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Air contamination control in Hybrid operating theatres.  
Particle content during different types of surgery with focus on diathermy

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## Preface

The main topic of this Master Thesis is the measurement of non-viable particle concentrations during several types of surgeries inside an Hybrid Operating Theatre. The focus is primarily on the use of electrosurgical instruments based on diathermy, which are supposed to considerably affect the concentration and distribution of airborne particles inside operating rooms, thus leading to a lower level of air cleanliness due to the generation of surgical smoke.

The research work was carried out between September 2013 and March 2014. It is worth noting that this study was possible thanks to the european connection between Politecnico di Milano and Chalmers University of Technology. In particular, both the Italian Dipartimento di Energia and the Swedish department of Energy and Environment are working on similar topics and with the same scientific viewpoint in the field of air conditioning and systems for controlled contamination environments.

The measurement campaign was performed at the Sahlgrenska University Hospital of Gothenburg, Sweden within the framework of a previously established collaboration with the division of Building Service Engineering from the Department of Energy and Environment of Chalmers University of Technology.

A special thanks goes to Christina Ekroth and to the whole personnel of the Operation Ward 2 at Sahlgrenska University Hospital of Gothenburg, Sweden for the helpfulness and support provided during measurements, and especially for the care shown throughout every phase of the research process.

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## Abstract

Air cleanliness in operating rooms is an important goal in order to preserve both the patient's and the medical staff's health. Particle contamination inside an Operating Theatre (OT) is supposed to depend mainly on the surgery process, clothing system and personnel routines. However, during open surgeries, a significant airborne contaminant load is given by the release of surgical smoke from electrosurgical tools. This is a work environment problem because of the smell and the risk for health consequences. Ordinary surgical masks are inadequate for filtering these ultrafine particles, emitted when using electrosurgical tools, due to their small size. This study is based on the analysis of airborne particle concentrations, obtained during a measurement campaign carried out at Sahlgrenska University Hospital of Gothenburg, Sweden in the new built Hybrid OT. The measurements were performed continuously for 18 operations. The OT comprises X-ray scanner while the air is supplied with a unidirectional vertical air flow by a ceiling equipped with H14 HEPA filters. Due to the air diffusion principle, surgical smoke may represent an health hazard in every part of the room. A data analysis was conducted between different kinds of surgeries, such as endovascular surgeries or open surgeries, taking into account valuable info about number of people inside operating room, door openings and clothing system adopted. The measurements were carried out with two optical particle counters and two ultrafine particle counters. Results revealed a strict connection between the use of electrosurgical tools and the increase of particles concentration near surgical area due to the surgical smoke motion from the operating table to the other part of the Hybrid operating theatre. Furthermore, the data analysis highlighted that, during activities which require an extremely clean environment such as open surgeries because of the massive use of electrosurgical tools, a part of the ultrafine particles flow back in the clean zone via the recirculation air system. The reintroduction of ultrafine particles can be motivated by the low air filter efficiency at low size range.

**Keywords:** Contamination control, Ultrafine particles, Airborne Particles, Electrosurgical instruments, Surgical smoke, Hybrid Operating Theatre









## Sommar

La pulizia dell'aria all'interno delle sale operatorie è uno dei requisiti fondamentali nella salvaguardia della salute sia dei pazienti sia del personale medico stesso. La contaminazione particolata dell'aria in questi locali dipende da diversi fattori, legati principalmente all'attività operatoria, agli indumenti utilizzati, ai movimenti del personale e al paziente stesso. Più nello specifico, le principali fonti di contaminazione presenti sono la flora batterica endogena del paziente e quella esogena della sala stessa, emessa per lo più dallo staff chirurgico. Inoltre, durante le operazioni di chirurgia invasiva, l'utilizzo di strumenti elettrochirurgici gioca un ruolo fondamentale in termini di generazione di particolato.

L'elettrochirurgia, infatti, è una tecnica chirurgica che si basa sull'utilizzo della corrente elettrica alternata ad alta frequenza direttamente sul tessuto biologico con effetto termico, in modo da ottenere un taglio oppure un coagulo. Questa particolare tecnica genera in larga misura il cosiddetto "fumo chirurgico", (surgical smoke in anglosassone) che, oltre a produrre un cattivo odore all'interno della sala operatoria, è stato dimostrato provocare problemi alla salute del personale chirurgico, così come aumentare il rischio di infezioni per il paziente stesso.

Questo studio si basa sull'analisi delle misure di contaminazione particolata non biologica condotte presso il Sahlgrenska University Hospital di Göteborg, in Svezia, all'interno di una sala operatoria ibrida di nuova concezione, dove gli stessi strumenti elettrochirurgici sono utilizzati durante operazioni di tipo invasivo. Le conte di particolato sono state realizzate in maniera continuativa per l'intera durata di 18 operazioni chirurgiche di varia natura, a queste si aggiungono altre attività di rilevazione e analisi a sala vuota, per un totale di circa 90 ore di misura.

Nella prima parte di questo lavoro verranno introdotti gli aspetti fondamentali della ricerca. Sarà inoltre fornita una valutazione preliminare dei problemi di salute riscontrati in seguito alla prolungata respirazione del fumo chirurgico quali enfisemi, asma, bronchiti croniche, dermatiti, irritazioni agli occhi e mal di testa etc. Ulteriori ricerche risultano necessarie per confermare i potenziali danni alla salute per il personale stesso. A tal proposito, è di fondamentale importanza l'analisi delle dimensioni delle particelle generate dai vari strumenti elettrochirurgici. Questi strumenti si basano su diversi principi di funzionamento, come ad esempio la diatermia con generazione di particelle di

dimensioni che oscillano in media tra 0.007  $\mu\text{m}$  e 0.42  $\mu\text{m}$ , oppure apparecchi ultrasonici che producono particelle nell'intervallo di grandezza compreso tra 0.35 e 6.5  $\mu\text{m}$ .

Il problema messo in luce da tali osservazioni ricorrente è l'inefficienza delle mascherine chirurgiche in termini di filtrazione di queste particelle ultra-fini. In altre parole, si è rilevato che le stesse mascherine sono ottimi sistemi filtranti solo ed esclusivamente per particelle con dimensioni maggiori a 5  $\mu\text{m}$ . Da questo dettaglio tecnico deriva l'importanza di valutare le concentrazioni particellari rappresentative durante l'utilizzo di questi strumenti.

Una volta presentate queste prime valutazioni, si passa alla descrizione delle caratteristiche generali delle sale operatorie ibride nelle loro peculiarità costruttive e impiantistiche. Queste sale, infatti, possiedono una tecnologia diagnostica elevatissima grazie a sistemi angiografici (scanner X-ray) installati nella sala operatoria stessa che permettono l'integrazione delle funzioni diagnostiche e terapeutiche. Data l'avanguardia tecnologica delle attrezzature, la sala operatoria ibrida è utilizzata in compartecipazione da diversi reparti ed è caratterizzata dalla presenza di un team multidisciplinare durante gli interventi chirurgici.

In seguito, verrà descritta in dettaglio la sala operatoria ibrida del Sahlgrenska University Hospital, focalizzando l'attenzione sulle attrezzature e sulla routine operatoria a livello di comportamenti e vestizione dello staff chirurgico. A tal proposito, merita una particolare considerazione il riferimento e la descrizione dell'impianto HVAC (Heating, Ventilation and Air Conditioning) che, grazie all'utilizzo di filtri H14 HEPA (High Efficiency Particulate Air filters), garantisce alti livelli di qualità dell'aria in termini di filtrazione particellare. Inoltre tale impianto assicura un flusso unidirezionale dell'aria dal soffitto verso il basso, che permette la pulizia della zona chirurgica dalle particelle generate durante le operazioni. Risulta anche degno di nota l'utilizzo di un sistema di ricircolo dell'aria che entra in conflitto con le elevate concentrazioni di particelle emesse durante l'impiego degli strumenti elettrochirurgici.

Successivamente verranno presentati gli strumenti di misura particellare usati durante la campagna di misure: due contatori di particelle ultra-fini e due OPC (Optical Particle Counter). I primi strumenti misurano la concentrazione totale delle particelle le cui dimensioni oscillano tra 0.02 e 1  $\mu\text{m}$ , range tipico delle particelle ultra-fini. Gli OPC, invece, registrano le concentrazioni cumulate di particelle con dimensioni maggiori di 0.5  $\mu\text{m}$  e di 5  $\mu\text{m}$ .

Si passa poi all'esposizione delle valutazioni statistiche effettuate sui dati di una precedente tesi sullo stesso argomento, da cui è stato possibile ricavare importanti risultati che permettono di motivare la scelta delle posizioni adottate

per le misurazioni realizzate all'interno di questo lavoro di tesi. Inoltre, verranno elencate le date delle misurazioni e le caratteristiche del foglio Excel progettato ad hoc per questa campagna di misure che ha consentito di rilevare i dati relativi al numero delle persone nonché all'apertura delle porte, nei periodi in cui gli strumenti elettrochirurgici erano in funzione. I valori così ottenuti hanno permesso di completare le misure particellari realizzate durante le operazioni con dati sulle attività della sala operatoria.

Le concentrazioni rilevate durante le misure nella sala operatoria ibrida in condizioni simili a quelle di riposo (at rest), caratterizzata dalla presenza di due operatori all'interno, hanno reso possibile la classificazione della pulizia dell'aria nella sala operatoria seguendo le procedure suggerite dalla norma ISO 14644-1:2001. Tali dati confermano che i valori di concentrazione particellare non superano i limiti dettati dalla norma per le sale operatorie, infatti almeno la classe di pulizia ISO 5 risulta soddisfatta.

Gli interventi chirurgici seguiti per tale studio sono di due tipi: endovascolare e a cielo aperto (invasivi). Del primo gruppo fanno parte le EVAR (riparazioni endovascolari dell'aneurisma), operazioni caratterizzate da un livello minimo di invasività e realizzate grazie all'utilizzo dello scanner a raggi X che consente la visualizzazione delle parti interne del corpo del paziente per il corretto posizionamento dello stent. Invece, per quanto riguarda gli interventi a cielo aperto (invasivi), il campione di analisi comprende alcune operazioni di ortopedia, in particolare fusioni spinali, e una operazione di resezione del fegato. In questi casi, lo scanner a raggi X è stato usato solo per le procedure ortopediche relative alla diagnosi iniziale e per il controllo del risultato finale dell'operazione.

I dati raccolti con il foglio Excel hanno permesso di effettuare alcuni utili confronti tra le operazioni endovascolari e a cielo aperto. La durata dei due tipi di operazione non può essere utilizzata come indicatore di differenza. Tuttavia, tramite la valutazione del numero medio di persone durante il periodo operatorio, sono stati riscontrati dei valori maggiori nel caso delle operazioni endovascolari, dovuti al team multidisciplinare richiesto. È possibile osservare lo stesso trend prendendo in considerazione la frequenza di apertura della porta di ingresso della sala operatoria ibrida, che risulta maggiore per le operazioni endovascolari rispetto a quelle a cielo aperto. Inoltre, sono state rilevate delle differenze a livello di abbigliamento tecnico dello staff chirurgico. Tutto il personale, durante le operazioni endovascolari, indossa gli stessi indumenti che caratterizzano l'intero staff ospedaliero. Al contrario, durante le operazioni a cielo aperto in generale viene riposta maggiore attenzione all'abbigliamento adottato, i cui capi sono fatti di un materiale particolare, volto a limitare la

dispersione particellare, e si richiede a tutto il personale medico di indossare le mascherine chirurgiche.

Dall'analisi di questi dati risulta evidente che le operazioni a cielo aperto (invasive) sono maggiormente protette, a causa del minor numero di persone nella sala ibrida, e della minore frequenza di apertura delle porte, in modo da limitare la contaminazione interna e l'ingresso di particelle. Le suddette valutazioni confermano in altre parole una attenzione maggiore alla pulizia interna della sala dovuta al maggior rischio di infezione per il paziente. D'altro canto, la natura stessa delle operazioni endovascolari, che sono meno invasive, implica un'attenzione inferiore sia al contenimento del numero delle persone, e delle aperture della porta, sia alla qualità del vestiario tecnico.

Nonostante la maggiore cura riscontrata nel mantenere un elevato livello di pulizia all'interno della sala operatoria ibrida durante operazioni a cielo aperto le concentrazioni particellari rilevate tra la zona chirurgica e le griglie di ripresa dell'aria, all'altezza di 1.5 m dal pavimento, presentano valori più alti rispetto alle operazioni endovascolari. La causa di tali risultati imprevisti può essere associata unicamente all'uso degli strumenti elettrochirurgici e la conseguente generazione di fumo chirurgico. I dati medi relativi alle operazioni a cielo aperto risultano maggiori sia per particelle di dimensioni  $\geq 0.5 \mu\text{m}$ , e  $\geq 5 \mu\text{m}$ , che per particelle ultra-fini nell'intervallo 0.02-1  $\mu\text{m}$ .

