Operating Theatres: Study of Unidirectional Flow Ventilation

Conditions for microbiological air cleanliness during advanced surgeries

Master's Thesis in the Master's Programme Structural Engineering and Building Technology

ALESSANDRO NAVA

Department of Architecture and Civil Engineering
Division of Building Services Department
CHALMERS UNIVERSITY OF TECHNOLOGY
Master's Thesis ACEX30-19-18
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SE-412 96 Göteborg
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Abstract

Design of a heating, ventilating and air conditioning (HVAC) system for an operating room is aimed at preventing the risk of infections during surgical operations while maintaining an adequate comfort condition for the patient and the surgical staff.

One of the key elements to ensure the OT (operating theatre) cleanliness is the control of the airborne microbiological contaminants in the room through the air ventilation system, equipment and medical staff routine. Generally, in OT two types of air ventilation systems are mainly adopted: turbulent system, which mixes all the air volume of the operating room following the dilution principle concept; and the unidirectional airflow (UDF) ventilation system, which concentrates all the airflow over the sterile zone. The idea of UDF system is to sweep away the dirtiness present in the sterile zone and to avoid disturbances or entrainment of contaminated particles from the external dirty zone. The aim of this Master Thesis is to study more in details UDF ventilation system by means of UFP (Ultrafine Particles) and CFU (Colony Forming Unit) concentration measurements performed during different types of advanced real surgeries in two different hospitals in Sweden.

The common hospital type of technical gowning available inside the OT are: the single use type with high performances and the ordinary scrub suit, more comfortable but less performing in the particles retention from the staff. Therefore, there are two main types of protection for the diffusion of airborne particles: technical clothing systems and the air ventilation technology. The deployment of low performance technical clothing allows a more direct testing of the UDF capacity to keep the surgery table area clean. Furthermore, the current standards do not make a clear distinction between the air distribution systems used and their cleaning capacity over the cleaning table. According to the standards, sterile area protection mostly depends upon the technical gowning quality, and the use of less performing technical clothing leaves the ventilation system as key determinant of contamination control. The airborne samples collected during the surgeries data collection allowed new scenarios in this field, also due to the small number of available studies and data in the literature. The experimental values measured have shown the UDF’s capacity to ensure a high degree of cleanliness on the surroundings of the surgery table. Despite the use of less performing technical clothing, the UDF ventilation system can keep the surgical area safe throughout all the surgery routine. Furthermore, this work defines an outlook over the specific positions required for the optimal measurement campaign. Moreover, the amount of measurements allows an understanding of the weak points of the UDF ventilation system in combination with medical procedures, especially during the medical staffs shift changes.

Keywords: Operating theatres; Unidirectional airflow; LAF; UDF; Ultrafine Particles; Colony Forming Units; CFU;

Sommario

La progettazione di sistemi di riscaldamento, ventilazione e di condizionamento dell'aria per una camera operatoria hanno il fine di prevenire il rischio di infezioni durante operazioni chirurgiche mantenendo, inoltre, una condizione confortevole per paziente e lo staff medico. Uno degli elementi chiave per assicurare la pulizia all'interno delle camere operatorie è il controllo dei contaminanti microbiologici aerotrasportati nella sala operatoria, tramite il sistema di ventilazione dell'aria, le apparecchiature e la routine dello staff medico.

Generalmente nelle camere operatorie sono due i tipi di ventilazione maggiormente utilizzati: il sistema a flusso turbolento, che miscela tutto il volume d'aria della stanza basandosi sul principio di diluizione, e il sistema di ventilazione a flusso unidirezionale (UDF) che concentra tutto il flusso d'aria sopra l'area sterile. L'idea di questo concetto è spazzare via tutto ciò che potenzialmente nocivo ed evitare che disturbi e trasporto dell'aria provenienti dalla zona esterna possano interferire con la zona sterile. Lo scopo di questa tesi è stato quello di studiare in maniera più approfondita il sistema UDF tramite l'utilizzo di misure della concentrazione di particolato ultra-fine e di unità formanti colonia, avvenuto durante differenti tipi di operazioni chirurgiche avanzate in due ospedali in Svedesi.

Nell'ambiente ospedaliero i vestiti tecnici disponibili sono principalmente di due tipi: quelli a singolo uso ad alte performance e quelli ordinari multiuso, più confortevoli, ma meno propensi nel limitare la perdita di particelle provenienti dallo staff medico. Considerando che i due principali sistemi di protezione alla diffusione di particelle per via area sono i vestiti tecnici e i sistemi di ventilazione. L'utilizzo di vestiti tecnici meno performanti potrebbe esser utile al fine di valutare la capacità del sistema di ventilazione UDF nel mantenere la zona del tavolo chirurgico pulita.

Inoltre le normative vigenti non fanno una netta separazione tra sistemi di diffusione dell'aria utilizzati e la loro capacità di pulizia nella zona del tavolo operatorio. Di conseguenza considerano quanto espresso dagli standard, la protezione della zona sterile dipenderebbe maggiormente dagli indumenti tecnici utilizzati piuttosto che dal sistema di ventilazione, di conseguenza l'utilizzo di vestiti tecnici meno performanti lascerebbe al sistema di ventilazione un ruolo chiave determinante nel controllo dei contaminanti.

Il campionamento di particelle aerotrasportate durante le operazioni chirurgiche ha permesso l'apertura di un nuovo scenario in questo ambito, anche a causa di un ridotto numero di studi e dati disponibili in letteratura. I valori sperimentali misurati hanno permesso di mostrare la capacità del sistema UDF nell'assicurare un alto livello di pulizia nell'intorno del tavolo chirurgico. Nonostante l'utilizzo di vestiario tecnico a più bassa qualità, il sistema di ventilazione UDF è stato in grado di

mantenere l'area chirurgica sicura per tutte le routine chirurgiche. Inoltre questo lavoro ha definito una prospettiva riguardo le posizioni specifiche richieste per campagne di misura ottimali.

Per di più, la quantità di misure ha permesso una comprensione dei punti deboli del sistema di ventilazione UDF in combinazione con le procedure mediche, ad esempio il cambio del personale medico.

Parole chiave: Camere operatorie; Flusso unidirezionale; LAF; UDF; Particolato ultrafine; Unità formanti colonia; CFU;

Extended summary

In the hospital world, the air cleanliness is a fundamental element, which is necessary to guarantee the health of patients and medical staffs. This work is concentrated over the surgery field and the risk related to the surgical site infection. There are different way how bacteria could reach the sterile zone and became dangerous for the patient, one of these is the air.

The air ventilation system studied in this work is Unidirectional Airflow, which supplies all the clean air from Laminar Airflow (LAF) ceiling placed over the sterile zone and extract it from the corners of the Operating Theatre (OT). The concept of this kind of ventilation is to create a sort of tent around the sterile zone, in order to avoid penetration from the nearby zone, and swept away dangerous particles, coming from the medical staff, from the sterile zone.

In the following picture, taken during real surgery, is possible to understand the OT's structure. Equipped with the UDF technology, the air supplying in the ceiling over the operation table and the exhaust grills in the corners.

Figure 0.1: Picture of the Operating Theatre structure of Södertälje taken during ongoing surgery

This work was made following twenty-four surgeries in two hospitals in Sweden (Sahlgrenska University Hospital in Göteborg and Södertälje Hospital), both of these equipped with the UDF air system. The instruments used to study the air pattern inside the OTs were two Ultrafine Particles

(UFP) counters, one air sampler for detection of airborne microorganism and five velocity-temperature sensors.

In the Sahlgrenska Hospital, considering that it is a university hospital, the activities can be characterized as comparatively advanced surgeries, as liver transplant and pancreas resection. This include the length of the surgery, the number of people involved and several activities, which enriched this work with disparate aspects measured using the two ultrafine particles counters. The use of diathermy bistoury during this type of operations release in the air a huge amount of particles, easily readable by the instruments. For this reason, the author decide to place the instrument's probes in different locations inside the OT, and use this "free smoke" coming from the wound in order to understand the air pattern due to this air ventilation system. Initially the attention was focused on the present or not of vortices, which could take dirtiness from the floor zone and carry these on the sterile part, as instruments table and wound zone. The areas controlled with this approach were the: anaesthesia zone where the presence of vortices could be really dangerous considering the less performances clothes inside of this zone, and the instruments table zone, under and over the desk, in order to understand if disturbances around the LAF could be the cause of risky air movements.

Once the presence of vortices in these zones had been averted, the attention is moved inside the sterile zone, close to the patient's wound. The sampling interval in this area was important, in order to check the air ventilation washing capacity and the correlation between the particles source with the rest of the OT. This huge number of particles coming from the wound, due to the diathermy bistoury, allowed the author to understand the air pattern of the exhaust air.

The diathermy smoke has many benefits for the patient; however present dangerous aspects for the medical staff who breathe it. In fact, during the sampling inside the sterile zone, different measurements were collected in order to understand also, how to reduce the issue due to harmful diathermy bistoury's smoke.

The same approach was used inside the Södertälje Hospital. The operations followed were orthopaedic surgeries, larger number, mostly ordinary complexity and shorter length compared with Sahlgrenska University Hospital. The diathermy bistoury use in these type of operations is reduced more or less just during the opening of the wound, for this reason the sampling of the concentration of UFP is reduced and the in-depth study cannot be repeated as described in the previous hospital. It is important to make a comparison in order to highlight which are the aspects that are agreed and which are the differences noticed using the UFP counter. The washing capacity of the air ventilation system in the sterile zone was confirmed in both hospitals, in fact the cleaning time needed is really fast, both over the instruments table than close to the wound.

The main different aspect was that, due to the large diathermy bistoury using, the amount of particles present in the area is high and until the instruments using is blocked every movement made by the staff restore in the air particles, which are detected by the instruments.
The second element is related to a structure aspect: the type of doors of the OTs. Indeed, in Sahlgrenska University Hospital are in use the swing type with a direct connection with the corridor (dirty zone), while in Södertälje Hospital the sliding doors are preferred, with guidelines which strongly advice the passage of the medical staff, during surgeries, through the preparation room (cleaner than the corridor).
During the measurements session inside the anaesthesia zone in Göteborg (swing doors), peaks related to the doors opening were collected. Fortunately, not the same peaks were sampled into the sterile zone. While in Södertälje Hospital (sliding type), no consequences were measured due to door openings. The author considered that the disturbances due to the door, were not just related to the differences pressure that has to be maintain, but also to the type of doors which are in use inside the OT.

Furthermore in Södertälje Hospital also the rest of the instruments were used, in order to measure the velocity at different levels and, mostly, allowing to detect the airborne microorganism concentration inside the sterile zone using the CFU count (a CFU is a small particle that contains bacteria forming a colony of growth when applied to a culturing medium).
This last aspect is the one that made the work different and extraordinary. In fact, in literature the number of CFU concentration count inside the sterile zone (close to the wound and over the instruments table) is low for this type of air ventilation principle (UDF). Furthermore, all the considerations related to CFU concentration inside the sterile zone are related to the dilution principle, arising from the mixing ventilation system.
The main aspect, which is considered as the most important, is the technical clothing system in the literature. For this reason, the author decided to test the UDF system into maintain cleanliness inside the sterile zone, making the medical staff worn of ordinary scrub suit, technical clothing at lower performance compared to single-use clean air suit. In this way all responsibility related to airborne microbiological particles concentration, combined with advanced medical staff routine, is related to the UDF technology.
The optimal distance from the surgical area and the source of airborne microbiological particles, the surgeon, allowed to collect quality data in that environment. The UDF, if working correctly, should be able to sweep away the airborne microbiological particles. Those particles are normally higher in quantity when medical staff in the operating theatre wear a low quality technical gowning. Indeed,

research has provided evidence of the difference in penetration of microbiological particles between high level and low-level quality technical gowning.

Higher technical clothing qualities, air clean suit type, allow creating a barrier between surgeon and sterile zone, reducing the comfort for the medical staff. This type of gowning is a single use type recommended for infection prone surgeries (per instance orthopaedic surgery), disposable non-woven material, and spun bonded polypropylene 100%.

Lower technical clothing qualities, multi-use ordinary scrubs suit, is a less resistant type, less resistant to the particles penetration (scale of skin coming from the staff). Made of 69% cotton, 30% polyester, and 1% carbon fibre.

For the reasons listed before, a sampling position close to the source of airborne microbiological particles and the surgeon worn by less performances technical clothing system working into the sterile area, patient's wound, could be really useful for the study of the UDF system capacity.

In the following picture is possible to see a photo collected during a knee prosthesis surgery. The surgeon is using the surgical saw on the right knee of the patient. Over the anaesthesia barrier is fixed the air sampler pipe with the airborne microbiological filter applied, which after the sampling is placed on a culture plate in order to count and type Colony Forming Units.

Figure 0.2: An example of the proximity of the CFU counting to major source of airborne microbiological particles, the surgeon, in the sterile area during ongoing knee surgery

Considering that in a number of papers and in the Swedish Standard the idea is that the airflow over the table has been described as mixed as a result of obstacles and surgery activity. The use of the equations purposed by the standards as the representation of the result expected has to be compared with the results experienced during this work, in order to test the equations reliability in this type of air ventilation technology (UDF).

The comparison between the result collected with the ones calculated using the equations purposed by the Swedish and the Normative Standards are different:

Table 0.1: Comparison between the concentrations of CFU expected in according to the Standards with the level experienced in this work in the sterile zone.

Swedish standard equation [1]	*Netherlands standard equation* [2]	*Results of this work*
$c = \frac{q_s}{Q} \times n$ *[2]*	$c = \frac{q_s \times n}{Q \times CRE}$ *[3]*	$c = \frac{Sum\ of\ all\ the\ CFUs\ sample}{Total\ number\ of\ samples}$
$c = 12{,}8 \frac{CFU}{m^3}$	$c = 6{,}81 \frac{CFU}{m^3}$	$c = 3{,}6 \frac{CFU}{m^3}$

The difference between the result experienced compare with the ones forecast using the equations purposed by the standard is clear.

This result could be considered as important because, according with also the UFP results sampled in this work, is possible to reach the conclusion that:

- the airflow pattern over the sterile zones has to be considered as stable;
- the degree of cleanliness in the sterile zone, despite the source potential is increased due to the less performances technical gownings, is guaranteed by this ventilation principle (UDF or LAF);
- The protection to penetration from the zone outside the surgical site area.

This result could be considered as important, because in this way the hospital could save money using multi-use ordinary scrub maintaining the health of the patient in a sure condition.

This large amount of CFU and particles concentration sampling allow discovering some different aspects, which are weak points for this air diffusion technology.

In fact, during the knee prosthesis surgery, the amount of instruments needed is larger compared with others operation and consequently also the number of instruments desk increase inside the OT. Furthermore, all of the instruments tables, obviously, has to be maintained in the sterile zone (under the LAF system). The area of the LAF system has to be also keep smaller to reduce the amount of air supply needed in energy saving optic (in Södertälje Hospital the air flow rate is 2300 l/s = 2.3 m^3/s). In addition, the medical staffs needs space to operate, considering that orthopaedic surgeries are more active than other surgeries as the internal type followed in Sahlgrenska University Hospital. Considering all the elements listed previously, during one CFU and UFP sampling over the instruments desk placed outside the LAF, the values collected highlight a high level of dirtiness due to the vortices present in the periphery of the room.

In fact, if, for example, the corner nurse pass close to the instruments table, in case it is under the LAF technology, the system is able to protect the instruments from the penetration. In this case the CFU levels reach number over the 20 CFU/m^3 compared with the average of 3,6 CFU/m^3 experienced in the sterile area (wound zone and over the instruments table under the LAF).

The second weak point showed is that during the medical staffs exchange the number of CFU sampled increase considerably reaching high levels.

Despite that the cause of this high levels of sampling was known, the author decided to count inside the calculations of the previous average (3,6 CFU/m^3) also these values, because the medical staff exchange is an action scheduled and necessary, which is an integral part of the operating theatres field. By the way could be useful to report that without the consideration of the operations with medical staffs exchange the average reach a lower value (2,7 CFU/m^3).

The large number of operations followed, allowed the author also to consider aspects related to the medical staffs routines and habits which could be elements that obstruct the correct work of the air ventilation technology. A glaring example is showed in the following picture. Considering that a nurse, which works in the periphery of the sterile zone (outside the LAF), is not worn as the medical staffs who operate close to the operating desk (no mask, no double gloves, no supplementary single-use barrier). In the following picture, the nurse moved inside in order to take a picture of the wound, with one of the dirtiest objects that we use all of the day, a telephone.

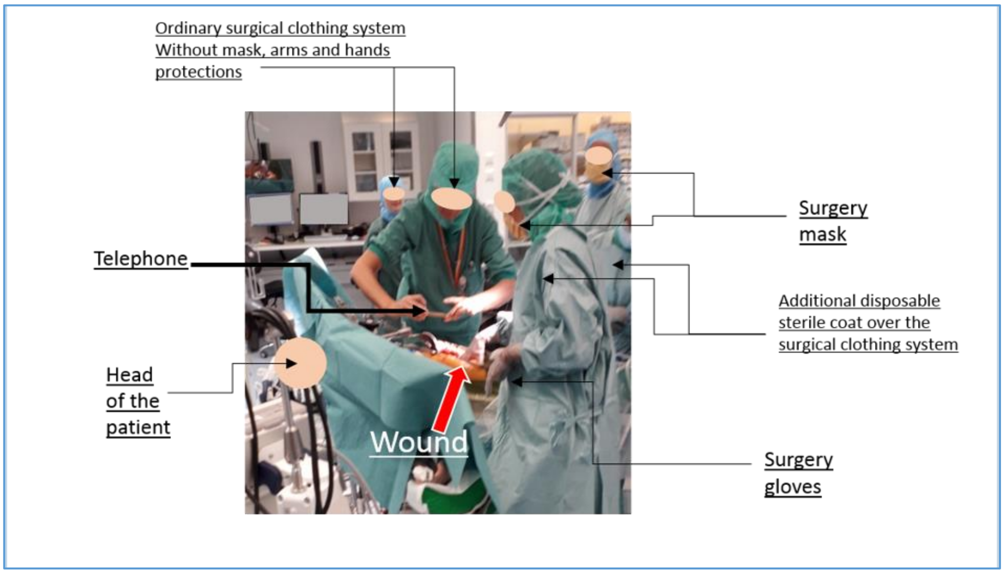


Figure 0.3: Risky situation inside the sterile zone: nurse that has to stay in the periphery move in the sterile zone in order to take a picture

Watching several operations and habits of the people who work inside the operating theatre. The idea of the author is that a good work made in the design filed has to be supported with good medical routines, which has to avoid disturbances, which could obstruct the correct air ventilation system working, inducing risky situation for the health of the patient.

1 Introduction

Postoperative surgical site infection (SSI) is one of the most common and one of the most hazardous of complications after surgery. Considering the experiences, also noticed during this work, it may constitute a disaster for the patients, if they get an infection a new operation could bring several complications for their future. These infections are a problem also for medical staff and is also a weight for the society for the economic point of view. The possible paths how the bacteria can reach the wound in operating theatres principally are: skin of the patient or the medical staff, contaminated instruments or implants or through contaminated air. The propensity for the patients to develop an SSI could be also correlated to their health status, which might be the presence of immunodeficiency, disturbed metabolic state, smoking, hypothermia etc. Furthermore, SSI caused by bacteria may be transferred to the patient from external sources or may be present on or within the patient prior to surgery. Bacteria from external sources could carry inside by a number of vectors such as the hands of staff, bed linen, contaminated instruments, intravenous fluids and, the main topic of this work, by air. In fact, considering that, fortunately, the SSIs are in the order of magnitude of 1 to 3% depending on definitions and type of surgeries. So quite large material is needed to have enough amount of values for a statistically approach. In order to avoid this main aspect of the work and the interpretation of the elements, the researches, in the past, started to focus on an aspect, which could represent important clinical outcomes. The way is the count of the number of colony forming units (CFU) in operating room air. A CFU is a small particle that contains bacteria forming a colony of growth when applied to a culturing medium, typically an agar plate, or also known as Bacteria-carrying particle, which can give rise to a colony on a culture plate. If airborne infection is indeed the problem generating SSIs, it seems reasonable to expect the number of CFU present into the room as to reflect the risk for SSI. To make these measurements the probe has to be placed in the sterile zone, so the instrument has to be sterile too and the handling of the filter has to happen in sterile condition. For this reason make these kind of measurements inside an OT during ongoing surgeries could not be easy as it seems. Concentrations vary markedly depending on site of sampling, traffic in and out of the room etc. To do this in the correct and safety way, first aspect has to carry out properly technical tests like particle counts, filter integrity tests and pressure test ORs. One also needs systems to keep track of disturbing factors like number of door-openings, number of people present in the room and their movements, the choice of technical clothing commonly used and the overall surface cleanliness. Without this information, moderate changes in CFU concentration become almost impossible to interpret. It is also important to sample from a clinically relevant location as the sterile zone (wound zone and instruments table).

The samples introduced could be useful to understand the capacity of the air ventilation technology to keep clean the sterile areas. This work has the aim, through the measurement of UFP and CFU concentration inside OT during ongoing surgeries, to understand if the Unidirectional Airflow type ensures the safety of sterile zone, and avoid that disturbances could allow the penetration of airborne inside the sterile zone. The air technology system is one of the main aspects, which has to be considered to reduce the airborne microbiological contamination presence inside the sterile zone.

1.1 SSI problem and the causes not related to air ventilation technology

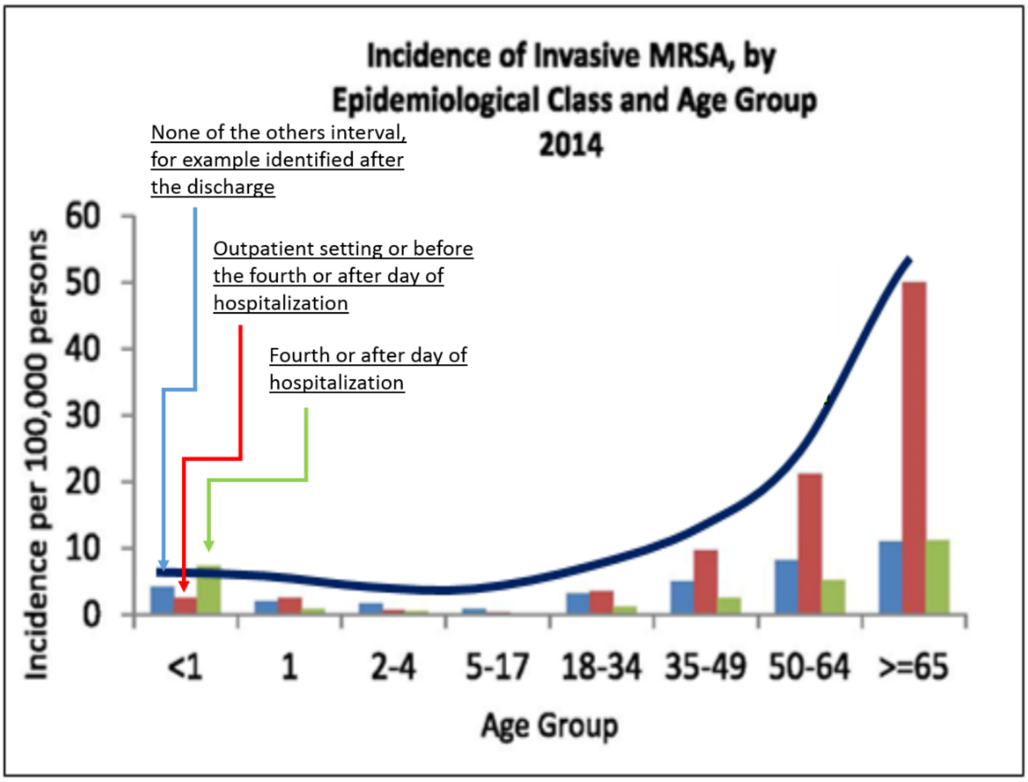
The Surgical Site Infection (SSI) is an element that many people know because heard through the media or, perhaps, because they suffered in first person. Firstly is important to underline that not all the infections are contracted during the surgeries (21.8% of the total infections), the element on which we are focused is one of the most common up to the likelihood. Per instance, the most common are also Pneumonia (21.8%) and gastrointestinal infections (17.1%) [3]. However, another important data is that among the surgical patients, SSIs were the most common nosocomial infections (38%) [4]. An aspect to highlight, several studies had shown that, is that the causes could be exogenous and endogenous. It is important to concentrate some attentions to the latter one; in fact, there are many studies, which have shown the link between endogenous elements and the SSI percentage. In the following list is possible to consider a general description of the main endogenous aspects, which could be considered as a factor in the increasing of SSI risk percentage for some patients:

- **Diabetes**: chronic disease that reduces the insulin presence into the blood that bring an increasing of the glucose concentration [5]. Above the fact that the risk ratio (diabetes people/nondiabetic people) for an infectious disease hospitalization or physician is higher than one [6] [7] (i.e. Odds Ratio (OR) 2.017 for Pull ter Gunne A.F. *et al.* [8]). Furthermore, it has been tried that the hyperglycaemia interferes with normal response that the body would have to an infection, both for nondiabetic and for diabetic, but for the latter the problem increase due to the predisposition at higher concentration levels [9]. In fact difference studies showed that the risk of the SSI for diabetic patients is higher than 2 or 3 times than the normal value [10] Even the value reaches an amount of OR=4.4, in the presence of an elevated glucose level (>200 mg/dL) [11].
- **Obesity**: another element that the diabetes people suffer is the BMI (Body Mass Index), on average, is higher than the nondiabetic [8] [12] [13] [14] [15]. Different works had shown that there is a correlation between high BMI and SSI higher levels. In case of spine surgery the correlation (BMI-SSI) has a parabolic trend:

- BMI 25 → SSI likelihood +14%;
- BMI 30 → SSI likelihood +20%;
- BMI 40 → SSI likelihood +36% [13].

We have other examples for other kind of surgeries (laparoscopic renal and adrenal surgery) where the likelihood increase for the 26% for the obese patients [15]. Furthermore, heavier patients need longer operative time and so, as deepened better later, is another factor that increase the SSI likelihood value [16].

- **Patient Age**: This aspect has to be considered as an element which infects the possibility to take SSI, as reported in the study of Tenney J.H. *et al*, respect an average age of 34 years old of the statistical population, the patients which contracts most dangerous wound infections have a mean age of 46 years old [17]. A clear example is the study regarding *Invasive methicillin-resistant Staphylococcus aureus (MRSA)* disease. The presence of this disease after the surgery varies considerably with the aging. As it is possible to check in the following graph the level increases substantially from the 35 years old.



Graph 1.1: Incidence of Invasive MRSA, Epidemiological Class and Age group 2014 (16)

- **Tobacco's use:** By now, the majority of people knows that smoking cigarettes is a source of problems for the human health, but other studies showed that it could increase the possibility to contract a SSI. In fact, the cigarettes smoke it has been considered as a cause of: inhibit wound healing; increasing wound dehiscence (a previously closed wound reopening [18]); decreasing circulation into the capillaries due to the obstruction from platelet aggregation; increasing the non-functioning of haemoglobin (that is the protein involved in the transport of the Oxygen [19]) and increasing the presence of osteonecrosis (i.e. death of bone tissues [20]) (9.2% vs 2.8% → 3.5 OR) [21] [22].

  All of the elements listed before could be resumed as that: SSI are detected 2.2 times more in smokers patients compared with non-smokers' ones.

  An important find that Durand F. *et al.* made was that there is a marked difference between people who smoke the same day of the surgery, and who does not do that (OR=1.51). According with this work OR between smokers which smoke the surgery's day respect non-smokers is 2.64 [23].
- **Poor nutritional status**: In the common knowledge the malnutrition status refer just to the percentage of people that is underweight (Body Mass Index lower than 18.5 kg/m^2 [24], for the table of the BMI intervals check Appendix D). Actually, malnutrition could refer to a wider interval of people, because it is refers to deficiencies, excesses or imbalances of energy and/or nutrients intake [25], with this definition should be easier to understand that everyone could face with the malnutrition issue.

  It is thought that it impairs wound healing and prolong inflammation by reducing collagen (main structural protein in the animal bodies and the main component of connective tissue [26]) synthesis and fibroblast (biological cell that synthesizes collagen [27]) proliferation. Additionally, malnutrition may reduce the capacity of the immune system to avoid infections due to the number reduction of Lymphocyte [28]. Most of the papers consider the low value of albumin (Serum albumin is the main protein of human blood plasma [29]) as an indicator of malnutrition status (<3,5 g/dL [30] [31] [32] [7] [33]). Some of these also add other parameters like the lymphocyte count (<1500 $cells/mm^3$ [31] [32]).

  Regarding the increasing of SSI risk, due to the malnutrition status, the values detected were at least 4 times higher than the patients with normal parameters [34] [31] [33]. As said before, also another category suffers this issue. In fact, obese people are exposed to this problem as is showed in Figure 1.1 [32] [33] [34].

Variable of interest	Underweight	Normal weight	Overweight	Obese
Total number of patients*	2	82	99	238
Number with laboratory parameters suggestive of malnutrition	1 (50%)	42 (51%)	27 (27%)	76 (32%)
p value (normal weight versus others)	1	–	0.0012	0.0023

Figure 1.1: malnutrition by BMI [32], for BMI parameters check Appendix A

Furthermore the SSI detected for malnutrition obese people is about three times higher than the ones with normal nutritional values (10.4% vs 3.2%) [33]. There are also different works that show the correlation between the age of the people and the malnutrition parameter, and the value increase considerably beyond the 50 years old [34], [33] as it's possible to see in the following Figure 1.2 [33].

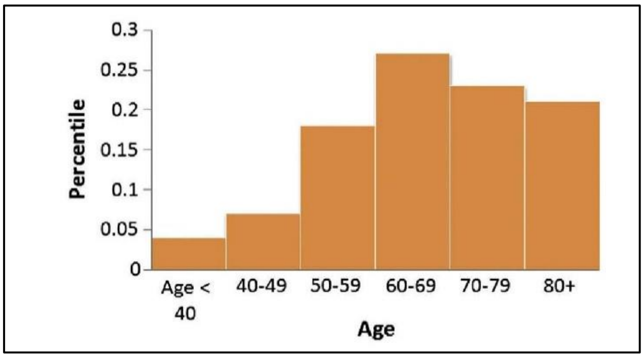


Figure 1.2: malnutrition parameter divided in age's interval [33]

- **Prolonged surgical time**: a longer duration of the operation exposes patient to a major risk of infection [8] [17] [16] [35] [36]. According to Tenney J.H. *et al* [17], the time increasing of surgeries increases also the number of deep wound infections detected: from 0,9% SSI with the length of operation lower than 2 hours, while the OR reaches 4,3% with surgeries longer than 4 hours. Consulting other works, the number of SSI increase starting from the 2 hours of operation. The following equation show the rapport between the percentage of SSI detected comparing different surgeries duration:

$$\frac{SSI\ (127\ \pm 45\ min)}{SSI\ (93\ \pm 28\ min)} \cong 5 \qquad [16]\ [35]\ [36].$$

The chance to contract a SSI increases even five times in a 40 minutes longer surgery.

- **ASA score:** From the 1941 the American Society of Anaesthetists started to resume all the elements listed above creating a classification related to the patients health and conditions, in fact this concept is not based to the ability of medicals [37]. In this classes division, every class define a state related to different signals or habits of the patient: starting from good health until bad conditions. During the years, the idea was improved until the 6 class systems, and in the recent works, there are also some examples that could be used in order to insert the patient inside of a group of the ASA score (reported in Appendix D [38]).

All the previous elements are resumed, thanks to the Culver et al. work [39], in a scale of points (from 0 to 3) which determines the risk index of surgical site infection [40].
The elements, which assigned 1 point, are:

- 1 point: The surgery is considered as contaminated or dirty (check following Section 1.2 for the classification of surgical wounds);
- 1 point: The ASA score (presented above) is equal to 3, 4 or 5;
- 1 point: The surgery duration is higher than the duration defined by the 75th percentile calculated on the others surgeries of the same type (examples from NNIS databases are: 75th for a colonic surgery is 3 hours [21]).

Could be useful to assign points for the surgeries, which are going to be faced in this work.

Table 1.1: Risk Index of SSI for the surgeries followed in this master thesis

	Classification Surgical Wound	ASA score	Duration	Total Score
Södertälje *Orthopaedic surgeries*	0 (no Dangerous area)	0[1][2]	0[3]	0
Sahlgrenska *Internal surgeries*	1 (Gastrointestinal area)	0[1]	0[3]	1

Considering the previous table just the operation in Sahlgrenska could be considered as risky operations. Unfortunately, there are not values, related to SSI, available from the operation followed in this work, which could confirm, or not, what supposed in the previous Table 1.1.

[1] Author retain that the patients operated were healthy considering the operation as scheduled, but it is just an idea of a person not prepared as medical.
[2] Same idea as before, but during the liver transplant a consideration about the non-scheduled operation is necessary. Considering that the donator is something not scheduling.
[3] Author considered the time of the operations as scheduled considering the informations obtained by the medical staffs. Just one hip prosthesys installation was longer than forecast (60 minutes longer compared with an average of 80-90 minutes)

1.2 Type of SSI infections

The scheme purposed by *Pear S.M.* [21] will be the one followed in this section. The risk of infections, obviously, is not just related to the endogenous causes. An important element to underline is the different positions of the site where the surgeons make incisions (as previously highlighted in the Classification of Surgical Wound) and how much in deep the instruments need to go. For example, bowel is a bacteria-laden body zone. For this reason, CDC [39] [41] divides the kinds of wound in four different classes, *Pear S.M.* adds to this division a short explanation of when we should find it and the SSI risk:

- *Clean wounds*: the operative procedure does not enter into the colonized viscus or lumen (the inside space of a tubular structure, such as an artery or an intestine [42]) of the body. SSI value below 2%. SSI originates from contaminants in the OR environment, surgical team or skin.
- *Clean-contaminated wounds*: the operative procedure enter into a colonized viscus or lumen, but under elective and controlled circumstances. 4% < SSI < 10%.
- *Contaminated wounds*: we have the presence of gross contamination but the infection is not obvious. SSI>20%.
- *Dirty wounds*: active infections already present in the surgical site. SSI>40%.

The correlation between the dirt detected and the SSI counted is strictly. An example is clear in the Mioton L.M. et al.'s work where they analysed 15,289 plastic surgeries, from 2006-2010. They found 81.95% procedures as clean, 7.18% clean-contaminated, 5.56% contaminated and 5.30% dirty. The results that they collected showed using the OR referred to clean surgical wound were: clean-contaminated 0.84, contaminated 2,81 and dirty surgical wounds 2.74 [43].

