD), cleanliness recovery rate (CRR), and air change effectiveness (ACE). The CV, $cDV_{Lv}$ and $TcAF_{Lv}$ ventilation systems showed a comparable mixing character in Area A, B, and AB when the air change rate was reduced to 20 per hour. Ventilation effectiveness decreased when the air change rate was reduced, with the exception of the ACE. At all points for the UDAF-$2_{Lv}$ and the center point (C3) of the $TcAF_{Lv}$, $RD10_{Lv,}$ and $CRR_{Lv}$ were higher compared to the other examined ventilation systems. These results demonstrate that the ventilation effectiveness decreases when an ultra-clean OR with an ultra-clean ventilation air supply system is switched to an air

change rate of $20h^{-1}$. Reducing the air change rate in the OR from an ultra-clean OR to a generic OR will reduce the recovery degree (RD10) by a factor of 10 to 100 and the local air change rate (CRR) by 42 to 81%.

## Chapter 6

### Significant reduction of energy demand in operating rooms

Energy consumption in healthcare is relatively high; worldwide, hospitals account for about 6% of total building energy use. Hospitals and other care institutions in the Netherlands signed a Green Deal on sustainable healthcare to minimize their waste, use less energy, and take actions to become more sustainable: by 2030, carbon emissions must be at least 55% lower than in 1990, and by 2050, all care organizations shall be carbon neutral. As the OR department is one of the most energy-intensive departments of a hospital, the environmental awareness of the need to reduce the carbon footprint in ORs is increasing. The aim of this study was to determine the energy savings potential of OR air handling installations in the Netherlands. Quantitative data was collected using a questionnaire that was sent to all Dutch hospitals. Data collected consisted of air volumes, type of air handling system, hours of operation, number of operating rooms, etc. In addition, the temperature and relative humidity of various components in the make-up and recirculation air handling units were measured at 9 hospitals. A calculation model based on air properties on hourly bases was used to calculate the energy that was theoretically required to condition the air.

In the Netherlands, 94% of the ORs have an ultra-clean air supply system, and 80% of the ORs are classified according to the highest OR classification. However, 60% of the hospitals are using less than half of their ORs for major (orthopedic) implant surgery, for which the highest classification is required. Comparing the results in this study with the design conditions of the hospitals studied showed that if the amount of outside air (ODA) is reduced to 1,000 $m^3/h$ during operating hours and to 500 $m^3/h$ outside operating hours, thermal energy demand is reduced by 53% on average and electrical/mechanical energy demand is reduced by 49%. When clock times were implemented, thermal energy demand was reduced by 41% and electrical/mechanical energy demand by 60%. When relative humidity limits were changed, thermal energy demand was reduced by 36% on average.

The greatest energy demand savings were achieved by reducing ODA and introducing clock times. However, modification of the ODA is more complicated to implement in existing air handling systems. Air handling installation typology C is the most suitable for modification of the total supply air (SUP). Relatively simple modifications

to reduce energy demand include widening relative humidity limits and introducing operational clock times. By contrast, lowering the OR classification has the least impact on the combined energy demand. In conclusion, the increasing demand for energy reduction requires an air handling system that can handle a changing demand.

## Chapter 7

### Capital investment and operational expenditures of different operating room air-handling installations with conventional or ultra-clean air supply systems

When deciding on the operating room air handling installation and the type of air supply system, it is relevant to know the expenditures on the different air handling installations and air supply systems. This study aimed to determine the capital and operational expenditures on air handling installations equipped with an ultra-clean system or with a conventional system. In addition, the study aimed to compare the technical requirements of Dutch air handling installations with European standards and guidelines and to evaluate the costs of surgical site infections in comparison with the capital expenditures. Multiple completed projects of 24 hospitals were examined to collect, analyze, and compare detailed technical information and costs of air handling installations and air supply systems. Per OR, capital expenditures on an air handling installation with an ultra-clean system were €62,491 to €139,018 higher than expenditures on an installation with a conventional system. This difference amounts to 3 to 7% of the total construction costs of a completely new OR department. The yearly operational expenditures per OR with an ultra-clean system were €673 to €1,896 higher than in an OR with a conventional system. The capital and operational expenditures of air handling installations with an ultra-clean system are considerably higher than those with a conventional system. The technical specifications of the ORs studied in the Netherlands correspond to European standards and guidelines. However, the investment can be justified when the impact on patient suffering and the costs associated with surgical site infections are weighed against the investment required for an air handling installation with an ultra-clean system.

## Part C

### Chapter 8

#### A baseline study of the number of microorganisms and particles during trauma surgery at the wound site, on the instrument table, and in the periphery

The objective of an OR ultra-clean ventilation (UCV) system is to eliminate or reduce the number of dust particles and colony forming units per cubic meter of air (CFU/$m^3$). To reduce the particle load and level of CFUs/$m^3$, higher air change rates per hour (ACH) are required. The Dutch Federation of Medical Specialists (FMS) recently introduced a guideline for air handling in operating and treatment rooms. According to this guideline, only major orthopedic implant surgery should be performed in a Class 1+ OR. Other surgeries could be performed in a generic OR. Currently, most ORs in Dutch hospitals are ultra-clean ORs (FMS Class 1+). Since the recent FMS advice to reduce the ACH for most surgeries, it is important to have a benchmark regarding the permissible number and type of microorganisms and dust particles measured during surgery at the wound site, instrument table, and periphery.

We measured the level of CFUs during 29 surgeries in an OR class 1+ equipped with a Uni-Directional Air Flow (UDAF) system with an ACH of 71. On average, the number of CFU/$m^3$ and particles during surgeries was at wound level ≤1 CFU/$m^3$ resp. 852.679 particles, on the instrument table ≤1 CFU/$m^3$ resp. 3.797 particles and in the periphery ≤8 CFU/$m^3$ resp. 4.355 particles. The levels of CFUs measured at the incision and on the instrument table were far below the defined ≤10 CFU/$m^3$ for ultra-clean surgery. There was a broad variety of microorganisms cultured at different locations. Most of the cultured organisms in this study are known as colonizing bacteria of the skin (Staphylococcus hominis, S. epidermidis, S. capitis), which could pose a risk for low-grade prosthetic infections. The number of dust particles measured during surgery was higher than the standards defined by ISO5 at-rest. The number of particles (≥0.5µm) during surgery complied with ISO8 at the wound site and with ISO6 on the instrument table and in the periphery. Determination of the type of microorganisms showed a paucity of primary pathogens, with the largest numbers of cultured bacteria being members of human colonizers or environmental contaminants that occasionally participate in prosthetic infections, and in this study, in an OR equipped with an UDAF, they were found sufficiently distant to pose a low risk for low-grade prosthetic infections.

In conclusion, before selecting an operating room (ultra-clean) air supply system, a Computational Fluid Dynamics (CFD) analysis can provide valuable insights for optimizing the selected OR air supply system, based on the relationship between airflow patterns, room layout, and contaminant control. The ultra-clean ventilation (UCV) air supply systems studied all achieved the level required for ultra-clean air in the ultra-clean zone of the operating room. When operating rooms are not used for major orthopedic implant surgeries, primary and revision prostheses and major spinal surgery (e.g. scoliosis), a lower OR classification is recommended.

To save energy on operating room air handling installations, a reduction in ODA and introducing clock times have the greatest impact on energy demand reduction. Relatively simple modifications to reduce energy demand include widening relative humidity limits and introducing operational clock times. Lowering the OR classification has the least impact.

When the impact on patient suffering and costs associated with surgical site infections are weighed against the investment required for an air handling installation with an ultra-clean system, the investment can be justified.

Our baseline study shows that an operating room equipped with a UCV system during an operational situation meets the ultra-clean air requirements with ease. The number of air changes and the method of air exhaust determine the classification of the operating room. The air supply system only takes care of how the air is brought into the operating room.

# Samenvatting

## Inleiding

De afgelopen jaren zijn operatiekamers in Nederland gebouwd volgens de hoogste ventilatie-eisen. Deze hoge eisen gaan gepaard met hoge investeringskosten, operationele kosten en een bijbehorend energiegebruik. Dit terwijl de huidige richtlijnen ruimte geven om te variëren in de classificatie van de operatiekamer. Nieuwe inzichten stellen ziekenhuizen in staat om energiebesparende maatregelen te nemen, zoals het verminderen van het aandeel verse buitenlucht, het stand-by zetten van de luchtbehandelingsinstallatie ‘s nachts, in het weekend of indien de operatiekamer niet in gebruik is. Er zijn al wel energiebesparende maatregelen geïmplementeerd in luchtbehandelingsinstallaties, maar er is nog ruimte voor verbetering om het energieverbruik verder terug te dringen.

Uit ons onderzoek van 2024 (zie hoofdstuk 6) blijkt dat 94% van de operatiekamers in Nederland een ultra-clean luchttoevoersysteem heeft. 80% van deze operatiekamers is geclassificeerd volgens de hoogste OK-classificatie ook wel ultra-clean OK genoemd. 60% van de ziekenhuizen gebruikt de helft of zelfs minder van de hoeveelheid OK’s op het OK-complex voor grote (orthopedische) implantaatchirurgie waarvoor deze hoogste OK-classificatie, volgens de SRI/FMS richtlijn, noodzakelijk is.

Een van de mogelijkheden om het energiegebruik van een luchtbehandeling systeem voor operatiekamers te verlagen is het verminderen van het aantal luchtwisselingen per uur. Dit kan worden gerealiseerd door het verlagen van het luchtvolume van de OK luchtbehandelingsinstallatie en het luchttoevoersysteem als het type operatie geen ultra-clean OK vereist. Dit kan worden gerealiseerd door het ventilatiesysteem om te schakelen van een ultra-clean naar een systeem geschikt voor een generieke operatiekamer. Voordat de instellingen van een luchtbehandelingsinstallatie worden gewijzigd van een ultra-clean naar een generieksysteem, is het belangrijk om te analyseren, bijvoorbeeld met Computational Fluid Dynamics (CFD), hoe het luchttoevoersysteem zich zal gedragen als het aantal luchtwisselingen wordt verlaagd. Voorts is het van belang om te weten wat de kosten zijn van de verschillende luchtbehandelingsinstallaties en luchttoevoersystemen, wat het energiebesparingspotentieel is en wat het effect op het chirurgische (ultra-clean) steriele gebied zal zijn, als we het aantal luchtwisselingen per uur verlagen. Ook is het raadzaam om voordat er aanpassingen aan het luchtbehandelingssysteem van



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de OK worden gedaan, te onderzoeken of de bestaande luchtbehandelingsinstallatie en het luchttoevoersysteem van de OK technisch aangepast kan worden om de energiebesparende maatregelen door te voeren. In de verschillende hoofdstukken van dit proefschrift is onderzoek gedaan om deze vragen te beantwoorden.

## Hoofdstuk 2

### Evaluatie van de ventilatie prestatie van een operatiekamer met een temperatuur gecontroleerd luchttoevoersysteem (TcAF) voor de beheersing van verontreinigingen: een numerieke studie.

In dit hoofdstuk wordt de effectiviteit van temperatuur gecontroleerde luchttoevoersystemen (TcAF) in operatiekamers onderzocht. Er wordt gekeken naar de effectiviteit van het systeem om de ontstane contaminatie (verontreinigingen) op de positie waar de operatie plaatsvindt af te voeren. Er zijn experimentele metingen uitgevoerd in een operatiekamer met temperatuur gecontroleerde ventilatie (TcAF) om de luchtstromingen en de verspreiding van contaminanten (in de lucht zwevende stofdeeltjes met een diameter van 0,5-1 µm) in kaart te brengen. De resultaten van de experimentele metingen werden gebruikt om het CFD-model te valideren. Het model werd vervolgens gebruikt om verschillende situaties te simuleren. Er is onderzoek gedaan naar de locaties waar de stofdeeltjes door middel van een vervuilingsbron werden vrijgelaten en welke invloed de luchttoevoersnelheid uit het temperatuur gecontroleerde luchttoevoersysteem hierop had. Het uitblaas patroon uit het luchttoevoersysteem en de verdeling van de verontreinigingen in de ruimte werden beoordeeld op basis van de ventilatie effectiviteit en het aantal luchtwisselingen op de verschillende gemeten posities in de ruimte. De resultaten toonden aan dat vervuiling effectief werd gereduceerd wanneer deze werd vrijgelaten in de buurt van de uitblaas ornamenten (perifere air shower) of onder het centrale uni directionele air flow systeem. De aanwezigheid van de OK-tafel veroorzaakte een grote verstoring op de centrale neerwaartse luchtstroom. Hierdoor ontstond er een horizontale luchtstroming in de richting van de periferie.

Bij deze unieke operatiekamer configuratie was een juiste luchttoevoerverhouding tussen centrale en perifere zones nodig om, vanuit een CFD-perspectief, optimale algemene ventilatieprestaties te behalen. De obstakels in de operatiekamers hebben een aanzienlijke invloed op de luchtstromingspatronen en de prestaties van de contaminatie beheersing. De effecten van de obstakels reiken verder dan alleen in de nabijheid van de obstakels in de luchtstroom. Computational Fluid Dynamics (CFD)-simulatie komt naar voren als een krachtig hulpmiddel in de ontwerpfase voor het beoordelen van de invloed van verschillende obstakels en het optimaliseren van de systeemconfiguratie. Het gebruik van CFD voor het

selecteren van een ultra-clean ventilatiesysteem geeft waardevolle inzichten in de optimalisatie van OK-ventilatiesystemen. De nadruk bij CFD ligt op de relatie tussen luchtstromingspatronen, indeling van de ruimte en de beheersing van de ontstane verontreinigingen.

## Deel A

### Hoofdstuk 3

Ventilatiesystemen voor operatiekamers: herstellend vermogen, hersteltijd luchtverversingseffectiviteit in het ultra-clean operatiegebied

In de meeste Europese normen en richtlijnen worden ‘entrainmenttest’ methoden beschreven om het beschermde gebied voor ultra-clean ventilatiesystemen (UCV) te bepalen. Nieuwe UCV-systemen, zoals temperatuur gecontroleerde luchttoevoer systemen (TcAF) en gecontroleerde verdunningsventilatie systemen (cDV) claimen dat de gehele operatiekamer (OK) ultra-clean is. De huidige test methoden zijn niet ontwikkeld om de effectiviteit van het ventilatiesysteem buiten het standaard beschermde operatiegebied te beoordelen. Het doel van dit onderzoek was om de ventilatie-effectiviteit van vier typen OK-ventilatiesystemen in de ultra-clean zone te beoordelen en met elkaar te vergelijken met behulp van een uniform test grid. In dit onderzoek is de ventilatie-effectiviteit (VE) van vier ventilatiesystemen geëvalueerd voor drie verschillende ultra-clean (beschermde) gebieden: het standaard beschermde gebied (A), gebied buiten het standaard beschermde gebied (B) en een groter beschermd gebied (AB). De VE was gedefinieerd als het herstellende vermogen na 10 minuten, de lokale hersteltijd per meetpunt (CRR) en de luchtverversingseffectiviteit (ACE) van de ingebrachte lucht.

De resultaten van het herstellend vermogen (Recovery Degree (RD)), de hersteltijd (Cleanliness Recovery Rate (CRR)) en luchtverversingseffectiviteit (Air Change Effectiveness (ACE)) waren significant beter voor het uni directionele air flow (UDAF) systeem in vergelijking met de andere systemen in gebied A. In gebied B waren UDAF en cDV vergelijkbaar voor wat betreft de RD en CRR. De UDAF en conventionele ventilatie (CV) waren vergelijkbaar voor wat betreft de ACE. In gebied AB waren UDAF en cDV vergelijkbaar voor wat betreft CRR en ACE, maar significant verschillend voor wat betreft de RD. Conclusie, in gebied A is de ventilatie-effectiviteit van het UDAF-ventilatiesysteem beter dan bij de andere ventilatiesystemen. In gebied B presteert cDV het beste, gevolgd door UDAF, TcAF en CV. In gebied AB presteert UDAF het beste gevolgd door cDV, TcAF en CV. Zie voor een overzicht van de resultaten hoofdstuk 3, tabel 3.2.

## Hoofdstuk 4

### Luchtkwaliteit in de periferie van operatiekamers tijdens een operatie

De meeste Europese normen en richtlijnen voor infectiegevoelige operaties zijn ontwikkeld om de grootte en de luchtkwaliteit in het beschermde ultra-clean gebied te bepalen. De periferie van de operatiekamer (OK) wordt in de meeste normen en richtlijnen buiten beschouwing gelaten. Soms wordt de periferie, waar niet-steriel gekleed personeel staat opgesteld, echter wel gebruikt om microbiologisch gevoelige instrumententafels geheel of gedeeltelijk te positioneren. Deze studie had als doel om de luchtkwaliteit in de periferie van de OK te bepalen door het aantal kolonievormende eenheden (KVE) te meten tijdens een werkelijke operatie. Dit onderzoek werd uitgevoerd in operatiekamers uitgerust met een klein uni directioneel air flow systeem (UDAF). Er werden KVE's gemeten in de periferie bij het begin van de incisie, op verschillende momenten tijdens de operatie en aan het einde van de operatie. De hersteltijd van de luchtkwaliteit werd gemeten in de operatiekamer in een 'at-rest' situatie. Een 'at-rest' situatie betekent dat er zich geen personen in de operatiekamer bevinden tijdens de meting. Alleen medisch apparatuur uit of in de stand-by stand was aanwezig tijdens deze meting. Tijdens 58 chirurgische procedures werd het aantal KVE's in de periferie gemeten. Bij het begin van de incisie en tijdens het sluiten van de wond was het gemiddelde aantal KVE/$m^3$ respectievelijk 7,0 (SD 10,7) en 6,2 (SD 9,5). Het aantal KVE's in de periferie overschreed het internationaal geaccepteerde ultra-clean luchtkwaliteitsniveau van <10 KVE/$m^3$ in 82,4% niet. De gemiddelde KVE-waarde in de periferie van alle KVE-metingen (tussen incisie en sluiting) was 5,9 /$m^3$ (SD 5,8). De gemiddelde 100-voudige reductie was 6,0 (SD 1,2) minuten in een at-rest situatie. In onze studie met in totaal 125 metingen is het maximaal gehaalde KVE-niveau van 30 KVE/$m^3$ drie keer tijdens de incisie en 4 keer tijdens de werkelijk ingreep overschreden. 30 KVE/$m^3$ is het hoogste aantal KVE dat, volgens de Zweedse richtlijn SIS-TS39:2015, mag worden gemeten tijdens de ingreep. Deze hogere gemeten KVE-waarden werden mogelijk veroorzaakt door additionele activiteiten van het chirurgische team in de operatiekamer tijdens de ingreep. De activiteiten waren onder andere het wisselen van het chirurgische team en het naar binnen brengen van medische apparatuur noodzakelijk voor de ingreep.

Conclusie, het aantal KVE's was niet hoger dan 10 KVE/$m^3$ in 82,4% van de metingen in de periferie. Gedurende de metingen is de maximaal aanvaarde waarde van 30 KVE/$m^3$ De luchtkwaliteit in de periferie is goed genoeg om de instrumententafels veilig te plaatsen als het beschermde gebied van de ultra-clean ventilatiesystemen niet groot genoeg is.

## Deel B

### Hoofdstuk 5

Wat is het effect van het verlagen van het aantal luchtwisselingen op de ventilatie-effectiviteit in ultra-clean operatiekamers?

De operatiekamer afdeling is een van de meest energie-intensieve afdelingen van een ziekenhuis. De meeste operatiekamers (OK's) in Nederland hebben een luchtbehandelingsinstallatie met een ultra-clean ventilatiesysteem (UCV). Niet alle operaties vereisen echter een ultra-clean operatiekamer. Het doel van deze studie was: wat is het effect van het verlagen van het aantal luchtwisselingen op de ventilatie-effectiviteit in ultra-clean operatiekamers? In dit onderzoek werd de ventilatie-effectiviteit met een lager luchtvolume ($VE_{Lv}$) van een conventioneel ventilatiesysteem (CV), gecontroleerde verdunningsventilatie systeem (cDV), temperatuur gecontroleerd systeem (TcAF) en twee uni-directionele air flow (UDAF) systemen geëvalueerd en gemeten binnen een vierkant meetraster van 4x4 meter. Er is een extra UDAF-systeem (UDAF-2) aan het onderzoek toegevoegd omdat het initiële UDAF-systeem (UDAF-1) niet zonder aanpassingen aan de luchttechnische installatie naar 20 luchtwisselingen gebracht kon worden. Bij de overige systemen kon de luchttechnische installatie via het gebouwbeheersysteem (GBS) aangepast worden. De $VE_{Lv}$ was gedefinieerd als het herstellende vermogen na 10 minuten, de lokale hersteltijd per meetpunt (CRR) en de luchtverversingseffectiviteit (ACE) van de ingebrachte lucht. De CV-, $cDV_{Lv}$- en $TcAF_{Lv}$-ventilatiesystemen vertonen een vergelijkbaar mengend karakter in het gebied A, B en AB wanneer de luchtverversingssnelheid wordt verlaagd van ca. 45 tot 73 naar 20 keer per uur. De ventilatie-effectiviteit neemt af wanneer de luchtverversingsgraad wordt verlaagd, met uitzondering van de ACE. Op alle punten voor de UDAF-$2_{Lv}$ en het middelpunt (C3) van de $TcAF_{Lv}$ werden hogere $RD_{10Lv}$ en $CRR_{Lv}$ gemeten in vergelijking met de andere onderzochte ventilatiesystemen. Conclusie, de ventilatie-effectiviteit neemt af wanneer een ultra-clean OK met een ultra-clean ventilatie luchttoevoersysteem wordt overgeschakeld op een luchtverversingssnelheid van 20 keer per uur. Als de luchtverversingssnelheid in de OK wordt verlaagd van een ultra-clean OK naar een generieke OK, daalt het herstellend vermogen na 10 minuten ($RD_{10}$) met een factor 10 tot 100 en de lokale luchtverversingssnelheid (CRR) tussen 42%-81%. Het verlagen van de luchthoeveelheid bij een UDAF systeem kan niet zondermeer uitgevoerd worden. Het type en de opbouw van het UDAF systeem dient bekend te zijn voordat er aanpassingen aan de luchthoeveelheid worden gedaan. Niet ieder type UDAF systeem is geschikt om aangepast te worden. Daarnaast is het van belang te weten hoe de luchttechnische installatie achter elk ultra-clean ventilatie systeem is opgebouwd. Niet iedere luchttechnische installatie kan aangepast worden.

## Hoofdstuk 6

### Significante reductie van de energievraag in operatiekamers

Ziekenhuizen en andere zorginstellingen in Nederland hebben een Green Deal duurzame zorg ondertekend om hun afvalproductie te minimaliseren, minder energie te gebruiken en acties te ondernemen om duurzamer te worden. In 2030 moet de CO2-uitstoot ten minste 49% lager zijn dan in 1990. In 2050 moeten alle zorgorganisaties CO2-neutraal zijn. De operatiekamer afdeling is een van de meest energie-intensieve afdelingen van een ziekenhuis. Het merendeel van de operatiekamers in Nederland heeft een luchtbehandelingsinstallatie met een ultra-clean ventilatiesysteem (UCV). Niet alle operaties vereisen echter een ultra-clean operatiekamer. In deze studie analyseerden we verschillende operatiekamers in Nederland. Kwantitatieve gegevens werden verzameld van 51 ziekenhuizen door middel van een vragenlijst. Informatie over luchtvolumes, type luchtbehandelings-systeem, bedrijfsuren, aantal operatiekamers, etc. van ziekenhuizen in Nederland konden uit de vragenlijst worden gehaald. Het werkelijke energieverbruik en het energie besparingspotentieel van de luchtbehandelingsinstallaties en luchttoevoersystemen is bij benadering bepaald. Er is een rekenmodel van TNO gebruikt dat werkt op basis van toestandsgrootheden. Met dit rekenmodel kunnen we het energieverbruik van een luchtbehandelingsinstallatie bepalen. De temperatuur en relatieve vochtigheid van verschillende componenten in de luchtbehandelingskast en het energieverbruik van de ventilator werden gemeten bij 9 luchtbehandelingsinstallaties in drie academische ziekenhuizen, vier perifere ziekenhuizen en twee privéklinieken geografisch verdeeld over Nederland.

94% van de OK's in Nederland is uitgerust met een ultra-clean ventilatie luchttoevoersysteem. 80% van de OK's is ingedeeld volgens de hoogste OK-classificatie. 60% van de ziekenhuizen gebruikt minder dan de helft van het aantal OK's voor grote (orthopedische) implantaatchirurgie waarvoor de hoogste OK klasse vereist is. Wanneer de hoeveelheid buitenlucht (ODA) tijdens en buiten werkuren wordt teruggebracht tot respectievelijk 1.000 en 500 $m^3$/h, daalt de energievraag met gemiddeld 53% thermisch en 49% elektrisch/mechanisch. Als de grenzen van de relatieve vochtigheid worden verruimd naar 30-70%, daalt de thermische energievraag met gemiddeld 33%. 41% thermisch, resp. 60% elektrisch/mechanisch, kan worden bespaard als luchtbehandelingsinstallaties van operatiekamers 's nachts of in het weekend, door bijvoorbeeld kloktijden, worden teruggezet naar een lager niveau. Het verlagen van de operatiekamer classificatie, van klasse 1+ naar klasse 1, zorgt voor een elektrisch/mechanische besparing van 36%.

Er zijn verschillende manieren om energie te besparen in bestaande operatiekamers met betrekking tot het luchtbehandelingssysteem. Energiebesparing kan worden gerealiseerd door 1) de hoeveelheid buitenlucht (ODA) te verminderen, 2) de installatie in stand-by modus te zetten als de OK niet in gebruik is, 3) het bereik (onderste en bovenste setpoint) van de relatieve luchtvochtigheid te vergroten en 4) de classificatie van de operatiekamer te verlagen van ultraclean naar algemeen. Het verlagen van de ODA heeft het grootste effect op energiebesparing. Het verlagen van ODA is niet eenvoudig in bestaande faciliteiten. Voordat de ODA aangepast wordt is het belangrijk om het technische ontwerp van het luchtbehandelingssysteem en de luchtdichtheid van de gebouwschil van de operatiekamer te kennen. Relatief eenvoudige aanpassingen om energie te besparen zijn onder andere het verruimen van de relatieve vochtigheidslimieten en het invoeren van operationele kloktijden. Het verlagen van de OK-classificatie heeft het minste invloed op het energieverbruik.

Conclusie, de beschreven besparingsmogelijkheden zullen de CO2 voetafdruk van de luchttechnische installatie op de operatiekamer afdeling verminderen. De CO2 voetafdruk kan naast de luchttechnische installatie ook worden verminderd door het verlagen van de uitstoot van inhalatieanesthetica, een transitie naar de inkoop van circulaire goederen en het verminderen van de afvalproductie door ‘reduce’, ‘reuse’ en ‘recycle’. Veel operatiekamers lijken onnodig gebouwd als ultra-schone operatiekamer en het ODA-volume dat in de OK wordt geïntroduceerd is relatief hoog.

Het effect van het verlagen van het aantal luchtwisselingen vermindert de ventilatie-effectiviteit. Omdat het ultra-clean ventilatiesystemen een mengend karakter vertoont bij het verlagen van het aantal luchtwisselingen wordt er geen ultra-clean zone gecreëerd in de operatiekamer zoals bedoeld volgens internationale normen en richtlijnen bij de hoogste operatiekamer classificatie. Voordat een luchttechnische installatie wordt aangepast is het van belang te weten hoe deze is opgebouwd. Bij veel ziekenhuizen wordt de primaire luchttechnische installatie niet alleen voor de operatiekamer gebruikt. Andere ruimten binnen het operatiekamer complex zijn hieraan veelal ook aan gekoppeld. De toenemende vraag naar energiebesparing vereist een luchtbehandelingssysteem dat de veranderende vraag aankan.

## Hoofdstuk 7

### Kapitaaluitgaven en operationele kosten van verschillende luchtbehandelingsinstallaties voor operatiekamers met conventionele of ultra-clean luchttoevoersystemen

Bij het bepalen van de luchtbehandelingsinstallatie in de operatiekamer en het type luchttoevoersysteem is het relevant om de kosten van de verschillende luchtbehandelingsinstallaties en luchttoevoersystemen te kennen. Deze studie had als doel om de kapitaaluitgaven en operationele kosten te bepalen van luchtbehandelingsinstallaties die zijn uitgerust met een ultra-clean of een conventioneel ventilatiesysteem. In dit onderzoek zijn de technische eisen van Nederlandse operatiekamer luchtbehandelingsinstallaties vergeleken met Europese normen en richtlijnen. Er is een vergelijk gemaakt tussen de investering in een ultra-clean ventilatiesysteem en de kosten behorend bij postoperatieve wondinfecties. Gedetailleerde technische informatie en kosten van luchtbehandelingsinstallaties en luchttoevoersystemen van meerdere gerealiseerde projecten van 24 ziekenhuizen werden verzameld, geanalyseerd en vergeleken. De kapitaaluitgaven per OK stijgen met €62.491 tot €139.018 wanneer een luchtbehandelingsinstallatie met een ultra-clean systeem wordt vergeleken met een conventioneel systeem. De kapitaal uitgaven bedragen tussen de 3%-7% van de totale bouwkosten van een volledig nieuwe operatiekamerafdeling. De jaarlijkse toename in operationele uitgaven per OK met een ultra-clean systeem vergeleken met dat van een conventioneel systeem was €673 tot €1.896. De kapitaaluitgaven en operationele kosten van luchtbehandelingsinstallaties met een ultra-clean systeem zijn hoger dan die van een conventioneel systeem. De technische specificaties van de onderzochte OK's in Nederland komen overeen met de Europese normen en richtlijnen. Wanneer de gevolgen voor het lijden van de patiënt en de kosten van postoperatieve wondinfecties worden afgewogen tegen de hierboven gemelde meerkosten die nodig zijn voor een luchtbehandelingsinstallatie met een ultra-clean systeem, dan lijkt deze onzes inziens meer dan gerechtvaardigd.

## Deel C

### Hoofdstuk 8

#### Een baseline studie van het aantal en type micro-organismen en deeltjes tijdens traumachirurgie nabij de wond, de instrumententafel en in de periferie

Het doel van een ultra-clean ventilatiesysteem voor de operatiekamer (OK) is om het aantal stofdeeltjes en kolonievormende eenheden per kubieke meter lucht (KVE/$m^3$) te elimineren of te verminderen. Om dit doel te bereiken is een hoger aantal luchtwisselingen per uur (ACH) nodig om de deeltjesbelasting en het niveau van KVE's/$m^3$ te verminderen. De Nederlandse Federatie van Medisch Specialisten (FMS) heeft onlangs een richtlijn geïntroduceerd voor luchtbehandeling in operatie- en behandelkamers. Alleen grote orthopedische implantaatchirurgie zou moeten worden uitgevoerd in een Klasse 1+. Andere operaties kunnen worden uitgevoerd in een generieke OK met een aantal luchtwisselingen van tenminste 20 keer per uur. Op dit moment zijn de meeste OK's in Nederlandse ziekenhuizen ultra-clean OK's (FMS Klasse 1+). Sinds het recente FMS-advies om het aantal luchtwisselingen (ACH) voor de meeste type operaties te verlagen, is het belangrijk om een benchmark te hebben. Inzicht hebben in het aantal en type micro-organismen en stofdeeltjes dat tijdens de operatie wordt gemeten op de plaats van de wond, op de instrumententafel en in de periferie is van belang. We hebben het niveau van KVE's gemeten tijdens 29 operaties in een OK klasse 1+ uitgerust met een uni directionele air flow (UDAF) systeem. Het aantal luchtwisselingen in de operatiekamer was 71 keer per uur. Het aantal KVE/$m^3$ en deeltjes tijdens operaties was gemiddeld op wondniveau ≤1 KVE/$m^3$ resp. 852,679 deeltjes, op de instrumententafel ≤1 KVE/$m^3$ resp. 3,797 deeltjes en in de periferie ≤8 KVE/$m^3$, resp. 4,355 deeltjes. Het niveau van de gemeten KVE's lag bij de incisie en op de instrumententafel ver onder de in de normen en richtlijnen gedefinieerde grens van ≤10 KVE/$m^3$ voor ultra-clean operaties. Er werd een grote verscheidenheid aan micro-organismen gekweekt op verschillende locaties. De meeste gekweekte organismen in dit onderzoek staan bekend als koloniserende bacteriën van de huid (Staphylococcus hominis, S. epidermidis, S. capitis) die een risico kunnen vormen voor laaggradige prothese-infecties. Chronische (low grade) infectie. Een laaggradige prothese infectie is een infectie die minimaal 6 maanden na de protheseplaatsing wordt ontdekt. Deze infectie gaat niet altijd samen met koorts, roodheid en zwelling, maar wordt ontdekt door toegenomen pijn bij bewegen. Het aantal stofdeeltjes dat tijdens de operatie werd gemeten, was hoger dan de norm die door ISO5 in rust is gedefinieerd. Wat betreft het aantal deeltjes (≥0,5 µm) was dit tijdens de operatie ISO8 nabij de wond en ISO6 op de instrumententafel en in de periferie. Bepaling van het type micro-organismen toont een schaarste aan primaire pathogenen. Primaire pathogenen veroorzaken ziekte in een voorheen gezonde gastheer. De grootste



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aantallen gekweekte bacteriën zijn menselijke kolonisatoren of omgevingscontaminanten die mogelijke een prothese-infecties kunnen veroorzaken. In deze studie waarbij de OK was uitgerust met een UDAF en een hoog aantal luchtwisselingen werden deze omgevingscontaminanten op een dusdanige afstand van het wondgebied gevonden dat deze geen risico vormden voor laaggradige prothese-infecties.

Conclusie, voordat een luchttoevoersysteem voor een ultra-clean operatiekamer wordt geselecteerd, kan een CFD-analyse (Computational Fluid Dynamics) waardevolle inzichten geven in het optimaliseren van het geselecteerde luchttoevoersysteem voor de operatiekamer. De nadruk zal liggen op de relatie tussen luchtstromingspatronen, indeling van de ruimte en beheersing van verontreinigingen. De bestudeerde ultra-clean ventilation (UCV) luchttoevoersystemen haalden allemaal het niveau dat vereist is voor ultra-clean lucht in de ultra-clean zone van de operatiekamer. Wanneer operatiekamers niet worden gebruikt voor grote orthopedische implantaatoperaties, primaire en revisieprothesen en grote spinale chirurgie (bijv. scoliose) wordt een lagere OK-classificatie aanbevolen.

Om energie te besparen, kunnen de meeste luchtbehandelingsinstallaties voor operatiekamers en UCV-luchttoevoersystemen worden aangepast naar een lagere classificatie voor operatiekamers. Een lagere OK-classificatie vereist een lagere luchtverversingssnelheid per uur, wat energie bespaart. Andere energiebesparende maatregelen kunnen worden bereikt door de setpoints van verschillende parameters te wijzigen, zoals het buitenluchtvolume, het verlagen van het aantal luchtwisselingen, de grenzen van de relatieve vochtigheid en door het verkorten van de bedrijfsuren.

Als de gevolgen voor het lijden van de patiënt en de kosten van postoperatieve wondinfecties worden afgewogen tegen de kosten van een luchtbehandelingsinstallatie met een ultra-clean ventilatiesysteem, is onzes inziens de extra investering gerechtvaardigd.

Onze baseline studie toont aan dat de operatiekamer uitgerust met een UCV-systeem tijdens een operationele situatie voldoet aan de vereisten gesteld aan ultra-cleane lucht. Het aantal luchtwisselingen en de methode van luchtafvoer bepalen de classificatie van de operatiekamer. Het operatiekamer luchttoevoersysteem zorgt voor de distributie van de toegevoerde lucht in de operatiekamer.

# 1 Introduction ultra-clean air operating room ventilation

## 1.1 History of operating room ventilation systems and performance standards

Almost all the guidelines and standards for operating room ventilation requirements have their origins in research from the 1960s. Sir John Charnley discovered that under the operating room conditions that were normal at that time, inserting a large mass of foreign material into tissues, as in hip arthroplasty, carries an unacceptably high risk of infection at the surgical site [1]. Charnley found, however, that the infection did not become manifest until after the operation, and in about half the cases, the organisms identified were of a kind that are commonly found on the skin but rarely give rise to wound infection after other types of surgeries. He concluded that, for surgery with major implants, it would be necessary to develop clean-air operating conditions and in particular to isolate the open wound bacteriologically from the staff engaged in the operation.

Charnley started a collaboration with a commercial firm, Howorth Air Engineering, Farnworth, Bolton, that had been making filtered air systems for brewers for more than a hundred years. Together, Hugh Howorth and Charnley produced the first clean-air operating enclosure, better known as the greenhouse (Figure 1.1).
The system incorporated high-efficiency particulate air (HEPA) filtration to ensure an ultra-clean environment during surgical procedures. They also produced total body exhaust equipment for the surgeons and their assistants, comprising a helmet type of mask and a gown of impermeable material, from which air was removed by suction through narrow-bore plastic tubing to manifolds built into the floor of the enclosure.



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The Charnley-Howorth Unit effectively directed filtered air away from the surgical site, minimizing the risk of airborne contaminants entering the sterile surgical field. This system functioned as a "Uni-Directional Air Flow" (UDAF) system. The whole system was originally introduced in 1961-1962 by Sir John Charnley in an operating room at Wrightington Hospital, England. The enclosure was remarkably successful and reduced the incidence of surgical site infection during hip arthroplasty.

The enclosure has since been superseded, but owing to Charnley, a higher air change rate per hour is still considered an important factor in preventing surgical site infections (SSI) [1]. In his study, Charnley compared the quantity of Colony Forming Units in the air at an air change rate per hour of nil, 10, 130, and 300 [1]. The minimum level of infection to be expected in a conventional (generic) operating room was approximately 7%. At higher air change rates of 130 and 300, the infection rate was 3.1% and 1.4%, respectively [1].

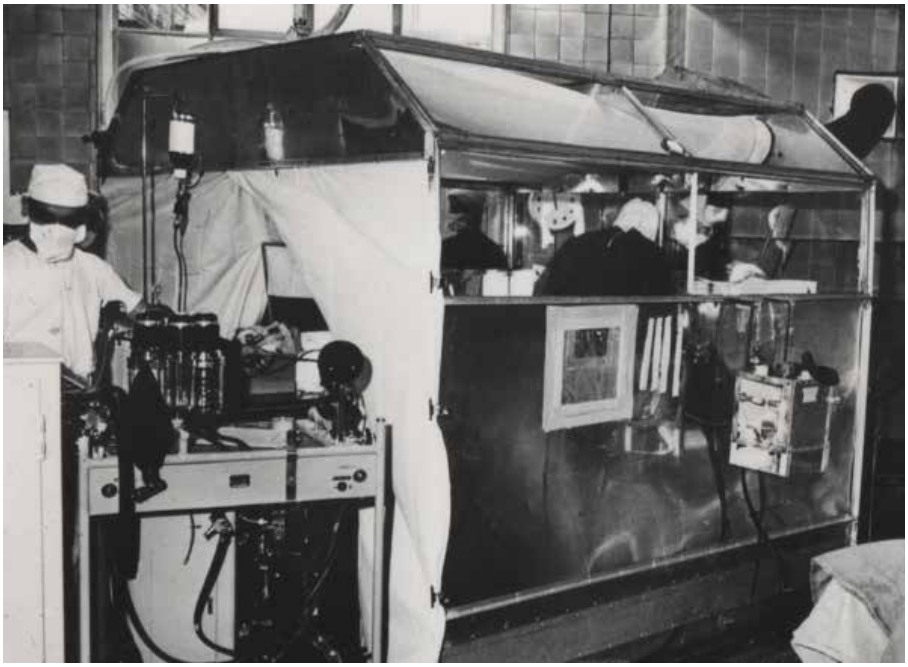

FIG. 1.1 the first clean-air operating enclosure in 1962, better known as the 'Greenhouse', at Wrightington Hospital. Source: https://howorthgroup.com, https://johncharnleytrust.org

After the research of Sir John Charnley, Lidwell et al performed a multicenter study of sepsis after total hip or knee replacement in 1982 at several hospitals in the United Kingdom [2]. The operations performed by each surgeon were allocated at random to conventional or ultra-clean air operating rooms. Records were obtained from over 8.000 of such operations. Among the patients whose prostheses were inserted in an operating room ventilated by an ultra-clean air system, the incidence of joint sepsis confirmed at reoperation within the next one to four years was about half that of patients who had had the operation in a conventionally ventilated room at the same hospital.

In the same study [2] Lidwell et al they found that when whole-body exhaust-ventilated suits had been worn by the operating team in a room ventilated by an ultra-clean air system, the incidence of sepsis was about a quarter of that found after operations performed with conventional ventilation. The design of the study did not include a strictly controlled test of the effect of prophylactic antibiotics, but their use was associated with a lower incidence of sepsis than in patients who had received no antibiotic prophylaxis at their operations.

In 1987 Lidwell et al [3] followed up 8,052 total hip- or knee-joint replacements for 1-4 years. For operations done in ultra-clean air, they found substantially less bacterial contamination of the wound, deep joint sepsis, and major wound sepsis than for operations done in conventionally ventilated rooms. Sepsis was also less frequent when prophylactic antibiotics had been given. The two precautions acted independently, as the incidence of sepsis after operations in ultra-clean air and with antibiotics was much lower than after operations for which either precaution was used alone. Wound sepsis was associated with an enhanced risk of joint sepsis. The most common joint pathogen was Staphylococcus aureus, but infections with other organisms, often considered to be of low pathogenicity, were almost as numerous. Most S. aureus infections were traced to sources in the operating room.

The research of Charnley [1,2] and Lidwell [2,3]. was the basis for most of the recommendations for operating room conditions in European standards and guidelines. The use of ultra-clean ventilation became the standard in operating rooms for procedures in which a large mass of foreign material is inserted into tissues, as in hip arthroplasty. Between 2004 and 2022, ultra-clean ventilation systems were installed in almost all operating rooms in the Netherlands. However, the choice of whether or not to install an ultra-clean ventilation system should be determined by the type of procedure performed in an operating room.

## 1.2 Ultra-Clean and Conventional Ventilation systems

The main objectives of an air handling system in the OR and an ultra-clean air supply ventilation (UCV) system are fourfold:

- creating a safe and comfortable working environment for the surgical staff [4].
- controlling the temperature and, in some cases, the relative humidity [5–7].
- diluting the concentration of harmful substances [8].
- minimizing the incidence of surgical site infections (SSI) [9].

An OR ventilation system maintains the constant air quality by introducing high-efficiency particulate filtered air (HEPA) [10] into the OR. Traditionally, ORs with conventional mixing ventilation (CV) systems are used for generic procedures, while Ultra-Clean Ventilation (UCV) systems are used for infection-prone surgeries [5,11–14]. CV systems mix the supply air evenly in the entire OR, thus diluting the concentration of harmful substances. UCV systems supply air via a Uni-Directional Air Flow (UDAF) into the protected area and displace the air that is present. The protected area or “clean zone” [13] is intended for positioning the patient wound, sterile staff, and instrument tables.

New ventilation systems such as temperature-controlled air flow (TcAF) and controlled Dilution Ventilation (cDV) systems are introduced in the market for ultra-clean ORs. The TcAF and cDV are, according to the manufacturers, suitable for all types of surgery [5,11–14]. They claim to make the whole OR ultra-clean during surgery [15,16], thus allowing more freedom of space to position the patient, sterile staff and instrument tables. .

The manufacturers of those newly introduced systems started from a different design principle than the manufacturers of UDAF or CV systems. The starting point of the new systems is the reduction of the quantity of microorganisms in the ultra-clean zone measured by means of colony forming units per cubic meter of air (CFU/$m^3$) during real surgery. By contrast, UDAF or CV systems are designed from a recovery rate [17] principle. The measurement of the recovery (decay) rate is also used in cleanrooms to evaluate a cleanroom’s ability to recover from episodes of airborne contamination [18].

In this thesis, the terms Conventional Ventilation (CV) system and Ultra-clean Ventilation (UCV) system are used to describe the method of air supply or air distribution in the operating room. We distinguish between the installed CV or UCV system in the operating room and the air handling installation (AHI) that supplies air to the CV system or the UCV system.

## Conventional Ventilation (CV)

A CV system (Figure 1.2) is a mixed–airflow system. The CV system introduces the HEPA filtered air into the OR through a perforated plate system installed above the operation table.

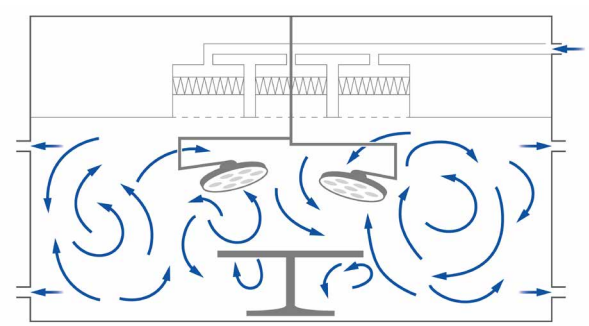

FIG. 1.2 Working principle Conventional Ventilation (CV).

## Temperature-controlled AirFlow Systems (TcAF)

A TcAF system (Figure 1.3) combines a mixed-airflow system in the periphery with a controlled unidirectional airflow (UDAF) directly above the OR table. A TcAF system is defined as a temperature-controlled ventilation system, in which cooler HEPA-filtered air is supplied above the OR table and warmer air with air diffusors is released in the periphery.

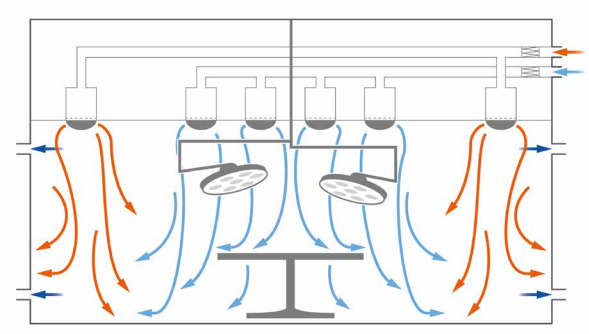

FIG. 1.3 Working principle Temperature-controlled AirFlow (TcAF).

## Controlled Dilution Ventilation (cDV)

A controlled Diluting Ventilation system (Figure 1.4) is a diluting mixed-airflow system. Air is filtered inside the air inlet modules by HEPA filters and supplied into the OR through air nozzles located in the ventilation system. The supply airflow from the ventilation system is directed partly towards the ultra-clean area and partly towards the room periphery, which ensures an optimal mixing of the supply air with the air present.

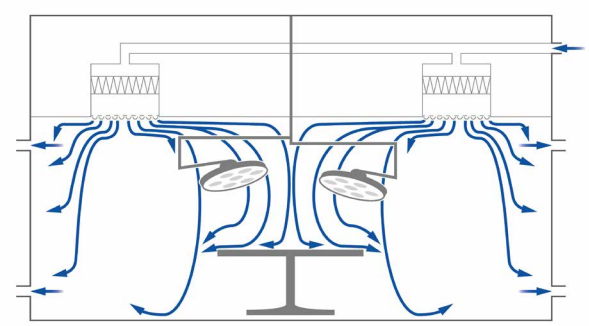

FIG. 1.4 Working principle controlled Dilution Ventilation (cDV).

### Uni-Directional AirFlow systems (UDAF)

Uni-Directional AirFlow (Figure 1.5) is defined as a controlled unidirectional airflow directly above the protected area which displaces the air present. It creates a HEPA-filtered airflow with a steady velocity [19,20] and parallel UDAF airstreams above the wound area, the surgical staff and all or some of the instrument tables.

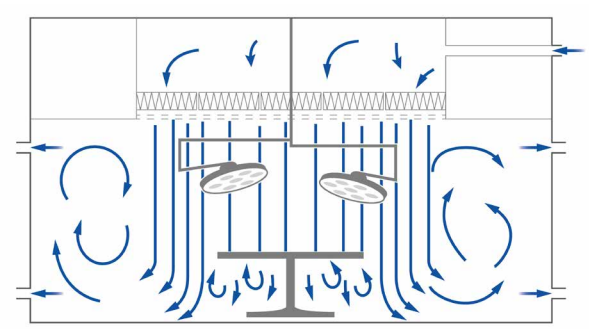

FIG. 1.5 Working principle Uni-Directional AirFLow (UDAF).

## 1.3 Standards and guidelines

For operating room air handling installations and air supply systems, several standards and guidelines with technical specifications and requirements have been issued in Europe (see Table 1.1). Various European countries have defined standards and guidelines [5,11–13] with boundary conditions and technical specifications with which an air handling installation should comply. Between 1995 and 2022, various Dutch guidelines for operating rooms were derived from these European standards and guidelines (see Table 1.2).