La ricerca di dati significativi in merito al fumo chirurgico è partita dall'analisi delle concentrazioni particellari generate dagli strumenti elettrochirurgici a 5-8 cm dalla punta dello strumento. Queste misure sono state possibili solo durante una operazione simulata su di un fegato di vitello, dove i vari strumenti sono stati utilizzati a rotazione, campionando le particelle generate durante tale pratica. I dati hanno dimostrato maggiori concentrazioni durante l'uso di strumenti chirurgici basati sul principio della diatermia.

Una seconda operazione simulata è stata realizzata al fine di indagare la reintroduzione di particelle ultra-fini dai filtri attraverso il sistema di ricircolo dell'aria. In tal caso si è nuovamente lavorato su di un fegato di vitello per simulare l'utilizzo degli strumenti elettrochirurgici. Ulteriore scopo della simulazione è stato quello di indagare le concentrazioni di particelle ultra-fini che raggiungono il chirurgo durante le fasi di un'operazione. La reintroduzione di particelle ultra-fini è stata confermata durante questa procedura e in aggiunta è stato osservato che le particelle che raggiungono la zona della testa del chirurgo arrivano direttamente dal soffitto filtrante grazie al flusso unidirezionale discendente dell'aria anziché dallo strumento. Questo testimonia la potenziale pericolosità dell'ingresso di queste particelle ultra-fini dai filtri HEPA posti sopra la zona chirurgica, grazie al sistema HVAC che ricircola aria proveniente dalla sala stessa durante l'uso degli strumenti elettrochirurgici che

generano fumo chirurgico. Le maggiori concentrazioni rilevate in questo caso confermano gli stessi dati della precedente simulazione.

In conseguenza a questi risultati si è voluto indagare approfonditamente quali fossero le concentrazioni delle particelle ultra-fini disperse durante le reali operazioni invasive. Durante tali interventi sono stati confrontati i dati relativi alle concentrazioni rilevate in prossimità della zona chirurgica e quelli raccolti a 20 cm sotto filtro nella zona chirurgica, al fine di verificare se tramite il sistema di ricircolo si verifica una reintroduzione di particelle nella zona pulita attraverso il soffitto filtrante posto sopra il letto operatorio. Inoltre, la rilevazione di particelle ultra-fini è stata messa a confronto con la generazione delle stesse tramite l'uso degli strumenti elettrochirurgici, mettendone in luce una stretta correlazione.

Il dato principale derivante da questo studio è la presenza di particelle ultra-fini nella zona chirurgica a valle dei filtri HEPA, i quali non riescono ad arrestare la totalità di questo tipo di particelle che rientrano dal sistema di ricircolo dell'aria. Tale problema può essere associato alle peculiarità intrinseche dei filtri, che hanno un MPPS (Most Penetrating Particle Size) - la dimensione delle particelle per le quali l'efficienza è minore - nell'intervallo 0.12-0.25  $\mu\text{m}$ , pari proprio alle dimensioni caratteristiche del fumo chirurgico. Ciò implica un potenziale rischio per la salute del personale chirurgico che, come già anticipato, non è in grado di proteggersi dalla inalazione di queste particelle.

I dati raccolti in riferimento alle particelle ultra-fini sotto filtro hanno evidenziato, inoltre, dei picchi in corrispondenza degli stessi massimi rilevati vicino alla zona chirurgica parallelamente ad un uso massiccio degli strumenti elettrochirurgici, e ciò conferma ulteriormente la tesi che la presenza di queste particelle sia da attribuire direttamente all'uso di tali strumenti, e non ad altri fattori.

Studi più approfonditi volti all'indagine della natura microbiologica di queste particelle e della loro pericolosità risultano più che mai necessari al fine di confermare il rischio di problemi di salute per il personale medico, derivanti dall'inalazione del fumo chirurgico. Questione peraltro molto delicata e dibattuta negli ambienti ospedalieri. Inoltre, si palesa l'utilità di testare l'efficienza di filtri maggiormente performanti per verificarne la migliore azione filtrante nei confronti del fumo chirurgico.

**Parole Chiave:** Controllo della contaminazione particellare, Particelle Ultra-fini, Particolato, Strumenti elettrochirurgici, Fumo chirurgico, Sala operatoria ibrida.



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# 1 Introduction

## 1.1 Purpose

Operating rooms are very clean environments and a lot of studies were performed to confirm that. Moreover, the cleaning operations and the use of clean clothes by the personnel play a primary function keeping a proper level of cleanliness. However the most important role to maintain a good cleanliness in operating rooms belongs to the ventilation system. The main aim of the ventilation system is to sweep away all the airborne contaminant particles spread by personnel movements and surgical procedures.

The purpose of this work is to measure and analyse particle concentrations inside the Hybrid OT (Operating Theatre) at the Sahlgrenska University Hospital of Gothenburg, Sweden in order to be able to improve the safeguarding of the surgical staff's and patients' health. The feature of such project is that particle measurements were performed continuously during ongoing operations.

The Site Surgical Infection risk is a key concept during the design process of the ventilation system in an operating room. However, the principal focus of this work is on the occupational problems related to the presence of surgical smoke inside operating rooms and how to preserve surgical personnel's health.

There is a general consensus in hospital environments, where surgeons and nurses are worried about the surgical smoke contamination, in relation to their unsecure exposure to these ultrafine particles spread during the use of electro surgical tools, commonly called diathermy tools. In addition, it is fundamental for the surgical staff to know whether the use of these instruments actually affects the air quality, thus increasing the risk of infections and health risk hazards.

The principle idea of this work is to follow the prescriptions of the Swedish technical specification SIS-TS 39:2012 [1] about prevention of airborne contamination in operating room environments which state that "The outdoor air flow must ensure a good air quality with acceptable contamination levels. Consideration must be given to the number of people, usage and management of non-microbiological contaminants (such as anaesthetic gases and diathermy smoke), the use of equipment and the maintenance of positive pressure with respect to adjacent rooms".

Owing to these, this work is focused on the experimental measure of airborne particle concentrations generated within the Hybrid OT under different scenarios, in order to compare the production and the spread of contaminants during different types of operations.

The airborne particle concentrations were measured with two OPCs (Optical Particle Counter) and two Ultrafine Particle Counters (UPC). The measurements of particle concentrations were completed by the recording of the number of people, the door openings and the use of electrosurgical tools during the different operations involved, as suggested by the Swedish technical specification [1] as already mentioned.

The data were collected during different types of ongoing surgeries, for example orthopaedic surgery, endovascular aortic repair (EVAR) and liver resection performed inside the Hybrid OT. In addition, the analysis included the experimental measurements performed inside the empty operating room, which allowed to assess the concentrations of particles in absence of particle sources.

Moreover, a more detailed evaluation on the concentration of ultrafine particles was undertaken in the case of open surgeries, which require a massive use of the electrosurgical instruments.

It follows, a detailed evaluation of the air movement inside the environment, that lead to the understanding of surgical smoke motion which is swept away by the supply air.

Afterwards, a measurement was performed about the local particle source during simulated surgery on a calf liver, that revealed higher ultrafine concentrations during the use of monopolar diathermy, argon diathermy and ultrasonic device than bipolar diathermy.

These values are confirmed during another simulated surgery on a calf liver, where the presence of ultrafine particles was revealed in the air coming from the H14 HEPA filters due to the use of the same surgical instruments. It was also shown that the ultrafine particles breathed by surgeons comes only from the recirculation system.

Moreover, part of the reintroduction of the potentially harmful surgical smoke, generated by such electrosurgical procedures, were detected and reported during real open surgeries. Results were in line with the outcomes of the simulations characterized by similar proportions among different particle concentrations detected.

Finally, it is important to highlight that the measurement results were not evaluated from a medical point of view.



## 1.2 Method

The Master Thesis work hereinafter proposed is organized in 5 chapters.

Chapter 1 gives a general description of the research work undertaken as well as of the problems related to the surgical smoke.

Chapter 2 presents a general overview of the characteristic of hybrid operating rooms, followed by a detailed description of the Hybrid OT at Sahlgrenska University Hospital – that is where the experimental measurements were carried out. The report mainly focuses on the technical equipment, the medical activities and the clothing system, and finally concentrates on the ventilation system that supplies air to the OT.

Chapter 3 deals with the description of the airborne particle counters adopted for measurements. Later, it is possible to examine the statistical analysis of rough data concerning the previous study, which was important to plan and optimise the new measurement campaign showed in this work. After that, the characteristics of the measurement campaign are outlined, including all details about the positioning of the instruments and the working strategy.

Chapter 4 initially introduces a sort of classification of the air cleanliness of the Hybrid OT, which followed the rules defined by the standard ISO 14644-1:2001. Then, the chapter offers an exhaustive discussion of the typical characteristics of the different operations in relation with the clothing system, the number of people inside the OT and the frequency of door openings. Moreover, it shows and analyses the particle concentration related to the three different kinds of operations attended, namely endovascular aortic repair (EVAR), liver resection and orthopaedic surgery. Particular attention is reserved to the use of electrosurgical instruments and their influence on the inert particles concentrations.

In Chapter 5 a special focus is provided on the presence of ultrafine particles during liver resection and orthopaedic surgery, in which the electrosurgical instruments are profusely used. Two simulated operations on a calf liver were performed, the first one was carried out in order to measure the different sources of particles spread during the use of these tools, the second to delineate the ultrafine particle concentrations of the supplied to the surgical area with the unidirectional air flow from the ceiling, which revealed the presence of ultrafine particles flowing back through the recirculation air system. These outcomes were confirmed by various measurements during real surgeries. The presence of these ultrafine particles can be considered a work environment problem due to the risk for personnel's and patient's health.

### 1.3 Previous work

This study starts from the previous evaluations of Nilsson and Lundblad, collected and explained in their Master of Science Thesis titled “Diathermy and airborne particles in operating rooms”[2]. Their data were useful to plan the new measuring campaign shown in this Master Thesis work.

Their research was carried out at the Sahlgrenska University Hospital of Gothenburg, Sweden and it was focused on the inspection of particle contamination in operating rooms. These authors collected data from several measuring points in the operating theatre and compared the different values obtained in order to determine which correlations existed between particle concentration and the operating instruments used by surgeons, like monopolar diathermy, bipolar diathermy, argon diathermy and ultrasonic devices. They carried out measurements in different operating theatres, equipped with two different types of ventilation: the conventional ventilation and the unidirectional air flow from the ceiling. The main conclusions of the abovementioned authors were:

- With conventional ventilation the operating staff is exposed to higher particle concentration compared with unidirectional one.
- The largest mean concentration was reached during the usage of argon diathermy
- Ultrafine particles (0,02  $\mu\text{m}$  – 1  $\mu\text{m}$ ) do not seem to be affected by door openings and the number of people inside the operating room
- In the surgical zone the mean concentration of particles is about twice as high as the other areas

This preliminary analysis was essential to understand the better cleaning action of unidirectional air flow compared to the conventional one. The observation of the measuring technique previously adopted was necessary to design a new efficient measurement system inside the operating room supplied by the unidirectional air flow. In effect, the rough data of the above-mentioned evaluations allowed to develop a preliminary statistical analysis related to particle concentration inside an Hybrid OT – here presented in Chapter 3. As a result, the collection of different statistical information was supposed to represent a valuable starting point for the preparation of the new measurement campaign performed inside the Hybrid OT.

Such research project can be consider unique due to its specific goal, which consists in detecting the airborne particle concentration during ongoing surgeries. Unfortunately, as a matter of fact, documentation on this topic is rather poor, since it cannot be assumed as a standard procedure.

## 1.4 Problem

Inside hospitals, one of the most sterile environments to find are operating rooms. Such rooms are expected to be clean, firstly, in order to prevent patients from being infected and, secondly, to preserve also the personnel health. Moreover, the ventilation system plays a principal role inside them, thus guaranteeing fresh and filtered air to keep the right environmental conditions in terms of indoor comfort and contamination control. In the normal practice the main causes of particle contamination in operating theatres are personnel and surgical procedures.

### 1.4.1 People as a contamination source

As state by Mangram et al [3], the microbial level in an operating room is proportional to the number of people inside. Moreover, the personnel movements are likely to increase the presence of skin debris, lint and respiratory droplets. As a result, during any kind of operation the staff movements should be minimized to avoid the spread of particles and the consequent rise in the risk of SSI (Surgical Site Infection). Furthermore, the authors state that the personnel technical clothing can limit the spread of microorganisms from hair, skin and mucous membranes. Their evaluations came from clinical studies which assessed the correlation between the personnel garments and the SSI risk. Therefore, it is important to underline the importance of using protective barriers, on the one hand, to reduce the patient's exposure and, on the other hand, to safeguard the surgical staff from the contact with blood and blood borne pathogens carried together with airborne particles.

### 1.4.2 Surgical procedures

During an operation, the surgeon usually uses a lot of different tools. Some of these medical devices release surgical smoke, which is a gaseous by-product coming out of the burnt tissue. These instruments are, for example, electro cautery, laser and ultrasonic devices, which generate potentially dangerous contaminating airborne particles of different sizes – that are likely to create problems for the surgical staff. As mentioned by Ulmer [4], electro cauterization is responsible for the production of the smallest and most harmful particles, with the mean aerodynamic size around  $0.07\ \mu\text{m}$ , which may easily penetrate the standard surgical masks.