Mangram T.C. *et al.* [4] in 1999 purposed new definitions for surgical wound infection:

- *Superficial incisional SSI*: a SSI is defined in this way if the infections occurs within 30 days after the operative procedure and involves only skin and subcutaneous tissue of the incision.
- *Deep incisional SSI*: the infection occurs within 30 days after the operative procedure if no implant were used, or within one year if an implant is in place and the infections appears to be related to the operative procedure, and the infection involves deep soft tissues of the incision.
- *Organ/Space SSI*: the infection involves any part of the anatomy, other than the incision, opened or manipulated during the operative procedure. As above the infections as to occurs within 30 days if there are not implant, otherwise within one year.

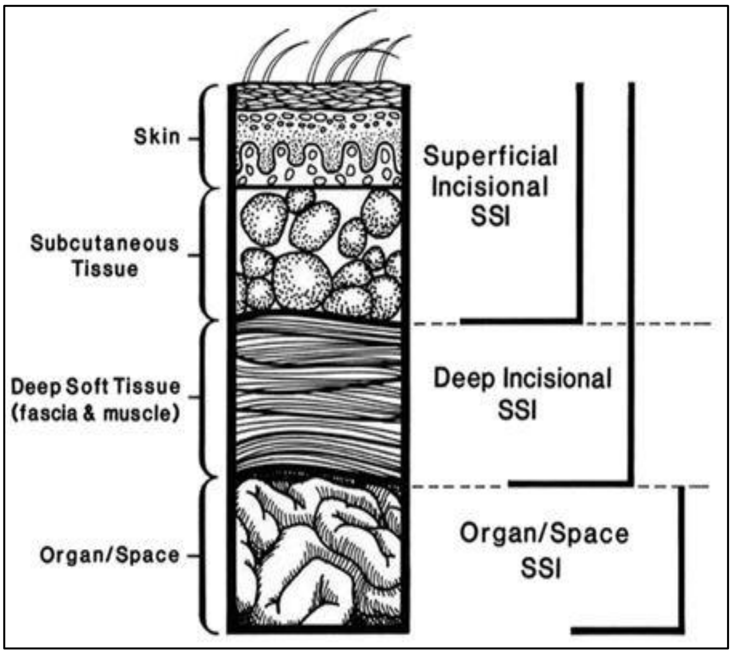


Figure 1.3: Schematic of SSI anatomy and appropriate classification [16]

More the infection is contracted in deep and more the consequences for the patient are difficult to face with. An important aspect for the SSI is when the disease is identified, a patient who has to come back to the hospital is also something costly. In the work of Gaynes R. P. *et al.* [44] that collected data from 738,398 operative procedures, they detected 14,949 (2 %) SSI and divide these in the three categories said above, but adding also the discovering period, as shown in Figure 1.4:

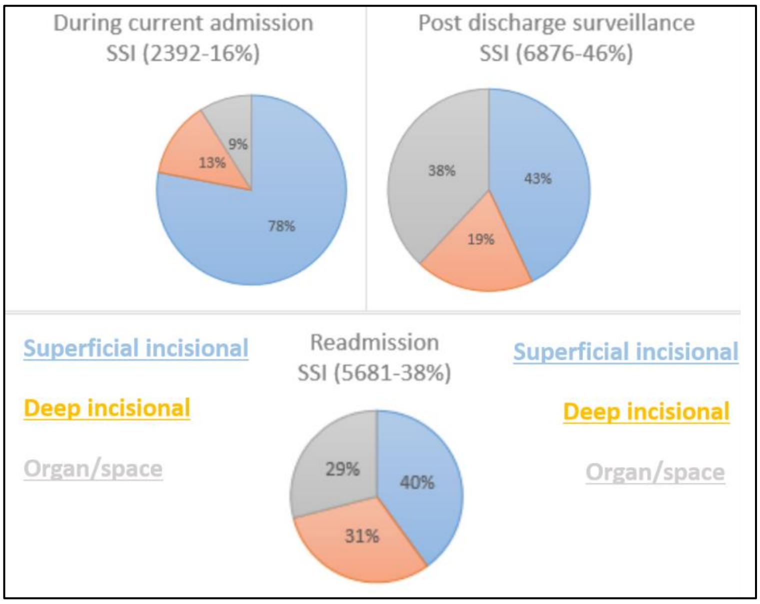


Figure 1.4: Detection of SSI during different periods, number of SSI and percentage over the total (14'949) [38].

If we watch the total amount of data collected (superficial incisional SSI 47.5%, deep incisional SSI 22.5% and organ space 30% SSI) without a separation related to the time interval, we can't understand that there is a marked difference between which these are and when appear. Therefore, after an appropriate knowledge of the patient and the situation, a good post-operative control could avoid many problems, because the worst infections appear after the discharge. Furthermore, in another research the data had shown that the median time to SSI diagnosis was 16 days and the SSI identified after the discharge was even 53.9% [45]. In a more recent work of the 2006 [46], the value decrease until 31% maintaining so an important value. For this reason Benenson *et al.* [47], increasing the sensitivity of surveillance, reducing the people that return to the hospital within 3 months to 30%.

1.3 How the ventilation could be an important element for the level of surgical site infections

There are many different aspects, which could be the causes of the infections, the direct contribution of airborne bacteria in increasing the SSIs is controversial due to the multifactorial origins of infections [48].

In a work of the 2003 Pasquarella et al. described that particles may reach patients wound or susceptible area generating SSIs either by direct fall out (30% of the cases), or indirectly by transportation after settling down on the instrument surfaces and surgeons' hands (70% of the cases). In the sections above, there are different endogenous aspects to consider as elements whose could favourite the growing of active organism into infections. However, could be good to find a correct agreement between the elements that could reduce the problem and the elements that should avoid it. Per instance, the implementation of an air distribution system could be one factor that can contribute to reduce the number of infections. A large air volume flow and a controlled airflow pattern in the room can reduce the content of airborne bacteria

In fact, it is not possible to dispense high quantities of antibiotics, both for the great ability of the bacteria to adapt and for the limit impose by the patient body. For this reason, one of the solutions is the control of the air and its pattern. As the Department of health list [49], the routs that airborne contaminants could follow are:

- Passing through the supply air (problems in filtration of the new air or in the recirculation technology)
- Transferred from adjacent spaces (problem connected with pressure differential and door opening)
- Through surgical activities
- Shed by the operating staff

The bio-organism are carried by little droplets, in fact called bio-aerosols, in the ranging size from 1-5 μm [50]. Considering the lightness of these particles, the role of the air is important. Another study underlines that more than half of clean surgery-site infection pathogens originate from normal skin flora of patients or staff [51, 52, 53].

Differents solutions have been treated, for example the transition from open operation to laparoscopy type in order to reduce the sensible surface area (in a study of Sauerland S. et al [54] over 2396 operations in the appendectomy operation the wound infections were reduced more than the half compared with the open surgery type).

There are a lot of different point of view about which is the correct way to follow to guarantee the cleanness inside of an operating room using the air, and a lot of those are correct. In fact, every approach has its strength and its weak points, so the idea is to understand which one could be the best compromise between the patient's health, energy saving related to the amount of air flow rate that as to be supplied and, unfortunately, less costly solution. In the following section, the reader could find an accurate analysis, sustained with real data, about one of these air ventilation technologies (the different types of air distribution technology are explained more in deep in Section 3 page 15). It's important to remember that the microorganisms could be carried in other ways (contact for example), but the behaviour of the air, as a means of transport, is the worst to forecast and the harder to handle also with a really good routines and habits. Some aspects related to habits and routines, which could be dangerous for the effectiveness of the air ventilation system are faced and analysed later (Section 8 page 89).

2 Research idea and how the work is developed

The aim of this master thesis is to understand the Unidirectional Air Flow capacity into keeping cleanliness into the sterile area and to guarantees safety for the health of the patient and the medical staff. This work was made in two different hospitals with operating theatres equipped with LAF air technology.

There are many works inside operating theatres and many people try to understand which technology could find an agreement between all of the things that have to collide (cleanness, comfort, expenses…). An example is carried by the a previous experience [55], where it is showed the importance of ventilation for contaminant control during orthopaedic surgery. In spite of routines, advanced clothing systems it was not possible to guarantee air cleanliness with displacement ventilation and air volume flow.

In the following picture there is a schematically description of the steps followed in this master thesis work. From the facing of the hospital world until the conclusions.

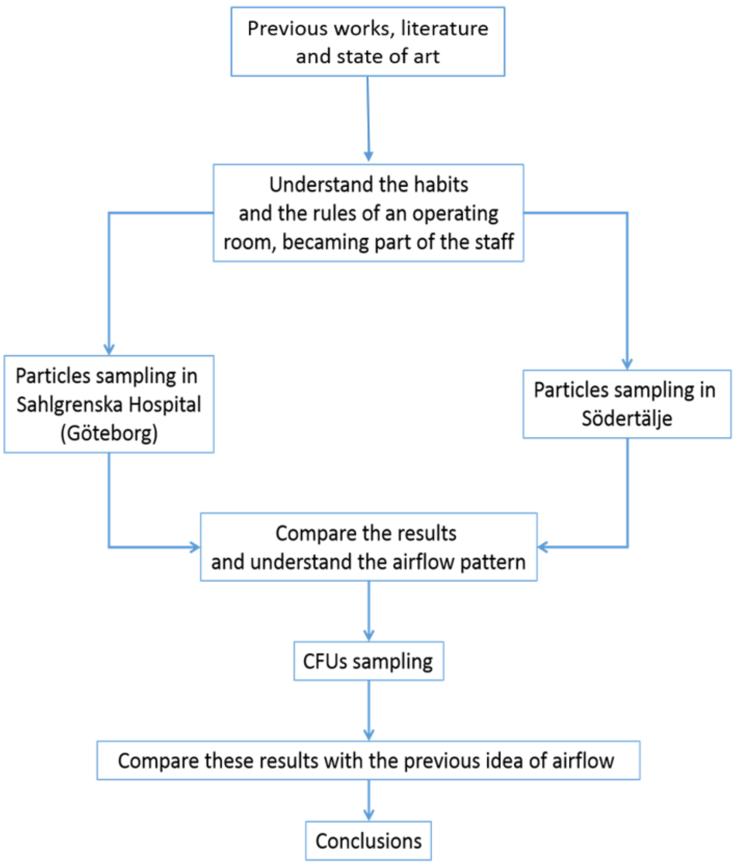


Figure 2.1: Schematic description of the master thesis work

2.1 The experimental approach

The knowledge acquired consulting the previous works, developed by Politecnico di Milano and Chalmers University and scientific articles, allow the author move inside the hospital with an important background. Before to start with the measurements the author follow several operations without instruments both in Sahlgrenska Hospital of Göteborg and in Södertälje Hospital. Once understand the correct procedures to follow, the sampling campaign started using different instruments (described in the following Section 5). Firstly, the instrument largely used was the optical UFP (Ultrafine Particles) counter, which show a close correlation between actions inside the OT (Operating Theatre) and the samples detected by the probes. This relation between action-reaction directly on the field, allow the author to connect samples and real surgeries activities.

Placing the probes in different parts of the OT gave the possibility to study the air pattern, and how much the elements inside the operating room could interfere with the airflow stability. The UFP study happened both in Göteborg and in Södertälje in order to find common elements in two hospitals with the same air distribution system (UDF), but with different structures of the OTs, different types of operation, different medical routines and different medical staff.

The studying related to the UFP was also combined, in a second moment, with the air sampler, which has the function to give an indication regarding the concentration of airborne microbiological particles in the sterile zone.

Once all the results were available, combined with the values collected using the UFP counters, the air movements inside the OTs became more clear and the different aspects were extrapolate and faced in results and conclusions.

3 Ventilation system in operating theatres and state of art

According with the department of health [49] the supply of air to an operating room has four main functions: to dilute airborne contamination; to control air movement in order to avoid movements from the dirty area to the clean zone; control operating theatre condition; to assist the removal, and dilute, of waste anaesthetic gases.

3.1 Description of the air distribution technologies

There are different types of airflow patterns, which could be designed:

Turbulent airflow: air is supplied through devices located homogeneously at high level which produce turbulence airflow inside the room; the air is considered as mixed because this principle is an high induction principle which mix the new air with the air present already in the room . According with UNI 11425 and with ISO14644-1 the concept used is the dilution principle to reduce the pollutants inside the room. The condition registered around the room about pollutants and conditions are more or less homogeneously. In this case is important to pay attention to not introduce air at high different temperatures to avoid condensation and/or stratification. The level of the diffusers is high while the exhaust grills are close to the floor. Furthermore the standard highlight that the diffusion of the concentration of the contaminants change in function of the three directions. This system could be the most comfortable for the patient and the medical staff for the room conditions. Nevertheless, this system can contribute to the raise of microbial dispersion into the sensible zone considering the possibility of transportation of airborne bacteria generated near the floor or in the peripheral of the operating room;

Displacement airflow: In this case, the direction of the flow starts from the low level at lower temperature than the room one. After a while, the temperature increase and the air reach the exhaust grids placed into the ceiling of the operating room. In a previous work this type of air ventilation technology was not indicated for prone infection surgeries [55].

Unidirectional airflow: this system is used when the demand of cleanness is extremely high. The concept follow the piston principle, which sweeps all the air through the room, as so-called piston flow. The most common type has the clean air supplied from the ceiling in order to push the airborne contaminants towards the exhaust grids placed in the floor. For this reason, a huge airflow is needed, considering that it is supplied through wide surfaces (floor, ceiling or walls) in vertical or horizontal direction and extracted on the opposite side. The horizontal direction is not advice as a good solution

because could bring bacteria from the staff into the patient wound. For this reason, the vertical unidirectional flow is preferred with the idea to wash away any particle close to the sterile area.
The weak point, highlighted in several works [56], is that some disturbances could bring some distortion to the unidirectional airflow. In fact, many disturbances have to keep in consideration, for example, heat gains due to lamps and instruments, cooling systems for electromedical devices and the medical staff bring the formation of plumes, which induce convective movements in the up direction due to the density different. This disturbances, due to the not-isothermal condition, for the laminar concept is more dangerous that for the turbulence one.

Mixed airflow: mixed air system is common in the operating theatres when there is a request of clean air in the sensible zone of the surgery and less protection for the positions in periphery. For this reason, this system has unidirectional airflow in the center and mixed vertical outside this zone. The exhaust grills are located at two different height levels in order to extract particles, anaesthetic gases and surgical smoke, which can have different density than air. The idea to avoid contaminations from the periphery zone is that the vertical unidirectional airflow in the center, which is supplying clean area, acts as an air curtain. Supply devices should not cause dumping or noises and they may guarantee air velocity level between 0,2 m/s-0,3 m/s at 1 meter of height on the operating point. [57]

The previous air ventilation technologies could be insert in the following diagram [58]. As it is possible to notice, on the left side there is the total cleanliness air distribution systems with low level of mixing in occupancy zone, where unidirectional airflow find its place. On the right side of the figure, the degree of mixing increase and is possible to find also others air ventilation technologies. The position of the air ventilation technology of both hospitals faced in this work, will be assigned in the results and discussion, Section 7.3.3.

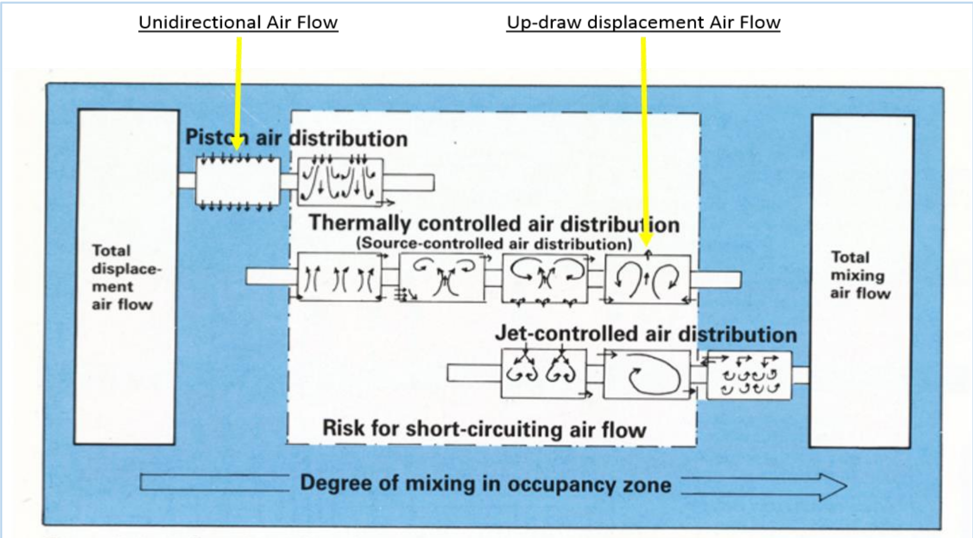


Figure 3.1: Schematic representation of the air ventilation technology divided by the degree of mixing

3.2 Ventilation principles in Swedish operating theatres

According with the Swedish Standards Institute (SIS-TS 39:2015) [1], in Sweden, as also in many countries, two main principles of ventilation system are in use in the operating rooms. One is based on turbulent mixed air (the first one described above), while the second follow the idea of parallel flow, also known as unidirectional airflow. It is defined in the ISO 14644-1 and 14644-4 as controlled airflow through the entire cross-section of a cleanroom, or a clean zone, with a steady velocity and airstreams that are considered parallel. The concept is based on that the supplied air is pressed through HEPA filters in the ceiling above the critical surgical zone, at a high airflow rate. The air velocity of the flow should be high enough to preserve a stable, controlled flow over the surgery table even when disturbed by personnel activity and equipment, but low enough to avoid turbulence. Compared with the unidirectional airflow described previously the size of the supply air device area and the air velocity are lower.

The air in a unidirectional downward flow is supplied at lower temperature than the level present inside the room, even to avoid stratification. Furthermore with a velocity level below 0.3 m/s with the aim to segregate a protected zone from the periphery area [2] and a protection against penetration of particles from the surgical team who is operating inside this zone. [59]

It is also important to underline, as the UNI 11425 said, that the analysis related to the contaminants diffusion does not follow the theoretical idea. The concept, as said above, found is application in the directionality of the air. An external disturbance could bring the direction of the air on another road. Therefore, the capacity of the system in the removal of contaminants could be seriously put in difficulty. Regarding this aspect, the disturbances bring by instruments and objects to the LAF technology in a previous thesis [57], a work was made in order to study this aspect and it was resumed with a representation of the airflow pattern around the operating room (
Figure 3.2).

When the unidirectional flow meet an obstacle change its direction and increase its velocity. As it is logical to understand, under the obstacle the pressure decrease and the chance to have vortices increase. In fact, even under the operational desk and behind the back of the surgeon the presence of non-linear airflow is highlighted.

Moving out the sterile zone the air starts to make large and low velocity vortices. In fact, without a diffuser, which should impose the direction, the air starts to move without precise direction. Furthermore, the exhaust grills do not have a fundamental capacity in impose the airflow direction as the supply devices.

In this representation, the heat gain due to medical staff and machines was not underlined, but it is another element, which could bring disturbances to the parallel flow together with the movements of the medical staff which are another important disturbance to the stability of the airflow pattern.

Furthermore, it is important to highlight that, as the previous picture (Figure 3.1), the author will discuss this airflow idea in the results and discussion after the presentation of the results collected in this work.

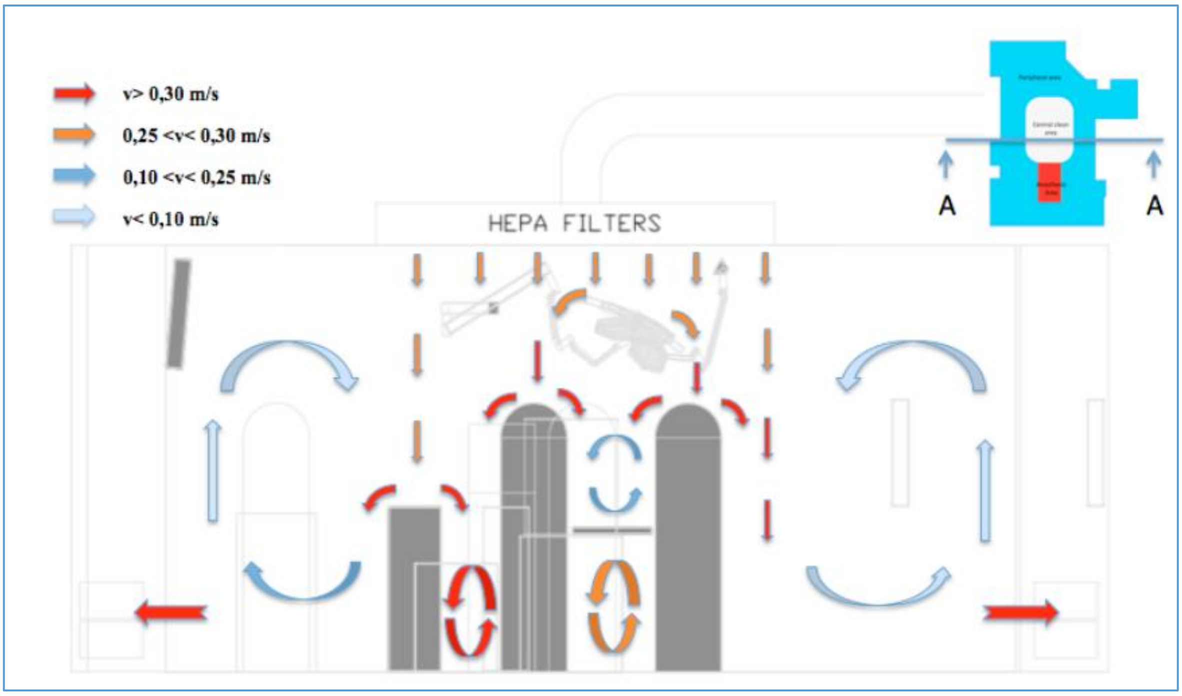


Figure 3.2: Air velocity representation in the operating theatre during EVAR (Endovascular Aneurysm Repair) surgery, Leonardo Amato thesis [57]

3.3 The issue related to the air exchanging per hour for the LAF technology

The definition of air exchange rate according with EN ISO 14644-3:2005 is: rate of air exchange expressed as number of air changes per unit of time, and calculated by dividing the volume of air delivered in the unit of time by the volume of the space.

When the definition talks about the volume of the space it is not easy to choose which zone of the room. In fact, considering the operating room in Södertälje (Section 4.2 page 24), if the choose of the volume is the sensible zone under the LAF technology, the calculus bring the value of air exchange rate to a high level:

$$AirExchangeRate = \frac{Air\ flow\ rate}{LAF_{area} \times h_{room}} = \frac{2{,}3\,\frac{\cancel{m^3}}{\cancel{s}} \times 3600\,\frac{\cancel{s}}{h}}{8{,}5\ \cancel{m^2} \times 3\cancel{m}} \cong 325\,\frac{1}{h}$$

While if the calculus is made for all the room the result will be:

$$AirExchangeRate = \frac{2{,}3\,\frac{\cancel{m^3}}{\cancel{s}} \times 3600\,\frac{\cancel{s}}{h}}{56{,}1\ \cancel{m^2} \times 3\cancel{m}} \cong 49\,\frac{1}{h}$$

So which result is the correct one? The air exchange rate in the sterile zone or for all the room? Furthermore, the air exchange level under the LAF is high, because there is not the mixing principle and the previous air is pushed away. While the air outside the sterile zone remain around maybe for more than the air exchange rate calculated (about 49 1/h) represent. In fact, considering also the representation showed previously (

Figure 3.2), the air exchange capacity of the LAF system in the periphery of the room is not easy to define.

If the calculus are moved over the mixed operating theatre in Sahlgrenska University Hospital, under the LAF the air exchange rate is:

$$AirExchangeRate = \frac{3{,}4\,\frac{\cancel{m^3}}{\cancel{s}} \times 3600\,\frac{\cancel{s}}{h}}{12{,}7\ \cancel{m^2} \times 3\cancel{m}} \cong 320\,\frac{1}{h}$$

While if the calculus is made for all the room the result will be:

$$AirExchangeRate = \frac{4{,}0\ \frac{\cancel{m^3}}{\cancel{s}} \times 3600\frac{\cancel{s}}{h}}{82{,}4\ \cancel{m^2} \times 3\cancel{m}} \cong 58\frac{1}{h}$$

Also considering the OT of the Sahlgrenska University Hospital of Göteborg the level of the air exchange rate under the LAF ceiling air supplier is high. While the level considering all the room is more or less as Södertälje Hospital. Both of the air exchange rate considering the entire OT as volume follow the guidelines purposed by the Standards, by the way the air exchange rate over the operating area has high levels for both hospitals.

For the reasons listed above the idea could be to highlight two different values of air exchange rate in case of LAF technology in use inside the OT.

.

4 Operating theatres structures

In this following section, there are the technical descriptions of the operating rooms in Sahlgrenska University Hospital in Göteborg and Södertälje Hospital in Södertälje.

It is useful to introduce shortly the concept of Unidirectional Flow (or LAF, Laminar Air Flow). The air is distributed into the inner sterile zone of the operating room as a controlled parallel airflow. The aim of this method is to create an area with lower concentrations of contamination in the air above the operating table, the surgical instrument table and other sterile areas in the surrounding areas [2]. The ventilation principle presents conditions to supply the room with a large air volume flow at comparatively low air velocities. In order to stabilize the airflow, the supply temperature is lower than the room temperature.

More detailed plants, of the surgery areas, for both hospitals are available in the Appendix F.

4.1 Sahlgrenska University Hospital operating theatre

In the following drawing is presented the layout plant of the operating theatre in Sahlgrenska where the measurements were made. It is a University hospital with a deep focus on more advanced medical treatment. It is possible to notice, as air technology systems, the Laminar Airflow technology at the center of the operating room and two turbulent diffusers over the anaesthesia zone. For the exhaust grills, the positions are in the periphery of the room at two different levels. The medical cabinet is inside the operating theatre without connection with the corridor. To avoid the open of the door there is a little window for the objects passing. Doors are of the swing type and the room is directly connected with the corridor.

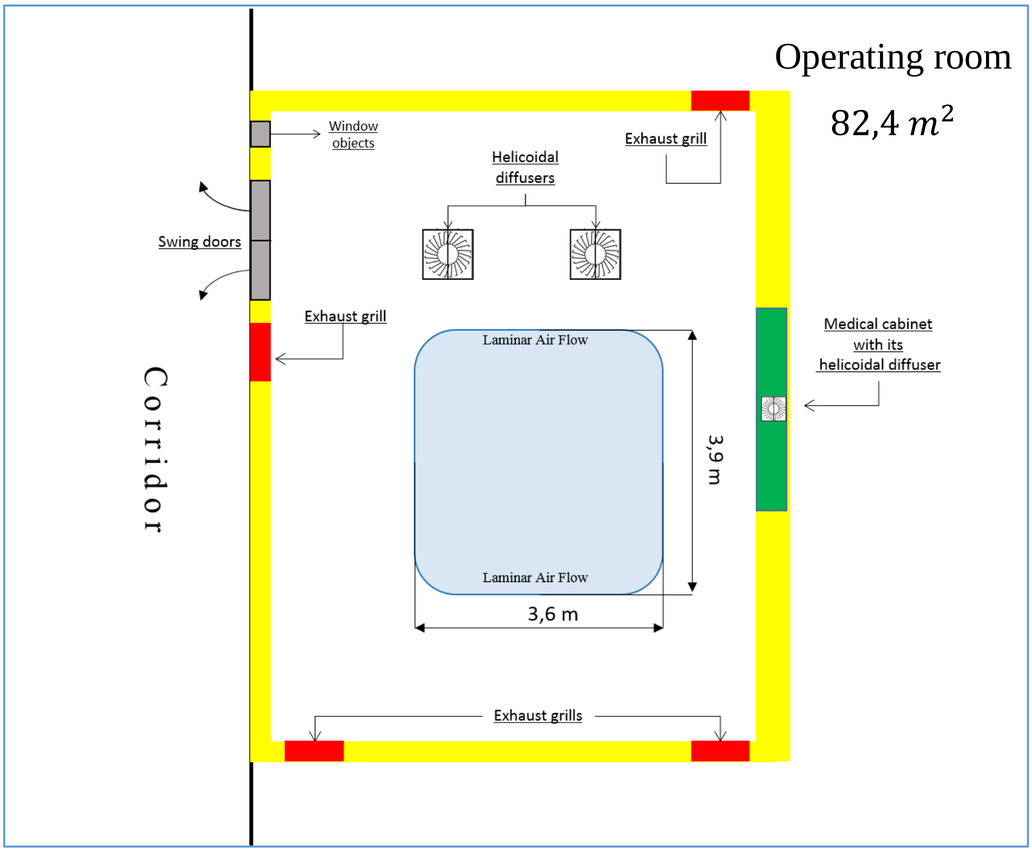


Figure 4.1: Operating room plant in Sahlgrenska University Hospital

Total Area of the operating room	LAF measures	LAF area	Air flow	Supply temperature	Air Velocity under the ceiling	Air filter class:	ΔP $[Pa]$	Air Exchange Rate (under LAF – total)
82,4 m^2 (8,24 $m \times 10$ m)	3,6 m $\times$ 3,9 m	12,7 m^2	$4000 \frac{l}{s}$ (LAF=3400 $\frac{l}{s}$)	$22°C$	$0,27\ \frac{m}{s}$	HEPA H14	10 Pa	$320\ \frac{1}{h} - 58\ \frac{1}{h}$

In the following picture is possible to connect what described above with a real photo taken before the start of the preparation of operation theatre.

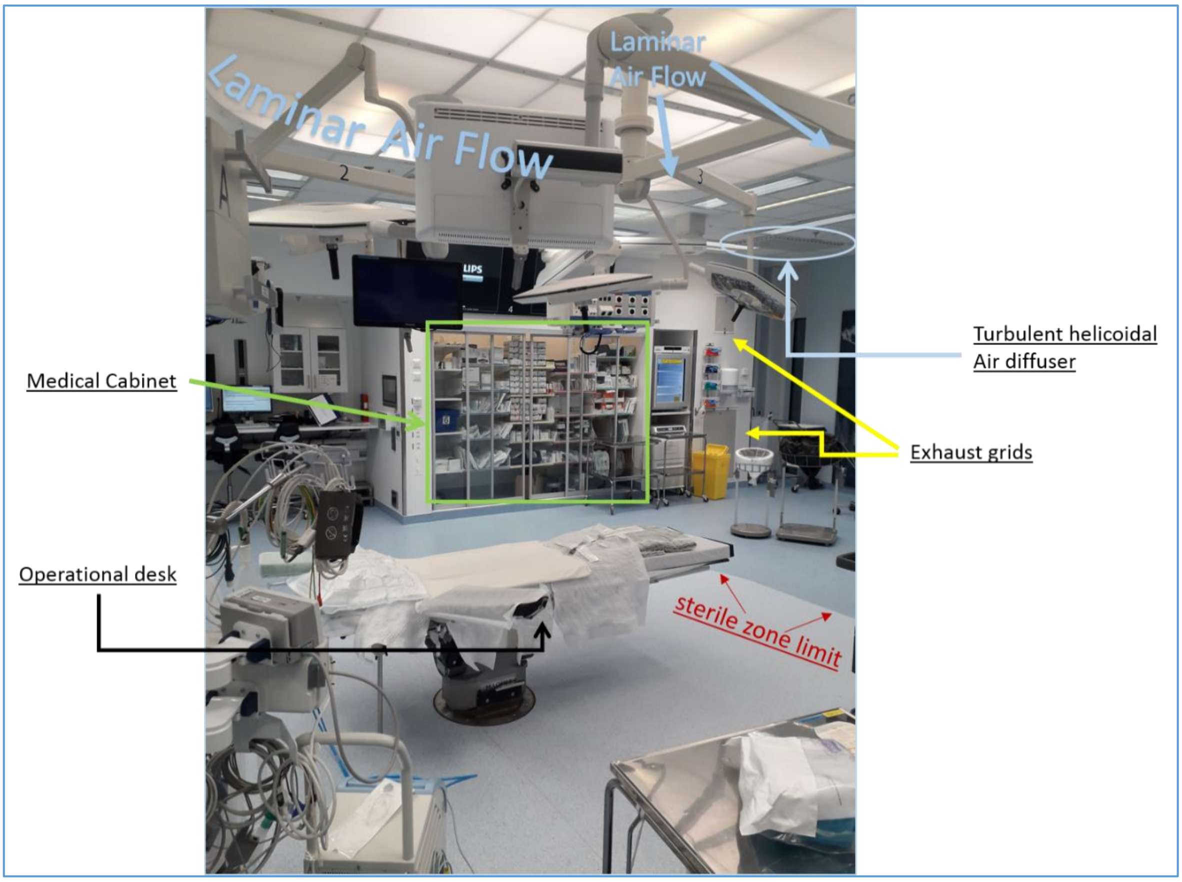


Figure 4.2: Picture of the operating room in Sahlgrenska University Hospital, 06/11/18, Göteborg

4.2 Södertälje hospital operating theatre

In the following map is presented the plant of the surgical operating room in Södertälje where the measurements were made. Compared with the Sahlgrenska University Hospital, this hospital is focused on surgeries that are more conventional. It is possible to notice, as diffusers, the Laminar Airflow technology at the center of the operating room and the turbulent diffusers inside the preparation room. For the exhaust air, the positions are in the periphery of the room at two levels. The medical cabinet is used as a direct connection between corridor and operating theatre for instruments passing. The door are of the sliding type and the OT is connected both with corridor and preparation room.