TABLE 1.1 Boundary conditions, technical specifications and requirements for air handling installation (AHI) according to standards and guidelines in Europe.

| National Standards or Guidelines | Classification type of operating room by standard/ guideline | Temp. [°C] | Relative humidity [%] | ACH or required air volume | Required CFU Level | Other requirement specifications | End Filter Supply air ( EN 1822) |
|---|---|---|---|---|---|---|---|
| **Norme Française (NF), France NFS90351** | Zone 4 | 19–26 | Only required in certain conditions | ≥6 outdoor air (ODA) | ≤1 CFU/$m^3$ | Unidirectional flow, discharge velocity ≥0.25–0.35 m/s, ISO 5 | HEPA H14 |
| | Zone 3 | 19–26 | Only required in certain conditions | ≥15 | ≤10 CFU/$m^3$ | Unidirectional flow or nonunidirectional flow, ISO 7 | HEPA H14 |
| | Zone 2 | 19–26 | Only required in certain conditions | ≥10 | ≤100 CFU/$m^3$ | Non-unidirectional, ISO 8 | HEPA H14 |
| **Health technical memoranda (HTM), England HTM 03-01** | Ultra Clean | 18–25 | 35–65 | ≥22 | ≤10 CFU/m3 Ultra Clean Area | Own dedicated Air Handling Unit per OR and UCV min. 2.8 × 2.8 m | EPA E10 |
| | Conventional | 18–25 | 35–65 | ≥22 | | Own dedicated Air Handling Unit per OR | EPA E10 |
| **Deutsches Institut für Normung (DIN), Germany DIN 1946/4** | 1a | 19–26 | 30–65 | ≥1,200 $m^3/h$ | Wound area ≤1 CFU/50 $cm^2$ Instrument table ≤1 CFU/50 $cm^2$ | Uni directional air flow with a supply air volume ≥900 $m^3/(h*m^2)$. Advised UDAF size 3.2 x 3.2 m Recovery rate under UDAF ≤1 min. 1000:1, DIN EN ISO 14644–3. | HEPA H13/H14 |
| | 1b | 19–26 | 30–65 | ≥1,200 $m^3/h$ | No indication | Turbulent dilution with a supply air volume ≥60 $m^3/(h*m^2)$ (around ≥ 20 times the air change rate, 1/h). Recovery rate ≤20 min. 100:1, DIN EN ISO 14644–3. | HEPA H13/H14 |

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TABLE 1.1 Boundary conditions, technical specifications and requirements for air handling installation (AHI) according to standards and guidelines in Europe.

| National Standards or Guidelines | Classification type of operating room by standard/ guideline | Temp. [°C] | Relative humidity [%] | ACH or required air volume | Required CFU Level | Other requirement specifications | End Filter Supply air ( EN 1822) |
|---|---|---|---|---|---|---|---|
| **Schweizerische Verein von Gebäudetechnik-Ingenieuren, Switserland SWKI VA105-01** | 1a | 18–24 | 30–50 | ≥800 $m^3/h$ | No indication | UDAF 9$m^2$ Differential flow - Protection degree measurement SG ≥ 2,0/SG ≥ 4,0 | HEPA H13 |
| | 1b | 18–24 | 30–50 | >25 or ≥800 $m^3/h$ | No indication | Recovery rate 100:1 ≤ 20 min. SN EN ISO 14644-3 | HEPA H13 |
| **Swedish Institute for Standards (SIS), Sweden SIS TS 39; 2015** | Infection-prone clean surgery | 18–26 | <70 | ≥0.56 $m^3/s$ | ≤5 CFU/$m^3$* - ≤10 CFU/$m^3$** | Mean Value ≤ 1.5 CFU/$m^3$ (highest value ≤ 5 CFU/$m^3$) *Clean air suits (everyone in the OR) Mean Value ≤ 5 CFU/$m^3$ (highest value ≤ 10 CFU/$m^3$) **Ordinary scrub suits (everyone in the OR) | HEPA H14 |
| | Other Surgery | 18–26 | <70 | ≥0.56 $m^3/s$ | ≤50 CFU/$m^3$* - ≤100 CFU/$m^3$** | Mean Value ≤ 50 CFU/$m^3$ (Highest value = ≤100 CFU/$m^3$) *Clean air suits (everyone in the OR) Mean Value ≤ 100 CFU/$m^3$ (highest value = ≤200 CFU/$m^3$) **Ordinary scrub suits (everyone in the OR) | HEPA H14 |

TABLE 1.2 Boundary conditions, technical specifications and requirements for air handling installation (AHI) according to guidelines in the Netherlands from 1995 to 2022.

| National Standards or Guidelines | Classification | Temperature [°C] | Relative humidity [%] | ACH or required air volume | Required CFU Level | Other requirement specifications | End Filter Supply air (EN 1822) |
|---|---|---|---|---|---|---|---|
| **1995 College for hospital facilities. (College voor ziekenhuisvoorzieningen)** | Class 1 Ultra-Clean | 16-26°C | 50-60% | 20 ≥2,000 $m^3/h$ | ≤10 CFU/ $m^3$ | Uni directional air flow or Horizontal (cross) flow. Discharge velocity 0.25 – 0.30 m/s, average discharge velocity 0.27 m/s. | HEPA H12 |
| | Class 2 | 16-26°C | 50-60% | 20 ≥2,000 $m^3/h$ | ≤200 CFU/ $m^3$ | Mixing ventilation | HEPA H12 |
| | Class 3 | 16-26°C | 50-60% | 20 ≥2,000 $m^3/h$ | ≤500 CFU/ $m^3$ | Mixing ventilation | HEPA H12 |
| | | | | | | | |
| **2004 College for hospital facilities. (College bouw ziekenhuisvoorzieningen)** | Class 1 Ultra-Clean | 18-24°C | No indication | 20 outside air (ODA) | No indication | Uni directional air flow size 8-9 $m^2$. Discharge velocity 0.24 – 0.30 m/s | HEPA H13 |
| | Treatment room | 18-24°C | No indication | ≥100$m^3/h$ outside air (ODA) per person | No indication | Mixing ventilation | HEPA H13 |
| | | | | | | | |
| **2005 Air handling management plan for the operating room Beheersplan Luchtbehandeling voor de Operatieafdeling** | Class 1 Ultra-Clean | 19°C | 50-65% | 20 ≥3,000 $m^3/h$ from which ≥2,000 $m^3/h$ outside air (ODA) | ≤10 CFU/ $m^3$ | Uni directional air flow (UDAF). Discharge velocity 0.30 - <0.35 m/s, UDAF size ca. 9$m^2$. | HEPA H13 |
| | Class 2 | 19°C | 50-65% | ≥3,000 $m^3/h$ from which ≥2,000 $m^3/h$ outside air (ODA) | ≤200 CFU/ $m^3$ | Uni directional air flow (UDAF). Discharge velocity 0.30 - <0.35 m/s UDAF size 1.2 x 2.4 m or mixing air supply system | HEPA H13 |
| | Treatment room | See guideline WIP | See guideline WIP | See guideline WIP | No indication | See guideline WIP Treatment room Infection Prevention Working Group | HEPA H13 |

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TABLE 1.2 Boundary conditions, technical specifications and requirements for air handling installation (AHI) according to guidelines in the Netherlands from 1995 to 2022.

| National Standards or Guidelines | Classification | Temperature [°C] | Relative humidity [%] | ACH or required air volume | Required CFU Level | Other requirement specifications | End Filter Supply air (EN 1822) |
|---|---|---|---|---|---|---|---|
| **2006 Infection Prevention Working Group, Circumstances (minor) surgical and invasive procedures WIP richtlijn, Omstandigheden (kleine) chirurgische en invasieve ingrepen** | Class 1 Ultra-Clean | 18-24°C | No indication | 20 outside air (ODA) | No indication | Non-mixing ventilation | HEPA H13 |
| | Class 2 | 18-24°C | No indication | 6 outside air (ODA) | No indication | Mixing ventilation | HEPA H13 |
| | Treatment room | 18-24°C | No indication | 6 outside air (ODA) | No indication | Mixing ventilation | F9 EN 779 |
| **2014 Infection Prevention Working Group (WIP) and RL7 / RL8 Contamination Control association the Netherlands (VCCN)** | Performance Level 1 | No indication | No indication | No indication | <10 CFU/$m^3$ | ISO 5, NEN EN ISO 14644-1 Recovery rate <3 min particle size ≥ 0,5 µm, NEN EN ISO 14644-3. | HEPA H13 |
| | Performance Level 2 | No indication | No indication | No indication | No indication | ISO 7, NEN EN ISO 14644-1 Recovery rate <20 min particle size ≥ 0,5 µm, NEN EN ISO 14644-3. | HEPA H13 |
| | Treatment room | No indication | No indication | No indication | No indication | | F9 EN 779 |
| **2022 Federatie Medisch Specialisten (FMS) / Dutch Orthopedic Association (NOV)** [23] | 1+ | 18-23°C | <65% | 20 | <10 CFU/$m^3$ | ISO 5, NEN EN ISO 14644-1 Recovery rate <3 min particle size ≥ 0,5 µm, NEN EN ISO 14644-3. | HEPA H13 |
| | 1 | 18-23°C | <65% | 20 | No indication | ISO 7, (complete OR), NEN EN ISO 14644-1 Recovery rate <20 min particle size ≥ 0,5 µm, NEN EN ISO 14644-3. | HEPA H13 |
| | 2 | 18-23°C | <65% | 6 | No indication | ISO 7 (complete OR), NEN EN ISO 14644-1, No recovery rate | HEPA H13 |
| | Treatment room | No indication | <65% | 4 | No indication | | F9 EN 779 |

Most European standards and guidelines [5,11–13] are defined to assess the performance of an ultra-clean or conventional mixing ventilation system in an at-rest situation [21]. At-rest is the condition in which the cleanroom or clean zone is complete, with the equipment installed and operating in a manner agreed upon, but with no personnel present [21].

The technical specifications and requirements of the operating room air handling installation and air supply system, as set in the standards and guidelines, are defined to achieve the desired result of ≤10CFU/m$^3$ during surgery in ultra-clean conditions. The conventional mixing systems (CV systems) are assessed on recovery times or particle concentrations and are, according to the standards and guidelines, not intended to be used for surgeries in which artificial implants are used. The World Health Organization (WHO) does not recommend any specific type of ventilation system, only to ensure a proper ventilation rate in the OR [22].

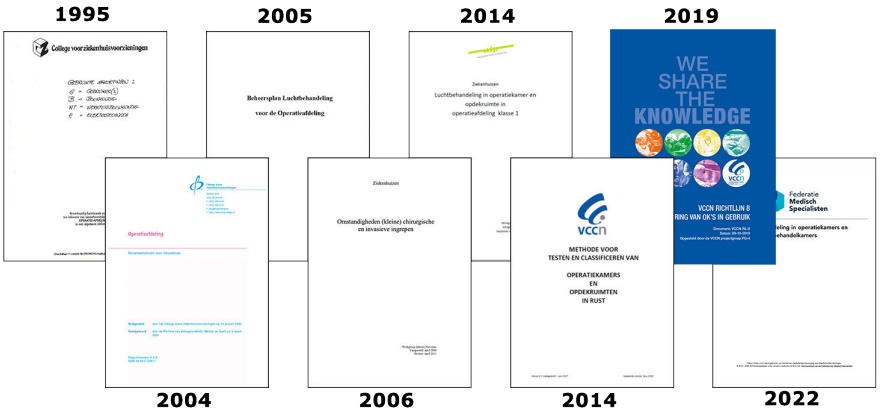


FIG. 1.6 Dutch guidelines over the last decades.

The Dutch guidelines that were developed between 1995 and 2022 all state that there is very little reliable information on the role of air handling or air supply systems in preventing infections at the surgical site. In the literature, there is no evidence that air is a relevant infection risk in the surgical area except for strictly aseptic procedures involving the insertion of large implants [9,24]. Air appears to be important in operations involving the insertion of large implants, without explicitly specifying the size of the implant.



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Despite the lack of evidence [25–27], European standards and guidelines have opted for different operating room classifications [5,6,13,28]. Likewise, in the Netherlands in 1995, the guideline of the College for Hospital Facilities [29] (in Dutch: College voor ziekenhuisvoorzieningen) made a distinction between three classifications of operating rooms, class 1, class 2, and class 3. In the revised guideline issued in 2004 [30], this distinction was abandoned, resulting in only one classification. The revised guideline recommended to equip each operating room with an ultra-clean air flow (UDAF) ventilation system with a minimum surface of 8 to 9 $m^2$. Since 2004, this recommendation was regarded as the Dutch operating room standard, and most of the ORs in the Netherlands have been equipped with a Uni Directional Air Flow system. In 2014, a new Dutch guideline was introduced by the Infection Prevention Working Group (WIP) and the Contamination Control Association of the Netherlands (VCCN), RL7 [12]. They recommended two different air quality performance levels in operating rooms: performance level one (P1) for an ultra-clean OR (class 1) and performance level two (P2) for a generic or conventional OR (class 2).

The most recent guideline was issued in 2022 by the Dutch Federation of Medical Specialists (FMS) [7]. It is a new guideline for air handling in operating and treatment rooms. The guideline recommends that an OR with the performance level P1, Class 1, now called class 1+, should only be used for major orthopedic implant surgeries, primary and revision prostheses and major spinal surgery (e.g. scoliosis) [7].

The indoor air quality of an OR class 1+ should comply with the internationally accepted definition of ultra-clean air, which is defined as air that contains less than 10 colony forming units per cubic meter of air (CFU/$m^3$) [31–35]. A level of ≤10 CFU/$m^3$ in the ultra-clean area [5,7,13,14] is recommended by most national standards and guidelines in Europe and used in scientific papers [1,2,36–38] as an ultra-clean (OR Class 1) reference level to prevent the incidence of surgical site infections.

The requirements of the FMS are in line with international standards and guidelines for infection-prone surgery [5,13,14,28] as well as with the recommendations of the Dutch Orthopedic Association (NOV) [23]. In an ultra-clean OR, a UCV system should be installed, according to the standards and guidelines [5,7,13,14,28], which results in higher air change rates to achieve the required number of ≤10 CFU/$m^3$ in the ultra-clean or protected [13] area.

# 1.4 Current situation operating rooms in the Netherlands

## Operating room and classification

Despite the fact that the most recent guidelines offer the opportunity to choose different OR air quality performance levels, it appears that practically all currently operative ORs in Dutch hospitals were designed and equipped as ultra-clean ORs. Of the Dutch operating rooms, 94% have an ultra-clean air supply system, and 80% are classified as an FMS OR class 1+ [7]. However, only 32% of Dutch hospitals use their ORs for major joint replacement procedures (FMS class 1+). In 60% of Dutch hospitals, this type of surgery is performed in half or even fewer of the ORs (see Figure 1.7).

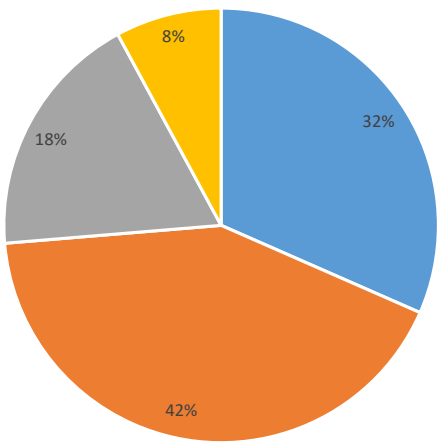


FIG. 1.7 Percentages of the Dutch hospitals that use all, three quarters, half or just one quarter of their operating rooms for major joint replacement procedures (FMS Class 1+).



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## Air volumes

In several Dutch hospitals, significantly more fresh outside air (ODA) is supplied to the OR than minimally required or prescribed in recent Dutch guidelines. Where outside air (ODA) is defined as air entering the system from outdoors before any air treatment[39]. The amount of fresh outside air from the make-up air unit (MUA) varies between 1,000 and 4,500 $m^3/h$, with peaks of up to 9,000 $m^3/h$. Conditioning this fresh outside air is energy-intensive because it must be heated or cooled and humidified or dehumidified in the MUA. By contrast, the secondary air (SEC) which is extracted from and reintroduced into the operating room is conditioned only to a limited extent in the recirculation air handling unit (RAU). Secondary Air (SEC) is the airflow taken from a room and returned to the same room after any treatment. The total air volume supplied (SUP) to Dutch operating rooms ranges from 2,200 $m^3/h$ to 12,500 $m^3/h$ (see Figure 1.8). Supply air (SUP) is defined as airflow entering the treated room or air entering the system after any air treatment [39]. Guidelines allow an air change rate per hour (AHC) of approximately $20h^{-1}$ for generic surgery, which is much lower and hence less energy-demanding than the ACH required for ultra-clean operating rooms[40].

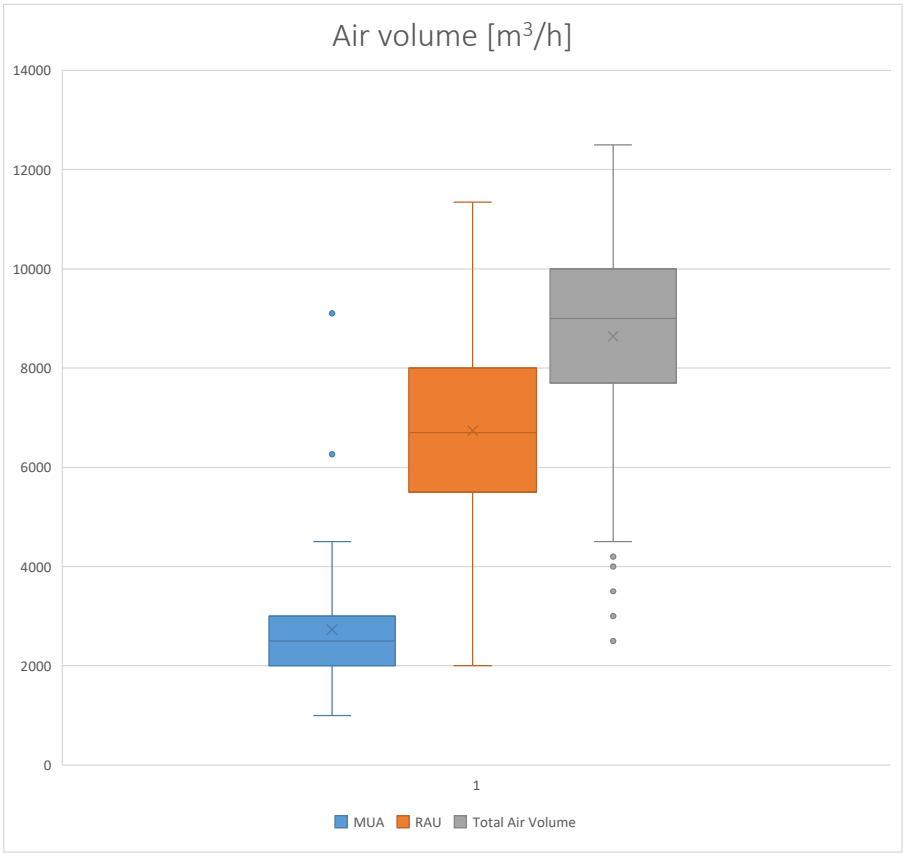


FIG. 1.8 Air volumes in Dutch operating rooms (n=51).

In 65% of the Dutch hospitals, the make-up air unit (MUA) and the recirculation air handling unit (RAU) are switched to a lower running mode after working hours and on weekends. In 2024, 22% of the hospitals do not switch their air handling installation to a lower air volume when after working hours or when the OR is not in use on weekends (see Figure 1.9).

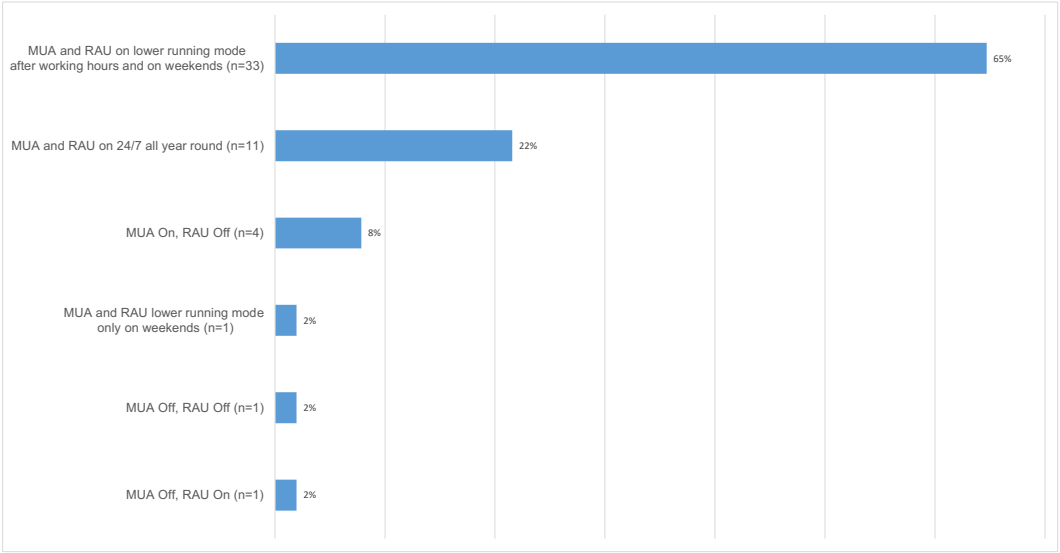


FIG. 1.9 Reduction air volume MAU or RAU in Dutch hospitals (n=51).

## Energy consumption

Energy consumption in healthcare is high. Worldwide, hospitals account for about 6% of the total building energy consumption [40]. An operating room department is three to six times more energy-intensive than all the other hospital departments. Of the total energy consumption of the operating room, 90-99% is due to the energy requirements of the Heating Ventilation and Air Conditioning (HVAC) system [41]. Hence it is important to ascertain how much room there is for energy savings without jeopardizing the health and safety of the patients and the medical staff.

The Dutch guideline of 1995 already stated that from an energy point of view, it is not necessary to meet the same ventilation requirements at night or on weekends as in the operational situation or the OR. However, when the OR is not in use, it is desirable to maintain a certain pressure hierarchy [42]. A minimum amount of fresh outside air (ODA) of 2,000 $m^3$/h is advised to avoid exceeding the maximum acceptable concentration (MAC value) in the operating room when using inhalation anesthesia. On the other hand, if it can be demonstrated that the MAC value remains below the required levels, the ODA may be reduced to 600 $m^3$/h to reduce energy consumption. Therefore, the 1995 guideline also described the requirements for the air tightness of the operating room and its surrounding areas. The guideline recommends maintaining relative humidity in the operating room during surgery.

When the operating room is not in use, the relative humidity can be loosened. Similar energy-saving advice is also given in other Dutch guidelines issued from 2004 to 2022.

To reduce the proportion of outside air, the guidelines allow recirculation of air in the operating room, which helps to save energy because treating outdoor air to achieve the required condition requires more energy than conditioning air that has been recirculated within the same room. Recirculation is allowed only within each operating room, not between multiple operating rooms. The amount of air supplied to the operating room is part ventilation air (outside air) and part recirculation air (secondary air). According to the EN-16798-3:2017 [39], the total supply air (SUP) to the operating room (OR) is the sum of outside air (ODA) and secondary air (SEC). Since the total air volume supplied (SUP) to the operating rooms ranges from 2,200 $m^3/h$ to 12,500 $m^3/h$ (see Figure 8), the energy saving potential of reducing ODA may vary considerably between hospitals.

## 1.5 Aim and structure of thesis

In this thesis, different types of ultra-clean air supply systems for operating rooms were compared with conventional air supply systems. We compared the different types of operating room air handling installations and types of operating room air supply ventilation systems on their ventilation effectiveness, the possibility to change the air change rate, the capital and operational expenditures and the energy consumption.

Various organizations [43,44] argue that ultra-clean air supply systems are expensive without a sound scientific basis. In this thesis, we examined this claim and provided a scientific basis for assessing the capital investment and operational costs of currently used ultra-clean systems compared to the capital investment and operational costs of generic operating rooms. We analyzed how capital expenditure compares with the costs associated with surgical site infections.

The increasing demand for savings in energy consumption requires insight into the energy demand of ORs and the possible energy-saving measures that can be implemented in a specific situation to reduce that demand. With a mathematical model based on air properties, we calculated the theoretic energy requirement to condition the air for an OR on an hourly basis. Insight is provided into the potential

energy savings that can be achieved with the existing operating room air handling installations, for instance by reducing the quantity of outside (fresh) air or the air change rate in the operating room.

The aim of this thesis was to provide insight into the different OR ventilation systems by elucidating the following perspectives:

- the ventilation effectiveness of the different types of operating room air handling installations and operating room air supply systems.
- the air quality in the periphery of operating rooms during surgery.
- the capital investment and operational expenditures of different operating room air-handling installations equipped with a conventional or ultra-clean air supply system.
- the energy consumption of an operating room air handling installation.
- the energy saving potential of OR air handling installations and the measures that can be taken to realize this energy saving potential.
- the current benchmark of the number of microorganisms and particles during trauma surgery at the wound site, on the instrument table and in the periphery.

The computational fluid dynamics (CFD) study in Chapter 2 aimed to enhance comprehension regarding the spatial variability of contaminant control capacity within modern ORs utilizing an ultra-clean ventilation air supply system (TcAF) and advances the knowledge related to the design of the UCV's air supply strategy.

At this moment, test methods of current standards and guidelines [5,11–13] are not primarily developed for assessing newly developed ventilation systems that focus on larger ultra-clean areas, or which claim the whole OR to be ultra-clean [15,16]. The study in chapter 3 assessed and compared the ventilation effectiveness of four types of OR ventilation systems by using a uniform test grid that covers a larger ultra-clean area.

For large surgical infection-prone procedures, the realized protected area of a UDAF is sometimes too small to contain all sterile instrument tables and to allow enough additional space between sterile staff and instrument tables [45–47]. If instrument tables are located outside or partly outside the protected area, the periphery should also meet the required cleanliness level of <10 CFU/$m^3$ [14,48]. The study in Chapter 4 determined the level of CFUs during surgery in the periphery to evaluate whether instrument tables can be positioned safely in the periphery outside the protected area of the UDAF if the protected area of the UDAF is not large enough.

The study in Chapter 5 provides insight into the effect on ventilation effectiveness [49] if the air change rate in ultra-clean operating rooms is reduced to approximately 20$h^{-1}$. We assessed the ventilation effectiveness (VE) of conventional ventilation (CV), controlled dilution ventilation (cDV), temperature-controlled airflow (TcAF), and Uni-Directional Airflow (UDAF) in the ultra-clean area when the ventilation system was switched to approximately 20 air changes per hour as advised for generic surgery [5,7,13,14].

In recent years, operating rooms in the Netherlands have been built to the highest standards, while the guidelines over the last few decades gave room to vary the classification of the operating room and to implement energy-saving measures such as reducing the amount of fresh air introduced and setting the air handling installation on standby at night or on weekends. Energy-saving measures have been implemented in air handling installations regarding the reduction of the air handling installation energy consumption. The study described in Chapter 6 determined the energy savings potential and identified opportunities to reduce the energy demand of OR air handling installations.

The study in Chapter 7 evaluated the capital and operational expenditures of different air handling installations with different [49] ultra-clean ventilation systems and related these expenditures to those of an air handling installation with a conventional ventilation system. Furthermore, the aim was to determine whether the technical requirements of Dutch OR air handling installations comply with European national standards and guidelines, and how the capital expenditure studied relates to the cost of a surgical site infection.

To date, most ORs in Dutch hospitals are ultra-clean ORs (FMS Class 1+). Since the recent FMS advice to reduce the ACH for most surgeries, it is important to have a benchmark regarding the number and type of microorganisms and dust particles measured during surgery at the wound site, on the instrument table, and in the periphery of an OR Class 1+. The baseline study described in Chapter 8 can be used as such a benchmark.

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# 2 Numerical study

## Ventilation performance evaluation of an operating room with temperature-controlled airflow system in contaminant control

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PUBLISHED **Journal of Building and Environment** | DOI: 10.1016/j.buildenv.2024.111619

KEYWORDS Operating room, temperature-controlled ventilation, contaminant dispersion, numerical simulation

ABSTRACT This article investigates the efficacy of temperature-controlled airflow systems in modern operating rooms for contaminant control, a critical factor in preventing surgical site infections. We have conducted experimental measurements in an operating room equipped with temperature-controlled ventilation to map the airflow field and contaminant dispersion (airborne particles with diameters ranging from 0.5–1 μm). The results were used to validate the computational fluid dynamics code, which was then employed to simulate and examine different conditions, including contaminant release locations and air supply rates. Realizable k-epsilon and passive scalar models were utilized to simulate airflow and airborne particle phases. We assessed the airflow distribution and contaminant dispersion, utilizing indices such as ventilation and air change efficiency scales. The analysis provided quantitative insights into the distribution and removal of contaminants, as well as the speed at which the room air was replaced. Contamination was found to be effectively

reduced when contaminants were released near exhaust outlets or under central unidirectional inlets. The presence of the operating table caused a big distortion of the central downward airflow, forming a horizontal air barrier at the periphery. Under this unique interior configuration, an appropriate air supply ratio between central and peripheral zones was required to achieve optimal overall ventilation performance.

| Nomenclature | |
|---|---|
| $C_0$ | Volume integral of the contaminant concentration throughout the room (kg) |
| $C_1$, $C_2$, $C_{1\varepsilon}$, $C_{3\varepsilon}$ | Model coefficients (-) |
| $C_p$ | Contaminant concentration at cell p (kg/m$^3$) |
| $C_s$ | Representative concentration (kg/m$^3$) |
| $d_c$ | Characteristics dimension of the obstacles (m) |
| $D_m$ | Mass diffusivity (m$^2$/s) |
| $d_p$ | Particle diameter (m) |
| $D_T$ | Thermal diffusivity (m$^2$/s) |
| $F$ | Body force per unit mass (m/s$^2$) |
| $G_i$ | Gravity center coordinate (m) |
| $G_k$, $G_b$ | Turbulent kinematic energy production terms (J/m$^3$/s) |
| $k$ | Turbulent kinematic energy (J/kg) |
| $P$ | Static pressure (Pa) |
| $q$ | Contaminant generation rate (kg/s) |
| $Q$ | Volumetric supply flow rate (m$^3$/s) |
| $Sct$ | Turbulent Schmidt number (m$^2$/s) |
| $S_k$, $S_\varepsilon$, $S_Y$ | Source term (kg/m/s$^3$, kg/m/s$^4$, kg/m$^3$/s) |
| $t$ | Time (s) |
| $T$ | Temperature (K) |
| $U_i$ | Mean velocity (m/s) |
| $U_\infty$ | Free-stream fluid velocity (m/s) |
| $V$ | Room volume (m$^3$) |
| $V_p$ | Volume of cell p (m$^3$) |
| $x_i$ | Spatial coordinate (m) |
| $X_i$ | Center coordinate of cell p (m) |
| $Y$ | Contaminant mass fraction (-) |
| $Y_p$ | Contaminant mass fraction at cell p (-) |
| $Y_p(0)$ | Initial contaminant mass fraction in cell p (-) |
| $Y_p(t)$ | Contaminant mass fraction at time t in cell p (-) |
| **Greek letters** | |
| $\delta_{ij}$ | Kronecker delta |
| $\varepsilon$ | Dissipation rate (m$^2$/s$^3$) |

>>>

| Nomenclature | |
|---|---|
| $\varepsilon_a$ | Contaminant removal efficiency (-) |
| $\mu$ | Dynamic viscosity (kg/m/s) |
| $\mu_t$ | Turbulent viscosity (kg/m/s) |
| $v$ | Kinematic viscosity ($m^2/s$) |
| $\rho$ | Fluid density ($kg/m^3$) |
| $\rho_d$ | Particle density ($kg/m^3$) |
| $\rho_{mixture}$ | Density of air-contaminant mixture ($kg/m^3$) |
| $\sigma_\varepsilon$, $\sigma_k$ | Model coefficients (-) |
| $\tau_n$ | Nominal time constant (s) |
| $\tau_p$ | Local age of the air (s) |
| **Subscripts and Abbreviations** | |
| ACE | Air Change Efficiency |
| BC(s) | Boundary Condition(s) |
| BCPs | Bacterial-Carrying-Particles |
| CAD | Computer-Aided Design |
| CDC | Centers for Disease Control |
| CFD | Computational Fluid Dynamics |
| CRW | Continuous Random Walk |
| DNS | Direct Numerical Simulation |
| DRW | Discrete Random Walk |
| G | Gravity Center |
| H | Height |
| HAIs | Hospital-Acquired Infections |
| L | Length |
| LAF | Laminar Airflow |
| LED | Light-Emitting Diode |
| LES | Large Eddy Simulation |
| OR(s) | Operating Room(s) |
| RANS | Reynolds-Averaged Naiver-Stokes |
| SSIs | Surgical Site Infections |
| Stk | Stokes number |
| SVE1 | Scale for Ventilation Efficiency 1 |
| SVE2 | Scale for Ventilation Efficiency 2 |
| TcAF | Temperature-controlled Airflow |
| TMA | Turbulent Mixing Airflow |
| UDAF | Unidirectional Airflow |
| UDF | User-Defined Function |
| UDM | User-Defined Memory |
| W | Width |

## 2.1 Introduction

According to previous prevalence surveys and progress reports on hospital-acquired infections (HAIs) published by Centers for Disease Control (CDC), surgical site infections (SSIs) have been the most common and costly HAI type, posing a substantial burden on public health [1–3]. To mitigate this healthcare challenge, infection control in ORs where surgical wounds are created plays a critical role. Early in the 1980s, abundant statistical research demonstrated the crucial link between a clean OR environment and the prevention of SSIs and revealed the effectiveness of ventilation technology in infection control for ORs [4,5]. Through clean and well-organized airflow streams, OR ventilation systems supply direct and continuous control of airborne pathogens, reducing the concentration level of air contamination and minimizing the incidence of infection.

Two types of conventional ventilation systems in ORs are turbulent mixing airflow (TMA) and laminar airflow (LAF) [6–8]. TMA primarily utilizes the ceiling-level air supply and floor-level air extract on side walls. A Large volume of clean air with high momentum is introduced with the aim of fully mixing with indoor air and diluting the contaminants in OR environments. LAF features a large air supply section throughout the whole ceiling area and flushes the contaminated indoor air away from the surgical zone to the floor-level exhaust grills. On the basis of these traditional ventilation systems, a hybrid ventilation system called temperature-controlled airflow (TcAF) has been recently developed and installed in several modern ORs [8]. It incorporates decentralized mixing air supply in the peripheral areas and concentrated unidirectional airflow in the central zone. In addition, the central air supply is kept 1–3 degrees cooler than the desired room temperature, and the warmer peripheral air regulates the OR temperature. The temperature gradient between two air supply sections enhances both the central downward airflow and the surrounding air mixing. In TcAF, the combination of TMA and LAF, as well as the utilization of buoyancy effect, aim to maximize performance and reduce operation costs. The novel ventilation strategy enhances infection control and aligns with global efforts to reduce energy consumption and carbon emissions in healthcare settings. As illuminated by Brenda et al. [9], the quest for infection control within ORs unites with the broader imperative for energy-efficient healthcare buildings. Advanced ventilation technologies like TcAF play an important role in achieving sustainable, green healthcare infrastructures without compromising hygiene standards or user comfort.

Several studies compared TcAF with conventional ventilation principles in OR environments. Alsved et al. measured viable airborne bacterial loads in three ORs equipped with TMA, LAF and TcAF and summarized that TcAF maintains very low levels of microbiological organisms in air with moderate air delivery [10]. Subsequent numerical studies confirmed the superiority of TcAF through the analysis of the spatial bacterial-carrying-particles (BCPs) concentration [11,12]. The existing literature suggests that TcAF can serve as an alternative to traditional ventilation principles. Meanwhile, they highlighted the significant role of airflow patterns in contaminant control performance and revealed the potential factors such as room layout and ventilation rate, etc.

In addition to critical physical properties, ventilation performance metrics are of great interest. It enables a straightforward understanding of the effectiveness of ventilation systems and easy benchmarking and comparison for system design and optimization. Cao et al. [13] summarized different assessment indices in terms of air exchange, pollutant removal, heat removal, exposure to contaminants, and airflow distribution. Considering the protective purpose of ventilation in OR, metrics describing local air quality or contamination level are commonly used. It includes air change efficiency (ACE), mean age of air, contaminant removal effectiveness (CRE), net escape velocity, purging flow rate, purge time, scales for ventilation efficiency, spread index, and visitation frequency [14 - 23]. These metrics serve to evaluate two main aspects of ventilation: air replacement and contaminant removal. The first two indicators, ACE and mean age of air, pertain to air replacement, measuring the system's capability to introduce fresh air and expel stale air. On the other hand, the remaining metrics focus on contaminant removal effectiveness, accounting for the characteristics of contaminant sources to assess ventilation performance in removing pollutants from the indoor environment. TcAF, as a novel ventilation technology, lacks comprehensive and in-depth quantitative analysis, particularly in terms of its non-uniform airflow pattern and contaminant distribution. Two scales of ventilation efficiency, namely SVE1 and SVE2, are selected to investigate the mechanisms by which TcAF eliminates contaminants released from various locations. Compared to other contaminant removal indicators, SVE1 and SVE2 offer a more detailed quantitative depiction of both contamination level and spatial dispersion range. In terms of TcAF's response to inadequate or imbalanced air delivery, the authors opt for customary measures, ACE and mean age of air, due to their broad applicability.

It is also worth noting that OR geometries and configurations in previous studies were often idealized and outdated. However, contemporary ORs significantly differ from their older counterparts. For instance, an image-guided system now commonly installed at the floor or ceiling compromises the flexibility of arranging air showers

and obstructs the introduced airflow. The critical role of room layout on ventilation performance is acknowledged, yet TcAF's ventilation performance in modern ORs with realistic configurations remains unclear.

This study aims to enhance comprehension regarding the spatial variability of contaminant control capacity within modern ORs utilizing the TcAF system and advances the knowledge related to the design of TcAF's air supply strategy. This paper offers a comprehensive numerical and experimental investigation analyzing the airflow distribution and contaminant dispersion in a recently built OR equipped with a TcAF system. Experimental measurements have been conducted on the air velocity, temperature, and aerosol particle diffusion throughout the OR under the standard TcAF operation, while computational fluid dynamics (CFD) simulations investigated various contaminant release positions and ventilation rates. Moreover, the contaminant control performance of TcAF under diverse working conditions was quantitatively assessed using specific ventilation effectiveness indices.

## 2.2 Method

### 2.2.1 OR layout descriptions

OR at Rijnstate Hospital in the Netherlands (see Figure 2.1.a) was selected for full-scale numerical and experimental investigations to evaluate its actual performance. The OR measures 11.6 m in length (L), 6.4 m in width (W), and 3.0 m in height (H). In the OR's center, air flows downward from three unidirectional airflow (UDAF) plenums comprising seven half-spherical air diffusers. Along the periphery, 18 diffusers, arranged in parallel, distribute filtered air across the remaining space. This configuration creates two zones (central and peripheral), each with an equal air supply of 6300 $m^3$/h. Consequently, with a uniform surface size of 0.18 $m^2$, internal air showers receive 300 $m^3$/h, whereas external air showers are supplied 350 $m^3$/h. Four exhaust grills, measuring 0.95 m in width (W) by 0.5 m in height (H), are located on the side walls at floor level. The air introduced above the operating table is colder by 1 K than the OR's ambient temperature. This temperature difference is achieved by regulating the supply temperature from 18 diffusers in the peripheral area. Illumination in the OR is provided by 17 ceiling-mounted square LED panels



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(0.6 m × 0.6 m) scattered around the periphery zone and six additional rectangular LED panels (1.2 m × 0.2 m) placed between three UDAF plenums. Furthermore, two surgical lamps, each with a radius of 0.3 m, are suspended symmetrically 2.2 m above the floor, with a 0.6 m offset from the operating table's centerline. The OR includes medical equipment such as an anesthesia machine, an endoscopy tower, and an image-guided therapy system (C-arm). The imaging system, integrated with a carrier, is ceiling-mounted via a rail system, and positioned in its parking configuration. A CAD model replicates the examined OR's interior layout, incorporating appropriate geometric simplifications illustrated in Figure 2.1.b.

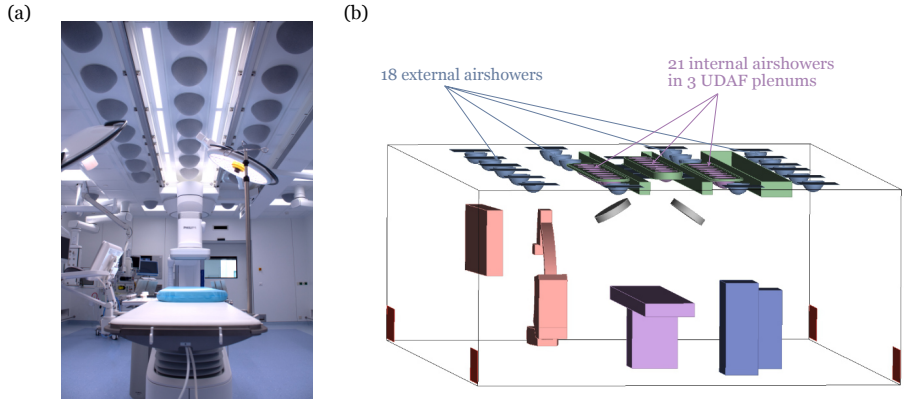


FIG. 2.1 Interior view of the state-of-the-art OR at Rijnstate Hospital, Netherlands; b) the replica CAD model.

### 2.2.2 Numerical model

This study investigates the airflow movement and airborne particle distribution within the OR environment using ANSYS Fluent 2021, a commercially available CFD software. A reference simulation case has been established for verification and validation purposes, replicating the experimental setup in the Rijnstate Hospital OR, Netherlands. Additionally, a series of simulations were conducted to assess the contaminant control performance of TcAF under various system configurations.



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### 2.2.2.1 Airflow model

Simulating indoor airflow accurately and reliably has long been a challenging endeavor due to its turbulent nature characterized by chaotic and disordered fluid motion. Direct Numerical Simulation (DNS) and Large Eddy Simulation (LES) could capture the transient flow features but require intensive computational resources. In contrast, the Reynolds-Averaged Navier-Stokes (RANS) method is a more practical scheme, offering a well-balanced combination of robustness, computational efficiency, and accuracy [24]. This method decomposes flow variables into time-averaged and fluctuating components. The flux due to turbulent fluctuations, known as the Reynolds stress term, requires additional modeling to achieve closure in the equation system. One commonly used approach for modeling turbulent stress is the eddy-viscosity hypothesis. Among the various eddy-viscosity turbulence models, the Realizable k-ε model has been widely applied for airflow simulation in ventilated rooms and has shown good performance in predicting particle flow [25,26]. Consequently, the Realizable k-ε model has been employed, and the reliability of the predicted results has been carefully validated through comparison with experimental data. Assuming a Newtonian, incompressible flow, the time-averaged transport equations for mass, momentum, turbulent kinetic energy, and turbulent dissipation rate are expressed in Eq. (2.1)-(2.4).

$$\frac{\partial(\rho u_i)}{\partial x_i} = 0 \qquad \text{EQ. 2.1}$$

$$\frac{\partial(\rho u_i)}{\partial t} + \frac{\partial(\rho u_i u_j)}{\partial x_j} = -\frac{\partial P}{\partial x_i} + \frac{\partial}{\partial x_j}[(\mu + \mu_t)(\frac{\partial u_i}{\partial x_j} + \frac{\partial u_j}{\partial x_i}) - \frac{2}{3}k\rho\delta_{ij}] + \rho F_i \qquad \text{EQ. 2.2}$$

$$\frac{\partial(\rho k)}{\partial t} + \frac{\partial(\rho k u_j)}{\partial x_j} = \frac{\partial}{\partial x_j}[(\mu + \frac{\mu_t}{\sigma_k})\frac{\partial k}{\partial x_j}] + G_k + G_b - \rho\varepsilon + S_k \qquad \text{EQ. 2.3}$$

$$\frac{\partial(\rho\varepsilon)}{\partial t} + \frac{\partial(\rho\varepsilon u_j)}{\partial x_j} = \frac{\partial}{\partial x_j}[(\mu + \frac{\mu_t}{\sigma_\varepsilon})\frac{\partial\varepsilon}{\partial x_j}] + \rho C_1 S\varepsilon - \rho C_2 \frac{\varepsilon^2}{k + \sqrt{\nu\varepsilon}} + C_{1\varepsilon}\frac{\varepsilon}{k}C_{3\varepsilon}G_b + S_\varepsilon \qquad \text{EQ. 2.4}$$

Here, $\rho$ represents the fluid density, $t$ is time, $u_i$ and $x_i$ are mean velocity, and the spatial coordinate in the $i^{th}$ direction. The terms $P$, $\mu$, and $\mu_t$ denote mean static pressure, dynamic viscosity, and turbulent viscosity, respectively. $k$ represents turbulent kinematic energy, $\delta_{ij}$ is the Kronecker delta, and $F$ is the body force per unit mass. $G_k$ and $G_b$ are the turbulent kinematic energy production terms due to mean velocity gradients and



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buoyancy, respectively. $\varepsilon$ is the dissipation rate, $S_k$ and $S_\varepsilon$ are source terms, and $v$ is the kinematic viscosity. The parameters $\sigma_\varepsilon$, $\sigma_k$, $C_1$, S, $C_2$, $C_{1\varepsilon}$, $C_{3\varepsilon}$ are model coefficients, with their specific values or expressions detailed in the ANSYS Fluent Theory Guide [27].

This study models a steady airflow field, neglecting the time derivative term in the equations. The Convective term is discretized using a second-order upwind scheme. To handle the staggered pressure and velocity grids, the PRESTO! pressure interpolation scheme is employed. In the iterative process, momentum and pressure-based continuity equations are simultaneously solved using the Coupled algorithm. Three convergences criteria are established: achievement of mass and energy balance, attainment of stable temperature solutions at monitor planes/points, and residuals below $10^{-3}$ (for energy, the convergence criteria are $10^{-6}$). These criteria ensure the accuracy and stability of the simulation results.

#### 2.2.2.2 Contaminant dispersion model

Two prominent numerical methods, Eulerian and Lagrangian models, are commonly employed for simulating contaminant dispersion in indoor environments. In the Eulerian approach, the focus is on the concentration of particles, calculating the overall diffusion and convection of a number of particles, which is particularly effective for simulating the fine particle dispersion in environments with high air exchange rates as observed in the OR. In contrast, the Lagrangian approach, which deals with individual particles and calculates the trajectory of each particle separately, is often preferred in usual enclosed environments with larger particles and lower airflow rates.

In our experiment, the measured particles have a density of 900 kg/m$^3$ and a diameter of 0.5 µm. The Stokes number (Stk) is calculated to be 1.7e-7 based on Eq. (2.5).

$$Stk = \frac{\rho_p d_p^2 U_\infty}{18 \mu d_c} \qquad \text{EQ. 2.5}$$

Where $\rho_p$ and $d_p$ are the density and diameter of the particle, $U_\infty$ is the free-stream fluid velocity, $\mu_g$ represents the dynamic viscosity of the fluid phase and $d_c$ is the characteristic dimension of the obstacles.

A Stokes number significantly below 0.1 indicates that particles closely follow fluid streamlines [17]. Under these conditions, airflow is the primary driving force, with minimal influence from gravity and inertia [18,19]. Furthermore, given the high air exchange rate in the OR, deposition loss of fine particles on solid surfaces is negligible [19,20]. Given such conditions, tracer particles exhibit dynamic characteristics akin to gaseous species.

While the Lagrangian model offers detailed insights into particle dynamics [28], it is less suited to the conditions of our experiment where fine particles closely follow fluid streamlines. Therefore, this paper employs a Eulerian model, specifically a species transport model, to determine the contaminant distribution. The governing equation for the tracer species is expressed in Eq. (2.6).

$$\frac{\partial(\rho Y)}{\partial t}+\frac{\partial(\rho Y u_j)}{\partial x_j}=\frac{\partial}{\partial x_j}[(\rho D_m+\frac{\mu_t}{Sc_t})\frac{\partial Y}{\partial x_j}+\frac{D_T}{T}\frac{\partial T}{\partial x_j}]+S_Y \qquad \text{EQ. 2.6}$$

In this equation, $Y$ signifies the local mass fraction of the species, $\rho$ is the fluid density, $t$ is time, and $T$ is the temperature. $u_j$ and $x_j$ are the velocity component and the spatial coordinate in the $j^{th}$ direction, respectively. $D_m$ and $D_T$ refer to mass and thermal diffusivity. $\mu_t$ is the turbulent viscosity, and $Sc_t$ is the turbulent Schmidt number, which is the ratio of kinematic viscosity and mass diffusivity. $S_Y$ represents the source term.

To validate the model, simulations of steady tracer release and transient tracer decay were conducted. A user-defined function (UDF) was employed to define the release location, and a constant source flux in kg/s was specified. Following computation of a converged steady-state airflow field, the species transport equation was iterated until achieving a stable tracer concentration distribution within the computational domain. This stable concentration distribution served as the initial condition for the subsequent tracer decay simulation. The simulation was then switched to transient mode, deactivating the source term to model tracer decay. A time step size of one second was assigned for the transient simulation.

### 2.2.2.3 Mesh and boundary conditions

To account for the complex geometry of the OR, we have adopted an unstructured space discretization strategy for grid generation. All surfaces are initially covered with a triangle mesh, with individual maximum size settings to ensure accuracy. This surface mesh is then converted into a tetrahedral grid to fill the computational domain. Three prism layers are created to capture the flow physics in the boundary layer better and accurately calculate the particle deposition. As we have used enhanced wall treatment, the thickness of the first layer is controlled to ensure that the y+ value is lower than 5. In addition, we have performed grid-independence tests with three different grid resolutions (5.4, 9, and 15 million cells) to ensure that the grid resolution does not influence the simulation outcomes [29,30]. Velocity and temperature profiles along the centerline of the long side of the OR are plotted in Figure 2.2, revealing negligible differences between the medium and fine mesh resolutions. As a result, a grid with 9 million cells seems fine enough and thus chosen for our simulations.