On the other hand, electrosurgical laser-based tools ( $0.31\ \mu\text{m}$ ) and ultrasonic devices ( $0.35\text{-}6.5\ \mu\text{m}$ ) generate particles with larger sizes, which can be filtered

and stopped without difficulty by surgical masks. Almost equal values in terms of particle sizes are analysed by Alp et al [5].

Additionally, the dimension ranges of particles already presented are confirmed by the work of Fan et al [6] with similar outcomes. According to these authors, particle sizes range between 0.007  $\mu\text{m}$  and 0.42  $\mu\text{m}$  in the case of electro cautery instruments, between 0.1  $\mu\text{m}$  and 0.8  $\mu\text{m}$  with laser devices and, finally, between 0.35  $\mu\text{m}$  and 6.5  $\mu\text{m}$  in the case of ultrasonic scalpels.

Furthermore, Ulmer [4] states that the surgical smoke is composed of 95% water and steam and 5% cellular debris. Obviously, water and steam are supposed to be harmless for human health. On the contrary, the cellular debris are potentially hazardous due to their main chemical composition of acetonitrile and benzene. On the same subject, Barrett and Garber [7] specify that the main chemicals in the electro cautery smoke are hydrocarbons, nitriles, fatty acids and phenols. These harmful substances and all the others contained in surgical smoke could bring about many different kinds of diseases. In particular, the most frequent long-term diseases are acute and chronic inflammatory respiratory changes, such as emphysema, asthma and chronic bronchitis, whereas the short-term ones are dermatitis, eye irritation and headache.

A more detailed description is available in the study carried out by Alp et al.[5], which provides a list of the main risks related to surgical smoke, that can be summarized in Table 1.1.

*Table 1.1. Risks of surgical smoke (Alp et al.[5])*

<b>Acute and chronic inflammatory changes in respiratory tract (emphysema, asthma, chronic bronchitis)</b>
<b>Hypoxia/dizziness</b>
<b>Eye irritation</b>
<b>Nausea/vomiting</b>
<b>Headache</b>
<b>Sneezing</b>
<b>Weakness</b>
<b>Light-headedness</b>
<b>Carcinoma</b>
<b>Dermatitis</b>
<b>Cardiovascular dysfunction</b>
<b>Throat irritation</b>
<b>Lacrimation</b>
<b>Colic</b>
<b>Anxiety</b>
<b>Anaemia</b>
<b>Leukaemia</b>
<b>Nasopharyngeal lesions</b>
<b>Human immunodeficiency virus</b>

The main protection from inhaling the surgical smoke is supposed to be offered by medical face masks. Several studies confirm that ordinary surgical masks are efficiently filter particles with a size of 5  $\mu\text{m}$  or more, as shown in Figure 1.1. However, the particles spread by electro cautery are smaller, which allows them to pass; therefore the ordinary mask's protective purpose is not achieved [7].

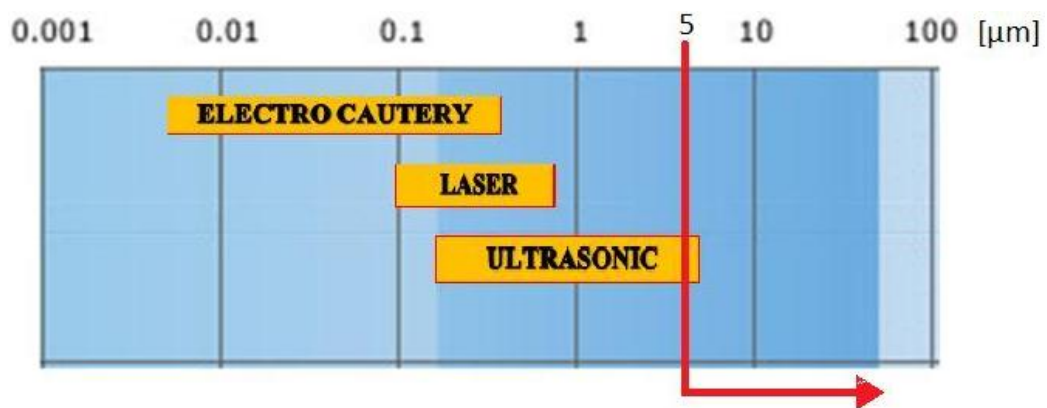


Figure 1.1. Characteristic sizes of particles generated by the use of electro cautery, laser and ultrasonic devices. These particles are too small to be filtered by ordinary surgical masks, which are able to block only particles  $\geq 5 \mu\text{m}$ .

As a result, it is necessary to evacuate the smoke near the site of generation, due to the difficulty in filtering it once it is spread. To this end, the authors suggest the use of a suction device at a distance of 3-4 cm from the blade of the instrument. Nevertheless, the wearing of the mask is compulsory, and sometimes it is better to use a double mask, besides keeping oneself as far as possible from the smoke plume.

To sum up, surgical smoke is likely to be harmful especially for surgeons and nurses. Therefore, they are required to be aware of the risks, in order to take the proper precautions to preserve their health.

## 1.5 Limitations

The particle analysis has been conducted on total concentrations of airborne particles without any distinction between viable and non-viable contaminants. It means that the results are not univocally related to an actual risk of infection for the patients [8].









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## 2 The Hybrid Operating Theatre

The main purpose of this chapter is to describe the main characteristics of hybrid operating rooms with a special focus on the one located within Sahlgrenska University Hospital of Gothenburg, Sweden where the measurement campaign was carried out.

The importance of this Chapter is to describe the technical features and procedures inside the operating room in order to be able to interpret better the results about inert particle contamination. The close connections and interferences between surgical procedures and the ventilation system which aims to maintain the supply air clean will be fundamental in this work

Chapter 2 is divided in two parts:

- A general overview of the features of hybrid operating rooms in terms of planning process, typical size, equipment, ventilation system and building costs
- An accurate description of the procedures and characteristics of the Hybrid OT inside Sahlgrenska University Hospital of Gothenburg, Sweden

## 2.1 General features of hybrid operating theatres

### 2.1.1 Definition

In scientific literature related with new medical technologies, it is possible to find a great variety of definitions of the hybrid procedures, which include all the specific operations carried out inside the hybrid operating room. Firstly, it is necessary to provide a general definition of the term hybrid. A general meaning of the term can be: “Anything derived from heterogeneous sources, or composed of elements of different or incongruous kinds”. In this case, the heterogeneous sources are the different procedures carried out during surgery in the same operating room.

One of the definitions of the above mentioned combination of hybrid operations was given by Nollert et al [9], who has stated that it is a kind of “procedure that combines a conventional surgical part including a skin incision with an interventional part using some sort of catheter-based procedure guided by fluoroscopic or MRI (Magnetic Resonance Imaging) in a hybrid room without interruption”. Owing to this definition, it is understandable the extremely relevant role of the fusion of the diagnostic and therapeutic functions. Obviously, the diagnostic and therapeutic techniques are usually available, but they are often applied in different operating rooms. For this reason, the newness is to find both of them in the same OT (Operating Theatre) or OR (Operating Room).

In addition, the level of overall care provided to patients has considerably increased due to the less invasiveness of these operating procedures. Moreover, the recovery length decreases if the endovascular approach is successful [10].

### 2.1.2 Description

The hybrid operating theatre is a new and innovative concept in the field of surgery. The basic aim of hybrid OT is to match the diagnostic and the therapeutic functions. As a result, the combination of these two elements implies a great challenge in relation with the development of advanced constructive technologies connected with new operative methods. To this end, Schaadt and Landau [11] specify that “the major differentiators of a hybrid OR versus a

standard OR include the system configuration and its imaging system, additional monitors, and the OR bed”.

Moreover, the planning process to design a new hybrid operating theatre involves a multifaceted team from various disciplines. As a matter of fact, this kind of projects needs the expertise of a variety of professional qualified people working in different fields, such as administrators, engineers, architects, nurses, anaesthetists, surgeons in various disciplines, interventionists.

Furthermore, the fusion of different techniques leads to an increase in dimensions of the operating room, compared with the old and standard OTs. In effect, as Urbanowicz [10] states, the new hybrid OTs are characterized by a floor area between around 1000 ft<sup>2</sup>(~93 m<sup>2</sup>) and 1200 ft<sup>2</sup>(~111 m<sup>2</sup>), bigger than conventional OTs, which are around 400 ft<sup>2</sup>(~37 m<sup>2</sup>) and 700 ft<sup>2</sup>(~65 m<sup>2</sup>).

One of the most relevant innovations of the hybrid OT is the introduction of an X-ray scanner inside the operating room, which allows surgeons to benefit from a real time visualization of the internal anatomic structure. Therefore, the application of this solution leads the operative technique to the next step, which entails the passage from open surgery to endovascular surgery. The type and the positioning of the X-ray scanner are defined in relation with the utilization of the OT and the needs of the operating staff.

The typical complexity and disposal of equipment is shown in Figure 2.1 about the hybrid operating room at Providence St. Vincent Medical Center in Portland.



Figure 2.1. This hybrid operating room, completed in 2004 at Providence St. Vincent Medical Center in Portland, is one of the first of its kind in the Northwest.

### 2.1.3 Planning

Urbanowicz [10] states that at the beginning of the planning process in order to design a functional hybrid OT, it is fundamental to define which will be its final utilization. All the features and factors of the various disciplines (radiology, trauma, orthopaedic, urology, vascular, neurology) connected with the use of the room need to be considered in the designing process.

In addition, the author highlights in his paper the importance of joining together different backgrounds and expertise in a multidisciplinary team. In other words, Urbanowicz suggests that this specialized decision maker team should include hospital administrators, engineers, architects, nurses, anaesthetists, surgeons of various disciplines, interventionists and the radiology technologists.

This polyhedral point of view is likely to lead the designing process towards the desired best outcome. Additionally, Nollert et al [9] stress the fundamental involvement of all technicians during the entire planning and implementation process, as well as a frequent sharing of ideas among them.

Another basic suggestion that Urbanowicz [10] makes is to visit other facilities which have already built hybrid OT. The visit can be helpful for having feedbacks from the OT users on their choices and on the problems they have met after the construction and utilization of the hybrid OT.

### 2.1.4 Size and workflow

As it was explained above, the hybrid OT cannot be considered a traditional operating room. In fact, the presence of all the instruments typical of the different disciplines involved is supposed to create a problem of space. For this reason, it is predictable that the size of the hybrid OT must be definitely larger. According to Urbanowicz [10], a common hybrid OT requires approximately 1000 ft<sup>2</sup> (~93m<sup>2</sup>) – 1200 ft<sup>2</sup> (~111 m<sup>2</sup>), which implies a significant increase in size compared to the traditional OT, whose dimensions are between 400 ft<sup>2</sup> (~37 m<sup>2</sup>) and 700 ft<sup>2</sup> (~65 m<sup>2</sup>). In other words, it means more or less a double size for a single OT. In the same paper, the importance of an efficient use of space is stressed. For instance, the storage of all equipment and materials for any kind of surgery, such as wires, stents, catheters and implantable material, needs to be inside the OT for simple access and availability. In addition, keeping the equipment in a clean environment, as the hybrid OT is, can permit to save time avoiding the cleaning procedures.

Further studies, carried out by Schaadt and Landau [11], have confirmed that the size of an efficiently functioning hybrid OT is between 1000 ft<sup>2</sup> (~93 m<sup>2</sup>) and 1200 ft<sup>2</sup> (~111 m<sup>2</sup>). Moreover, the latter authors state that “Adequate space means not only square footage, but the arrangement of equipment, supplies, and people, such that smooth transitions between and minimal protrusion into traffic areas are ensured. Drawings depict the overall room layout but do not convey the dynamic ability to ‘work’ in the room. According to AORN (Association of periOperative Registered Nurses), policies and procedures for traffic patterns for personnel, patients, supplies, and equipment in the operating room should be developed and reviewed periodically. The hybrid operating room is no exception”.

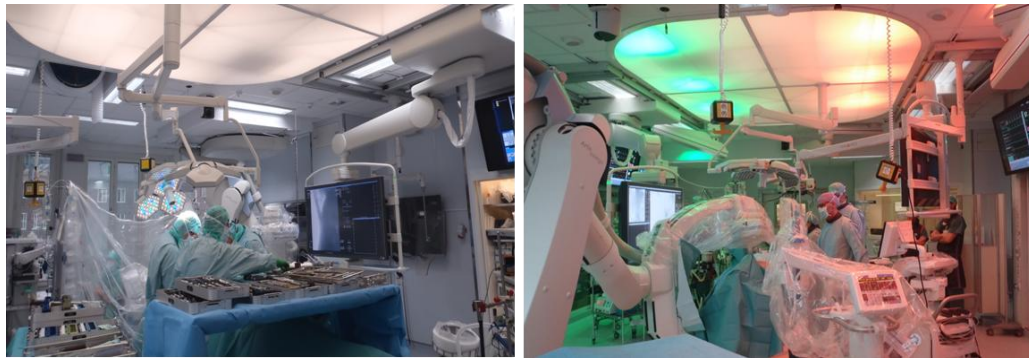
In addition, Rostenberg et al [12] state that the typical operating rooms size is between 500 ft<sup>2</sup> (~47 m<sup>2</sup>) and 650 ft<sup>2</sup> (~60 m<sup>2</sup>), but new hybrid operating rooms due to the increasing equipment quantities have a dimension between 800 ft<sup>2</sup> (~74 m<sup>2</sup>) and 1000 ft<sup>2</sup> (~93 m<sup>2</sup>).