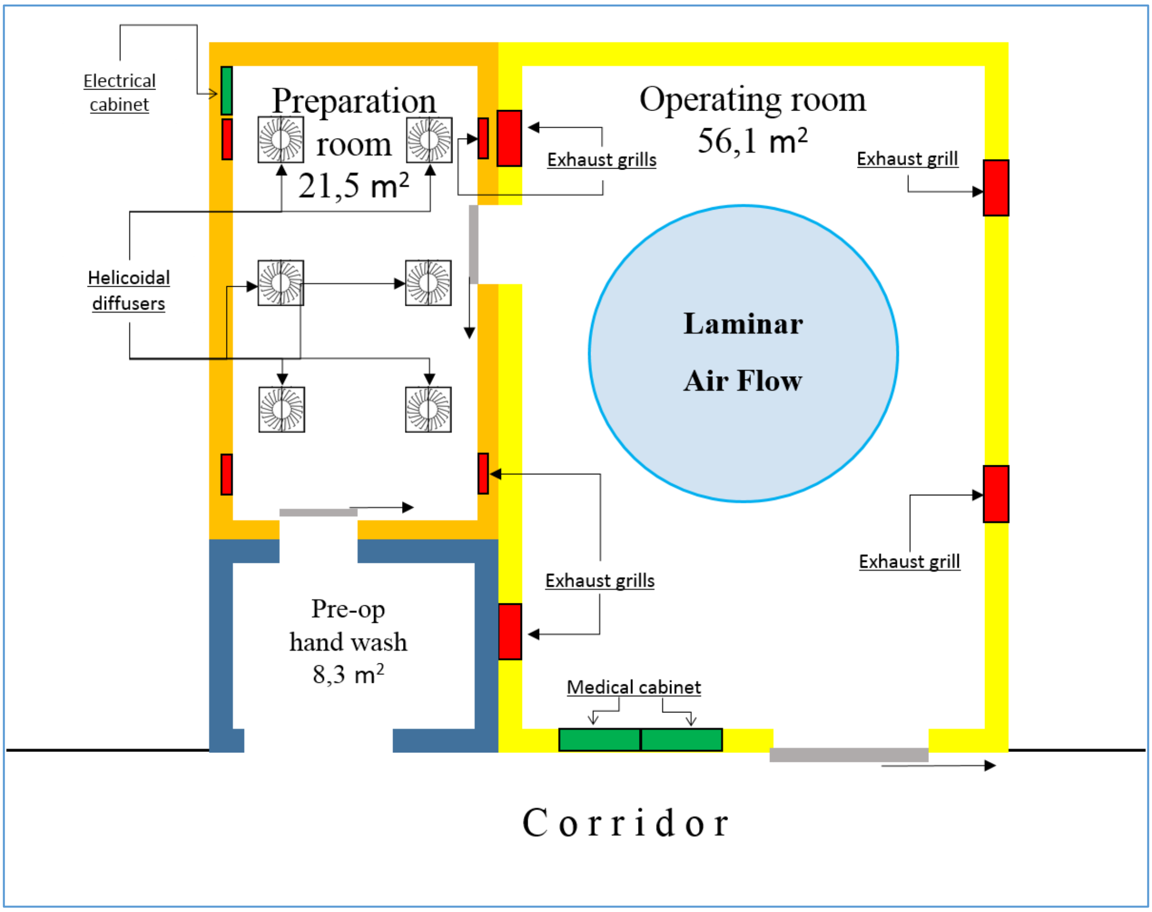


Figure 4.3: Plan 1: Operating room plan of Södertälje Hospital

Total Area of the operating room	LAF diameter	LAF area	Air flow	Supply temperature	Air Velocity under the ceiling	Air filter class:	ΔP $[Pa]$	Air exchange rate (under LAF-total)
$56.1\ m^2$ $(7.70 \times 6.60m)$	$3.3\ m$	$8.5\ m^2$	$2300\ \frac{l}{s}$	$21.5\ °C$	$0.27\ \frac{m}{s}$	HEPA H14	$10\ Pa$	$325\ \frac{1}{h} - 49\ \frac{1}{h}$

In the following picture is possible to see the LAF technology over the surgery table and the sliding door, which connect the OT with the instruments table's preparation room.

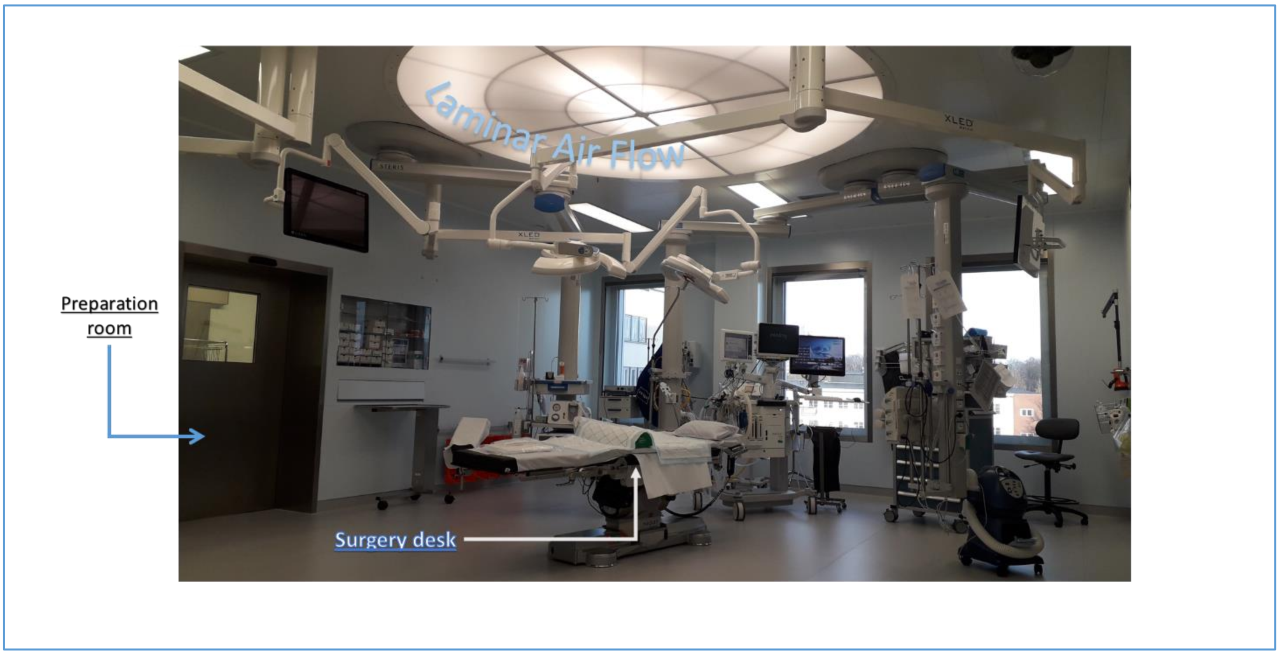


Figure 4.4: Operating room with the LAF technology inside the Södertälje Hospital in Södertälje, 29/10/18

4.3 Structure, general habits and operation differences between the hospitals

The first, which could appear watching the previous maps, could be that the operating room in Sahlgrenska are bigger than the one in Södertälje. In fact, also the area of the Laminar Air Flow and the airflow per hour are different. The filtering system is the same (HEPA H14). The exhaust flow is about the 90% of the supply air for both of the hospitals. The velocity under the ceiling is 0.27 m/s as the values recommended by the standard ($0.24\ m/s < velocity < 0.45\ m/s$ [2]). Furthermore, the map in Södertälje present also the preparation room that is shared with another symmetric room on the other side, while the Sahlgrenska has the preparation room not attached (precise position is presented in the Appendix F). The main difference in the preparation room is that the Sahlgrenska University Hospital presents a LAF technology system also there, while in Södertälje Hospital there is a turbulent airflow with helicoidal diffusers. Different aspects noticed during this experience underlined that it is important that the ventilation principles in the OT and in the preparation room have to be coordinates.

Another different in the habit is that in Sahlgrenska the use of single-use hood is a rule for all the people who stay in the surgeries theatres zone; while in Södertälje the rule impose the cap for all the time and not the hood that has to be wear just when going inside the operating theatre.

The type of operation followed were different so also the amount of people was different. During internal surgeries in Sahlgrenska the number reach even fifteen people inside the operating theatre during the liver transplant, while in Södertälje the number was around seven for all the operations.

5 Measurement technique and instrumentation

During this work are in using two ultrafine particles counter, one air sampler also known as CFU machine pump, five velocities/temperature sensors fixed and one portable velocity/temperature sensor. In the following section the characteristic of these instruments are described.

5.1 TSI, P-TRAK^{TM} 8525

The P-TRAK^{TM} 8525 Ultrafine Particle Counter (UPC) is an instrument to detect the number of ultrafine particles (UFP) presented in the air sampled. The most important characteristic is that this instrument counts the number of ultrafine particles in the 0.02 – 1 µm interval and not separates these in intervals related to different sizes. It should be an element to remember when could be useful to compare the number of UFP with the number of CFU/m^3 detected. In fact, Bio-aerosols ranging in size from 1.0 to 5.0 µm generally remain in the air, whereas larger particles are deposited on surfaces [60]. By the way, several studies shows that the presence of little particles it is related with the presence of bigger, while the presence of just big particles without UFP detected is rare. Therefore, this type of instruments should be enough to understand the presence of dirtiness. The measuring interval used is one measurement every second. The particles range is between $0 - 500'000$ pp/cm^3 with a tolerance of 5%. The total sucking capacity is 700 cm^3/min with a sampling of 100 cm^3/min according with the ISO 27891 of the 2015.

The working principle is the following: thanks to the using of a built-in pump, the air is sucked by the instrument's probe. The ultrafine particles, once they reach the instrument are mixed with isopropyl alcohol vapour, which condenses over the particles, bringing those to increase their size in larger droplets, which can be easily detected by the photo detector. The photo detector uses a laser beam, which hit the particles, and the light flashes produced by their passage allow counting these.

Following the guidelines presents over the manual, before every measurement it is important to verify if the instrument is operating normally. The daily zero check consist into place the filter over the pipe and check if the samplers show the 0 ultrafine particles level in 5-10 seconds.

The alcohol cartridge has to be place into the storage cap every day after the using and leave it there until a new use. The cartridge is refill everyday with the alcohol suggest by the company.

To guarantee the correct behaviour of the two instruments the author compare those in the same position and condition inside the laboratory of the Chalmers University.

In the following couple of pictures is possible to see the two TSI P-Trak, which are measuring in the same position. In fact, the probes (red circle) are sampling air from the same position and the instruments show the close measures of pp/cm^3 (yellow rectangle).

(a)

Left instrument: 1090 pp/cm^3

Right instrument: 1110 pp/cm^3

(b)

Left instrument: 1120 pp/cm^3

Right instrument: 1140 pp/cm^3

Figure 5.1: TSI ultrafine particles counter during the comparison, with the pipes attached closer on a book.

For the work necessary is important the order of magnitude so a little difference is not important. By the way, at least one time during the operation the ultrafine particles counters are reversed to be sure that the level counted remain the same for both of those. During the study no problems are detected related to these instruments. These instruments are dirty so is important to be sure not to interact with the sensible zones. Firstly, the instruments is cleaned with alcohol before to enter inside the operating theatres and leave inside the hospital in a secure room during the night. The second aspect is that the instruments are placed outside the sterile zone, or on the floor of the sterile zone if necessary for the length of the pipe. The pipe to suck the air is a sterile pipe and the medical staff place those where necessary for the sampling session (Figure 5.2).

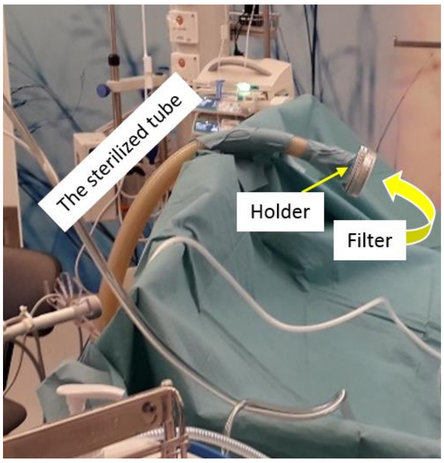
Figure 5.2: Pipe placed inside the sterile zone and connected with the UPC

5.2 Sartorius MD-8

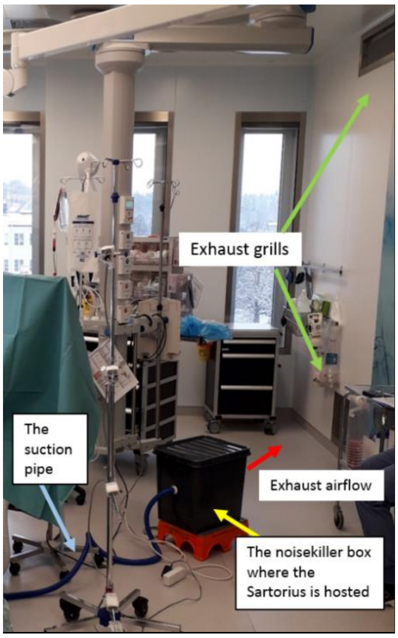
The air sampler suck a costant amout of air flow (1 m^3) through a sterile filter in a fixed interval of time (10 minutes), after the sampling the filter is moved using sterile procedure into the culture plate where the filter melt and will be incubated to count the number of Colony Forming Units.

This instrument is quite noisy, in fact there is a box introduced in order to reduce the sound (Figure 5.3 (c)). This box could release particles around the area when the air sampler starts (elements discovered by Beccio in her work [55]), the instrument suck the air and release that heated. For these reasons is important to keep the instrument far as possible from the sterile zone and with exhaust air directed far from the sensible zone and the measuring points.

(a)



(b)



(c)

Figure 5.3: The Sartorius MD8 before the start of an operation (a); the sterilized tube, holder and filter over the anaesthesia barrier (b); the box where the instrument is placed (c), Södertälje

The pipe, which sucks the air (Figure 5.3 (b)) has to be sterilized because enter in sensible zones. In fact, during the measurements campaign happened two times that the scheduled measurements change due to water presence inside the tubes, water could be the means to bring bacteria in the sterile zone.
The Swedish Standards Institute expressed suggest to use this instrument for the measurements, with the fixed air sampling of $0.1\ m^3/min$ or $6\ m^3/h$. Every ten minutes the filter, where airborne bacteria carrying particles are trapped, has to be removed and moved aseptically to blood agar plate using sterile tweezers. [1]. It has to be changed every ten minutes otherwise the bacteria levels will be falsely lowered because of drying out on the filter. Is also important to underline that the active air sampling is necessary consider the type of ventilation that is studying.
Furthermore, as described in the CEN/TC 156/WG 18 [2] standard and other works, the agar plates has to reach the room temperature in order to avoid condensation on the plate. One agar plate is keep together with the others without make melt any filter just to have a reference plate.

The filter has a diameter of 80 mm, with nominal pore size of 3 µm and a filtration area declared as 38.5 cm^2 [61], check the Appendix B for the Agar plates certification and the calibration certificate of the instrument.

Table 5.1: Airflow rate characteristic of the Sartorius MD-8 air sampler

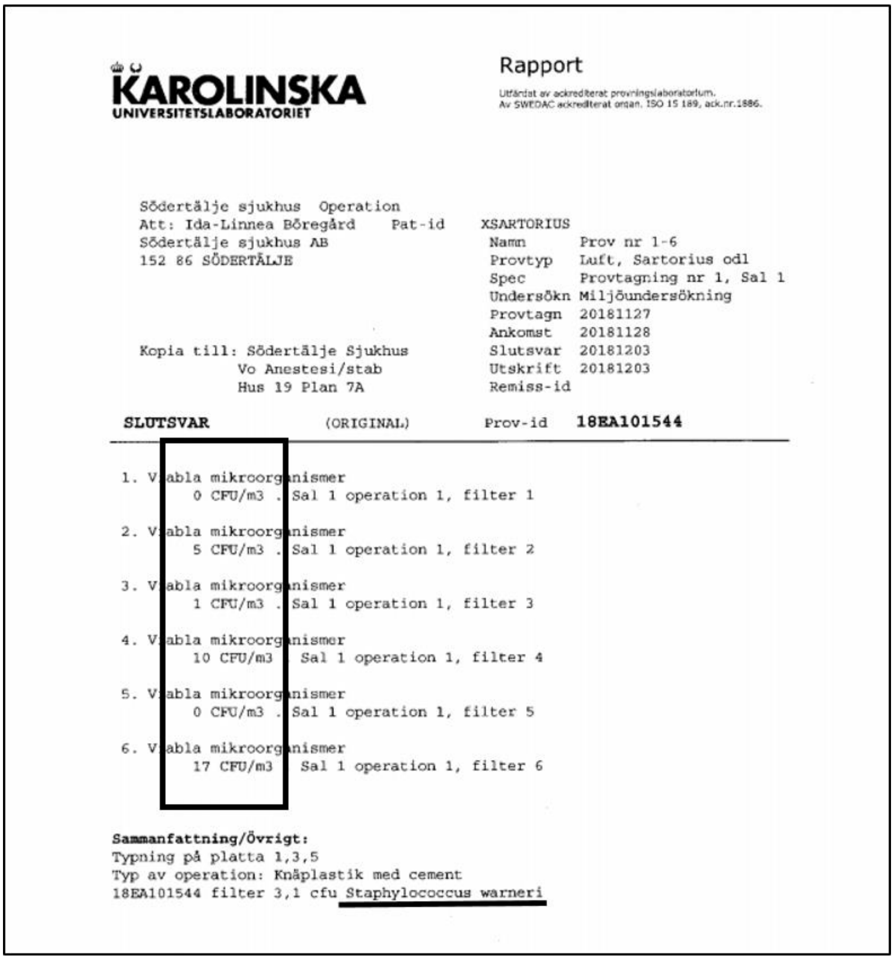
	Air flow rate Nominal value	Air flow rate declared [61]
Area specific airflow	$2.6\ \frac{l}{\min\times cm^2}$	$(2.2-3.2)\ \frac{l}{\min\times cm^2}$
Airflow per minutes in litres	$100\ \frac{l}{min}$	$(84.7-123.2)\ \frac{l}{min}$
Airflow per minutes in cubic meters	$\frac{1\ m^3}{10\ min}$	$(0.847-1.232)\ \frac{m^3}{10\ min}$

After the collection, the filters they are stored together and send to the laboratory ready to be incubated (Figure 5.4).

Figure 5.4: Petri's plates after that the filter is put inside ready to be sent to the laboratory

The standards SIS-TS 39 suggests to incubate the agar plates for two days at $35 \pm 2°C$. The plates were delivered to the Karolinska laboratory, which follow the guidelines purposed by the Standards. The operating nurse who takes the filter was in sterile condition for all of the measurements, furthermore take notes regard the number of door openings, number of people inside and choice of clothing regime, as suggest by Annette Erichsen Andersson [59]. In fact, Andersson substained that the door openings and the people presence (Section 7.1) will lead to increased levels of airborne bacteria and SSI. Check the Appendix B for more details about the paper note type used in this sampling campaign.

After three working days the results arrives in a paper like the added one (Figure 5.5). Beyond all the standard information regarding date, person who request it, type of operation, type of instruments and so on. It is possible to notice (inside the orange rectangle) the number of CFU/m^3 (Concentration of aerobic CFU) counted by the laboratory. Furthermore, for the filters requested (1-3-5 in this case) there is the typing of the bacteria detected, in this case was one from the most common family: Staphylococcus.



KAROLINSKA
UNIVERSITETSLABORATORIET

Rapport

Utfärdat av ackrediterat provningslaboratorium.
Av SWEDAC ackrediterat organ. ISO 15 189, ack.nr.1886.

Södertälje sjukhus Operation
Att: Ida-Linnea Böregård Pat-id XSARTORIUS
Södertälje sjukhus AB
152 86 SÖDERTÄLJE

Namn Prov nr 1-6
Provtyp Luft, Sartorius odl
Spec Provtagning nr 1, Sal 1
Undersökn Miljöundersökning
Provtagn 20181127
Ankomst 20181128
Slutsvar 20181203
Utskrift 20181203
Remiss-id

Kopia till: Södertälje Sjukhus
Vo Anestesi/stab
Hus 19 Plan 7A

SLUTSVAR (ORIGINAL) Prov-id **18EA101544**

1. Viabla mikroorganismer
0 CFU/m3 . Sal 1 operation 1, filter 1
2. Viabla mikroorganismer
5 CFU/m3 . Sal 1 operation 1, filter 2
3. Viabla mikroorganismer
1 CFU/m3 . Sal 1 operation 1, filter 3
4. Viabla mikroorganismer
10 CFU/m3 . Sal 1 operation 1, filter 4
5. Viabla mikroorganismer
0 CFU/m3 . Sal 1 operation 1, filter 5
6. Viabla mikroorganismer
17 CFU/m3 . Sal 1 operation 1, filter 6

Sammanfattning/Övrigt:
Typning på platta 1,3,5
Typ av operation: Knäplastik med cement
18EA101544 filter 3,1 cfu Staphylococcus warneri

Figure 5.5: CFU results from the laboratory, 27/11/18, knee surgery, Södertälje

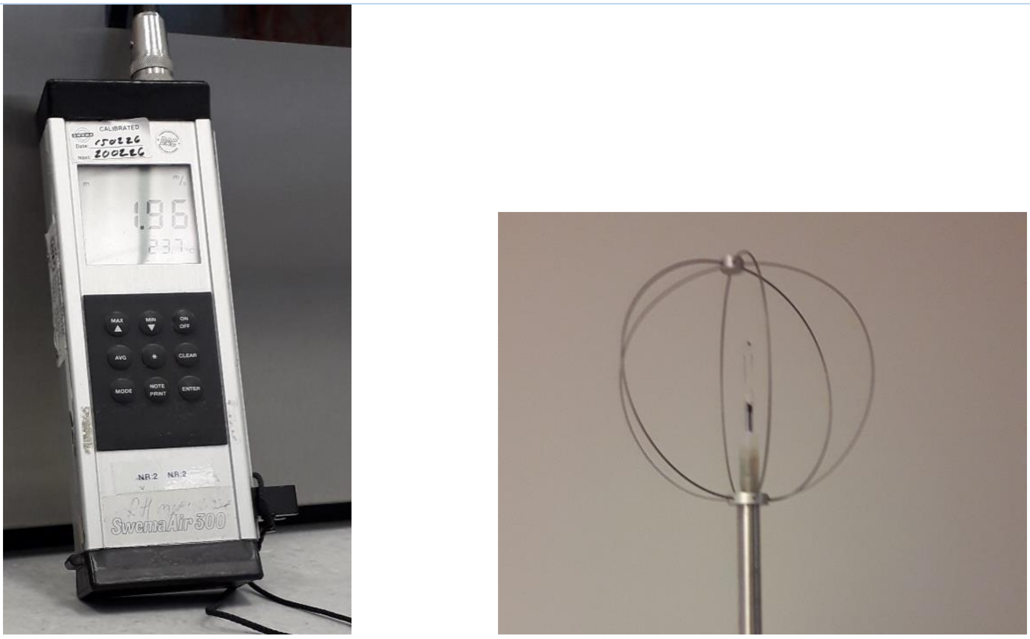
The standard highlight that every operations where the data could be used has to be longer than 45 minutes (time interval between incision and final sewing) and all the measurement followed were at least 60 minutes. Another element evaluated as important is the number of operations followed (at least 5 or 10 operations), in this study thirteen operations (5 knees prosthesis, 7 hip prosthesis and 1 broken hip) were followed using the air sampler.

The idea from different standard is more or less the same about the CFU count. The CEN/TC 156/WG 18 [2] ask to have at least 4 (preferably 6) samples of 10 minutes during the ongoing of the surgery, every sample need information as previously listed. Select sampling location around 1.2 m above the floor level and ≤0.5 m from the surgical site. The instrument description is the same for the Sartorius MD-8. What we can notice is that the position declared is not precise and there is enough freedom regarding which are the positions where to take. In fact, 0.5 m from the surgical site could be also on the side of the surgeon or also behind where all the samples results cloud change.

By the way, as it is possible to check in the following sections, all the measurements happened as requested by the standard.

5.3 Swema Air 300

This instrument could be used or to detect the instantaneous velocity connecting the "hot-wire probe" or to detect the pressure differential connecting two pipes. The first situation was used to understand some focused velocities in same determinate positions, as the exhaust grill, electrical cabinet and several places around the operating theatres where necessary. In picture Figure 5.6 (b) is possible to notice the head of the instrument with the "hot wire" technology for the velocity measurement. The circular pieces all around are just a protection for the probe.
Secondly, it was used in order to understand the differential pressure between the internal of the operating theatre compared with the corridor. Mostly it was useful to study the behaviour of the air around the medical cabinet.



(a) (b)

Figure 5.6: Picture of the SwemaAir 300 while in use for the differential pressure calculation, 29/11/18, Södertälje (a); Specific picture of the probe for the velocity measurement 23/10/18, Chalmers Laboratory, Göteborg (b).

Measuring range of velocity $(0.05 \div 3.0) \pm 0.03\ m/s\ at\ 23\ ℃$ with the response time of 0.2 s.

Measuring range of temperature $(10 \div 40) \pm 0.3\ ℃\ at\ 20℃$.

Pressure sensor interval $(-300 \div 1500) \pm 0.3\%\ Pa\ at\ 20℃$. [62]

5.4 Air Distribution Measuring System AirDistSys 5000

The AirDistSys5000 is a wire-less system, which makes it convenient for field and laboratory measurements. The velocity sensor is made of special wire pressed into the shape of a sphere with diameter of 2 mm. Thanks to the convection heat exchange the sensor change is temperature which induce a different tension that allow to understand the velocity of the air. While the temperature sensor is made of the thin nickel wire and its shape is cylindrical.

In the following picture is possible to see these five sensors placed over a medical stand at different levels. Every little picture is a zoom on the hooking of each probe and its level measured with a ruler.

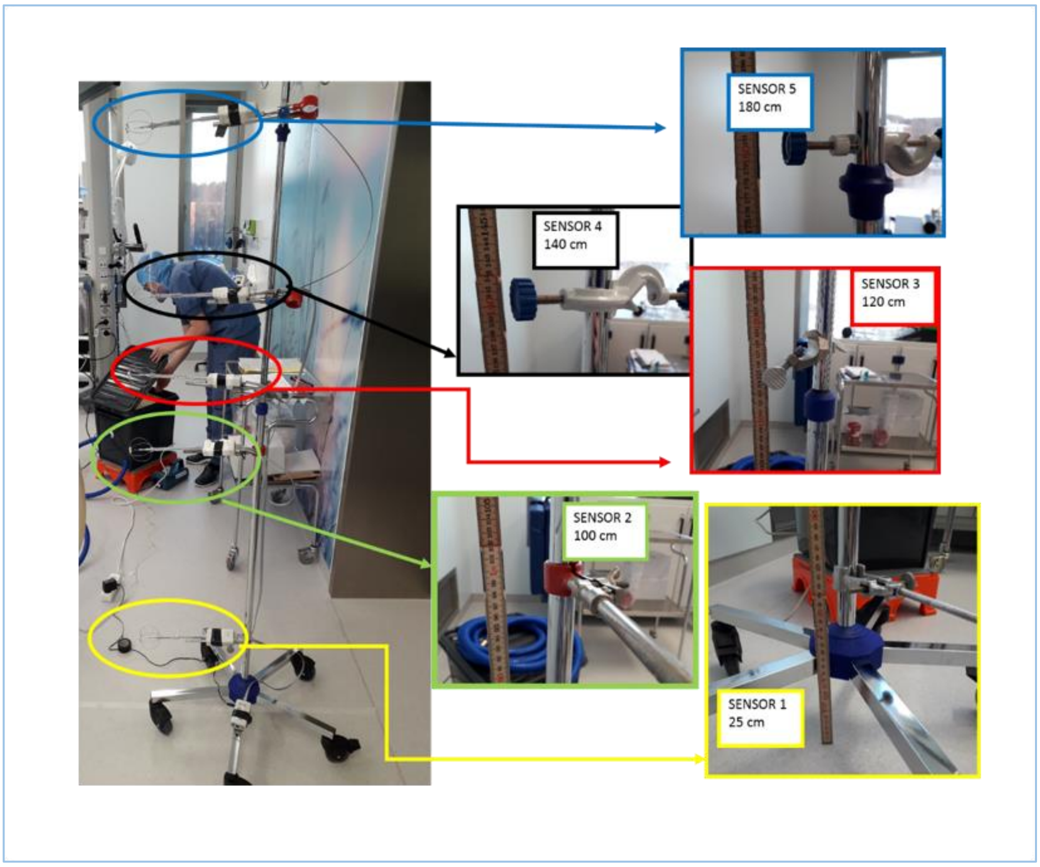


Figure 5.7: Temperature sensors fixed at different levels before the start of measuring in Södertälje, 27/11/18

The measurement speed range is $(0.05 \div 5) \pm 0.02\frac{m}{s} \pm 1.5\, m/s\ \ of\ readings$.

Temperature range is: $(-10\ \pm 50) \pm 0.2\ ℃$ [63]

This type of instrument is used in Södertälje in many days to understand the airflow pattern, regarding velocity and temperature, in different situations.

6 Technical Clothing systems

A lot of work is ongoing related to the technical clothes, even correlated with the article Ljungqvist et al. work [64] where is highlighted that "clothing systems in operation rooms need to be upgraded when used during orthopaedic and trauma surgery. When patients are highly sensitive to infections it is of vital importance that the concentration of airborne bacteria carrying particles is as low as possible through e.g., the use of clean air suits".

Hospitals have the possibility to choose which technical clothing system could use inside the operating room, obviously the standards advice to use the most protective technical clothes. The ordinary scrub suit is a working garment for operation room staff, made from materials that are more permeable and not intended to prevent airborne dispersal from staff. While the clean air suit are single use technical suits, which have shown to minimize contamination of the operating room air from skin scales originating on the skin of persons and carrying infective agents [1]. In fact, for orthopaedic surgeries the single use technical clothes system is recommended, while for others operations, internal surgeries followed in Sahlgrenska for example, the ordinary scrub is considered sufficient.

All the technical clothes used in the previous articles are described in the Appendix A.

The technical clothes for hospital to be considered adapted as to presents that the textiles should have barrier effect and reduction of SSI (UNI EN 13795:2013). To test if this characteristic are satisfied the technical gowning have to passing through different tests modulated on the zone where they are going to be used [65].

The main different between multiuse ordinary scrubs and single use technical clothes is the reuse possibility, as emphasized by the names. Multiuse technical clothes receive washing, drying, sterilization process for several times. The number of cycles is guaranteed by a system, which enumerate the numbers of WDS (Washing Drying and Sterilisation) processes. Considering also the higher number of particles related and the transpiration capacity this type of clothes are not advice for prone-infection surgeries. Furthermore, after several WDS procedures also the performances of the material reduce, as reported by Romano et al. [66].

Different works made during the years confirm the presentation highlighted by the Swedish Standards Institute. In the Tammelin et al. work [67], they compared the single-use clothing system and reusable clothing system by testing both in a dispersal chamber and during surgical procedures. With the single-use clothing system, all of the five studied operations had a mean value $< 10 \frac{CFU}{m^3}$ as requested by the standards (SIS-TS 39:2015) [1]. In another work by Tammelin Ann [68], three types of clothing systems were compared (mixing material and two single uses with differents weight) inside a mixing ventilation operating theatre close to the wound. In addition, these measurements confirm the largely capacity of the single use compared with the mixed material technical clothes. In addition, another work made in Stockholm confirmed these large differences [69]. Even at least seven times better than the mixed material clothing system.

Many different works confirm that the clean air suite type, single use, guarantees a lower level of CFU losses than the ordinary scrub. The Swedish Standard Institute [1], resumes all the information of several works in two values: $5\ CFU/s$ for the ordinary scrub and $1{,}5\ CFU/s$ for the clean air suit type. Even in the Borgqvist et al work [70] report that the CFU-levels for clothing system of cleanroom quality is about $1/10^{th}$ of the levels measured for clothing system of conventional quality.

Comfortability of the clothing systems is important, according with Swedish standards institute [1], the comfort level may be reduced if the material of the surgical gown and work clothing is impermeable or heavy.

Another idea for the author is that, could be considered that medical staffs that has to work with less comfortable clothes could be more prone in the making of errors. In fact, air clean suit type of technical clothing may be reduced if the material is impermeable or heavy [1]. A person who has to itch or have trouble could reduce the technical clothing performances.

It is important to specify the technical clothing characteristic for the operations followed in:

- Sahlgrenska University Hospital:

  Multi-use technical clothing, ordinary scrub suit: *50% polyester and 50% cotton, no wristlets, used during ordinary surgeries.*

  Single-use technical clothing, clean air suit: *Disposable non-woven material, spun bonded polypropylene 100%, 35 g/m2*

  Barrier Clean Air Suite: *wristlets, used during orthopaedics (check Appendix A (Clothing materials in the different tests) for the related articles).*

- Södertälje Hospital:

  Multi-use technical clothing, ordinary scrub suit: *69% cotton, 30% polyester, and 1% carbon fibre* (Figure 6.1 (a))

  Single-use technical clothing, clean air suit: *Disposable non-woven material, spun bonded polypropylene 100%, 35 g/m²* (Figure 6.1 (b))

  Barrier Clean Air Suite: *wristlets, used during orthopaedics (check Appendix A (Clothing materials in the different tests) for the related articles).*

(a) (b)

Figure 6.1: The author dressed with the two technical clothing systems of the Södertälje hospital. (a) ordinary scrub suit multi-use.; (b) Clean air suit single-use

6.1 What we could expect from our measurements

Considering the large amount of articles related to this aspect, the values that could be associated to as source strength of technical clothing are several. The author decide to use the ones purposed by Ullmann et al. [69]. In case of mixed material (ordinary scrub), during real operation and high activities (orthopaedic surgery) they purposed to use $4{,}2\ CFU/s$. While in the same condition for the single use material they purposed to use $1{,}2\ CFU/s$ .Furthermore, the authors and the Swedish Standard suggeste to use the following formula, in order to calculate the air flow necessary for the cleanliness of the operating theatre. Considering as known elements:

$$Q = n \times \frac{q_s}{c} \qquad \text{(Eq.1)}$$

with:

n = number of people

c = concentration of CFUs per cubic meter limit

q_s =source strength of aerobic CFU for technical clothes

The author in this work decide to use the same formula with another unknown. In fact, this formula is used to predict the amount of airflow needed to guarantee the concentration of CFU requested (<5 CFU/m^3), considering that the operating room where the sampling happens already exist the equation is used to forecast the CFU concentration expected in according with the Swedish Standard.

The airflow rate of the operating theatre in the Södertälje hospital, where the microbiological air sampling was made, is $2{,}3\ m^3/s = 8280\ m^3/h$.

The total number of personal inside the operating theatre during the sampling is seven (n=7; two surgeons; one operating nurse; one corner nurse; one anaesthesiologist; the author and the operating nurse who participate at the project).

Regarding the $q_s = 4{,}2\ CFU/s$ ordinary scrub; $q_s = 1{,}2\ CFU/s$ clean air suit. As better explained in the following Section 7.2, the medical staffs wears technical gowning made of mixing material, in fact the author will make the calculus with $q_s = 4{,}2\ CFU/s$.