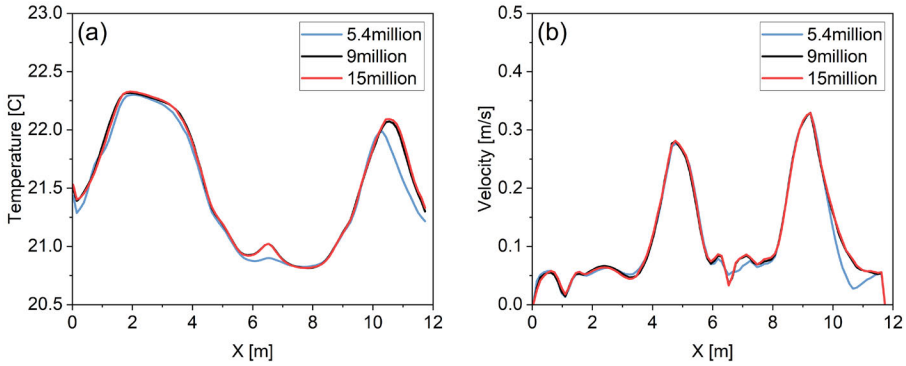


FIG. 2.2 Comparative analysis of temperature and velocity distributions for three distinct grid resolutions

A no-slip condition is applied to all solid surfaces in the OR, including walls, ceiling, floor, lamps, and medical devices. Velocity inlets are assigned to both internal and external air showers, while the four exhausts are specified as outflow boundaries. The ceiling lights are subjected to a constant heat flux. The surgical lamps' bottom and top surfaces are set to their respective measured operating temperatures. All remaining solid surfaces are treated as adiabatic, indicating no heat transfer occurs through these surfaces. Details of the boundary conditions for the reference scenario are provided in Table 2.1.



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TABLE 2.1 The simulated parameters defined in the reference case.

| Objects | Size [$m^2$] | BC type | Thermal BC | Momentum BC | Species BC |
|---|---|---|---|---|---|
| **Internal air showers** | 0.18 × 21 | Velocity-inlet | 293.65 K | 0.48 m/s | 0 |
| **External air showers** | 0.18 ×18 | | 295.15 K | 0.55 m/s | 0 |
| **Outlets** | 0.48 × 4 | Outflow | – | – | – |
| **Anesthesia**<br>**Endoscopy** | 4.03<br>3.09 | Wall | 160 Watt<br>230 Watt | No-slip | Zero diffusive flux |
| **C-arm**<br>**C-arm screen** | 5.75<br>4.49 | | 0 heat flux | | |
| **Operating table** | 10.97 | | | | |
| **Room walls** | – | | | | |
| **Room ceiling**<br>**Ceiling structure** | –<br>– | | | | |
| **Room floor** | – | | | | |
| **Surgical lamp** | 0.71 × 2 | | Top surface: 321.15 K, Bottom surface: 297.15 K | | |
| **Ceiling square light**<br>**Ceiling bar light** | 0.36 × 17<br>0.18 ×6 | | 30 Watt per lighting panel | | |
| **Tacer generation** | 6.94e-7 kg/s tracer flux from a single cell at the specific releasing location. | | | | |



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### 2.2.2.4 Ventilation performance indices and simulation cases

The primary objective of ventilation in ORs is to ensure a healthy indoor environment for both patients and healthcare providers during surgical procedures, with a particular emphasis on air cleanliness and contaminant control [8]. In order to evaluate the TcAF ventilation performance, we consider different locations and scales of contaminant release and select appropriate assessment indices. First, we designated individual point sources in the OR equipped with the TcAF system under standard air supply conditions. To assess the elimination of passive contaminants released from these fixed points by the TcAF system, the scale for ventilation efficiency 1 (SVE1), center gravity for contaminant distribution (G), and scale for ventilation efficiency 2 (SVE2), indices proposed by Kato and Murakami [17]. The SVE1 index represents the spatial average contaminant concentration, while the G and SVE2 indices specify the concentration centroid and the mean radius of contaminant diffusion. These indices quantify the contaminant removal capacity of the ventilation at different locations and provide a clear and concise description of the spatial distribution. In comparison to conventional measures such as local contaminant removal efficiency ($\varepsilon_a$ in [31]) or complex contaminant contours, these indices provide more informative and quantitative insights.

Secondly, the TcAF system's response to contaminant sources of unknown scales and locations was analyzed by examining the local mean age of air ($\tau_p$) or the local air change efficiency (ACE). The local mean age of air is defined as the average time it takes for a fluid parcel to travel from the inlet to a particular point. For the region with inactive air movement and mixing, its air age tends to be older. Therefore, the concept of air age gives a reflection of the airflow pattern in the ventilated room [32]. It is assumed that the age of air at the inlet equals zero. After the air enters the room, it is a mixture of fresh air and recirculated air. Older air age corresponds to a higher ratio of recirculated air, therefore indicating the freshness of the air and the dilution capacity at a specific point. Kato and Murakami [17] defined a new ventilation performance parameter called scale for ventilation efficiency 3 (SVE3) with the same physical meaning as the local mean age of air. In this context, the fluid parcel is considered as the fresh clean air entering through inlets, and SVE3 corresponds to the mean traveling time required by the fluid parcel to reach the point concerned.

The local mean age of air can be obtained by either experimental measurements or simulations. According to Sandberg and Sjoberg [16], its expression varies with different injection procedures. As for SVE3, it is a "virtual concept" based on the simulated results and cannot be directly measured in practice. Under uniform and continuous contaminant generation throughout the room, the supplied air mass is gradually contaminated, and its concentration is proportional to the mean traveling time, i.e., SVE3. Therefore, SVE3 corresponds to an expression of the age-of-air concept under a steady-state uniform injection procedure.

On the basis of the age-of-air concept, the local ACE index was proposed by Etheridge and Sandberg [19], and widely utilized for quantifying the airflow pattern features. It is defined as the ratio between the nominal time constant ($\tau_n$) and the local mean age of air ($\tau_p$). The theoretical concept $\tau_n$ represents perfect mixing airflow distribution, corresponding to the shortest possible mean age of air. The local ACE offers direct information on air quality at specific locations, indicating if the air is too old and indirectly reflecting contamination potential. This index, based solely on the airflow pattern, remains independent of the contaminant release state [33]. At the same time, it maintains a straightforward relationship with contaminant control. Regions exhibiting low ACE values indicate inadequate air exchange, posing risks of contaminant accumulation and unsatisfactory contaminant removal performance.

For calculating SVE1 and SVE2, a steady tracer release simulation was conducted, and a UDF compiled to specify the source location and strength. The relevant functions used in the simulation are defined as follows:

$$C_s = \frac{q}{Q} \qquad \text{EQ. 2.7}$$

$$SVE1 = \frac{C_0}{C_s V} = \frac{\int_V C_p dV_p}{C_s V} = \frac{\int_V (Y_p \rho_{mixture}) dV_p}{C_s V} \qquad \text{EQ. 2.8}$$

$$G_i = \int_V \frac{X_i C_p}{C_0} dV_p \qquad \text{EQ. 2.9}$$

$$SVE2 = \sqrt{\frac{\int_V (X_i - G_i)^2 C_p dV_p}{C_0}} \qquad \text{EQ. 2.10}$$



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Here, $C_s$ represents the representative concentration, equal to the average concentration at the exhaust, $q$ is the contaminant generation rate, and $Q$ signifies the total volumetric flow rate supplied to the room. $C_0$ is the volume integral of the contaminant concentration throughout the room. $C_{p,}$ $V_p$ and $Y_p$ correspond to the contaminant concentration, volume, and contaminant mass fraction of cell $p$, respectively. $V$ is the room volume, while $\rho_{mixture}$ represents the density of the air-contaminant mixture. $G_i$ indicates the gravity center coordinate for contaminant distribution, and $X_i$ is the center coordinate of cell $p$ ($i$=1,2,3). During post-processing, these indices were computed utilizing custom field functions.

Various methods determine the age of air distribution in enclosed rooms, including the step-up injection, step-down, steady-state, and particle-marker methods [14]. In this study, the step-down method, involving a transient tracer decay process, was employed. Using a uniform mass fraction of a tracer contaminant as the initial condition, Eq. (2.6) was iterated over time without source generation, based on a frozen airflow field. The local age of the air of a single cell can be found from:

$$\tau_p = \int_0^\infty \frac{Y_p(t)}{Y_p(0)} dt \qquad \text{EQ. 2.11}$$

Where, $\tau_p$ is the local age of the air within a single cell $p$, $Y_p(t)$ is the mass fraction of a tracer contaminant at time $t$ in the cell $p$, and $Y_p(0)$ is the initial mass fraction of the tracer in cell $p$. A time integral for each cell in the fluid zone is calculated using a User-Defined Function (UDF) and stored in User-Defined Memory (UDM). To illustrate the disparity in air exchange ability among the central, periphery, and whole OR, the respective volume-averaged age of the air is also calculated.

This study initially investigated the non-uniform contaminant control capabilities of the TcAF system, equipped with a standard airflow supply. To capture regional variations, twelve contaminant release locations were considered, six in the periphery and six in the central area of the OR. The spatial variability of the TcAF system, in terms of air exchange and cleanliness, was further explored using the air-age distribution theory, without specifying contaminant sources. Additionally, four more ventilation rates were examined to assess the system's performance under inadequate or imbalanced air supply conditions. Overall, 16 simulation scenarios were studied, as outlined in Table 2.2.

TABLE 2.2 Details of different scenarios

| Case No. | Supply airflow [$m^3/h$] | Contaminant method | Contaminant release location | Contaminant initial conditions | Aim and indices |
|---|---|---|---|---|---|
| **Reference** | 300/350 * | Steady release | In the periphery | Point source | Validation: particle number concentration |
| | | Transient decay | N/A | Read from case 1 | Validation: decay rate |
| **Case E1-E6** | | Steady release | In the periphery | Point source | Contaminant removal efficiency: SVE1,SVE2 |
| **Case CM-C5** | | | In the central zone | | |
| **Case 1** | 300/350 | Transient decay | N/A | Uniform contaminant throughout OR | Air change efficiency: age of the air |
| **Case 2** | 225/262.5 | | | | |
| **Case 3** | 150/175 | | | | |
| **Case 4** | 300/175 | | | | |
| **Case 5** | 150/350 | | | | |

**: The first value indicates the supply flow rate for internal air showers, whereas the second value refers to the supply flow rate designated for external air showers situated in the periphery area of the OR.*

### 2.2.3 Experimental setup

Two objective experiments were conducted in the hybrid OR, as described in Section 2.2.1: a). temperature and velocity measurement; and b). tracer particle decay measurement. An 'at-rest' situation, with equipment installed and operating in a customers manner and no personnel present, is considered in such experiments. Specifically, medical equipment and surgical lights were activated and positioned as per operational standards (DIN 1946-4 [34]) while the C-arm remained in its parking position. Prior to conducting measurements, a technical inspection of the TcAF system ensured its functional integrity. Furthermore, TcAF operational parameters, such as supply air temperature and flow rate, were pre-set to guarantee stable measurement conditions. Given the TcAF system's sensitivity to horizontal variations in temperature and velocity over vertical trends, 48 monitoring points (see Figure 2.3) were strategically placed around the OR at a height of 1.20 meters above the floor level, in accordance with ISO14644-3 [35]). Measurements were taken using a TSI 966 thermoanemometer articulated probe, with a range of 0 to 50 m/s and -10 to 60°C, a resolution of 0.01 m/s and 0.1°C, and an accuracy of ±0.015 m/s and ±0.3°C, at each location for three minutes with 15-second intervals. This experimental data later served to validate the airflow field in the results section.

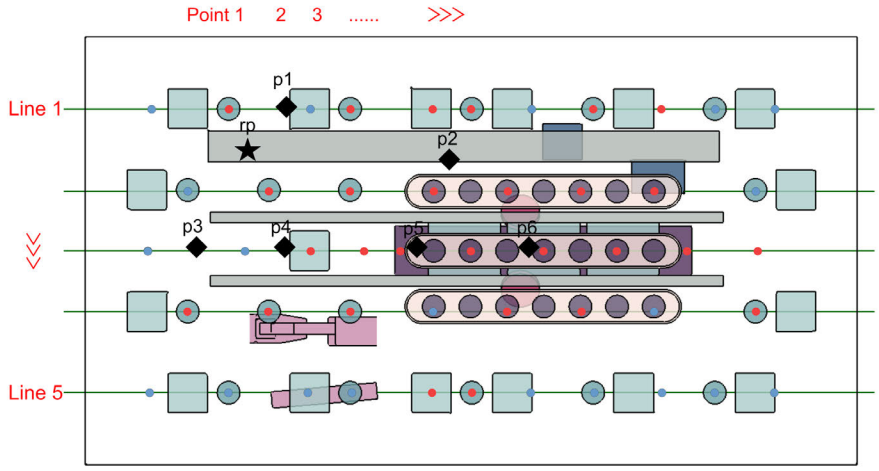


FIG. 2.3 Measurement setup, illustrating temperature and velocity monitoring points, represented by blue and red points respectively (48 in total). The location for particle release is denoted by a black star, while particle concentration monitoring points (6 in total) are indicated by black diamonds.

The tracer particle decay experiment, conceived to assess the recovery rate, was conducted in accordance with ISO 14644-3 [35]. Within the OR, a calibrated Topas aerosol generator (model ATM 226) was strategically positioned at a release point 1.8 meters above the floor level, as denoted by the star mark in Figure 2.3). Particle number concentration, for particles of size greater than 0.5μm) at six monitoring points situated 1.2 meters above the floor level (P1-P6), was quantified using Lighthouse 3016 handheld particle counters, operating at a flow rate of 2.83 l/min. The substance utilized, ATI PAO-4 (chemically identified as 1-Decene, homopolymer, hydrogenated, or 1-Decene, tetramer mixed with 1-decene), was atomized into spherical aerosols ranging in size from 0.5-1 μm, and subsequently discharged into the OR to establish a background concentration. The emission was halted once all particle counters (with the exception of P6, positioned under the Opragon 21) indicated a concentration $\geq 10^7$ particles/$m^3$. A 10-minute decay process at the six monitoring points was documented, employing a measuring cycle of one minute. This manuscript leverages experimental data for the verification of the contaminant dispersion field.



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## 2.3 Results and Discussion

### 2.3.1 Numerical Model Validation

Before conducting parametric studies to evaluate the TcAF system's efficacy, validating the employed numerical models is imperative. To this end, a comparison of representative indoor air and contaminant characteristics was conducted between simulation outcomes and experimental data.

Given the turbulent nature of the OR's airflow field, air velocity measurements exhibited fluctuations during the 3-minute measurement period, whereas temperature variations were comparatively minor. A preliminary analysis of the velocity measurement data facilitated the identification of 28 out of 48 points (indicated by red points in Figure 2.3) that satisfied the criteria for steady-state measurements, rendering them suitable for validation purposes.

Figure 2.4 compares the simulated temperature and air velocity at a floor level of 1.2 meters against the corresponding experimental data. The comparison reveals a commendable concordance between the simulation and experimental findings. Nevertheless, minor variances were noted at line 2, point 5 (adjacent to the Anesthesia and Endoscopy devices), line 3, points 3 and 4, along with line 4, points 4 and 5 (in proximity to the two surgical lamps). These variances are likely attributable to minor geometrical divergences between the replica CAD model and the actual physical setup.

Simulations of tracer particle release and decay were conducted to validate the contaminant dispersion field, adhering to the setup depicted in Figure 2.3. To facilitate a more accurate comparison between experimental data and simulation outcomes, concentration values were normalized against the average concentration observed at all six monitoring points.

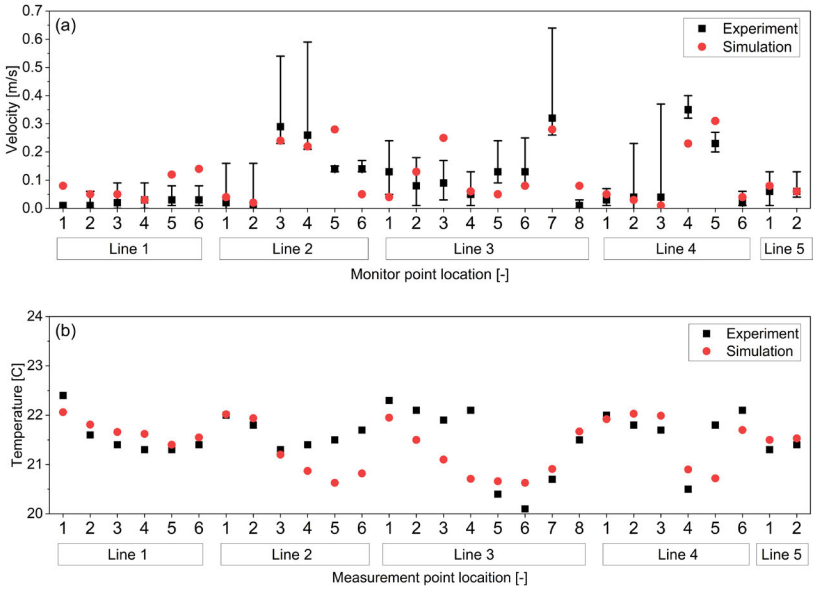


FIG. 2.4 a) validation of the airflow field through a comparison of velocity data, and b) validation of the thermal environment through a comparison of temperature data. The monitor points are numbered according to Figure 3, arranged from left to right, with emphasis solely on those marked in red.

Figure 2.5.a illustrates the steady-state tracer concentration levels at the six designated locations, following several minutes of tracer injection at a release rate of 6.94e-7 kg/s. The experimental scenario revealed lower concentrations at points 1, 3, and 4, yet displayed higher values at points 2 and 5 compared to those in the simulation. This difference suggests an enhanced dispersion of contaminants into the OR's interior during the experimental phase, possibly due to door openings required for laboratory personnel to activate or deactivate experimental apparatus.

These unavoidable behaviors have posed challenges to maintain a steady state during measurements, leading to significant deviations from the simulated result, especially at the location of p2 and p3. To minimize the potential distortion, the data for these two points are excluded for the quantitative error analysis. The Root Mean Square Error (RMSE) of normalized particle concentration for the rest four locations is calculated as 0.39. Compared to literature data [36], this deviation level is within the acceptable range.



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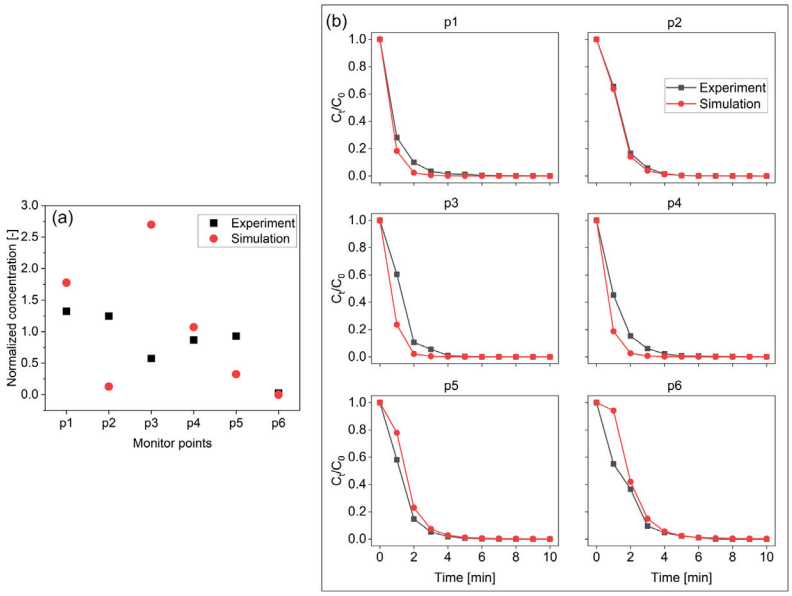


FIG. 2.5 a) The steady-state contaminant field validation, and b) The contaminant decay validation, where Ct represents the concentration after time t (minutes), and C0 denotes the initial concentration.

Evaluating the TcAF system's contaminant removal efficiency necessitates a numerical model that precisely mirrors the decay process. Figure 2.5.b shows good agreement between the simulated and experimental outcomes in terms of the tracer concentration changes over a 10-minute decay interval. This temporal variation is quantified into the index of cleanliness decay rate. Table 2.3 shows the quantitative comparison between the measured and simulated contaminant decay rates at different monitor points. The maximum relative error of 16%, aligns with the uncertainty levels reported in other literature.

TABLE 2.3 Measured and simulated contaminant decay rates at six monitor points.

| Cases | Contaminant decay rate [$min^{-1}$] | | Percentage error [-] |
|---|---|---|---|
| | Measured | Simulated | |
| p1 | 0.75 | 0.85 | 12% |
| p2 | 1.02 | 0.98 | 4% |
| p3 | 1.21 | 1.40 | 16% |
| p4 | 0.74 | 0.86 | 17% |
| p5 | 0.99 | 1.03 | 5% |
| p6 | 1.26 | 1.45 | 15% |



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Various studies have elucidated that factors such as the background contaminant concentration, uncertainties associated with measurement equipment, and human elements can significantly impact the accuracy of particle dispersion experiments, thereby complicating the validation of the contaminant field [37-40]. Considering these factors, the alignment observed between the experimental and simulated tracer concentrations in this study is deemed acceptable and sufficiently validated.

Upon a thorough evaluation of both the airflow and contaminant dispersion fields, it is concluded that the simulation model employed in this research is aptly suited for exploring the dynamics within an OR equipped with the TcAF system.

### 2.3.2 Contaminant removal and dispersion under point sources

To assess the TcAF system's capability in addressing passive contaminant releases from diverse locations, the validated numerical model was employed to simulate twelve distinct scenarios, each featuring pollutants originating from individual release points, as depicted in Figure 2.6. The complex airflow patterns and contaminant distributions encountered were encapsulated into various indices, designed to quantify the concentration levels and spatial distribution of contaminants, respectively.

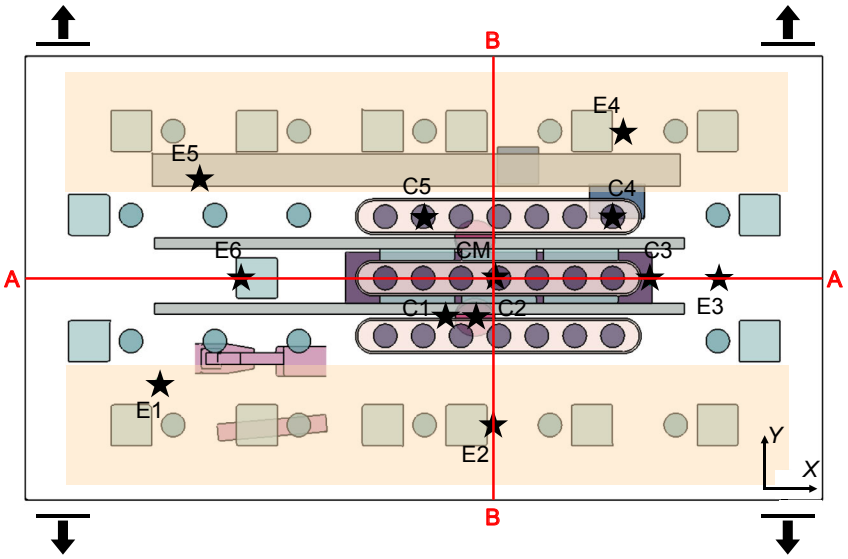


FIG. 2.6 The location of contaminant injection for 12 cases. Points labeled with 'E' signify particle releases in the peripheral regions, whereas points prefixed with 'C' indicate releases in the central area of the OR. The diagram also features two vertical planes: A-A, positioned at y=3.25 m, and B-B, situated at x=6.9 m, providing a reference for the spatial orientation. Yellow boxes delineate the areas extending outward along the long side of the operating table, offering a visual guide to the spatial configuration under investigation.



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### 2.3.2.1 SVE1: Spatial average contaminant concentration

To quantify the dispersion of contaminants across various release points, the spatial average contaminant concentration, denoted as SVE1, was calculated for different scenarios. These calculations have been synthesized and are presented in Table 2.4.

TABLE 2.4 The SVE1 values for the 12 cases studied. Values highlighted in red font signify outliers within each group, providing insights into the variability and extremities of contaminant distribution under different conditions.

| Group | Location | | | | | | Average value* |
|---|---|---|---|---|---|---|---|
| **Periphery** | E1 | E2 | E3 | E4 | E5 | E6 | 0.67 |
| | 0.50 | 0.80 | 1.75 | 0.66 | 0.74 | 1.30 | |
| **Central zone** | CM | C1 | C2 | C3 | C4 | C5 | 0.95 |
| | 1.03 | 0.83 | 0.92 | 1.04 | 0.49 | 0.61 | |

**: Excluding outliers*

In general, case studies reveal that lower SVE1 values are typically observed when contaminants are released from points situated in the OR's periphery compared to those cases where pollutants are introduced in the central zone. This phenomenon can be attributed to the superior efficiency of contaminant extraction by exhaust outlets over the pollutant sweeping capabilities of the UDAF21 system, which comprises three unidirectional airflow (UDAF) plenums positioned above the surgical area. Contaminants originating from peripheral locations benefit from a shorter transit to exhausts, facilitating quicker removal and resulting in lower concentration levels. Conversely, central zone releases encounter longer paths to exit, compounded by obstructions like the surgical lamp and operating table that disrupt the unidirectional downward airflow, leading to insufficient air movement and potential contaminant accumulation.

Beyond physical locations, the local airflow structures markedly influence SVE1 values [17,41]. Notably, the SVE1 values for cases E3 and E6 stand at 1.75 and 1.30, respectively, significantly surpassing the average SVE1 value (0.67) recorded for other periphery scenarios. Figure 2.7 delineates the velocity and streamline distribution in plane A-A, highlighting the positioning of points E3 and E6.

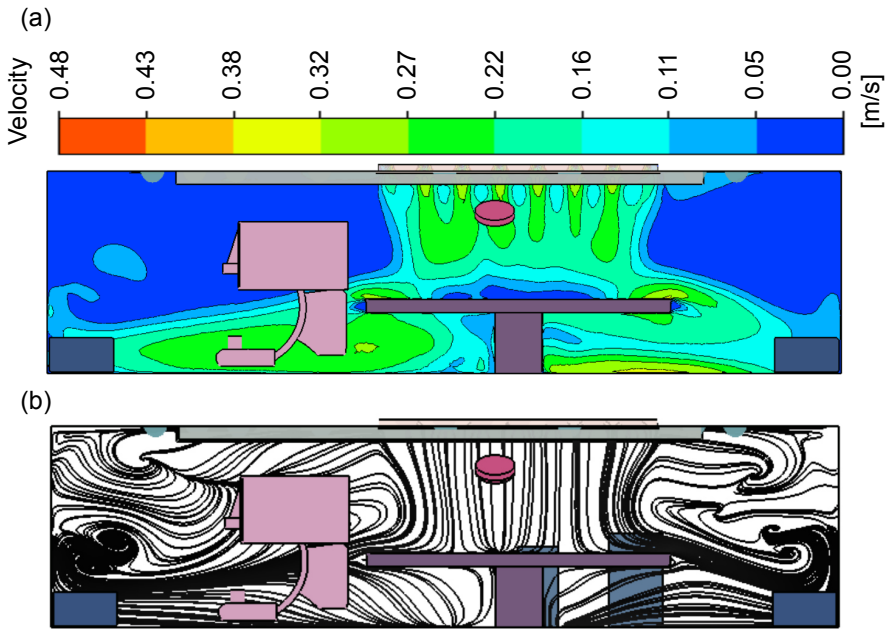


FIG. 2.7 The airflow pattern in Plane A-A: a) velocity contour plot, b) streamline distribution.

The internal 'laminar' air supply within the OR interacts with the operating table, causing a shift in the airflow stream from a vertical orientation to a horizontal one, which then spreads along the long side of the table. The high momentum of the incoming airflow, combined with the operating table's substantial length-to-width ratio, ensures that the outflow maintains its horizontal trajectory upon departing the long plate. Upon reaching the side walls, the airflow deflects, curling back to create nearby circulation. This specific airflow pattern establishes a barrier, inhibiting vertical air and contaminant mixing on both sides of the operating table along the X-axis. Given the placement of exhaust vents at floor level, contaminants released above this airflow barrier—particularly in cases E3 and E6—experience delayed removal from the OR. Case E3 is further exacerbated by the constrained space on the table's right side, which intensifies the airflow barrier effect. In the Y-axis direction, exemplified by case E2 (illustrated in Figure 2.8), the inflowing air navigates around the obstruction, reaching down to floor level. However, the transition from vertical to horizontal directionality is less pronounced due to the obstacle's relatively narrow width.



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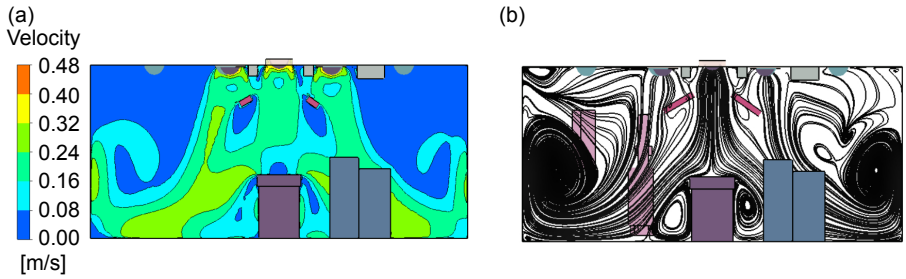


FIG. 2.8 The airflow pattern in Plane B-B: a) velocity distribution, b) streamline distribution.

In the space extending outward along the long edge of the OR table, marked by yellow boxes in Figure 2.6, there is ample room, ensuring that contaminant diffusion is not restricted. Consequently, this spatial arrangement does not significantly influence pollutant discharge. As for contaminant releases in the central zone, particularly cases C4 and C5, they exhibit notably low SVE1 values (0.49 and 0.61). They are located in the outer part of the UDAF 21 area. Analysis of Figure 2.8 reveals that this region benefits from a robust air supply and minimal streamline deformation. Owing to the minimal obstruction and prevailing unidirectional airflow, case C4 records the lowest SVE1 among the twelve-point source scenarios studied. The slightly higher SVE1 value for case C5, compared to case C4, is attributed to its greater distance from the exhaust vents.

For other central zone locations (CM – C2), under-table flow circulation tends to accumulate tracer particles, resulting in elevated spatial average contaminant concentration (SVE1) levels. This comprehensive assessment of SVE1 underscores the variability in contaminant removal efficiency across different locations, illustrating a clear correlation between SVE1 values and proximity to exhaust outlets. Contaminants originating from the OR's outer regions, closer to the outlets, typically undergo a quicker removal process, leading to lower room-average pollutant concentrations. In the case of central area releases, the forceful momentum of airflow flushing mitigates the disadvantages of distance from exhaust outlets, achieving low spatial average concentration levels. However, this dynamic is susceptible to disruption by obstacles. Specifically, the operating table obstructs internal downward air jets, redirecting high-speed airflow laterally. This air barrier hampers vertical mixing, rendering the upper periphery of the OR less effective in contaminant removal.



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### 2.3.2.2 G and SVE2: Spatial extent of contaminant dispersion

Building upon the simulations described in section 2.3.2.1, the characterization of passive contaminant dispersion, is quantified through two distinct indices: G and SVE2. The method of quantification draws an analogy with the concept of a probability density function, where G signifies the mean of the distribution, and SVE2 denotes its variance.

Figure 2.9 presents an isosurface visualization that captures varying levels of contaminant concentration. Originating from the point of release, contaminant concentrations exhibit a gradual decline. Influenced by both convection and diffusion, the contaminants disperse in all directions, displaying varying intensities, which culminate in the formation of these three-dimensional irregular isosurfaces.

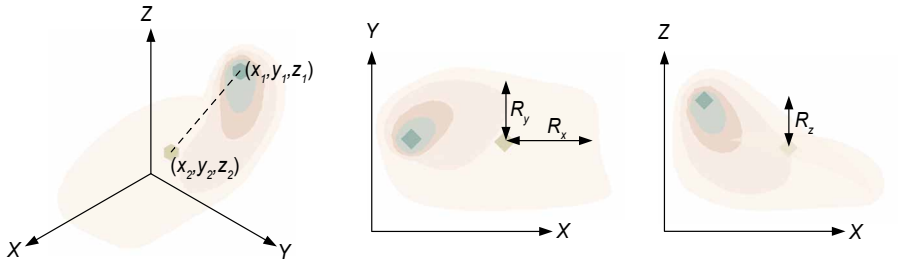


FIG. 2.9 The dynamics of contaminant dispersion within a three-dimensional space, a) 3D diagram, release point $(x_1,y_1,z_1)$ and center gravity G $(x_2,y_2,z_2)$, b) the projection in xy plane, $R_x$: the component of mean dispersion radius in the x direction, $R_y$: the radius component in the y direction, c) the projection in xz plane, $R_z$: the radius component in the z direction.

Considering the space enclosed by isosurfaces as representing an inhomogeneous substance, the center of gravity G functions as the mass centroid, pinpointing the primary concentration of mass, while the release point denotes the area of highest density. With G established as the reference point, the 3D spatial spread of contaminants is characterized by a key dimension, SVE2, representing the mean dispersion radius

$$\sqrt{(R_x^{\ 2} + R_y^{\ 2} + R_z^{\ 2})}$$



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Figure 2.10 illustrates the deviation between the concentration centroid and the contaminant source across 12 simulation scenarios. A comparison between cases of internal releases and those originating from the external periphery reveals that internal cases exhibit significantly larger deviation distances. The dynamic fluid motion induced by UDAF21 facilitates a robust flushing effect, swiftly moving contaminants away from the central critical zone (the source location). Assisted by exhaust outlets, pollutants are efficiently directed and subsequently evacuated from the OR. The directionality of the arrows in the xy plane elucidates the primary path through which contaminants are expelled, indicating the prevailing trend of dispersion. The vertical deviation direction further underscores distinct dynamics between external and internal release scenarios. Central releases predominantly exhibit a downward trajectory, whereas the dispersion of peripheral contaminants is shaped by their proximity to exhaust outlets and the prevailing local airflow patterns. When examining individual release points, nuanced differences become apparent. For instance, C3, due to its intermediary position, does not exhibit enhanced contaminant transport compared to other internal points. Influenced by surgical lamps, case C2 shows a reduced vertical deviation relative to the adjacent C3 case. As for case E3, contaminants tend to accumulate above the release point. The air barrier effect—resulting from a potent central air supply and the extensive operating table—overriding the pressure gradient from inlets to outlets, thus manifesting an atypical upward vertical deviation.

The spatial extent of contaminant dispersion, quantified by SVE2 for the 12 individual point injection cases, is detailed in Table 2.5. It is noted that a proximity to exhaust outlets is associated with a reduced dispersion radius, underscoring the role of the migration process—from source to exit—in contaminant removal. Central zone cases CM, C1, C2, and C5 exhibit enlarged dispersion distances due to their considerable separation from exhaust outlets. Periphery cases E2 and E6, situated between exhaust outlets, demonstrate extensive spread in both horizontal and vertical directions, reflected in larger SVE2 values. As for cases C3, C4, and E3, the constrained space on the right side dispersion, resulting in a more compact spatial extent. These findings affirm the pivotal influence of physical location on SVE2. However, the effect of local airflow patterns, shaped by the ventilation system, on dispersion dynamics remains indistinct.

In this section, we explore 12 contaminant fields within the standard operation of the TcAF system. Each scenario involves generating contaminants from a single, precisely identified point. The objective is to illuminate the characteristics of local contaminant removal and dispersion through these representative cases. Thus, the analysis of distinct contaminant fields encompasses two dimensions: spatial average concentration level and range of spatial spread.

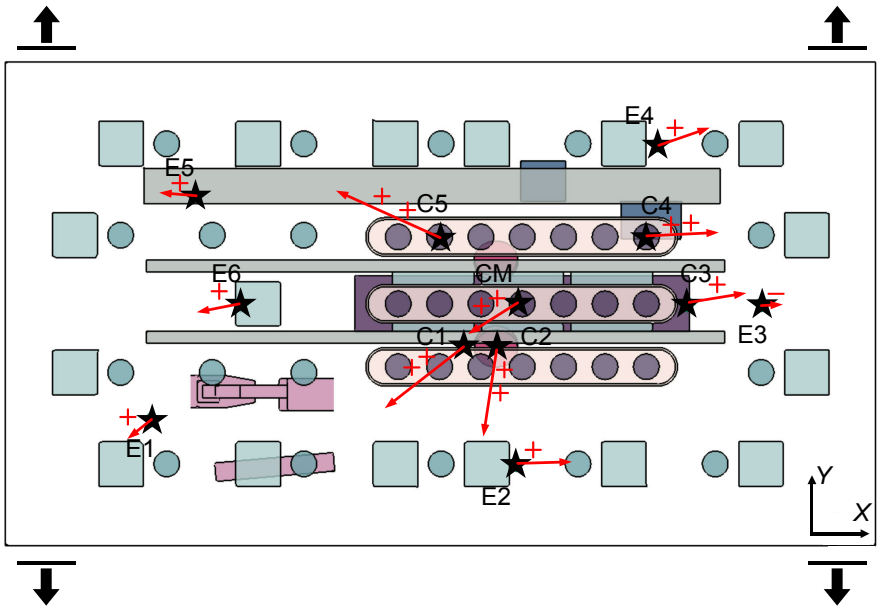


FIG. 2.10 The deviation between each release point and the corresponding center of gravity G. The length of each arrow signifies the distance between these two points, while the arrow's direction indicates the orientation of dispersion in the xy plane. The symbols '+' or '-' denote the degree of deviation in the z-direction, offering insights into the vertical spread of contaminants.

TABLE 2.5 The VE2 values for the 12 cases, measured in meters.

| Group | Location | | | | | | Avg. |
|---|---|---|---|---|---|---|---|
| **Periphery** | E1 | E2 | E3 | E4 | E5 | E6 | 1.56 |
| | 1.24 | 1.85 | 1.58 | 1.26 | 1.56 | 1.87 | |
| **Central zone** | CM | C1 | C2 | C3 | C4 | C5 | 2.33 |
| | 3.26 | 2.66 | 2.59 | 1.50 | 1.55 | 2.39 | |

The SVE1 index, indicating the mean contaminant concentration within the room, serves as a direct measure of local contaminant removal capability [17,42]. A lower SVE1 value, given a consistent contaminant generation rate, signifies enhanced pollutant removal from the environment. Conversely, G and SVE2 indices quantify the extent of contaminant displacement and distribution within the room, respectively, shedding light on dispersion characteristics across different locations [7,13,17]. A significant deviation between G and the contaminant source indicates rapid pollutant migration, whereas a minimal SVE2 value represents the pollutants are exhausted with limited diffusion.



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The evaluation of SVE1 demonstrates that contaminants released near exhaust outlets or beneath unobstructed internal air supplies are efficiently removed. Furthermore, the extraction effect of outlets is found to be more effective and consistent than the flushing impact of internal inlets. Air extraction via outlets has been validated as a potent mechanism for contaminant removal, with proximity to exhaust ports playing a crucial role in ensuring optimal efficiency [43,44]. As the distance from exhausts extends, extraction efficacy wanes, and the role of intricate local air patterns becomes predominant. Unidirectional air jets, a strategy commonly employed in controlled environments such as clean rooms, intensive care units, and ORs, are recognized for their washing/sweeping effect [45,46]. Within an OR utilizing the TcAF system, the internal high-momentum air supply is instrumental in maintaining air cleanliness, especially around UDAF 21. However, obstructions from subjects and thermal plumes significantly impact the performance of unidirectional downward airflow [47-50]. Ideal parallel streamlines are disrupted by obstacles, leading to unexpected mixing and inconsistent contaminant removal within the internal air supply zone. Achieving comparable SVE1 levels to scenarios near exhausts requires central locations to be enveloped in sufficiently filtered air, free from nearby obstructions—a challenging criterion during surgical operations.

Based on the analysis from SVE1, the superiority of contaminant control performance in the central zone compared to the periphery is not clear. This finding is inconsistent with previous literature [10,11], all of which have confirmed lower pollutant levels in the central zone. The reason for this discrepancy is that SVE1 is based on overall room averages, sacrificing some of the spatially uneven characteristics. It is possible that when pollutants are released from the center of the room and escape into the surrounding areas, they are not effectively removed, resulting in higher boundary concentrations and consequently increasing the overall pollutant concentration levels in the room. In pursuit of creating an ultra-clean environment throughout ORs, SVE1 remains an appropriate parameter, but it is not suitable for quantifying the performance of local areas.

During the spatial extent analysis, the authors discovered that the deviation between G (the center of gravity for contaminant distribution) and the release point offers more insight into airflow patterns and contaminant dispersions than does SVE2. The magnitude of this deviation illustrates the contaminant transport characteristics—whether they are predominantly convective or diffusive—while the direction of deviation indicates whether contaminant removal is facilitated or hindered. In the internal section of the OR, characterized by strong forced convection, substantial deviations with a pronounced downward direction were observed, indicating that contaminants are effectively swept away by the internal airflow. Conversely, in periphery cases, deviations were smaller and exhibited less vertical orientation, reflecting a less active contaminant transmission due to mixed air movements.

The disparity in contaminant dispersion characteristics between the internal and external sections of the OR is pronounced. Regarding SVE2, which is closely linked to the physical location of the contaminant release point, it was found that ample space around the release point results in larger SVE2 values. Contaminants released in central areas, equidistant from outlets, tend to disperse in all directions, whereas those released in corners primarily spread in one direction in a more confined manner. However, the distinct deviation distances from the release point can obscure local contaminant spread features. The reliability of SVE2 as a metric for assessing contaminant distribution has been critiqued by Essa et al. [51] , who noted that each SVE2 value is normalized by individual concentration integral values ($C_0$ in Eq. (2.10)), leading to varied spatial extent scale criteria across different cases. Relying solely on SVE2 for case comparison may yield misleading interpretations.

### 2.3.3 Age of the air

The concept of "age of the air" or Air Change Effectiveness (ACE) is frequently utilized during the design phase, particularly when the specifics of contaminant release and room usage remain undetermined [33]. Unlike SVE1, G, and SVE2, which serve as quantitative indices for specific cases, the age of the air or ACE offers a more instructive and generalizable perspective [52]. To investigate the correlation with the indices discussed in Section 2.3.2, the ACE values for 12 distinct contaminant release locations are presented in Table 2.6.

TABLE 2.6 Air Change Effectiveness (ACE) values at 12 locations with Standard Ventilation Rate.

| Group | Location | | | | | |
|---|---|---|---|---|---|---|
| **Periphery** | E1 | E2 | E3 | E4 | E5 | E6 |
| | 1.94 | 1.31 | 0.98 | 1.40 | 2.18 | 1.57 |
| **Central zone** | CM | C1 | C2 | C3 | C4 | C5 |
| | 9.01 | 8.76 | 5.93 | 1.08 | 3.57 | 8.10 |

The analysis reveals a spatial correlation between Air Change Effectiveness (ACE) and spatial average contaminant concentration (SVE1). Specifically, locations exhibiting lower ACE levels tend to have higher SVE1 values, exemplified by E3 in the periphery and C3 in the central zone. Similar to the findings from the analysis of the center of gravity (G) and mean dispersion radius (SVE2), the ACE assessment underscores a notable distinction between the internal and external air supply sections. This difference is particularly stark in ACE measurements, with the central zone demonstrating



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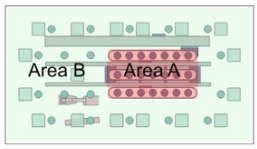
significant advantages over the periphery zone. However, there isn't a straightforward correlation among ACE, SVE1, G, and SVE2 values. Regions characterized by suboptimal airflow patterns are readily identifiable by their ACE values, which typically correlate with elevated room-averaged contaminant concentrations and inefficient dispersion. Nonetheless, high ACE levels do not inherently ensure effective contaminant control, especially in the presence of sources. While the assessment of ACE distribution aids in design optimization, it also presents notable limitations [33,52].

Thus, the air age theory or the ACE index is utilized in this subsection for a preliminary examination of how deviations from standard air supply configurations affect the potential for contaminant control throughout the OR. This evaluation includes comparing the volume-averaged ACE across different regions of the OR under varying ventilation rates. Additionally, the local air age patterns at a critical juncture, plane A–A, are visualized to highlight the distinctions among cases. Table 2.7 outlines the ventilation parameters across five simulation scenarios, including a breakdown of the regional divisions. The initial three cases feature total ventilation rates set at standard, modest, and low levels, respectively, maintaining a 1:1 fresh air volume ratio for areas A and B. The final two scenarios operate with a modest ventilation volume but with imbalanced air supply ratios between the central and periphery zones.

TABLE 2.7 Ventilation parameters of five simulation scenarios

| Case No. | Total airflow [$m^3/h$] | Ratio of area A, B | Airflow of each airshower [$m^3/h$] | Nominal age of the air [s] | Avg. ACE of area A | Avg. ACE of area B | Avg. ACE of area AB | Volume with ACE>1 [$m^3$] |
|---|---|---|---|---|---|---|---|---|
| **Case 1** | 12600 | 1:1 | 300/350 | 64 | 3.69 | 1.16 | 1.27 | 183.22 |
| **Case 2** | 9450 | 1:1 | 225/262.5 | 85 | 3.15 | 1.07 | 1.17 | 177.57 |
| **Case 3** | 6300 | 1:1 | 150/175 | 127 | 2.38 | 1.00 | 1.09 | 173.69 |
| **Case 4** | 9450 | 2:1 | 300/175 | 85 | 3.30 | 0.89 | 0.98 | 161.80 |
| **Case 5** | 9450 | 1:2 | 150/350 | 85 | 2.86 | 1.23 | 1.32 | 190.31 |




The top view delineates the boundaries of areas A and B. Area A corresponds to the central region, defined as the room volume beneath the internal air supply section. Conversely, Area B designates the perimeter region, representing the room volume beneath the external air supply section. Area AB encompasses both Area A and Area B, collectively representing the entirety of the OR.



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The analysis reveals that preferential air supply from the internal section facilitates fresh air replacement at a rate 2-3 times faster than what is observed in a perfectly mixed scenario (ACE=1), highlighting the efficiency of unidirectional airflow with minimal mixing or diffusion. An ACE value of approximately 1 in area B signifies the presence of mixed flow in the periphery. Given that the peripheral region encompasses most of the OR's volume, the trend of the average ACE in area AB aligns closely with that observed in area B, indicating that the room volume with an ACE greater than 1 correlates with the peripheral ACE level. Consequently, a higher ACE value in the periphery indicates a larger volume that is effectively ventilated.

Figure 2.11.a demonstrates the air change performance in the central area is highly responsive to variations in the total ventilation rate, whereas the periphery zone's performance remains largely stable despite reductions in ventilation volume. The presence of strong downward airflow in the central area underpins its superior ventilation performance. Incremental enhancements in external airflow supply, as depicted in Figure 2.11.b, may slightly increase the volume with an ACE greater than 1. However, such adjustments are unlikely to alter the fundamentally mixed airflow characteristics of this region, with the average ACE remaining approximately 1.

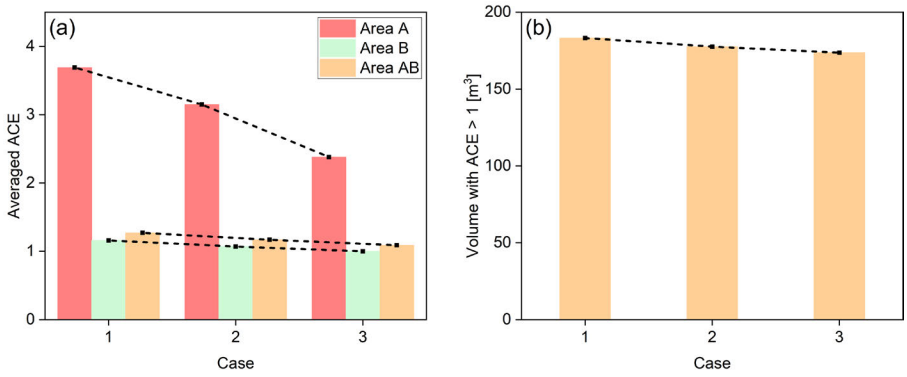


FIG. 2.11 The variation of two ventilation indices with the reduction of total ventilation rates: a). The volume-averaged ACE of three regions under different ventilation rates, b). The room volume with ACE>1 in the OR under different ventilation rates.

Case 4 aims to sustain the strong downward airflow in the central zone while reducing the peripheral airflow rate to half its original value. Despite maintaining the same total ventilation volume as case 2, the overall Air Change Effectiveness (ACE) level sees a 16% reduction. This decrease in ACE, attributed to inadequate air change in the periphery, is vividly illustrated in Figure 2.12.d.



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With the initial momentum flux diminished, the airflow from decentralized peripheral diffusers becomes further weakened and increasingly prone to obstruction. This results in insufficient ventilation in the external section and disruption of the internal air barrier, fostering a large stale air zone in the upper periphery of the OR. Consequently, contaminants are likely to accumulate around the operating table, posing a risk of encroaching into the central critical zone. Adjustments to air supply rates in case 4 exacerbate the imbalance between the two sections, thwarting efforts to establish an ultra-clean environment throughout the OR.

In contrast, case 5 presents a reversed scenario in which the internal airflow rate is halved, while the external ventilation rate remains at 350 $m^3/h$. As anticipated, the average ACE in area A decreases due to the reduced internal air supply. Nonetheless, the periphery zone achieves the highest ACE level under a modest total ventilation volume. Figure 2.12.e depicts the air-age field for case 5, showing that the increased airflow rate in the periphery significantly expands the area with a modest air age. Most air around the operating table can be replaced with fresh air within 50 seconds, indicating a quicker response to potential passive pollutants compared to case 2. Notably, the air barrier effect along the operating table is less pronounced in case 5, resulting in a weaker hindrance to contaminant mixing in the periphery zone. The contour lines exhibit a smooth spreading pattern without the marked bumps and depressions seen in cases 1-3. Areas of inefficient ventilation are confined to near the room walls, distant from air terminal devices.

A comparative analysis of the five cases consistently demonstrates that the center area of the operating room (OR) maintains a lower age of the air compared to the periphery zone. This pattern arises due to the centralized placement of internal diffusers, contrasted with the decentralized installation of external air terminals. Notably, this characteristic of airflow persists even in the face of inadequate or imbalanced air supply rates. The ventilation efficacy in the central zone is predominantly influenced by the absolute volume of air supplied. In contrast, the efficiency of ventilation in the periphery zone hinges on maintaining an optimal ratio of air supply between the internal and external sections, that is, the relative volume of air provided.