Nollert et al [9] highlight in their paper the fundamental importance of the layout, which needs to be ergonomic and workflow driven. Also, the angiography system is a non-standard installation, which requires particular structural conditions to be installed as well as a certain space to be correctly positioned and used inside the OT.

### 2.1.5 Lighting

An efficient lighting system is fundamental in operating rooms. Usually, it is possible to find two different types of light sources:

- Surgical lights, mainly used for open surgery, shown in the middle of Figure 2.2, left picture
- Ambient lights illustrated in Figure 2.2, it is in the left picture characterized by a yellow color and in the right by green and orange color.



**Figure 2.2. Typical surgical lights during open surgeries in the middle of the picture on the left , different ambient lights in both of the pictures.**

The former light source need to cover the whole surgical area over the operating table. The most frequent position for the surgical lights is above the table, with a particular attention to the possible interferences with the X-ray scanner. In general, a double arm OR-light system is required, which is installed against the ceiling in the central part, as shown by Figure 2.1 in both of pictures . Moreover, there are several restrictions about the surgical lamps as state by [13] “The shape and position of the operating lamps are of great importance. Small cross-formed lamps should be used. The lamps must never be positioned directly over instrument tables or over the wound area but instead at approximately a 45-degree angle, leaving free space for the sterile LAF (Laminar Air Flow)” [9].

On the other hand, ambient lights pose less problems due to the normal kind of lights mounted in the suspended ceiling and the less importance of their function.

## 2.1.6 Imaging system configuration

### 2.1.6.1 Magnetic Resonance Imaging

As it has been mentioned before, the new concept expressed with hybrid theatres is the meeting of diagnostic and therapeutic functions. There are two different approaches for the design of an hybrid operating room in relation with the position and features of the X-ray machine inside it. In more detail, Rogosky et al [14] point out that the first approach presupposes the patient's movement from the surgical area to the MRI (Magnetic Resonance Imaging), which has a fixed position in the room. The second manner, instead, allows the patient to lie in an immovable position, since it focuses on the possibility to move the X-ray scanner. As a result, all the team components are expected to collaborate effectively during the preliminary planning in order to decide which is the best solution for their requirements.

### 2.1.6.2 Ceiling vs floor system

The presence of the X-ray scanner is newness inside operating rooms and it is fundamental to understand which are the best position and the best configuration for it. The X-ray scanner is also called C-arm because of its shape that resembles the letter "C". Schaadt and Landau [11] assert that there are two different configurations for the so-called C-arm:

- Ceiling mounted, as illustrated in Figure 2.3 on the left
- Floor mounted, as shown in Figure 2.3 on the right.



Figure 2.3. On the left, a ceiling mounted C-arm (Schaadt and Landau, (2013)), on the right a floor mounted X-ray scanner (Nollert et al, (2012)).

The ceiling mounted system leaves more space available on the floor. In addition, this system can be placed in a corner of the OT if not in use, for example during traditional surgery when no images are needed. Nevertheless, the movements of the C-arm are performed by means of tracks. These tracks - installed below the ceiling from where the air usually comes - may become sites of dust deposition, which implies the risk of obstructing the unidirectional air flow coming from the filters. Furthermore, the ceiling mounted scanner can prevent surgeons and nurses from watching the monitors.

The floor mounting system permanently occupies a large portion of space on the floor and often impedes the anaesthetists' movements due to its position near the patient's head. However, unlike the other type of scanner, the floor mounted system makes the space near the ceiling free, thus removing any interference with vertical unidirectional airflow and less risk of dust deposition.

### *2.1.6.3 Biplane vs Multi-axis imaging*

Another fundamental step in the definition of the X-ray system is to describe the different technical solutions for image acquisition. According to Schaadt and Landau [11], the two basic principles which make it possible to acquire x-ray images are:

- Biplane imaging
- Multi-axis imaging

Biplane imaging is based on the utilization of both the different models of C-arm mentioned above, one ceiling mounted and the other floor mounted. Moreover, the main concept of the biplane acquisition method is to collect images from two distinct points of view, in order to examine the same object from different perspectives. In addition, the images are visualized on two different screens. Thanks to the double image visualization, the physicians are able to obtain a 3-D picture of small vessels and arteries. Another important issue to take into account is that the visualization of small vessels is not possible with a single X-ray scanner that can only be used to detect larger vessels. On the other hand, thanks to its 3-D visualization, biplane imaging allows paediatric and neural-angiography procedures to be carried out without any difficulties. Nevertheless, the installation of two different C-arms inside the OT causes critical space problems to arise, and may also produce interference with personnel movements and other instruments.

Multi-axis imaging is the most recent technique. It consists of a single plane, floor-mounted X-ray scanner, which, however, has the peculiarity to rotate on eight different axes. This feature makes it possible to acquire different images



suitable for all types of surgery. Moreover, multi-axis imaging allows better sterility maintenance due to the presence of a single floor-mounted scanner, which, as highlighted before, prevents unidirectional airflow coming from being obstructed.

#### *2.1.6.4 Fluoroscopy and angiography*

The new hybrid OT offers the surgical staff the possibility to use the X-ray scanner inside the operating room. This is an unusual, but highly valued opportunity which, however, presupposes a different design compared to the conventional OT. The radiologic procedures that can be carried out with an X-ray scanner are:

- Fluoroscopy
- Angiography

Fluoroscopy is a medical technique which provides low contrast images with the use of an X-ray scanner. This procedure enables surgeons to acquire 2D pictures of the patient's internal anatomic structure in order to place or move accurately the medical devices, such as catheters, during the operation. Moreover, the peculiarity of fluoroscopy is to allow a real-time monitoring of the ongoing operation due to the continuous use of X-rays [9]. For instance, thanks to this technique, the surgeon can insert the catheter into the patient's body, being able to easily find the best position for the tool. Furthermore, fluoroscopy is a procedure which avoids the use of contrast media, since it needs only digital image intensification.

The aim of angiography, on the other hand, is image acquisition: this procedure makes it possible to record the pictures automatically on the system with the idea to archive them after the end of the operation. "While standard fluoroscopy is predominantly used to guide devices and to re-position the field of view, data acquisition is applied for reporting or diagnostic purposes. In particular, when contrast media is injected, a data acquisition is mandatory, because the stored sequences can be replayed as often as required without re-injection of contrast media. To achieve a sufficient image quality for diagnoses and reporting, the angiographic system uses up to 10 times higher x-ray doses than standard fluoroscopy. Thus, data acquisition is not recommended as long as fluoroscopy is sufficient or the images do not need to be stored" [9].

#### *2.1.6.5 Training for imaging*

In relation with the intensive use of the X-ray scanner, the staff training is fundamental in order to learn how this sophisticated machinery works. The importance of the correct position of the scanner is directly proportional to the

precision in the evaluation of the diagnosis. As mentioned by Nollert et al [9], at least one member of the surgical staff needs to be properly trained in the use of the X-ray scanner in all its functionalities. In addition, he is appointed to teach the other team members the basic rules to employ this tool and he is required to choose some special users. These users can substitute the specially trained operator during emergency cases or during his absence.

### 2.1.7 Ventilation system

The main target in the design process of operating rooms is to achieve optimal cleanliness conditions. Therefore, the importance of clothing system and behaviours of the OR team members is emphasized. Furthermore, the air conditioning and ventilation system has the main role to maintain a high cleanliness level [9].

The main aim of the ventilation system in the operating rooms is to dilute and remove airborne bacteria-carrying particles. The old conventional ventilation systems used to supply around 16 to 20 Air Changes per Hour (ACH) in order to mix spread particles with the clean air. LAF (Laminar Air Flow) systems, or called in a more scientific way UDF (UniDirectional air Flow), recirculate excessive volumes and usually have up to 50 to 200 ACH, blowing this air through High-Efficiency Particulate Air filter (HEPA) filters. For instance, terminal H14 HEPA filters removes 99.995% of particulate matter greater than 0.3  $\mu\text{m}$ . Moreover, The most diffused system is the vertical LAF, characterized by an airflow from the ceiling toward the floor. The other and less used is the horizontal LAF, characterized by a cross flow from one of the other wall [13].

In the Appendix B of the standard UNI 11425:2011 [15] is highlighted the better efficacy of the unidirectional airflow to maintain the cleanliness of the clean area in all the operating rooms.

The technical specification SIS-TS 39:2012(E) [1] underlines the importance of the ventilation inside operating rooms “to provide a safe and comfortable environment for patients and personnel working in the room”. The maintenance of a low level of airborne microorganisms inside the operating room is the primary goal for the ventilation, followed by the importance to avoid the air inflow from the surroundings and, finally, to clean up the air after surgery.

In addition, the same technical specification describes the two main principles used for ventilation systems in Sweden:

- Turbulent mixed air flow
- Unidirectional air flow

The turbulent mixed air flow is usually called conventional, based on the dilution of the spread microorganisms with clean air. This decrease the average level of contaminants, thanks to the turbulent air motion. On the contrary, the unidirectional air flow is based on the parallel air flow above the operating table, in order to move the bacteria-carrying particles from the surgical zone to the periphery by a sweeping action.

As stated by Nollert et al [9] the HVAC (Heating, Ventilation and Air Conditioning) system supply a unidirectional air flow which creates a defined protection zone. This zone can be considered with a higher cleanliness level and in it can be placed the tables for materials and instruments to avoid their contamination.

The vertical unidirectional air flow pattern allows the air to be thrown through a uniform, regular displacement to sweep away all the airborne particles, like a piston, without mixing the air inside the OT from the higher filter surface towards the return grilles located in the lower part of the walls as explained in Figure 2.4.

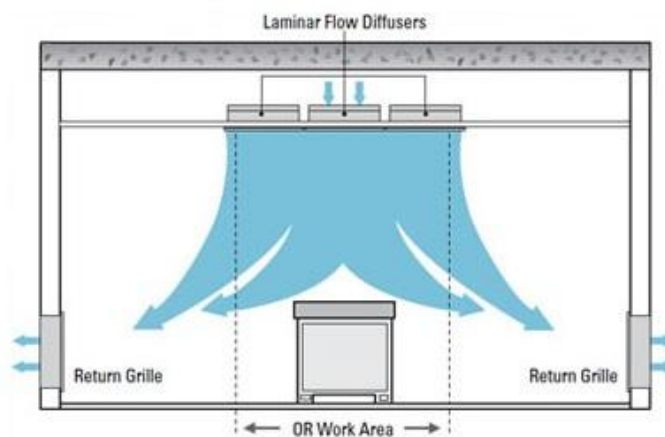


Figure 2.4. Scheme of the unidirectional airflow pattern in an OT (Price-Hvac 2013)

As can be seen in Figure 2.4, the air is supplied through terminal H14 HEPA filters installed in the room ceiling and it is blown directly on the operating table. The air then flows following an ordered path which sweep away the airborne particles from the table to the return grilles. Afterward, the air use to be recirculated in the air handling unit and reintroduced in the room at the typical speed of 0.3 m/s. Air velocity is assumed to result in the abolition of convection currents due to heat or movement, thus preventing the entrainment of particles into the operative clean area delimited by footprint of the ceiling equipped with H14 HEPA terminal filters.

### **2.1.8 Costs**

The challenge of this new hybrid operating rooms implies an increase in building costs compared to standard operating rooms. However, the financial success is guaranteed if the hybrid OT is used at 100% of its possibilities [9].

In a recent study Neumann [16] compared the different investments for hybrid OTs, angiography suites and standard operating rooms. He focused his attention on extra costs for room setup, building costs and costs for the equipment. Predictably, the outcomes of his analysis showed that the standard operating room is the cheapest investment. The angiography suite demands a total investment that is around 25% higher than the standard operating room, whereas the hybrid OT is the most expensive one, since its costs are 120% higher than the standard OR. In addition, the above mentioned research highlighted the same trend also taking in account the operating costs, such as maintenance costs, debt service and amortization.

Nevertheless, the presence of a hybrid OT can significantly increase the reputation of the hospital and is likely to have a positive financial impact. Furthermore, it can attract the top medical staff to work in the hospital and also the patients, due to the high quality and efficiency of its sophisticated medical service [9].

## **2.2 Hybrid OT at Sahlgrenska University Hospital**

This second part of Chapter 2 describes the characteristics of the Hybrid Operating Theatre at Sahlgrenska University Hospital of Gothenburg, Sweden.