Explaining the concentration of CFU/m^3 the previous formula became:

$$c = \frac{q_s}{Q} \times n \qquad \text{(Eq.2)}$$

Using the previous formula and the data listed above, the results that our measuring campaign might obtain, according with Ullmann et al. and the Swedish Standard equation, will be:

$$c = \frac{4{,}2\,\frac{CFUs}{s \times people}}{2{,}3\,\frac{m^3}{s}} \times 7\ people = 12{,}8\ \frac{CFUs}{m^3}$$

In addition, the European Committee for standardization [2] purposed a similar equation in order to calculate the probable concentration amount of CFU related to the airflow rate capacity, occupancy and technical clothes characteristic. Compared with the previous equation the standard add another element at the denominator:

$$CRE = contamination\ removal\ efficiency = \frac{concentration\ in\ the\ exhaust}{mean\ concentration\ in\ the\ room}$$

The formula purposed by the Netherlands standard is:

$$c = \frac{q_s \times n}{Q \times CRE} \qquad \text{(Eq.3)}$$

The detailed calculus will be made in the results part (Section 7.3.2 page 82), where the data necessary for the calculation of the CRE will be available.

7 Results and discussion

In this work different operations were studied, starting from internal surgeries in the Sahlgrenska University Hospital of Göteborg until orthopaedic surgeries in Södertälje Hospital.

In the following table are reported the operations followed, their characteristics and the instruments used.

Table 7.1. List of operation followed

N° of op.	Date	Hospital	Type of operation	Instrumentation used
1	06/11/18	Sahlgrenska	Pancreas resection	2 UPC
2	07/11/18	Sahlgrenska	Pancreas resection	2 UPC
3	08/11/18	Sahlgrenska	Liver transplant	2 UPC
4	12/11/18	Sahlgrenska	Pancreas operation	2 UPC
5	13/11/18	Sahlgrenska	Pancreas resection	2 UPC
6	14/11/18	Södertälje	Ankle surgery	2 UPC
7	14/11/18	Södertälje	Foot plate	2 UPC
8	15/11/18	Södertälje	Hip prosthesis	2 UPC
9	15/11/18	Södertälje	Knee prosthesis	2 UPC
10	16/11/18	Södertälje	Knee prosthesis	2 UPC
11	16/11/18	Södertälje	Broken hip	2 UPC
12	27/11/18	Södertälje	Knee prosthesis	2 UPC - 1 MD8
13	27/11/18	Södertälje	Hip prosthesis	2 UPC - 1 MD8
14	27/11/18	Södertälje	Hip prosthesis	2 UPC - 1 MD8 - 5 AirDistsSys
15	28/11/18	Södertälje	Hip prosthesis	2 UPC - 1 MD8
16	28/11/18	Södertälje	Knee prosthesis	2 UPC - 1 MD8 - 5 AirDistsSys
17	29/11/18	Södertälje	Knee prosthesis	2 UPC - 1 MD8 - 5 AirDistsSys
18	29/11/18	Södertälje	Hip prosthesis	2 UPC - 1 MD8
19	18/12/18	Södertälje	Knee prosthesis	2 UPC - 1 MD8 - 5 AirDistsSys - Swema
20	18/12/18	Södertälje	Hip prosthesis	2 UPC - 1 MD8 - 4 AirDistsSys
21	18/12/18	Södertälje	Hip prosthesis	2 UPC - 1 MD8 - 4 AirDistsSys
22	19/12/18	Södertälje	Knee prosthesis	2 UPC - 1 MD8 - 4 AirDistsSys
23	19/12/18	Södertälje	Broken hip	2 UPC - 1 MD8
24	19/12/18	Södertälje	Hip prosthesis	2 UPC - 1 MD8

Legend:

<u>Sahlgrenska</u>: Sahlgrenska University Hospital, Göteborg; <u>Södertälje</u>: Södertälje Hospital, Södertälje;
<u>UPC</u>: Ultrafine Particle Counter P-Trak, TSI; <u>MD8</u>: MD8 Airscan Sartorius;
<u>AirDistsSys</u>: AirDistsSys 5000 Sensor Electronic; <u>Swema</u>: Swema Air300.

7.1 Study of the airflow pattern using ultra fine particle counters

The exhaust air, which is coming from the wound in case of diathermy bistoury use, is rich of fine particles. The several UPC's probes placed inside the sterile zone, allowed to focus on the UDF airflow technology and its cleanliness capacity. One of the most important aspects, which has to be restrained, is the presence of vortices, and their uncontrolled behaviour. Inside an OT, it is easy to understand how much could be dangerous to have uncontrolled airflows, considering that there are less clean and sterile areas. The air ventilation system inside an OT has to avoid this issue.

In Sahlgrenska University Hospital, during the five operations followed, in order to study the presence of vortices, the UFP probes were placed in the positions indicated with the crosses (Figure 7.1). In the following map, it is possible even to notice the air ventilation system adopted, hybrid type, with the Laminar Airflow ventilation technology over the operation table and the mixing diffusers over the anaesthesia zone. The exhaust grills are in the corners at low and high level.

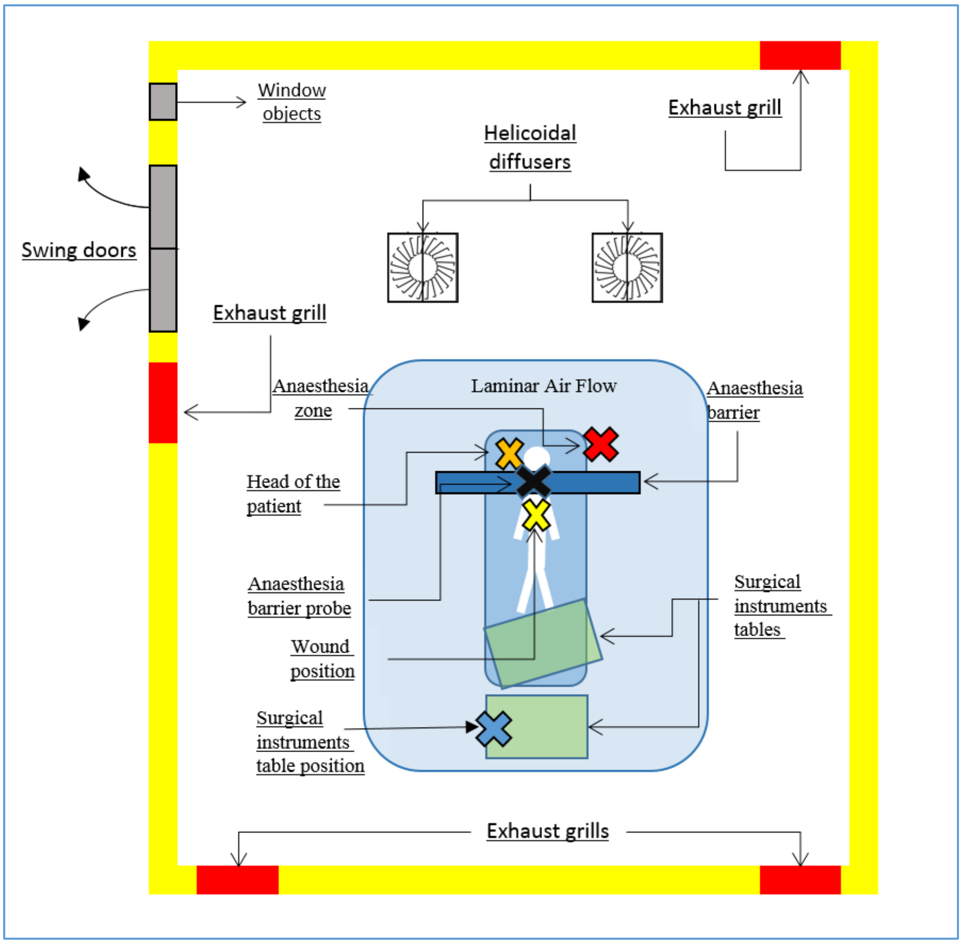


Figure 7.1: Map of the pp/cm³ measurements in Sahlgrenska University Hospital in the anaesthesia zone

The presence of obstacles between the air suppliers and the parts that has to keep clean, could induce disturbances which reduce the airflow capacity in keeping the zone as sterile area.

One of the most interesting parts inside an OT, that has to remain sterile are the surgery instruments and the hosting tables. The instruments tables usually are placed at the end of the operating table or behind the back of the medical staffs, all the time under the LAF ceiling canopy. In order to check the LAF capacity, the probes were placed as in the picture below. One probe close to the surgery instruments and the second at a lower level on the table support.

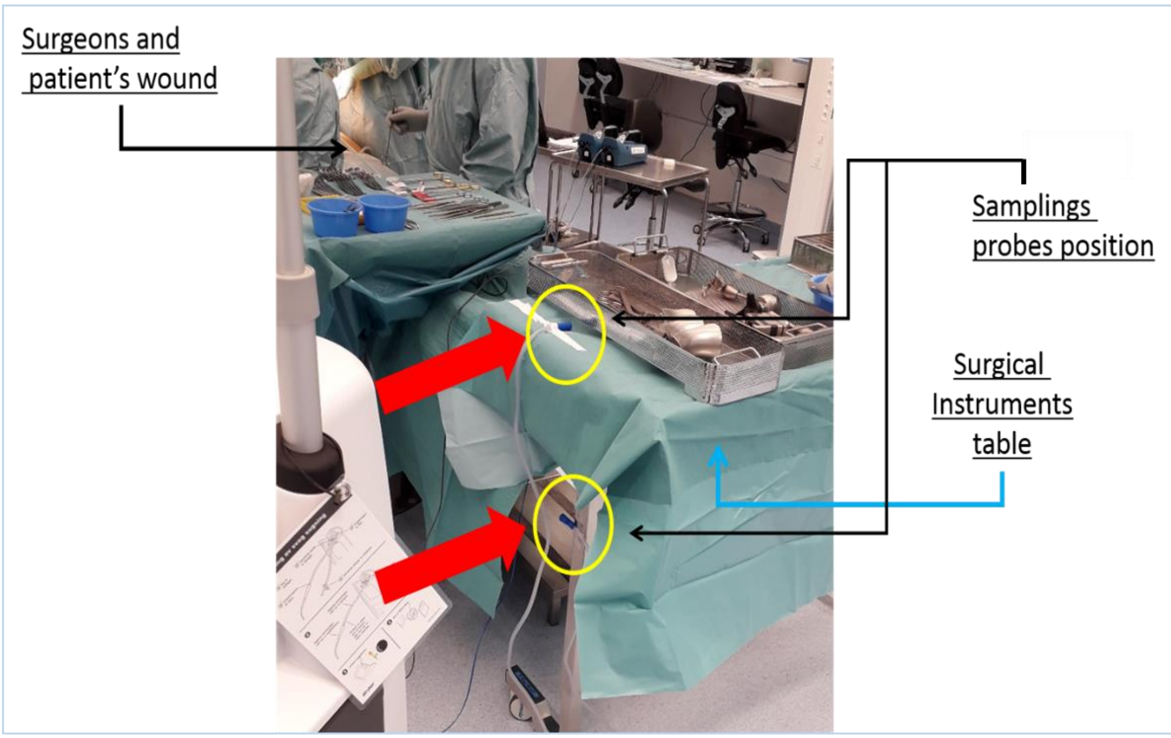


Figure 7.2: Photo of the instruments table (5th operation, pancreas resection)

The presence of vortices close to the instruments table was faced in three different operations (number 1, 2 & 5 of the Table 7.1). In the following table all the samples collected in this position are resumed. Every row represents one of the three operations, with: total number of samples, UFP concentration average close to the instruments and under the instruments table.

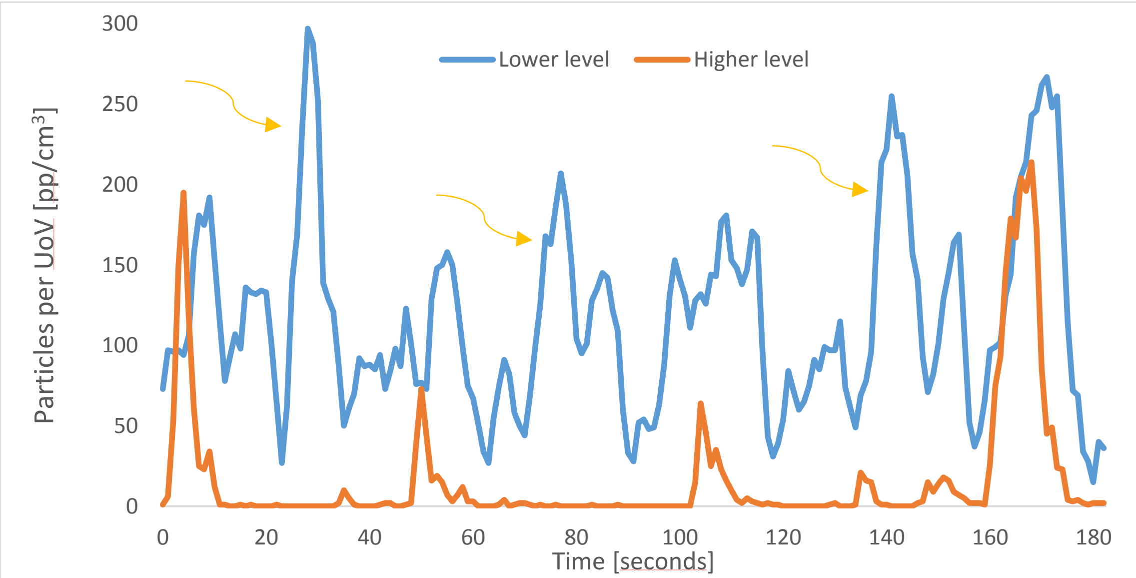
Table 7.2: Average values above and below the instruments table

ID. operation	N° of $\left[\frac{pp}{cm^3}\right]$ samplings taken [s]	Average $\left[\frac{pp}{cm^3}\right]$ *higher table level*	Average $\left[\frac{pp}{cm^3}\right]$ *lower table level*
1st operation	4627	15.79 [pp/cm^3]	33.59 [pp/cm^3]
2nd operation	7090	18.47 [pp/cm^3]	79.44 [pp/cm^3]
5th operation	6629	0.59 [pp/cm^3]	1.52 [pp/cm^3]

The ultrafine particles concentration varies considerably related to the diathermy bistoury usage. Despite this, the main aspect is that the average UFPs concentration over the instruments table is less than the half of the value measured under the table. By the way, the average could hide several aspects as the presence of air vortices, which is the most dangerous situation. The following graph could be used as the representation of the airflow pattern around the instruments table. The blue line represent the UFP concentration at the lower part compared with the surgery instruments area, marked with the orange line.

The trend of the samples close to the instruments is well defined, there is the peak but after that, the area return clean fast. However, the second probe highlight a less clean area and less stability at the lower level.

The elements, which could be used as important to highlight the stability over the instruments desk and the absence of vortices, are that the direction of the particles concentration is from the instruments desk to the bottom part and that when high levels of UFP are collected below no consequences are sampled by the probe placed over the instruments desk.



Graph 7.1: focusing about possible vortices close to the instruments table (2nd operation, pancreas resection)

In the previous graph is possible to see the defined trend of the orange line compared with the blue one which is more confused. In fact, could be possible to highlight that the cleaning velocity close to the instruments is faster than under the table. That’s could understand as a demonstration that at the level of the instruments desk (100-120 cm) the air exchange is fast and the air velocity supplied from the ceiling guarantees a continuously washing. While at the lower level, the air technology system needs more time to reduce the value.

An average recovery time of the UFP concentration is calculated at both levels: the system needs 14 seconds to clean the area over the instruments desk compared with the 70 seconds at the lower part.

All the data collected could be resume with a schematic representation of the airflow pattern around the instruments desk zone (Figure 7.3). The blue arrows represent the HEPA filtered clean air, which is coming from the air distribution system. The air keeps clean the area over the instruments table and avoid that disturbances and dirtiness, marked with red arrows, reach the sterile zone.

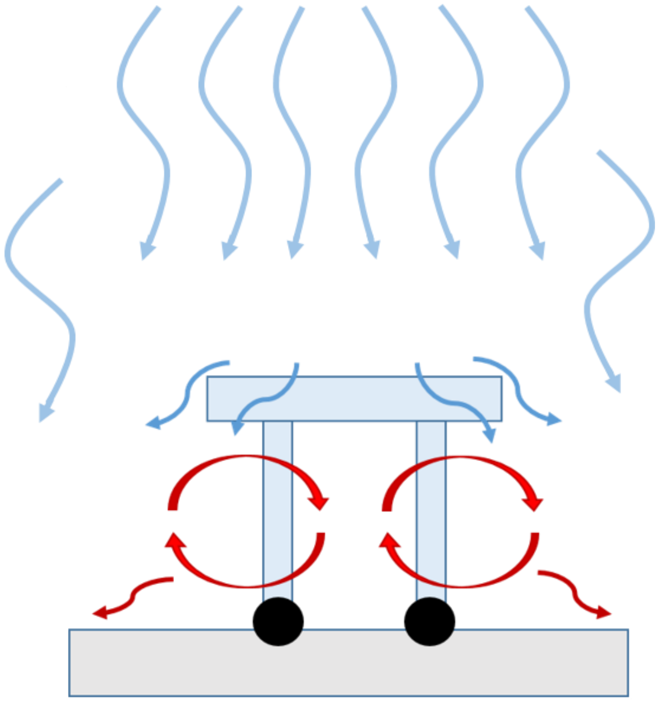


Figure 7.3: Theoretical idea of the air behaviour around the instruments table

The study regarding the presence of vortices has been carried out also inside the anaesthesia zone. This zone is one of the zone with most occupancy level inside the Operating Theatre. In fact, at least one anaesthesiologist is present all the time, and furthermore, the sterile precautions are not important as in the sterile area.

The probes positions are highlighted in the following pictures (Figure 7.4). The idea was firstly to understand the presence of vortices detached from the anaesthesia barrier and in a second moment moved closer to the patient. In fact, in the first picture the probes were placed over a stand at different levels on the left side of the patient. While in the second one, the pipes were close to the patient's head and over the anaesthesia zone on the patient's right side.

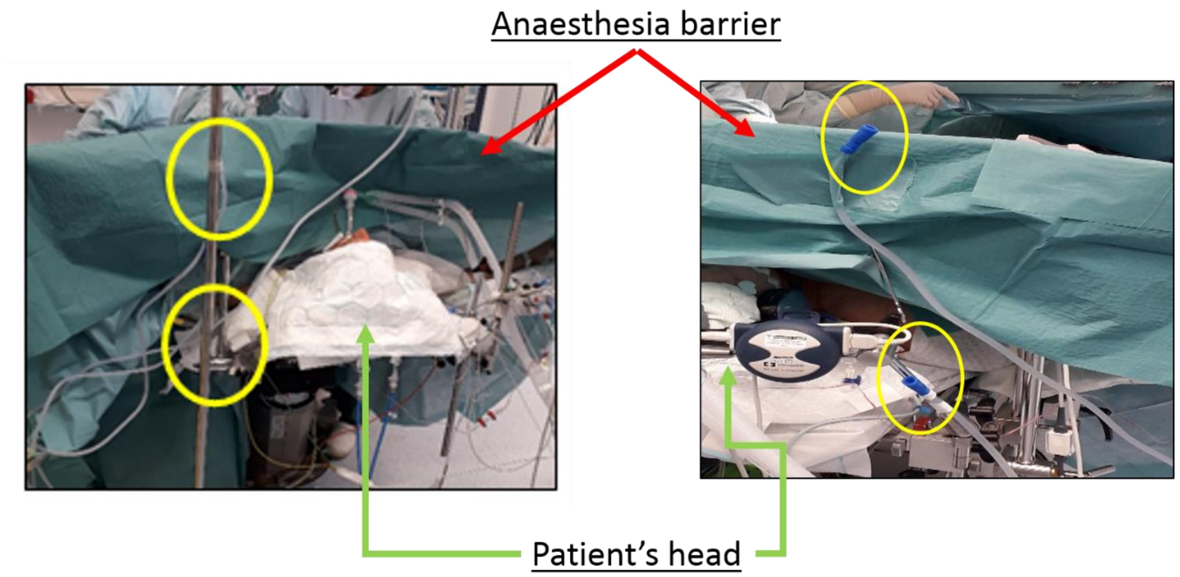
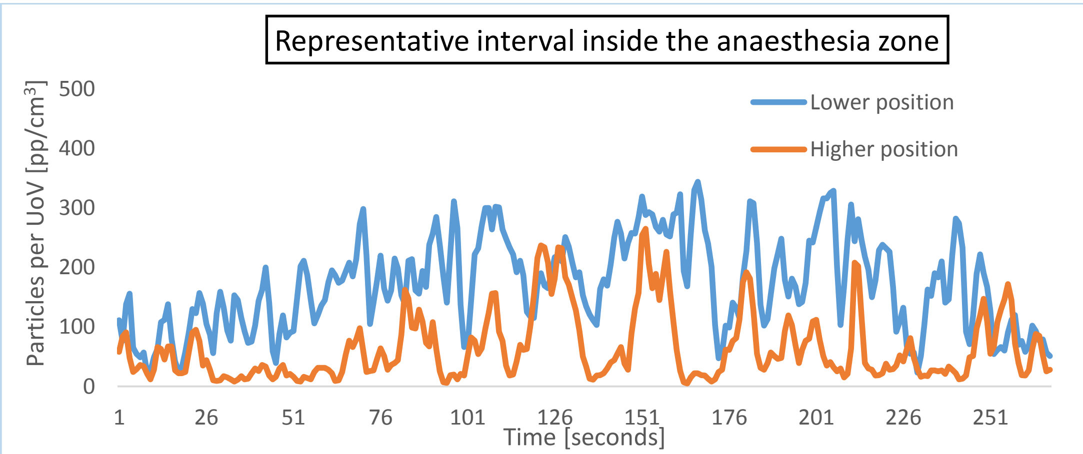


Figure 7.4: Above and below the stand position on the left (3rd operation, Liver transplant); barrier and patient's head positions on the right (2nd operation, pancreas resection).

This area is important at least as the instruments table. In fact, during internal surgeries, the wound of the patient is really close to the anaesthesia area, and the presence of vortices could be dangerous for the patient's safety.

The samples collected in this part are not stable as the previously experienced in the instruments table zone. In fact, is important to noticed that over the anaesthesia zone there are two air turbulent diffusers, which induce vortices that reduce the stability (Figure 4.1).

Furthermore, the nearness to the wound, that is the most particles source, induce a higher presence of ultrafine particles inside this zone. The lines trend is not clear as the previous graph for the instruments table area, despite this, is possible to notice the lower level of UFP concentration at the higher probe position and the airflow direction from the upper to the lower height.



Graph 7.2: Above and below the stand (3rd operation, Liver transplant)

The large amount of ultrafine particles collected in this area is strongly related to the diathermy bistoury using. In the following table is possible to notice the different levels of UFP inside the anaesthesia zone related to the status of diathermy bistoury. When the instrument is on, the percentage of samples over 5 or 10 particles per cubic centimetre is high. While when the instrument is not ongoing the level decrease at lower concentrations.

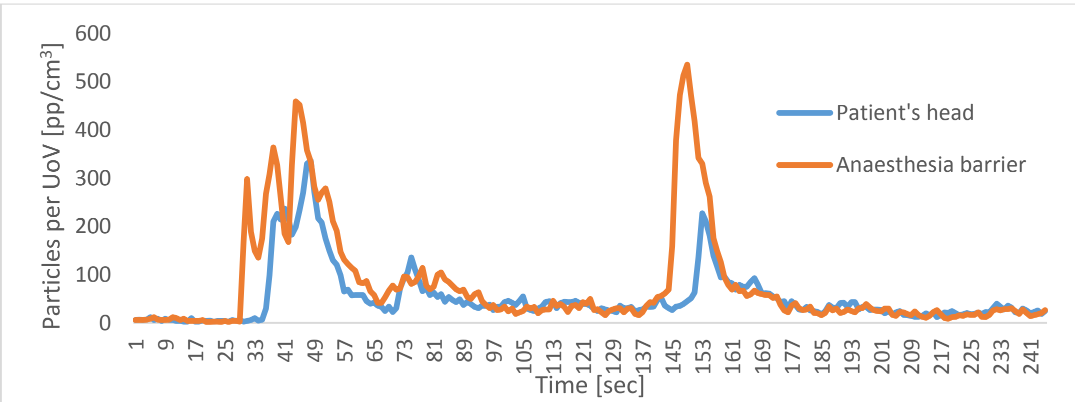
In the following Table 7.3 the first important element is that, the clean capacity of the system in this zone is not efficient as in the previous one (instruments table zone). By the way, the also in this samples collection the higher level is cleaner compared to the lower one.

Table 7.3:: Percentage of pt/cc correlated with the using of the diathermy bistoury (3rd operation, Liver transplant)

	Status of the diathermia	$\#values\ in \frac{pp}{cm^3} > 5\ \frac{pp}{cm^3}$	$\#values\ in \frac{pp}{cm^3} > 10\ \frac{pp}{cm^3}$
Higher level	ON	92,32%	87,68%
	OFF	0,56%	0%
Lower level	ON	98,21%	96,41%
	OFF	4,80%	0%

Referring to the second photo in the Figure 7.4, the probes are applied over the anaesthesia barrier and close to the patient’s head. The goal of this positions are firstly, to confirm what the measurements along the stand have showed and confirmed that understanding the movements of the air over the anaesthesia barrier. It is important to notice that the wound zone is divided by the anaesthesia area just from this barrier, for this reason a sampling session in this part it is necessary to evaluate the airflow pattern in this area.

In the following graph the values sampled underline the behaviour of the UFP, that come from the wound’s zone and moving over the anaesthesia barrier flow down close to the head of the patient.



Graph 7.3: second comparison inside the anaesthesia zone (2nd operation, pancreas resection)

It is important to underline that the extraordinary aspect of this work is the active participation of the medical staffs. In fact, all the probes placed over the operating desk or in the sterile area (a number of at least four probes in every operation), are placed following sterile procedures in the positions asked by the author as showed in the previous pictures. Having the possibility to use two different ultrafine particle counters, the author change probes that the instruments are connected with change, allowing to the author to take data from different positions during the same operation (for example in the 2nd operation there were even 8 UFP's pipes placed).

The relation between the particles source and the rest of the operating theatre is curious. For this reason, the instrument is connected to one probe placed inside the sterile zone, maybe the most beautiful position of this work (Figure 7.5). In this way it's possible to use the different probes position and compare the flow of the "particles cloud" from the wound zone when the diathermy bistoury is ongoing, until the others part or vice versa. Indeed using the special position is possible to create a useful plot of measurements (wound-anaesthesia barrier-stand-head of the patient).

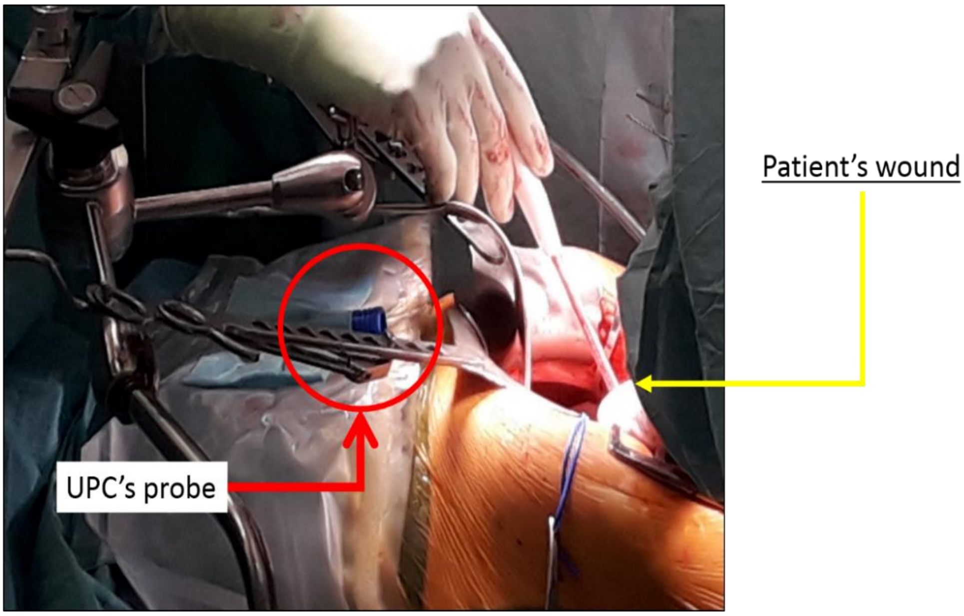


Figure 7.5: Wound position (2nd operation, pancreas resection)

More than ten thousand values were taken in the relation between wound and anaesthesia barrier, (almost three hours in two days). The amount of data confirm all the time that what was discovered in the previous section is confirmed. The direction of the airflow is from the wound zone to the anaesthesia area. The air ventilation system in this zone is not like the previous situation when there was just the LAF ceiling over the instruments desk. Over the anaesthesia zone there are two turbulent air diffusers, which make the airflow pattern less stable compared with the flow over the instruments table.

Furthermore, the presence of lamps, medical staffs movements and anaesthesia barrier could be the cause of supplmenetary disturbances. In fact, the trend at the higher level is less defined compared with the trend analyzed over the instruments table. Despite these elements, the samples experienced were directred to the bottom part of the room, avoiding risky vortices.

In the following picture there is a schematically representation of the air pattern in the anaesthesia zone and close to the wound area. The airflow appears stable in the sterile area, but more disturbed in the anaesthesia zone where there also a different air diffusion system. Despite that the direction to the floor is manteined.

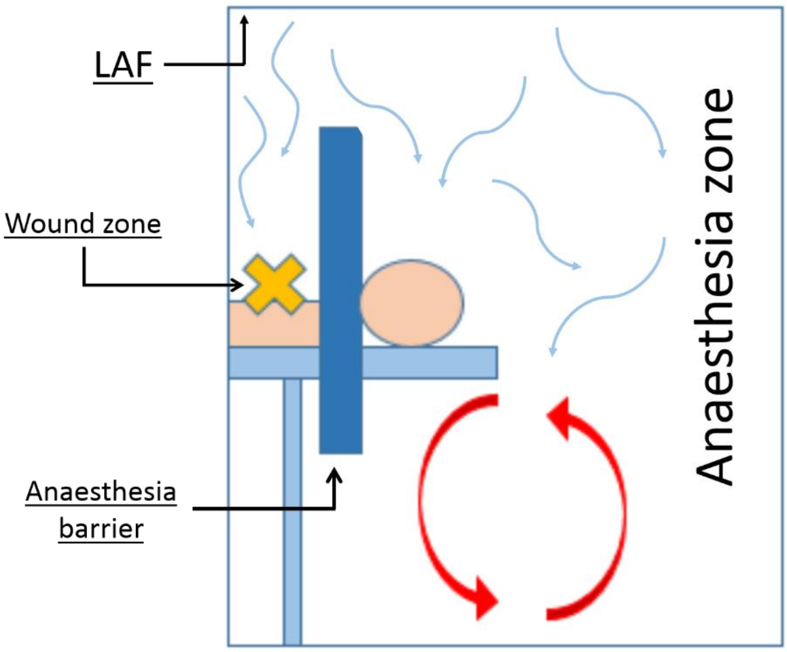


Figure 7.6: Theoretical representation of the air movements based on the data collected

Regarding the part under the desk the red arrows are just an idea correlated with other measurements, because in this part of the study no probes were placed under the head of the patient. Furthermore, the red arrows stops just under the operation desk because no values related to this vortices were collected close to the patient’s head probe.

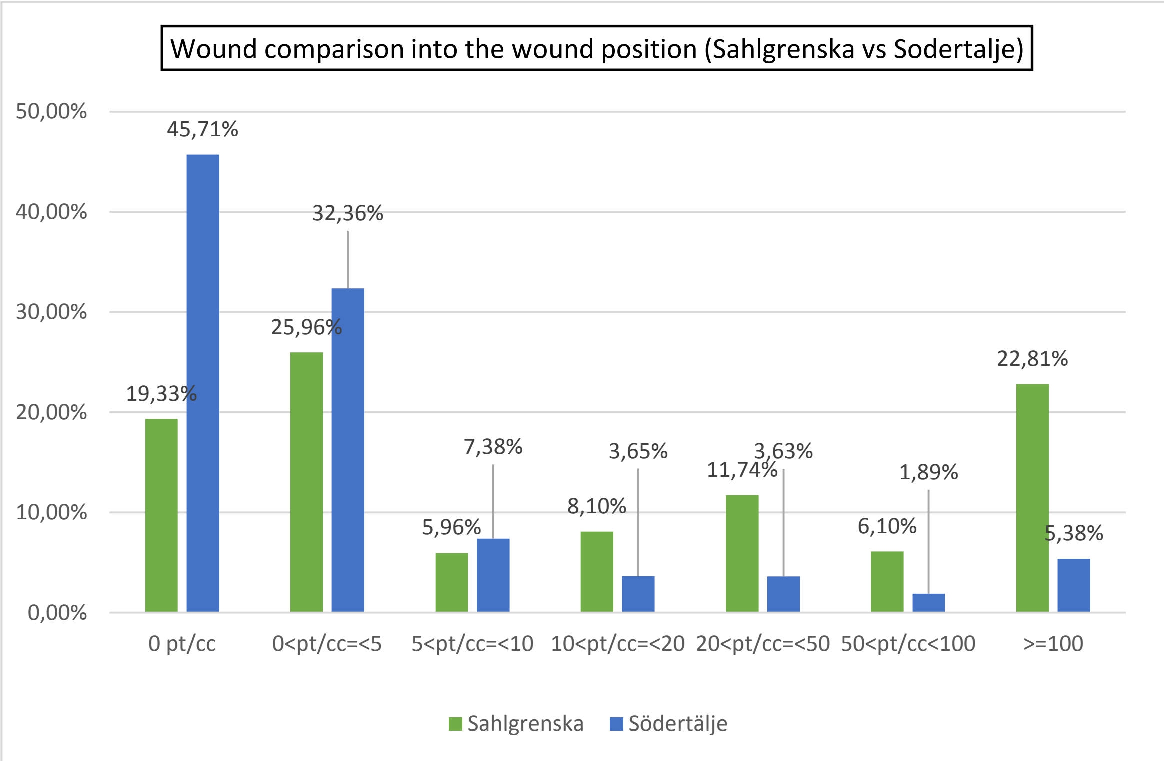
Considering the large amount of samples collected in Sahlgrenska University Hospital the idea for the sampling session in Södertälje was inherited from the previous experience. The UFP counters positions were chosen with the scope to compare both airflow patterns.
The operations attended in Södertälje are orthopaedic operations, so the use of diathermy it's reduced just at the opening of the wound and in others short intervals. Furthermore, the position of the wound is far from the anaesthesia zone compared with the internal surgeries followed in Sahlgrenska Hospital.
The first six operations were followed just with two Ultrafine Particle Counter (UPC) as instruments, while the remaining thirteen are observed with also the microbiological particles counters. For this reason during the thirteen operations, where the air sampler for the detection of airborne microorganism is sampling, the UFP counter pipes are placed close to the air sampler filter.
The results experienced during this sampling session confirmed the airflow pattern idea inside the sterile zone. Rather the washing capacity of the clean air, which is coming from the LAF ceiling, inside the sterile zone appears more performing. However, the idea of the author is related to the lower number of particles that are coming from the wound zone.
The main different is related to the anaesthesia zone, where the stability of the airflow pattern is better compared with the airflow pattern experienced in Sahlgrenska University Hospital. In fact, during this type of operations, which are ordinary, the number of anaesthesiologist is one more or less for all of the time. Furthermore the air supplying system is different, does not present any others diffuser beyond the LAF system.