The dynamic of high-momentum airflow encountering various obstructions within the OR's critical zone leads to its redirection towards the periphery, thereby disrupting the initially low-speed mixing flow typical of this region. Strategies that increase the proportion of air supply directed to the external section have been recognized as beneficial, serving to diminish the air barrier effect and enhance the overall ventilation performance of the OR.

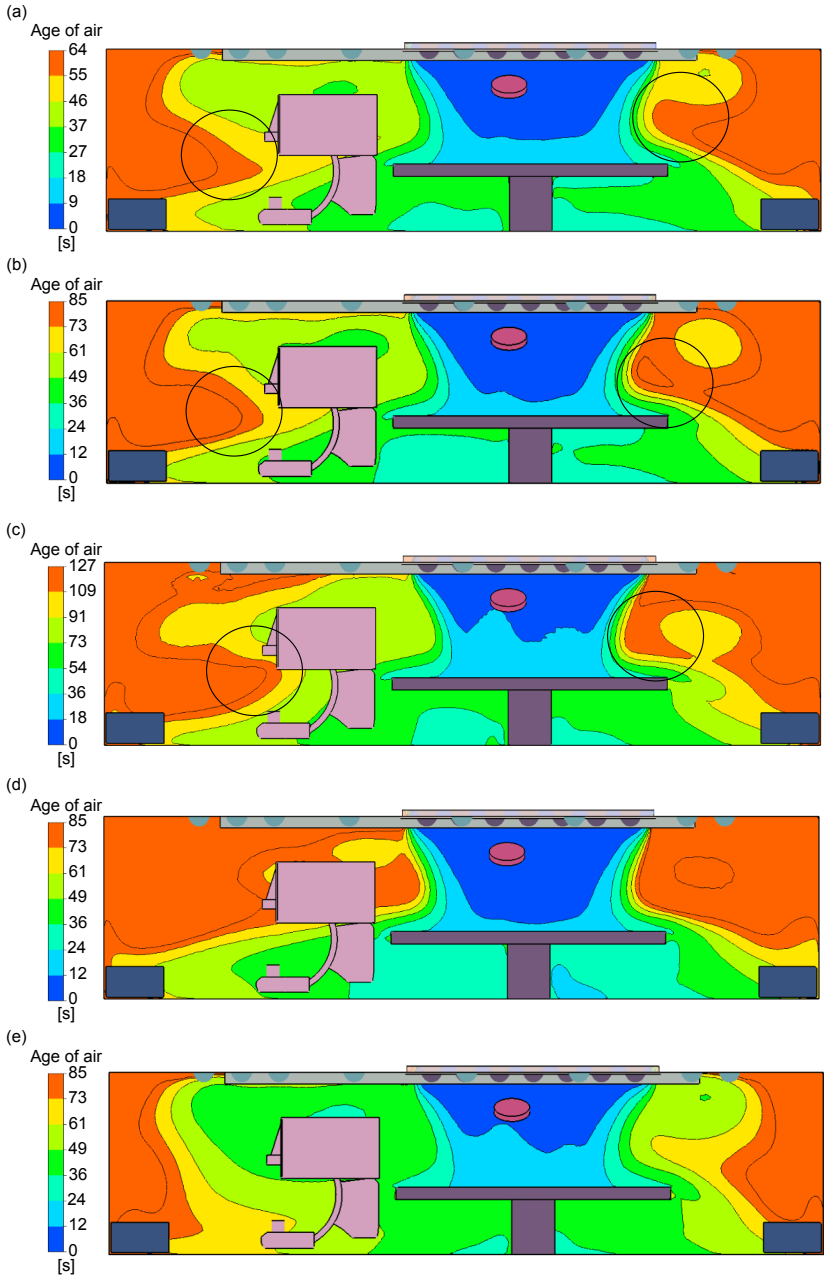


FIG. 2.12 The distribution of the local age of the air across the plane at y=3.25 m for cases 1 through 5. The legend for this figure is calibrated to range from 0 to an upper limit, with the specific range denoted as (0, ). Areas highlighted in orange on the graph represent regions where the Air Change Effectiveness (ACE) value is less than 1, indicating zones of relatively lower air change efficiency.



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## 2.4 Conclusion

This study presents a pioneering investigation into the contaminant control performance of a novel hybrid ventilation scheme, the temperature-controlled airflow (TcAF) systems, through both experimental and numerical analyses. It elucidates the contaminant removal capabilities and the characteristics of spatial spread across different locations under the TcAF system, as well as detailing the air exchange performance under conditions of insufficient and imbalanced air supply. The key findings and recommendations are summarized as follows:

1. Effective management of point contaminant sources in ORs ventilated by the TcAF system necessitates leveraging the exhaust ports' extraction effect and the internal air showers' flushing effect. In the periphery zone, where air mixing prevails, proximity to outlets correlates with lower contaminant concentrations and reduced dispersion ranges. Positioning contaminant sources near exhaust ports is more advisable. In the central zone, where high-momentum air is introduced, avoiding obstacles is crucial for optimal contaminant control, and implementing localized exhaust can be effective.
2. The standard airflow configuration ensures a near-piston flow above the operating table and a mixing flow in the periphery zone. Optimal ventilation in the critical zone is achieved by supplying an adequate volume of fresh air, while the performance in the periphery zone depends on a balanced ratio between internal and external air supplies. Insufficient air supply, particularly when fresh air is concentrated in the central area, compromises contaminant control in the periphery. Conversely, ensuring an adequate airflow rate for external air showers can expand the ultra-clean area and mitigate the disruption caused by internal airflow on external low-speed air mixing. Additionally, adjusting the air supply configuration, such as centralizing the air shower in the periphery zone, can be considered as a strategy to overcome the disruptions.
3. SVE1 and G are suitable for evaluating contaminant removal and spread under specific point source scenarios. SVE2, significantly affected by physical location and the deviation between G and the release point, renders spatial extent characterization less clear. Relying solely on SVE2 and aiming for the smallest possible value without considering the employed ventilation scheme is impractical.
4. The ACE index can effectively quantify airflow patterns, independent of contaminant nature, making it valuable for identifying potential contamination zones and optimizing ventilation design. However, ACE analysis tends to overemphasize the superiority of the internal air supply in contaminant control.

In terms of future works, the authors will continue with a quantitative assessment of ventilation performance regarding the contaminant control aspect. More factors will be included such as obstacles, contaminant types, etc. For obstacles that are relatively fixed in position, our focus will be on optimizing the configuration of inlets and outlets to overcome potential airflow distortion. For obstacles that are mobile, such as healthcare personnel, our prospect is to reproduce the airflow and contaminant dispersion under the influence of moving objects, quantify the intensity and extent of contamination and propose corresponding optimization strategies. As for contaminant types, the authors intend to investigate how human skin shedding and surgical smoke disperse under the TcAF system. By addressing this aspect in future studies, we hope to advance our understanding and contribute to the improvement of airflow control mechanisms in indoor environments.

## Acknowledgment

This study was supported by the Swedish Research Council - Formas (Grant No. 2021-01422) and the China Scholarship Council (CSC) (No. 202108310037). Computational support was facilitated by the Swedish National Infrastructure for Computing (SNIC) at PDC Center for High-Performance Computing, KTH Royal Institute of Technology, under the auspices of the Swedish Research Council (Grant No. 2018-05973). The authors would also like to thank the staff of Rijnstate hospital Arnhem, the Netherlands, for making the operating rooms available for the measurements.

## Conflict of interest statement

J.L.A. Lans is CEO of Medexs BV, a company that supplies and install OR ventilation systems. All other authors report no conflict of interest relevant to this article.

## Funding statement

This study supported by the Swedish Research Council - Formas (Grant No. 2021-01422) and the China Scholarship Council (CSC) (No. 202108310037). Computational support was facilitated by the Swedish National Infrastructure for Computing (SNIC) at PDC Center for High-Performance Computing, KTH Royal Institute of Technology, under the auspices of the Swedish Research Council (Grant No. 2018-05973).

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# Part A


Hospital Rijnstate

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# 3 Operating room ventilation systems

## Recovery degree, cleanliness recovery rate and air change effectiveness in an ultra-clean area

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PUBLISHED **Journal of Hospital Infection** | DOI: 10.1016/j.jhin.2021.12.018

KEYWORDS Cleanliness Recovery Rate, Air Change Effectiveness, Recovery Degree, Operating Room, Ventilation Effectiveness, Ultra-Clean Ventilation systems

ABSTRACT **Background –** Entrainment test methods are described in most European standards and guidelines to determine the protected area for Ultra-Clean Ventilation (UCV) systems. New UCV systems, such as temperature-controlled airflow (TcAF) and controlled-dilution ventilation (cDV) claim the whole Operating Room (OR) to be ultra-clean. Current test standards are not developed for assessing ventilation effectiveness outside the standard protected area.
**Aim –** To assess and compare the ventilation effectiveness of four types of OR ventilation systems in the ultra-clean area by using a uniform test grid.
**Methods –** In this study the ventilation effectiveness (VE) of four ventilation systems is evaluated for three different ultra-clean (protected) areas;

standard protected area (A), area outside standard protected area (B) and large protected area (AB). The VE is defined as the recovery degree (RD), cleanliness recovery rate (CRR) and air change effectiveness (ACE).
**Findings –** RD, CRR and ACE were significantly higher for the Uni Directional AirFlow (UDAF) system when compared to the other systems in area A. In area B, UDAF and cDV were comparable regarding RD and CRR and UDAF and Conventional Ventilation (CV) were comparable regarding ACE. In area AB the UDAF and cDV were comparable regarding CRR and ACE but are significantly different in RD.
**Conclusion –** In area A the ventilation effectiveness of the UDAF ventilation system is outperforming other ventilation systems. In area B, cDV is performing the best followed by UDAF, TcAF and CV. In area AB, UDAF is performing the best followed by cDV, TcAF and CV.

## 3.1 Introduction

Contaminated air in operating rooms (ORs) is considered a risk factor for surgical site infection (SSI) due to the possibility that airborne bacteria from the OR, the surgical staff, medical devices or from patients themselves can infect the wound [1,2]. SSI is a public health problem with a major impact on the healthcare system and community cost [3–6]. Furthermore, SSI has great impact on patient well-being due to increased hospital stay, possible morbidity or even mortality [6]. Ventilation systems are widely used in the OR to prevent SSI, next to other measures as regular cleaning, disinfecting the operated body parts and hand disinfecting by washing and the topic application of disinfectants.

The aim of OR ventilation systems is to create a comfortable and save environment for the patient and surgical staff, to lower the concentration of anesthetic gasses and odors and above all to reduce the airborne bacteria burden in the ultra-clean area [7–9]. The wound area, the area surrounding the surgical staff and instrument tables are defined as ultra-clean areas.

An OR ventilation system maintains the constant air quality by introducing high-efficiency particulate filtered air (HEPA) [10] into the OR. Traditionally ORs with conventional mixing ventilation (CV) systems are used for generic procedures. Ultra-Clean Ventilation systems (UCV) are used for infection-prone surgeries [11–15]. CV systems are mixing the supply air evenly in the entire OR diluting the concentration of harmful substances. UCV systems are supplying the air via a

Uni-Directional Air Flow (UDAF) into the protected area and displace the air present. The protected area or “clean zone” [14] is intended for positioning the patient wound, sterile staff, and instrument tables.

New ventilation systems such as temperature-controlled air flow (TcAF) and controlled Dilution Ventilation (cDV) systems are introduced in the market for ultra-clean ORs, to provide a system suitable for all types of surgery (class 1a, 1b) [11–15] and to allow more freedom of space to position the patient, surgical staff and instrument tables because the whole OR is claimed to be ultra-clean during surgery [16,17].

The WHO is not recommending any specific type of ventilation system, they only advise to ensure a proper ventilation rate in the OR [18]. The studies included for this WHO guideline have been criticized in various articles, with the result that the advice is also under discussion [2,19,20]. European standards and guidelines [11–14] have been defined to assess the performance of the UDAF or CV ventilation systems in an ‘at rest’ situation [21]. For the UDAF these standards differ in the method of assessing the ventilation systems but have in common that they focus on the performance by means of defining an ultra-clean protected area. The mixing systems (CV systems) are assessed on recovery times or particle concentrations and are, according to the standards and guidelines, not intended to be used for infection-prone clean surgeries.

However, at this moment test methods of current standards and guidelines [11–14] are not primarily developed for assessing newly developed ventilation systems which focus on larger ultra-clean areas, or which claim the whole OR to be ultra-clean [16,17]. Therefore, the goal of this study was to assess and compare the ventilation effectiveness of four types of OR ventilation systems by using a uniform test grid that covers a larger intended ultra-clean area. This means that the four systems in the ultra-clean areas were being tested and evaluated in exactly the same way. The ventilation effectiveness of the systems was assessed and compared in three ultra-clean areas by means of the Recovery Degree (RD), Cleanliness Recovery Rate (CRR) and Air Change Effectiveness (ACE).

## 3.2 Methods

This study was performed in the operating rooms of four fully functioning OR departments in four hospitals in the Netherlands.

For this study ORs are selected which were newly built, handed over in 2020 and currently fully functional. All the selected ORs had comparable room sizes and heights. One exception is the conventional ventilation system, this system was > 20 years old. This CV system is added to this study to compare the ventilation effectiveness of an old generic OR equipped with a CV system with the ventilation effectiveness of the newly built UCV systems.

TABLE 3.1 Characteristics of the examined ORs and OR ventilation systems.

| Ventilation System | Number of different ORs | Filter class EN 1822-1 | Air volume [$m^3/h$] | Air changes [per h] | Ceiling height [m] | Average Room dimensions [$m^2$] | Volume OR [$m^3$] | Position extraction | System description |
|---|---|---|---|---|---|---|---|---|---|
| **Conventional (CV)** | 5 | H13 | 3,220 -3,344 | 24-26 | 2.90 | 43-45 | 125-135 | Low & high | 3.0 x 2.4 m Perforated plate inlets |
| **Controlled Dilution Ventilation (cDV)** | 6 | H14 | 9,800 | 69 | 3.05 | 47 | 143 | Low & High 4 corners | 3.6 x 3.6 m – 20 air inlets with adjustable nozzles |
| **Temperature Controlled Airflow (TcAF)** | 5 | H14 | 6,848 -7,180 | 45-53 | 3.00 | 50 | 135-150 | Only Low 4 corners | Ø 2 m plenum box with 8x half-spherically shaped air diffusors in the center and 12x in the periphery |
| **Uni Directional Flow (UDAF)** | 6 | H14 | 10,032 -10,379 | 66-73 | 2.90 | 49-52 | 141-151 | Low & high 4 corners | Plenum 3.1 x 3.1 m |



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Before measurements were performed, a technical inspection of the ventilation performance was carried out to ensure that the system functioned as intended. In Table 3.1 the characteristics of the ORs and ventilation systems are indicated.

## 3.2.1 Operating Room ventilation systems

The four different ventilation systems are categorized as unidirectional and non-unidirectional airflow operating rooms according to the ISO 14644-3 [22]. To understand the ventilation effectiveness and air distribution of the compared OR ventilation systems technical dissimilarities and working principles are explained.

### Conventional Ventilation (CV)

A CV system (Figure 3.1b) is a mixed–airflow system. The CV system is introducing the HEPA filtered air into the OR through a perforated plate system installed above the ultra-clean area (Figure 3.1a).

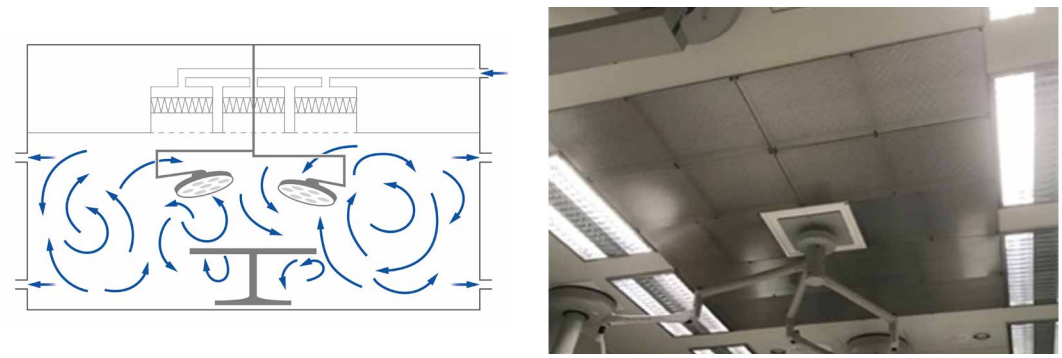


FIG. 3.1 Working principle (a) and photo CV (b)

### Temperature Controlled Airflow Systems (TcAF)

A TcAF system (Figure 3.2.b) combines a mixed-airflow system in the periphery with a controlled unidirectional airflow (UDAF) directly above the OR table. A TcAF system is defined as a temperature-controlled ventilation system were cooler HEPA-filtered air is supplied above the OR table and warmer air with air diffusors is released in the periphery. The introduced air above the OR table flows downwards out of a circular UDAF (Ø 2.0 meter) with 8 air diffusors. A mixed-airflow is created in the periphery (Figure 3.2.b).

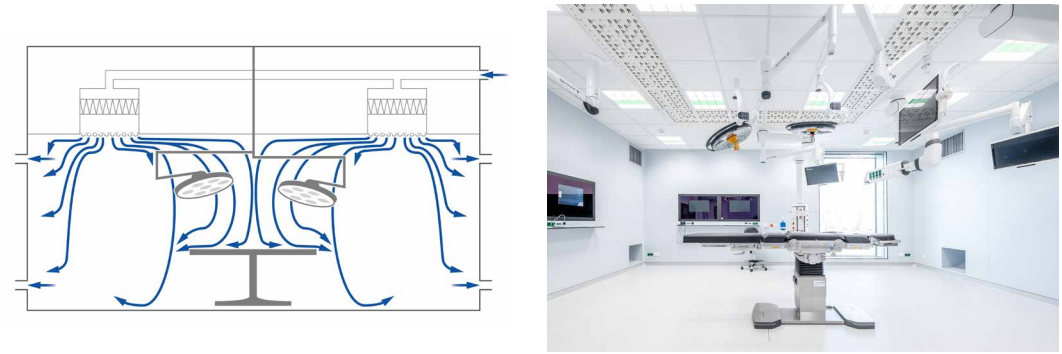


FIG. 3.2 Working principle (a) and photo TcAF (b)

## Controlled Dilution Ventilation (cDV)

A controlled Diluting Ventilation system (Figure 3.3.b) is a diluting mixed-airflow system. Air is filtered inside the air inlet modules by HEPA filters and supplied into the OR through air nozzles located in the ventilation system. The supply airflow from the ventilation system is directed partly towards the ultra-clean area and partly towards the room periphery creating an optimal mixing of the supply air with the air present (Figure 3.3.a).

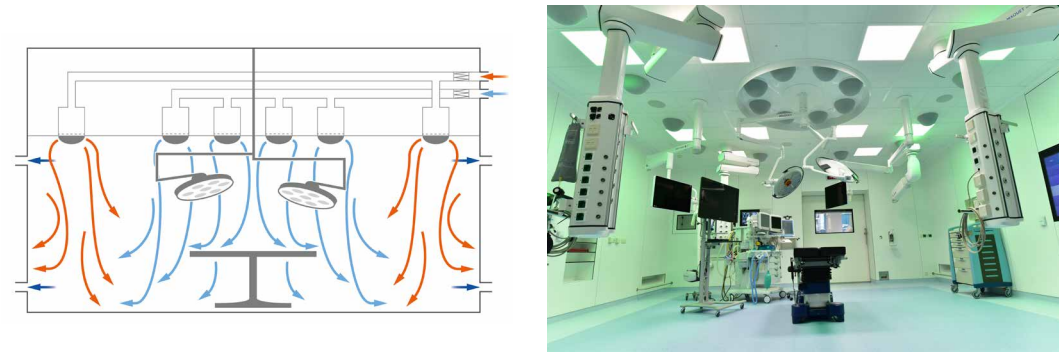


FIG. 3.3 Working principle (a) and Photo cDV (b)

## Unidirectional airflow systems (UDAF)

Unidirectional airflow (Figure 3.4.b) is defined as a controlled unidirectional airflow directly above the protected area displacing the air present. It creates a HEPA-filtered protected area with a steady velocity [23,24] and parallel UDAF airstreams (Figure 3.4.a) above the wound area, surgical staff and (partly) instrument tables.

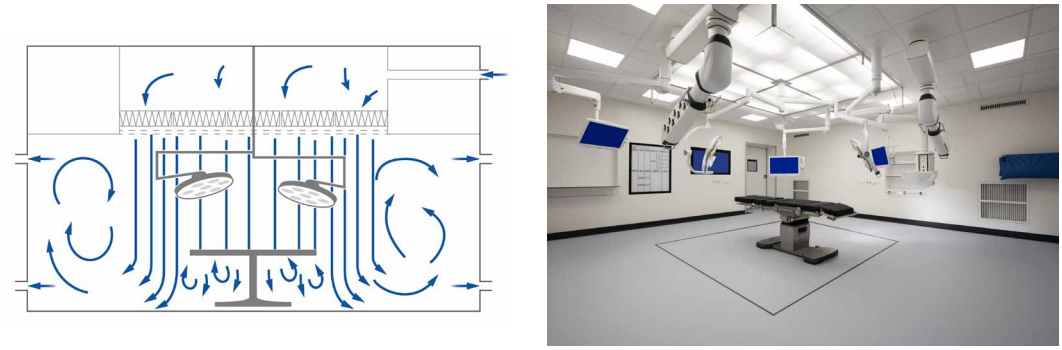
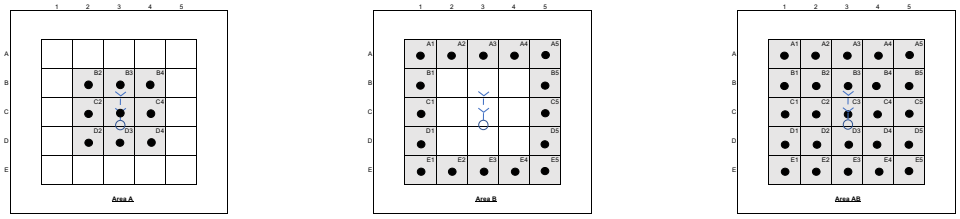


FIG. 3.4 Working principle UDAF (a) and photo UDAF (b)

### 3.2.2 Measurements

Within a 4x4 meter square measuring grid of 1x1 meter, three measuring areas were defined:

- Area A with 9 measuring points (Figure 3.5.a),
- Area B with 16 measuring points (Figure 3.5.b),
- Area AB with 25 measuring points (Figure 3.5.c).




3.5.a 3.5.b 3.5.c

FIG. 3.5 Measuring point, dots are the position of particle counters, Figure 3.5.a. Area A, 9 measuring points (B2-B3, C2-C3, D2-D4). Figure 3.5.b. Area B, 16 measuring points (A1-A5, B1 and B5, C1 and C5, D1 and D5, E1-E5). Figure 3.5.c. Area AB, 25 measuring points (A1-A5, B1-B5, C1-C5, D1-D5, E1-E5).

The used methodology is based on the recovery test described in ISO 14644-3; B.12 [22].



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Each measuring grid, with measuring points at a height of 1.20 meter above floor level, is situated with its center (point C3) in the middle of the operating room. Measuring points are at a distance of 1 meter from each other. Measurements are performed per row.

At each measuring row five Lighthouse 3016 handheld particle counters with a flow rate of 2.83 l/min (0.1 $ft^3$/min) were placed at the measuring points locations. The measurement cycle of each row is 10 minutes and the total duration of the measurements of the OR lasted approximately 1.5 hours. On each point the particle counter measured, with a measuring cycle of 1 minute for 10 minutes, the quantity of particles with a particle size of ≥ 0.5 µm.

During the measurements, medical equipment, respirators and operating lights (switched on) were positioned in operational position. The operating lights were positioned according to VCCN RL7 and DIN 1946-4 [12,13].

Before the measurements started, particles were emitted in the whole operating room with a calibrated Topas aerosol generator (model ATM 226, aerosol Emery 3004). The emitting stopped when all particle counters in the measuring row displays a background concentration between ≥ $10^7$ and $10^9$ particles per $m^3$ (≥ 0.5 µm). The exact route of the emitted particles cannot be indicated with this measurements. From the number of particles measured at each point, the Recovery Degree (RD), Cleanliness Recovery Rate (CRR) and the Air Change Effectiveness (ACE) were calculated.

#### 3.2.2.1 Recovery Degree (RD)

In this paper we introduce the term Recovery Degree (RD). The RD shows the ability of the ventilation system to eliminate or reduce the quantity of airborne particles, at the measuring locations, from the maximum concentration after emitting. The RD is defined as the logarithm of the quotient (ratio) of the number of particles ≥ 0.5 µm per $m^3$. In this study the RD is measured every minute during 10 minutes and therefore $RD_{10}$ is used in this study. $RD_{10}$ is the recovery degree over a period of 10 minutes.

The RD is derived from the recovery test as described in the ISO 14644-3: B12 [22]. A RD of 2 means that the number of particles at the measuring locations is a factor 100 times ($^{10}\log 100 = 2$) lower than at the start of the measurement during the period of 10 minutes. To avoid disproportional outcomes, in relation to outcomes of other ventilation systems in this study, of the RD, the result was trimmed to a maximum of 6 ($^{10}\log 10^6$).



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The RD is calculated by equation 3.1.

$$RD_{tx} = -log \frac{C_{tx}}{C_{t0}} \quad (1)$$ EQ. 3.1

Where:
$RD_{tx}$ = *Recovery Degree after time tx,*
$C_{tx}$ = *Concentration of particles at location at time tx,*
$C_{t0}$ = *Initial concentration at start measurement* $t_0$*, directly after emitting.*

### 3.2.2.2 Cleanliness Recovery Rate (CRR)

The Cleanliness Recovery Rate (CRR), or decay rate, is closely related to the RD. The CRR is used as a method [25] to determine the local air change rate at the measuring locations. Local air change rate per minute is equal to the CRR. Calculation of the CRR, as given in ISO 14644-3, was carried out over the period of exponential decay. This period is ascertained by plotting the particle concentration over time [25] and defines the inclination angle of the particle decay. In this study the CRR is used to compare the air distribution in the OR of the different ventilation systems.

To avoid disproportional outcomes, in this study, of the CRR, the result was trimmed to a maximum of 6 meaning a local air change rate ≥ 360 $h^{-1}$.

The CRR (local air change rate) can be calculated by using equation 3.2:

$$CRR = -\frac{1}{t}\ln\left(\frac{C1}{C0}\right) = -2.3\,\frac{1}{t}log\frac{C_1}{C_0} \quad (2)$$ EQ. 3.2

Where:
*CRR is the cleanliness recovery rate,*
*t is the time in minutes, elapsed between the first and last measurement in the measurement interval,*
$C_0$ *is the concentration at the start of te exponential decay,*
$C_1$ *is the concentration at the end of the exponential decay.*



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### 3.2.2.3 Air change effectiveness (ACE)

The ventilation effectiveness is determined by the Air Change Effectiveness (ACE) [25–27].

This study compares the average CRR per system in the measured areas A, B and AB to the overall average air change rate. The overall average air change rate is the total air volume ($m^3/h$) introduced in the OR divided by the OR's volume ($m^3$). If introduced HEPA filtered air and room air volume are perfectly mixed, the ACE will have a value of 1 at all measuring points. If less introduced air reaches the measuring location than the OR volume average the ACE will be below 1. If more introduced air reaches the measuring points, the ACE index will be above 1. The aim of a UCV system is to have a higher ACE (> 1) in the ultra-clean area [25].

The ACE is calculated by equation 3.3.

$$ACE = \frac{local\ air\ change\ rate\ per\ minute\ (CRR)\ at\ measuring\ location\ x\ 60}{overall\ average\ air\ change\ rate\ (\frac{m3}{h})\ operating\ room} \qquad \text{EQ. 3.3}$$

Local air change rate per minute is the average cleanliness recovery rate per measuring location per system,

Overall average air change rate operating room is the total air volume introduced ($m^3/h$) / OR's volume ($m^3$).

### 3.2.2.4 Statistical analysis

To determine differences between the ventilation systems regarding CRR, ACE and $RD_{(10)}$, a Kruskal-Wallis test was performed, since a normal distribution could not be assumed. As post hoc analysis, a Mann Whitney U Test was performed, with Bonferroni correction.

IBM SPSS version 25 (IBM Corp. Armonk, NY: IBM Corp) was used. A *p*-value of 0.05 or less was considered statistically significant.

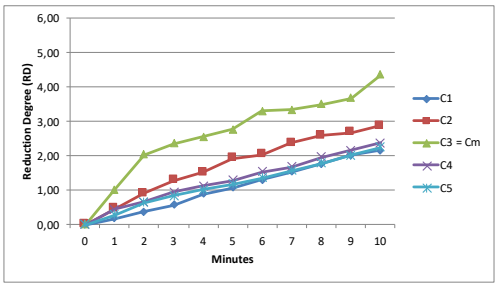
## 3.3 Results

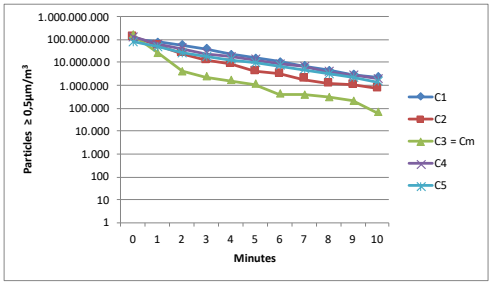
Airborne particle concentration and RD per minute for the four ventilation systems of the middle row (C1-C5, Figure 3.5.c) are shown in Figure 3.6.

The CV and cDV ventilation system showed a stable decay of airborne particles on each measuring point (figure 6a and 6b) over time. The decay of airborne particles over time on each measuring point of the cDV system is faster than the decay of airborne particles of the CV system. Contrary, the decay of airborne particles at point C3 (TcAF, Figure 3.6.c) and C2-C3-C4 (UDAF, Figure 3.6.d) is faster than the decay of the other points in the measuring row.

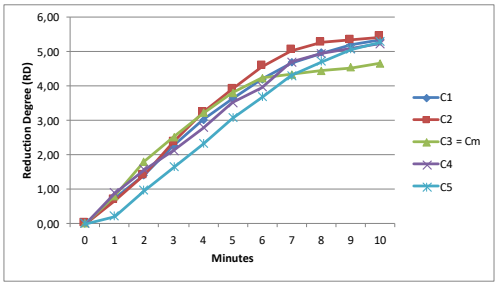
High RDs and a faster decay of airborn particles are seen when higher air volumes are introduced into the OR (Figure 3.6.b and 3.6.d). Introducing clean air in ultra-clean areas, via a plenum (Figure 3.6.c and 3.6.d) also realizes higher RDs in the center of the OR. The RD of an UDAF at measuring point C2-C3-C4 (Figure 3.6.d) and at point C3 (Figure 3.6.b) for a TcAF was 6.

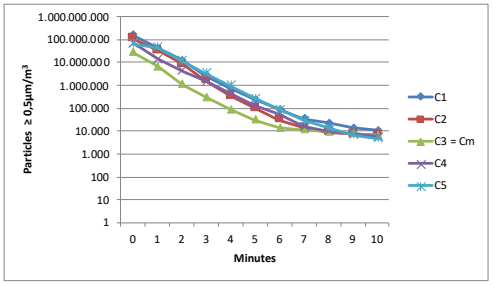
All other measuring points in the measuring row did not reach this level.



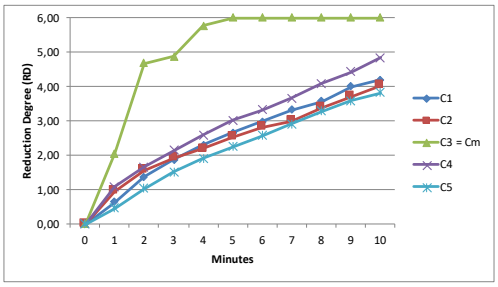



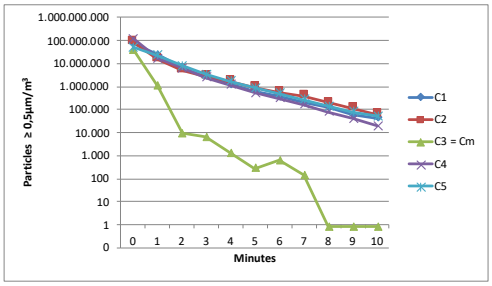

3.6.a The RD (left) and decay of airborne particles concentration (right) per minute at row C1-C5 of the CV systems



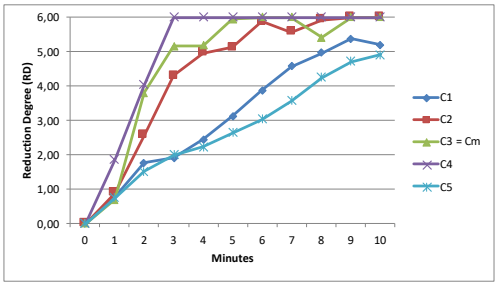



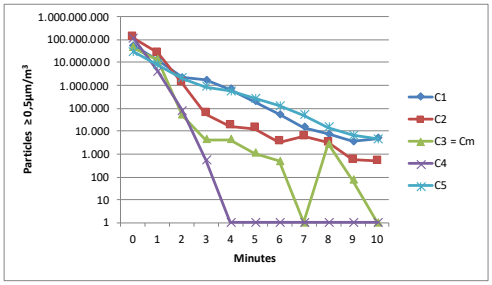

3.6.b The RD (left) and decay of airborne particles concentration (right) per minute at row C1-C5 of the cDV systems.




3.6.c The RD (left) and decay of airborne particles concentration (right) per minute at row C1-C5 of TcAF systems.




3.6.d The RD (left) and decay of airborne particles concentration (right) per minute at row C1-C5 of UDAF systems

FIG. 3.6 The RD (left) and decay of airborne particles concentration (right) per minute at row C1-C5.



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### 3.3.1 Ventilation effectiveness

Results of the ventilation effectiveness of the examined ventilation systems in area A, B and AB are presented in Table 3.2. Comparison of the four ventilation systems in area A is shown in Figure 3.7, area B in Figure 3.8 and area AB in Figure 3.9.

$RD_{10}$, CRR and ACE were significantly higher for the UDAF system when compared to the other systems in area A. In area A, no differences in $RD_{10}$ and CRR between CV and TcAF or in ACE between cDV and Tcaf and cDV and CV were found.

In area B, UDAF and cDV were comparable regarding $RD_{10}$ and CRR and UDAF and CV were comparable regarding ACE. Further, significant differences in area B were found in the ventilation effectiveness between all other examined ventilation systems.

The ACE of the cDV and CV were comparable in area AB. In area AB the UDAF and cDV were comparable regarding CRR and ACE. All $RD_{10}$ of the ventilation systems in area AB were significantly different.

TABLE 3.2 Descriptive examined OR ventilation systems, Area A, B and AB. Results are presented as median (IQR).

| Ultra-clean Area | CV | cDV | TcAF | UDAF |
|---|---|---|---|---|
| **Area A** | | | | |
| **n** | 45 | 54 | 45 | 54 |
| **$RD_{10}$** | 2.22 (1.72 3.42) | 4.18 (3.67 4.49) | 2.96 (2.75 3.61) | 6.00 (5.00 5.00) |
| **CRR** | 0.50 (0.38 0.66) | 1.21 (1.11 1.34) | 0.73 (0.58 0.86) | 5.41 (3.20 5.96) |
| **ACE** | 1.20 (0.91 1.58) | 1.07 (0.98 1.18) | 0.97 (0.74 1.11) | 4.62 (2.96 5.05) |
| **Area B** | | | | |
| **n** | 80 | 96 | 80 | 96 |
| **$RD_{10}$** | 1.82 (1.59 2.33) | 4.60 (4.02 5.58) | 2.91 (2.34 3.98) | 4.45 (3.86 5.00) |
| **CRR** | 0.38 (0.33 0.42) | 1.21 (1.09 1.30) | 0.67 (0.55 0.73) | 1.10 (0.96 1.29) |
| **ACE** | 0.93 (0.81 1.05) | 1.06 (0.96 1.14) | 0.81 (0.73 0.96) | 0.96 (0.84 1.15) |
| **Area AB** | | | | |
| **n** | 125 | 150 | 125 | 150 |
| **$RD_{10}$** | 1.94 (2.52 5.00) | 4.40 (3.95 4.95) | 2.92 (2.41 3.86) | 5.20 (4.16 5.00) |
| **CRR** | 0.41 (0.54 1.27) | 1.21 (1.10 1.31) | 0.70 (0.55 0.77) | 1.34 (1.02 3.45) |
| **ACE** | 0.98 (0.87 1.21) | 1.07 (0.97 1.15) | 0.87 (0.73 1.00) | 1.17 (0.95 3.21) |

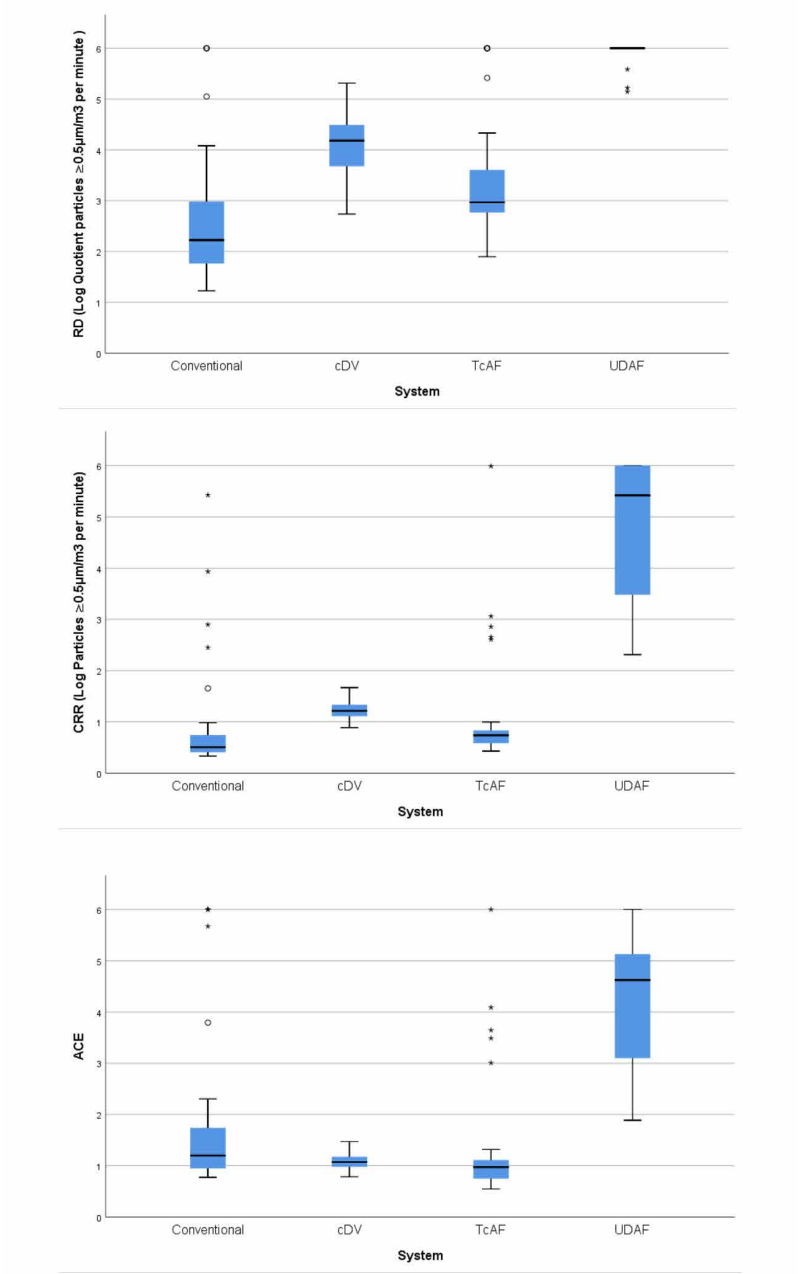


FIG. 3.7 $RD_{10}$ (3.7.a), CRR (3.7.b) and ACE (3.7.c) for a CV, cDV, TcAF and UDAF in Area A. CV and TcAF were comparable regarding $RD_{10}$ (p=0.09) and CRR (p=0.60). TcAF and cDV (p=0.62) and CV and cDV (p=0.51) were comparable in ACE. All other comparisons between systems showed a significantly different $RD_{10}$, CRR and ACE (p<0.01).



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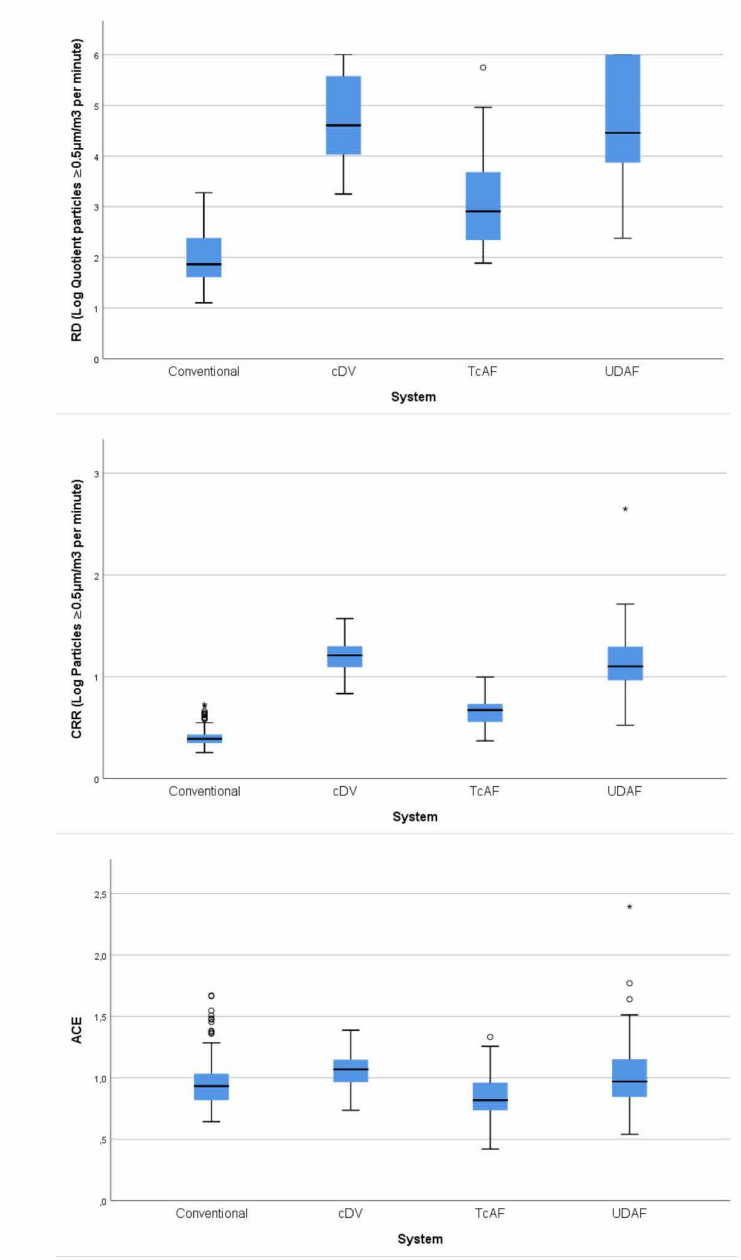


FIG. 3.8 $RD_{10}$ (3.8.a), CRR (3.8.b) and ACE (3.8.c) for a CV, cDV, TcAF and UDAF in Area B. cDV and UDAF were comparable regarding $RD_{10}$ (p=0.73) and CRR (p=0.05). UDAF and CV were comparable regarding ACE (p=1.00). All other comparisons between systems showed a significantly different $RD_{10}$, CRR and ACE (p<0.01).



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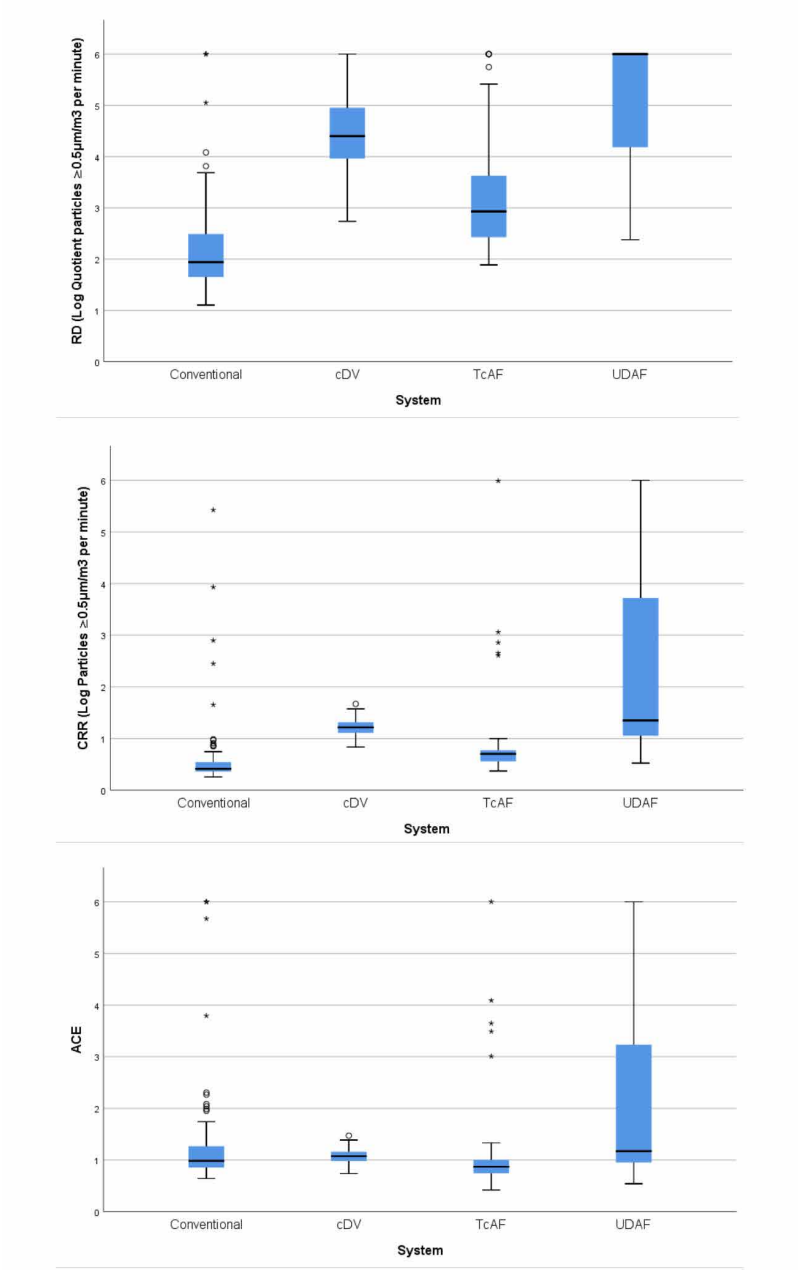


FIG. 3.9 Figure 3.9. $RD_{10}$ (3.9.a), CRR (3.9.b) and ACE (3.9.c) for a CV, cDV, TcAF and UDAF in Area AB. cDV and UDAF were comparable regarding CRR (p=0.93) and ACE (0.40). CV and cDV were comparable regarding ACE (p=0.17). All other comparisons between systems showed a significantly different CRR and ACE (p<0.01). In area AB all systems showed a significant different $RD_{10}$.



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## 3.4 Discussion

This study compares the ventilation effectiveness of operating room ventilation systems in different ultra-clean areas. The goal of the present study was to assess and compare four types of OR ventilation systems by using a uniform test grid and methodology. In this way, the performance of the systems in the ultra-clean areas could be evaluated using comparable measurements. The ventilation effectiveness of the systems was assessed by means of the Recovery Degree ($RD_{10}$), Cleanliness Recovery Rate (CRR) and Air Change Effectiveness (ACE).

In this study the ventilation effectiveness of the UDAF outperforms all other examined systems in area A. This can be explained due to the technical design of a UDAF system [24]. No significant differences in area A were found in $RD_{10}$ and CRR between CV and TcAF and no significant difference in ACE between the cDV and CV and TcAF. The reason for lower CRRs of the CV and TcAF as well as lower ACE of the CV, TcAF and cDV compared to the UDAF is due to the design of the CV, TcAF and cDV, resulting in the introduction of less air into area A.

In area B and AB significant differences were found in the ventilation effectiveness of the ventilation systems. The CRR of the UDAF and cDV are comparable for area B and AB. A possible explanation could be the higher air volumes introduced [28,29] by the UDAF and cDV systems.

An important ability of the ventilation system for the protection of the ultra-clean area is the level of displacement of the air and the dilution of airborne particles (RD) in the ultra-clean area [25]. Since the RD is expressed on a logarithmic scale, the difference in $RD_{10}$ between the ventilation systems in area AB is approximately a factor 10 (logarithm) per system (table 3.2).

In the current study the wound area, the area surrounding the surgical staff and the instrument tables are defined as ultra-clean areas. Current standards [11–14] are, however, not developed to measure the performance of ventilation systems within the whole OR [16,17] or larger ultra-clean areas. Standards and guidelines for infection-prone surgeries are focused on a protected area only and for generic ORs on a recovery test. However, new systems are developed that claim that the whole OR is ultra-clean during surgery since the standard protected area is sometimes not large enough to position and protect all instrument tables and to allow enough additional space between sterile staff and instrument tables [30–32].

The ventilation effectiveness in this study is the result of the CRR and ACE values of the examined ventilation systems and calculated in accordance with other studies [25,33]. We propose to additionally determine the Recovery Degree ($RD_{10}$) for assessment of the ventilation effectiveness. The $RD_{10}$ gives us the ability to compare the different ventilation systems over a measuring period of 10 minutes after emitting.