The various information presented in this part of the chapter was collected thanks to the daily observations - done in first person - completed by the collection of data and technical documents. In addition, technical information about procedures and equipment is extract by the interview done with the technical manager that is also a surgical nurse working for the Sahlgrenska University Hospital.

## 2.2.1 Hybrid OT layout

The size of the Hybrid Operating Theatre is around 100 m<sup>2</sup>, including the operating room, the near office and the server room.

The different areas of the Hybrid OT, shown in Figure 2.5, are:

- The clean area
- The periphery of the clean area
- A small office
- The IT room

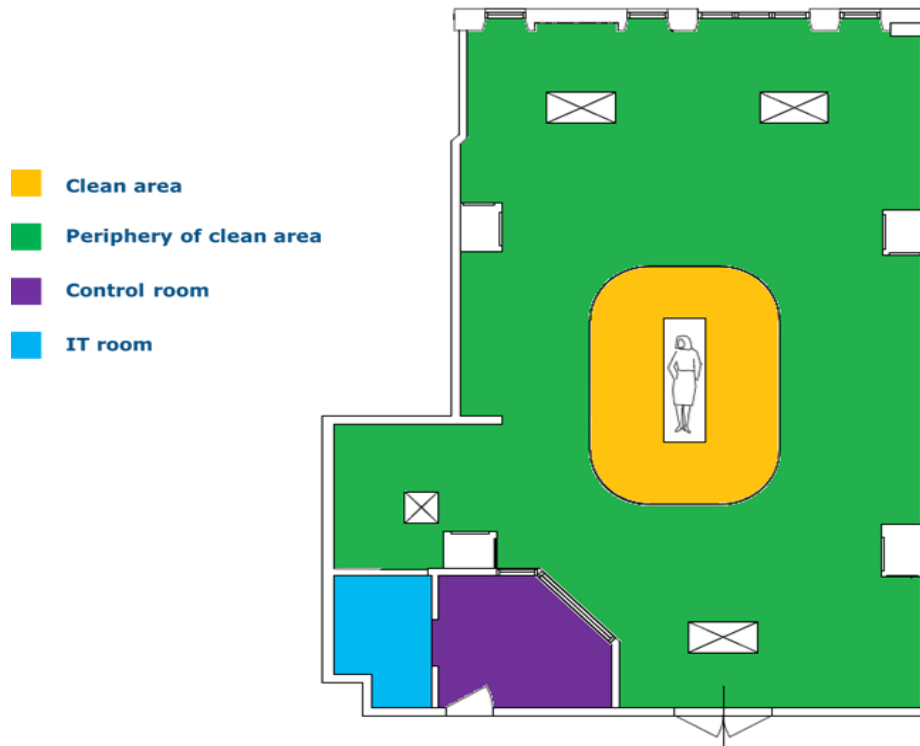


Figure 2.5. Representation of the different areas of the Hybrid OT at Sahlgrenska University Hospital. The zones indicated are the clean area (orange), the periphery of the clean area (green), a small office (purple) and the IT room (light blue)

The clean zone (area of 12.6 m<sup>2</sup>) is characterized by a downward unidirectional air flow from the ceiling. In addition, the operating table is positioned in this clean area in which the surgery is carry on. Moreover, the UDF from the ceiling allows this area to be clean. Owing to this, after a careful and accurate clothing

procedure, in this zone the personnel must be instructed to avoid any contact with people or instruments that are outside the clean zone. Furthermore, the cleanliness of this area imposes the location of the sterile surgical instruments and equipment in this zone.

The periphery of the clean zone (total area of 78.4 m<sup>2</sup>) is furnished by several equipment. More precisely, there are 4 wall-mounted monitors, several PCs to manage the camera system and to work on the pictures captured during surgery. Moreover, on the two side of longer walls are present two closets in which all the surgical instruments are stored.

The accessibility to the operating room is guaranteed by a large sliding door (2000 x 2000 mm). This door is provided with a silicone seal gasket which prevents the exit of the air due to the difference of pressure between the OT environment and the adjacent corridor. This door can be opened in two different ways:

- Half of the door, for the personnel's entrances and exits with a time between the opening and the closing around 11 seconds
- The whole door, for the entrance and exit of big equipment or the hospital bed, with a time between the opening and the closing around 22 seconds

There is also a little pass-box in the wall (400 x 500 mm) near the door, which allows the passage of some materials and tools, as well as the communication with people outside the OT in order to avoid the door opening.

Near the operating room there is a small office (area of 7 m<sup>2</sup>) accessible independently from the adjacent corridor, from which it is possible to follow the operation thanks to a glass window. Moreover, from the office the use of video cameras pointing towards the operating room allows a precise overview of surgery through the visualization of the video in screens. However, there is no possibility to have a direct access to the operating theatre from the office. Moreover, near the office there is a small IT room which has an area around 4 m<sup>2</sup>.



### 2.2.2 The intensity and the use variety

The Hybrid OT is designed for various uses. The main operations performed in the room are

- EVAR (EndoVascular Aortic Repair)
- Orthopedic Surgery (usually spinal surgery)
- Liver Resection

Due to the type of surgery performed, the Hybrid OT is planned for a programmed use, and not for emergencies. Generally, only a single operation takes place inside it each day, usually in the morning. After the operation the room is cleaned by the personnel and it is ready for the following day. The room is usually used from Monday to Thursday.

There are mainly two different configurations of the Hybrid OT linked to the position of the anaesthesia equipment. The ordinary anaesthetist position is near the patient's head, which usually points to the opposite side of the entrance. However, in some particular operations the anaesthesia equipment could be arranged on one side of the patient's bed. The decision is up to the surgeon, who has the authority to choose in relation to the type of surgery that will take place.

Usually, during orthopaedic surgery and liver resection, the position of the anaesthetist is at the head of the patient. In these open operations, it is common practice to use a plastic drape to separate the anaesthesia zone from the sterile area for the care of surgical wound. Moreover, this drape prevents the anaesthetist from any contact with blood or other liquids. The model of the anaesthesia machine used is ADU Carestation produced by GE Healthcare.

The possible number of people in the Hybrid OT is between 15 and 20, in around 100 m<sup>2</sup> area. This number is bigger than in the case of conventional OT, where the maximum acceptable number is 6-8 due to the dimension of the room, that is about 34-40 m<sup>2</sup>. Furthermore, approximately 4-5 of the 15-20 people staff can stay within the clean zone under the unidirectional air flow, wearing the proper clothes. The maximum presence can be reached only during endovascular operations, in which the risk of infection is low due to the percutaneous surgery. On the contrary, during orthopaedic surgery and liver resection the risk of infection is higher than the previous kind of operation, therefore a lower number of people are required. Other reasons of the difference in the number of people can be found in the distinct procedures performed and the various needs for surgeries.

### 2.2.3 Imaging system

The C-arm is of the floor-mounted type. The C-arm it is usually called X-ray scanner due to his function. This kind of device permits the 3-D angiography, thanks to the possibility to rotate the system of 360° around the operating table. The X-ray scanner is a robotic imaging system that can bring advanced CT imaging technology, equivalent to a 16-slice spiral CT (computed tomography), into the operating room [17].

In the left picture of Figure 2.6 it is possible to see a picture of the X-ray scanner installed in the Hybrid OT and - on the right - its real position inside the same room is pointed out with a blue circle, that also indicates the real space occupied on the floor.

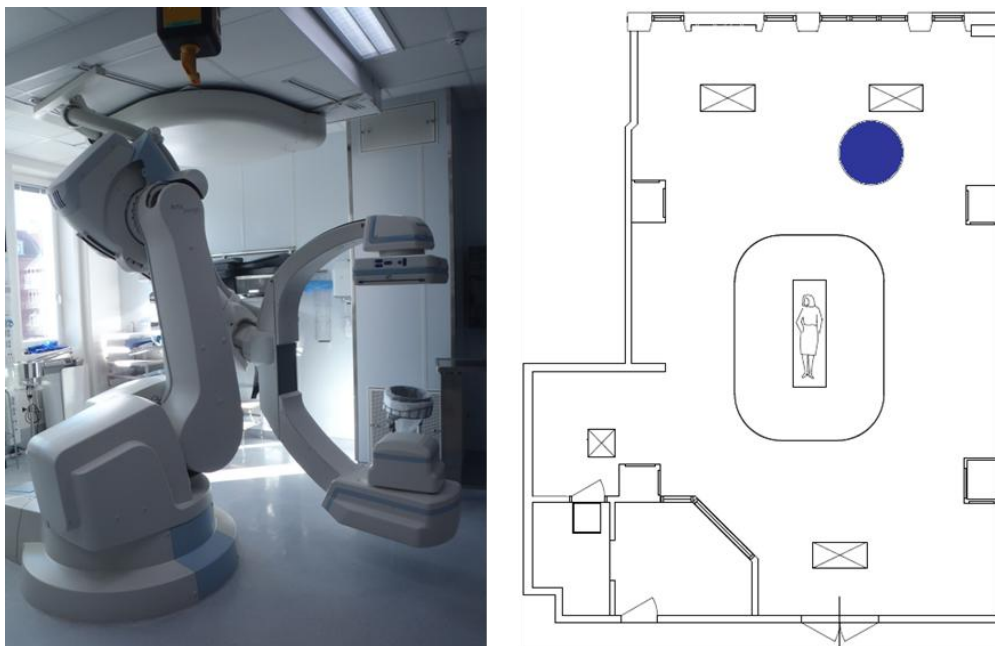


Figure 2.6. The X-ray scanner Artis zeego (SIEMENS) on the left, and its position inside the Hybrid OT on the right (blue circle in the layout).

Several lead movable barrier shields - with a width of 15 mm - are positioned inside the OT in order to protect the staff during the use of the X-ray scanner.

During orthopaedic surgeries the surgeon is more likely to use the X-ray machine, due to the simple scanner movements needed during this type of operations. On the other hand, during EVAR operations it is the X-ray nurses

who are responsible for the movements of the X-ray machine, since they are competent in the use of contrast media as well as handling the scanner with all its possible movements.

### 2.2.4 Clothing system

The clothing system is the same for all the personnel inside the operating room and in the whole hospital. These clothes are stored in the changing room as depicted in Figure 2.7. The clothing system consists of

- a pair of trousers (50% polyester and 50% cotton) to be worn only one day
- a blouse (50% polyester and 50% cotton) to be worn only one day
- a pair of ordinary shoes used only inside the hospital
- a single-use head cover
- protective gilet and skirt from radiation (only for EVAR surgeries)



Figure 2.7. Changing room where the ordinary clothes are stored

In addition, during the EVAR operations, only surgeons in the protected zone need to wear a surgical gown, the face mask and double gloves.

In the case of orthopaedic surgery and liver resection greater attention is paid to prevention from infection during open operations and, as a result, some important differences occur in terms of staff clothing, as showed in Figure 2.8:

- a disposable pair of trousers made of Mertex (30% nylon and 70% cotton) (single use)
- a disposable blouse made of Mertex (30% nylon and 70% cotton) (single use)
- a pair of common shoes used only inside the hospital
- a single-use helmet that covers the whole head and the neck
- a face mask



Figure 2.8. Mertex clothes supplied inside sterilized cover bags (on the left), and the same clothes worn by an operator (on the right).

Furthermore, as in the case of EVAR surgery, during orthopaedic and liver resection operations, only surgeons in the protected zone need to wear a surgical gown and a double pair of gloves.

The characteristics of the surgical gowns used in the Hybrid OT are shown below [18].

“BARRIER Surgical Gown Classic

- Gown body and sleeves: Nonwoven pulp/polyester fibers

- All high performing surgical gowns are reinforced:
  - Front reinforcement: Breathable polyethylene plastic film
  - Sleeve reinforcement: Polyethylene plastic film, viscose/polyester

Packaging:

Vacuum single packed gowns are provided in a double box packaging system, which ensures perfect condition and optimises storage space.”

In Figure 2.9, it is possible to see a surgeon wearing the gown described above, with all the garments as gloves and face mask.



Figure 2.9. Surgeon during the preparation of the medical instruments, wearing the typical surgical gown, gloves, helmet and face mask.

The surgical team members are required to wear sterile gowns and gloves only at the moment of entering in the clean zone, thus becoming ready to start the operation.

### 2.2.5 Gloves

The gloves have an important role to maintain the sterility of the surgical area and to protect the staff and the patient from possible contamination. For this reason, the attention to the correct use of gloves is maximum. The distinction of the two areas inside the OT implies also a different glove use. For example, in the clean zone the surgical team needs to wear double gloves during all the operation time the first pair of gloves worn is green and the second is yellow. Moreover, the gloves are made of Neoprene. The choice of this new material was made to replace the previous gloves made of Latex, in order to preserve patients from allergic reactions and possible presence of powder.

The use of two pairs of gloves is motivated by reasons of staff and patient safety as well as the greater facility to notice if the glove is broken. In relation to this latter consideration, the choice of two different colours allows the surgeon to detect the presence of a hole in the gloves.