The amount of UFP samples collected in both hospitals is reported in the following table (Table 7.4). The positions with more samples is the most important one, used to understand the cleaning capacity of the air diffusion system and to correlate the particles peaks due to surgery instruments to the other positions of the OT.
The measurements took close to the wound are divided in order to show the weight of each interval of UFP. In fact in the following graph (Graph 7.4) it's possible to see how many times, in percentage, the UPC detects $0\ pp/cm^3$., or the samples experienced is inside a defined interval.
It is important to underline that the percentage it's calculated over the total amount of values collected close to the wound zone, 36826 in Sahlgrenska and 54478 in Södertälje. The large use of diathermy

using during internal surgeries, bring a lot of UFP and for more the 20% of the time the level is higher than 100 pp/cm^3.

Furthermore, could be useful to remind that the diathermy smoke remain more in suspension compared with UFP at the same temperature of the supply air.

Watching the intervals, the column, which indicates Södertälje, overcomes the light grey one and remain bigger starting from the interval $10\ pp/cm^3 < \#values < 20\ pp/cm^3$.



Graph 7.4: UFP interval comparison between Sahlgrenska and Södertälje close to the wound

Another weight of the type of instruments and the amount of the time when they are ongoing, is highlighted by the columns which indicates the UFP $> 100\ pp/cm^3$. The high necessity of diathermy use explain these values.

An important element, which could give more explanation to these values, is the different kind of UFP that we are talking about. It is not a discussion related to the sizes (also because the UPC used does not separate intervals), but related of the weight of those. In fact, if we take as example the saw using during a knee prosthesis, the UFP spread are measured just when the instrument is ongoing, we can consider those as spray. While the diathermy smoke goes up due to the temperature gradient and remain in the air longer.

In order to quantify, for the reader, the amount of values collected for the UFP point of view, here is reported a table with the hospital and the positions:

Table 7.4: Total amount of UFP (Sahlgrenska and Sodertalje)

	Total numbers of [particles/cubic centimetre] counted in the different positions	
Probe position	Sahlgrenska #samples [s]	Södertälje #samples [s]
Wound	36826	54748
Over the anaesthesia barrier	12923	3658
Above the instruments table	11256	16189
Under the instruments table	13273	-
Under the blanket (border with anaesthesia zone)	-	3470
LAF system, under the ceiling	-	27476
Back of the surgeon	-	4784
Back of the surgeon low level	-	3056
Exhaust grill	-	3078
TOTAL	**74278**	**116459**

The large amount of samples in different parts of the operating theatres (Table 7.4), could also allow to experienced external actions, which could create disturbances close to the operating area.

It's important to remember that the mechanism which push the air into several movements are a combination of density differences (temperature gradient), mechanical ventilation, motion of a person through the opening and the motion of the doors [71]. The last element is one of the most important and the pressure differential between the adjoining areas is one of the must to keep contaminants far from the operating theatre. Little drafts are compensated with the big amount of clean air supplied inside (2).

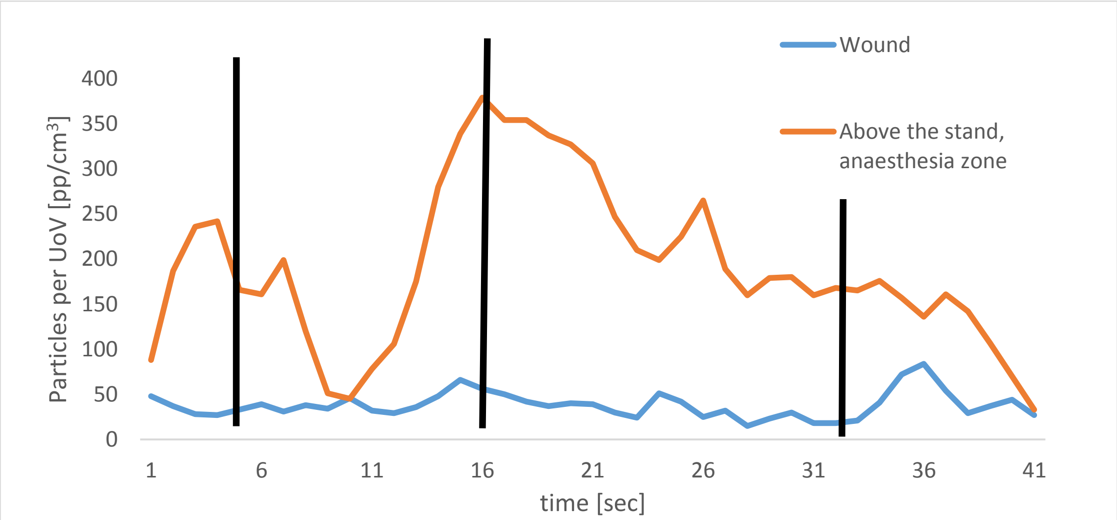
According with the Swedish Standard [1] and the Netherlands one [2], when a door is opened the pressure difference decrease and air may flow into the room and cause a risk of inflow of bacteria carrying UFP. Furthermore, the performed calculations by Ljungqvist et al. [71] showed that operating rooms used for operations, susceptible to infections, should not have door openings in direct connection to uncontrolled areas such as corridors. In fact in Södertälje, as soon as the instruments table is uncovered, is forbidden the open of the corridor door. It's possible to pass just through the preparation room avoiding contemporary open of the two doors of the preparation room, otherwise you will skip the barrier guaranteed by the preparation room itself (check the Section 4.1 to understand the positions).

While in Sahlgrenska the preparation room is separated from the surgery rooms, the instruments are prepared in a sterile condition, covered and remain like that until the start of the operation. This reduced element of separation between dirty zone (corridor) and sterile zone could be a problem, but the large measure of the operation theatres (around 100 m^2 compared with the ones in Södertälje which are more or less the half) perhaps could explain this choice.

According with Ljungqvist et al [71], generally, the number of door openings should be at the minimum and the door open hold time should be as short as possible. In order to cater this element a little window to pass objects is realized close to the door. Furthermore, an alarm start to sound in the entire floor when the pressure difference is too low.

The main difference is that the doors in Sahlgrenska are slamming doors and the ones in Södertälje are of the sliding type. The Netherlands standard highlight that sliding doors are recommended to be used instead of a revolving door, because the last type creates disturbances to the airflow pattern when moving [2]. In addition, a big size door that slam could bring disturbances in all the area compared with a sliding one. During the 3rd operation in Sahlgrenska hospital strange measurements are detected inside the anaesthesia zone. To check the correlation between door and UFP peak, several doors openings have to happen. However, when the elements are linked the correlation becomes clear, in fact, as it is possible to see in the

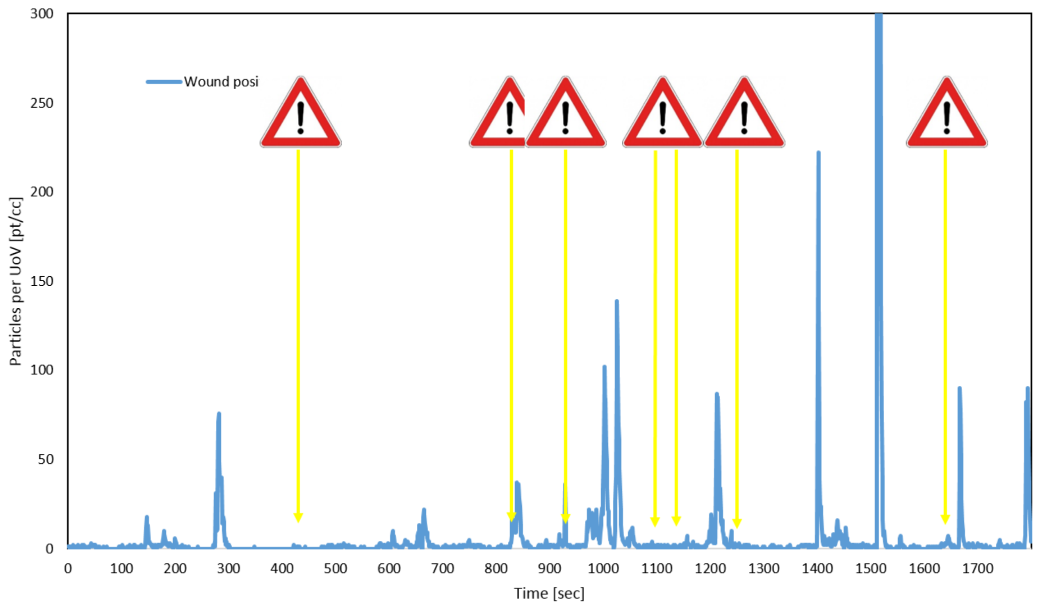
Graph 7.5, the disturbance creates by the door increase the levels of UFP in two of the three cases highlighted. Fortunately, the same problem is not detected close to the wound zone.



Graph 7.5: The door issue in Sahlgrenska, the black lines indicate the door opening (3rdd operation, Sahlgrenska)

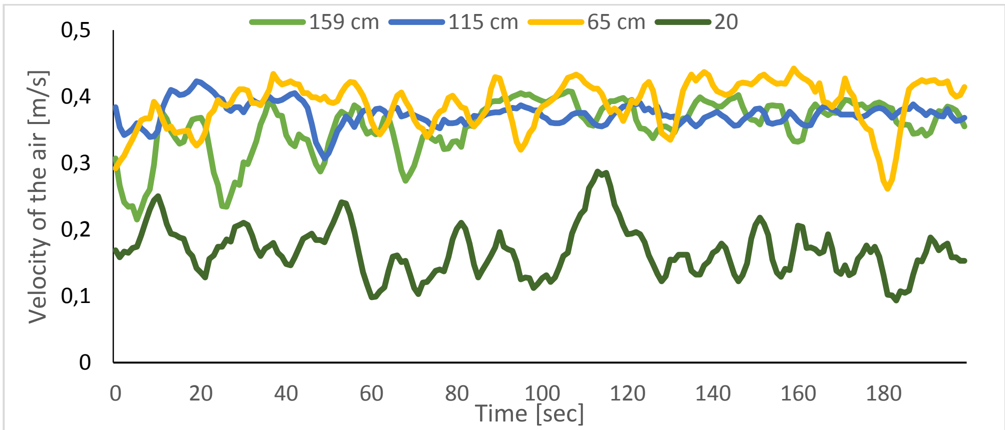
While talking about Södertälje, as said before, the type of doors are sliding type. All the measurements taken close to the wound while the doors opening is under control never shows any evidence of disturbances related by door openings.

When the preparation door is opened, is signed in the following graph with "dangerous signal" and it is possible to see that no consequences are connected with the door opening.



Graph 7.6: Wound position with the danger sign when the door is open (1st operation, Södertälje)

Furthermore, also the velocity sensors are activated behind the back of the surgeon and close to the preparation room's door. The velocity sensors are placed at four different levels, one higher than the wound (159 cm), one at the same level of the wound (120 cm), the other one below the table (65 cm) and the last one over the floor (20 cm).



Graph 7.7: Velocity levels behind the back of the surgeon, the behaviour of the 159 cm level is the main important (16th operation, Södertälje)

For this reason, the levels most important to check the presence or less of vorticles are the higher ones. In fact is important to check that at the 0 second the door is open and the green line starts to oscillates and needs, at least, one minute to be back stable. So this element could be important to highlight the disturbance of the door, fortunately confined just far from the wound.

In the end, in their work Ljungqvist et al. [71] present equations in order to forecast the CFU/m^3 due to the door openings, but considering the approach the is ongoing in this work (2) the idea of dilution and so the capacity that the disturbances have to reach the sterile position are not considered.

7.2 Microbiological air contamination in Operating Theatres

The active air sampling is a collection of particle bacteria-carrying from a specified volume of air through collection on a filter or impaction on an agar surface. The measurements collected in this work use active air sampling. In the last years, the level of CFU (bacteria-carrying particle which gives rise to a colony on a culture plate), becomes the main element to understand how clean the area is. Several works using these data start to purpose different solutions to reduce these numbers. By the way, it is important to highlight that many bacteria cells on a plate give rise to one colony, as an airborne skin fragment usually carries many bacteria [1].

All the measurements are taken using the medical competence of the surgery team, who are involved in the project. In fact, differently from the previous capitol, where a sterile pipe is placed where necessary by the surgeon and leave there for all the operation. The membrane filters in gelatin have to be changed every ten minutes, with a safety procedure in order to avoid any disturbances to the patient and the measurements. Furthermore, when the filter is close to the wound is the medical staff inside the sterile zone (operating nurse and surgeon) that have to change the filter for the safety of the patient.

Another important element is that the Air Sampler has to stay outside the sterile zone, because previous works [55], shows a UFP peak when the instruments is switched on. For this reason, the filter is placed where necessary but the instrument is placed far from the microbiological UFP filter and also the exhaust pipe of the instrument faced far away, to remove any influence in the measurements and, mostly, any consequence for the safety of the patient.

Talking about this work the idea behind the CFU measuring is to have the same position in two different type of orthopaedic operation; it will be clearer in the following Table 7.5.

.Considering, as said before, that the machine that have to suck a default airflow rate has to be placed outside the sterile zone, to reach the position close to the wound or over the instruments table the tube has to be sterilized before. In fact, the tube and holders (check the Section 5.2 for the photos) arrive with the operation instruments after the sterilization procedure. The operating, nurse who has to prepare the instruments table, before all the operations check if the instruments show any signs of possible contamination, dirtiness or drops of water. In fact, two times happened that the scheduled positions have to be changed, because water was find inside the air sampler sterile tube.

An important element to highlight is that just one air sampler is using, so the measurements in two positions are not collected at the same time, rather these are alternated, otherwise placed to verify some specified situations that have to be controlled. This capitol his structured in order to compare the CFU/m^3 detected in the different positions listed. In the following table is possible to see when the measurements were taken, in which position, in which operation and how many CFU/m^3 (as specified by the BS EN ISO 14698-1-2003) were collected. Five knee prosthesis and six hip prosthesis installation were followed placing the filter for the CFU counting in the sterile zone. In total, 53 sterile sampling filters close to the wound have been sampled, 22 for hip and 31 for knee respectively. Meanwhile over the instruments table were used three and six sterile samplings filters during knee and hip prosthesis.

Furthermore, measurements were collected in other positions, the aim behind these positions are firstly to understand if the air behaviour, observed during the UFP counting , can be confirmed or not, by the active microbiological air sampling. Secondly, comparing with positions of previous works, when available. In the following sections, it will be explained and justified the choice of each sampling positions chosen.

Table 7.5: Date, positions of the filter, kind of operation and number of filters collected (Södertälje)

#operation	Date	Position	Kind of operation	Number of filters used (1st position)	Number of filters used (2nd position)
1	27/11/18	Wound and under the table	Knee prosthesis	3	3
2	27/11/18	Wound and under the table	Hip prosthesis	4	3
3	27/11/18	Wound and behind the back of the surgeon	Hip prosthesis	4	4
4	28/11/18	Wound and instruments table	Hip prosthesis	3	2
5	28/11/18	Wound and behind the back of the surgeon	Knee prosthesis	4	4
6	29/11/18	Wound	Knee prosthesis	6	-
7	29/11/18	Wound	Hip prosthesis	10	-
8	18/12/18	Wound	Knee prosthesis	6	-
9	18/12/18	Wound	Hip prosthesis	8	-
10	18/12/18	Wound and instruments table	Hip prosthesis	2	4
11	19/12/18	Wound and instruments table	Knee prosthesis	3	4
12	19/12/18	Behind the back of the surgeon (low lvl) and exhaust grill	Broken hip	2	2
13	19/12/18	Behind the back of the surgeon and exhaust grill	Hip prosthesis	3	3

The Swedish Standard Institute (SIS TS 39:2015) also presents the results expected inside the operating theatre to show how to consider a zone as sterile. In the following table (Table 7.6) took from the standard is presented the microbiological requirements for operating rooms for infection-prone clean surgery. The sterile measurement position have to be or over the instrument table or less than 50 cm far from the surgical site. While the measurements in the periphery of the room are not considered as necessary to understand the condition of the room.

Table 7.6: Swedish Standards Institute SIS TS 39:2015, microbiological requirements for operating rooms for infection-prone clean surgery [1]

	Sterile position		In the peripehry of the room	
Clothing type	Clean air suits (single use)	Ordinary scrub suits (re-usable)	Clean air suits (single use)	Ordinary scrub suits (re-usable)
$average\ CFU/m^3$ (maximum level of CFU/m^3 for measure)	$\leq 5\ (15)$	$\leq 10\ (30)$	Not necessary	Not necessary

According to several works listed before (Section 6 page 35), the distance for the performances point of view between ordinary scrubs and clean air suit type is substantial. According to the standards, sterile area protection mostly depends upon the technical gowning quality, for this reason the use of less performing technical clothing (Figure 7.7 (a)) during the airborne microbiological particles sampling, leaves the ventilation system as key determinant of contamination control.

In the Swedish standard is clearly written that: “ordinary scrub suits is not a medical device” [1].

In this way considered that the two main aspects are the clothing systems and the mechanical ventilation system. Removing one of the constraints, the fault or the merit, is just up to the ventilation technology plus the advanced medical routines. During surgical procedures, the surgeons and the surgical nurses worn an additional disposable sterile coat over the standard surgical clothing system, as it is possible to see in the Figure 7.7 (b).

Last but not the least, it is important to say that this choice regarding the clothing systems change was granted between the author, the medical staff and the university team. It is important to report that during all the operations followed there were an average of 3 people inside the sterile zone dressed as in the picture Figure 7.7 (b). Outside, a fixed number of 4 people were dressed with ordinary scrubs (anaesthetist, external nurse, operating nurse who helps the author with the CFU count and the author himself). Therefore, the average total number of people inside the operating theatre were about 7.

(a) (b)

Figure 7.7: Surgeon who is wearing ordinary scrub (a) and the operating nurse with clean air suit type (single use) under and additional disposable sterile coat over (b) (respectively 10th and 8th operations with CFU count, Södertälje)

All the different sampling positions are listed in the following page (Figure 7.8).

It is possible to notice the large amount of different position in order to understand if there are different samples related to different distances from the sterile zone.

Obviously, the larger amount of samples were collected in the sterile zone close to the wound and on the instruments table.

Under the LAF ceiling filter, microbiological air sampling were also taken, at the same level of the sterile zone measurements, other samples also behind the back of the medical staff. Moreover, at the lower level, always under the LAF ceiling, samples were collected behind the back of the surgeon and under the blanket of the anaesthesia barrier.

The only sampling session made in the periphery of the OT was close to the exhaust grill.

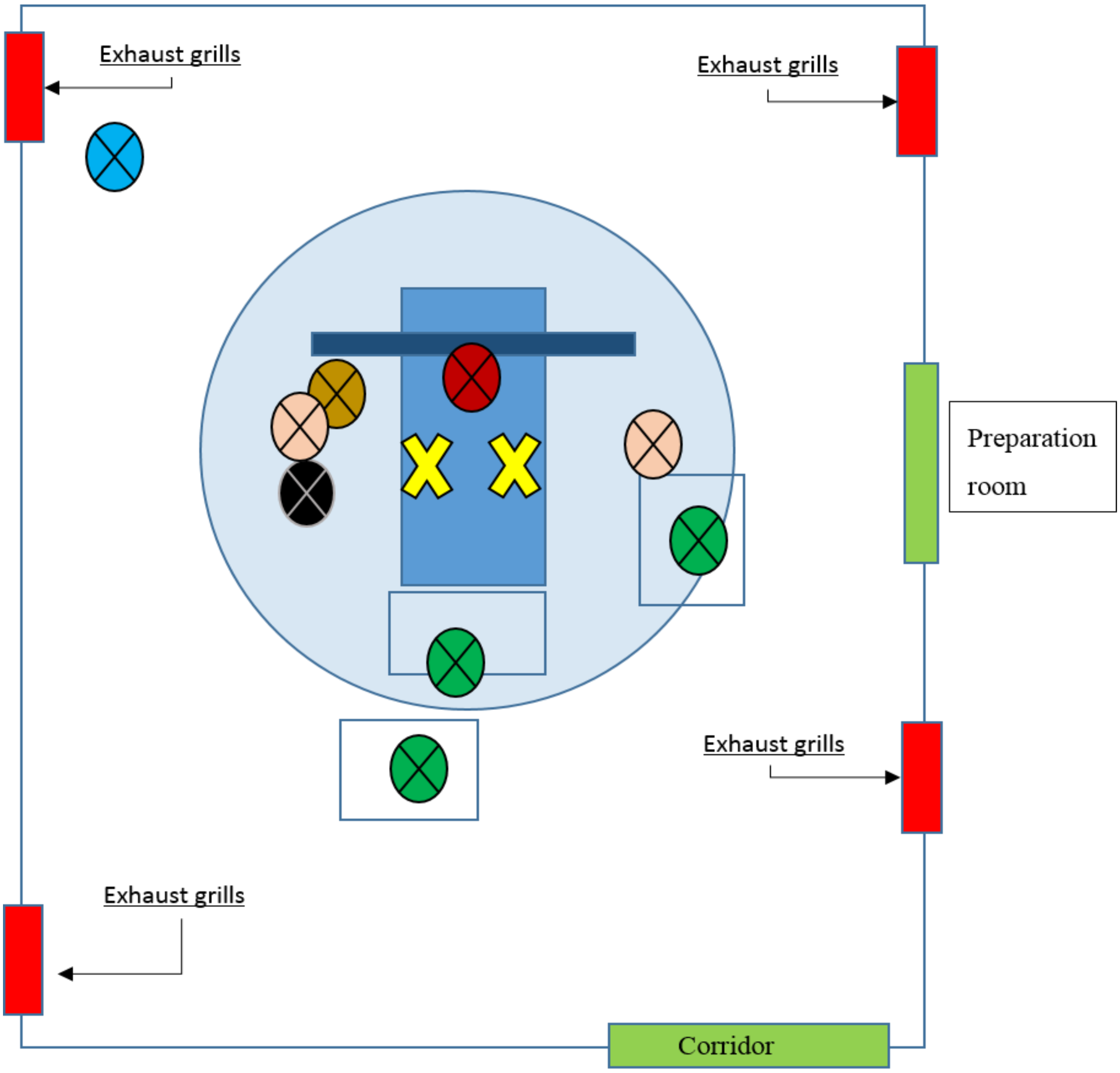


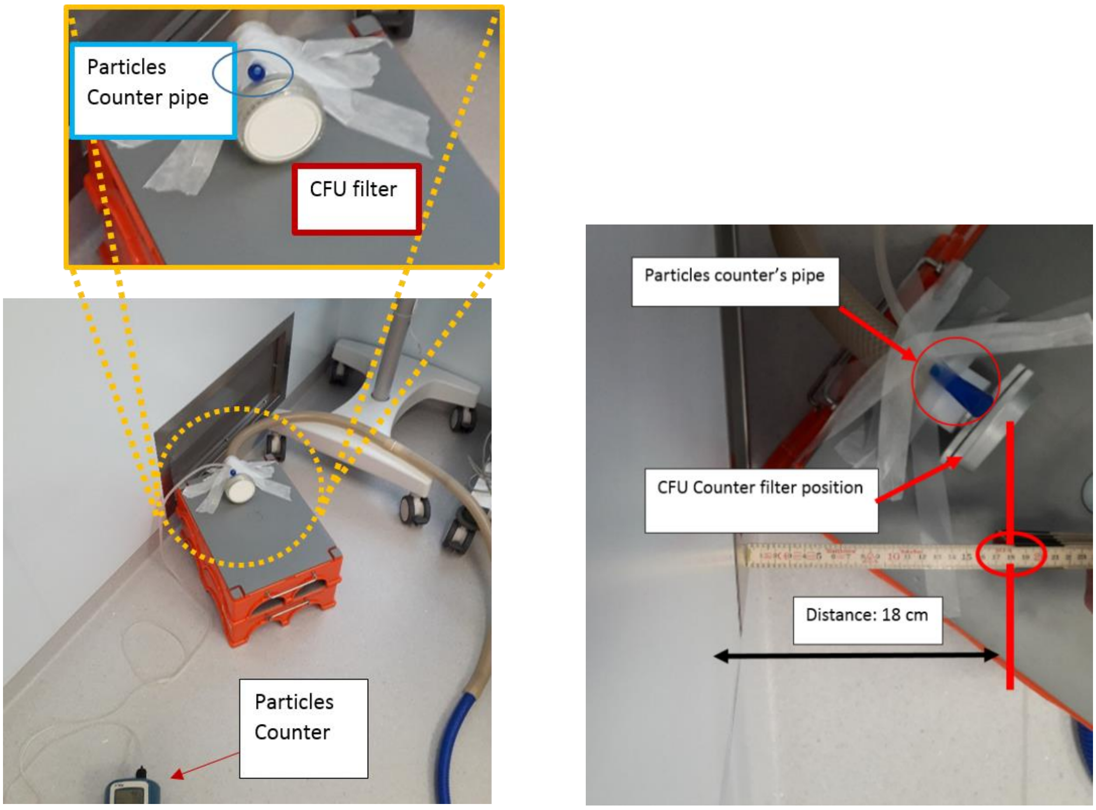
Figure 7.8: Map of the CFU measurements, Södertälje

Legend

Symbol	Sampling Position	#number of operation *(reference Table* 7.5 *pag.57)*	# total sterile filter sampled
	Close to the wound	1-2-3-4-5-6-7-8-9-10-11	57 (knee=22; hip=35)
	Instruments table	4-10-11	10 (knee=4; hip=6)
	Under the blanket	1-2	6 (knee=3; hip=3)
	Behind the surgeon	3-5-13	11 (knee=4; hip=7)
	Behind the surgeon, low level	12	2 (broken hip=2)
	Exhaust grill	12-13	5 (hip=3; broken hip=3)
	Wound position, left or right side		

7.2.1 Exhaust grill

These measurements are taken in order to have a comparison with the rest of the operating theatre. In fact, it is known that measurements far from the sterile zone are not significant to understand if the system is working good or not [1]. Once that an idea about the number of infections present in the dirtier zone of the operating theatre is possible to understand how is working the air system.



(a) (b)

Figure 7.9: The exhaust grill position, instruments during the 12^{th} operation (a) and during the 13^{th} operation (b)

It's also important to underline that the Sartorius (air sampler) is rotated in order to push the exhaust air in the direction of the other exhaust grill (on the other corner).

These two measurements report the following data:

Table 7.7: CFU concentration sampled close to the exhaust grill position

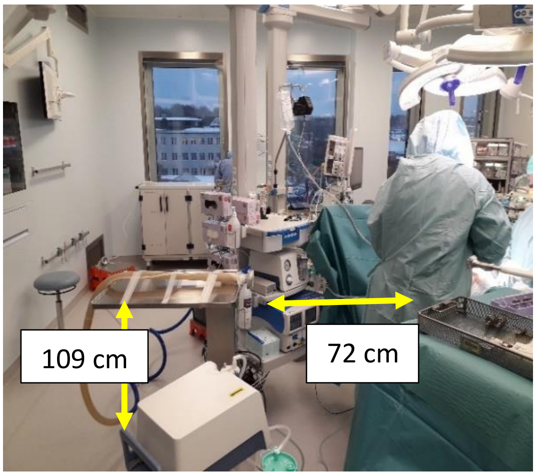
OT conditions and samples collected					
ID operation	OT:T-UR	# sterile filters	# CFU/m^3	Average # CFU/m^3	(Min-Max) # CFU/m^3
12^{th} operation (a)	20°C-27%	2	Filter 1: 60 Filter 2: 30	45	(30-60)
13^{th} operation (b)	20°C-25%	3	Filter 1: 20 Filter 2: 14 Filter 3: 100	44.67	(14-100)

7.2.2 Surgeon rear side

This position is selected in order to show that the position does not represent what happens close to the wound. The sampling height is at the same level of the wound (110-120 cm), more or less one meter from the wound position. The measurement is carried out always behind the back of the "main surgeon". The position behind the surgeon could be on the right or the left side. On the right side the occupancy level is higher due to the medical staff passage, in fact it is the path followed to reach the anaesthesia zone and the preparation room (Figure 7.10 (a)). While on the left side of the operating theatre the occupancy is close to zero all the time (Figure 7.10 (b-c)).

(a)

(b)



(c)

Figure 7.10: Measurements behind the back of the surgeon, respectively close to the preparation room's door, 3rd operation (a), on the other side of the preparation room's door 5th (b) and the 13th with the distances (c), Södertälje

The measurements are all the time under the LAF system in both the operations, is important to understand the position compared with ceiling. Second picture of the figure 7.10 (a) and 7.10 (b).

These three measurements report the following data:

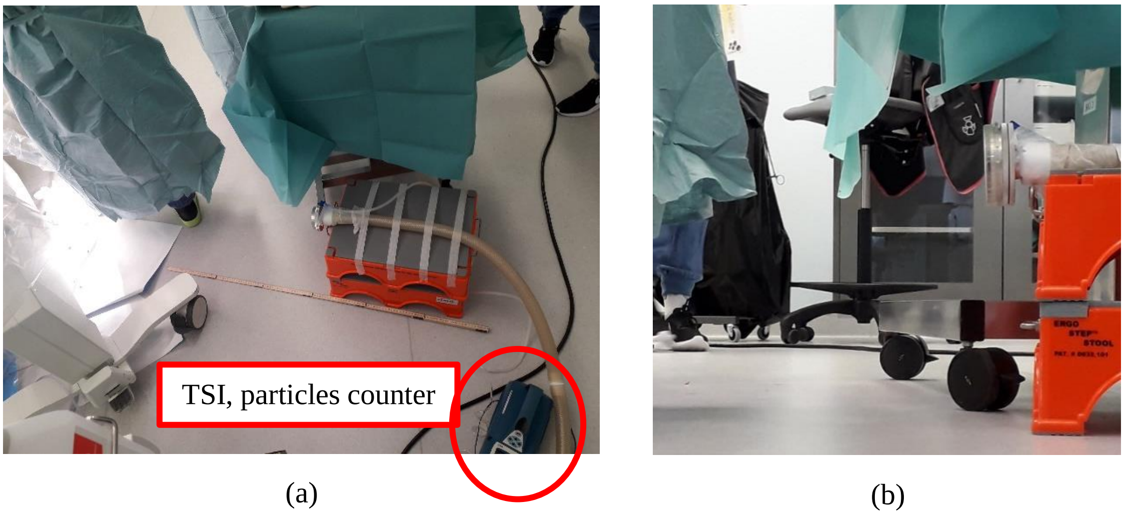
Table 7.8: CFU concentration sampled behind the back of the surgeon position

OT conditions and samples collected					
ID operation	OT:T-UR	# sterile filters	# CFU/m^3	Average # CFU/m^3	(Min-Max) # CFU/m^3
3rd operation (a)	20°C-23%	4	Filter 1: 0 Filter 2: 37 Filter 3: 4 Filter 4: 1	10.5	(0-37)
5th operation (b)	20°C-23%	4	Filter 1: 0 Filter 2: 0 Filter 3: 0 Filter 4: 0	0	(0-0)
13th operation (c)	20°C-25%	3	Filter 1: 3 Filter 2: 1 Filter 3: 0	1.33	(0-3)

In this case, the different side of the operating theatre is important. In fact, where the path and movements of the medical staff is higher also the CFU/m^3 detected are higher. On the contrary, on the left side of the OT, where the passage is lower also the concentration of CFU detected is low. It is important to notice that the medical staff movements are concentrated in the right side zone (thanks to the medical experience reported by Cederlund et al. [72]). In fact, to reach the preparation room and the anaesthesia zone the preferred road is to pass on the right side of the OT where the measurements were sampled in the 3rd operation. This is the idea of the author referred to these differences in the values between left and right side.

7.2.3 Surgeon rear side (lower level)

This position was considered in order to confirm that airflow pattern showed thanks to the UFP counting experienced in Sahlgrenska University Hospital. The position is behind the back of the surgeon but at lower level. As it is possible to see consulting the map of the positions (Figure 7.8) the position is under the LAF as before but at lower level.



(a) (b)

Figure 7.11: Lower level behind the back of the surgeon (59 cm) and 32 cm from the floor (b), 12th operation, Södertälje

Table 7.9: CFU concentration sampled behind the back of the surgeon at the lower level position

		OT conditions and samples collected			
ID operation	OT:T-UR	# sterile filters	# CFU/m^3	Average # CFU/m^3	(Min-Max) # CFU/m^3
12th operation	20°C-27%	2	Filter 1: 100- Filter 2: 25	62.5	(25-100)

Not a lot of measurements were taken in this position because the focus of the work is obviously related to the sterile zone. These two measurements underline high dirtiness levels close to the floor under the LAF technology.

7.2.4 Under the blanket

These measurements are taken in order to compare the dirtiness under the table with the ones close to the wound. In the first photo (a) the filter is applied and the measurements is ongoing, on the right side of the photo is possible to notice the dress of the surgeon. While in the second picture (b) the photo was taken before the start of the operation, in fact is possible to notice that no blankets are present. While on the side, it is possible to see the UFP suction pipe of the UPC and the ruller use to define the height of the sampling.

(a)

(b)

Figure 7.12: photo take while the measurements is ongoing and with the surgeon on the right, 1st operation (a) and photo with the ruler (27 cm in the center of the holder) in the 2nd operation (b), Södertälje

The results collected are highlighted in the following table:

Table 7.10: CFU concentration sampled under the anaesthesia barrier blanket position

		OT conditions and samples collected			
ID operation	OT:T-UR	# sterile filters	# CFU/m^3	Average # CFU/m^3	(Min-Max) # CFU/m^3
1st operation	19°C-22%	3	Filter 1: 5 Filter 2: 10 Filter 3: 17	10.67	(5-17)
2nd operation	20°C-24%	3	Filter 1: 2 Filter 2: 6 Filter 3: 25	11	(2-25)

7.2.5 Instruments table

These measurement settings are significant, because the instruments table is important at least as the wound position. In fact, if a microbiological active particle settle over an instrument could be even worse than it goes close to the wound. Indeed the instrument has to be use in the sensible part of the patient and in this way, there is the possibility for the probable infections to have a free transfer to the sensible zone. So could reach the deeper parts and give rise to organ/space SSI, the worst possible for a patient, check the Section 1.2 pag.7 for more. In the following pictures for each position will be a theoretical representation of the air behaviour correlated with the position of the instruments table respect to ceiling. It is important to say that the representation is just an idea extrapolated watching the video of the operation and the CFU and UFP data collected by the instruments.
In this case is important to put again the map of these measurements (Figure 7.13), because one of those happens outside the LAF technology and a map of the positions could be useful.