The ventilation effectiveness is measured by the recovery test, which is adapted from the ISO 14644-3 standard [22]. This test is primarily designed for cleanrooms, not for operating rooms, and does not prefer a unidirectional air flow installation to be tested accordingly [22]. However, we did use the recovery test in this study for the UDAF systems. The reasons for using the recovery tests were that operating lights were positioned underneath the UDAF and the ultra-clean areas B and AB were larger than the size of the UDAF. With the recovery test we were able to compare all systems in all areas in the same way, as part of the ventilation effectiveness.

Cost savings by introducing a new measuring method based on this test grid method could be achieved when larger ultra-clean areas are needed. Measurements performed according to the latest standards and guidelines [11–14] are time consuming. In some cases, measurements can take a whole day and during these test, the OR cannot be used for surgeries. In contrast, the measuring method in our study only takes 1.5 hours per OR.

This study has several limitations. First, the study is executed in an ‘at-rest’ situation. In this study we did not take into consideration the dispersion and contamination dynamics in the OR caused by the behavior of surgical staff, the number of surgical staff, the quality of the clothing [34,35] used, number of door openings during surgery [36–38], etc. The aim of the used methodology in this study is not to test the performance of the ventilation systems during real surgery individually, but to test all ventilation systems technically in the same way. The methodology can be seen as a technical evaluation of the installed ventilation system. It would be interesting to see how the four different systems will behave in the examined areas while real surgery is performed, taken into account the dispersion dynamics and other parameters influencing the contamination in the ultra clean area. Furthermore, no measurement outside the AB area have been performed. We think the examined areas are most important to determine the ventilation effectiveness of the OR in an ‘at rest’ situation.

Second, the total introduced amount of air was not the same per compared system. We tested the four systems as if functioning during surgery. However, the amount of air introduced might have influenced the ventilation effectiveness. Furthermore, it would be interesting to see what the minimum $RD_{10}$ and minimum amount of air is, to maintain ultra-clean air in an ultra-clean area.

Third, each system is calculated without considered other known parameters reported to affect the ventilation effectiveness. There may be locations where clean air out of the OR ventilation system does not reach the ultra-clean area because of position of air inlets, characteristics of air inlet diffusers, temperature differences between supply and room air, placement of exhausts, obstructions to airflow, air rising from heat sources, surgical lights [39] and room geometry [40,41]. These variables can influence the airflow patterns within the ultra-clean area and reduce the amount of ultra-clean air that reaches the ultra-clean area.

A further study to explore how the different systems behave in ultra-clean areas, during real surgery, and the total cost of ownership per ventilation system is recommended. Since environmental awareness and economical aspects are becoming more and more important in the decision-making process it is important to know the minimum recovery degree ($RD_{10}$) to achieve the level of ultra-clean air in the ultra-clean area. Future studies will have to address this in further detail and will have to consider the recovery degree (RD), the microbiological (CFU), environmental and economic aspects as well.

## 3.5 Conclusions

This study shows a high ventilation effectiveness of the UDAF system in area A and the, in general, mixing character of the other examined systems. In area A the ventilation effectiveness of the UDAF ventilation system is outperforming all other ventilation systems. In area B and AB significant differences were found regarding venitlation effectiveness of the examined ventilation systems.

This study offers insights in the technical functioning of different OR ventilation systems currently available on the market. The test procedures that are presented in this study assist to compare, enhance and facilitate decision making for the selection of OR ventilation systems when building new ORs or renovating old ones. The type of surgical procedure, and not the standard, should determine the size of the ultra-clean area. Possible effects of measuring in an empty operation room versus obtaining data in the real situation during a complex surgical procedure needs further investigation.

## Acknowledgements

The authors would like to thank the staff of the Dutch hospitals: IJsseland - Capelle a/d IJssel, Leiden University Medical Center - Leiden, Rijnstate - Arnhem and Nij Smellinghe - Drachten for making the operating rooms available for the measurements.

## Conflict of interest statement

Jos Lans is owner of Medexs BV, a company that supplies and install the different mentioned OR ventilation systems. All other authors report no conflict of interest relevant to this article.

## Funding statement

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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# 4 Air quality in the periperhy of operating rooms during surgery

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PUBLISHED **Journal of Hospital Infection** | DOI: 10.1016/j.jhin.2023.01.015

KEYWORDS Operating Room, Colony Forming Units, Ultra clean ventilation systems, Instrument tables, Surgical procedure

ABSTRACT **Background –** Most European ventilation standards and guidelines for infection-prone clean surgeries are developed to determine the size and the air quality of the protected (ultra clean) area. The periphery of the operating room (OR) is not taken into account by most standards and guidelines. However, sometimes the periphery is used to partly position microbiological sensitive instrument tables.
**Aim –** The aim of this study is to determine the air quality in the periphery of the OR by means of measuring the number of Colony Forming Units (CFU) during surgery.
**Methods –** CFUs were measured in the periphery at start incision, at several moments during surgery and at the end of the surgery. The recovery time was measured in an 'at–rest' situation.

**Findings –** During 58 surgical procedures the number of CFUs in the periphery was measured. At start incision and during closure of the wound the mean number of CFU/$m^3$ was 7.0 (SD 10.7) and 6.2 (SD 9.5), respectively. The number of CFUs in the periphery, measured during surgery, did not exceed the international accepted level of <10 CFU/$m^3$ in 82.4%. The mean CFU value in the periphery of all CFU measurements during surgery (between incision and closure) was 5.9/$m^3$ (SD 5.8). The mean 100-fold reduction was 6.0 (SD 1.2) minutes in an 'at-rest' situation.
**Conclusion –** The number of CFUs did not exceed 10 CFU/$m^3$ in 82.4% of the measurements in the periphery of the OR during surgery. The air quality in the periphery might be good enough to safely position instrument tables in case the protected area of the ultra-clean ventilation systems is not large enough.

## 4.1 Introduction

Ultra Clean Ventilation (UCV) systems are used in the Operating Room (OR) to reduce the quantity of airborne bacteria in the ultra clean area and to reduce the incidence of surgical site infections (SSI). When the number of Colony Forming Units (CFUs) in the ultra-clean (protected) area is too high, this is considered a risk factor for SSI [1–3]. SSIs are influenced by many factors. For many SSIs, the responsible pathogens originate from the patient's endogenous flora [4,5]. Exogenous factors like OR staff discipline [6], type of OR clothing [7,8], air cleanliness [9], ventilation effectiveness [10] and the type of ventilation system [2,11] might contribute to the incidence of SSIs.

Underneath an Uni-Directional AirFlow (UDAF) UCV system the number of CFUs, in general, is <10 CFU/$m^3$ during surgery. However, for large surgical infection prone procedures, the realized protected area of an UDAF is sometimes too small to contain all sterile instrument tables and to allow enough additional space between sterile staff and instrument tables [12–14]. When instrument tables are located (partly) outside the protected area it should meet also the required cleanliness level of <10 CFU/$m^3$ [5,15].

To date, standards and guidelines [16–19] focus only on air quality of the UDAF in the protected area. Air quality in the periphery outside the protected area of the UDAF is not taken into account.

Therefore, the aim of this study was to determine the level of CFUs during surgery in the periperhy in order to determine whether instrument tables can be positioned safely in the periphery outside the protected area of the UDAF when the protected area of the UDAF is not large enough.

## 4.2 Methods

Peripheral CFU measurements were performed at two different locations of one hospital organization in the Netherlands between 2014 and 2021. Type of surgery was noted and described as infection prone surgery or generic surgery.

The operating rooms included in this study were equipped with a uni-directional air flow (UDAF). The UDAF system introduces the air directly (and only) above the protected area and not directly into the periphery (Figure 4.1). All ORs were equipped with an UCV UDAF system. The staff present during surgery wore modern scrub suits made out of 99% polyester and 1% carbon fibers [8]. The source strength using this type of clothing was 2.9 (0.9-5.7) CFU/s per person [8].

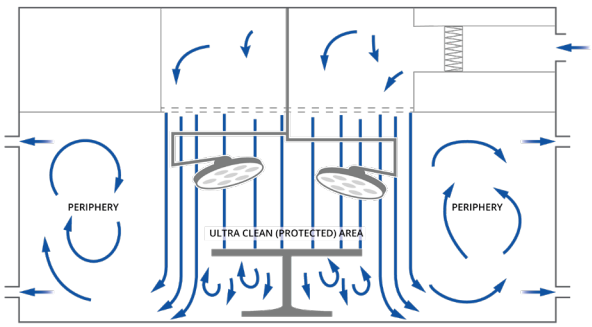


FIG. 4.1 Uni-Directional AirFlow (UDAF) with the UDAF ultra clean (protected) area and periphery.

Data of the OR location, room sizes, air changes and type of ultra clean ventilation system can be found in Table 4.1.



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TABLE 4.1 The OR location, room sizes, air changes and type ultra clean ventilation system.

| OR TYPE | Hospital Location | System type (No. of ORs) | Surface UDAF [$m^2$] | OR Length [m] | OR Width [m] | OR Height | Volume OR [$m^3$] | Total air volume [$m^3/h$] | Air changes [no.] |
|---|---|---|---|---|---|---|---|---|---|
| 1 | A | UDAF (10) | 6.4 | 7.4 | 5.9 | 2.8 | 123 | 5,593 – 7,282 | 46-59 |
| 2 | A | UDAF (2) | 5.7 | 5.4 | 6.2 | 2.8 | 96 | 5,599 – 6,013 | 58-63 |
| 3 | B | UDAF (10) | 7.1 | 6.8 | 6.1 -6.9 | 3 | 127 - 142 | 7,412 – 8,690 | 56-68 |

### 4.2.1 CFU Measurements

CFU measurements were performed on two fixed locations in the periphery (Figure 4.2) outside the protected area of the UDAF with a Biomarieux Sampl'air air sampler. This location was chosen since it is often, at this hospital, the location of instrument tables during (large) surgical procedures. CFU measurements were performed based on the Swedish standard SIS – TS 39: 2015 [5].

We defined four moments to measure the number of CFUs: patient on table (during positioning of the patient, before surgery starts), at incision, between incision and closure (in this study defined as "during surgery") and during closure of the wound.

The measurement cycle of each sample at the location measured was 2.5 minutes. For 2.5 minutes 250 $dm^3$/min was sampled. The air sampling started directly after the incision was made and was repeated several times during sugery. The last measurement took place during closure of the wound. A measurement technician was present in the OR (periphery) and exchanged the Agar plates after 2.5 minutes. The Agar plates (Biomerieux COS) were incubated aerobically for 2 x 24 hours at 37°C. During the measurements the number of staff present, number of door openings and duration of surgery were noted.

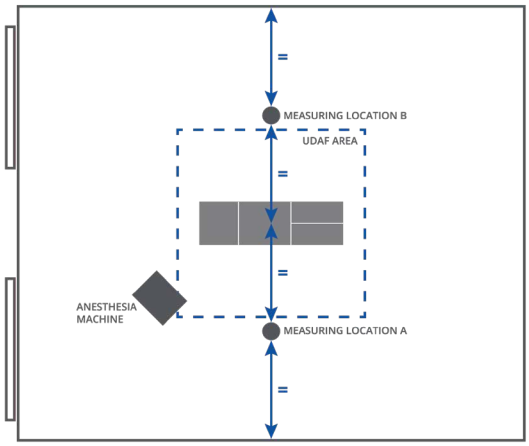


FIG. 4.2 Measuring locations, dot was the position of the air sampler at measuring location A and B.

### 4.2.2 Recovery Rate Measurements

On four positions (see Figure 4.3) in the operating room periperhy the 100-fold recovery rate was determined with a Lighthouse 3016 handheld particle counter with a flow rate of 2.83 l/min (0.1 $ft^3$/min). For the determination of the 100-fold recovery rate the used methodology is based on the recovery test described in ISO 14644-3; B.12 [20].

Before the recovery rate measurements started, particles were emitted in the whole operating room with a calibrated Topas aerosol generator (model ATM 226, aerosol Emery 3004). The emitting stopped when the particle counter on the measuring locations displayed a background concentration between ≥ $10^7$ and $10^9$ particles per $m^3$ (≥ 0.5 µm). On each point, at a height of 1.2 m, the particle counter measured the quantity of particles with a particle size of ≥ 0.5 µm, with a measuring cycle of 1 minute for 10 minutes. From the number of particles measured at each point the average room periphery 100 fold recovery rate was calculated.

During the measurements, medical equipment, respirators and operating lights (switched on) were positioned in the operational position. The operating lights were positioned according to VCCN RL7 and DIN 1946-4 [16,17].

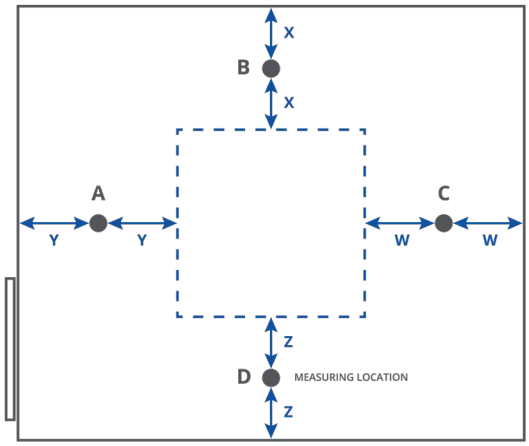


FIG. 4.3 Measuring locations, dots are the position of the particle counters. Measuring location is mid 'OR wall – UDAF'.

### 4.2.3 Statistical analysis

Descriptive statistics were used to determine number of CFUs at incision, during surgery and during closure. Scatterplots were used to explore relations between number of CFUs and recovery rate, number of CFUs and length of surgery, number of CFUs and number of door openings during surgery. To explore differences in number of CFUs between infection prone surgeries and generic surgeries a non parametric Mann Whitney U test was performed.

IBM SPSS version 25 (IBM Corp. Armonk, NY: IBM Corp) was used.

## 4.3 Results

Measurements were performed during 58 surgeries from which 17 surgeries were infection prone surgeries and 41 were generic surgeries. During 29 surgeries measurements were performed at measuring point A (see Figure 4.2). During the other 29 surgeries measurements were performed at measuring point B (see Figure 4.2).



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Average duration of the surgery was 56.9 (SD 50.6) minutes. During surgery the average number of staff was 7.6 (SD 1.1, n=54). The number of door openings was 6.4 (SD 8.3, n=53), the 100 fold recovery time was 6.0 minutes (SD 1.2, n=58).

The number of CFU/$m^3$ was 36.9 (SD 48.8) during 'patient on table' before the surgical procedure started (n=48). In 35.4% the number of CFUs was < 10 CFU/$m^3$.

At incision, the number of CFUs in the periphery was in 78.9% lower than 10 CFU/$m^3$. After 10 minutes (SD 10.7, n=37) the number of CFUs was in 83.8% < 10 CFU/$m^3$ and at the end of the surgery (during closure of the wound) the number of CFUs was in 77.8% lower than 10 CFU/$m^3$. Results of the CFU measurements in the periphery are shown in Table 4.2.

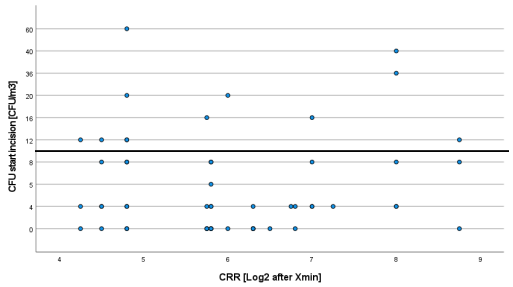
During 58 surgeries in total 125 CFU measurements in the periphery were performed, from which 82.4% (103 measurements) were < 10 CFU/$m^3$. The mean CFU/$m^3$ in the periphery was 5.9 (SD 5.8).

TABLE 4.2 Data and results measurements periphery operating rooms. Results are presented as mean (SD).

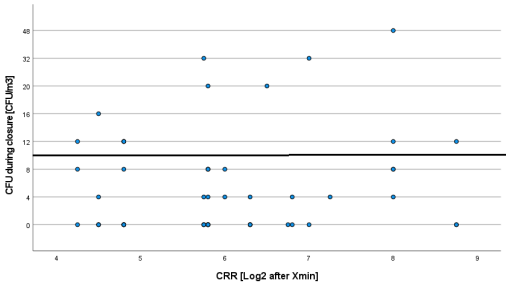
| CFU Measurements Periphery | Patient on table | At incision | At 10 min. | During closure wound |
|---|---|---|---|---|
| n | 48 | 57 | 37 | 54 |
| Number of CFUs Mean [CFU/$m^3$] (SD) | 36.9 (48.8) | 7.0 (10.7) | 5.0 (6.7) | 6.2 (9.5) |
| <10 [CFU/$m^3$] | 35.4% | 78.9% | 83.8% | 77.8% |

No statistical differences were found in the number of CFU/$m^3$ between generic and infection-prone surgeries.

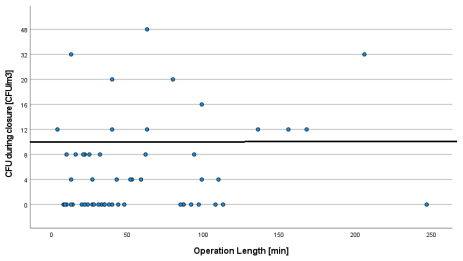
The scatter plots shown in Figure 4.4.a, 4.4.b, 4.4.c and 4.4.d do not indicate any relationship between measured quantity of CFUs, the recovery rate (RR) (100 fold reduction), duration of surgery and number of door openings in the periphery.



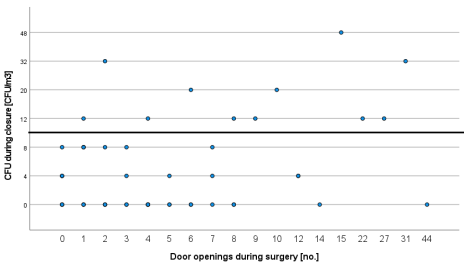

4.4.a




4.4.b




4.4.c




4.4.d

FIG. 4.4 Scatter plots of relation recovery rate and level of CFUs at incision (4.4.a), relation recovery rate and level of CFUs during closure (4.4.b), relation level of CFUs and operation length (4.4.c) and relation level of CFUs and quantity of door openings (4.4.d).



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## 4.4 Discussion

The wound area, the area of the surgical staff and the instrument tables are areas that need to be protected by ultra clean ai [3,22–25]. For infection prone surgeries [5] those areas are defined as ultra clean (protected) areas. Most standards and guidelines for infection-prone surgeries focus on a pre-defined protected area only. However, the size of an UDAF system, described in standards and guidelines [17–19], is sometimes not large enough to position all instrument tables [12–14] underneath the UDAF system. Therefore, the aim of this study was to determine the air quality in the periphery by means of the number of colonies forming units during surgery.

Our results show that the number of CFUs in the periphery of the operating room between start incision to closure of the wound, did not exceed the international accepted level of <10 CFU/$m^3$ [1,3] in approximately 82.4% of the cases. In our study, with in total 125 measurements, the highest accepted level of 30 CFU/$m^3$ [5] was exceeded three times at incision and four times during surgery. 30 CFU/$m^3$ is the highest number that is accepted for one measurement during a surgical procerdure in the SIS-TS39:2015. Possibly the higher numbers during surgery were measured because of activities in the OR like changing the OR team or bringing in equipment necessary for the surgical procedure [21–24]. During surgery the surgical staff was wearing modern scrub suits.

The number of CFU/$m^3$, when the patient was positioned on the surgical table before incision was made, was on average 36.9 (SD 48.8). In 35.4% the level of CFUs was below 10 CFU/$m^3$. These numbers are high and do not comply with the standards. At incision, these numbers were reduced to <10 CFU/$m^3$ in 45 of the 57 measurements. However, a decrease of the number of CFUs after positioning the patient might result in a further reduction of CFUs in the periphery at the moment the incision is made. A reduction of the number of CFUs could be achieved when a 'clean-up time' is introduced and/or the surgical staff is wearing clean air suits [5,7,8]. A clean up time is related to the recovery rate and dependent on the number of air changes in the periphery. A lower number of air changes [25], as advised in some guidelines [26], will result in a longer clean-up time and higher numbers of CFUs [2]. In our study the number of air changes in the periphery was approximately 57 and the average 100-fold reduction in the ORs was 6.0 (SD 1.2) minutes. With clean air suits [7,8] the dispersion of bacteria-carrying skin particles from the staff into the air of the operating room will also be reduced [8,27,28].

We explored the relationship between number of CFUs, recovery rate [10,29], duration of the surgery and number of door openings [30–33]. The scatter plots do not indicate any relationship between measured quantity of CFUs and the recovery rate of the periphery. This could be explained by the fact that all ORs have more or less the same room geometry, equal type of clothing [8], equal amount of air changes, recovery rate [29], number of door openings and surgical staff [30–32].

This study has several limitations.

First, CFU measurements were conducted at only two locations in the periphery and during two types of surgical procedures (infection prone and generic). However, in this study the examined locations are locations often used by the hospital to position instrument tables in case instrument tables cannot be positioned in the protected area of the UDAF [12,13].

Second, the recovery rate was measured in a 'at-rest' situation and not during surgery. During surgery there may be locations where air does not reach the measurement location due to obstructions, heat sources, room geometry etc. they influence the airflow patterns [34–36].

Third, the sampling volume was not fully executed according to the Swedish standard SIS – TS 39: 2015. The sampling volume is advised to be 100 $dm^3$/min for 10 minutes. In this study we used a sampling volume of 100 $dm^3$/min for 2.5 minutes. A shorter sampling time is chosen since we wanted to measure the number of CFUs during the positioning of the patient on the OR table, at incision, after 10 minutes and at the closure of the wound for that particular event. A longer sampling time would give us insight in the mean number of CFUs after 10 minutes, however this would gain no insight in the specific activity as for example the incision.

## 4.5 Conclusion

The number of CFUs did not exceed 10 CFU/$m^3$ in 82.4% of the measurements in the periphery of the operating room during surgery. The air quality in the periphery might be good enough to safely position instrument tables in case the protected area of the ultra-clean ventilation systems is not large enough.

## Acknowledgements

The authors would like to thank the staff of the Antonius hospital group, the Netherlands, for making the operating rooms available for the measurements and providing the CFU data.

## Conflict of interest statement

Jos Lans is CEO of Medexs BV, a company that designs, builds, supplies and installs complete operating room and hotfloor departments. All other authors report no conflict of interest relevant to this article.

## Funding statement

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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# Part B


Nij Smellinghe Hospital

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# 5 What is the effect of reducing the air change rate on the ventilation effectiveness in ultra-clean operating rooms?

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PUBLISHED **Journal of Hospital Infection** | DOI: 10.1016/j.jhin.2024.02.007

KEYWORDS Cleanliness Recovery Rate, Air Change Effectiveness, Recovery Degree, Operating Room, Ventilation Effectiveness , Ultra Clean Ventilation systems

ABSTRACT

**Background –** The operating room (OR) department is one of the most energy-intensive departments of a hospital. The majority of ORs in the Netherlands have an air handling installation with an ultra-clean ventilation (UCV) system. However, not all surgeries require an ultra-clean operating room.

**Aim –** What is the effect of reducing the air change rate on the ventilation effectiveness in ultra-clean operating rooms?

**Methods –** In this study lower airvolume ventilation effectiveness ($VE_{Lv}$) of a Conventional Ventilation (CV), controlled Dilution Ventilation (cDV), Temperature controlled AirFlow (TcAF) and Uni Directional AirFlow (UDAF) system was evaluated and measured within a 4x4 meter square measuring grid of 1x1 meter. The $VE_{Lv}$ is defined as the recovery degree (RD), cleanliness recovery rate (CRR) and air change effectiveness (ACE).

**Findings –** The CV, $cDV_{Lv}$ and $TcAF_{Lv}$ ventilation systems show a comparable mixing character in Area A, B and AB when reducing the air change rate to $20h^{-1}$. Ventilation effectiveness decreases when the air change rate is reduced, with exception of the ACE.

At all points for the UDAF-$2_{Lv}$ and at the center point (C3) of the $TcAF_{Lv}$, higher $RD_{10Lv}$ and $CRR_{Lv}$ were measured when compared to the other examined ventilation systems.

**Conclusion –** The ventilation effectiveness decreases when an ultra-clean OR with an ultra-clean ventilation air supply system is switched to an air change rate of $20h^{-1}$. Reducing the air change rate in the OR from an ultra-clean OR to a generic OR will reduce the recovery degree ($RD_{10}$) with a factor 10 to 100 and the local air change rate (CRR) between 42%-81%.

# 5.1 Introduction

Energy consumption in healthcare is high. Worldwide, hospitals account for about 6% of total building energy consumption [1]. An operating room department is three to six times more energy-intensive than all other hospital departments combined. Heating Ventilation and Air Conditioning (HVAC) energy requirements account for 90-99% of the total energy consumption of the operating room [2]. The main objectives of an air handling system in the OR and an ultra-clean air supply ventilation (UCV) system are to create a safe and comfortable working environment for surgical staff by controlling the temperature and, in some cases, the relative humidity, diluting the concentration of harmful substances and minimizing the incidence of surgical site infections (SSI) [3].

The Dutch Federation of Medical Specialists (FMS) [4] introduced a new guideline for air handling in operating and treatment rooms. The guideline recommends that major orthopedic implant surgeries, primary and revision prostheses and major spinal surgery (e.g. scoliosis), should be performed in an OR class1+ [4]. The indoor air quality of an OR class 1+ should comply to the internationally accepted definition of ultra clean air which is defined as air which contains less than 10 colony forming units per cubic meter of air (CFU/$m^3$) [5–9]. This in line, for infection prone surgery, with international standards and guidelines [10–13] as well as with the recommendation of the Dutch Orthopedic Association (NOV) [14]. In an ultra-clean OR with the highest classification a UCV system should be installed, according to the standards and guidelines [4,10–13], which results in a higher air change rate to achieve the required number of ≤10 CFU/$m^3$ in the ultra-clean or protected [11] area. In the Netherlands the average air changes rate per hour (ACH) of ultra-clean ORs with a UCV system is 69 [15]. Practically all operating rooms in Dutch hospitals are designed and equipped as an ultra-clean OR (FMS OR class1+ [4]). However, not all ORs in an operating room department are used for major (orthopedic) implant surgeries or large joint procedures. One of the possibilities to reduce energy consumption of a HVAC system for operating rooms is to reduce the number of air changes (air volume) [16,17] of the OR air handling installation and air supply system when the type of surgery does not require an ultra-clean OR.

International standards and guidelines [4,10–13] recommend for generic surgeries or other than the major orthopedic implant and spinal surgeries [4], an air change rate of ≥20 which is in line with the WHO [18] and other international standards and guidelines [4,10,12]. In an ultra-clean operating room, the number of air changes per hour or the required outside air (ODA) volume varies per international standards and guidelines.

Therefore, the goal of this study was to provide insight into what the effect is on ventilation effectiveness [19] when the air change rate in ultra-clean operating rooms is reduced to approximately 20$h^{-1}$. We assessed the ventilation effectiveness (VE) of a conventional ventilation (CV), a controlled dilution ventilation (cDV), a temperature controlled airflow (TcAF) and a Uni-Directional Airflow (UDAF) in the ultra-clean area when the ventilation system was switched to approximately 20 air changes per hour as advised for generic surgery [4,10–12].

## 5.2 Methods

This study was performed in five operating rooms of four hospitals and one clinic in the Netherlands. To reduce the number of air changes per hour the setpoints of the supply air (SUP) [20] of the air handling installation via the building management system were changed. Supply air (SUP) was the sum of outside air (ODA) and secondary air (SEC). Supply air (SUP) is defined according to the EN-16798-3:2017 [20] as airflow entering the treated room, or air entering the system after any treatment. Secondary Air (SEC) as airflow taken from a room and returned to the same room after any treatment. Outside air (ODA) as air entering the system or opening from outdoors before any air treatment. In this study, ODA remained the same for CV, cDV, TcAF and UDAF-2 and SEC was reduced. For the UDAF-1, ODA was reduced and the SEC air system turned off.

### 5.2.1 Operating Room ventilation systems

As in our previous study [19], four different ventilation systems were selected. The selected ventilation systems are categorized as unidirectional and non-unidirectional airflow operating rooms according to the ISO 14644-3 [21]. To understand the ventilation effectiveness and air distribution of the compared OR ventilation systems technical dissimilarities and working principles are explained in our previous study [19].

Before measurements were performed, a technical inspection of the ventilation performance with the systems working on a lower air volume was carried out to ensure that the system was functioning as intended for this study.

The measurements were performed in the same hospitals in order to be able to compare the $VE_{LV}$ with the VE out of our previous study. Because it was, without major modifications, not possible to reduce the number of air changes per hour (ACH) of the UDAF system used in our previous study, we assessed another UDAF system as well to be able to compare equally the $VE_{LV}$ with the other CV and Ultra Clean Ventilation (UCV) systems. The UDAF out of the former study is called UDAF-1 and the newly assessed UDAF, UDAF-2. The number of air changes per hour in our previous study [19] for the examined ultra clean ventilation systems varied from 45 to 73 ACH (see Table 5.2). In the current study this number of ACH was reduced to approximately 21 ACH per OR for all systems except for the conventional ventilation system (CV), for which the number of ACH was 24 (see Table 5.1).



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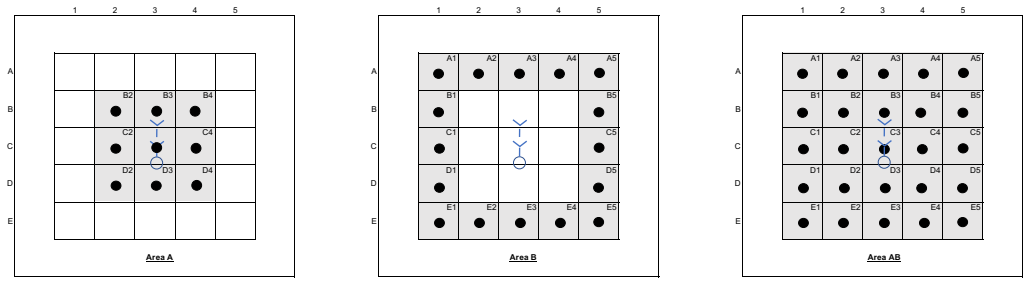
### 5.2.2 Measurements

The used measurement methodology was based on the recovery test described in ISO 14644-3; B.12 [21]. Within a 4x4 meter square measuring grid of 1x1 meter, three measuring areas were defined, Area A with 9 measuring locations, Area B with 16 measuring locations, Area AB with 25 measuring locations (see Figure 5.1.a, 5.1.b and 5.1.c). Each measuring grid, with measuring locations at a height of 1.20 meter above floor level, was situated with its center (point C3) in the middle of the operating field. Measuring locations were at a distance of 1 meter from each other and were performed per row. At each measuring row five Lighthouse 3016 handheld particle counters with a flow rate of 2.83 l/min (0.1 $ft^3$/min) were placed at the measuring locations (grid positions). On each point per row the particle counters measured, with a measuring cycle of 1 minute for 10 minutes, the quantity of particles with a particle size of ≥ 0.5 µm. During the measurements, medical equipment, respirators, and operating lights (switched on) were positioned in the operational position. The operating lights were positioned according to VCCN RL7 and DIN 1946-4 [12,22]. Before the measurements started, particles were emitted in the whole operating room with a calibrated Topas aerosol generator (model ATM 226, aerosol Emery 3004). The emitting stopped when all particle counters in the measuring row displays a background concentration between ≥ $10^7$ and $10^9$ particles per $m^3$ (≥ 0.5 µm). The exact route of the emitted particles cannot be indicated with these measurements. From the number of particles measured at each point, the Recovery Degree (RD), Cleanliness Recovery Rate (CRR) and the Air Change Effectiveness (ACE) were calculated.




5.1.a 5.1.b 5.1.c

FIG. 5.1 Measuring location, dots are the position of particle counters.
A: Area A, 9 measuring locations (B2-B3, C2-C3, D2-D4).
B: Area B, 16 measuring locations (A1-A5, B1 and B5, C1 and C5, D1 and D5, E1-E5)
C: Area AB, 25 measuring locations (A1-A5, B1-B5, C1-C5, D1-D5, E1-E5).

### 5.2.3 Recovery Degree

The RD shows the ability of the OR ventilation system to eliminate or reduce the quantity of airborne particles, at the measuring locations, from the maximum concentration after emitting within 10 minutes ($RD_{10}$). The Recovery Degree (RD) [19] shows the ability of the ventilation system to eliminate or reduce the quantity of airborne particles, at the measuring locations, from the maximum concentration after emitting. The RD is defined as the logarithm of the quotient (ratio) of the number of particles ≥0.5 µm per $m^3$. In this study the RD is measured every minute for 10 minutes and therefore $RD_{10}$ is used in this study. $RD_{10Lv}$ is the recovery degree over a period of 10 minutes with a lower air change rate.

The RD is derived from the recovery test as described in the ISO 14644-3: B12 [21]. A RD of 2 means that the number of particles at the measuring locations is a factor 100 times ($^{10}\log 100 = 2$) lower than at the start of the measurement during the period of 10 minutes.

The RD is calculated by equation 5.1.

$$RD_{tx} = -log \frac{C_{tx}}{C_{t0}} \ (1) \qquad \text{EQ. 5.1}$$

Where:
$RD_{tx}$ = *Recovery Degree after time tx,*
$C_{tx}$ = *Concentration of particles at location at time tx,*
$C_{t0}$ = *Initial concentration at start measurement* $t_0$*, directly after emitting.*

### 5.2.4 Cleanliness Recovery Rate (CRR)

The Cleanliness Recovery Rate (CRR) is used as a method [23] to determine the local air change rate at the measuring locations. Cleanliness Recovery Rate (CRR), or decay rate, is closely related to the RD. The CRR is used as a method [23] to determine the local air change rate at the measuring locations. Local air change rate per minute is equal to the CRR. Calculation of the CRR, as given in ISO 14644-3, was carried out over the period of exponential decay. This period is ascertained by plotting the particle concentration over time [23] and defines the inclination angle of the particle decay. In this study the $CRR_{Lv}$ is used to compare the air distribution in the OR of the different ventilation systems with a lower air change rate.

The CRR (local air change rate) can be calculated by using equation 5.2:

$$CRR = -\frac{1}{t}\ln\left(\frac{C1}{C0}\right) = -2.3\,\frac{1}{t}log\frac{C_1}{C_0} \quad (2)$$ EQ. 5.2

Where:
*CRR is the cleanliness recovery rate,*
*t is the time in minutes, elapsed between the first and last measurement in the measurement interval,*
*$C_0$ is the concentration at the start of the exponential decay,*
*$C_1$ is the concentration at the end of the exponential decay.*

### 5.2.5 Air change effectiveness (ACE)

The ventilation effectiveness is determined by the Air Change Effectiveness (ACE) [23–25]. This study compares the average CRR per system in the measured areas A, B and AB to the overall average air change rate. The overall average air change rate is the total air volume ($m^3$/h) introduced in the OR divided by the OR's volume ($m^3$). If introduced HEPA filtered air and room air volume are perfectly mixed, the ACE will have a value of 1 at all measuring locations. If less introduced air reaches the measuring location than the OR volume average the ACE will be below 1. If more introduced air reaches the measuring location, the ACE index will be above 1. The aim of a UCV-system is to have a higher ACE (>1) in the ultra-clean area [23].

The ACE is calculated by equation 5.3.

$$ACE = \frac{local\ air\ change\ rate\ per\ minute\ (CRR)\ at\ measuring\ location\ x\ 60}{overall\ average\ air\ change\ rate\ (\frac{m3}{h})\ operating\ room} \quad (3)$$ EQ. 5.3

Where:

Local air change rate per minute is the average cleanliness recovery rate per measuring location per system,

Overall average air change rate operating room is the total air volume introduced ($m^3$/h) / OR's volume ($m^3$).

In this study the Ventilation Effectiveness (VE) was defined as the recovery degree (RD), cleanliness recovery rate (CRR) and air change effectiveness (ACE). Because the number of air changes per hour in this study was reduced, lower air volumes were introduced in the operating room. The lower air volume ventilation effectiveness ($VE_{Lv}$) of the four ventilation systems was determined for three different ultra clean protected areas; standard protected area (A), area outside standard protected area (B) and large protected area (AB).

In Table 5.1 the characteristics of the examined OR ventilation systems as well as the ventilation effectiveness in Area A, B and AB are shown.

TABLE 5.1 Descriptive ventilation effectiveness low volume ($VE_{Lv}$) examined OR ventilation systems, Area A, B and AB. Results are presented as median and interquartile range (IQR).

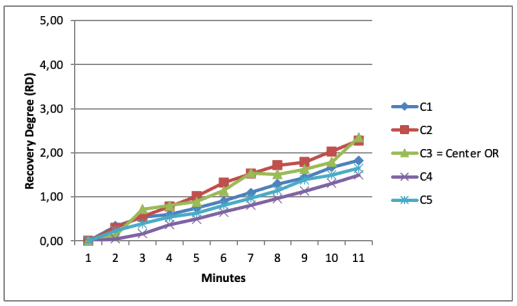
| Ultra-clean Area | $CV_{Lv}$ | $cDV_{Lv}$ | $TcAF_{Lv}$ | $UDAF\text{-}1_{Lv}$ | $UDAF\text{-}2_{Lv}$ |
|---|---|---|---|---|---|
| Air volume [$m^3/h$] | 2,678 | 3,000 | 3,500 | 1,750 | 2,400 |
| Number of Air Changes per hour (ACH) | 24 | 21 | 21 | 12 | 22 |
| **Area A** | | | | | |
| n | 9 | 9 | 9 | 9 | 9 |
| $RD_{10Lv}$ | 1.86 (1.21 2.52) | 1.45 (1.22 1.69) | 1.63 (1.21 2.05) | 0.96 (0.47 1.46) | 4.24 (1.46 7.02) |
| $CRR_{Lv}$ | 0.39 (0.28 0.50) | 0.35 (0.29 0.40) | 0.30 (0.19 0.40) | 0.20 (0.04 0.36) | 0.91 (0.56 1.26) |
| $ACE_{Lv}$ | 0.98 (0.71 1.26) | 1.09 (0.85 1.17) | 0.85 (0.56 1.15) | 0.99 (0.23 1.74) | 2.47 (1.52 3.41) |
| **Area B** | | | | | |
| n | 16 | 16 | 16 | 16 | 16 |
| $RD_{10Lv}$ | 1.69 (1.17 2.22) | 1.59 (1.06 2.13) | 1.57 (1.02 2.12) | 1.36 (0.80 1.91) | 3.75 (2.96 4.54) |
| $CRR_{Lv}$ | 0.37 (0.32 0.43) | 0.33 (0.27 0.39) | 0.32 (0.27 0.38) | 0.26 (0.20 0.31) | 0.75 (0.66 0.83) |
| $ACE_{Lv}$ | 0.93 (0.80 1,06) | 0.97 (0.79 1.14) | 0.97 (0.80 1.13) | 1.25 (0.99 1.52) | 2.02 (1.80 2.25) |
| **Area AB** | | | | | |
| n | 25 | 25 | 25 | 25 | 25 |
| $RD_{10Lv}$ | 1.71 (1.13 2.29) | 1.49 (1.06 1.93) | 1.58 (1.20 1.96) | 1.27 (0.67 1.87) | 3.75 (2.76 4.75) |
| $CRR_{Lv}$ | 0.37 (0.32 0.43) | 0.34 (0.28 0.39) | 0.32 (0.24 0.39) | 0.25 (0.16 0.34) | 0.77 (0.62 0.91) |
| $ACE_{Lv}$ | 0.94 (0.80 1.07) | 0.98 (0.82 1.13) | 0.94 (0.73 1.15) | 1.23 (0.80 1.66) | 2.08 (1.68 2.48) |

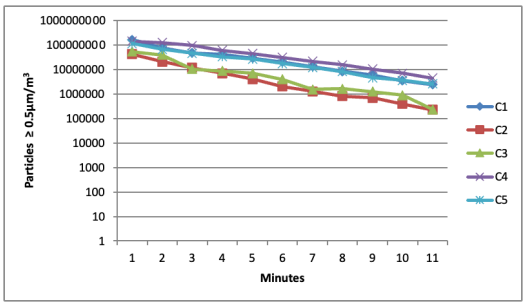
## 5.3 Statistical analysis

To determine differences between the ventilation systems regarding recovery degree (RD), cleanliness recovery rate (CRR) and air change effectiveness (ACE), a Kruskal-Wallis test was performed, since a normal distribution could not be assumed. As post hoc analysis, a Mann Whitney U Test was performed, with Bonferroni correction. IBM SPSS version 25 (IBM Corp. Armonk, NY: IBM Corp) was used. A *p*-value of 0.05 or less was considered statistically significant.

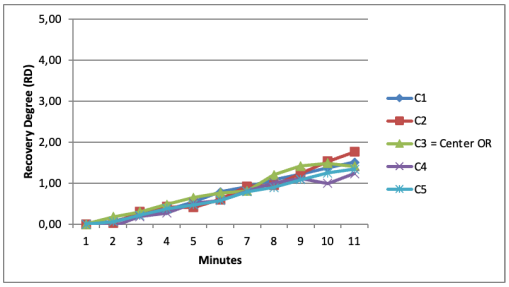
## 5.4 Findings and results

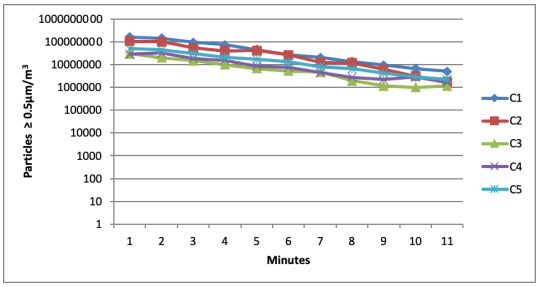
Results of the ventilation effectiveness low volume ($VE_{Lv}$) in area A, B and AB are presented in Table 5.1. The Conventional Ventilation (CV), controlled Dilution Ventilation (cDV) and Temperature controlled AirFlow (TcAF) ventilation systems show a comparable and stable recovery degree (RD) and cleanliness recovery rate (CRR) over time in Area A, B and AB when reducing the air change rate. Airborne particle concentration and $RD_{10Lv}$ per minute for the four ventilation systems of the middle row (C1-C5, Area AB) are shown in Figure 5.2.a-e. At all points for the UDAF-$2_{Lv}$ and at the center point (C3) of the $TcAF_{Lv}$, higher $RD_{10Lv}$ and $CRR_{Lv}$ were seen when compared to the measuring locations of the other examined ventilation systems (figure 2e). In the center of the operating room, at measuring location C3 (Figure 5.1.c) a higher $RD_{10Lv}$ (3.5) $CRR_{Lv}$ (0.8) and $ACE_{Lv}$ (2.1) were measured for the TcAF due to the working principle and design of this UCV-system [19]



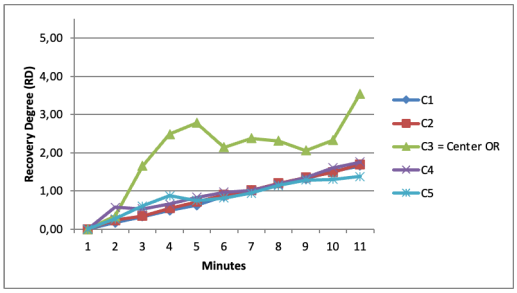



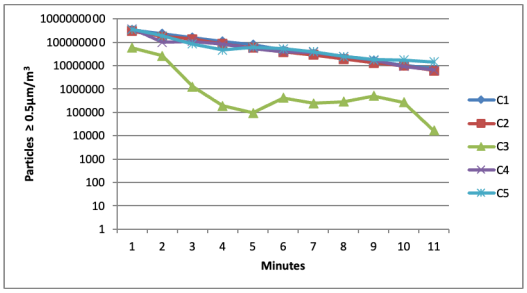

5.2.a The $RD_{10Lv}$ (left) and decay of airborne particles concentration $CRR_{Lv}$ (right) per minute at row C1-C5 of the CV system.




5.2.b The $RD_{10Lv}$ (left) and decay of airborne particles concentration $CRR_{Lv}$ (right) per minute at row C1-C5 of the cDV system.




5.2.c The $RD_{10Lv}$ (left) and decay of airborne particles concentration $CRR_{Lv}$ (right) per minute at row C1-C5 of TcAF system.

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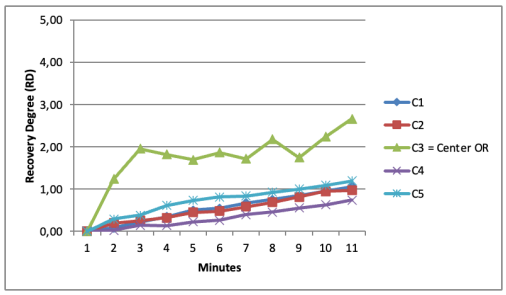
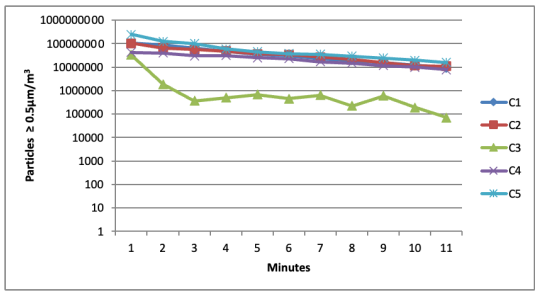
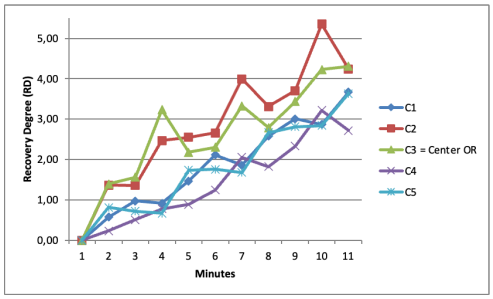
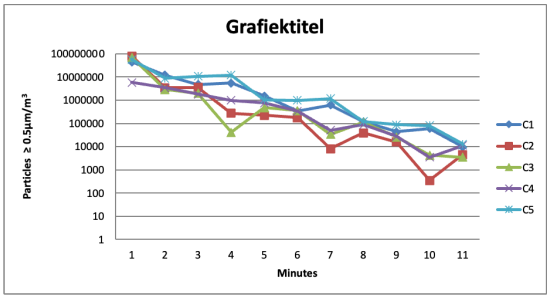



5.2.d The $RD_{10Lv}$ (left) and decay of airborne particles concentration $CRR_{Lv}$ (right) per minute at row C1-C5 of UDAF-1 system.




5.2.e The $RD_{10Lv}$ (left) and decay of airborne particles concentration $CRR_{Lv}$ (right) per minute at row C1-C5 of UDAF-2 system.

FIG. 5.2 The $RD_{10Lv}$ (left) and decay of airborne particles concentration $CRR_{Lv}$ (right) per minute at row C1-C5.

Comparison of the four types of ventilation systems in area AB is shown in Figure 5.3. The $VE_{Lv}$ ($RD_{10Lv}$, $CRR_{Lv}$ and $ACE_{Lv}$) was significantly higher for the UDAF-$2_{Lv}$ system compared to the other ventilation systems (Figure 5.3). For comparison, results of our previous study are presented in Table 5.2.

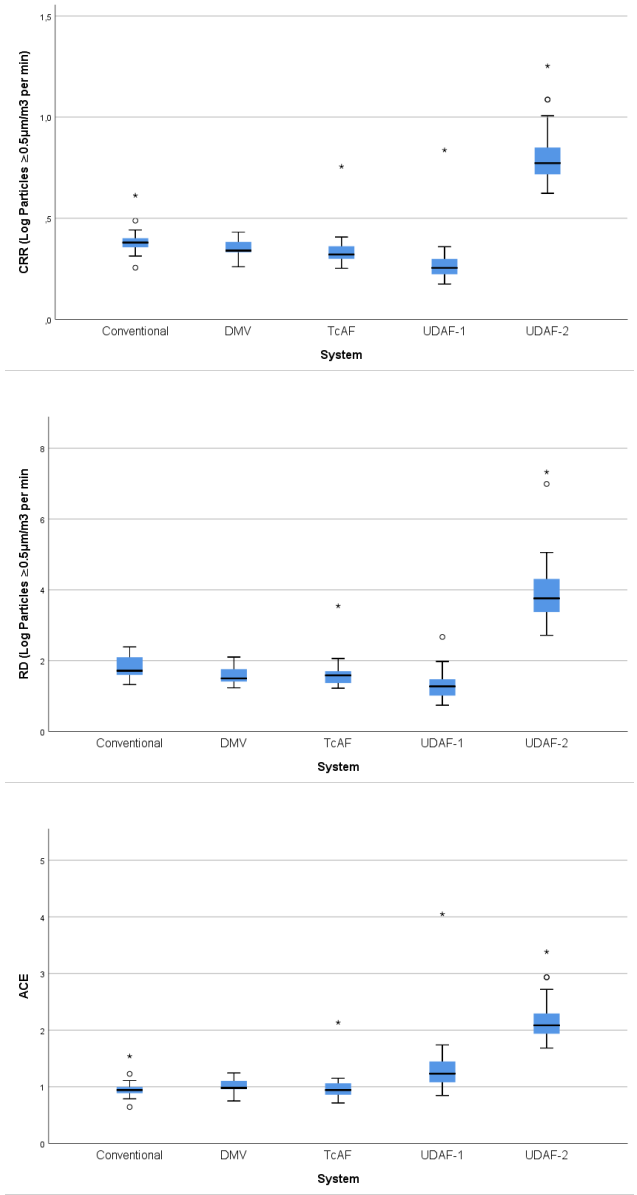



FIG. 5.3 Boxplots of Area AB to compare the ventilation effectiveness (VELv) of the different ventilation air supply systems. $RD_{Lv}$ (a), $CRR_{Lv}$ (b) and $ACE_{Lv}$ (c).