More precisely, a stronger colour contrast, which is originated by the contact of humidity with the two gloves, is the hole indicator, as shown with a red circle in Figure 2.10. Indeed, the hole itself makes it possible for humidity to easily enter through the first yellow glove.



Figure 2.10. The red circle points out a stronger color contrast which is the hole indicator.

On the other hand, outside the clean zone the use and the type of gloves are different. The gloves are required to be worn only if the staff needs to take care of some drapes or other medical instruments contaminated by urine or blood. The material of these gloves is poly-isoprene powder-free.

Furthermore, hand cleaning with isopropyl alcohol is supposed to be sufficient to manage all the common tools. Outside the clean zone, the use of gloves is considered a false security due to the less attention that people pays when they touch objects in the room, thus increasing the risk to contaminate clean things, maybe in the sterile area.

Moreover, once a month a control takes place to be sure that the rules about the use of gloves and alcohol are respected.

### 2.2.6 Electrosurgical instruments

In order to understand deeply the characteristics of the Hybrid OT it is necessary to know which electrosurgical tools are used during surgeries. In addition, it is important to remember these instruments are responsible for the generation of surgical smoke, as mentioned in Chapter 1.

The functioning of main instruments used during open surgeries as orthopaedic surgery or liver resection in the Hybrid OT at Sahlgrenska University Hospital is based on the diathermy principle. “Diathermy is a form of physical therapy in which deep heating of tissues is accomplished by the use of high-frequency electrical current. American engineer and inventor Nikola Tesla in 1891 first noted that heat resulted from irradiation of tissue with high-frequency alternating current” [19]. In addition, electro surgery (another name to indicate diathermy) is defined as “Electro surgery, using high frequency (i.e., radio frequency) electrical current, is used routinely to cut, coagulate, dissect, ablate, and shrink body tissue” [20]. However, inside the Hybrid OT it is possible to find also some ultrasonic devices, which have a different operating principle based on the use of ultrasonic vibrations to cut and coagulate tissues.

There are several types of surgical instruments which perform different tasks. The ones used at Sahlgrenska University Hospital are:

- Monopolar diathermy
- Bipolar diathermy
- Ultrasonic device
- Argon diathermy



### 2.2.6.1 Monopolar diathermy

“Monopolar diathermy generates electrical energy at 200 kHz to 6 MHz. The energy is applied between two electrodes (neutral and active). The neutral electrode has a large conductive surface area producing a low current density with no measurable heating effect. The active electrode has a very small contact area resulting in a very high current density. The heating effect beneath the active electrode is considerable producing deliberate tissue damage” [21].

In Figure 2.11 it is possible to see the active electrode on the top of the instrument (on the left). The image also shows the local exhaust system (white part), which is fundamental to draw the surgical smoke produced by the burnt tissues. During the open surgeries attended this was the most used electro surgical instrument in use. This tool is connected to the machine Force Triad made by Covidien.



Figure 2.11. Monopolar diathermy attached to local exhaust system

### 2.2.6.2 Bipolar diathermy

“Bipolar diathermy operates with a much lower power output. The output is applied between the points of a pair of specially designed forceps producing high local current density. No current passes throughout the rest of the body” [21].

In addition, the bipolar technique is applied to smaller tissue areas, compared to those treated by monopolar diathermy. However, unlike the previous tool, this instrument is not provided with an exhaust system. This was the second most used tool during the open surgeries attended.

It is possible to see the bipolar instrument in Figure 2.12. This instrument is connected to the machine Coacomp made by Instrumenta.



Figure 2.12. Bipolar diathermy tweezers model

### 2.2.6.3 Ultrasonic device

This surgical device uses energy generated by ultrasonic vibrations. “Ultrasonic energy is an efficient alternative to electro surgery and the basis for an efficient surgical instrument. The device cuts and coagulates by using lower temperatures than those used by electro surgery or lasers. No electricity goes to or through the patient” [24]. This tool was used only during the liver resection surgery attended.

It is possible to see the ultrasonic instrument in Figure 2.13. This instrument is connected to the machine Harmonic made by Johnson&Johnson.



Figure 2.13. Ultrasonic dissector, forceps model.

#### 2.2.6.4 Argon diathermy

Also the argon diathermy was used only during the liver resection surgery. It is possible to describe the functioning of this instrument as “Argon coagulation uses the phenomenon of good conduction of high frequency current by ionized argon. Argon is a chemically inert gas, devoid of physiological effects and non-combustible. Under the effect of current, it becomes ionised and forms a plasma cloud in which electric arcs are formed. In argon coagulation, there is no contact of the active electrode with the tissue. The thermal effect occurs at the time when a spark jumps from the active electrode tip to the tissue” [23].

It is possible to see argon instrument in Figure 2.14. This instrument is connected to the machine System 7550 made by ConMed.



Figure 2.14. Argon electrode handle.

### 2.2.7 Ventilation system

The ventilation system inside the Hybrid OT has the main role in guaranteeing the personnel comfort and good air quality in terms of contamination control of airborne particles.

First of all, in order to discuss in a proper way about the features of the ventilation system it is necessary to define the different parts of the system itself. In the ventilation system two main parts can be identified:

- The HVAC (Heating, Ventilation, Air Conditioning) system
- The air flow diffusion system

Figure 2.15 shows the two main parts of the ventilation system. The scheme in the Figure is about the ventilation system designed to supply air to the Hybrid OT. The HVAC system is signed in red and the airflow diffusion is signed in green.

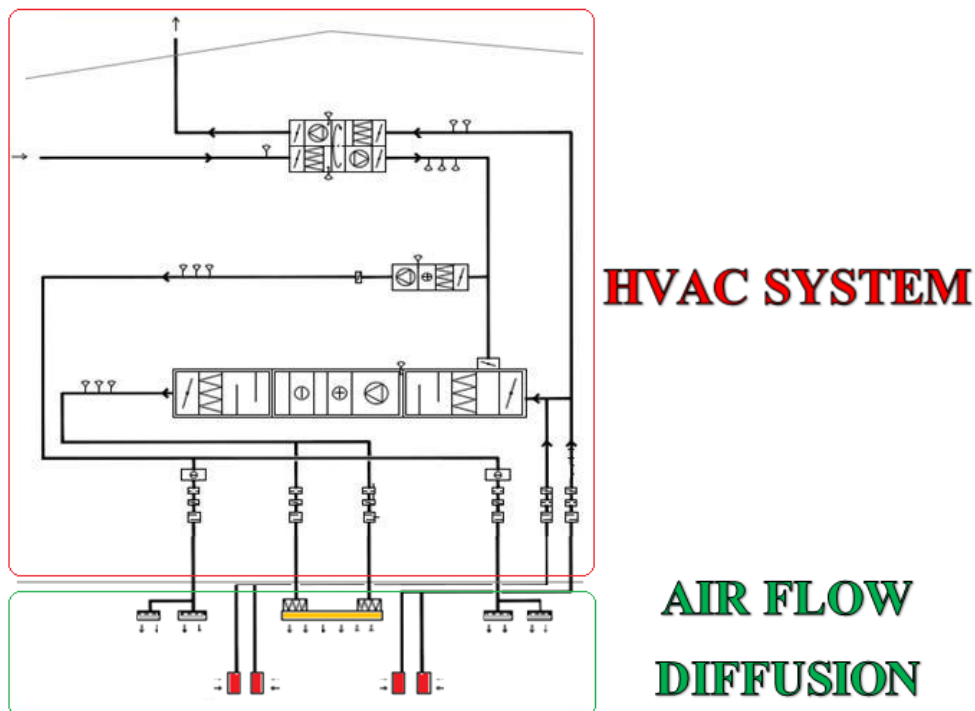


Figure 2.15. Technical representation of the ventilation system divided in two main parts, the HVAC system and the airflow diffusion system.

The HVAC system is composed by the Air Handling Units (AHU) and the distribution system. The AHU is a device with the purpose of conditioning and circulating air. Usually, it is a large metal box containing fans, heating and cooling coils, filters, sound attenuators and dampers. On the other hand, the distribution system is composed by the ducts which distributes the conditioned air and extract the exhaust air from the room.

The air flow diffusion include the final H14 HEPA filters, the air flow pattern inside the Hybrid OT and the local exhaust grilles. The final H14 HEPA air filters provide the filtration before the introduction in the controlled environment, and they can be considered the border between the HVAC system and the air flow pattern inside the room. The air flow pattern inside the room is the main air motion inside the room. It depends by the type and position of the air diffuser, or by the position of the exhaust grilles, or by the air velocity through diffusers, or by the object disposal in the room such as the movements and the people presence. In general, the air flow pattern is theoretically associated to the design conditions and the basic air movement inside the supplied environment depending on the magnitude of air velocity, flow rate, obstacles during path and temperature conditions. Finally, the exhaust grilles such up the air from the Hybrid OT.

### 2.2.7.1 HVAC system

As mentioned before, the HVAC system is composed by the AHU and the distribution system. In the system of the Hybrid OT of Sahlgrenska University Hospital there are 3 different AHUs connected by the distribution system as displayed in Figure 2.16.

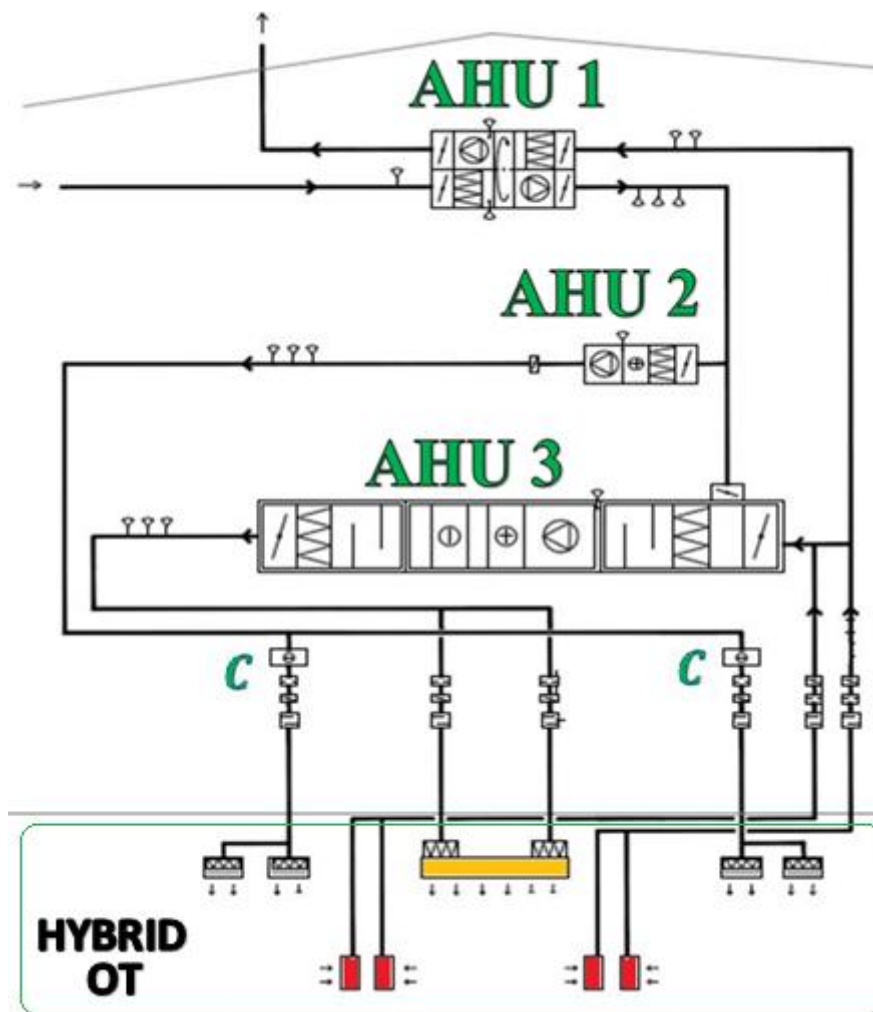


Figure 2.16. Technical representation of the ventilation system, with the indication of the 3 AHUs and the local cooling coil signed with the letter "C".

As it can be seen in Figure 2.16, AHU 1 can be considered the main unit because it handles the fresh air coming from outside the building, throwing out

the exhaust air. This unit is provided by F7 filters for both of the ducts which filter ingoing fresh air and the outgoing air. In the unit 1 there is also a rotary heat exchanger that recovers the heat from the exhaust air in order to pre-heat the incoming air. AHU 1 has also a supply fan and an exhaust fan. The supply air from the unit 1 is divided in two branches that direct the air towards AHU 2 and AHU 3.

AHU 2 handles only outside air and it supplies the same air to the periphery of the clean area that will be described in the description of the air flow pattern. This unit is provided by an intermediate filter of the F9 type, by a heating coil and by a supply fan. The air handled by AHU 2, before arriving to the diffusers, has the possibility to be handled by a cooling coil – defined by the letter C in Figure 2.16 - in order to reach the desired supplying temperature.