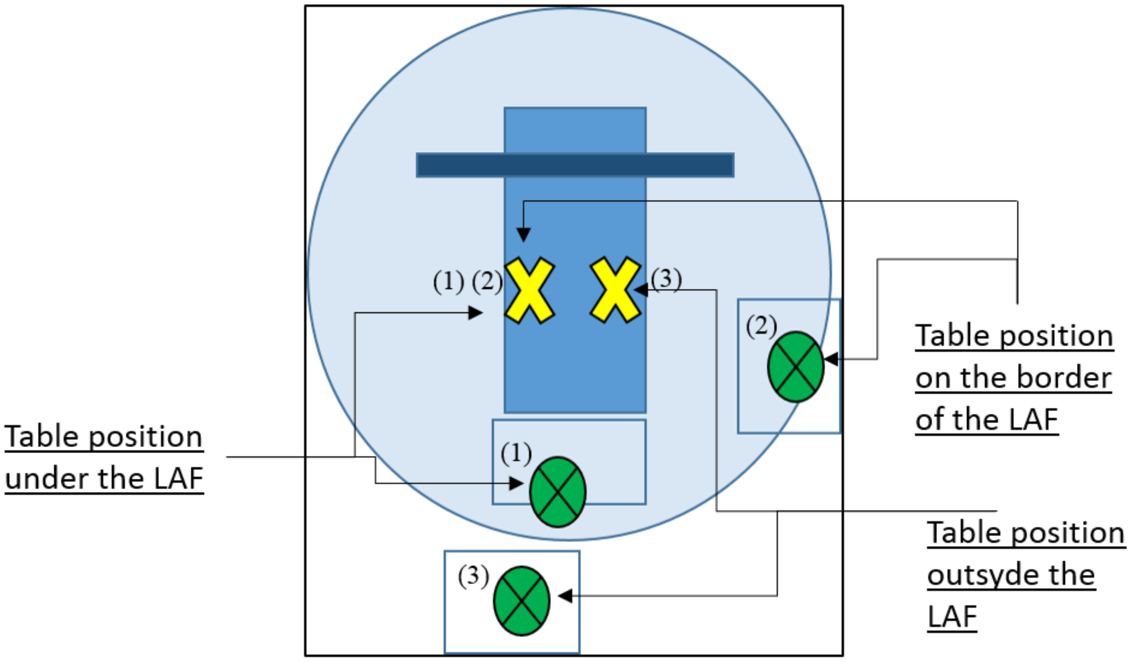
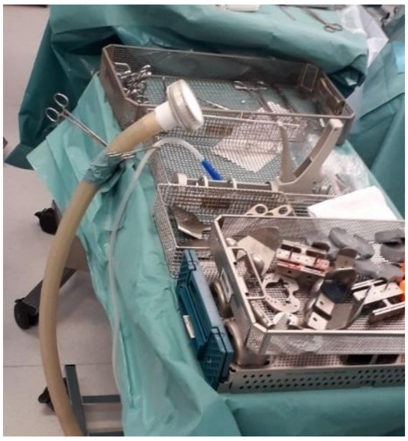


Figure 7.13: Map of the instruments table CFU measurements

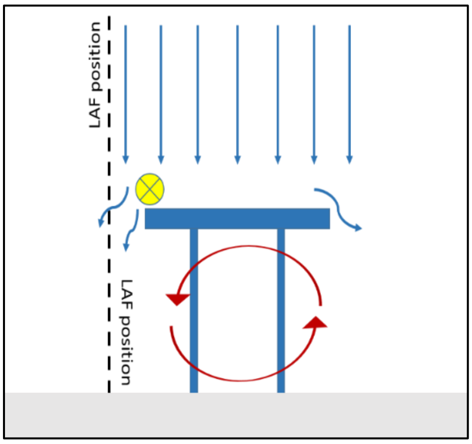
Table 7.11: CFU concentration sampled on the instruments table

	OT conditions and samples collected				
ID operation	OT:T-UR	# sterile filters	# CFU/m^3	Average # CFU/m^3	(Min-Max) # CFU/m^3
4th operation (1)	19°C-19%	2	Filter 1: 1 Filter 2: 0	0.5	0-1
10th operation (2)	20°C-23%	4	Filter 1: 1 Filter 2: 0 Filter 3: 3 Filter 4: 1	1.25	0-3
11th operation (3)	20°C-24%	4	Filter 1: 45 Filter 2: 15 Filter 3: 17 Filter 4: 7	21	7-45

Considering the wound position with the yellow crosses, the number in brackets is to correlate the instruments table with the wound's position related. In the fourth operation, the instrument position is the standard one, under the LAF system (Figure 7.13 (1)) and reported low concentration of CFU in this zone, result confirmed also by other works [73]. In fact, the big part of the operations has the instruments table under the air distribution system. Mostly because it is expressly indicated by the rules of the hospital. In the Figure 7.14 (a) there the instruments during a hip operation. The filter of the air sampler is just above the instruments table (not more than 15 cm) and close it is possible to see the UPC's pipe (blue head). While the (b) picture tries to represent the air behaviour in this position with the yellow circle as the filter of the air sampler. The blue arrows as clean air which come directly from the ceiling (not necessarily parallel but here is not important). The red arrows as a representation of the dirty air under the table recovering the study made in Sahlgrenska (Section 7.1).



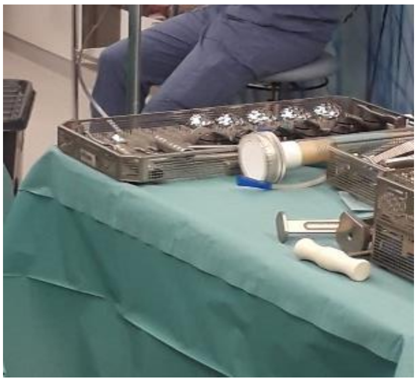
(a)



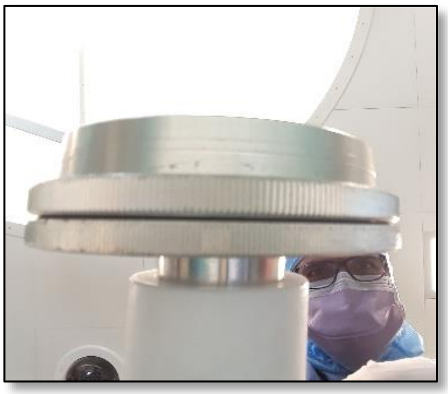
(b)

Figure 7.14: Measurements over the instrument table with the particle counter pipe beside (a). The theoretical behaviour of the air based on the UFP/CFU data (b).4th operation with CFU, Södertälje.

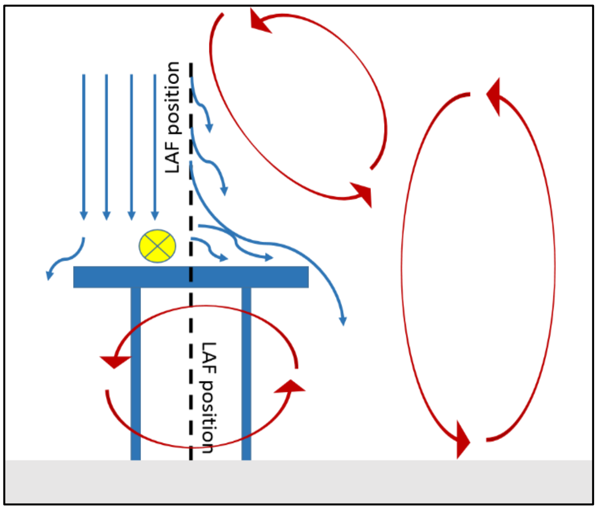
Another interest position is the one placed by the operating nurse during a hip surgery. It is possible to see the position of the instruments table on the border of the LAF in the Figure 7.13 (2) and in the Figure 7.15 (b) (took from under the holder in order to check the position related with the ceiling). In Figure 7.15 (a), the filter is placed between the instruments, flanked by the UPC's pipe. The theoretical idea of the behaviour of the air is maybe the most controversial one, in fact the results collected (four filters, video record and 40 minutes UPFs counting in parallel with the filter) appears to confirm that the system is working in the right way. Nevertheless, the arrows on the right side of the picture (Figure 7.15 (c)) are a representation to show that the system create a sort of barrier over the table also if it is outside of the LAF. The behaviour under the table is the same for all the situations and far from the LAF system is an approximation without data confirmation.



(a)



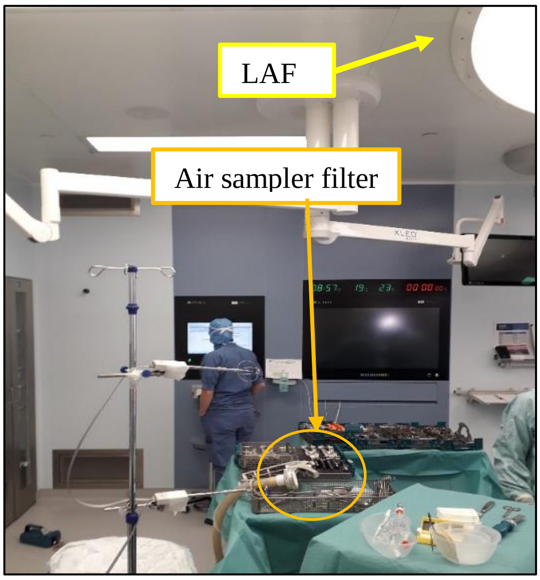
(b)



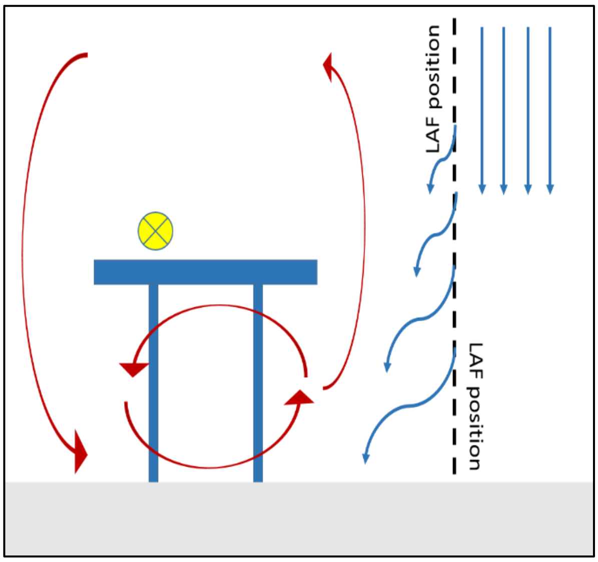
(c)

Figure 7.15: Filter over the instruments table (a) and the picture from below to understand the position compared with the ceiling (b). The theoretical behaviour of the air based on the UFP/CFU data (b). 10th operations with CFU count, Södertälje.

One of the most important position is the one which highlights the limits of this LAF technology. In fact, knee prosthesis operation needs more tables and so more space. Watching the map added above is not easy to imagine that around the patient there are three people fixed. The medical staff has to move around the wound, and mostly during an orthopaedic operation, the activity is high. Compared with the operations attended in Sahlgrenska, where the medical staff in the sterile zone movements are limited. During an orthopaedic surgery the surgeon use instruments, which needs space to operate and, furthermore, the operating nurse has to move more to reach different tables where all of these are placed. In an internal surgery, the most using instruments are collected over two tables.
The simplification in the schematically Figure 7.16 (b) is just to show that far from the LAF the air movements are not fixed and the stability of the airflow is not guaranteed.



(a)



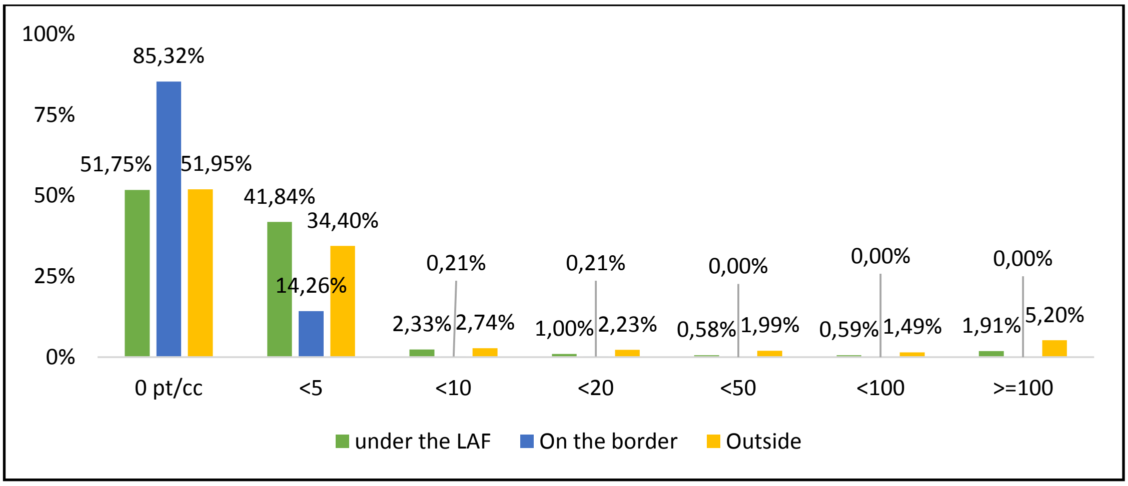
(b)

Figure 7.16: instruments table placed outside of the LAF system (a) and the theoretical air behaviour watching CFU/UFP count (b). 11th operation with the CFU count, Södertälje.

To confirm or less the different position and how the author represent the behaviour the UFP data collected are reported below. The entire UFP are in pp/cm^3, all the results of the intervals are in percentage. The intervals are cumulated, for the single interval value check the following graph.

Table 7.12:Single frequency percentiles of pp/cm^3 in the table above and relative frequency percentiles pp/cm^3 in the graph below

		Percentage of number of samples in pp/cm^3 collected divided in the intervals below, for example 51.75% in the column equal to 0 pp/cm^3 represent that of in all the samples collected during the 4th operation the 51.75% was equal to 0 pp/cm^3							
#operation	#samples	Average	=0	<5	<10	<20	<50	<100	≥100
		$[pp/cm^3]$							
4th	1200	1.046	51.75	93.59	95.92	96.92	97.50	98.09	1.91
10th	2411	0.234	85.32	99.58	99.79	100	100	100	0
11th	2558	21.57	51.95	86.36	89.09	91.32	93.32	94.80	5.20



The percentage of cleanliness is reached under the LAF ceiling and on its border. Otherwise the differences for the UFP point of view were not marked, but the 5,20% of samplings outside the laminar air flow bigger than 100 pp/cm^3, could be understand as a clear example of the presence of turbulence. This idea is also confirmed by the airborne microbiological concentration sampled, where the CFU concentration is twenty times the level collected under the LAF. Considering also this aspect, is possible to supposed that there are vortices outside the UDF and those are rich of dirtiness.

7.2.6 Microbiological active UFP sampling in the sterile zone, close to the wound of the patient

The most important aspect of the CFU count is the position of the filter over the instrument desk, close to the wound in operational condition. It is important to remember the using of ordinary scrubs during all the CFU measurements. Eleven operations were attended close to the wound. The filter needs a tube, which connect it with the air sampler in order to aspirate a fixed airflow of 1 m^3/10 minutes. This tube has to be sterilized because it stays inside the sterile zone. The pipe is fixed over the anaesthesia barrier and the filter bring closer to the sensible position.

Table 7.13: Results of the CFU counts

N° operations in Södertälje	Type of operation	# Filters	Results [CFU/m^3]
1	Knee	3	0 – 1 - 0
2	Hip	4	4 - 6 - 5 - 7
3	Hip	4	1 – 0 – 10 - 0
4	Hip	3	1 - 0 - 0
5	Knee	4	3 – 3 – 0 - 4
6	Knee	6	3 – (a)[4] - 1 – 0 - 0 - 0
7	Hip	10	3 – 3 – 2 – 5 – 2 – 1 – 9 – 0 – 1 – 9
8	Knee	6	5 – 3 – 0 – 1 – 1 - 3
9	Hip	8	6 - 16 – 15 – 4 – 9 - 100 – 10 - 9
10	Hip	2	13 - 0
11	Knee	3	6 – 12 - 0
TOTAL		53	

[4] (a): The plate was reported as ruined and impossible to type

All the measurements sampling close to the wound positions are added in the following picture. All the samples taken inside the sterile zone, not considering the instruments table, are over the anaesthesia barrier until the wound position. In the following photos (Figure 7.17) there are all the positions of the filter over the operation table circled by a yellow circle.

In the previous table there are all the results, the number in the first column is the same of the pictures in the following figures. Furthermore, there are the type of operation, number of filters connected and the results associated.

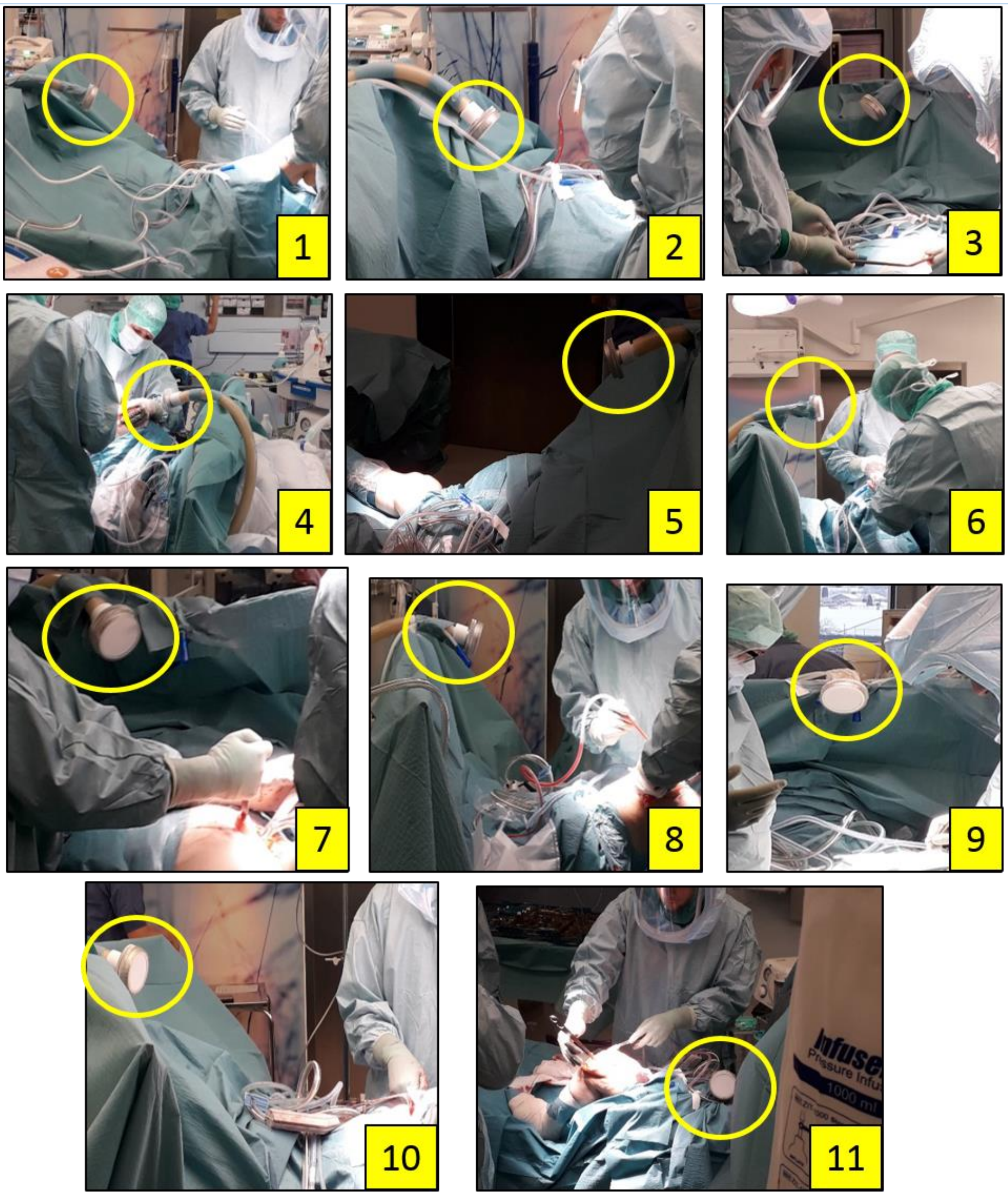
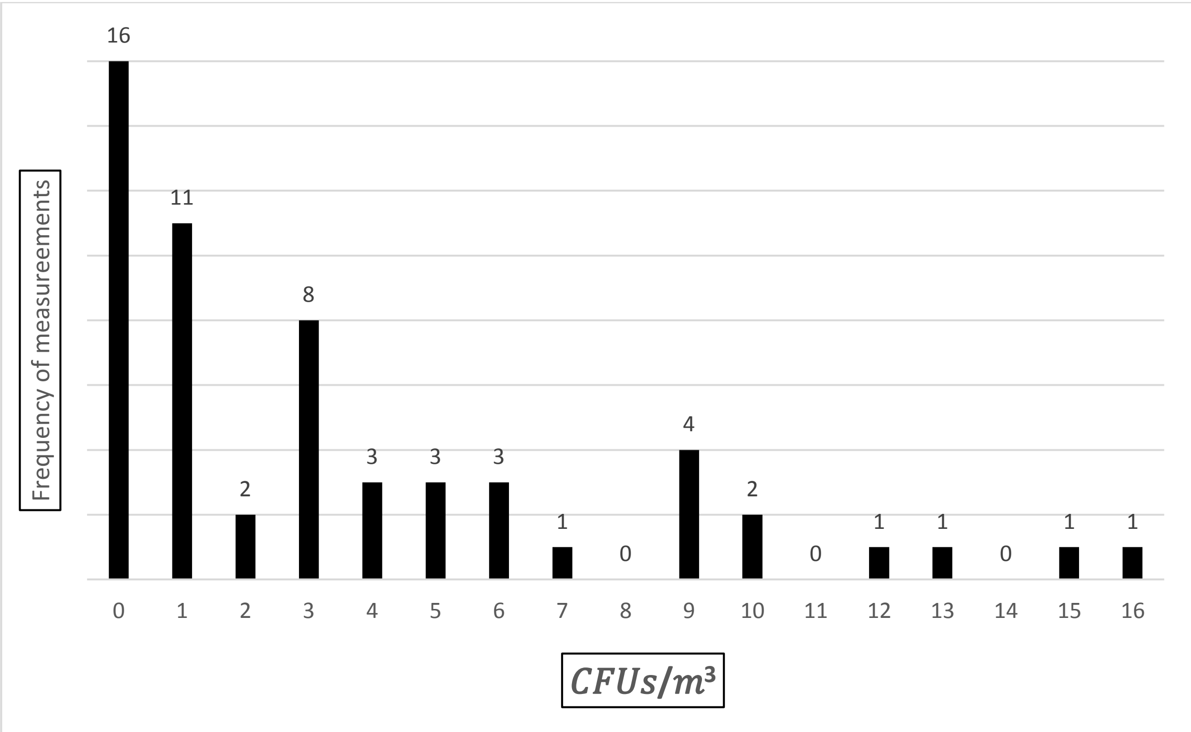


Figure 7.17: Pictures of all the air sampler's filter for every operation, Södertälje

In the following section the author try to make a read of all the data collected, comparing these with the others position and trying in this way to rebuild the air behaviour and the capacity, or not, of this system to limit the presence of microbiological active UFP in the sensible zones.

Could be useful to resume all the samples collected in the sterile position (51 samples in the wound zone and 6 samples on the instruments table when placed inside the sterile area defined by the LAF ceiling) in a most visually comprehensive way.

The graph below shows the number of times in which a single measurement experienced a certain cfu concentration, within the sterile zone.



Graph 7.8: Resuming table with all the CFU/m3 collected inside the sterile zone

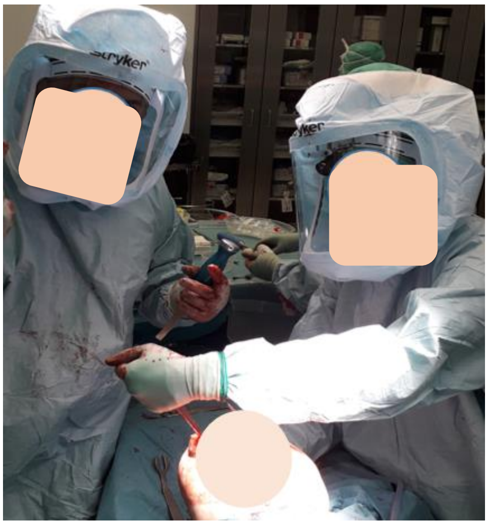
Several calculations are possible with the values presented in the previous graph, the author decide just to evaluate the percentage of CFU concentration in four different intervals for a total of 57 microbiological air samplings in the sterile zone:

Table 7.14: Resuming table for all the CFU/m3 divided by interval

	CFU concentration range			
	$0 \leq \frac{\text{CFU}}{\text{m}^3} \leq 5$	$5 < \frac{\text{CFU}}{\text{m}^3} \leq 10$	$10 < \frac{\text{CFU}}{\text{m}^3} \leq 15$	$15 < \frac{\text{CFU}}{\text{m}^3} \leq 20$
Frequency of the interval	75,4%	17,5%	5,3%	1,8%
Cumulative Frequency	75,4%	92,9%	98,2%	100%

Considering the previous table, just one sample was taken outside the limit impose by the Swedish Standard and it happened during operation with staff exchange (in the following section will be more clear). More than the 90% of all the samples collected inside the sterile zone recorded a CFU concentration lower than 10 CFU/m^3 . It is also important to highlight, as it is possible to check in the following photos, that every medical person who stay inside the sterile zone (surgeons and operating nurse) can choose which protection use for the head. In fact, the mask of the surgeon is a protection for the patient and not the reverse. The important element is to guarantee the health for the patient and every member of the medical staff can decide how to dress him/herself in the limits allowed by the standards. Per instance, the surgeon present in the pictures number 4 and 6 prefer to use just the mask avoiding the use of glasses. While in the others photos the staff prefer to wear the complete covering which allow having a complete view, without something on the mouth. However, the author noticed that the conversation it is harder due to the rumble inside the “astronaut mask”. Obviously, the protection it is also for the staff in case of splashes from the wound. Nevertheless, the present of splashes is limited more or less at just orthopaedic operations.

(a)



(b)

Figure 7.18: Different types of mask, surgeon without glasses (a) and surgeons with the complete mask (b), Södertälje

Could be useful to see if the results collected during the operations with less protection (4th, 5th and 6th) show this difference. The average recorder is 1.25 CFU/m^3, with a minimum of 0 and a maximum of 4 CFU/m^3. Therefore, the level is low and does not appear the difference type of headdress as an element, which has to be considered as a cause of some issues. So could be useful to purpose that the system avoid that the losses from a less covered staff interact with the sterile zone. While the same reasoning in the other case needs more explanation before to show it.

7.2.7 The personal staffs exchange: a weak point of the UDF air ventilation technology

The measurements close to the wound, furthermore allow to take more information about some elements which could be a limit for the air ventilation system. In fact, as already presented in the Section 7.2.5 about the positions of the instruments table, there are some aspects related to habits or necessities, which cannot guarantee a low level of CFU/m^3. Initially watching the results from the Karolinska Lab about the levels of CFU/m^3 , the team and the author were surprised. Fortunately, the author and operating nurse involved in the project took many notes and the operations were recorded. In this way was possible to understand that, during the seventh and ninth operation in Södertälje there was medical staff exchange.

The CFU/m^3 collected in these intervals are listed in the table below. The samplings where the person staffs exchange is highlight with the value underlined.

Table 7.15: CFU/m3 collected in two operations, during medical staffs exchange in two operations

	#filter sampling									
#operation	1st	2nd	3rd	4th	5th	6th	7th	8th	9th	10th
Seventh operation *[CFU/m^3]*	3	<u>3</u>	2	5	2	1	<u>9</u>	0	<u>1</u>	<u>9</u>
Ninth operation *[CFU/m^3]*	6	16	<u>15</u>	<u>4</u>	9	<u>100</u>	<u>10</u>	9	-	-

Considering the data reported in the previous table, is possible to notice different levels of CFU/m^3 mostly when the medical staff exchange. The medical staff exchange is a necessity related to emergencies or time schedule, but watching this data could be considered to think about different solutions for the health of the patient.

The author want to add a personal read of the data listed above. In fact, appears that when there is personal exchange necessity the level of microbiological active UFP detected increases, not just in the interval of the medical staffs exchange, but also in the intervals which come first or after.

The idea is that the large movements, which precede or follow the medical staff exchange, could create disturbances that the system toil to compensate. Considering the idea of Laminar Air Flow, presented in technical Section 3, where the aim of the air distribution technology is to create a sort of tent around the operating desk. The staff exchange could be an element, which breaks this curtain and disturbs the stability that this system aim to create around this zone. This instability could be persist for several minutes.

In the following picture is possible to notice, a moment of the ninth operation in Södertälje, the large presence of medical staffs inside the operating room (nine people) before the operating nurse exchange. The operating nurse, which stays outside the LAF, already wears the sterile technical gowning. The new operating nurse could carry inside some dangerous UFP accumulated over the technical clothes during the time passed outside the LAF zone.

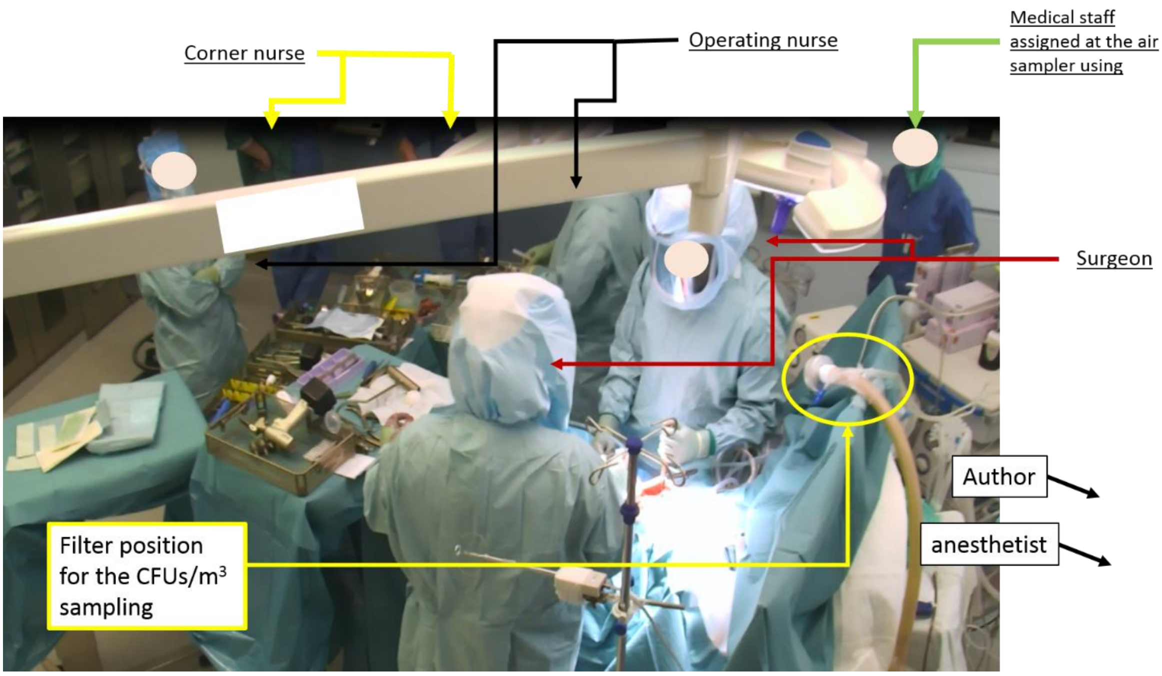


Figure 7.19: Photogram of the video recorded during the second operation of the 18/12 in Södertälje during the personal staff exchange and high occupancy level

The medical staff exchange could be considered as a problem for the calculations of the CFU concentration, in fact the author considered necessary to underline that during the exchange of the medical staff two aspects have to be considered as differences related to the standards calculations:

- *Number of medical staffs inside the OTs* (n): the equations should be evaluated again considered the different amount of medical staff present inside the OTs. However, it is not possible considered that the interval of sampling is defined (10 minutes) and the time interval of staff exchange is not defined as the sampling interval.

- The CFU concentration experienced during operations with staff exchange, is different compared with samples collected in operations with the number of medical staffs fixed.

For the reasons listed previously the author considered to make a calculation without the samples experienced during operation with staff exchange. Checking the list of results in Table 7.13, in the following calculation the samples collected during the 7^{th} and the 9^{th} operation, where the staff eschange happened, are not considered.

$$c = \frac{93\,\frac{CFUs}{m^3}}{35} \cong 2{,}7\ \frac{CFUs}{m^3}$$

Despite the author believe the motivations behind this idea valid, the medical staff exchange is a routine which is needed and scheduled. For this reason the comparison with the results expected is made considering all the samples experienced inside the sterile zone (Section 7.3.2), cases where also the staff exchange is involved, and will be even the only one considered in the conclusions of this work.

7.3 Discussion of the results: airflow pattern and microbiological particles concentration

In this section all the results collected are resumed. There is the description of the airflow pattern around the sterile zone of the operating theatre and also in its nearby, furthermore the comments related to the results collected inside the sterile zone and the comparison with the results expected according to the Swedish and the Netherlands Standards.

7.3.1 OTs airflow pattern described using the CFU and UFP samples

Considering the concentration of colony forming units highlighted previously at the level of the wound, and considering the ones collected also at lower levels (Sections 7.2.3-7.2.4) and the UFP counting faced in the Section 7.1 a schematically representation of the airflow pattern is shown below.

The first representation deals with the relation between the medical staff and the wound zone within the sterile area and furthermore, the capacity of the air ventilation system in avoiding the penetration of disturbances present outside of the LAF. It is mindful to remind the importance of the technical clothing system gowned by the medical staff, e.g. mixed material ordinary scrub. The air pattern represented in the picture below is based on the experimental measurements carried out (UFP concentration, airborne microbiological concentration, air velocity and temperature).