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TABLE 5.2 Descriptive ventilation effectiveness (VE) OR ventilation systems, Area A, B and AB. Results are presented as median and interquartile range (IQR).

| Ultra-clean Area | CV | cDV | TcAF | UDAF |
|---|---|---|---|---|
| Air volume [$m^3/h$] | 3,220 -3,344 | 9,800 | 6,848 -7,180 | 10,032 -10,379 |
| Number of Air Changes per hour (ACH) | 24-26 | 69 | 45-53 | 66-73 |
| **Area A** | | | | |
| n | 45 | 54 | 45 | 54 |
| $RD_{10}$ | 2.22 (1.72 3.42) | 4.18 (3.67 4.49) | 2.96 (2.75 3.61) | 6.00 (5.00 5.00) |
| CRR | 0.50 (0.38 0.66) | 1.21 (1.11 1.34) | 0.73 (0.58 0.86) | 5.41 (3.20 5.96) |
| ACE | 1.20 (0.91 1.58) | 1.07 (0.98 1.18) | 0.97 (0.74 1.11) | 4.62 (2.96 5.05) |
| **Area B** | | | | |
| n | 80 | 96 | 80 | 96 |
| $RD_{10}$ | 1.82 (1.59 2.33) | 4.60 (4.02 5.58) | 2.91 (2.34 3.98) | 4.45 (3.86 5.00) |
| CRR | 0.38 (0.33 0.42) | 1.21 (1.09 1.30) | 0.67 (0.55 0.73) | 1.10 (0.96 1.29) |
| ACE | 0.93 (0.81 1.05) | 1.06 (0.96 1.14) | 0.81 (0.73 0.96) | 0.96 (0.84 1.15) |
| **Area AB** | | | | |
| n | 125 | 150 | 125 | 150 |
| $RD_{10}$ | 1.94 (2.52 5.00) | 4.40 (3.95 4.95) | 2.92 (2.41 3.86) | 5.20 (4.16 5.00) |
| CRR | 0.41 (0.54 1.27) | 1.21 (1.10 1.31) | 0.70 (0.55 0.77) | 1.34 (1.02 3.45) |
| ACE | 0.98 (0.87 1.21) | 1.07 (0.97 1.15) | 0.87 (0.73 1.00) | 1.17 (0.95 3.21) |

## 5.5 Discussion

The goal of this study was to provide insight in what the effect is on the ventilation effectiveness when the air change rate in an ultra-clean operating room is reduced from in average 69 $h^{-1}$ to approximately 20 $h^{-1}$. The air volume of a class 1+ air handling installation and air supply system, according to the Dutch Federation of Medical Specialists (FMS) [4], was lowered to achieve the required air change rate per hour (≥ 20) as required for a FMS class 1 operating room.

When reducing the number of air changes to approximately 20 $h^{-1}$ the CV, cDV, TcAF and UDAF-2 measured in the current study comply to an OR Class I as described in the FMS [4]. These systems comply as well to other international standards and guidelines like the Swedish SIS TS 39, other surgery [10], the English HTM 03-01, conventional surgery [11], the German DIN1946-4, OR Class 1b [12] and French NF S 90 351, class zone 3 [13]. The UDAF-1 system in this study did not comply to an OR Class 1 as it was, without major modifications, not possible to increase the number of air changes to ≥ 20 $h^{-1}$. The OR air handling installation and CV, cDV, TcAF and UDAF-2 air supply systems in the current study can be, when not used for major (orthopedic) implants, large joints procedures or other infection prone surgeries, switched to a lower ACH. Reducing the ACH will reduce the energy consumption of the air handling installation [16,17]. Further study should be conducted to determine the extent to which reducing the air volume of UCV air supply systems translates into the reduction of energy consumption and the resulting level of Colony Forming Units (CFU) when reducing the air volume of UCV air supply systems.

In this study no major technical modifications were executed to reduce the ACH or air volumes of the air handling installation and air supply system, to allow for an equal ventilation effectiveness comparison of the results out of our previous [19] study. When comparing the $VE_{Lv}$ with the VE of our previous study, lower RDs and CRRs were seen in the current study (Table 5.1 and 5.2). Compared to our previous study, the 10 minutes recovery degree in area AB was 1,000 times lower for the cDV and UDAF when the number of air changes was reduced to 20$h^{-1}$. However, when reducing the ACH to 20, the recovery degree of the TcAF and UDAF-2 was only 100 times lower compared to the original design conditions. The local air change rate (CRR) was, compared to our previous study, decreased by 72% for the cDV and 81% for the UDAF-1, whereas the decrease in the local air change rate was lower for the TcAF and the UDAF-2 by 52% and 42%, respectively. In Area AB the results of the ACE were comparable with the ACE of the previous study, with exception of the UDAF-2 and TcAF. The ACE of the UDAF-2 and TcAF were

higher than the ACE in the previous study. In this study, the UDAF-2 and the TcAF performed best regarding VE when air change rates were reduced from an ultra-clean operating room to a generic operating room.

Reducing the air change rate in the operating room from an ultra clean operating room to a generic operating room will reduce the recovery degree ($RD_{10}$) with a factor 10 to 100. The local air change rate (CRR) will be reduced between 42% - 81%. The effect of lowering the air change rate possibly reduces contaminant removal effectiveness [26]. Because the examined ultra clean ventilation systems show a mixing character when reducing the air change rate per hour, no ultra-clean area or protected area [11] was created in the operating room as intended according to international standards and guidelines [4,10,12].

The $VE_{Lv}$ of an UDAF is not self-explanatory. A Uni directional air flow is designed to introduce the air directly above the ultra-clean area with a discharge velocity of 0.25-0.3 m/s [13,27]. The aim of the UDAF is to displace the body convection (thermal plume) generated by the surgical staff [27] and to reduce the microbiological concentration in the ultra-clean area [3,28]. When reducing the air volume of an existing UDAF system as executed in this study, it is important to know how the air handling system and air supply system is constructed. The $VE_{Lv}$ of an UDAF depends on whether it is possible to create an equal velocity under the entire surface of the UDAF. Without first making a comparable measurement corresponding to this study, it is not advisable to adjust the air volume of a UDAF. A study on how the different designed UDAF systems behave when reducing the air volume is recommended.

One limitation of the current study is that it was executed in an 'at-rest' situation. We therefor did not take the dispersion and contamination dynamics in the OR into consideration. We did not measure the level of CFU/$m^3$ in operating room when the air change rate was lowered. A further study should investigate what the effect is on the level of CFU/$m^3$ in the surgical field when reducing the number of air changes per hour in the operating room, taking into account the discipline of the surgical staff, number of door openings during surgery [29–31], the quality of the clothing [28,32,33] used, etc. The methodology used in this study offers a technical evaluation of the installed air handling installation and air supply system when reducing the air change rate.

Second, the number of ACH and total introduced air volume was not exactly the same per system. In case of the UDAF-$1_{Lv}$ it was technically not possible to adjust the air volume without major technical changes. This resulted in a lower number (12, see Table 5.1) of air changes at the UDAF-$1_{Lv}$. Another UDAF-$2_{Lv}$ system, at a different clinic, was selected and assessed for comparison with the CV system and other UCV systems.

Third, the conventional ventilation (CV) system in this study was designed as a mixing system Class 1 [4] according to the FMS and not as an ultra-clean ventilation air supply system. The effect of reducing the air volume or number of air changes for this system was not assessed in this study. **Conclusion,**

The ventilation effectiveness decreases when an ultra-clean OR with an ultra-clean ventilation air supply system is switched, from in average 69 $h^{-1}$ [15], to an air change rate of 20$h^{-1}$. Reducing the air change rate in the operating room from an ultra clean operating room to a generic operating room will reduce the recovery degree ($RD_{10}$) with a factor 10 to 100 and the local air change rate (CRR) between 42% and 81%. The low volume ventilation effectiveness ($VE_{Lv}$) was higher for the UDAF-$2_{Lv}$ system compared to the other ventilation systems. In this study, the UDAF-2 and the TcAF performed best regarding the ventilation effectiveness (VE), as defined in this study, when air change rates were reduced from an ultra-clean operating room to a generic operating room.

## Acknowledgements

The authors would like to thank the staff of the Dutch hospitals: IJsseland - Capelle a/d IJssel, Leiden University Medical Center - Leiden, Rijnstate – Arnhem, Nij Smellinghe – Drachten, Boerhaave Medical Centre - Utrecht, for making the operating rooms available for the measurements.

## Conflict of interest statement

J.L.A. Lans is CEO of Medexs BV, a company that supplies and install OR ventilation systems. All other authors report no conflict of interest relevant to this article.

## Funding statement

None, this research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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# 6 Significant reduction of energy demand in operation rooms

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PUBLISHED Submitted to Journal

KEYWORDS Operating Room, Ultra-clean Ventilation systems, Energy demand, Energy savings

ABSTRACT **Background –** An operating room (OR) department is one of the most energy-intensive departments in a hospital. Due to the strict air-conditioning requirements, the OR air handling system demands the most energy of the entire OR department.
**Aim –** To determine the possible reduction of the energy demand of OR air handling installations in the Netherlands.
**Methods –** Quantitative data was collected using a questionnaire sent to 91 Dutch hospitals. Data collected included air volumes, type of air handling system, hours of operation, number of operating rooms, etc. The temperature and relative humidity of various components in the make-up and recirculation air handling units were measured at 9 locations. The theoretic energy requirement to condition the air was calculated using a model based on air properties on hourly bases.
**Findings –** Of the ORs in the 51 responding hospitals, 94% have an ultra-clean air supply system, and 80% of the ORs are classified according to the highest OR classification. Reducing the amount of outside air (ODA) to 1,000 $m^3/h$ during and to 500 $m^3/h$ outside operating hours would reduce thermal energy demand by 53% on

average and electrical/mechanical by 49%. Implementing clock times would reduce thermal energy demand by 41% and electrical/mechanical by 60%. Changing relative humidity limits would reduce thermal energy demand by 36% on average. **Conclusion –** Reducing ODA and introducing clocktimes have the greatest impact on energy demand. Relatively simple modifications to reduce energy demand include widening relative humidity limits and introducing operational clock times. Lowering the OR classification has the least impact.

## 6.1 Introduction

Energy consumption in healthcare is relatively high; worldwide, hospitals account for about 6% of total building energy use [1]. One of the most energy-intensive departments of a hospital is the operating room (OR) department, and there is an increasing awareness of the need to reduce the carbon footprint in operating rooms [2]. Hospitals and other care institutions in the Netherlands signed a Green Deal on sustainable healthcare to minimize their waste, use less energy, and take actions to become more sustainable: by 2030, carbon emissions must be at least 55% lower than in 1990, and by 2050 all care organizations shall be carbon neutral.

In hospitals, the heating ventilation and air-conditioning (HVAC) system or air handling installation (AHI) is responsible for the greatest share of the total hospital end-use energy consumption ranging from 50% to 75% [3,4].In the OR, the air handling and air supply system is essential for reducing the risk of surgical site infections (SSI) [5,6] and to create a safe and comfortable working environment for the surgical staff [7]. An operating room can be equipped with a conventional (CV) or ultra-clean (UCV) air supply system. For ORs that are used for large artificial implants, most national standards and guidelines in Europe [8–13] advise or require an UCV system [5,14,15]. An operating room equipped with an UCV system entails higher air volumes [6,15,16] than a conventional ventilation (CV) system [11] ], which implies a higher energy consumption.

Due to the stringent air conditioning requirements in ORs compared to other inpatient areas, the operating room air handling installation uses most of the energy of the operating room complex (i.e. 90-99% of energy consumed at the operating room complex [2,17]).

The energy used by the AHI and the air supply system mainly depends on the type of ultra-clean or generic ventilation system and on the settings for air volume, temperature, humidity, etc. [8–10,18,19]. The required air volume and the boundary conditions of the temperature and relative humidity are described in standards and guidelines [8–13].

The aim of this study was to determine the energy demand and the energy saving potential of air handling and air supply systems in ORs in the Netherlands.

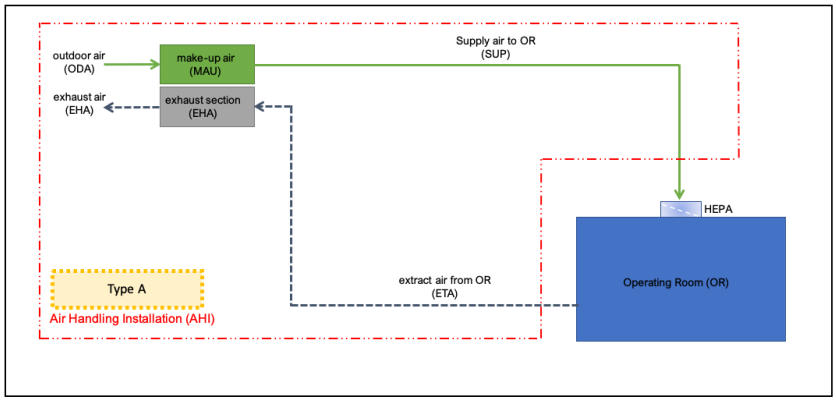
The data obtained from this study will provide valuable insights into the energy demand of OR air handling installations and OR air supply systems [19] and into the potential reduction of energy demand that can be achieved through four realistic scenarios.

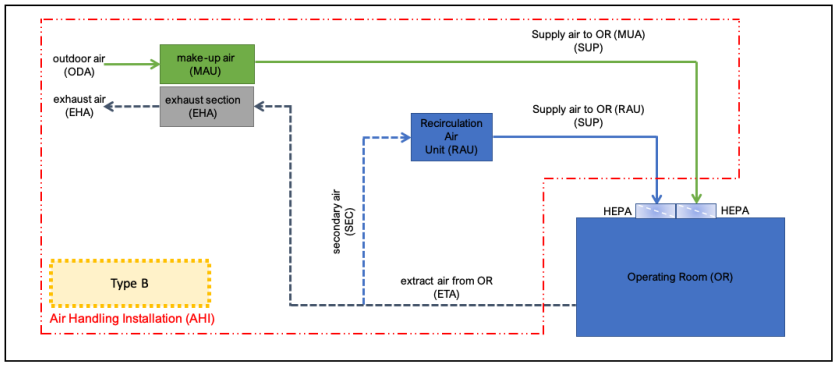
## 6.2 Methodology

### 6.2.1 Questionnaire

Qualitative data were collected by means of a questionnaire sent to 91 hospitals in the Netherlands. We used a structured questionnaire with close-ended questions about the operating rooms. The requested data concerned the running hours, the type of air handling and air supply system, air volumes, number of operating rooms, OR classification, the boundary conditions of the relative humidity and temperature, and the amount of outdoor and recirculation air.

Three air-handling installation typologies were defined [18]: type A, type B, and type C (Figure 6.1) and four OR air supply systems [20] were defined; Conventional ventilation (CV), controlled Dilution Ventilation (cDV), Temperature-controlled AirFlow (TcAF), and Uni-Directional AirFlow (UDAF) [20]. The different air handling typologies and working principles are explained in our previous studies [18,20].



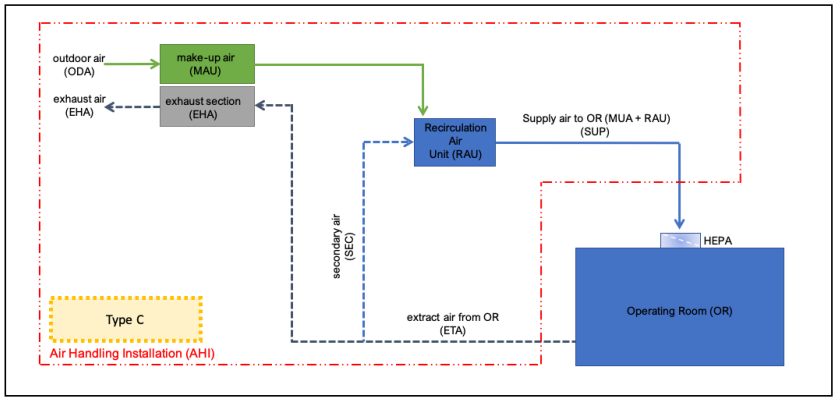




FIG. 6.1 Three typologies of OR air handling systems, type A, type B, and type C.



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### 6.2.2 Measurements

During a period of 3 months, quantitative data were collected of 9 operating rooms in 3 academic hospitals, 3 regular hospitals and 2 private clinics geographically distributed throughout the Netherlands. Once every 10 minutes, the temperature and relative humidity were measured upstream and downstream of components in the make-up air handling unit (MUA) and the recirculation air handling unit (RAU).

The following parameters were measured per hospital:

- Supply air temperature OR [°C].
- Extraction air temperature OR [°C].
- Temperature increase fan [°C].
- Humidity RH [%].

Measurements were performed with RF Sensors (T Comm Telematics, the Netherlands) during the months of June, July and August 2024. Temperature (T) range was -20 to +50°C with an accuracy of ± 0.5°C, resolution 0.1°C, and relative humidity (RH) range was 20 to 80% with an accuracy of ± 4.5% (at 25°C), resolution 0.04%.

### 6.2.3 Reference situation

For each hospital, a reference situation was determined based on the results of the questionnaire and the conducted measurements. See Table 6.2, paragraph 6.3.2. The reduction of the energy demand in this study was based on the energy demand needed to condition the air in the operating room to the required conditions for an ultra-clean OR and a conventional (generic) OR [21]. For all hospitals, we assumed a reference situation in which the air handling system had no clock times, the strict OR conditions were maintained, and air volumes were in accordance with the design criteria.

For the calculation model used in this study, the following parameters were either calculated [21] or derived from scientific literature or standards and used as input:

- Moisture gains in the operating room [g/kg],
- Moisture efficiency of the heat recovery system when a heat rotary wheel is used (heat rotary wheel, EN 13141-7:2021),
- Temperature efficiency of the heat recovery system (according to EN 13141-7:2021),
- Start time, End time, Weekend off.

The temperature increase in the operating room was calculated by subtracting the temperature of the supply air from the average temperature of the return air. To determine the moisture increase in the operating room, we subtracted the value of the absolute moisture in g/kg of the air supplied into the OR from the absolute moisture in g/kg of the return air.

For the make-up air handling unit (MUA), outside air (ODA) conditions were used that correspond to a typical Dutch climate year according to the NEN 5060. The NEN 5060 contains representative Dutch reference climate data on hourly bases for determining the energy performance of buildings and for dimensioning heating, cooling and air-conditioning installations for buildings.

### 6.2.4 Calculation model

The theoretic energy requirement to condition the air [21] for the operating room on an hourly basis was calcaulted with a calculation model developed by the Netherlands Organization for Applied Scientific Research (TNO), based on air properties.

Compared to the reference situation, the energy saving potential was determined for different scenarios via a calculation model. For this study, four realistic scenarios were defined:

1. Scenario A, expanding the boundary conditions for relative humidity [22]. The relative humidity was changed from a range of 50-65% to a range of 30-70%.
2. Scenario B, switching to a standby mode when the OR is not in use, at night or on weekends [23]. The running hours were changed from 00:00h – 24:00h, weekends ON to 07:00h-18.00h, weekends OFF.
3. Scenario C, lowering the volume of outside air (ODA) [9,11]. The ODA was lowered from the original design values to 1,000 $m^3/h$ during operating hours and 500 $m^3/h$ in standby mode and on weekends.
4. Scenario D, lowering the total supply air (SUP) introduced into the OR [24]. The SUP was set to 3,000 $m^3/h$ (generic/conventional operating room).

The results of the four independently defined scenarios cannot be added together. The scenarios are inextricably linked to onanother.

The boundary conditions of the relative humidity were based on the report of TU/e, TNO, 2021, Humidification requirements in care facilities: knowledge base [25].

Based on the advice of the Dutch Federation of University Medical Centers (in Dutch Nederlandse federatie van Universitair Medische Centra), we reduced the amount of outdoor air to 1,000 $m^3/h$ [26] during operating hours. The reduction of the total supply air (SUP) into the operating room was based on the research of Lans et al [24].

The efficiency of the heat rotary wheel and the twin coil system installed in the air handling units may vary during this time frame as the system switches on and off to avoid unnecessary heating or cooling. The calculation model considers that the heat recovery is turned off when the temperature after heat recovery is higher than the temperature of the incoming air. If the outdoor temperature rises above the return temperature, then the heat recovery is turned on again to cool. In one hospital, we conducted a sensitivity analysis to assess the influence of different efficiencies at the installed heat recovery system on the results in the calculation model. These analyses showed that this influence is not negligible; therefore, in the calculation model, we used a temperature efficiency of the heat recovery system of 47% for the twin-coil (run around) system [27] and calculated temperature efficiency of the heat rotary wheel with equation 1 [28].

$$\eta_t = 0.007\Delta t + 0.54 \quad (1)$$ EQ. 6.1

Where:
*ŋt = temperature efficiency heat rotary wheel.*
*Δt = temperature difference between fresh outdoor air and return air temperature.*

The fan power of the recirculation air handling unit (RAU) and of the make up air handling unit (MUA) [kWh] was measured at several hospitals and used as input for the model of TNO. In this model, we calculated the energy demand, including the heat and cold demand (thermal) of the air handling installation and the energy demand for the fans (electrical/mechanical).

Based on the reference situation defined in this study, the energy-saving potential of an ultra-clean and generic operating room was determined for each of the scenarios (A,B,C and D) (see Figure 6.3.b).

# 6.3 Results

## 6.3.1 Questionnaire

TABLE 6.1 Results questionnaire. SD is standard deviation.

| Results Questionnaire | n | | | | |
|---|---|---|---|---|---|
| **Operating Room (OR) Ventilation system** | 51 | Ultra Clean air supply system | Classified as ultra-clean (OR Class 1+) | | |
| | | 94% | 80% | | |
| **ORs used as ultra-clean OR (OR Class 1+)** | 48 | All ORs | ¼ of the ORs | ½ of the ORs | ¾ of the ORs |
| | | 32% | 42% | 18% | 8% |
| **Air handling system** | 51 | Typology A | Typology B | Typology C | |
| | | 16% | 41% | 43% | |
| **Type of air supply systems*** | 51 | Conventional Ventilation (CV) | controlled Dilution Ventilation (cDV) | Temperature controlled Air Flow | Uni Directional Air Flow (UDAF) |
| | | 6% | 8% | 8% | 86% |
| **Type of heat recovery air handling installation** | 48 | Twin-coil system | Heat recovery wheel | Plate heat exchanger | No heat recovery system installed |
| | | 46% | 46% | 2% | 2% |
| **Air volume** | 49 | Make Up Air (MUA) [$m^3/h$] | Recirculation Air Unit (RAU) [$m^3/h$] | Total amount of air (SUP) [$m^3/h$] | |
| Minimum | | 1,000 | 2,000 | 2,363 | |
| Maximum | | 9,100 | 11,340 | 12,500 | |
| Mean (SD) | | 2,728 (1,317) | 6,737 (2,044) | 8,641 (2,363) | |
| **Setpoint relative humidity (RH) between** | 51 | 50-65% RH | 30-70% RH | 40-80% RH | Other setpoint RH |
| | | 57% | 27% | 4% | 12% |
| **Reduction AHI when not in use**** | 51 | Capacity reduced to >50% | Capacity reduced to 30-40% | Capacity reduced to 20% | Installation remains on 365 days, 24/7 |
| | | 32% | 38% | 10% | 20% |

**The total is higher than 100% because some respondents had installed different types of air supply systems in the OR complex. **Outside operating hours and on weekends.*



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Respondents in 51 hospitals completed the questionnaire (56%). The results of the questionnaire (see Table 6.1) show that 94% of the participating hospitals have an air handling installation with an ultra-clean ventilation (UCV) system installed, and 80% of the ORs were classified according to the highest OR classification. 60% of the hospitals were using half or even fewer of the ORs on the OR department for major (orthopedic) implant surgery, for which the highest classification is required [19].

The amount of fresh outside air from the makeup air unit (MUA) varied between 1,000 and 4,500 $m^3/h$, with one peak up to 9,100 $m^3/h$, see Table 6.1 and Figure 6.2.

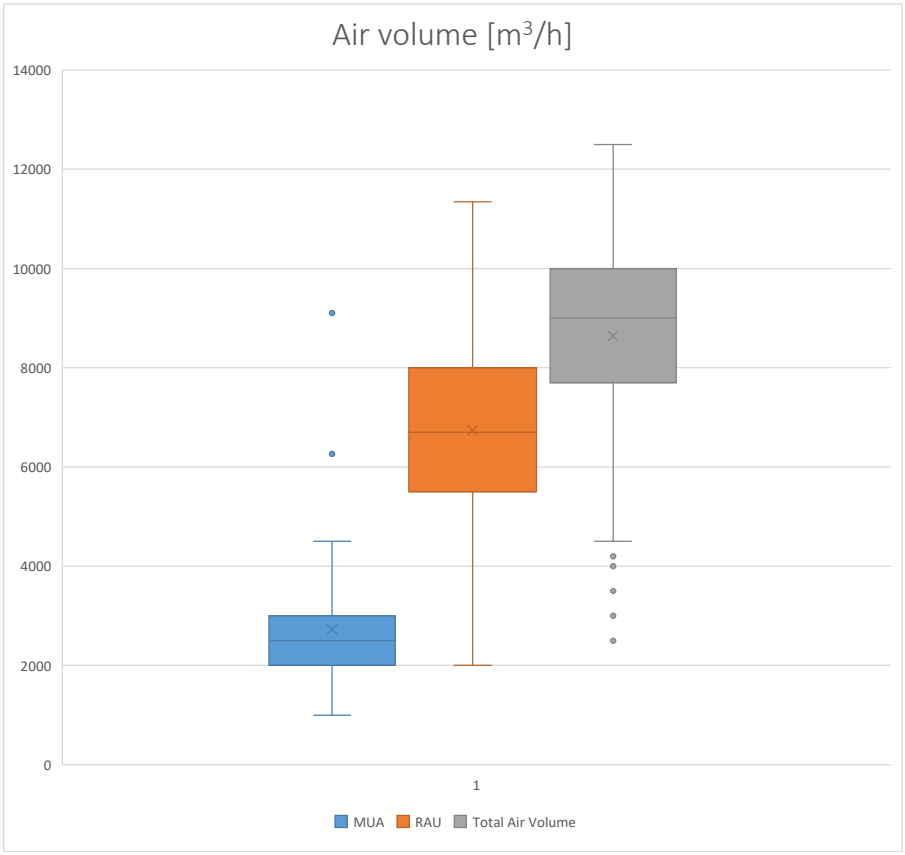



FIG. 6.2 Air volumes in operating rooms of 51 Dutch hospitals.

In 80% of the participating hospitals, the air handling installation was switched to a lower running mode after operating hours and on weekends, while this was not done in the remaining 20% of the hospitals. The setpoint of the relative humidity was between 50 and 65% in 57% of the hospitals, between 30 and 70% in 27% of the hospitals and and between 40 and 80% in 4%, other boundaries 12% of the hospitals. Almost all the hospitals (98%) use heat recovery systems to exchange heat between the exhaust air and fresh outdoor air flow.

### 6.3.2 Calculation model and reference situation

Table 6.2 presents the reference situation per hospital derived from the measurements conducted in 6 hospitals, 2 private clinics with in total 9 operating rooms. This data was used as input for the calculation model. The Dutch hospitals and private clinics were the measurements were conducted completed the questionnaire as well.

TABLE 6.2 Reference situation in 9 operating rooms, data used for input in the model.

| Hospital | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|
| Typology air handling system* | C | B | C | C | C | C | B | B | B |
| Typology heat recovery system* | Ro | Ru | Ru | Ro | Ro | Ro | Ru | Ro | Ro |
| Average inlet temperature OR [°C]** (SD) | 20.06 (0.97) | 21.17 (0.87) | 19.00 (1.26) | 19.08 (1.03) | 19.52 (0.18) | 20.02 (0.42) | 18.95 (0.15) | 19.19 (0.51) | 20.54 (0.60) |
| Temperature increase OR [°C]** | 2.05 | 0.77 | 0.80 | 0.95 | 0.81 | 0.95 | 1.34 | 0.10 | 0.00 |
| Temperature efficiency HRS (EN 13141-7:2021) | Ro | Ru | Ru | Ro | Ro | Ro | Ru | Ro | Ro |
| Moisture increase OR [g/kg]** | nihil | nihil | nihil | nihil | nihil | nihil | nihil | nihil | nihil |
| Moisture efficiency HRS (Ro) EN 13141-7:2021) | 65 | n.a. | n.a. | 65 | 65 | 65 | n.a. | 65 | 65 |
| Temperature increase fan [°C]** | 1.50 | 0.78 | 1.33 | 1.42 | 1.33 | 0.62 | 0.81 | 1.49 | 1.47 |
| Cooling to dew point and reheat | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| Maximum Relative Humidity (RH)* | 65 | 65 | 65 | 65 | 65 | 65 | 65 | 65 | 65 |
| Minimum Relative Humidity [RH]* | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 | 50 |
| Working hours (start) | 0:00 | 0:00 | 0:00 | 0:00 | 0:00 | 0:00 | 0:00 | 0:00 | 0:00 |
| Working hours (end) | 24:00 | 24:00 | 24:00 | 24:00 | 24:00 | 24:00 | 24:00 | 24:00 | 24:00 |
| Weekend Off | No | No | No | No | No | No | No | No | No |
| Outside air (ODA) [$m^3/h$]* working hours | 2,000 | 2,500 | 2,000 | 2,800 | 2,000 | 1,000 | 3,000 | 3,000 | 3,000 |
| Fan power [kW]** ODA working hours | 1.0 | 1.0 | 2.6 | 2.7 | 1.0 | 1.0 | 1.7 | 4.8 | 2.9 |
| Outside air (ODA) [$m^3/h$]* non-working hours | 900 | 750 | 500 | 1,368 | 500 | 500 | 900 | 900 | 900 |
| Supply air (SUP) *or* secondary air (SEC) [$m^3/h$]* working hours | 11,728 | 7,300 | 15,040 | 7,000 | 15,129 | 2,000 | 7,368 | 7,836 | 1,320 |
| Fan power [kW]** (SUP or SEC) working hours | 3.5 | 2.1 | 8.0 | 3.8 | 2.0 | 0.3 | 1.6 | 1.2 | 0.4 |
| Supply air (SUP) *or* secondary air (SEC) [$m^3/h$]* non-working hours | 3,968 | 2,190 | 3,500 | 3,500 | 1,690 | 1,190 | 2,200 | 2,350 | 400 |

HRS: Heat Recovery System, Ro: Rotary heat wheel, Ru: Run around coil.
*Data based on questionnaire. ** Data from measurements in hospitals and private clinics.

### 6.3.3 Thermal and electrical/mechanical energy saving potential

Table 6.3 presents the energy saving potential for the defined scenarios A, B, C and D. Compared to the defined reference situation in this study, widening the limits of relative humidity, scenario A, from a range of 50-65% to a range of 30-70% will reduce thermal energy demand by an average of 33%, while the electrical/mechanical energy demand remains the same. Scenario B, changing the operating hours from 00:00h – 24:00h, weekends ON to 07:00h - 18:00h, weekends OFF, will reduce the thermal energy demand on average by 41% and the electrical/mechanical by 60%. Lowering the amount of outside air (ODA) to 1,000 $m^3$/h during operating hours and 500 $m^3$/h outside operating hours (scenario C) will reduce the thermal energy demand by an average of 53% and the electrical/mechanical by 49%. In scenario D, reducing the SUP to 3,000 $m^3$/h during operating hours will not change the thermal energy demand, while the electrical/mechanical energy demand will decrease by 36%. See Figure 6.3.a for the thermal and Figure 6.3.c for the electrical/mechanical energy saving potential for the different scenarios A,B, C and D. For the energy saving potential, see Table 6.3.

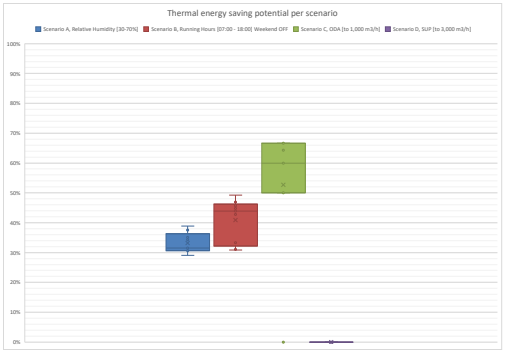
TABLE 6.3 The energy saving potential, thermal and electrical/mechanical, for the defined scenarios compared to the reference situation and the energy saving potential for an ultra-clean and generic operating room if all scenarios are implemented.

| Scenario | A | B | C | D | Generic All scenarios implemented | Ultra-Clean All scenarios implemented |
|---|---|---|---|---|---|---|
| **Thermal (min-max)** | 33% (29%-39%) | 41% (31%-49%) | 53% (0%-67%) | 0% (0%) | | |
| **Electrical / Mechanical (min-max)** | 0% (0%) | 60% (47%-64%) | 49% (0%-92%)* | 36% (0%-64%)* | | |
| **Thermal (min-max)** | | | | | 78% (52%-85%) | 78% (52%-85%) |
| **Electrical / Mechanical (min-max)** | | | | | 93% (56%-99%) | 82% (56%-99%) |

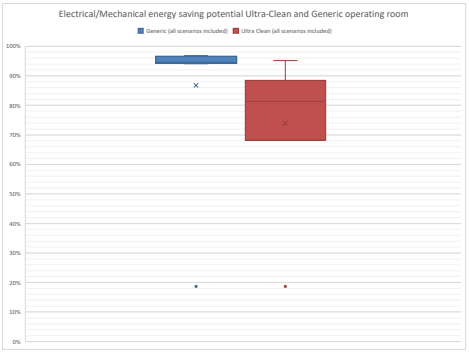
**The variation arises because the reference set also includes ORs that are generic/conventional with lower air volumes, where no savings occur. If those generic/conventional ORs are excluded, the electrical/mechanical energy demand for scenario D varies from 31%–64%. However, the current variation of the data set provides a representative view of the energy demand saving potential.*

If all described scenarios in this study are implemented, a 78% thermal and an 93% (min. electrical/mechanical energy demand reduction can be realized for a generic operating room. Changing the OR classification from ultra-clean to generic shows that there is no difference in thermal energy demand. The electrical/mechanical energy demand reduction for a generic and ultra-clean operating room is 93% and 82%, respectively. Changing the OR from an ultra-clean to a generic operating room shows that there is a decrease in electrical/mechanical energy demand of on average 11%.

The combined results of the studied energy-saving scenarios (A, B C and D) for an ultra-clean operating room and for a generic operating room are presented in Figure 6.3.b (thermal) and Figure 6.3.d (electrical/mechanical).




6.3.a

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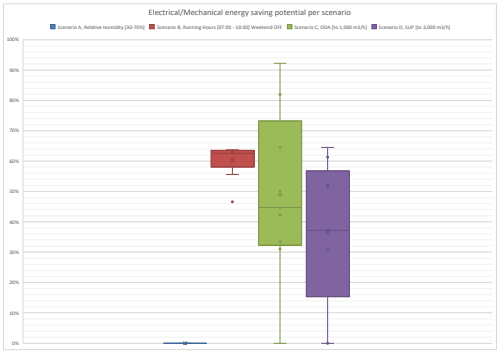
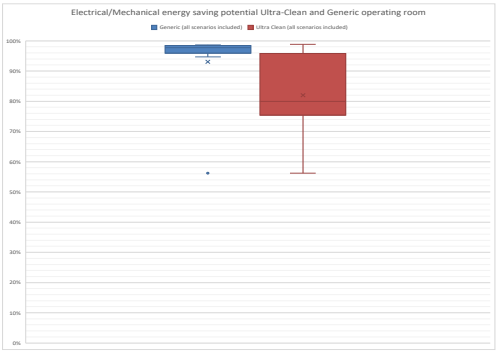



6.3.c




6.3.d

FIG. 6.3 Thermal energy demand saving potential per scenario (6.3.a). Thermal energy demand saving potential for an Ultra-clean and Generic operating room air handling installation when implementing all scenarios (6.3.b). Electrical/ mechanical energy demand saving potential per scenario (6.3.c). Electrical/ mechanical energy demand saving potential for an Ultra-clean and Generic operating room air handling installation when implementing all scenarios (6.3.d).

## 6.4 Discussion

The aim of this study was to determine the energy demand and to calculate the energy saving potential of air handling and air supply systems in ORs in the Netherlands. Based on qualitative data of 51 Dutch hospitals and quantitative measurements in 8 of these hospitals, at 9 locations, the energy savings were calculated that can be achieved through four realistic scenarios.
Implementing all the scenarios A, B, C and D described in this study can achieve a reduction of the thermal energy demand of the air handling system of 78% and a reduction of the electrical/mechanical energy demand of 82%-93%.

This study shows that several hospitals supply significantly more outside air (ODA) than minimally required or prescribed in guidelines [8,10,19]. Outside air is energy-intensive because it must be heated, cooled, humidified or dehumidified (thermal) and distributed (electrical) in the MUA. Reducing the amount of outdoor air (ODA) to 1,000 $m^3$/h during operating hours and to 500 $m^3$/h during non-operating hours will reduce thermal energy demand by an average of 53% per OR per year compared to the defined reference situation. Electrical/mechanical energy demand can be reduced by 49%. The power output of the fans in the MAU and RAU seemed to be higher than what would theoretically be expected in some hospitals. This may be due to the typology of the air handling installation or higher resistances in the air handling system. It is recommended to pay attention to this when designing the OR air handling installation.

Reducing the amount of ODA to 1,000 m3/h during operating hours is in accordance with the advice of the Dutch Federation of University Medical Centers (in Dutch Nederlandse federatie van Universitair Medische Centra)[26]. According to the EN-16798-3:2017 [29], the total supply air (SUP) introduced into the operating room (OR) is the sum of outside air (ODA) and secondary air (SEC). To reduce the amount of outside air, European norms and guidelines [5,6,8,21] allow recirculation of air in the same operating room [8–11,19,30]. Standards do advise a minimum amount of outside air (ODA) of 2,000 $m^3$/h to reduce the concentration of inhalation anesthesia gasses in the OR as low as reasonably achievable (ALARA) or when surgical smoke is generated [31,32]. With the advice to reduce the use of anesthetic gasses [33] and to use better extraction methods, it is possible to reduce the ODA. The German DIN 1946-4: 2018-09 [9] and the Swiss SWKI VA105-01 [11] recommended an ODA of 1,200 $m^3$/h and. 800 $m^3$/h, respectively.



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Before making any modifications to the OR air handling installation to reduce the ODA, it is advisable to investigate whether the existing air handling installation and OR air supply system can be technically modified to implement this energy-saving measure. When the OR is not in use, it is necessary to maintain a certain pressure hierarchy [34,35]. Therefore, lowering the ODA is not a given for each individual operating room. Before any changes are made to the OR air handling system to lower ODA, a blower door test is recommended to determine room leakage.

The defined reference situation for each OR includes the continuous operation of the air handling installation. Of the Dutch hospitals that participated in this study, 20% do not switch their air handling installation to a lower air volume after operating hours or when the OR is not in use on weekends. However, 80% of the hospitals did use clocktimes. The energy demand savings for those hospitals will differ from our results and should be calculated per hospital. Energy savings can be realized by switching the operating room air handling and air supply systems to standby during the daytime when the OR is not in use, at nights and on weekends, or, if technically possible, by switching the system off completely [23,36]. When the air handling installation is set to a standby mode through clock times from 07:00h - 18:00h, thermal energy demand is reduced by 41% compared to the defined reference situation. Electrical/mechanical energy demand can be reduced by 60%.

Our study shows that in 57% of the operating rooms in the participating hospitals, relative humidity is set between 50 and 65%. In various standards and guidelines, the relative humidity during surgery is advised to be between 30 and 70% [8–10]. This advice is in line with the outcomes of other studies and reports [22]. Changing the boundary conditions of the relative humidity to 30-70% will reduce the thermal energy demand by 33% compared to the defined reference situation of 50-65% described in our study.

Guidelines [8–11,19,30] allow room to vary the classification of the operating room, and not all surgeries require an ultra-clean operating room. However, the present study showed that most operating rooms in the Netherlands have an air handling system with an ultra-clean ventilation (UCV) system installed in the operating room, while 60% of hospitals use half or even less of the number ORs in the OR complex for major (orthopedic) implant surgery. If the ultra-clean ventilation system is switched from an ultra-clean to a generic operating room level, the energy demand is reduced. Lowering the classification from an ultra-clean to generic operating room will reduce the number of air changes (air volume) of the OR air handling installation [37,38] and air supply system [24]. Contrary to our expectations, however, lowering the classification of the operating room from an ultra-clean to a generic operating room generates no decrease in thermal energy demand and an electrical/

mechanical energy demand reduction of 11% per operating room per year. However, it is important to analyze in advance how the air supply system will behave when the air change rate is reduced [39] before the settings of an air handling installation are changed from an ultra-clean to a generic operating room level.

For scenario D, reducing the air volume, the inlet temperature, and temperature increase remained constant in our study. We did not consider the possible temperature increase and a changing heat load. Further research on the impact of a possible temperature increase and changing heat load when reducing the air volume is recommended.

### Limitations

The results of this study are based on data out of the questionnaire and measurements in Dutch hospitals in an average Dutch climate. The selected hospitals are geographically distributed throughout the Netherlands, have different typologies of air technology installations and heat recovery systems, vary in the amount of outside air that is introduced and have different OR classifications. This variation found at the hospitals causes a relatively great standard deviation in the energy demand results of the electrical/mechanical for scenario C and D as presented in the results section. However, the measurements show small differences in the reference situation and therefore the results of this study can be used for most Dutch hospitals. Since we found different air handling typologies in these hospitals, the results in this study are not applicable to all hospitals to the same extent. A further study is recommended to investigate if the energy saving potential is similar in ORs in other European countries.

This study did not consider the energy saving potential of the hospital heating and cooling plant, which is an important factor in a hospital's total energy consumption and energy cost savings. Since heat and cold generation varies from hospital to hospital, we did not include the possible energy reduction of the heating and cooling pland in our study.

The energy saving potential was calculated with a calculation model with input from measurements of the temperature and relative humidity of various components in the make-up and recirculation air handling units at 9 different locations. The type of surgery, the number of people in the OR, the medical equipment used, the internal heat load etc. varied during our study and were considered, but we did not measure the real energy consumption through heating and cooling coils nor the energy consumption of the humidifier or other air handling system components which consume energy.

We took measurements during the months of June, July and August 2024, and the results show a limited standard deviation between the different measurements, although the climate conditions differed during these three months. We consider our measurements to be representative for the entire year. The efficiency of the heat rotary wheel and twin coil system may vary during this time frame because the system switches due to the control system, which prevents unnecessary heating or cooling. In our calculation model, we assumed an average annual efficiency for the moisture efficiency.

The scope of the present study did not include energy-saving measures such as switching off medical equipment or switching the air handling system off completely [23,36] at night and on weekends. Future research should study the impact of those measures on the energy consumption of an OR.

In the model, we calculated the thermal and electrical/mechanical energy demand. We calculated the heat and cold demand (thermal) of the air handling installation and the energy demand for the fans (electrical/mechanical). We did not calculate the overall energy consumption based on efficiencies of the heat, cold and electrical/mechanical installation.

The results of the present study enable hospitals to estimate the energy-saving potential of their ORs that can be realized by implementing rational energy-saving measures such as reducing the amount of fresh air introduced, setting the air handling installation on standby at night or on weekends and widening the limits of the relative humidity. The study revealed that energy-saving measures have been implemented in most OR air handling installations but there is room for improvement regarding energy consumption.

**Conclusion**

Reducing ODA and introducing clocktimes have the greatest effect on energy demand, although modification of the ODA is more complicated to implement in existing air handling systems. Air handling installation typology C is the most flexible in terms of modifying ODA and SUP. Relatively simple modifications to reduce energy demand include widening the relative humidity limits and introducing operational clock times. Lowering the OR classification has the least impact on the combined energy demand. The increasing demand for energy reduction requires an air handling system that can handle a changing ODA demand.

## Acknowledgements

The authors would like to thank the staff of the Dutch hospitals: Antonius Hospital – Sneek, Erasmus MC – Rotterdam, University Medical Center Utrecht – Utrecht, Leiden University Medical Center - Leiden, Maxima Medical Center – Veldhoven, IJsseland Hospital - Capelle a/d IJssel, FlexClincs – Utrecht, Eyescan - Utrecht, for making the operating rooms and air handling installations available for the measurements.

## Conflict of interest statement

J.L.A. Lans is CEO of Medexs BV, a company that supplies and installs OR ventilation systems. All other authors report no conflict of interest relevant to this article.

## Funding statement

This research is funded from the Ministry of Health, Welfare and Sport (VWS) under the Urgenda Agenda Measure 51.

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# 7 Capital and operational expenditures of different operating room air-handling installations

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PUBLISHED **Journal of Building Engineering** | DOI: 10.1016/j.jobe.2023.107714

RUNNING TITLE Capital and operational expenditures of different operating room air-handling installations with conventional or ultra-clean air supply systems

KEYWORDS Capital expenditures, Operational expenditures, Air handling installation, Operating room, Surgical Site Infection

ABSTRACT When making a decision on the operating room air handling installation and type of air supply system, it is relevant to know the expenditures of the different air handling installations and air supply systems. The aim of this study was to determine the capital and operational expenditures of air handling installations equipped with an ultra-clean or with a conventional system. To compare the technical requirements of Dutch air handling installations with European standards and guidelines and evaluate the costs of surgical site infections in comparison with the capital expenditures. This study fills a gap in knowledge, detailed technical information and costs of air handling installations and air supply systems from multiple completed projects of 24 hospitals were collected, analyzed and compared. Per OR capital expenditures increase by €62,491 to €139,018 when an air handling installation with an ultra-clean system is compared to a conventional system, which is 3%-7% of the total construction costs of a completely new OR department. The yearly increase in operational expenditures per OR with an ultra-clean system compared to a conventional system was €673 to €1,896. The capital and operational expenditures of air handling installations with an ultra-clean system are higher than those with a conventional system. The technical specifications of the ORs studied in the Netherlands correspond to European standards and guidelines. When the impact on patient suffering and costs associated with surgical site infections are weighed against the investment required for an air handling installation with an ultra-clean system, it is worth considering.

## 7.1 Introduction

An air handling installation (AHI) in the operating room is used to create an overpressure and a comfortable and safe environment for the patient and surgical staff [1]. There are several ways to supply air to an operating room (OR). Operating room air handling installations with a conventional (CV) air supply system are mixing the supplied air evenly in the entire OR diluting the concentration of harmful substances. An air handling installation with an ultra-clean (UCV) air supply system distributes the introduced clean air towards the ultra-clean zone [2]. The ultra-clean zone is intended for positioning the wound area of the patient, sterile staff, and instrument tables during the surgical procedure [3–7].

New UCV systems such as temperature-controlled airflow (TcAF) and controlled Dilution Ventilation (cDV) systems are introduced in the market and claim the whole OR to be ultra-clean during surgery. They provide a system suitable for all types of surgery (class 1a, 1b) [3–8]. The ultra-clean air quality standard for a UCV system in the ultra-clean zone, in terms of micro-organism counts, should not exceed 10 CFU/

$m^3$ during surgery [3,4,6,8]. To meet these requirements higher air volumes are introduced in the OR [9–11]. The air supply volumes of UCV systems are higher (approximately 7,000 – 10,000 $m^3$/h) when compared to the air volumes of CV systems (approximately 2,000 – 3,000 $m^3$/h). When lower air volumes are used the number of micro-organisms in the whole OR will be higher, which is a risk factor for the incidence of Surgical Site Infections (SSI) [9,12,13]. With air volumes defined by standards and guidelines [4–7], it is not possible to achieve a protected area [5,6] or clean zone [4] as with a UCV system.

The World Health Organization (WHO) recommends an optimum of around 20 Air Changes per Hour (ACH) to dilute the micro-organisms generated in the OR [20]. The by WHO [14] advised 20 ACH is in most cases not sufficient to achieve the desired number of <10 CFU/$m^3$ in the ultra-clean zone [3,4,9,13].

National standards and guidelines in Europe are advising the number of ACH [4,7] or a fixed introduced air supply volume [3,5,6]. They define technical or performance requirements for an OR air handling installation such as temperature, number of ACH or air volumes, type of OR air supply or UCV systems, and sometimes relative humidity [3,4,6,7]. National standards and guidelines in Europe are summarized in Table 8.1. The different OR air handling installations have various specifications and differ regarding costs. The Centers for Disease Control and Prevention (CDC) [15] describes higher installation costs for a UCV system and the WHO [14] state that a cost analysis by a European single hospital study (Italian study [16]) found a UCV system to be more expensive compared to a CV system.

The World Health Organization (WHO) [14] states that existing research on ventilation systems for operating rooms (ORs) is flawed and there is weak evidence [17–19] that Ultra Clean Ventilation (UCV) systems help to reduce Surgical Site Infections (SSIs). The financial costs of treating SSIs are increasing every year. Over the past decade, however, clear evidence [9,11,20] has been published contradicting WHOs view and recommending the use of a UCV-system rather than a conventional ventilation (CV) system to reduce the incidence of SSIs. According to the WHO and Centers for Disease Control and Prevention, the installation cost of a UCV-system is higher and more expensive than a CV-system [14,15].

This study aims to evaluate the capital and operational expenditures of different air handling installations with different [2] ultra-clean ventilation system and relate them to an air handling installation with a conventional ventilation system. Furthermore, the study aims to compare the technical requirements of Dutch OR air handling installations with European national standards and guidelines, and the costs related to a surgical site infection with the capital expenditures studied.

This research can be used to support the decision-making process. Capital expenditures (CAPEX) and operating expenditures (OPEX) are becoming increasingly important. Before choosing an air handling and air supply system for the operating room, it is relevant to know the CAPEX and OPEX of different air handling and air supply systems and whether they meet national standards and guidelines. It is also relevant to know the return on investment if the incidence of a surgical site infection can be reduced by investing in an air handling installation with an ultra-clean air supply system.