AHU 3 handles part of the air coming from the AHU 1 and part of the extract air coming from the grilles positioned in the Hybrid OT. The air - after the mixing - passes through the main parts of the AHU 3 that are a pre-filter of the F7 type, a sound attenuator, a supply fan, heating coils, cooling coils, a sound attenuator and another filter of the F9 type. AHU 3 supplies air to the clean zone in the centre of the Hybrid OT.

It worth to be highlighted that the exhaust air is recirculated in the AHU 3 with a 70% rate. The leading idea is to reutilize this air flow – which has more or less the right termo-hygrometric conditions – and filter it through the 3 stage filters in the AHU 3 in order to guarantee the air cleanliness. The role of the recirculation system will be crucial in the development of the work and for the final results.

The exhaust air is extract by 8 exhaust grilles, that will be described, and part of it is reintroduced in the AHU 3 and the other part goes to the AHU 1, in order to recover the heat and after it is thrown out the building.

All the distribution ducts and the AHUs are installed at the upper floor of the Hybrid OT in the machinery room.

The airflow pattern will be defined in the next section, with a detailed description of the filters installed in the Hybrid OT.

### 2.2.7.2 Air flow diffusion

The typical air flow pattern in the operating theatres is a vertical unidirectional air flow. This is the case of the Hybrid OT at Sahlgrenska University Hospital for the central zone.

In Figure 2.17 it is shown that the total area of the OT can be divided in two main zones from a ventilation point of view,:

- The clean area
- The periphery of the clean area

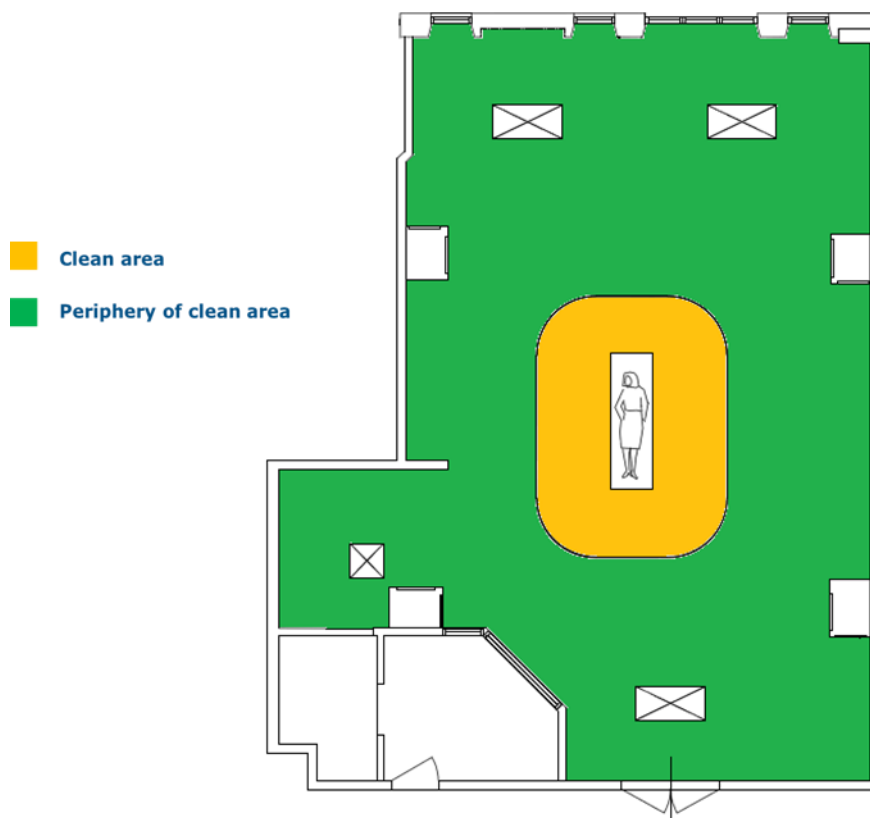


Figure 2.17. Representation of the clean area (orange) and the periphery of the clean area (green).

The clean area is the central part of the room where the operation takes place. In this zone, the cleanliness of the air and of the equipment is highly necessary. For this reason, the clean area is supplied with a unidirectional vertical air flow from



the ceiling to the floor. This air is coming from the AHU 3. In addition, the air flow is around  $3.6 \text{ m}^3/\text{s}$  and the air is blown through 8 HEPA (High Efficiency Particle Arresting) filters of the kind H14. These HEPA filters are 6 with the dimensions of  $305 \times 610$  and the other 2 with the dimensions of  $610 \times 610$ . The air coming from these filters is collected in a plenum. The aim of the plenum chamber is to let the air calm down before it enters the clean area in order to guarantee an equal air velocity distribution to create the vertical unidirectional air flow. The data collected by Leonardo Claudio Amato inside the Hybrid OT reveal an air velocity around  $0.3 \text{ m/s}$  at a distance of  $200 \text{ mm}$  under the plenum. The unidirectional air pattern in this zone allows the air to be expelled through a uniform, regular displacement to sweep away all the airborne particles, like a piston from top to bottom, without mixing the air inside the clean area. The plenum covers the whole clean area (around  $12.4 \text{ m}^2$ ) signed in orange on Figure 2.17 and the following Figure 2.18.

The periphery of the clean area is the remaining part of the operating room. This zone doesn't need the same level of cleanliness due to its distance from the surgical area. As a result, in the zone outside the clean area, which is around  $78 \text{ m}^2$ , the airflow is approximately  $0.7 \text{ m}^3/\text{s}$ . This air is coming from the AHU 2. This air flow passes through 7 HEPA filters of the kind H14 with the dimension of  $557 \times 557$ . These HEPA filters - installed in 4 different positions in the suspended ceiling - provide a downwards vertical air motion. Figure 2.18 indicates in grey the 4 different positions of these filters. The main purpose of the unidirectional airflow in this zone is to supply fresh air for the personnel outside the clean area, and to mix it with the contaminants, thus obtaining a lower particle concentration. In this case, the air goes out the filters directly in the Hybrid OT with an air velocity around  $0.3 \text{ m/s}$ .

It worth to be mentioned that the temperature of the supply air in the inner zone is maintained  $2^\circ\text{C}$  lower than the one of the periphery in order to guarantee the uniform downward air motion, in order to satisfy the conditions prescribed for this kind of air systems. In addition, from the control touch panel it is possible to change the supply air temperature in the inner zone, which causes a modification of the temperature of the outer zone air in order to keep a difference of  $2^\circ\text{C}$  between them.

Moreover, the exhaust grilles are positioned around the clean area near the walls. The extract airflow is around  $4.2 \text{ m}^3/\text{s}$  and comes out from 8 grilles of  $600 \times 600 \text{ mm}$  each - two for each extraction point on two sides of the same column - placed at the height of  $200 \text{ mm}$  from the floor. Each couple of grilles is positioned in a different place around the peripheral area.

Figure 2.18 indicates the different positions of the plenum, the H14 HEPA filters in the peripheral zone and the exhaust grilles.

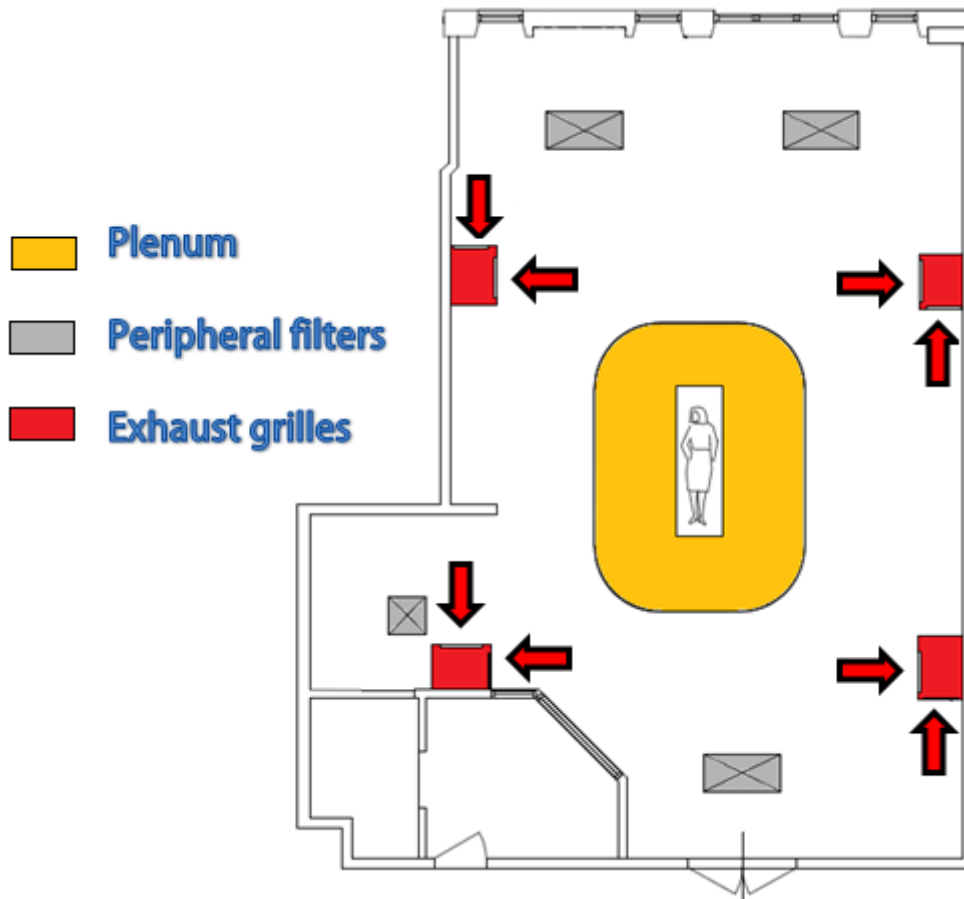


Figure 2.18. Representation of the different positions of the plenum (orange), in grey are defined the 4 different positions of the HEPA filters in the peripheral zone. The figure indicates also in red the 4 different positions of the extraction grilles indicated by arrows.

The characteristics of the HEPA filters installed in the clean zone of the Hybrid OT of Sahlgrenska University Hospital are described in the following Table 2.1. The data shown are representative of trial conditions in laboratory.

Table 2.1. Technical data related to the filters. The red rectangle highlights the characteristics of the filters installed in the Hybrid OT in the clean zone.

### Technical Data

Filter type	N-	H13-V40	H14-V35	U15-V30
Rated air flow <sup>2)</sup> ( $V_N$ ) <sup>1)</sup>	m <sup>3</sup> /h	4000	3500	3000
Rated face velocity	m/s	3.0	2.6	2.25
Initial pressure drop <sup>3)</sup> at $V_N$	Pa	290	250	250
Recommended final pressure drop <sup>4)</sup>	Pa	600	600	600
Continuous operating temperature	°C	125/100 <sup>7)</sup>	125	125
<b>Typical Efficiencies</b>				
EN 779 (average efficiency)	%	-	-	-
EN 1822 (typ. MPPS <sup>5)</sup> integral value)	%	99.98	99.998	99.9998
EN 1822 (min.MPPS <sup>5)</sup> integral value)	%	99.95	99.995	99.9995
EN 1822 (min. MPPS <sup>5)</sup> local value <sup>6)</sup> )	%	99.75	99.975	99.975
Filter class acc. to EN 779 / EN 1822		H13	H14	U15
Flam. classification acc. to DIN 53 438		K1/F1	K1/F1	K1/F1

The typical Most Penetrating Particle Size (MPPS) mentioned in the table refers to the range of 0.12-0.25 µm. In addition, there are two different dimension types of filters supplying the clean area described in the Figure 2.19:

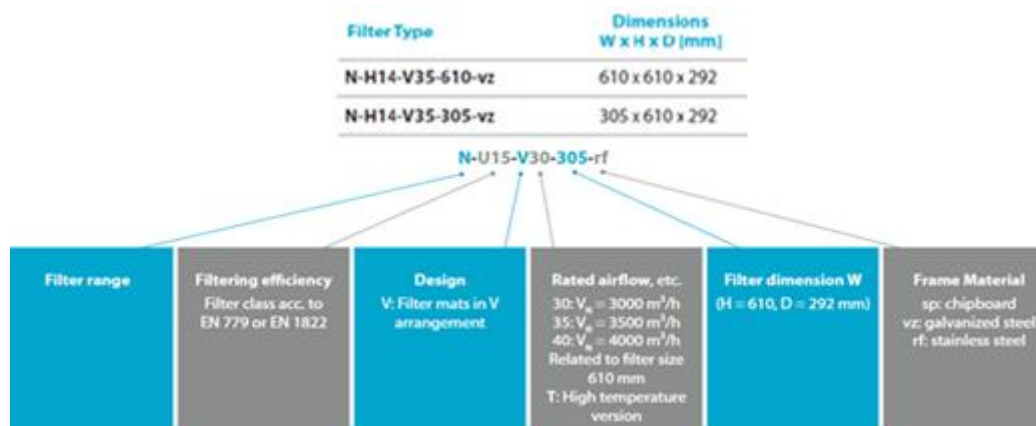


Figure 2.19. Technical data related to the filter types. The installed filters in the Hybrid OT in the clean zone are described in the table.