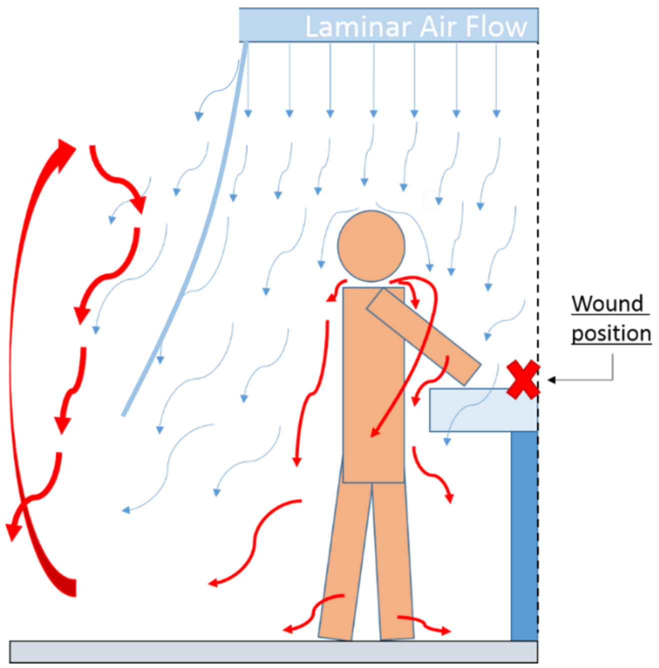


Figure 7.20: Representation of the air pattern considering surgeons UFP and wound zone using technical gowning made of mixed materials

Observing the rapresentation, the air stream lines lost the unidrectionality as they move away from the LAF ceiling, nevertheless the data shows that the system is able to keep the airstream direction towards the floor.
In the wound zone, the air distribution system appears to be able to avoid vortices close to the wound, unlike what reported in the other works [57], in fact the presence of air instability in this area could bring dirtiness from the staff close to the patient's wound. Unlike noticed in some works [55], where the upward displacement air system appears not able to guarantee the cleanliness close to the wound. Considering the previous works, the use of low performance technical clothing highlights the capacity of this system in sweptwing away medical staffs 'airborne particles.

Regarding the area behind the medical staffs, under the LAF ceiling, to describe the air pattern the author used the concentration of UFP and CFU. These measurements were collected: behind the back of the surgeon (wound level and 30 centimetres above the floor, Section 7.2.2-7.2.3 pages 62-64) and under the blanket position (28 centimetres above the floor, Section 7.2.4 page 65). It seems that the dirty particles coming from the wound area and lost by the medical staff are swept away from the sterile zone and directed towards the OT floor.
Furthermore, it is possible to notice the big red vortices present outside the LAF, as underlined in different works. Unlike the representation used by other previous works Figure 3.2 [57], the LAF appears to be able to spread away the dirtiness carried on by these vortices. In fact, as represent in the following picture, the different samples during different positions of the instruments table could be use an example of the capacity of this system, but also a weak point in case of instruments table position outside the LAF. In the following representation with little red crossed circles the author represented a dangerous particle and an example path followed due to the presence of vortices.
This marked difference between the measurements collected in the different positions of the instruments table are confirmed both in UFP and concentration of CFU in the Section 7.2.5 (page 66). In fact, the low level of airborne microbiological particles and UFP sampled when the instruments table is placed inside or on the border of the LAF, could be used as a another example which confirms the capacity of the air ventilation system in keeping the air cleanliness over the instruments' table. Moreover, the high levels of CFU's concentration ($\sim 20\ CFU/m^3$) collected and several UFP peaks sampled over a concentration of $> 100\ pp/m^3$ could be considered as an example of the lower stability outside the UDF ceiling.
This limit highlighted by this type of air ventilation system has to be kept in mind. In fact, the area outside the LAF appears to be unstable and not adequate for the instruments table position. The dirtiness present close to the floor appears to be carried on the instruments table due to the vortices that are outside the LAF system.

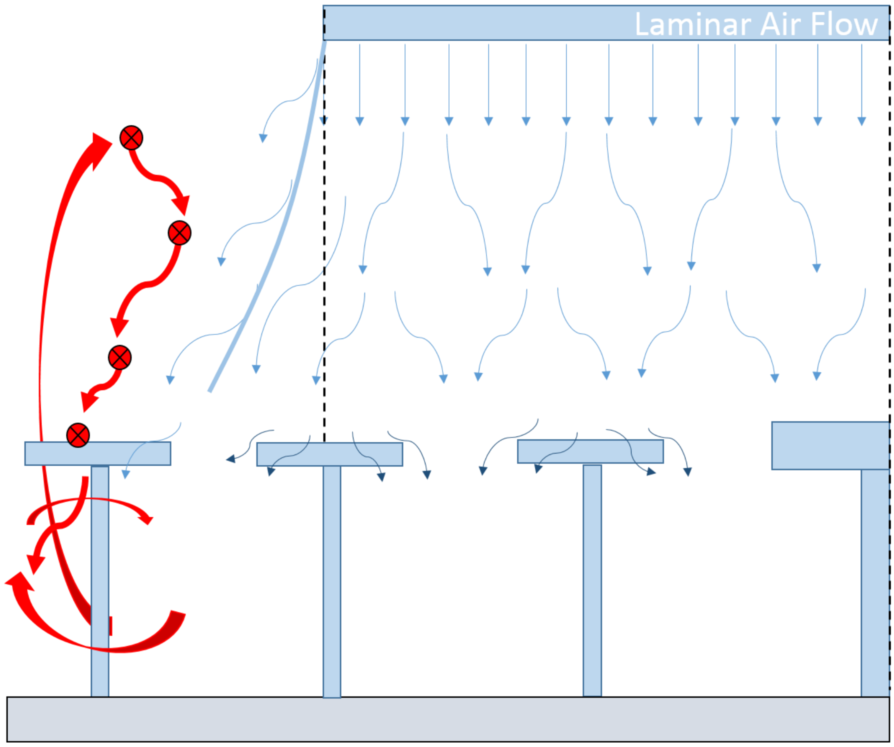


Figure 7.21: Representation of the air pattern over the instruments table placed in different positions compared to the Laminar Air Flow system.

Another important aspect discovered is schematically represent in the following picture. It is an important aspect that has to be considered when this type of air ventilation system is in use, it is related to the staff exchange introduced in the previous part (Section 7.2.7). During two operations, when the staff exchanges, the samples close to the wound reported higher levels compared with the expected values.

The idea of the author is that the medical staff staying outside the LAF gets a lot of dirtiness over the sterile technical clothing brought by the air vortices described previously. Once this airborne dirtiness is deposited over the technical gowning, the medical staffs bring it inside with them (signed with red circles). Furthermore, the dirtiness which is floating in the air (signed with yellow circles) outside the LAF, get dragged inside by the movements of the medical staff.

An idea of the author is that the staff exchange, with a new medical staff that has to move inside the sterile zone bounded by the UDF, creates a temporary disturbance in the stability and mainfunction of the unidirectional airflow. The idea is that the sort of curtain created by the UDF system is broken by this staff entrance. Furthermore, the clean air which is coming from the LAF/UDF changes its normal direction and the passage induces a pressure variation behind the person who is moving inside. These others elements could improves turbolence and air vortices.

This pressure reduction caused by the medical staffs passage, improves the turbulence in the lower part of the operating theatre and could allow the dirtiness present outside to move inside the sterile zone.

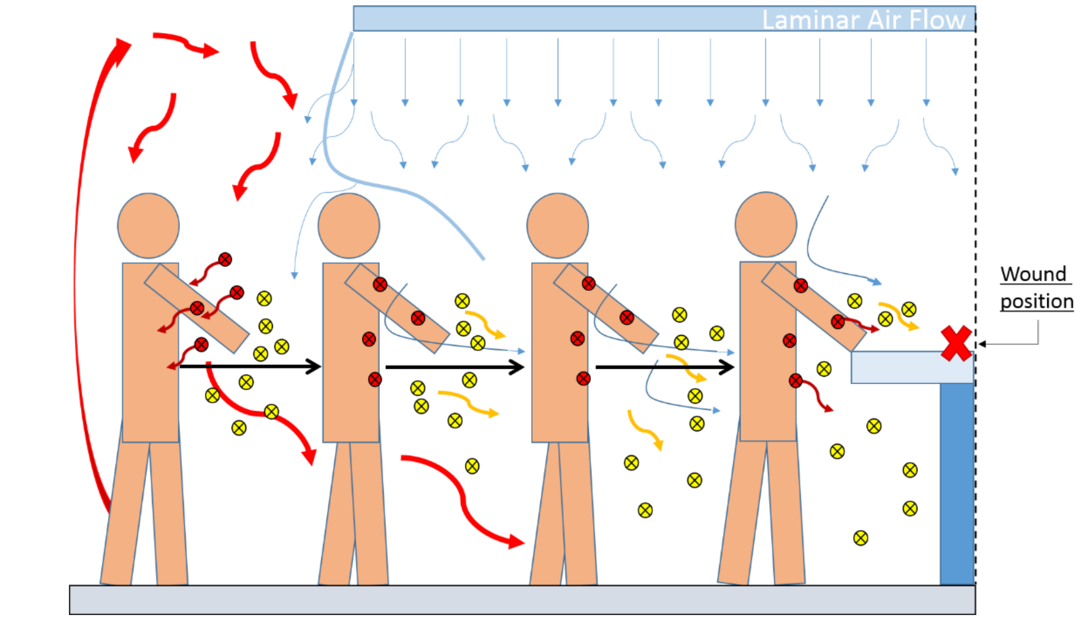


Figure 7.22: Schematic representation of the airflow behaviour during the personal exchange

7.3.2 The microbiological active particles concentration: analysis and comparison with the results expected

The results collected in the OTs with UDF technology have to be compared with actual state of art. The Swedish and the Netherlands Standards defined some guidelines that have to be respected and, mostly, suggest respectively two equations [2],[3] to defined the CFU concentration expected measuring inside the sterile zone (already presented in Section 6.1). The second equation was already solved in the previous Section 6.1 considering that all the elements necessary were known: total number of medical staffs inside the OTs: $n = 7$; Air flow rate $Q = 2{,}3\ m^3/s$; Source strength defined for ordinary scrub (technical clothing type used during all the air microbiological samples experienced in this work) $q_s = 4{,}2\ CFU/s$.
The concentration of Colony Forming Units expected according with the equation [2] should be:

$$c = \frac{q_s}{Q} \times n = 12{,}8\ \frac{CFU}{m^3}$$

While to make the calculations of the third equation [3] the data needed were more: the CFU concentration in the exhaust and the mean concentration in the OTs are necessary. In fact, factor CRE (contamination removal efficiency) has to be estimated. $CRE = \frac{concentration\ in\ the\ exhaust}{mean\ concentration\ in\ the\ room}$.
The concentration in the exhaust is considered by the author as the average of the values collected close to the exhaust grill (Section 7.2.1). While the mean concentration is considered as the average between the values collected in: wound zone (Section 7.2.6), the instruments table position when placed outside the LAF (Section 7.2.5) and the exhaust grill sample.

$$CRE = \frac{concentration\ in\ the\ exhaust}{mean\ concentration\ in\ the\ room} = \frac{44{,}8}{23{,}8} = 1{,}88$$

Now is possible to estimate the CFU concentration expected in accordance with the Netherlands standard [3]:

$$c = \frac{q_s \times n}{Q \times CRE} = \frac{4{,}2 \times 7}{2{,}3 \times 1{,}88} = 6{,}81\frac{CFU}{m^3}$$

Talking about the measurements experienced in this work according with the Swedish standard the sterile zone is the part over the instruments table and close to the wound. Following the guideline presented by Swedish standard regarding the measurements position ($\leq$ 50 cm from the surgical side (height of 120 cm) and on the instrument table), the sampels used to make the following count are the ones close to the wound (51 samples) and over the instruments table (10 samples) (rispectly Section 7.2.5-7.2.6).

The concentration obtained from the data sampels collected is:

$$c^{5} = \frac{Sum\ of\ all\ the\ CFUs\ samples}{Total\ number\ of\ samples} = \frac{287\ \frac{CFU}{m^3}}{61} = 4{,}7\ \frac{CFU}{m^3}$$

A important element that the author decide to evaluate is that, the sterile zone considered in the OTs with the UDF technology is the zone under the LAF.

Considering that during one measurement over the instruments table, the instruments desk position was outside the sterile area guaranteted by the LAF ceiling. Taking into consideration these samples, it would not consistently represent the area defined as sterile by the UDF distribution system.

For the reason explained previously the author does not consider the four sampels experienced on the instruments table outside the LAF during the 11th operation (7.2.5):

$$c = \frac{Sum\ of\ all\ the\ CFUs\ samples}{Total\ number\ of\ samples} = \frac{203\ \frac{CFU}{m^3}}{57} = 3{,}6\frac{CFU}{m^3}$$

The author considered this result (the average of the concentration of the CFU collected in the sterile zone of the UDF) the one that has to be used to make the comparison with the results expected using the equation presented previously [2] [3].

In the following table is possible to check the comparison between the different CFU concentration expected in this condition:

- OT ventilation system: UDF technology (Section 4.2 page 24)
- Occupancy state: operational
- Surgeries type: advanced surgeries (orthopaedic)
- Positions of the samples: sterile zone (Sections 7.2.5-7.2.6)
- Technical clothing system: ordinary scrub suit (Section 6 page 35)

In the first two columns is possible to check respectively the Swedish [2] and the Netherlands Standard [3], while in the third column is showed the average of the samples experienced in this work inside the sterile zone. It is possible to notice that the results obtained using the equations purposed by both standards are not similar with the ones collected during this work.

[5] The author decide to not include the sampling of 100 CFU/m3 collected during the 9th operation, considering this sample as a contaminated filter. The result of the previous calculation, with also this sample, will be 6,2 CFU/m3.
The total number of filter was 63, but without the previous one and another one (reported as ruined by the Karolinska laboratory) the final number is 61.

Table 7.16: Comparison between the concentrations of CFU expected in according to the Standards with the level experienced in this work in the sterile zone.

Swedish standard equation	[1]	Netherlands standard equation	[2]	Results of this work
$c = \frac{q_s}{Q} \times n$	[2]	$c = \frac{q_s \times n}{Q \times CRE}$	[3]	$c = \frac{Sum\ of\ all\ the\ CFUs\ samples}{Total\ number\ of\ samples}$
$c = 12{,}8 \frac{CFU}{m^3}$		$c = 6{,}81 \frac{CFU}{m^3}$		$c = 3{,}6 \frac{CFU}{m^3}$

The principle behind the equations purposed by the Swedish [2] and Netherlands standards [3] to estimate the concentration of CFU, considers the UDF technology as a total mixing air flow [71] [74] and so estimate the concentration of CFU to the dilution principle of the air mixing ventilation.
Considering also the samples collected in the Bonomi's work [75]. The samples experienced in this work compared with the values expected show that the use of the dilution principle for the estimation of the CFU concentration for the UDF ventilation system is not correct. For this reason the LAF system faced in this work (Södertälje OT: Section 4.2 page 24) cannot be considered as mixing airflow.
Another element not just related to the previous equations is that, if the airflow pattern has to be considered as mixed, the measurements collected in every part of the OT room might be similar. Instead, the data collected have shown a marked difference between measurements within the sterile zone under the LAF system, than the ones collected outside the sterile area and close to the exhaust grill. In the following picture (Figure 7.23), a representative map is created in order to resume the average values of CFU concentration sampled in the OT during this study. The map is divided by colours, starting from the white (high cleanliness level) until the red colour (low cleanliness level).
All the samples compared in the following picture were at the same level of the wound as request by the normative, except the red zone where the values refer to a height of 30 centimetres close to the exhaust grills.

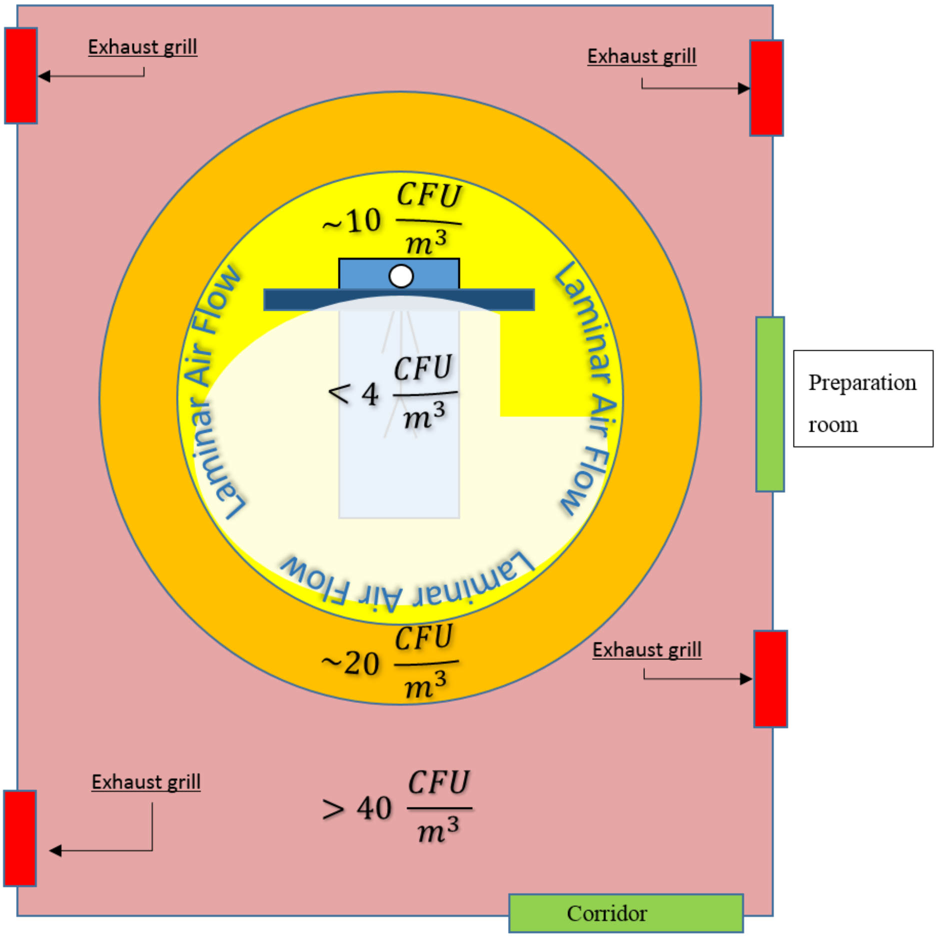


Figure 7.23: Resuming map of the measurements of CFU/m3 collected in Södertälje.

- The sterile part ("white zone") includes: wound zone (Section 7.2.6 page 71), the sampling over the instruments table under the LAF (Section 7.2.5 page 66) and the samplings behind the back of the surgeon, higher level, left side (Section 7.2.2 page 62).
  The calculation made to evaluated this zone is the sum of the CFU concentration collected divided by the total number of samples (51 close to the wound, 6 over instruments table, 7 behind the back of the surgeon, high level, left side) :$\frac{207\ \frac{CFU}{m^3}}{64} = 3{,}23\ CFU/m^3$.

- The "yellow zone" is considered of $\sim 10\ CFU/m^3$ using the samples collected behind the back of the surgeon on the right side of the room. In fact as described in Section 7.2.2 (page 62) the occupancy in this zone is higher compared the same zone on the other side [72]. The author considers that this different occupancy level could be the cause of higher CFU concentration. It is important to highlight that the yellow zone inside the anaesthesia zone is just an estimation, because no samples were experienced there.

- The “orange zone” measurements estimate this zone with a predict level CFU concentration of $\sim 20\ CFU/m^3$ considered the samples taken over when the instruments table was placed outside the sterile zone (Section 7.2.5 page 66).

- All the rest of the room (“red zone”) is indicated with red colour. It could be considered just an estimation, in fact the only measurement in this area is the one close to the exhaust grill (Section 7.2.1 page 61) which report an average higher than $> 40\ CFU/m^3$, so the value is just an indicative value for the periphery of the OT.

Considering the different areas defined in the previous picture (Figure 7.23), the most important zone is the one highlighted with the white colour: the sterile zone. For this zone, the Swedish standard institute [1] gives strict guidelines regarding the limits correlated to the different technical clothing system that is in use during ongoing surgery. As it is possible to check, the higher limit imposed for the less performances technical clothing is higher than for the clean air suit type.
Despite the table below shows that the average lower than $5\ CFU/m^3$ should be reach just through the use of clean air suit clothing system, the samples collected in this work shows that this level could be reached also when all the medical staffs wear ordinary scrub:

Table 7.17: microbiological requirements for operating room

Type of technical clothes	Clean air suit	Ordinary scrub suit
$\left[\frac{\mathrm{CFU}}{\mathrm{m}^3}\right]$	$\leq 5\ (15)$ Mean value per operation (highest value)	$\leq 10\ (30)$ Mean value per operation (highest value)

The important element to highlight is that the technical clothing performances are the same of all the others work as presented in the Section 6 (page 35), but the different is correlated to the ventilation system. Considering the samples collected in this work: inside an OT with UDF technology and a defined routine capacity as in Södertälje hospital, a medical team worn by ordinary scrubs during ongoing advanced surgeries could reach the performances of the clean air suit clothing system.

7.3.3 Discussion to the air ventilation technology related to the actural state of art

Considering all the results presented in the last sections could be possible to add these ventilation principles in the map previously presented (Figure 3.1), which divides the air distribution technologies in function of the turbulence level in the occupancy zone. It is important to remember that the measurements in Sahlgrenska University Hospital were focused only on UFP. While the measurements in Södertälje Hospital add also the concentration of microbiological airborne UFP to the UFP samples. The airflow pattern studied in this work (UDF), in view of the results discussed above cannot be considered as mixing airflow, at the same time is not possible to define it a fully undisturbed laminar airflow pattern, due to different disturbances aspects. For these reasons the definition could be disturbed laminar flow.

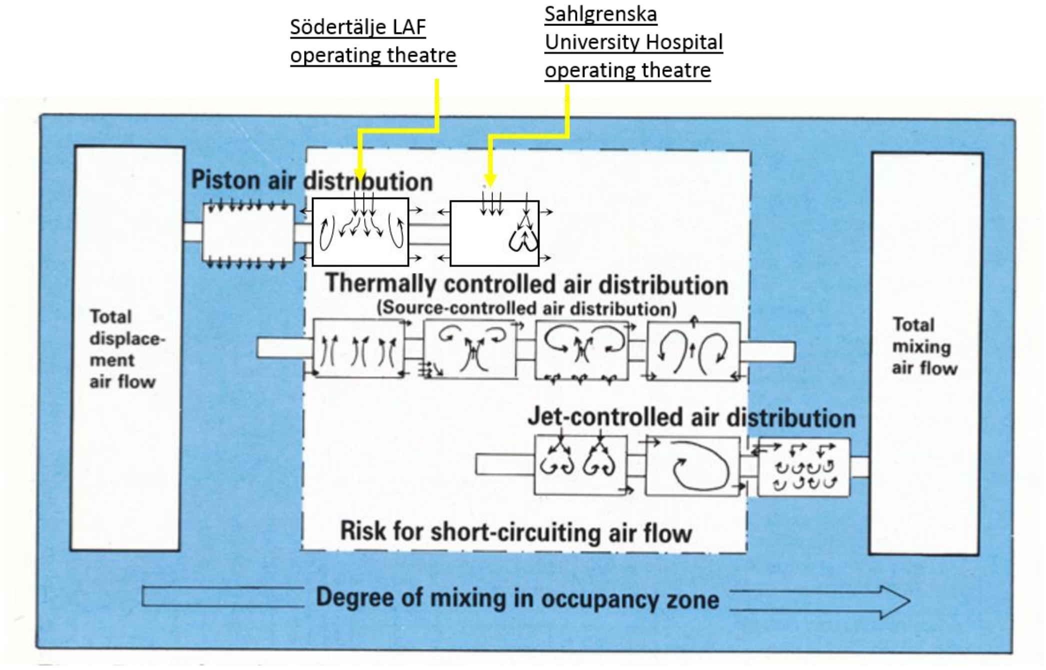


Figure 7.24: Schematic representation of the air ventilation technology divided by the degree of mixing with also the LAF system and hybrid operating system

The degree of mixing inside the occupancy zone in Södertälje operating theatre (structure reported in Section 4.2 page 24) is not possible to consider as unidirectional flow, by the way could be considered as disturbed laminar flow as previous defined. So the level of mixing has to be considered as low. While the Sahlgrenska operating theatre could be thought as most mixed than the previous one, also if the UFP values show a good capacity in washing up the sterile area, but concentration of CFU were not collected to confirm it. In fact, the turbulent diffusers over the anaesthesia zone, create turbulence in this zone increasing the degree of mixing in occupancy zone.

7.3.4 Identifies bacteria type

When the CFU counting happens, it is possible to ask to the laboratory to analyse the bacterias detected. Considering that, this second possibility bring an increasing to the costs, just the agar plates with the filters collected in the sterile zone are analysed, the definition of this procedure is typing. In the following table are shown the total number of filters collected and the amount of these which are typed.

Table 7.18: CFU filter typed in Karolinska Lab

#total filters	Considered as sterile	Actually in the sterile zone
87	A total of 61, of which: • 51 (wound zone) • 6 (instruments table inside the LAF) • 4 (instruments table outside the LAF)	A total of 57, of which: • 51 (wound zone) • 6 (instruments table inside the LAF)

The author decide to make a distinction related to one sample of CFU concentration realized over the instruments desk, but outside of the Laminar Air Flow system (Section 7.2.5 page 66). In fact, the Swedish Standard underline that the measurements have to happens in the sterile zone, $\leq 50\ cm$ from the wound and over the instruments table [1]. For this reason, all the agar plates with the filters collected in these positions are typed. However, for this technology the sterile zone is the one considered under the LAF system (Section 4.2 page 24) so the author makes the previous distinction. Nevertheless, a typing outside the LAF system could be useful in the comparison with the sterile zone.

The total number of CFU typed inside the sterile zone (57 filters) is 192. Considering also the four filters over the instruments table outside (61 filters) the total number became 276 (all the detailed samples and a short description of the bacterium type is reported in Appendix C.

In the sterile zone the 88% of the bacterial detected are: Micrococcus luteus (29,2%), Staphylococcus epidermidis (18,2%), Staphylococcus capitis (18,2%), Staphylococcus hominis (13,5%) and Staphylococcus Hameliticus (8,9%). All of these bacterium are part of the human flora. These data confirmed what expressed in several articles and in the Swedish standard [1] [59].

8 Routines and possible contamination consequences

Having an experience inside an operating theatre for a person who normally have to project without the direct contact with the people that have to use it, teach that a good project to be good need the help of everyone. Because if the people that have to use it do not know how the system works and with which principles, all of your reasonings lost their sense. In this capitol, the idea is not to teach to the medical staff how to work and how to save life. The aim is to make examples from real surgeries to show how some routines could bring negative reaction to the patient.

One of the main problems related surgical site infections is that there is not a directly consequence correlated to some actions. While for the UFP when the measuring happens every one second the action-reaction could be clearer for the CFU where a 10 minutes interval contains many movements is impossible. You can’t have choice to understand which action or habits should be the cause of an infection which could appears also one year later (see Section 1.2). Just with a huge data collection is possible to understand some macro aspects as causes of surgical site infections. In the following section it is possible to see some examples noticed by the author which could be improved.

In the entire following section there are just some pictures taken as examples, because burdening these sections with too much pictures is not considered appropriate.

8.1 Movements close to the uncovered instruments table without protection

The preparation of the tables for both the hospitals happens in separated room: Södertälje has the preparation room adjoining with the operating room (check Section 4.1, page 22) while Sahlgrenska University Hospital has it separated for all the operating theatres in the department. The preparation happens with all the precautions necessary and in a sterile condition. When the instruments are ready, they are covered and bring inside the operating theatre where when the operation starts the instruments are unprotected. Talking with the staff more operations you have better is for the hospital, so the time is precious. For this reason was common to see unprotected staff moves inside the sterile zone or close to sterilized instruments.

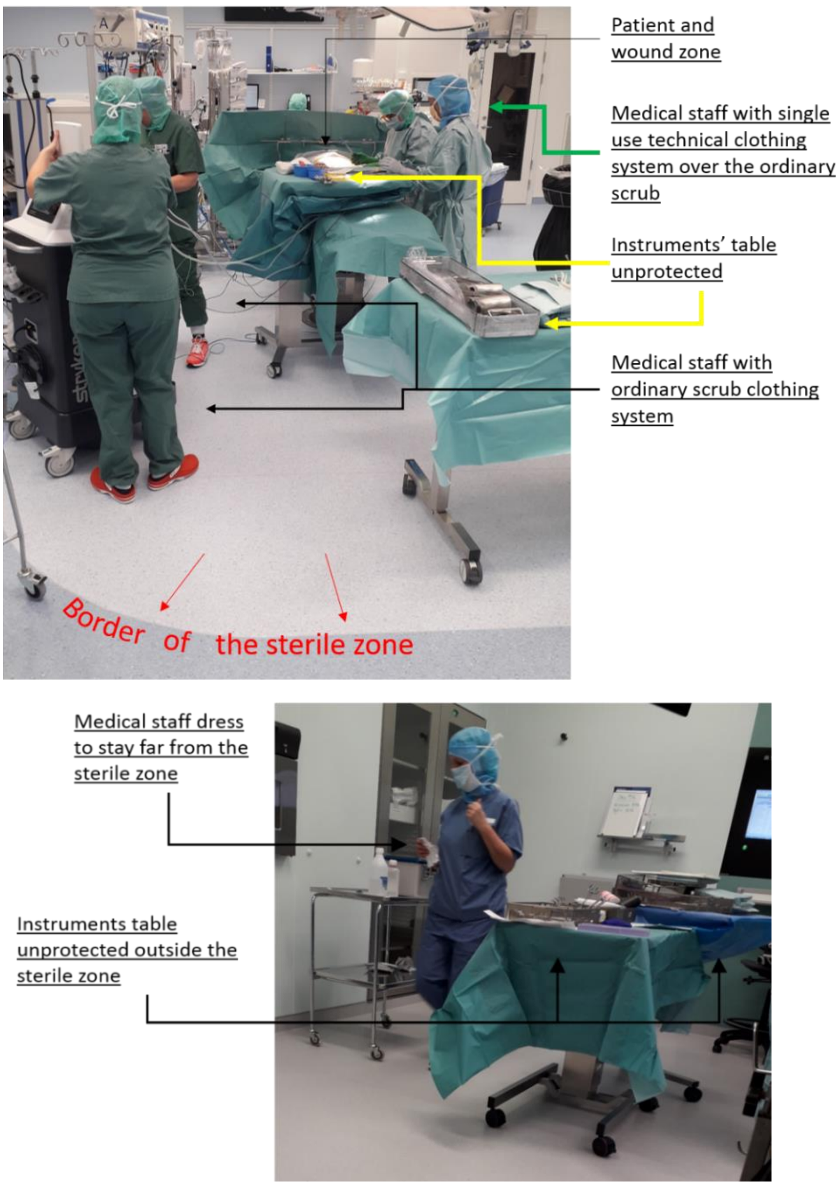


Figure 8.1: Examples of behaviour which could bring dangerous microbiological particles over the surgery instruments

8.2 Uncovered people talk over the anaesthesia barrier

When special operations are ongoing, different staff from others operations comes to give advices or just for curiosity. People who speak over the anaesthesia barrier without mask could splits inside the wound zone, so be the source of microbiological active particles.

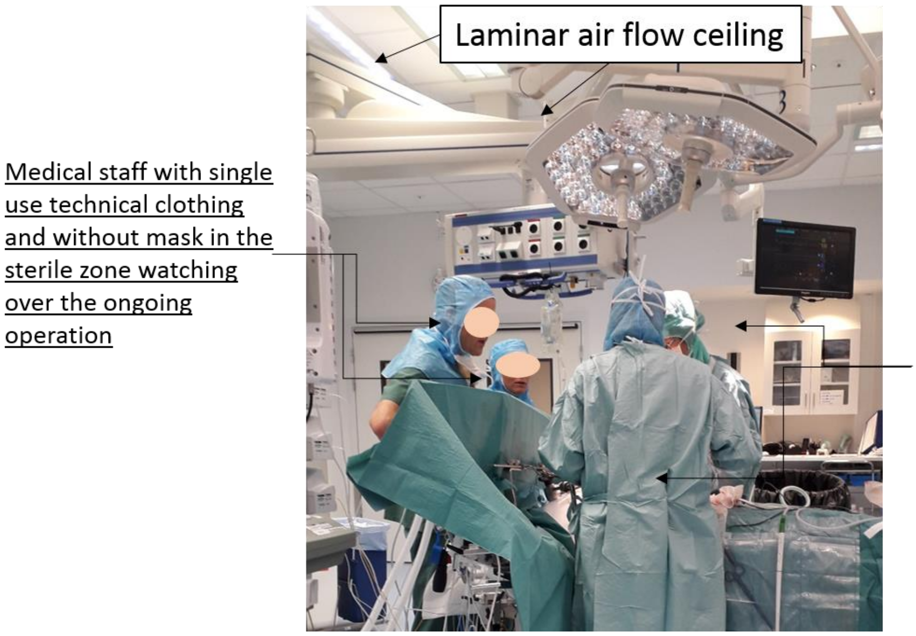


Figure 8.2: Surgery staffs which is talking over the anaesthesia barrier without mouth protection

8.3 X-ray clothes used over the sterile technical gowning

During some type of operations the use of the X-ray machine is necessary to check the correct insert of the implant inside the patient. When this machine is ongoing a protection is significant in order to avoid consequences. This type of clothes are stored inside a dirty zone, the corridor (Figure 8.3 (b)). This type of clothing are keep clean by the cleaning staff, however it is not comparable with the sterile technical clothing system. This procedur skip all the protections, which the differents technical gowning give.

(a)

(b)

Figure 8.3: A member of the medical staff moves inside the operating theatre (a); where the x-ray clothes are stored (b)

8.4 The more glaring example

The last picture could be the most important one. In fact, it is possible to notice a telephone using in order to take a picture, during the ongoing of operation, over the wound of the patient.