## 7.2 Methodology

Our methodology is based on the study of Sdino et al [21], were they defined four different phases: theoretical, practical, interactive and comparative. In our study in the theoretical phase, we analyzed and mapped the different European standards and guidelines. We also analyzed literature related to costs associated with surgical site infection. In the practical phase, we collected information from 24 hospital case studies where construction costs of operating room air handling installations and air supply systems were collected. Additional cost information was, by means of a questionnaire provided by healthcare consultants, manufacturers and installation companies collected in the interactive phase. In the comparative phase, we compiled all the information obtained.

In this study, the terms Conventional Ventilation (CV) system and Ultra Clean Ventilation (UCV) system are used to describe the method of air supply or air distribution in the operating room. We distinguish between an air handling installation (AHI) that supplies air to the conventional (CV) or ultra-clean (UCV) system and the installed CV or UCV system in the operating room.

Technical and financial data were collected from 24 hospitals built or under construction in the Netherlands from 2015-2022. In total, information on 166 ORs was analyzed.

Three air-handling installation typologies were defined: type A, type B, and type C (Figure 8.1). Four OR air supply systems [2] were defined; Conventional ventilation (CV), controlled Dilution Ventilation (cDV), Temperature-controlled Air Flow (TcAF), and Uni-Directional Air Flow (UDAF). Detailed information on the functioning of these different air supply systems is described in the study on operating room ventilation systems [2]. The technical information of these systems was compared

to national standards and guidelines (Table 8.1) in order to allow for a balanced CAPEX and OPEX comparison. Specifications of the air handling installations, system components, and requirements are described in Figure 8.1 and Table 8.1.

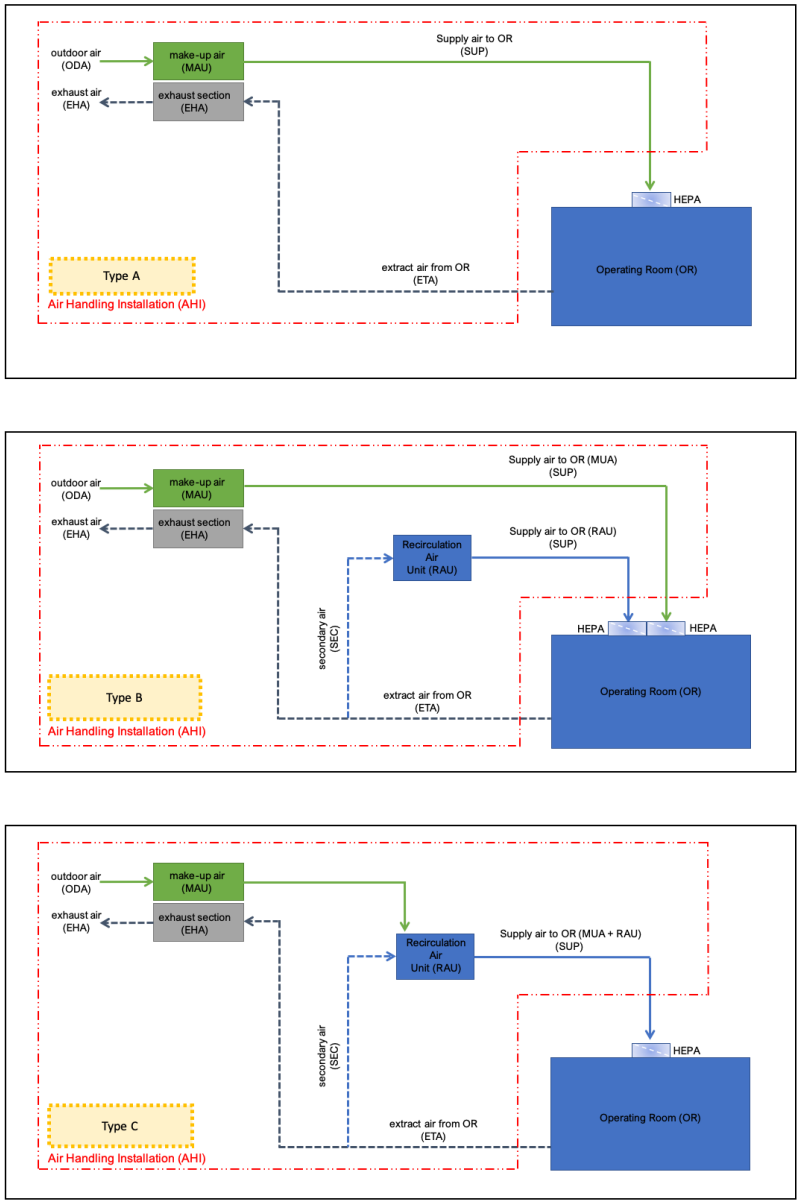


FIG. 7.1 Three typologies of OR air handling installations, type A, type B, and type C.



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The CAPEX of an air handling system type A was constructed from all components defined in figure 1 type A including a CV system which consisted of six standard High-Efficiency Particulate Air (HEPA) filter outlets, with HEPA H14 filter [22].

The CAPEX of an air handling installation type B and C was constructed from all components defined in figure 1 type B and C including one of the three different types of UCV systems: cDV, TcAF, or UDAF.

The CAPEX of five entire newly constructed operating room departments was also collected. These CAPEX consisted of the total construction cost of an operating room department, including ancillary areas such as corridors, changing rooms, airlocks, storage, and air handling installations for those areas. Only the entire complete newly constructed department projects were considered to allow for a balanced cost comparison. Total costs were normalized per OR, as for air-handling installations and air supply systems.

Operational expenditures (OPEX) were defined as costs related to maintaining the UCV systems according to the UCV manufacturer specifications and qualifying the systems yearly according to the national Dutch guideline [7]. This includes: 1) replacement of the HEPA filters every 5 years, 2) replacement of the laminar airflow diffusor for the UDAF every 10 years, 3) replacement of the air showers for the TcAF every 5 years, 4) replace the HEPA filters of the CV air supply filter air outlets after 5 years, 5) cost to technically qualify the OR CV and UCV air supply system yearly according to the national Dutch guideline [7] and 6) to determine the ultra-clean area of the UCV air supply system after every 5$^{th}$ year according to the national Dutch guideline [7].

TABLE 7.1 Technical and requirement specifications air handling installation (AHI) and Conventional (CV) or Ultra Clean (UCV) systems according to national standards and guidelines in Europe.

| National Standards or Guidelines | Classification type of operating room by standard/ guideline | Temperature [°C] | Relative humidity [%] | ACH or required air volume | Required CFU Level | Other requirement specifications | End Filter Supply air (EN 1822) |
|---|---|---|---|---|---|---|---|
| **Norme Française (NF), France NF S 90 351** | Zone 4a | 19-26 | Criteria for special conditions only | ≥6 outdoor air (ODA) | ≤1 CFU/$m^3$ | Unidirectional flow, discharge velocity >0,25-0,35 m/s, ISO 5 | HEPA H14 |
| | Zone 3 | 19-26 | Criteria for special conditions only | ≥15 | ≤10 CFU/$m^3$ | Unidirectional flow or non-unidirectional flow, ISO 7 | HEPA H14 |
| | Zone 2 | 19-26 | Criteria for special conditions only | ≥10 | ≤100 CFU/ $m^3$ | Non-unidirectional, ISO 8 | HEPA H14 |
| **Health technical memoranda (HTM), England HTM 03-01** | Ultra Clean | 18-25 | 35-65 | >22 | ≤10 CFU/$m^3$ Ultra Clean Area | Own dedicated Air Handling Unit per OR and UCV min. 2.8 x 2.8 m | EPA E10 |
| | Conventional | 18-25 | 35-65 | >22 | | Own dedicated Air Handling Unit per OR | EPA E10 |
| **Deutsches Institut für Normung (DIN), Germany DIN 1946/4** | 1a | 19-26 | 30-60 | ≥1,200 $m^3$/h | Wound area <1 CFU/50 $cm^2$ Instrument table <1 CFU/50$cm^2$ | Advised UDAF size 3.2 x 3.2 m | HEPA H13/ H14 |
| | 1b | 19-26 | 30-60 | ≥1,200 $m^3$/h | | Recovery rate <20 min (DIN EN ISO 14644-1) 3,520/ $m^3$ for 0.5 µm | HEPA H13/ H14 |

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TABLE 7.1 Technical and requirement specifications air handling installation (AHI) and Conventional (CV) or Ultra Clean (UCV) systems according to national standards and guidelines in Europe.

| National Standards or Guidelines | Classification type of operating room by standard/ guideline | Temperature [°C] | Relative humidity [%] | ACH or required air volume | Required CFU Level | Other requirement specifications | End Filter Supply air (EN 1822) |
|---|---|---|---|---|---|---|---|
| **Schweizerische Verein von Gebäudetechnik-Ingenieuren, Switserland SWKI VA105-01** | 1a | 18-24 | 30-50 | ≥800 $m^3/h$ | | UDAF 9 $m^2$ Differential flow - Schutzgradmessung SG≥2,0/ SG≥4,0 | HEPA H13 |
| | 1b | | | 25 or ≥800 $m^3/h$ | | Recovery rate 100:1 ≤20 min (SN EN ISO 14644-3) | HEPA H13 |
| | £ 1 | | | | | | |
| **Federatie Medisch Specialisten (FMS) / Vereniging Contamination Control Nederland VCCN RL7 / RL 8, The Netherlands** | 1+ | 18-23°C | <65 | ≥20 | <10 CFU/$m^3$ | ISO 5, recovery rate ≤3 min. NEN EN ISO 14644-1 | HEPA H13 |
| **FMS** | 1 | 18-23°C | <65 | ≥20 | | ISO 7, (complete OR) recovery rate ≤20 min NEN EN ISO 14644-1 | HEPA H13 |
| **FMS** | 2 | 18-23°C | <65 | ≥6 | | ISO 7 (complete OR), No recovery rate NEN EN ISO 14644-1 | HEPA H13 |

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TABLE 7.1 Technical and requirement specifications air handling installation (AHI) and Conventional (CV) or Ultra Clean (UCV) systems according to national standards and guidelines in Europe.

| National Standards or Guidelines | Classification type of operating room by standard/ guideline | Temperature [°C] | Relative humidity [%] | ACH or required air volume | Required CFU Level | Other requirement specifications | End Filter Supply air (EN 1822) |
|---|---|---|---|---|---|---|---|
| **Swedish Institute for Standards (SIS), Sweden SIS TS 39; 2015** | Infection-prone clean surgery | 18-26°C | <70 | ≥0.56 $m^3/s$ | ≤5 CFU/$m^3$* - ≤10 CFU/$m^3$** | Mean Value ≤1.5 CFU/$m^3$ (highest value ≤5 CFU/$m^3$) *Clean air suits (everyone in the OR) Mean Value ≤5 CFU/$m^3$ (highest value ≤10 CFU/$m^3$) **Ordinary scrub suits (everyone in the OR) | HEPA H14 |
| | Other Surgery | 18-26°C | <70 | ≥0.56 $m^3/s$ | ≤50 CFU/$m^3$* - ≤100 CFU/$m^3$** | Mean Value ≤50 CFU/$m^3$ (highest value = ≤100 CFU/$m^3$) *Clean air suits (everyone in the OR) Mean Value ≤100 CFU/$m^3$ (highest value = ≤200 CFU/$m^3$) **Ordinary scrub suits (everyone in the OR) | HEPA H14 |

## 7.3 Results

An OR with an air handling installation type A was not identified separately in this study, this is part of the basic construct of an operating room AHI. In our study we could extract from 54 ORs, out of the received data, the CAPEX of an air handling installation type A. 62 ORs had an air handling installation type B and 104 type C, all with a UCV system.

The mean amount of fresh supply air from the Make-up Air Unit (MAU) and Recirculation Air Unit (RAU) was 2,173 $m^3$/h and 7,683 $m^3$/h respectively (Table 8.2). The average total number of ACH (supply air to OR) was with 69 ACH higher than required by most national standards and guidelines [3,4,7,8] (Table 8.1 and 8.2).

For the design conditions temperature, relative humidity, and type of end filter for the ORs in this study see Table 8.2. These design conditions were in line with the guidelines and standards for all ORs (Table 8.1 and 8.2).

TABLE 7.2 Technical specifications air handling installations (AHI) operating rooms of hospitals in the Netherlands per AHI typology and UCV system. Standard Deviation (SD).

| No. ORs (n=166) | Mean OR volume [$m^3$] | Type Air Handling Installation (no. hospitals) | UCV Type | Temperature [°C] | Relative humidity [%] | volume MAU [$m^3$/h] | No. ACH MAU | Air volume RAU [$m^3$/h] | No. ACH total air volume |
|---|---|---|---|---|---|---|---|---|---|
| 16 | 162 | Type C (3) | cDV | min. 15 max. 23 | min. 45 max. 70 | 2,213 | 15 | 7,178 | 64 |
| 47 | 178 | Type C (9) | TcAF | min. 16 max. 24.5 | min. >45 max. 70 | 2,014 | 14 | 6,376 | 56 |
| 54 | 129 | Type B (9) | UDAF | min. 17.5 max. 24 | min. >40 max. 70 | 2,458 | 21 | 7,734 | 78 |
| 49 | 156 | Type C (4) | UDAF | min. 17 max. 24 | min. 50 max. 65 | 2,000 | 13 | 9,046 | 74 |
| **Mean total (SD)** | | | | | | 2,173 (466) | 16 (5) | 7,683 (1,719) | 69 (13) |



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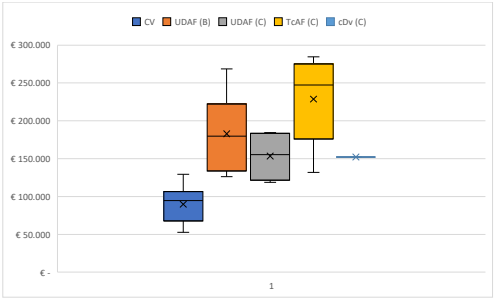
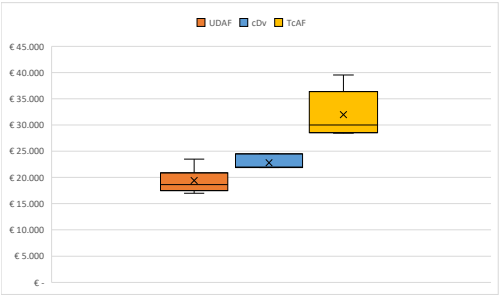
For 121 ORs we were able to equally compare the CAPEX (Figure 8.2.a) of the air handling installation types A, B, and C with a CV or UCV system. The CAPEX of a type A CV system was € 89,715 per OR. The difference in CAPEX of an air handling installation type B with a UDAF system was €93,158 per OR. The additional CAPEX per OR of an air handling installation type C with a cDV was €62,491 with a TcAF €139,018 and with a UDAF €63,765, see Table 8.3. When compared to the total building cost of an OR, the CAPEX of an operating room AHI with a UCV air supply system versus a conventional system represented a 3 to 7% increase.




7.2.a Capital Expenditures of an OR air handling installation type A, B and C with a CV or UCV system.




7.2.b Operational expenditures of OR UCV systems, UDAF, cDV and TcAF over 10 years' time

FIG. 7.2 Capital and Operational expenditures

The yearly increase in OPEX of an operating room with a UCV system versus a CV system is between €281 and €783, calculated over a 5 years period and between €673 and €1,896, calculated over a 10 years period, see figure 8.2.b and Table 8.4.

TABLE 7.3 Mean operational expenditures (OPEX) of CV and UCV systems. All mentioned expenditures in EUR, excluding VAT. Standard Deviation (SD).

| OPEX | 5 years CV | 10 years CV | 5 years cDV (SD) | 10 years cDV (SD) | 5 years TcAF (SD) | 10 years TcAF (SD) | 5 years UDAF (SD) | 10 years UDAF (SD) |
|---|---|---|---|---|---|---|---|---|
| | 5,750 | 13,000 | 9,667 (1,010) | 22,800 (1,473) | 9,417 (1,062) | 31,960 (4,258) | 7,154 (916) | 19,726 (2,154) |
| **+ difference EUR. OPEX CV to UCV** | | | 3,917 | 9,800 | 3,667 | 18,960 | 1,404 | 6,726 |

TABLE 7.4 Mean CAPEX per OR of the air handling installation typology A, B or C with a CV or UCV system and CAPEX of complete OR department. All mentioned expenditures in EUR, excluding VAT. Standard Deviation (SD).

| CAPEX Air handling installation (AHI) per OR | | | | | | | CAPEX UCV system | CAPEX Air Handling Installation (type A, B, C) with CV or UCV air supply system | | | | | CAPEX OR department (n=5) | CAPEX OR department per OR |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MAU | Ductwork MAU | RAU | Ductwork per RAU | Controls MAU | Controls RAU | Total AHI per OR | UCV | AHI Type A with CV (SD) | AHI Type C with cDV | AHI Type C with TcAF (SD) | AHI Type B with UDAF (SD) | AHI Type C with UDAF (SD) | 9,490,000 | 1,943,167 |
| 23,971 | 33,239 | 17,370 | 37,550 | 44,876 | 18,874 | 175,878 | 38,520 | 89,715 (25,145) | 152,206 | 228,733 (56,061) | 182,872 (51,788) | 153,480 (33,638) | | |
| | | | | | | | | + difference EUR. CAPEX CV to UCV per OR | | | | | | |
| | | | | | | | | | 62,491 | 139,018 | 93,158 | 63,765 | | |

## 7.4 Discussion

The type of surgery, the internal heat load due to the medical equipment used, the number of people and clothing system, temperature and sometimes humidity requirements determine the needed air handling installation to supply the air to the OR and the type of the air supply system. The air handling installation and air supply systems in the current study all complied to the European standards and guidelines (table 1). Therefore, insight in the costs of the different ventilation systems currently on the market is important. The results of this study indicate per OR an increase in capital expenditures (CAPEX) of €62,491 to €139,018 and an increase in yearly operational expenditures (OPEX) per year of €673 and €1,896 per OR of a UCV compared to a CV system calculated over a 10 years period.

The results of our study are in accordance with the results of Cacciari et al [16]; CAPEX and OPEX increase when an air handling installation with a UCV system is installed in an OR compared to air handling installation with a CV system. However, the increase in their study is less compared to the increase in CAPEX and OPEX in the current study (see table 3); they found an increase of 24% of the OR air handling system costs and an increase of 36% in annual operating costs (OPEX). The higher CAPEX can be explained by the fact that we collected data from 24 hospitals with different types of air handling installations and three types of UCV systems compared to one project with one type of UCV system as in the study by Cacciari et al.

This study dated from 2004 and our study used data from 2015-2022. When compared to the total building costs the results in our study are in line with the results of Cacciari et al (see table 4). In their study, the increase in CAPEX was only 5% compared to the total building costs of an OR [16]. In our study, the increase in CAPEX was, per operating room, between 3%-7% depending on the type of air handling installation and UCV system.

In infection-prone surgeries where artificial implants are used, a level of <10 CFU/$m^3$ in the ultra-clean area [3,4,6,7] is recommended by most national standards and guidelines in Europe and used in scientific papers [10,23,24]. Recommendations to equip an operating room with an ultra-clean (UDAF) ventilation is not recommended by the WHO [14], CDC [15] and some studies claim UCV systems fail to prevent the incidence of surgical site infections (SSI) [24,25].

The WHO noted that existing research on OR ventilation systems is flawed and that there is only weak evidence that OR ventilation systems help in the reduction of SSIs [17–19]. However, in the last decade clear evidence has been published in peer-reviewed journals that contradicts this position. Several studies [9,11,20] advise to use a UCV system for infection-prone surgery [3,4,25] instead of a CV system [17,18]. UCV systems do reduce the number of CFUs in the OR [13,23,24] and do contribute to a lower number of SSIs [9,24]. In terms of micro-organism counts, ultra-clean air quality in the ultra-clean zone, should not exceed 10 CFU/$m^3$ [3,4,6]. To meet these micro-organism counts during infection-prone surgery, higher air volumes are introduced in the OR [9–11]. When lower air volumes are used, such as with a CV system, the number of micro-organisms in the whole OR will be higher [13,23], which is a risk factor for the incidence of SSIs [9,12]. In this study, all ORs had an air handling installation and OR UCV system installed with a mean of 69 ACH (see table 2) and a mean total air volume of 9,857 $m^3$/h.

The costs of treating SSIs are increasing every year. Prolonged length of stay of the patient in general wards or intensive care units (ICUs) as a result of an SSI was reported to constitute a major cost burden in multiple studies [14,26,27]. The infection risk for hip and knee arthroplasty is expected to increase from 2.18% [28] to 6.5% and 6.8% [29] in 2030, respectively. The additional cost of a surgical site infection per patient varies from €17,434 (France) to €32,000 (Italy) [24]. The majority of studies do not consider the wider impact of SSIs on society like absence from work or reduced work productivity. In a period of 10 years, if only 2-4 infections can be prevented by implementing an ultraclean system, then its application is certainly worth considering.

According to the CDC, there is a relationship between SSIs and increasing antimicrobial resistance. Antimicrobial resistance is an urgent global public health threat [30]. With a higher proportion of resistant bacteria, the effect of antibiotic prophylaxis will be reduced. When considering the cost of a surgical site infection and the increasing antimicrobial resistance and thus the diminished effect of surgical prophylaxis, the additional investment in an OR air handling installation with a UCV system may be considered to prevent the incidence of SSIs during infection-prone surgery. Future studies should consider evaluating the potential reduction in SSIs and other health-related benefits associated with improved air quality.

This study has several limitations.

First, we did not consider inflation rates. The costs received were those prevailing at the time the ORs in the hospital were built or when the OR department was renovated. External factors, such as changes in regulations, inflation, or variations in energy prices, are big uncertainties in cost estimation. Risk analysis should be conducted to identify all potential sources of cost increase or decrease.

Secondly, most of the air handling installations in the hospital were exclusively built for the OR department, in some cases, the air handling installation was used to supply air to other areas of the OR department. As a result, it was not possible to estimate exactly what the cost would have been if the air handling installation had been used only for the OR. Costs of the air handling installation could also vary because the numbers of ORs built differed per hospital, the manufacturer of the air handling installation control technology was not the same and the locations of the ORs relative to the plant room were not identical. The investment costs of the delivery and supply of cooling and heating needed for the air handling installations as well as the heating and cooling plants and their maintenance costs were not considered in this study. Some of those costs, such as maintenance and energy costs, may vary significantly between locations and over time.

Third, the OPEX can vary by hospital and region. Some hospitals have higher maintenance requirements for OR air handling installations and OR UCV or CV air supply systems than others. In this study, we considered the maintenance specification of the UCV and CV system supplier or manufacturer. The mentioned OPEX relates only to the CV and UCV air supply system. Due to differences in the design and parameters of the complete OR air handling installation, heating and cooling systems, we could not include energy consumption and maintenance costs in the OPEX based on an equal costs comparison.

In the study on the ventilation effectiveness of different air supply systems we investigated the air quality and actual performance of UCV-systems and CV-systems [2]. Further research, e.g. on infection control, energy efficiency, and comfort, as well as the need for evidence-based comparison between the two types of air ventilation systems as described in this study, would be beneficiary to make informed decisions about air handling installations.

## 7.5 Conclusions

Choosing an air handling installations with an ultra-clean ventilation system over a conventional ventilation system, results in an increase in capital and operational expenditures. The capital expenditures for an air handling installation with an ultra-clean system represents an additional investment of about 3 to 7% of the total cost of building a completely new OR department. The operational expenditures of a UCV system represented an increase per operating room per year of €673 and €1,896 over the OPEX of an operating room equipped with a conventional system calculated over a 10 years period.

All Dutch operating rooms in this study complied to the technical specifications and requirements as described in the national European standards and guidelines. Therefore, the results from this study can be used for other European countries as well.

When the impact on patient suffering and costs associated with surgical site infections are weighed against the costs associated with an air handling installation with an ultra-clean system, the investment is worth considering. If you can prevent two to four surgical site infections over 10 years, the investment will already be recovered.

This study provides relevant research focusing on the economic aspects of air handling installations and the different air supply systems in operating rooms. It provides valuable information to healthcare administrators, facility managers, and policymakers when making decisions about air handling installations and air supply systems for operating rooms.

## Acknowledgments

The authors would like to thank the healthcare consultants, UCV manufacturers, installation companies, and hospitals for sharing the technical and financial data.

## Conflict of interest statement

J.L.A. Lans is CEO of Medexs BV, a company that designs, builds, supplies, and installs healthcare facilities. All other authors report no conflict of interest relevant to this article.

## Funding statement

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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# Part C


Medical Centre Jan van Goyen

TOC

TOC

# 8 Baseline study ultra-clean air system at trauma surgery

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PUBLISHED **Health Environments Research & Design Journal (HERD) |** DOI 10.1177/19375867241302406

KEYWORDS Operating Room, Colony Forming Units, Infection prevention, Ultra clean ventilation systems, Instrument tables, Surgical procedure

RUNNING TITLE Baseline study of number and type of microorganisms and particles during surgery at wound site, instrument table and periphery

ABSTRACT **Background –** The objective of an operating room (OR) ultra-clean ventilation (UCV) system is to eliminate or reduce the quantity of dust particles and colony forming units per cubic meter of air (CFU/$m^3$). To achieve this ultra-clean goal high air change rates per hour (ACH) are required to reduce the particle load and number of CFU/$m^3$.

**Aim –** To determine the air quality in an ultra-clean OR during surgery, in terms of the number and type of microorganism and quantity of dust particles in order to establish a benchmark.

**Methods –** Number of CFUs and the quantity of dust particles were measured. For measuring the CFUs, sterile extraction hoses were positioned at the incision, the furthest away positioned instrument table and the periphery. At these locations air was extracted to determine the quantity of dust particles.
**Findings –** The number of CFU/$m^3$ and particles was in average at wound level ≤1 CFU/$m^3$ resp. 852,679 particles, at instrument table ≤1 CFU/$m^3$ resp. 3,797 particles and in the periphery ≤8 CFU/$m^3$, resp. 4,355 particles.
**Conclusion –** The number of CFUs in the ultra-clean area is below the defined ultra-clean level of ≤10 CFU/$m^3$ for ultra-clean surgery. The quantity of dust particles measured during surgery was higher than the defined ISO 5.

## 8.1 Introduction

The objective of an operating room (OR) ultra-clean ventilation (UCV) system is to eliminate or reduce the quantity of dust particles and colony forming units per cubic meter of air (CFU/$m^3$). To achieve this goal high air change rates per hour (ACH) are required to reduce the particle load and number of CFU/$m^3$ [1,2].

The Dutch Federation of Medical Specialists (FMS) recently introduced a guideline for air handling in operating and treatment rooms [3]. Only major orthopedic implant surgeries and major spinal surgeries (e.g. scoliosis) should be performed in a Class 1+ [3] OR. A Class 1+ operating room corresponds to a Class 1 [4,5] operating room according to international standards, where ultra-clean [5,6] air is defined as air which contains ≤10 CFU/$m^3$. Other surgeries [3] could be performed in a generic operating room with a conventional (mixing) ventilation (CV) system with an air change rate of ≥ 20$h^{-1}$. This is in line with the WHO [7] and for generic surgery with other international standards [4–6,8,9]. Evidence of the relation between higher air change rates per hour and a reduction of the number of surgical site infections (SSI) at most types of surgeries is weak [3,7]. Therefore, in accordance with their guideline, the FMS recommends a lower number of air changes per hour. Previous studies, during real [10–12] or simulated surgery [13], defined the air quality in terms of CFUs and sometimes dust particles directly and only underneath the Uni Directional Air Flow (UDAF) system and did not determine the measured number and type of microorganism close to the wound site and at the instrument table or in the periphery.

To date, most operating rooms in Dutch hospitals are built as an ultra-clean [14] operating room. Since the recent FMS recommendation to reduce the number of air changes per hour for most surgeries, there is a need for a primary benchmark regarding the number and type of microorganisms and dust particles measured during real surgery at the wound site, instrument table and periphery, measured in an ultra-clean operating room. The present base line study can be used as such a benchmark.

## 8.2 Methods

The measurements were executed in an operating room at Reinier de Graaf Hospital (Delft, the Netherlands) during 29 different types of surgeries. The operating room in this study was equipped with a uni-directional air flow (UDAF) system and classified as an ultra-clean operating room class 1+. The UDAF system introduces the air directly (and only) above the protected area, see Figure 9.1. The staff present during surgery wore modern scrub suits made out of 99% polyester and 1% carbon fibers [15]. The source strength using this type of clothing was 2.9 (0.9-5.7) CFU/s per person [15]. The surface of the UDAF was 10.5 $m^2$, the total air volume introduced 11,340 $m^3/h$ and the number of air changes per hour in the OR 71.

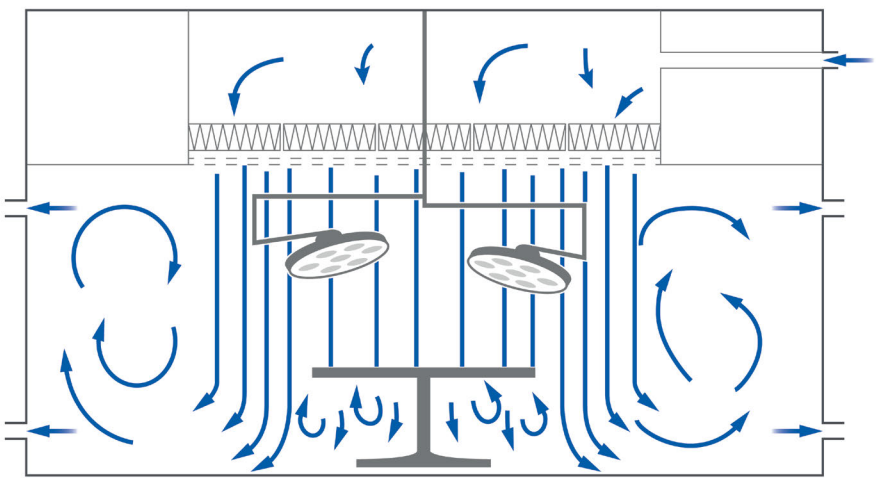

FIG. 8.1 Working principle UDAF.



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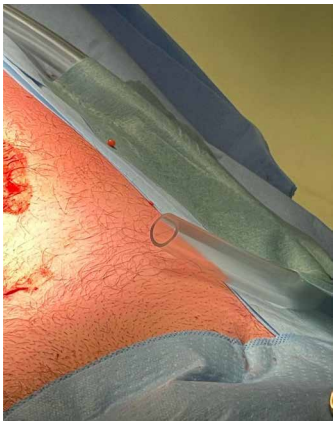
### 8.2.1 CFU measurements

For the CFU measurements sterile sample extraction hoses were positioned by the surgical staff at the location (<5 cm) of the incision, at the furthest away positioned instrument table from the surgical site and in the periphery close to an air extraction point, see figure 2. The material of the sample tube was 1515 “python” neoprene hose dimensions Ø15x21(mm), temperature resistance: -20°C to +100°C. The maximum length of the sample hoses was 3 meters. Portable Lighthouse H100 active-air samplers were used for microbial air sampling, according to the slit principle. For 10 minutes 100 $dm^3$/min was sampled. Airborne bacteria-carrying particles were trapped via impaction on Tryptose Soy Agar (TSA) cultivation plates. The plates were incubated aerobically for 2x24 hours at 30-35°C. Directly after the incubation period, the hospital laboratory determined and reported the type of microorganism. The level of CFUs was assessed by means of the Swedish standard SIS–TS39:2015 [5]. In contrary to other international standards [4,8], the focus in this standard [5] is on biological contamination and the use of microbiological methods for the assessment.



8.2.a


8.2.b

8.2.c

FIG. 8.2 Photos of sample extraction hoses at the wound site (8.2.a), Lighthouse 3016 handheld particle-counters and portable Lighthouse H100 active-air samplers during measurements at instrument table (8.2.b) and extraction point (8.2.c).



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### 8.2.2 Particle count measurements

The quantity of dust particles was measured at the same positions as the CFU measurements (see figure 2). For the particle measurements Lighthouse 3016 handheld particle-counters with a flow rate of 2.83l/min (0.1 $ft^3$/min) were used. Particles with a size of ≥0.5µm were measured. The ISO level of particles was assessed by means of the ISO 14644-1 [16] standard, at-rest situation. At-rest is the condition where the operating room or clean zone is complete with equipment installed and operating in a manner agreed upon, but with no personnel present [16].

During all measurements the number of staff present, door openings, activity level and extra ordinary occasions were recorded.

## 8.3 Results

The number of CFU/$m^3$ and particles during the surgeries was on average at wound level ≤1 CFU/$m^3$ resp. 852,679 particles, at instrument table ≤1 CFU/$m^3$ resp. 3,797 particles and in the periphery ≤8 CFU/$m^3$, resp. 4,355 particles. The level of CFUs measured at the incision and instrument table was on average 0.5 resp. 0.7 CFU/$m^3$. This is below the defined ≤10 CFU/$m^3$ for ultra-clean surgery [5], see table 8.1 for number of CFU/$m^3$, type of microorganism and quantity of dust particles measured.

## 8.4 Discussion

Reducing energy consumption in hospitals has a high priority [17,18]. One possibility to save energy is to reduce the air change rate per hour in the operating room [19,20]. For new construction projects, the choice is sometimes made to lower operating room classifications [3], to lower the air change rate per hour and modify the existing air handling installation fitted in existing operating rooms [19]. The World Health Organization (WHO) [7] and FMS [3] stated that existing research on OR ventilation systems is flawed and that there is only weak evidence that OR ventilation systems help to reduce the incidence of SSIs [21–23]. Other studies declare the opposite [1,24,25] and advise to use a UCV system for infection prone surgeries [5,6,26] where artificial implants are used.

This benchmark study has been performed to enable a comparison regarding the number of CFU/$m^3$, type of microorganism and quantity of dust particles in an ultra-clean [5,6] operating room. Since the recent FMS advice to reduce the ACH for most surgeries, it is important to have a benchmark regarding the number and type of microorganisms and particles measured during surgery at the wound site, instrument table and periphery, measured in a OR Class 1+.

In this study there was a broad variety of micro-organisms cultured at the different locations, often there was little correlation between the types of organisms found during one operation at different locations or in subsequent uses of the OR. In general, it can be said that an overwhelming majority of the cultured bacteria are not known as primary pathogens, such as Staphylococcus aureus [27]. The majority of the cultured organisms in this study are known as colonizing bacteria of the human skin (Staphylococcus hominis, S. epidermidis, S. capitis) which could pose a risk for low-grade prosthetic infections but were found in this study distant from the operating table to form a risk to the patient. Determination of the type of microorganisms show a paucity of primary pathogens, with the largest numbers of cultured bacteria members of human colonizers or environmental contaminants that occasionally participate in prosthetic infections, and in this study in an OR equipped with an UDAF, were found distant from the site of the surgery to form a threat in those special cases. Besides the known SSI prevention measures [28] an ever-increasing air change rate is a concept that is on most occasions already beyond a reasonable expectation dose/response effect as long as the six general strategies supported by randomized trials are followed for prevention of SSIs: avoiding razors for hair removal, decolonization with intranasal antistaphylococcal agents and antistaphylococcal skin antiseptics for high-risk procedures, use of chlorhexidine

gluconate and alcohol-based skin preparation ,maintaining normothermia to keep the body temperature warmer than 36 °C, perioperative glycemic control and use of negative pressure wound therapy.

During the measurements, the ultra-clean ventilation system did not meet the at-rest ISO class 5 [3,4] standards at the measuring locations during surgery. This is consistent with previous studies [13,29]. Our study showed that the desired ISO5 [3,4,9] classification was exceeded on every measurement location despite the high air change rate per hour [1]. The quantity of particles measured during surgery was on average ISO8 at the wound site and ISO6 at the instrument table and in the periphery [16]. This is consistent with other studies [30,31].

When changing the air change rate in an existing OR or when building a new OR, the selection of the classification of the operating room and air change rate per hour should depend on the type of the surgical procedure. As well the number of people present, the heat load in the OR, the clothing procedure [15] etc. are important criteria. The impact of reducing the air change rate per hour on the measured numbers of CFUs and particles cannot be determined without considering the aforementioned parameters.

This study has several limitations.

First, the impact on surgical site infections when reducing the air change rate [19] in the operating room is not determined. To date, most ORs in Dutch hospitals are designed as ultra-clean ORs (FMS Class 1+). Changing from an ultra-clean ventilation (UCV) to a conventional mixing ventilation (CV) air supply system can have an effect on the use of surgical smoke and contaminant removal effectiveness [32]. However, reducing the air change rate will decrease the energy consumption of the operating room air handling installation [13,33]. A study is recommended to evaluate the impact on the number of SSIs and cultured bacteria when reducing the air change rate per hour according to the FMS. This study is recommended despite the fact that the outcomes will be influenced by parameters such as number and the behavior of staff present [34,35], number of door openings [36–38], amount of air introduced [2], type of surgical clothing [15,39], type of surgical procedures [40], etc.

Secondly, the number of staff present, door openings, activity level and extra ordinary occasions have influence on the number of CFU during surgery. Although we recorded these, we did not assess the impact of those activities on the we did not assess the impact of those activities or occasions on the number of CFUs or the quantity of dust particles [36–38,41].

Third, in the current study we only examined one hospital operating room location. It is recommended to conduct a similar study in other hospitals and operating rooms were room geometry [42], the air change rate per hour [1,19] and type of ultra-clean ventilations system vary [2]. The merging of all these data will give a more comprehensive picture of whether it is needed to apply high air change rates per hour.

## 8.5 Conclusion

The level of CFUs in the ultra-clean surgical area is below the, in standards, defined ultra-clean level for ultra-clean operating rooms. The quantity of dust particles measured during surgery was higher than the in standards defined ISO5 [16] at-rest. Regarding the number of particles (≥0.5 µm) during surgery ISO8 [16] levels were reached at the wound site and ISO6 [16] at the instrument table and in the periphery.


### Acknowledgements

The authors would like to thank the staff of the Reinier de Graaf hospital group, the Netherlands, for making the operating rooms available for the measurements and determine the type of microorganism.


### Conflict of interest statement

J.L.A. Lans is CEO of Medexs BV, a company that supplies and install OR ventilation systems. All other authors report no conflict of interest relevant to this article.


### Funding statement

None, this research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

TABLE 8.1 Descriptives operating room. Number (CFU/m$^3$) and type of microorganism and quantity of dust particles measured. All surgeries were performed in the same OR equipped with an UDAF and in total 71 air changes per hour.

| Type of Surgery [Duration] | Measurement cycle [10 min] | Quantity Particles, CFUs and Measurement location | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Wound | | | Instrument table | | | Periphery | | |
| | | Mean quantity Particles [0.5µm] | Mean level of CFU [CFU/m$^3$] | Type of micro organism | Mean quantity Particles [0.5µm] | Mean level of CFU [CFU/m$^3$] | Type of micro organism | Mean level of CFU [CFU/m$^3$] | Mean level of CFU [CFU/m$^3$] | Type of micro organism |
| Distal humeral fracture [105 min] | 1 | 74193 | 0 | ND** | 2954 | 0 | ND** | 1477 | 3 | ND** |
| | 2 | 23532 | 1 | ND** | 1092 | 0 | ND** | 3853 | 3 | ND** |
| | 3 | 1413 | 0 | ND** | 193 | 0 | ND** | 1894 | 2 | ND** |
| | 4 | 32 | 0 | ND** | 32 | 0 | ND** | 514 | 4 | ND** |
| | 5 | 835 | 0 | ND** | 1798 | 0 | ND** | 449 | 4 | ND** |
| | 6 | 12521 | 0 | ND** | 1027 | 0 | ND** | 0 | 20 | ND** |
| | 7 | 1702 | 2 | ND** | 3403 | 0 | ND** | 0 | 4 | ND** |
| | 8 | 385 | 0 | ND** | 1926 | 1 | ND** | 0 | 9 | ND** |
| | 9 | 88 | 0 | ND** | 417 | 0 | ND** | 0 | 5 | ND** |
| | 10 | 32 | 0 | ND** | 4848 | 0 | ND** | 0 | 11 | ND** |
| | 11 | 424 | 1 | ND** | 3602 | 0 | ND** | 0 | 13 | ND** |
| | 12 | 247 | 0 | ND** | 2825 | 0 | ND** | 1024 | 6 | ND** |
| | 13 | 4077 | 0 | ND** | 424 | 0 | ND** | 417 | 3 | ND** |
| | 14 | 64 | 0 | ND** | 0 | 0 | ND** | 1926 | 12 | ND** |
| Laparoscopic inguinal hernia repair [30 min] | 1 | 7544 | 0 | ND** | 1284 | 0 | ND** | 3114 | 8 | ND** |
| | 2 | 2440 | 0 | ND** | 803 | 2 | ND** | 3853 | 8 | ND** |
| Open inguinal hernia repair [30 min] | 3 | 69634 | 0 | ND** | 6967 | 0 | ND** | 2215 | 17 | ND** |
| | 4 | 117341 | 0 | ND** | 0 | 3 | ND** | 161 | 3 | ND** |
| | 5 | 67419 | 0 | ND** | 289 | 0 | ND** | 1124 | 4 | ND** |
| Elbow fracture [30 min] | 6 | 81160 | 0 | ND** | 2761 | 0 | ND** | 4398 | 4 | ND** |
| | 7 | 59907 | 0 | ND** | 64 | 2 | ND** | 3692 | 6 | ND** |
| Open inguinal hernia repair [30 min] | 1 | 1157230 | 0 | ND** | 264 | 0 | ND** | 5072 | 15 | ND** |
| | 2 | 13933 | 0 | ND** | 0 | 0 | ND** | 1637 | 26 | ND** |
| Laparoscopic inguinal hernia repair [30 min] | 3 | 9471 | 0 | ND** | 0 | 0 | ND** | 1284 | 3 | ND** |
| | 4 | 54545 | 0 | ND** | 0 | 0 | ND** | 1284 | 8 | ND** |

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TABLE 8.1 Descriptives operating room. Number (CFU/m$^3$) and type of microorganism and quantity of dust particles measured. All surgeries were performed in the same OR equipped with an UDAF and in total 71 air changes per hour.

| Type of Surgery [Duration] | Measurement cycle [10 min] | Quantity Particles, CFUs and Measurement location | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Wound | | | Instrument table | | | Periphery | | |
| | | Mean quantity Particles [0.5µm] | Mean level of CFU [CFU/m$^3$] | Type of micro organism | Mean quantity Particles [0.5µm] | Mean level of CFU [CFU/m$^3$] | Type of micro organism | Mean level of CFU [CFU/m$^3$] | Mean level of CFU [CFU/m$^3$] | Type of micro organism |
| Laparoscopic inguinal hernia repair [30 min] | 5 | 4495 | 0 | ND** | 0 | 0 | ND** | 1637 | 2 | ND** |
| | 6 | 4559 | 0 | ND** | 0 | 0 | ND** | 1220 | 0 | ND** |
| Open inguinal hernia repair [45 min] | 1 | 10113 | 0 | ND** | 32 | 2 | ND** | 1188 | 3 | ND** |
| | 2 | 8540 | 0 | ND** | 32 | 4 | ND** | 1156 | 1 | ND** |
| | 3 | 5169 | 0 | ND** | 10017 | 3 | ND** | 15603 | 4 | ND** |
| Open inguinal hernia repair [30 min] | 4 | 1414930 | 0 | ND** | 3660 | 0 | ND** | 2472 | 9 | ND** |
| | 5 | 161 | 0 | ND** | 10402 | | ND** | 5554 | 5 | ND** |
| Plate osteosynthesis clavicle fracture [30 min]* | 6 | 14961 | 2 | ND** | 0 | 2 | ND** | 771 | 1 | ND** |
| | 7 | 2321 | 0 | ND** | 3114 | 0 | ND** | 11301 | 2 | ND** |
| Laparoscopic inguinal hernia repair [30 min] | 1 | 35989 | 0 | None | 3371 | 0 | None | 1059 | 3 | 1x Staphylococcus caprae<br>1x Micrococcus luteus<br>1x Staphylococcus epidermidis |
| | 2 | 11012 | 0 | None | 3307 | 1 | 1x Staphylococcus epidermidis | 674 | 23 | 13x Staphylococcus epidermidis<br>8x Micrococcus luteus<br>2x Bacillus sp |

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TABLE 8.1 Descriptives operating room. Number (CFU/$m^3$) and type of microorganism and quantity of dust particles measured. All surgeries were performed in the same OR equipped with an UDAF and in total 71 air changes per hour.

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|---|---|---|---|---|---|---|---|---|---|---|
| | | Wound | | | Instrument table | | | Periphery | | |
| | | Mean quantity Particles [0.5µm] | Mean level of CFU [CFU/$m^3$] | Type of micro organism | Mean quantity Particles [0.5µm] | Mean level of CFU [CFU/$m^3$] | Type of micro organism | Mean level of CFU [CFU/$m^3$] | Mean level of CFU [CFU/$m^3$] | Type of micro organism |
| Patellar fracture repair [45 min]* | 3 | 325216 | 0 | None | 74771 | 0 | None | 15121 | 17 | 6x Micrococcus luteus<br>6x Staphylococcus epidermidis<br>1x Bacillus sp<br>4x Staphylococcus warneri |
| | 4 | 1926 | 0 | None | 3307 | 0 | None | 0 | 3 | 1x Staphylococcus capitis<br>1x Micrococcus luteus<br>1x Staphylococcus epidermidis |
| | 5 | 8957 | 0 | None | 6325 | 0 | None | 963 | 10 | 5x Micrococcus luteus<br>3x Stphylococcus haemolyticus<br>2x Staphylococcus epidermidis |
| | 6 | 289773 | 0 | None | 5532 | 0 | None | 1830 | 10 | 5x Micrococcus luteus<br>5x Staphylococcus haemolyticus |
| Ankle fracture fixation [45 min]* | 7 | 3177296 | 0 | None | 4225 | 2 | 2x Micrococcus luteus | 5121 | 41 | 1x Bacillus sp<br>16x Micrococcus luteus<br>20x Staphylococcus epidermidis<br>4x Staphylococcus capitis |
| | 8 | 78976 | 0 | None | 2538 | 3 | 2x Corynebacterium sp<br>1x Micrococcus luteus | 21285 | 6 | 4x Micrococcus luteus<br>2x Staphylococcus warneri |
| Open inguinal hernia repair [90 min] | 1 | 2613831 | 2 | 1x Micrococcus luteus<br>1x Staphylococcus hominis | 128 | 0 | None | 83118 | 3 | ND** |
| | 2 | 867 | 0 | None | 64 | 0 | None | 3018 | 6 | ND** |

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TABLE 8.1 Descriptives operating room. Number (CFU/$m^3$) and type of microorganism and quantity of dust particles measured. All surgeries were performed in the same OR equipped with an UDAF and in total 71 air changes per hour.

| Type of Surgery [Duration] | Measurement cycle [10 min] | Quantity Particles, CFUs and Measurement location | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Wound | | | Instrument table | | | Periphery | | |
| | | Mean quantity Particles [0.5µm] | Mean level of CFU [CFU/$m^3$] | Type of micro organism | Mean quantity Particles [0.5µm] | Mean level of CFU [CFU/$m^3$] | Type of micro organism | Mean level of CFU [CFU/$m^3$] | Mean level of CFU [CFU/$m^3$] | Type of micro organism |
| Laparoscopic inguinal hernia repair [90 min] | 3 | 12360 | 0 | None | 32 | 0 | None | 3178 | 10 | ND** |
| | 4 | 35315 | 2 | 1x Micrococcus luteus<br>1x Staphylococcus epidermidis | 7159 | 1 | 1xStaphylococcus warneri | 9663 | 8 | ND** |
| Laparoscopic inguinal hernia repair [45 min] | 5 | 1148947 | 0 | None | 5040 | 0 | None | 5458 | 2 | ND** |
| | 6 | 61833 | 0 | None | 0 | 0 | None | 2921 | 3 | ND** |
| | 7 | 55637 | 0 | None | 0 | 0 | None | 4697 | 4 | ND** |
| Removal of implants of the ankle [10 min] | 1 | 5648228 | 0 | None | 22345 | 0 | None | 15057 | 7 | ND** |
| Ankle fracture fixation [50 min] | 2 | 4109118 | 0 | None | 5426 | 0 | | 1316 | 0 | ND** |
| | 3 | 2278310 | 0 | | 6421 | 8 | 1x Staphylococcus epidermidis<br>7x Micrococcus luteus | 2279 | 0 | ND** |
| | 4 | 7045822 | 5 | 3x Staphylococcus aureus<br>2x Staphylococcus pettenkoferi | 18010 | 10 | 1x Paracoccus yeei<br>3x Staphylococcus hominis<br>5x Kocuria rhizophila<br>1x Acinetobacter lwoffii | 8861 | 2 | ND** |
| Laparoscopic inguinal hernia repair [45 min] | 5 | 25809339 | 0 | | 835 | 0 | None | 10370 | 2 | ND** |
| | 6 | 2689437 | 1 | 1x Paenibacillus urinalis | 96 | 0 | None | 13869 | 5 | ND** |
| | 7 | 33388 | 0 | | 64 | 0 | None | 9278 | 1 | ND** |
| Removal of lipoma swelling [10 min] | 1 | 318185 | 0 | None | 193 | 0 | | 11879 | 21 | 1x Staphylococcus epidermidis<br>1x Moraxella osloensis<br>1x Micrococcus luteus |

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TABLE 8.1 Descriptives operating room. Number (CFU/m$^3$) and type of microorganism and quantity of dust particles measured. All surgeries were performed in the same OR equipped with an UDAF and in total 71 air changes per hour.

| Type of Surgery [Duration] | Measurement cycle [10 min] | Quantity Particles, CFUs and Measurement location | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Wound | | | Instrument table | | | Periphery | | |
| | | Mean quantity Particles [0.5µm] | Mean level of CFU [CFU/m$^3$] | Type of micro organism | Mean quantity Particles [0.5µm] | Mean level of CFU [CFU/m$^3$] | Type of micro organism | Mean level of CFU [CFU/m$^3$] | Mean level of CFU [CFU/m$^3$] | Type of micro organism |
| Removal of lipoma swelling [10 min] | 2 | 9760 | 1 | 1x Moraxella osloensis | 11012 | 0 | None | 5394 | 19 | 1x Staphylococcus vitulinus<br>1x Staphylococcus hominis<br>1x Micrococcus luteus<br>1x Moraxella osloensis |
| Laparoscopic inguinal hernia repair [50 min] | 3 | 8857047 | 0 | None | 5137 | 0 | None | 0 | 14 | 1x Staphylococcus epidermidis<br>1x Paracoccus yeei<br>1x Moraxella osloensis<br>1x Corynebacterium simulans<br>1x Micrococcus luteus |
| | 4 | 110567 | 0 | None | 12103 | 0 | None | 0 | 17 | 1x Staphylococcus hominis<br>1x Acinetobacter johnsonii<br>1x Staphylococcus warneri |
| | 5 | 14415 | | None | 3981 | 0 | None | 0 | 19 | 1x Staphylococcus epidermidis<br>1x Staphylococcus aureus<br>1x Staphylococcus hominis<br>1x Micrococcus luteus |
| | 6 | 1605 | 0 | None | 4495 | 0 | None | 0 | 12 | 1x Staphylococcus hominis<br>1x Moraxella osloensis<br>1x Mirococcus luteus |

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|---|---|---|---|---|---|---|---|---|---|---|
| | | Wound | | | Instrument table | | | Periphery | | |
| | | Mean quantity Particles [0.5µm] | Mean level of CFU [CFU/m$^3$] | Type of micro organism | Mean quantity Particles [0.5µm] | Mean level of CFU [CFU/m$^3$] | Type of micro organism | Mean level of CFU [CFU/m$^3$] | Mean level of CFU [CFU/m$^3$] | Type of micro organism |
| Laparoscopic inguinal hernia repair [35 min] | 7 | 68831 | 0 | None | 4141,4 | 0 | None | 417,4 | 7 | 1x Staphylococcus epidermidis<br>1x Micrococcus luteus<br>1x Moraxella osloensis<br>1x Kocuria rhizophila |
| | 8 | 33581 | 1 | 1x Micrococcus luteus | 4173,6 | 0 | None | 32,1 | 8 | 1x Staphylococcus hominis<br>1x Staphylococcus petrasii<br>1x Micrococcus luteus<br>1x Corynebacterium amycolatum |
| | 9 | 5522 | 1 | 1x Staphylococcus hominis | 2889 | 0 | None | 0 | 9 | 1x Staphylococcus epidermidis<br>1x Micrococcus luteus<br>1x Moraxella osloensis |
| Ankle fracture fixation [10 min] | 1 | 31526 | 0 | None | 24496 | 0 | None | 18877,3 | 1 | 1x S. epidermidis |
| Laparoscopic inguinal hernia repair [60 min] | 2 | 321813 | 0 | None | 257 | 0 | None | 995,2 | 1 | 1x M. luteus |
| | 3 | 7994 | 0 | None | 0 | 0 | None | 160,5 | 1 | 1x S. epidermidis |
| | 4 | 13323 | 0 | None | 0 | 0 | None | 545,8 | 5 | 1x M. osloensis<br>2x M. luteus<br>1x S. saprophyticus<br>1x P. scleromae |
| | 5 | 125913 | 0 | None | 0 | 0 | None | 642,1 | 1 | 1x S. warneri |
| | 6 | 36631 | 0 | None | 482 | 0 | None | 385,3 | 3 | 2x C. propinquum<br>1x M. luteus |
| | 7 | 33196 | 1 | 1x M. luteus | 0 | 0 | None | 1380,5 | 0 | None |
| | 8 | 33099 | 0 | | 963 | 0 | | 866,8 | 0 | None |

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| Type of Surgery [Duration] | Measurement cycle [10 min] | Quantity Particles, CFUs and Measurement location | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Wound | | | Instrument table | | | Periphery | | |
| | | Mean quantity Particles [0.5µm] | Mean level of CFU [CFU/m$^3$] | Type of micro organism | Mean quantity Particles [0.5µm] | Mean level of CFU [CFU/m$^3$] | Type of micro organism | Mean level of CFU [CFU/m$^3$] | Mean level of CFU [CFU/m$^3$] | Type of micro organism |
| Laparoscopic inguinal hernia repair [30 min] | 9 | 16598 | 0 | None | 0 | 0 | None | 577,9 | 0 | None |
| Clavicle plate removal/ fracture [20 min] | 1 | 0 | 3 | 1x B. simplex<br>1x M. luteus<br>31x grams of positive rods not determinable | 0 | 1 | 1x M. luteus | 64,2 | 8 | 3x S. epidermidis<br>3x S. hominis<br>1x M. luteus<br>1x grams of positive rods not determinable |
| | 2 | 0 | 2 | 1x C. cellulans<br>1x Paenibacillus sp | 0 | 1 | 1x S. capitis | 0 | 3 | 2x S. hominis<br>1x M. luteus |
| Fracture fixation of ankle fracture [30 min] | 3 | 56680 | 10 | 4x C. minutissimum<br>3x S. epidermidis<br>1x E. coli<br>1x E. casseliflavus<br>1x B. pumilus | 0 | 2 | 2x M. luteus | 2439,9 | 20 | 3x S. epidermidis<br>1x S. warneri<br>3x M. luteus<br>9x S. warneri |
| | 4 | 51701 | 0 | None | 0 | 0 | None | 0 | 20 | 1x S. haemolyticus<br>6x S. saprophiticus<br>8x M. luteus |
| | 5 | 11159 | 3 | 1x E. coli<br>2x S. capitis | 0 | 0 | None | 0 | 46 | 4x P. yeei<br>26x S. warneri<br>4x M. luteus |
| Laparoscopic inguinal hernia repair [20 min] | 6 | 29276 | 1 | 3x M. luteus | 0 | 0 | None | n.a. | 6 | 3x S. epidermidis<br>3x M. luteus |
| | 7 | 181588 | 0 | None | 0 | 4 | 2x S. hominis<br>2x M. luteus | n.a. | 4 | 2x M. luteus<br>1x S. epidermidis<br>1x S. capitis |
| MEAN | | 852679 | 0,5 | | 3797 | 0,7 | | 4355 | 7,9 | |

*: *C-arm used during surgical procedure*

**: ND: ND**

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# 9 Conclusions, general discussions and future direction of research

This dissertation offers insights into CFD analysis of Ultra-Clean ventilation systems, their technical functioning, capital and operational expenditures, ventilation effectiveness, and the energy-saving potential of different operating room (OR) air handling installations and air supply (ventilation) systems.

# 9.1 Conclusions

## 9.1.1 Ventilation Effectiveness

When we compare the different ultra-clean ventilation (UCV) air supply systems currently available on the market, we find a high ventilation effectiveness (VE)[1] of the unidirectional airflow (UDAF) system in the ultra-clean area. The conventional ventilation (CV), temperature-controlled dilution ventilation (cDV), and temperature-controlled airflow (TcAF) systems show an, in general, mixing character in the ultra-clean area. Because of the uni-directional flow of the TcAF installed above the surgical table a higher VE was found at the measuring point in the center. A UDAF ventilation system is outperforming the other ultra-clean ventilation systems and the conventional ventilation system in the ultra-clean area[2]. The VE decreases when an ultra-clean OR with an ultra-clean ventilation (UCV) air supply system is switched, from its default setting to an air change rate of 20 per hour. A temperature-controlled airflow or a controlled dilution ventilation system can be, because of its design principle, switched to a lower air change rate. When lowering the air change rate to 20 per hour these systems comply with standards and guidelines for generic surgery. However, switching a uni-directional airflow system installed in an existing operating room that was not initially designed to operate at a lower air change rate per hour, is not a sinecure. When reducing the air change rate per hour of a UDAF system it is important to know how the air handling system and air supply system are constructed. A further study on how the different designed UDAF systems behave when reducing the air change rate is recommended.

Most European ventilation standards and guidelines for infection-prone clean surgeries are developed to determine the size and the air quality of the ultra-clean area. The periphery of the operating room (OR) is not considered by most standards and guidelines.

1 In this thesis, unless otherwise stated, ventilation efficiency (VE) is defined as the sum of the recovery degree (RD), cleanliness recovery rate (CRR) and air change effectiveness (ACE).

2 The wound area, the area surrounding the surgical staff and instrument tables are defined as ultra-clean areas.

However, when the size of the UDAF system is too small to position all instrument tables sometimes the periphery is used to partly position microbiological-sensitive instrument tables. In the Netherlands between 2014 and 2021 peripheral CFU measurements were performed [1] in an OR equipped with an UDAF with a surface of 5.7–7.1 $m^2$ and an air change rate of 46-68 per hour. The number of CFUs did not exceed 10 CFU/$m^3$ in 82.4% of the measurements in the periphery of the operating room during surgery. The air quality in the periphery, in this study, is good enough to safely position instrument tables in case the protected area of the ultra-clean ventilation system is not large enough.

The ventilation effectiveness of the studied ultra-clean ventilation (UCV) air supply systems all complied to the defined ultra-clean air quality level in the ultra-clean zone of the operating room. When the size of an existing UCV UDAF system is too small to position all instrument tables underneath the UDAF, they can be partially positioned in the periphery on most occasions.

### 9.1.2 Investment costs, cost savings and energy reduction

Choosing an air handling installation with an ultra-clean ventilation system over a conventional ventilation system increases capital and operational expenditures. The capital expenditures for an air handling installation with an ultra-clean system represent an additional investment of about 3 to 7% of the total cost of building a completely new OR department. When the impact on patient suffering and costs associated with surgical site infections are weighed against the costs associated with an air handling installation with an ultra-clean system, the investment is worth considering. If you can prevent two to four surgical site infections over 10 years, the investment will already be recovered.

At this moment test methods of current standards and guidelines [2–5] are not primarily developed for assessing newly developed ventilation systems. Controlled dilution ventilation (cDV) and temperature-controlled airflow (TcAF) focus on larger ultra-clean areas and claim the whole OR to be ultra-clean [6,7]. By using a uniform test grid [8,9] described in chapters 3 and 5, all current and future developed ultra-clean or generic operating room air supply systems can be tested and evaluated in the same way. The test grid measurement methodology provides an overview and insight into the air balance in the operating room. It is focusing on the ultra-clean area where the patient, surgical team, and instrument tables are located. Cost savings can be achieved when finetuning the performance within these or even larger ultra-clean areas using this new measuring method. Further, measurements

performed according to the latest standards and guidelines [2–5] are time-consuming. In some cases, measurements can take up a whole day and during these tests, the OR cannot be used for surgeries. In contrast, the uniform test grid [8,9] measurement only takes 1.5 hours per OR.

Ultra-clean ORs with higher air change rates are recommended for surgeries where artificial implants are used. The World Health Organization [10] (WHO) and Federation of Medical Specialist [11] (FMS) noted that existing research on OR ventilation systems is flawed and that there is only weak evidence that OR ventilation systems help in the reduction of SSIs [12–14]. However, in the last decade clear evidence has been published in peer-reviewed journals that contradicts this position. Several studies [15–17] advise to use a UCV system for infection-prone surgery [3,18,19] instead of a CV system [12,13]. UCV systems do reduce the number of CFUs in the OR [20–22] and do contribute to a lower number of SSIs [17,21]. For most types of surgeries higher air change rates are not necessary. Therefore, not all operating rooms should automatically be equipped with an Ultra Clean Ventilation (UCV) system.

In recent years, most operating rooms in the Netherlands have been built to the highest standards. Guidelines over the last few decades gave room to vary the classification of the operating room. It is advised to make use of energy-saving measures such as reducing the amount of outside air introduced and/or putting the air handling installation on standby at nights or on the weekends [23]. When lowering the air change rate per hour [9], it is no longer possible to talk about an ultra-clean zone [24] as defined in international standards and guidelines. Other parameters [25–27] become more important to ensure that clean air quality is maintained, comfort [28,29] levels are met, and staff safety [26,27] is guaranteed. If it is decided to build the operating room according to a lower classification, the aforementioned parameters should be considered.

Energy-saving measures have been implemented in the air handling installations. However, there is room for improvement regarding the reduction of the air handling installation energy consumption.

Some examples are:

- lowering the classification of the operating room.
- switching the installation based on the type of surgery (‘demand-based ventilation’).
- reducing the amount of outdoor air (ODA) or the total supply air (SUP).
- increase the boundary conditions (lower and upper setpoint) of the relative humidity.

The average air change rate of Dutch operating rooms is 69 per hour. To date, 94% of all operating rooms in the Netherlands are built as ultra-clean operating rooms. Our survey indicated that only 32% of operating rooms are used for major implant surgery.

When only the operating rooms used for major implant surgery are built as ultra-clean operating rooms less air needs to be supplied in most of the operating rooms. One of the possibilities to reduce energy consumption in an operating room is to reduce the number of air changes (air volume) [30,31]. In an exisiting ultra-clean OR situation the OR air handling installation can be switched from an ultra-clean to a generic operating room when not used for major orthopedic implant surgeries.

Energy-saving measures with existing and new to-be-built operating rooms can be achieved by:

- lowering the air change rate (supply air) to an OR when not in use.
- extending the boundaries for relative humidity from 30 - 70%.
- no boundaries applicable for relative humidity overnight and on weekends.
- reducing the outside air volume to 1,000 $m^3$/h during operating room in use.
- reducing the outside air volume to 500 $m^3$/h when the operating room is not in use.
- Fixed Start and End time operating hours, normal operation modus during weekdays. Night, weekends, and when OR not in use standby modus.
- Lowering the air change rate (supply air) to an OR for generic surgery when not used for major (orthopedic) implants or other infection-prone surgeries

### 9.1.3 Primary Benchmark

Reducing energy consumption in hospitals is a high priority. As a result, there is a trend to reduce the air change rate per hour in the operating room. For new construction projects, the choice is sometimes made to lower operating room classifications [11] . In other hospitals to modifies the existing air handling installation and ultra-clean air supply systems fitted in the existing operating rooms.

In this thesis, a benchmark (2024) was made of the current (ultra-clean) air quality level in most operating rooms (80%) in the Netherlands. The type and quantity of microorganisms are determined in this benchmark. The level of CFUs in the ultra-clean surgical area was at this study with ≤1 CFU/$m^3$ far below the standard defined ultra-clean level of ≤10 CFU/$m^3$. Determination of the type of microorganisms shows a paucity of primary pathogens, with the largest numbers of cultured bacteria members of human colonizers or environmental contaminants that occasionally participate in

prosthetic infections were found distant from the site of the surgery to form a threat in those special cases. The impact of these changes on the air quality and quantity and type of microorganisms measured in the ultra-clean area on possible incidence of SSI needs further investigation. We don't know yet if changing from ultra-clean ventilation (UCV) to a conventional mixing ventilation (CV) air supply system with a lower air change rate per hour will increase the likelihood of environmental contaminants as found in our benchmark study being a threat. This benchmark can be used as a base line study to compare current, future new and modified operating rooms.

## 9.2 Dynamics in defining standards and guidelines[3]

Healthcare professionals trust recommendations in standards and guidelines that are supposedly evidence-based [32]. However, often healthcare professionals are the creators of standards or guidelines themselves. There is a difference in approach between healthcare professionals, epidemiologists, and medical specialists on the one hand and engineers and other scientists on the other hand regarding the scientific approach to be taken when creating standards or guidelines. Since 1982 healthcare professionals have elevated "double-blind randomized" research to the "gold standard" [33], which has brought much good, especially with drug development and testing. Healthcare professionals often assume that Randomized Control Trials (RCTs) and their meta-analyses [32] offers a ground truth. Evidence-based does not equal just accepting RCTs as evidence. Properly applied evidence-based research does seek and strive for RCT as the highest quality evidence, but if there is none, then other evidence levels should be considered/used like observational studies, cohort studies, experimental studies, expert opinion, etc. This does not always happen when standards or guidelines are developed. In some specific areas of work, it is not possible to conduct RCTs on ethical grounds. One such area is ultra-clean air quality and the incidence of a surgical site infection (SSI) in the operating room. It is, obviously, not ethical to perform infection-prone surgery in an operating room with a low ultra-clean air change rate and compare this to an operating room with a high ultra-clean air change rate.

3 This paragraph is partially extracted from correspondence (25.08.2020) between Em. Prof. Ir. P.G. Luscuere and Em. Prof. Dr. G.H.I.M. Walenkamp.

The Dutch Federation of Medical Specialists (FMS) [11] wrote a new guideline in 2022 that did not include some essential aspects. Their key question was: "Which air handling system should an operating room be equipped with to prevent surgical site infections as much as possible?" The focus of the FMS was mainly on the relationship between the type (Uni-Directional Air Flow or Conventional Ventilation) of the OR air supply system and the incidence of an SSI. Other important objectives of an air handling installation, such as creating a stable temperature, relative humidity, and overpressure as well as the compensation of internal heat load, removal of surgical smoke, odors [26,27] etc. from the operating room itself were not considered but should be considered as well before writing a new guideline.

The FMS' recommendation for the OR classification is based on the fact that the overall quality of evidence is (very) low due to the observational nature of the studies, the presence of static heterogeneity, and uncertainty about the extrapolability. When compiling this new evidence-based guideline the foundation of the guideline was the systematic review executed by Bischoff et al, 2017 [34]. An exploratory search, a relation between a surgical site infection and air handling was made of existing foreign guidelines and systematic reviews in Medline and Embase databases from Jan 1, 1990, and Jan 31, 2014. They updated the search for MEDLINE for the period between Feb 1, 2014, and May 25, 2016. All studies before January 1st,1990 were not considered including the study of Lidwell et al.[4] and more recent studies [15–17]. Those studies advise to use a UCV system for infection-prone surgery [3,18,19] instead of a CV system [12,13]. UCV systems do reduce the number of CFUs in the OR [20–22] and do contribute to a lower number of SSIs [17,21].

The predefined question of the FMS was: "is the use of laminar airflow in the operating room associated with the reduction of overall or deep SSI as outcomes in patients of any age undergoing surgical operations?" Technical (international) operating room standards or guidelines and scientific studies on air handling installations were not included in the literature review. The precise definition of laminar airflow or conventional ventilation and the corresponding air change rates used to make the comparison are also not clear. Details about OR size, type and size of UDAF, extraction location, clothing details, no. of persons in the OR etc. were not considered in this Meta Analysis.

4 The study Ultra-clean air and antibiotics for prevention of postoperative infection: A multicenter study of 8,052 joint replacement operations[48]

There are studies showing a high air change rate contribute to lower surgical site infections [16,35]. Despite the meta-analysis performed, there is no evidence provided by the FMS that the suggested changes will be beneficiary for preventing the incidence of surgical site infections. Absence of evidence is not evidence of absence [36]. The FMS acknowledges that more and especially better-quality research on the effect of different air handling installations and air supply systems on surgical site infections is urgently needed, hence the before-mentioned ethical grounds will remain in place.

The by FMS per OR classification defined air change rate, ISO classification, recovery rates, etc. are not evidence-based and deviate from international standards and guidelines [3,5,37,38]. Lowering the air change rate in the operating room could have other effects on the (ultra-clean) air quality, the temperature, relative humidity, and the removal of surgical smoke and odors. In the past, a higher air change rate was advised by guidelines, therefore sufficient air was automatically introduced into the operating room to keep the temperature and relative humidity into the boundary conditions and to dissipate the internal heat load caused by the number of people present and medical equipment used. In addition, it ensured the dilution of carcinogenic surgical smoke. When having lower air change rates in the operating room other measures are becoming (more) important to keep the operating room on the required (ultra) clean air, temperature, and relative humidity conditions. The number of persons, type of OR clothing, and heat load of medical equipment used will influence the quality of the air and comfort of the surgical team.

The financial costs of treating SSIs are increasing every year. Most studies only calculate the direct costs of an SSI and do not consider the wider impact of SSIs to society like absence from work or reduced work productivity. According to the WHO, there is a relationship between SSIs and increasing antimicrobial resistance [39,40]. Antimicrobial resistance is an urgent global public health threat [41]. With a higher proportion of resistant bacteria, the effect of antibiotic prophylaxis will be reduced. When writing standards or guidelines, one should look more broadly than just the specific area of expertise the standard or guideline is about. In the case when writing the guideline on air handling in operating rooms and treatment rooms [11], one should have included the technical air handling installation and air supply aspects, the cost of surgical site infection(s) and the increasing antimicrobial resistance and thus the reduced effect of surgical prophylaxis.

The type of air handling installation and air supply system installed in the operating room cannot be seen separately from the complete package of measures aimed at preventing surgical site infections such as compliance with work agreements, dress code, door policy, correct placement of surgical lights and other equipment, disciplined behavior in the operating room and infection registration and monitoring.

Despite the limited scientific basis of the FMS guideline, it does cause both technicians and medical specialists to look differently at operating room design and its classification. While in the past the various Dutch guidelines allowed for different classifications of operating rooms over the years, in recent decades most operating rooms were designed the same. This is reflected in the survey result, which shows that currently 94% of the operating rooms in the Netherlands are fitted with an ultra-clean (FMS class 1+) ventilation system. To reduce energy consumption, it is advisable to make an accurate assessment of what type of intervention the operating room will be used for. The FMS guideline offers some guidance here. When air change rates in existing operating rooms are altered following FMS guidelines, several parameters are important for maintaining air quality, OR staff safety, and comfort temperature and humidity levels. These parameters include the air leak rate of the operating room, the number of people present, the internal heat load, the clothing procedure and type of clothing, the door policy, the type of medical intervention, and the devices or methods used for this intervention such as diathermy or carbon dioxide (CO2) insufflation. Changing an existing operating room one-to-one to a new (lower) FMS classification without looking at these parameters will be a major non-scientific experiment where the outcome will only be learned later.

## 9.3 Future direction of research

With this dissertation, the conversation about the usefulness and necessity of the air change rate per hour in operating rooms has not ended. Since 1995, the air change rate per hour in operating rooms has only increased. The question of whether this has led to a lower incidence of surgical site infections cannot be answered at present. The WHO noted that existing research on OR ventilation systems is flawed and that there is only weak evidence that OR ventilation systems help in the reduction of SSIs [12–14]. However, in the last decade, clear evidence has been published in peer-reviewed journals that contradicts this position. Several studies [15–17] advise to use of a UCV system for infection-prone surgery [3,18,19] instead of a CV system [12,13]. UCV systems do reduce the number of CFUs in the OR [1,20–22] and contribute to a lower number of SSIs [17,21]. In general, in surgical procedures, open procedures are more likely to lead to an SSI than closed procedures (RIVM 2023).

What we do know from Prevention of Hospital Infections by Surveillance (PREZIES)[5] is that, in the Netherlands between 2018-2022, the cumulative incidence of surgical site infections (SSIs) varies considerably between surgical interventions. Especially in colon (large intestine) (7.0%, n=760) and gallbladder surgery (2.8, n=760) are showing a higher risk of infection than, for example, hip replacement insertion (1.2%, n=1,243). Whether this low number of surgical site infections measured at hip or knee arthroplasty is caused due to the high air change rate is scientifically not (easy) to prove. Besides the air quality, many other parameters are influencing the incidence of a surgical site infection. General strategies [42] supported by randomized trials are followed for the prevention of SSIs: avoiding razors for hair removal, decolonization with intranasal anti-staphylococcal agents and anti-staphylococcal skin antiseptics for high-risk procedures, use of chlorhexidine gluconate and alcohol-based skin preparation, maintaining normothermia to keep the body temperature warmer than 36°C, perioperative glycemic control and use of negative pressure wound therapy.

The role of an ever-increasing air change rate in the ORs built, as seen over de last decades, to control SSIs, seems a concept that is already far beyond a reasonable expectation dose/response effect. However, simply reducing the number of air changes in the operating room is not recommended. A further study should be conducted on what the effect is on the level of CFU/$m^3$ in the surgical field and on the incidence of a surgical site infection when reducing the number of air changes per hour in the operating room. Taking into account the discipline of the surgical staff, the number of door openings during surgery [43–45], the quality of the clothing [25,46,47] used, the internal heat load, the influence of surgical [26,27] smoke, etc.

Given the investment required to build an entire hospital, and the investment costs to equip an operating room with an ultra-clean ventilation system, the question remains why not equip all operating rooms with the same ultra-clean air supply system? The operating room should be designed in such a way that the air change rate can be variably adjusted. This “demand-based” ventilation is more energy efficient and will give operating rooms because they are all the same, more flexibility in planning and makes maintenance and service less complex. Another possible reason is that it is

5 https://www.vzinfo.nl/zorginfecties/ziekenhuizen/postoperatieve-wondinfecties. Participating healthcare institutions generate comparable and nationally representative data on healthcare-associated infections, which, besides providing a national overview, serve to support infection prevention policies in healthcare institutions. The aim of hospital infection registration is to contribute to the reduction of (risk factors for) healthcare-associated infections in Dutch healthcare institutions.

difficult to upgrade an operating room to a higher classification when it is built. A decision to build all ORs the same will depend on the type of hospital and the type of surgeries executed. Further research into investments related to energy consumption and possible cost savings related to operating room planning/scheduling should be investigated when all operating rooms are built identically is recommended so that an informed choice can be made.

Patient safety remains the most important, but the impact of the number of air changes on staff safety using surgical smoke or other toxic gases/substances should be further investigated when reducing the air change rate. Patient safety and achieving energy savings are and will continue to be important, but we cannot neglect comfort and staff safety.

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TOC

# 10 Valorization

**This thesis provides valuable information that can be used by healthcare and engineering consultants, manufacturers of Ultra Clean Ventilation or Conventional Ventilation systems, installation companies, real estate and construction managers of hospitals, and medical specialists. It will assist in comparing, enhancing, and facilitating decision making for the selection of the type of air handling installation and air supply system, investment and operational costs, and possible energy-saving measures when building or renovating operating rooms.**

This thesis provides insights into:

- the application of CFD simulation,
- differences between various European standards and guidelines,
- different typologies of air handling systems for operating rooms used in Europe,
- the functioning of different air supply systems for operating rooms when operating under the design conditions and with reduced airflow,
- capital and operational expenditures of different operating room air handling installations and air supply systems,
- energy-saving potential measures that can be used for existing operating room air handling installations or that can be considered when realizing a new one, and
- energy-saving potential in terms of reduction of energy demand of installed operating room air handling installations in the Netherlands.

In addition, a benchmark is presented regarding the numbers and types of microorganisms and dust particles in the ultra-clean area of an OR class 1+, so that a comparison can be made between a OR class 1+ and OR class 1 when a downgrade of the OR classification is considered.

Insights into the optimization of a selected OR air supply system, emphasizing the relationship between airflow patterns, room layout, and contaminant control, are given through Computational Fluid Dynamics (CFD). CFD simulation provides guidance on what effect obstacles in the operating room have on the airflow introduced in the operating room supplied through an ultra-clean or conventional air supply system.

Ultra-clean ORs with higher air change rates are recommended for surgeries in which artificial implants are used. Insight is provided into the functioning of the different types of air supply systems currently available in the market and their ventilation effectiveness (VE) in the ultra-clean area of different types of Ultra-Clean air supply Ventilation (UCV) systems compared to Conventional air supply Ventilation (CV) systems. These insights enable decision makers to make an equitable comparison of the performance of the different types of OR air supply systems that are currently available.

In some situations, the size of the Uni-Directional Airflow (UDAF) system is too small [1] to position all microbiological-sensitive instrument tables underneath the system. It is important to know the effects of positioning the instrument tables outside the protected zone of the UDAF. When the air change rate is ≥46 per hour, the air quality in the periphery might be good enough to safely position instrument tables there if the protected area of the ultra-clean ventilation systems is not large enough. Based on the outcomes of this study, one could decide to postpone a renovation or decide not to replace all the systems.

The World Health Organization [2] (WHO) and Federation of Medical Specialist [3] (FMS) noted that previous research on OR ventilation systems was flawed and that there is only weak evidence that OR ventilation systems help in the reduction of SSIs [4–6]. However, in the last decade, this position has been contradicted by clear evidence published in peer-reviewed journals. Several studies [7–9] advise to use a UCV system for infection-prone surgery [10–12] instead of a CV system [4,5]. They demonstrated that UCV systems do reduce the number of CFUs in the OR [13–15] and do contribute to a lower number of SSIs [9,14]. For most types of surgeries, higher air change rates are not necessary to prevent surgical site infections. Therefore, not all operating rooms should automatically be equipped with an ultra-clean ventilation system. In recent years, most operating rooms in the Netherlands have been built to the highest standards, while the guidelines over the last few decades gave room to vary the classification of the operating room and make use of energy-saving measures, such as reducing the amount of outside air introduced or setting the air handling installation on standby at nights or on the weekends. When the air change rate per hour is lowered [16], an OR is no longer an ultra-clean zone [17] as defined in international standards and guidelines. In that case, other parameters [18–20] become more important to maintain clean air quality, meet comfort [21,22] levels and guarantee and staff safety [19,20]. If it is decided to build an operating room according to a lower classification, the aforementioned parameters should be considered.

Energy-saving measures have been implemented in air handling installations over the last few years, but there is room for improvement regarding the reduction of energy consumption of an air handling installation. Some of the possibilities to reduce energy consumption are reducing the amount of outdoor air (ODA) or the total supply air (SUP), setting fixed operating hours, widening the boundary conditions (lower and upper setpoint) of the relative humidity, and lowering, if technically possible, the classification of the operating room from ultra-clean to generic.

Economic aspects of air handling installations and of the different air supply systems in operating rooms were investigated. Valuable financial information is given for making decisions about air handling installations and air supply systems for operating rooms. The capital expenditures for an air handling installation with an ultra-clean system represents an additional investment of about 3 to 7% of the total cost of building a completely new OR department [23]. The costs of treating surgical site infections are increasing every year. Multiple studies reported that prolonged length of stay of patients in general wards or intensive care units (ICUs) because of SSIs constitutes a major cost burden [2,24,25]. When the impact of patient suffering and the costs associated with SSIs are weighed against the investment required for an air handling installation with an ultra-clean system, this investment is worth considering. Given the investment required to build an entire operating room department and the investment costs to equip an operating room with an ultra-clean ventilation system, the question remains: why not equip all operating rooms with the same ultra-clean air supply system? The operating room should be designed in such a way that the air change rate can be variably adjusted. This “demand-based” ventilation is more energy-efficient, and operating rooms that are all the same will ensure more flexibility in planning and make maintenance and service less complex. Another possible reason to equip all operating rooms with an ultra-clean air supply system is that it is difficult to upgrade an operating room to a higher classification when it is built. The decision to build all ORs the same will depend on the type of hospital and on the type of surgeries executed. To make the most economically and energetically advantageous choice, additional research is recommended into possible cost savings through flexibility in planning if all operating rooms are built the same in terms of air quality.

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# 11 Take Home Message

- Be careful in considering CFD simulation results. Not all fieldmeasurements match the simulation results. When CFD simulations are validated against field measurements, they can assist in studying the consequences of technical or infrastructural changes in the operating room (OR).

- Current test standards are not developed for assessing ventilation effectiveness outside of the standard protected area, the clean zone. Whereas those areas are sometimes used to locate microbiologically sensitive instrument tables or where sterile surgical staff may be present.

- The air quality in ORs should be measured in an 'operational' situation and not 'at rest'.

- Reducing the air volume from an ultra-clean to a generic operating room lowers the ventilation efficiency.

- There are various ways to reduce the energy of the ventilation system. Reducing the amount of outside air, introducing operational periods, expanding relative humidity limits and lowering the OR classification. Reducing the amount of outside air has the most impact on saving energy and lowering the OR classification the least.

- An air handling installation for an ultra-clean operating room is 3-7% more expensive than a generic operating room. The operating cost for an ultra-clean air supply system is between € 673 and € 1,896 higher per year than the cost of a generic air supply system.

- If the impact on patient suffering and the costs associated with surgical site infections are weighed against the cost of an air handling system with an ultra-clean air supply system, the investment pays for itself when 2 to 4 surgical wound infections are prevented over the lifetime of the OR.

- In Dutch ultra-clean operating rooms, the number of CFUs in the ultra-clean zone is below the defined ultra-clean level of ≤10CFU/m3 required for ultra-clean surgery. The amount of dust particles during surgery was higher than the defined ISO 5 at rest. The effect on air quality when lowering the classification during surgery was not measured due to operational constraints.

- Expert opinion from different disciplines should be the norm for research on air volumes in operating rooms and their possible association with surgical site infections rather than the ‘gold standard’ of randomized controlled trials.

- The absence of evidence that surgical site infections are prevented in operating rooms equipped with ultra-clean ventilation systems is not evidence that surgical site infections are not prevented.

# Dankwoord

Dit proefschrift zou niet tot stand zijn gekomen zonder de hulp van anderen. Alle medewerkers van ziekenhuizen, privéklinieken, adviesbureaus, architecten, installateurs en collega's die bereid waren om deel te nemen aan de verschillende onderzoeken, luchttechnisch metingen en het verstrekken van benodigde informatie ten behoeve van dit proefschrift verdienen een woord van dank. Alle hiervoor genoemde bedrijven en instellingen waren enthousiast en bereid zonder voorwaarden aan de verschillende onderzoeken mee te werken.

Daarnaast wil ik iedereen bedanken die een bijdrage heeft geleverd aan dit proefschrift, met een aantal in het bijzonder.

Promotor, prof.ir. P.G. Luscuere, beste Peter, allereerst hartelijk dank voor de geboden mogelijkheid voor het starten van een promotietraject aan de faculteit Architecture and the Built Environment. Wij kwamen elkaar begin 2019 voor het eerst tegen in Maastricht bij een promotie over "aerogenic contamination control in operating theatres". Bij verschillende door ons bedrijf gerealiseerde operatiekamer projecten kwam uw naam vaak ter sprake. Echter hadden wij elkaar tot op dat moment nog nooit bewust getroffen. Vanaf het eerste moment hadden wij een klik en filosofeerden wij gepassioneerd over luchttoevoersystemen in operatiekamers en de ervaring die u heeft opgedaan met dit onderwerp bij de vele projecten en onderzoeken door u uitgevoerd over de jaren heen. Zonder u was ik zeker niet aan deze reis begonnen. Bij u thuis op de koffie, met wat lekkers, aan de keukentafel (met dank aan Mieke) hebben wij diverse gesprekken gevoerd over de verschillende uit te voeren onderzoeken, de wijze waarop en de onderzoeksrichting. Tijdens onze gesprekken hadden we het niet alleen over de promotie, maar hebben we ook voor mij waardevolle gesprekken gevoerd over uw ervaring met ondernemen en de keuzes die u hierin heeft gemaakt. Met hier en daar bijsturen, onze bijna wekelijkse contactmomenten en open gesprekken zullen me altijd bijblijven. U heeft mij richting gegeven maar me wel de regie laten behouden en de onderzoeken laten uitvoeren zoals wij gezamenlijk met de andere promotoren en mede auteurs hadden uitgezet. Heel veel dank voor het vertrouwen, de kritische blik en uw snelle reactie als ik om feedback vroeg. Dit is niet vanzelfsprekend en dat heb ik enorm gewaardeerd.

Promotor, prof.dr. M. van der Elst, beste Maarten, dank voor uw bijdrage. Wat is het een voorrecht om een medisch specialist als promotor in het team te hebben. Uw kritische blik met de vraag over medisch nut of noodzaak is belangrijk geweest in mijn onderzoekstraject. Vanaf dag één heeft u gehamerd op een kop en een staart van het proefschrift. Verlies de focus niet! Als een van de eerste medisch specialisten heeft u, op de wijze waarop we voor ons onderzoek hebben gemeten, meegewerkt aan luchttechnische metingen tijdens chirurgische (trauma) ingrepen. Wij hebben zeer nabij het wondgebied zowel micro organismen als stofdeeltjes mogen meten. We hebben zelfs het type mico organisme gedetermineerd. Echt uniek! U maakte het mogelijk en uw hele chirurgische team werkte met ons mee. Mijn enthousiasme brengt me vaak ver, maar zorgt er ook voor dat ik de focus nog wel eens verlies. U heeft mij in dit traject bijgestuurd, af en toe weer even terug op de plek gezet en ervoor gezorgd dat de focus op het einddoel bleef bestaan. Heel veel dank voor de gesprekken, de positieve feedback en de open maar ook waardevolle zakelijke gesprekken die wij hebben gevoerd tijdens het promotie traject.

Promotor, prof.ir. J.J. van den Dobbelsteen, beste John, heel bijzonder dat we dit mooie traject met elkaar hebben kunnen doorlopen. Verbonden aan de faculteit Mechanical Engineering als hoogleraar Medical Process Engineering, heeft u mij ondersteund in de noodzakelijke processen, zoals het data management platform en andere processen noodzakelijk voor mijn promotie. Uw focus op het verbeteren van de interactie tussen operatiepersoneel en medische technologie past goed in het door ons uitgevoerde onderzoek. Ook luchtbehandeling in operatiekamers interacteert met medische apparatuur en operatiekamer personeel. Bij het beoordelen van de verschillende door ons opgestelde manuscripten en mijn proefschrift heeft u een waardevolle bijdrage geleverd. Heel veel dank voor het vertrouwen en uw kritische maar zeer gewaardeerde feedback tijdens dit gehele traject.

dr. N.M.C. Mathijssen, beste Nina, enorm bedankt voor jouw hulp. Je stond altijd voor me klaar. Hele fijne gesprekken hebben we gevoerd over de analyse van data en de wijze waarop we de data gingen verwerken. Jouw statistische analyses en de input in SPSS hebben mij enorm geholpen. De leuke, inhoudelijke en diepgaande discussies die we hebben gehad over de verschillende manuscripten waren erg leerzaam. Dit noemen we wetenschap, zei je tegen me. “Kan je er een tabel van maken, dat scheelt weer tekst en het is overzichtelijker” heb je met enige regelmaat tegen me gezegd. Meestal stond de kern wel in het manuscript alleen de volgorde en indeling vond ik nog wel eens lastig. Ik ben mede door jou anders naar het schrijven van manuscripten gaan kijken. Aan alle artikelen in dit proefschrift heb je een bijdrage geleverd dank je wel hiervoor. Zonder jouw hulp had ik het zeker niet gered en daarvoor kan ik je niet genoeg bedanken. Hier stopt het niet, ik hoop nog veel met je te mogen samenwerken.

dr. A.A.L. Traversari, beste Roberto, dank je wel voor je bijdrage en “suggesties”. Wij hebben heel veel met elkaar gesproken over de uitgevoerde metingen en over het promoveren. Niet alleen gedurende de werkweek maar ook in de weekenden. Tijdens de verschillende door mij gegeven presentaties op bijeenkomsten heb je me altijd directe feedback gegeven. Een van mijn valkuilen is dat ik te veel tegelijkertijd wil vertellen. Hierdoor kan een leek mij niet altijd volgen. Dankzij jou ben ik daar meer over gaan nadenken en doe ik mijn uiterste best wat rustiger te zijn en langzamer te praten. Dat is voor mij niet altijd even makkelijk maar je blijft volharden in je feedback. Dank hiervoor. Door jouw opbouwende suggesties heb ik heel veel kunnen leren. Enorm bedankt en ik hoop nog veel met je te mogen samenwerken.

De overige leden van mijn promotiecommissie. Prof. em. dr. G.H.I.M. Walenkamp, Prof. dr. A.A. Zadpoor, dr. C. Wagenaar en dr. A. Bogdan hartelijk dank voor uw tijd en bereidheid om in mijn commissie plaats te nemen en mijn proefschrift te beoordelen. Ook dank aan Prof. dr. ir. J.C. Diehl die bereid is geweest reserve lid te zijn mocht een van de commissieleden op het laatste moment niet beschikbaar zijn.

André Bode, dank je wel voor het uitvoeren van de metingen en het analyseren van de data. Vele dagen, weekenden en avonden hebben wij samen doorgebracht ergens in een operatiekamer in Nederland. Veel leuke gesprekken gevoerd tijdens de metingen maar zeker ook bij het voorbereiden van de metingen. Heel erg fijn dat je me met enige regelmaat naar huis hebt gestuurd en de metingen zelf hebt afgerond. Zonder de door jouw uitgevoerde metingen was dit proefschrift niet tot stand gekomen.

De paranimfen Saadet Ozcamuzcu en Jurgen Verstraeten. Wat fijn dat jullie aan mijn zijde staan deze dag. Saadet, dank je wel voor je hulp en bijdrage bij de verschillende artikelen en de baseline study in het Reinier de Graaf. Je hebt dagenlang, samen met prof.dr. M. van der Elst en zijn team in de operatiekamer gezeten, TSA plaatjes gewisseld, genummerd en afgeleverd bij het laboratorium en de data verzameld. Dank je wel voor je geduld en je hulp. Jurgen dank je wel voor de telefoon gesprekken in de vroege ochtend tijdens de werkweek. Altijd fijn om samen de dag te beginnen en te sparren over de verschillende zaken die ons bezig houden. Ik ben dankbaar een vriend zoals jou te hebben.

Rob van den Berg, dank je wel Rob dat jij in 2001 in mij geloofde. Jij hebt mij in de wereld van operatiekamer luchttoevoersystemen geïntroduceerd en mij de kans gegeven me te ontwikkelen in dit segment. Dank je wel voor het vertrouwen! Ik ga ervan uit dat we ook nog na je naderende pensioengerechtigde leeftijd lekker blijven samenwerken.

Cleem Diemers, dank je wel voor het overnemen van de verschillende taken en overleggen. Mijn zakelijke linker -en rechterhand en sparringpartner. Het combineren van deze parttime promotie tezamen met het runnen van “ons” bedrijf was zonder jou niet mogelijk geweest. Enorm dank voor al je support en steun over de jaren heen. We gaan samen nog veel avonturen beleven!

Bo Koperdraat, dank je wel voor het maken van onder andere de research poster en de illustraties van de verschillende luchttoevoersystemen die in dit proefschrift en artikelen zijn opgenomen. Heel fijn dat je dit voor mij hebt willen doen.

De co-auteurs van de verschillende artikelen; Ilse Jacobs, André Bode, Ton Sprangers, Nan Hu, Annika Gram, Sasan Sadrizadeh en Pulak Goswami allen hartelijk dank voor jullie hulp bij het schrijven van de artikelen.

De board of directors van Daiwa House Modular Europe en Medexs Harry van Zandwijk en Richard Brinkman, en overige collega’s van Medexs en Daiwa House Modular Europe. Dank jullie wel voor de support en het vertrouwen. Zonder het begrip en de support vanuit jullie was het combineren van een parttime promotie en het leiden van Medexs niet mogelijk.

Paps en mams, bedankt voor alle kansen die jullie mij hebben gegeven. Jullie support en vertrouwen is onvoorwaardelijk. Jullie staan altijd als een blok achter me welke richting ik ook kies. De traditie van samen leren en “prutsen” aan de keukentafel wordt in mijn eigen gezin doorgezet. Jullie staan altijd voor ons gezin en mij klaar en daarvoor kan ik jullie niet genoeg bedanken.

Lieve Michelle, Rosanne en Willemijn, aan de keukentafel hebben we samen vaak gezeten. Jullie aan het leren voor de studie of het maken van huiswerk, ik bezig met mijn promotie onderzoek of nog bezig met het wegwerken van mijn (e-mail) achterstand. Persoonlijk vond en vind ik het altijd erg gezellig samen met jullie “te werken” al realiseer ik me dat ik (te) weinig tijd voor jullie heb gehad de afgelopen jaren. Was het niet de promotie dan was het wel het werk. Mijn voornemen is te proberen wat meer tijd voor jullie vrij te maken nu ik wat meer ruimte denk te ga krijgen. Ik realiseer me dat ik wel aan de keukentafel zat maar er niet altijd was of een luisterend oor heb gehad voor jullie verhalen. Jullie verdienen een vader die er iets meer is voor jullie. Ik ga als het goed is wat tijd overhouden en wil deze tijd graag met jullie invullen.

Lieve Daan, je hebt me altijd gesteund en tijd gegund voor dit promotietraject. Dit is echt niet vanzelfsprekend. Bijzonder dat jij mij deze ruimte geeft en hebt gegeven. Je hebt mij vele avonden en bijna alle weekenden laten werken aan het onderzoek. Je regelde dat ik niets te kort kwam en in ieder geval nog wat dronk en at tijdens het schrijven of het analyseren van de data. Dat vergeet ik namelijk nog wel eens als ik er helemaal in zit. Daarnaast heb je me soms laten beseffen om ook te ontspannen en niet altijd maar door te gaan. Dankjewel dat je mij al de tijd dat we elkaar kennen in evenwicht houdt en je jouw vrije tijd met mij veelvuldig hebt moeten missen.

Als we kijken naar operatiekamer luchttechnische installaties en waar deze aan dienen te voldoen volgens richtlijnen worden veel beslissingen genomen op basis van emotie, bijvoorbeeld omdat we het gewend zijn om het zo te doen, gebrek aan wetenschappelijke kennis, vanwege angst voor infecties, of vanwege het gebrek aan bewijs dat luchttechnische systemen wel of niet bijdragen aan het verminderen van post operatieve wond infecties. We moeten keuzes maken op basis van feiten, zodat ziekenhuizen de juiste afwegingen kunnen maken tussen veiligheid, kosten én energiebesparing. Ik vertrouw erop dat mijn proefschrift hier een bijdrage aan kan leveren.

“Absence of evidence is not evidence of absence”[6]

6 Altman, D. G., & Bland, J. M. (1995). Statistics notes: Absence of evidence is not evidence of absence. BMJ, 311(7003). https://doi.org/10.1136/bmj.311.7003.485

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# Curriculum Vitae

Jos Lans was born in Amersfoort on 25 September 1974. After obtaining his bachelor's degree in mechanical engineering from Utrecht University of Applied Sciences in 1997, he studied at Nyenrode Business University. He completed his Master of Science in Management in 2003 with a thesis on the failure of organisational change. He won the Nyenrode Entrepreneur Award in 2002 with his concept for a relocatable modular operating room.

After a successful career and various management positions in companies active in the medical sector, he has been an entrepreneur since 2007 and is the , among other companies, owner of several companies, one of which is Medexs BV. Besides his full-time job as the CEO of Medexs, he started his part-time PhD research at the Faculty of Architecture and Built Environment of Delft University of Technology in 2021. His research focuses on innovations and the effectiveness of ventilation in generic and super-clean operating rooms, which forms the basis of this thesis.

Jos is married and has three daughters.

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# List of publications

Ventilation performance evaluation of an operating room with temperature-controlled airflow system in contaminant control: A numerical study
Building and Environment 2024-05 | journal-article
DOI: 10.1016/j.buildenv.2024.111619
Part of ISSN: 0360-1323

What is the effect of reducing the air change rate on the ventilation effectiveness in ultra-clean operating rooms?
Journal of Hospital Infection 2024 | journal-article
SOURCE-WORK-ID: dcfc5d74-1335-4e5e-8c3c-c9d95e26540d
EID: 2-s2.0-85189530187
PMID: 38423130
DOI: 10.1016/j.jhin.2024.02.007

Air quality in the periphery of operating rooms during surgery
Journal of Hospital Infection 2023 | journal-article
SOURCE-WORK-ID: 2895d1bb-b2c3-4ed8-bd75-1f7ed9d3cded
EID: 2-s2.0-85151304377
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DOI: 10.1016/j.jhin.2023.01.015

Capital and operational expenditures of different operating room air-handling installations with conventional or ultra-clean air supply systems
Journal of Building Engineering 2023 | journal-article
SOURCE-WORK-ID: ed196832-5bb2-4e06-893d-114f4301eb5f
EID: 2-s2.0-85171168705
DOI: 10.1016/j.jobe.2023.107714

Corrigendum to 'Operating room ventilation systems Recovery Degree, Cleanliness Recovery Rate and Air Change Effectiveness in an ultra-clean area'
Journal of Hospital Infection 2022 | other
SOURCE-WORK-ID: 2572ba03-2dfb-4270-acfb-00bbc2f696c8
EID: 2-s2.0-85135937856
DOI: 10.1016/j.jhin.2022.07.014

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Journal of Hospital Infection  2021 | other
SOURCE-WORK-ID: 13cd02ba-d789-45b8-919b-ad025320d5e1
EID: 2-s2.0-85125148876
DOI: 10.1016/j.jhin.2021.12.018

Baseline study of number and type of microorganisms and particles during surgery at wound site, instrument table and periphery
Health Environments Research & Design Journal (HERD)
DOI: 10.1177/19375867241302406

24#21

# Operating Room Ventilation

A View From Different Perspectives

**Jos Lans**

This thesis explores different ventilation systems used for operating rooms (OR). Entrainment test methods are used in most European standards to determine the protected zone whereas the air quality in the periphery is often excluded. Furthermore, these measurements are mostly carried out in an at-rest situation where intermittent sampling during operation should be required. Most ORs in the Netherlands have an air handling system with an ultra-clean ventilation system (UCV). ORs are energy-intensive departments, where air handling systems consume the most. Relatively simple adjustments can be made to the air handling system to reduce energy, such as expanding relative humidity limits and introducing operational clock times. Lowering outside air quantity has the biggest impact on energy reduction, lowering the OR classification the least. Reducing the air change rate in the OR from an ultra-clean to a generic OR will reduce the recovery degree and the local air change rate. Lowering the air change rate in operating rooms could harm comfort conditions and (ultra-clean) air quality. The capital and operational expenditures of air handling installations with an UCV-system are higher than those with a conventional system. The investment pays for itself when 2 to 4 surgical wound infections are prevented over the lifetime of the OR. The type of surgery should be a leading consideration in determining the typology of the air handling system and the type of air supply system. Absence of evidence that surgical site infections are prevented in ORs equipped with UCV-systems is not evidence that these are not prevented.

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