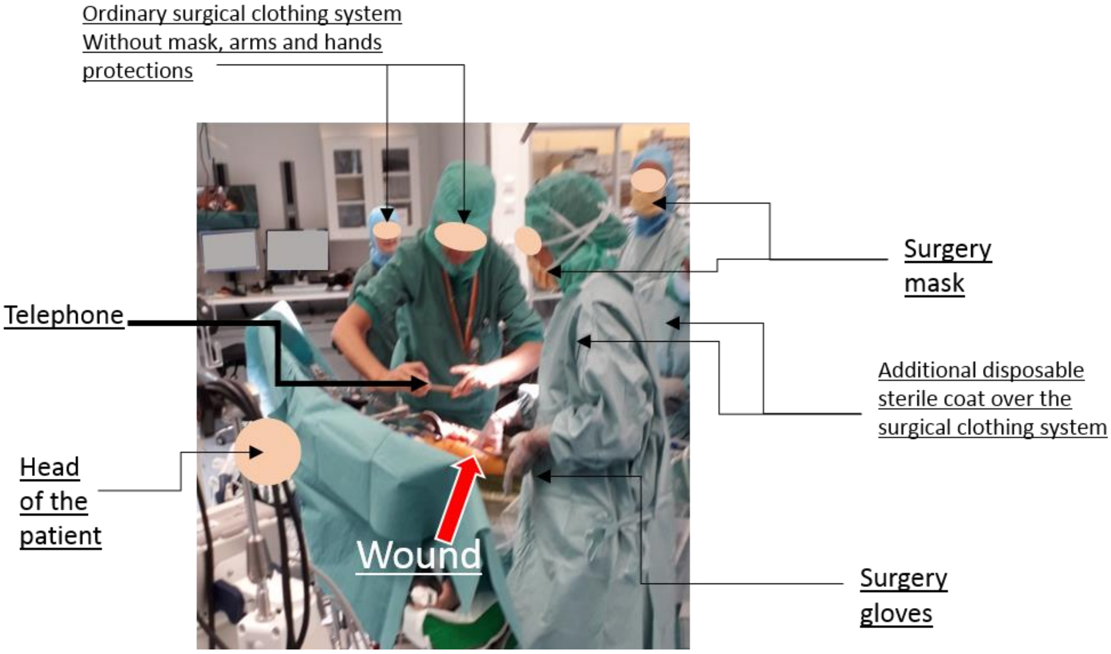


Figure 8.4: Risky situation inside the sterile zone: nurse that has to stay in the periphery move in the sterile zone in order to take a picture

In fact, during the ongoing of the surgery the medical staff is divided in two groups: the part who stays in the periphery of the room who wears just the ordinary technical gowning and the medical staff who stays inside the sterile zone close to the wound. The main elements, which differ the medical staff inside the sterile zone with the staffs outside the LAF, are: two pair of gloves; arms protection; mask, clothing differences. With the aspect just listed, the situation could be dangerous. Furthermore could be possible to talk about the weak characteristic of the LAF technology for personal who break the “tend” entering in the sterile zone bringing inside also the dirtiness collect due to the vortices in the nearby of the LAF system (Section 7.3).
However, the most important elements to underline is the using of the telephone, considering as one of the dirty ordinary object.

9 Conclusions

The amount of data collected has shown that in spite of surrounding conditions, the LAF principle seems to secure high degree of air cleanliness in the surgery area. The ultrafine particles and microbiological concentration measurements indicate that the airflow is not mixed over the surgical and instruments table. The airflow on these areas cannot be considered as fully laminar, due to obstacles and activities which give rise to such a kind of disturbed laminar flow. Furthermore, the large amount of clean air, filtered by HEPA H14 filters, coming from the ceiling and supplied in the clean zone, results as an effective protection against contamination penetration from the nearby area. In the following representation, it is possible to understand the clear separation between the LAF zone, compared with the external mixed zone. The stability inside the sterile area under laminar flow, guarantees that different actions during surgeries with high activity levels, as the orthopaedic type, do not interact and create disturbances inside the sterile zone.

This marked difference between central area and the periphery zone, suggests to avoid the placement of instruments table outside the LAF system area, some measurements experienced in this position confirm that. The only moment when the penetration resistant and the LAF stability is embarrassed is during the medical staff exchange, where the air curtain breakage induces high values of CFU in the sterile area.

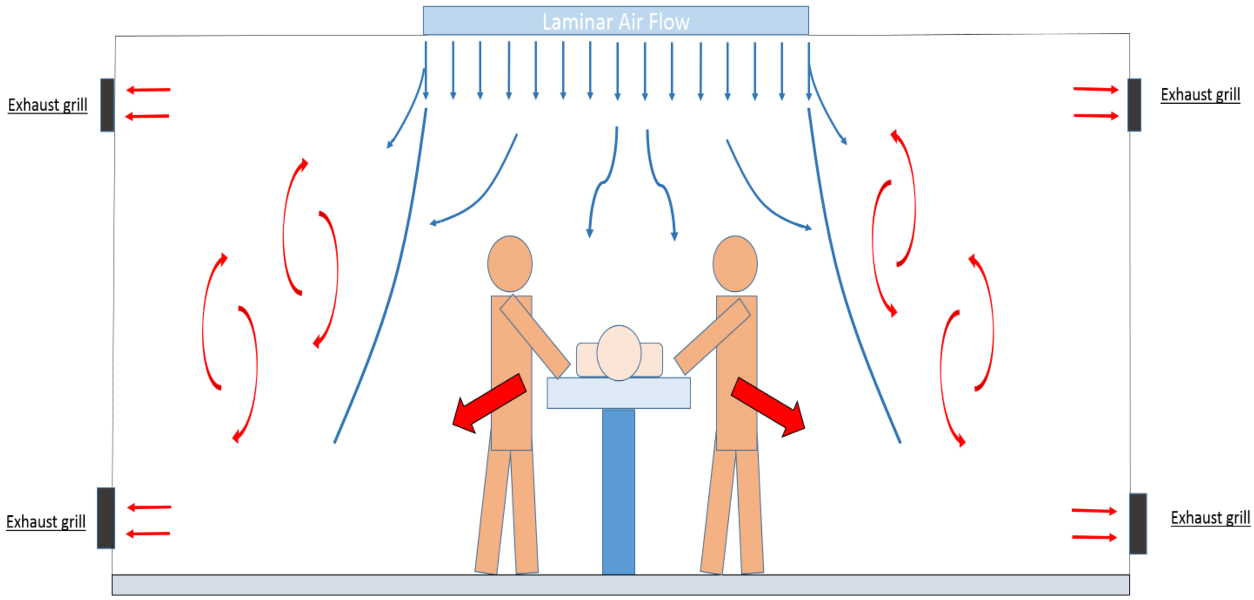


Figure 9.1: Schematic representation of the different zone inside an OT with LAF technology and the system capacity in the sweeping away of dirtiness coming from the medical staffs

Furthermore, the measurements showed no-correlation between the type of technical clothing systems and the concentration of airborne microbiological particles sampled. The measurements were collected inside the sterile zone while the medical staff was wearing less performing technical gowning. This type of technical clothes released higher levels of CFU/s compared with the air clean suit type. The measurements collected showed that the ventilation principle in the room, UDF or laminar system, seems to reduce the influence of the technical clothing systems performance compared with mixed ventilation. The following table resume the CFU/m^3 expected using the equations suggested by Standards' based on the dilution principle and compares these values with the results experienced in this work.

Table 9.1: Comparison between the concentrations of CFU expected in according to the Standards with the level experienced in this work in the sterile zone.

Swedish standard equation	[1]	Netherlands standard equation	[2]	Results of this work
$c = \frac{q_s}{Q} \times n$	[2]	$c = \frac{q_s \times n}{Q \times CRE}$	[3]	$c = \frac{Sum\ of\ all\ the\ CFUs\ samples}{Total\ number\ of\ samples}$
$c = 12{,}8 \frac{CFU}{m^3}$		$c = 6{,}81 \frac{CFU}{m^3}$		$c = 3{,}6 \frac{CFU}{m^3}$

The result emerged from this work inside the OT with LAF technology does not align with the Standards' level predicted. Therefore, the current results highlight how the equations proposed by the Standards are not the optimal tool to predict the level of airborne microbiological concentration in OT with LAF technology.

A second element, which creates a defined distinction between the mixing air ventilation system and the LAF system studied in this work is the sampling position.
The concentration of CFU experienced during this work highlights a significant difference between the sampling locations inside the operating theatre. Indeed, to study the concentration of CFU inside an OT with LAF ventilation, the measurements should be taken in the sterile area (close to the wound and over the instruments table), behind the back of the surgeon and outside of the LAF system at the same level of the samples collected in the sterile zone.

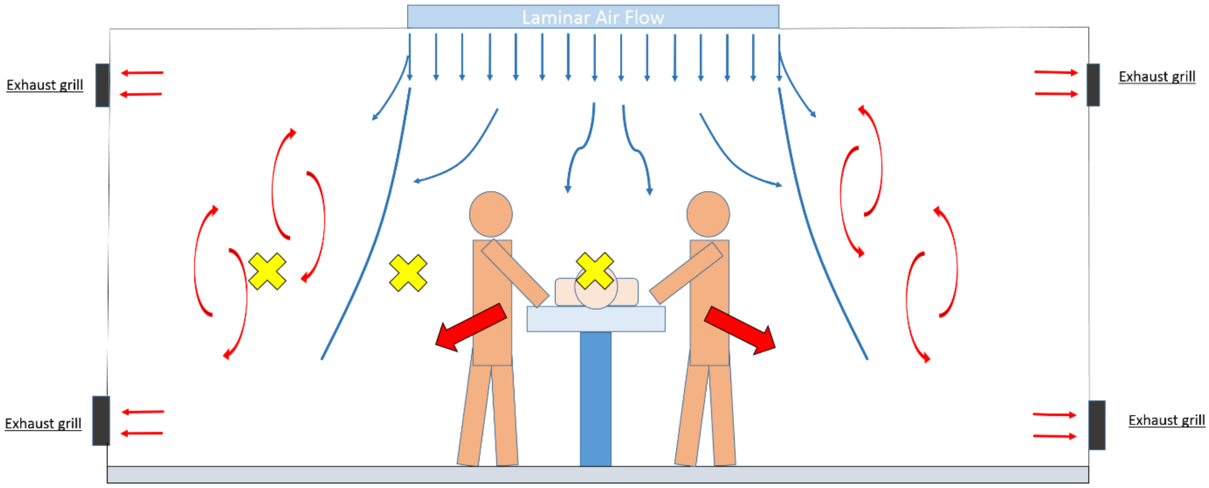


Figure 9.2:Schematic representation of the different sampling positions for an optimal measurements session inside an OT equipped with LAF technology

The experimental results obtained and the knowledge acquired in this work should always be combined with correct advanced medical routines, which have a critical role for the air cleanliness inside the OT with and without UDF system. Namely, an optimal design project is always viable of challenges whenever the medical staff does not comply with clinical medical routine..

10 Future works

The idea for future works could be the collection of a larger amount of samples in the sterile zone, in order to have a statistical contribution to confirm, or not, what was made in this work.

In fact, in literature are not available many numbers of data collected during real surgeries in OT with UDF air technology system. The coloured map (Figure 7.23), which schematically represent the different values of CFU collected inside the OTs, has to be study in deep, mostly understand the microbiological active particles inside the anaesthesia zone and in the areas where the samples were not specifically made. A most detailed study is necessary to understand the personal exchange routines and its consequence for the numbers of microbiological active particles inside the sterile zone. Several operations have to be followed to check this aspect, studying which member of the medical staff has to be changed and which are the consequences close to the wound. The same study could be made regarding the position of the instruments table outside the Laminar Air Flow zone.

As it is possible to notice in the Södertälje Hospital structure, the preparation room has a mixing technology, could be useful to understand more in deep, if there are consequences during the instruments preparation related to this air technology making airborne microbiological concentration samples. Another aspect noticed was the trolleys of surgery instruments inside the sterilization area of Södertälje Hospital, which are not effectively arranged considering the air distribution system design.

Regarding the UFP aspect, the UFP counter are useful because allow to connect actions to reaction. In Sahlgrenska University Hospital, the issue related to the diathermy smoke was faced but the problem was just partially solved. In fact, could be useful to check the UFP behaviour with the turbulent diffusers switched off and with a higher orthopaedic barrier.

The aspects listed are just a little part of the possible aspects ready to be treated, an engineer with some instruments inside this world has an infinite number of study choices.

Swedish legislation (Act 2003:460 (Amended SFS 2008:192)) does not demand ethical permission for this kind of purely observational studies that does not involve patients. However, as mentioned above, informed consent in line with the Declaration of Helsinki was given by all OR participants (World Medical Association, 2013). The head of department gave informed consent carry the study.

Appendix A

Clothing materials in different tests

[68]:Mixed material consisting of 69% cotton, 30% polyester, and 1% carbon fibre. Weight 150 gram per square meter, Polyester material consisting of 99% polyester and 1% carbon fibre. Weight 100 gram per square meter. Polyester material consisting of 99% polyester and 1% carbon fibre. Weight 120 gram per square meter

[67] The reusable scrubs consisted of mixed material: 69% cotton, 30% polyester, and 1% carbon fibre; weight 150 g/m2; washed for w50 times. The material fulfils the requirements for clean air suit according to the standard EN 13795:2011. The single-use scrubs consisted of non-woven spun-bonded polypropylene weight 35 g/m2, antistatic-treated

[69] The common clothing system is of mixed material consisting of 69% cotton, 30% polyester and 1% carbon fibre. The weight is 150 g/m$_2$. The clothing system was evaluated after being laundered up to approximate 50 times. The fabric consists of 98% and 2% carbon fibre. The blouse with cuffs at arms and neck, and trousers with cuffs at the wrists were laundered about 20 times, but not antimicrobial treated. The weight is 125 g/m$_2$. Textile hoods with cuffs at the face and buttons below the chin (laundered about 20 times), sterile disposable face-masks and disinfected gloves were also worn.

Articles related to air clean suit:

(Clean Air Suit improved air quality ($< 10\ CFU/m^3$) even when ordinary ventilation was used in the OR) [67].

Clean Air Suits achieved a CFU concentration (CFU/m^3, mean (SD)) of 11.5 ± 6 and a source strength of $1.15 \pm 0.6\ CFU/s$ under the stated conditions [76].

Clean Air Suits all resulted in a >75% reduction in CFU concentration and a >90% reduction in particles emitted from the test subjects, compared to the mixed cotton/ polyester reusable material [77].

Appendix B

MD8 Air Sampler SARTORIUS Calibration Certificate:

MyAir Test and Validation

Place
Linköping
Organisation unit
MyAir AB
Handled by/I
Per-Erik Karlsson +46 72 503 84 58
per-erik.karlsson@myair.se
Calibrated by
Per-Erik Karlsson

CALIBRATION CERTIFICATE

This calibration is traceable to National and International standards.

Date of calibration	Registration No	Page
2018-12-14	MAL18-157	1(3)

COSTUMER

CRC Medical AB
Datavägen 12A
SE-436 32 Askim, Sweden
Att: Anders Rehn

ORDER

Calibration. (Control and adjustment).

OBJECT

Air sampler Sartorius MD8.
Serial number: 24901612.

EQUIPMENT USED

Equipment	Model	Serial #	Next cal.	Cal. Rep No.
Test chamber	FEV 0400540	Nr. 1-3	-	-
Digitalmultimeter	Fluke 114	93271414	2019-01	1079177-1
Mass Flow meter	TSI 4043	40431710003	2019-03	20180312
Gelatine Plate	Special	-	-	-

DOCUMENTATION

International Standard SS- EN ISO 14698-1.

Postadress/Postal address
My Air AB
Datavägen 12A, 436 32 Askim
Sweden

Besöksadress/Visit
Norra Oskarsgatan 27C
582 73 Linköping
Sweden

F-skatt/Org. no.
556995-1733

Moms nr./VAT no
SE556995-173301

Registration No	Page
MAL18-157	2(3)

MAINTENANCE PERFORMED

Measuring sampling volume.
Check sampling flow.
Measuring sampling time.
Final test.

CALIBRATION RESULTS

Test results given in this report only relate to the items described and registered in the report. See table1.

Table 1 Test Results

Calibration notes	As Found	As Left	Tolerance
Sampling volume/h	5,71	5,71	6,00±5% m^3/h
Temperature RH	22,3 40,5	22,3 40,5	22,0 ±2°C 50±10 RH
Sample time m^3 0,476 0,952	 5,0 10,0	 5,0 10,0	 Minutes, seconds Minutes, seconds

The adjustments have no influence on previous measurements.

CALIBRATION INTERVAL

12 months.

MyAir Test and Validation in Sweden AB

Per-Erik Karlsson

Date: 2018-12-14

AGAR PLATES CERTIFICATION, example of the plates used for the operation followed in Södertälje on the 27/11/18.

Quality Assurance Certificate

1

sartorius stedim

Gelatine Disposables

Bestell-Nr.: / Order-no.: 17528--80----BZD
Stückzahl: / No. of units: 10
Abscheiderate nom.: / Retention rate nom.: 3 µm
Sterilisationsdatum: / Date of sterilization: 07.17
Verfalldatum: / Expiration date: 07.22
Chargen-Nr.: / Lot no.: 17528 170081

82380-000-06

Sartorius Stedim Biotech GmbH 37070 Goettingen Germany

This certifies that the designated product was manufactured by Sartorius Stedim Biotech in accordance with the applicable current Good Manufacturing Practice standards.

This product has been subjected to and has fulfilled Sartorius Stedim Biotech' rigorous quality control standards from the raw material to the final product.

Op Sal 1 27/11
1 platta wound
2 platta floor
3 platta wound

Each manufacturing lot was sampled, tested and released by quality assurance with respect to the following characteristics:

- Sterility
- Performance-Test (Thickness, Air-Flow, Solubility)
- Inhibition-Test
- Growth Test

Details of the methodologies used in each test can be obtained from Sartorius Stedim Biotech GmbH.

QA released sartorius stedim

Dr. Hartmut Hennig
Site Manager QA Filtration Products

Manufactured by
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen, Germany
www.sartorius-stedim.com

S--9063-e150302 · 85037-539-51 · Ver. 03 | 2015

TYPE OF DOCUMENT USED TO TAKE NOTES DURING THE CFU SAMPLING. In this document are noticed, as requested by the Standards, door openingsm number of people inside the OT and how they are dressed, time of sampling and notes about the sampling positions.

CRC medical

Mikrobiologisk luftprovtagning

Uppmätt av:

Uppmätt-/Kontrolldatum: 2018-11-27

Dokumentklass/dokumenttyp: Servicedokument CRC

Bilaga 1

Number of medical staffs with steril technical clothings, mixed multiuse scrub combined with supplementary single use (surgeons and operating nurse) openings in the interval

Number of door openings in the interval

Number of people with just the ordinary mixed scrub suit inside the Operating Theatre

Nota campionamento

CFU concentration received from the LAB

Incision start: 08.37

Startpå suturering/förband: 09:40

Nr 1, sal 1	Starttid	Sluttid	Pat.	Antal dörr-öppningar	Sterilt klädda	Osterilt klädda	Anmärkning provtagning	Anm avläsn	Totalantal cfu per platta	Avläst datum
Referens-platta									<1	
1	08:37			–	3	4	Wound		0	
2	08:48			–	3	4	Floor, the dressing attached 1 time		5	
3	08:59			–	3	4	Wound		1	
4	09:10			3	3	4	Floor		10	
5	09:20			–	3	4	Wound		0	
6	09:30			–	3	4	Floor		17	

Appendix C

Type of Bacterial Typed

Here there is a table with the number of agar plates typed and the results reported by Karolinska Lab through the documents sent (Figure 5.5 page 31):

ID operation	Number of filters: *Total (of which typed)*	Results on the filters typed in CFU/m^3
1	6 (3)	0-1-0
2	7 (4)	4-6-5-7
3	8 (4)	1-0-10-0
4	5 (5)	1-1-0-0-0
5	8 (4)	3-3-0-4
6	6 (6)	3-(a)-1-0-0-0
7	10 (10)	3-3-2-5-2-1-9-0-1-9
8	6 (6)	5-3-0-1-1-3
9	8 (7)	6-16-15-4-9-(b)-10-9
10	6 (6)	13-1-0-3-1-0
11	7 (7)	6-45-15-17-7-12-0
12	4 (0)	-
13	6 (0)	-

(a):sampling not possible; (b): sampling infected

#num.op.	S.E.	S.W.	M.L.	S.C.	S.H.	R.D	S.V.	S.Ha.	M.	Mo.x.	K.R.	S.P.	M.Sp.	K.M.	C.S.	C.A.	C. sp.	m.Fl.	Tot
1	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
2	2	0	9	7	2	2	0	0	0	0	0	0	0	0	0	0	0	0	22
3	1	2	3	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	11
4	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	2
5	1	0	2	5	2	0	0	0	0	0	0	0	0	0	0	0	0	0	10
6	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
7	4	0	5	11	5	0	0	9	1	0	0	0	0	0	0	0	0	0	35
8	4	0	2	0	0	0	0	3	0	1	1	0	0	0	0	0	0	0	11
9	15	0	28	3	5	0	0	0	0	3	6	1	0	0	0	0	0	0	61
10	3	0	3	0	6	0	0	5	0	0	0	0	0	0	0	0	0	0	17
11	0	4	4	4	6	0	0	0	0	0	0	0	0	0	0	0	0	0	18
TOTAL sterile:	35	7	56	35	26	2	1	17	1	4	7	1	0	0	0	0	0	0	192
11bis [6]	3	0	28	0	11	0	0	0	0	0	0	14	11	4	6	3	2	2	84
TOTAL	38	7	84	35	37	2	1	17	1	4	7	15	11	4	6	3	2	2	276

Legend

S.E.=Staphylococcus epidermidis;

S.W.= Staphylococcus warneri;

M.L.= Micrococcus luteus;

S.C.= Staphylococcus capitis;

S.H.= Staphylococcus hominis;

R.D.= Rothia dentocariosa.

S.V.= Streptococcus vestibularis

M.= mold

Mo. : Moraxella

K.R. = Kocuria rhizophila

S.Ha.= Staphilococcus Hameliticus

S.P. = Staphilococcus pettenkoferi

M. Sp.= micrococcus sp.

K.M. = Kocuria Marina

C.S.= Corynebacterium similans

C. A. = Corynebacterium afertmans

C. sp.= Corynebacterium sp

M.F. Micrococcus Flavus

[6] 11 bis: is related to the samples collected over the instruments table outside the LAF ceiling zone. In fact, as specificated previously, the sterile zone in OT equipped with UDF technology has to be consider under the LAF.

Description of the main kind of bacterium detected:

Staphylococcus epidermidis: Staphylococcus epidermidis is a Gram-positive bacterium, and one of over 40 species belonging to the genus Staphylococcus. It is part of the normal human flora, typically the skin flora, and less commonly the mucosal flora [78]. Moreover, it is supplied with a glycocalyx, which allows it to adhere to numerous surfaces including the prostheses, the catheters and the skin itself. Contamination of hip prosthesis is very frequent where it often proliferates. It often has antibiotic resistance [79].

Staphylococcus warneri: Staphylococcus warnery is a Gram-positive bacterium belonging to the genus Staphylococcus. It has spherical cellules which appears in cluster.. Lo S. warneri is presented over the human and animal skin. This bacterium rarely cause diseases, but occasionally could cause infections for patients with compromised immune system.

Micrococcus luteus: M. luteus is found in soil, dust, water and air, and as part of the normal flora of the mammalian skin. The bacterium also colonizes the human mouth, mucosae, oropharynx and upper respiratory tract. M. luteus is considered a contaminant in sick patients and is resistant by slowing of major metabolic processes and induction of unique genes [80].

Staphylococcus capitis: Staphylococcus capitis is a coagulase-negative species (CoNS) of Staphylococcus. It is part of the normal flora of the skin of the human scalp, face, neck, and ears and has been associated with prosthetic valve endocarditis, but is rarely associated with native valve infection. Furthermore, CoNS produce a slimy biofilm enabling them to adhere to medical devices such as prosthetic valves and catheters and makes them difficult to remove by patient immune response to antibiotic therapy. As native flora of the skin and mucous membranes, they may be introduced anytime these are punctured. S. capitis, fortunately, has a lower propensity to antibiotic resistance and produces less biofilm than many other CoNS. This improves chances of successful eradication of S. capitis in per prosthetic infections (as total knee and total hip arthroplasty infections) relative to other CoNS such as S. epidermidis [81].

Staphylococcus hominis: Staphylococcus hominis is a coagulase-negative member of the bacterial genus Staphylococcus, consisting of Gram-positive, spherical cells in clusters. It occurs very commonly as a harmless commensal on human and animal skin and is known for producing thio alcohol compounds that contribute to body odour. Like many other coagulase negative staphylococci, S. hominis may occasionally cause infection in patients whose immune systems are compromised, for example by chemotherapy or predisposing illness Of these species, S. epidermidis and S. hominis are the most abundant. While S. epidermidis tends to colonize the upper part of the body, S. hominis tends to colonize in areas with numerous apocrine glands, such as axillae and the pubic region [82].

Rothia dentocariosa: Rothia dentocariosa (previously known as Stomatococcus mucilaginosus) is a species of Gram-positive, round- to rod-shaped bacteria that is part of the normal community of microbes residing in the mouth and respiratory tract. First isolated from dental caries Rothia dentocariosa is largely benign, but does very rarely cause disease. The most common Rothia infection is endocarditis, typically in people with underlying heart valve disorders [83].

Streptococcus vestibularis: Streptococcus vestibularis is a normal inhabitant of vestibules of the human oral cavity, and it has rarely been associated with human disease except that two cases of infectious endocarditis of the prosthetic valve, early neonatal sepsis and bacterial in both cancer and rheumatic valve disease patients [84].

Staphylococcus aureus: Staphylococcus aureus is a Gram-positive, round-shaped bacterium that is a member of the Firmicutes, and it is a usual member of the microbiota of the body, frequently found in the upper respiratory tract and on the skin [85].

Staphylococcus haemolyticus: is a member of the coagulase-negative staphylococci (CoNS). It is part of the skin flora of humans, and its largest populations are usually found at the axillae, perineum, and inguinal areas. S. haemolyticus also colonizes primates and domestic animals. It is a well-known opportunistic pathogen, and is the second-most frequently isolated CoNS (S. epidermidis is the first). Infections can be localized or systemic, and are often associated with the insertion of medical devices. The highly antibiotic-resistant phenotype and ability to form biofilms make S. haemolyticus a difficult pathogen to treat [86].

Appendix D

Category	BMI (kg/m^2)		BMI Prime	
	from	to	from	to
Very severely underweight		15		0.60
Severely underweight	15	16	0.60	0.64
Underweight	16	18.5	0.64	0.74
Normal (healthy weight)	18.5	25	0.74	1.0
Overweight	25	30	1.0	1.2
Obese Class I (Moderately obese)	30	35	1.2	1.4
Obese Class II (Severely obese)	35	40	1.4	1.6
Obese Class III (Very severely obese)	40	45	1.6	1.8
Obese Class IV (Morbidly Obese)	45	50	1.8	2
Obese Class V (Super Obese)	50	60	2	2.4
Obese Class VI (Hyper Obese)	60		2.4	

Source: Wikipedia [87]

ASA SCORE Table [38].

ASA-Physical Status Class	Definition	Examples, Including, but Not Limited to
I	A normal healthy patient	Healthy, nonsmoking, no or minimal alcohol use
II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to) current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease
III	A patient with severe systemic disease	Substantive functional limitations; one or more moderate to severe diseases. Examples include (but not limited to) poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥ 40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (> 3 months) of MI, CVA, TIA, or CAD/stents
IV	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to) recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARDS, or ESRD not undergoing regularly scheduled dialysis
V	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to) ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
VI	A declared brain-dead patient whose organs are being removed for donor purposes	

The addition of "E" denoted emergency surgery: an emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part.

ARDS = acute respiratory distress syndrome; BMI = body mass index; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; CVA = cerebrovascular accident; DIC = disseminated intravascular coagulation; DM = diabetes mellitus; ESRD = end-stage renal disease; HTN = hypertension; MI = myocardial infarction; PCA = post conceptual age; TIA = transient ischemic attack.

Adapted from https://www.asahq.org/resources/clinical-information/asa-physical-status-classification-system.

List of examples ASA score [38]

Table 2. Correct ASA-Physical Status Classification for Each Case and Comorbidities from ASA-approved Examples

Case Number	ASA-Physical Status Class	Patient's Comorbidities from ASA-approved Examples
1	III	BMI > 40
2	II	Controlled HTN, current smoker
3	III	Poorly controlled DM, controlled HTN
4	II	Mild lung disease (controlled asthma, mild OSA), obesity (30 < BMI < 40)
5	II	Mild lung disease (controlled asthma), controlled DM
6	II	Current smoker, alcohol use
7	III	Controlled HTN, ESRD undergoing regularly scheduled dialysis
8	III	Obesity (30 < BMI < 40), controlled HTN, history of MI, COPD, poorly controlled DM, ESRD undergoing regularly scheduled dialysis
9	II	Obesity (30 < BMI < 40), controlled HTN
10	I	Healthy 81 yr old

BMI = body mass index; COPD = chronic obstructive pulmonary disease; DM = diabetes mellitus; ESRD = end-stage renal disease; HTN = hypertension; MI = myocardial infarction; OSA = obstructive sleep apnea.

Appendix E

Definitions:

Recovery time: the 100:1 recovery time is defined as the time [that the system] required for decreasing the initial concentration [of particles] by a factor of 0,01 times

Definition taken by EN ISO 14644-3:2005

CFU (Colony Forming Unit): a small particle that contains bacteria forming a colony of growth when applied to a culturing medium.

OT: Operating Theatres

pp – pt = particles

cc – cm^3= cubic centimetre

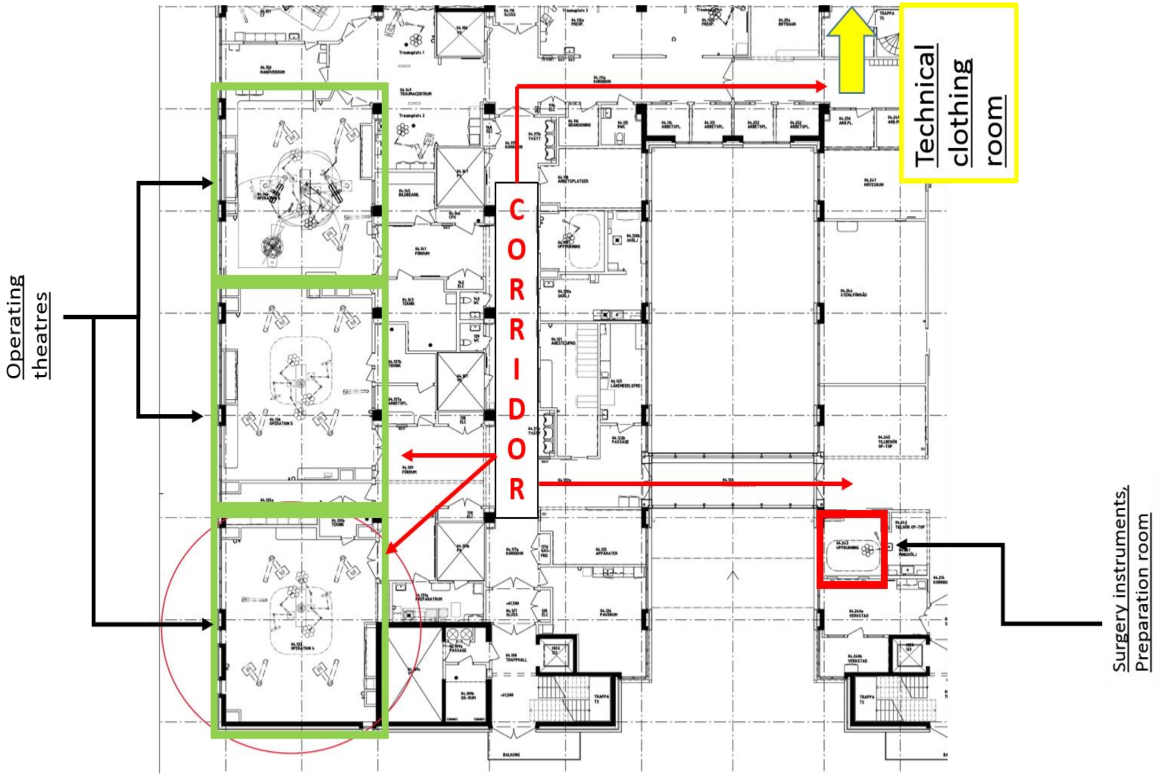
UFP = Ultrafine Particles

UDF= Unidirectional Flow

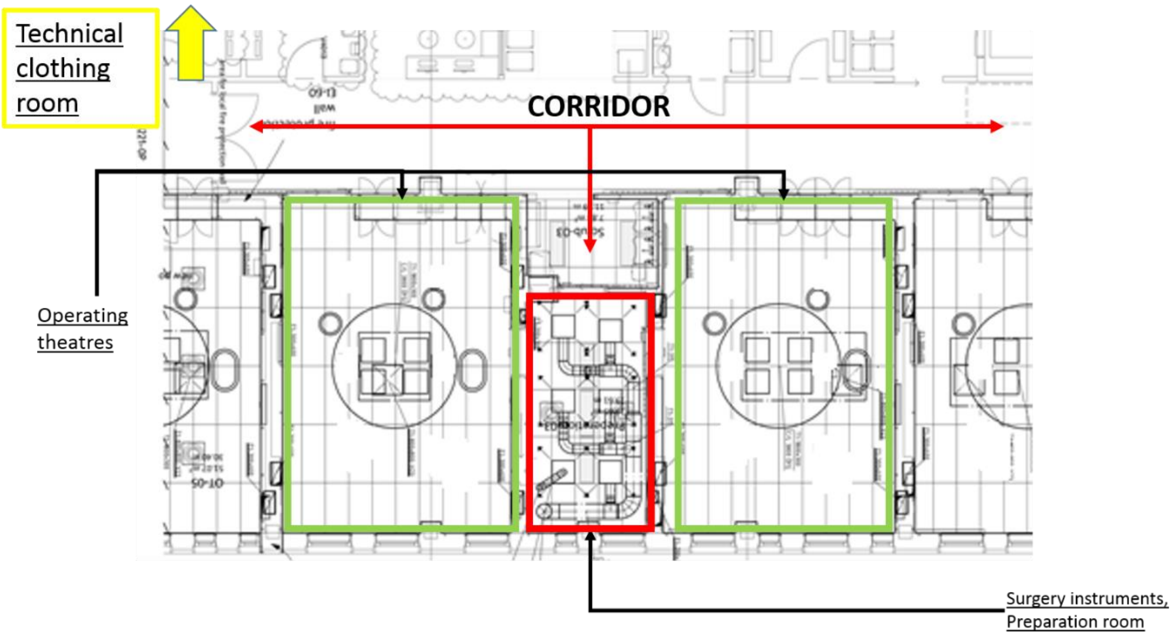
LAF= Laminar Airflow

Appendix F

Operating theatres plant: Sahlgrenska University Hospital, Göteborg



Operating theatres plant: Södertälje Hospital



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