The same brand VOKES AIR for the HEPA filters were chosen for the ones installed in the periphery of the clean zone of the Hybrid OT of Sahlgrenska University Hospital, and their general characteristics are described in the following Table 2.2. The data shown are representative of trial conditions in laboratory.

Table 2.2. Technical data related to the filters the red rectangle highlights the characteristics of the filters installed in the Hybrid OT in the periphery of the clean zone.

### Technical Data

Hepatex CR	Units	AS-H14	AL- H14	AS- U15
<b>Nominal air flow</b> <sup>(1)(2)</sup>	m/s	0.45	0.45	0.45
<b>Pressure drop at nominal flow</b> <sup>(2)</sup>	Pa	120	85	170
<b>Recommended final pressure drop</b> <sup>(3)</sup>	Pa	240	150	340
<b>Filter surface area per m<sup>2</sup> face area</b> <sup>(1)</sup>	m <sup>2</sup> /m <sup>2</sup>	24	38	24
<b>Filter Efficiencies</b>				
<b>EN 1822 integral value (typ. for CR)</b> <sup>(4)</sup>	%	99.998	99.998	99.9998
<b>with MPPS-DEHS-aerosol (min.)</b> <sup>(4)</sup>	%	≥ 99.995	≥ 99.995	≥ 99.9995
<b>EN 1822, MPPS-DEHS, local value</b> <sup>(4)</sup>	%	≥ 99.975	≥ 99.975	≥ 99.9975
<b>Filter class to EN1822</b>	-	H14	H14	U15

The model of the 7 filters placed in the periphery of the clean zone is AE-H14-557x557-B. The sign AE is the same of AL signed in Figure, but with a different reference to the pressure difference. In addition, H14 is the defined class for this filters looking at the filtration efficiency. Moreover, 557x557 (mm) are the dimensions of each filter and the letter B show that the face guard is on both sides.

The efficiency data of Table 2.2 are referred to a different MPPS from the previous kind of filters. In fact, in this case, the data are referred to MPPS-

DEHS, the typical particle dimensions spread with an aerosol test. DEHS (Di-Ethyl-Hexyl-Sebacat) is a solution which has the main proportion of droplets generated by aerosol generators with in the most penetration particle size of 0.2 - 0.3  $\mu\text{m}$ .

The standard EN 1822-5(2009) [24] states that “Measure integral penetration of the filter element with membrane filter medium as per this standard with DEHS aerosol at its MPPS (typically between 0.06  $\mu\text{m}$  and 0.08  $\mu\text{m}$ ), using corresponding aerosol generation and detection methods (typically CNC, Condensation Nuclei Counter)”. As a result, the MPPS related to these efficiency data is between 0.06 and 0.08  $\mu\text{m}$ .

The ACH related to the whole ventilated operating room is around 57.

To sum up, the supply airflow is 3.6  $\text{m}^3/\text{s}$  from the ceiling in the clean area, plus 0.7  $\text{m}^3/\text{s}$  from the surrounding area. As a result, the total supply airflow is around 4.3  $\text{m}^3/\text{s}$ . On the other hand, the exhaust airflow is around 4.2  $\text{m}^3/\text{s}$ . As a result, the difference is 0.1  $\text{m}^3/\text{s}$  in favour of the supply air flow and it permits to maintain the Hybrid OT in overpressure in relation with the close corridor.

The difference of pressure maintained between the room and the corridor is about 10 Pa. The maintenance of the pressure difference is demanded to the return fan of AHU 1, in fact his speed, and in consequence the exhaust air flow from the grilles, is regulated in connection with the pressure signal between the Hybrid OT and the corridor.

The Hybrid OT is in overpressure than the corridor to permit the air exfiltration during the door or the pass box opening. On the contrary, if the air flew in the opposite direction, it would be difficult to maintain the cleanliness of the OT thus risking a contamination. Furthermore, when the difference of pressure reaches a too low value, an acoustic alarm signals the problem. Usually, the pressure difference decreases reaching levels around zero Pascal due to the prolonged opening of the small window or of the door. However, in this case the personnel is expected to immediately close the door or window, being aware of the importance of environmental cleanliness of the room.

### 2.2.8 Room conditions

The choice of the temperature inside an OT results in a difficult trade-off between the different necessities of both the patient and the surgical staff. The temperature range defined for operating rooms by the Swedish Standards Institute in the technical specification SIS-TS 39:2012 [1] is  $22^{\circ}\text{C} \pm 4^{\circ}\text{C}$ .

For the patient it is important to be warm, since if he feels cold he loses blood easily due to the increasing of the blood flux, therefore he may be exposed to an higher risk of infections and finds it more difficult to wake up after the end of surgery. In the case of orthopaedic surgery, it is better to maintain a lower temperature, which is expected to reduce the risk of surgeon fatigues due to the more manual and laborious procedures than EVAR surgeries.

This raises a delicate question, as the patient is always more important but, on the other hand, the success of the operation depends on the surgeon's skilfulness and thermo hygrometric comfort which affect the patient too. The final solution is maintaining a lower temperature in order to help surgeons to be clear in mind, which is counterbalanced by more heating blankets and a localised warming system, in order to achieve the most important goal for everyone, that is definitely the patient's health.

The control panel for the temperature regulation inside the Hybrid OT under evaluation is shown in Figure 2.20.

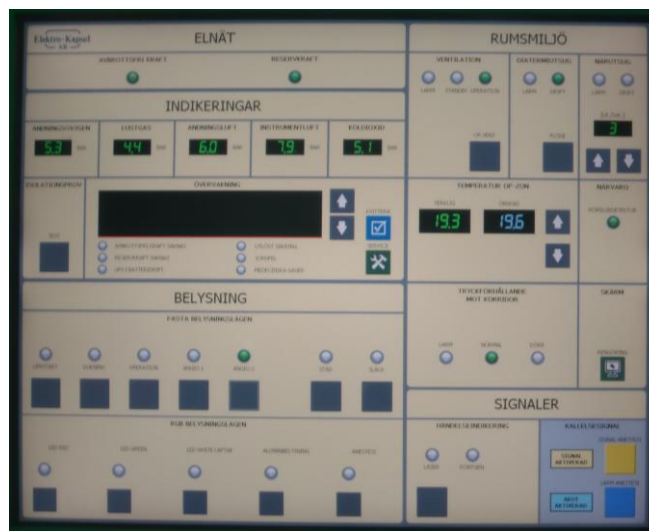


Figure 2.20. Touch screen control panel positioned inside the Hybrid OT of Sahlgrenska University Hospital.

All the personnel can change the ventilation system setting manually. The functions of the touch screen panel are: to change the lighting of the room, to start the local suction air system of the electrosurgical instruments and to signal if the system has some alarming values.

There are two different types of light sources as usual: the surgical lights which thanks to a double arm system cover the surgical area over the operating table, and the ambient lights to enlighten the whole room. It worth to be mentioned that there is an integrated camera in the middle of the surgical lights, in order to provide real time images of the surgical area to the staff that stands far from the operating table.





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## 3 Description of the measurement campaign

In Chapter 2 a detailed description of the Hybrid OT was presented, with particular emphasis on the characteristics of the new-built operating room in which diagnostic and therapeutic functions are matched.

It is worth noting that not only the procedures concerning the main surgeries performed in the above-mentioned room – such as EVAR (EndoVascular Aneurism Repair), orthopaedic surgery (usually spinal surgery) and liver resection – but also the instruments used during these operations are significantly different. In fact, only orthopaedic surgery and liver resection required the use of electrosurgical tools.

In the first part of this Chapter 3, all the typologies of particle samplers used during the measurement campaign inside the Hybrid OT will be described in detail.

The second part of this chapter will focus initially on the statistical analysis of the rough data obtained from a previous study. These data allow also to introduce the concepts and issues which are essential to outline the criteria for the new measurement program developed in this project

Finally, the characteristics of the measurement campaign carried out in this research will be discussed, including all relevant information about the routine for the preparation and positioning of particle samplers inside the Hybrid OT, as well as a detailed report of the types and numbers of the attended operations.

### 3.1 Particle samplers

Four particle counters of three different types were used in this research work:

- 2 instruments of the same model TSI P-TRAK™ 8525
- Laser particle counter 3313 by Metone
- CI-500 Innovation by Climet

#### 3.1.1 TSI P-TRAK™ 8525

The P-TRAK™ Ultrafine Particle Counter (UPC) - shown in Figure 3.1 - gives a real-time measurement of ultrafine particle concentrations in the range between 0.02  $\mu\text{m}$  and 1  $\mu\text{m}$ . The unit of measurement is particles per cubic centimetre ( $\text{pt}/\text{cm}^3$ ) in the range from 0 up to 500,000. In addition, the flow rate is around 100  $\text{cm}^3/\text{min}$  during the sample collection [25].



Figure 5.1.P-TRAK™ 8525 TSI

Particles are drawn by the instrument thanks to a built-in pump. At the entrance of the instrument, particles are mixed with an alcohol vapour. The alcohol condenses onto the particles after passing in the condenser tube, where it causes them to grow into larger droplets, which can be easily detected by the photo detector, as shown below. The photo detector counts the light flashes produced by the passage of the droplets through a laser beam [26].

### 3.1.2 OPC Metone 3313

The MET ONE 3313 – shown in Figure 3.2 - is an Optical Particle Counter (OPC) with a flow rate of 1.0 CFM (cubic foot per minute = 28.316 L/min). The unit of measurement is particles per cubic meter ( $\text{pt}/\text{m}^3$ ) in the range from 0 up to 9,999,999 . This instrument has six particle channels for counting, namely: 0.3, 0.5, 1.0, 3.0, 5.0 and 10.0  $\mu\text{m}$ . Moreover, it can provide continuous monitoring of clean areas, storing up to 2000 readings in its memory buffer. The stored data can be reviewed on the front panel, printed, or downloaded to a computer [27].

The counter is provided with a laser-diode light source. The light is scattered by the particle and a photo diode converts the burst of light into an electrical pulse. The particle size detected depends on the pulse height. The instrument records the data in two different modes: as a differential count or as a cumulative count [27].



Figure 3.2. OPC Metone 3313

### 3.1.3 CI-500 Innovation by Climet

The CI-500 – shown on Figure 3.3 - is an Optical Particle Counter (OPC) with a flow rate of 1.0 cubic foot per minute. This instrument has six particle channels for counting, namely: 0.3, 0.5, 1.0, 5.0, 10.0 and 25.0  $\mu\text{m}$ . The unit of measurement is particles per cubic foot ( $\text{pt}/\text{ft}^3$ ) in the range from 0 up to 1,000,000. Results can be printed according to two different criteria: as a differential count or as a cumulative count [28].

The Climet CI-500 works with the same principles as the Metone 3313. A scattered light is detected by a photo diode which converts the signal to an electrical pulse. The magnitude of the pulse is detected by the instrument, which then places its value into an appropriate sizing channel.



Figure 3.3. Innovation by Climet CI-500 (Certification and calibration Service, 2014)

### 3.2 Data analysis of the previous work

The treatment of the rough data from the measurements carried out during the previous research work [2] was useful to plan the measurement campaign presented in this Master Thesis work.

The first step was to take the rough data and divide them depending on the kind of operation, in order to be able to collect all results in the same datasheet. Every document contained the following information:

- First of all, a general description of the operation, with some important details such as the specification of the operating room in which it had been performed as well as of the positioning of the particle counter.
- Secondly, a schematic picture of the operating room with the instrument location.
- Thirdly, all data taken from measurements with P-track and Climet.
- Finally, the graphics showing the relationship between the measurements and the surgical tools used.

Moreover, this arrangement was fundamental in order to analyse the rough data collected in [2] with a statistical approach. Owing to this, it was easier to obtain an explicit snapshot of trends of airborne contaminants during the different operations.

Furthermore, in some cases, a significant incongruity among different particle counters was registered about the log interval (between different particle counters), or even, in some other cases, a lack of data occurred. In other words, the recurring problem concerned the sample times, which were usually 5 seconds for the first P-track, 10 seconds for the second one and 1 minute for the Climet. In addition, some data were lost due to technical problems of the particle counters.

In order to use in a proper way the statistical analysis, which is extremely useful for this kind of scientific research, it is necessary to collect data with the same sample time and uniform periods of measurements without holes or interruptions. Therefore, all data were rearranged with a sampling time of 1 minute.

### 3.3 Statistical analysis

#### 3.3.1 Box plots

The first step of the statistical analysis was the use of the visual power of box plots in order to give a clear screenshot of the values. In Figure 3.4 two of the most representative diagrams are described as examples. The data shown below were acquired through P-track measurements, so the values refer to the total number of particles whose aerodynamic diameter is between  $0.02 \mu\text{m}$  and  $1 \mu\text{m}$  (UFP, Ultrafine Particles).

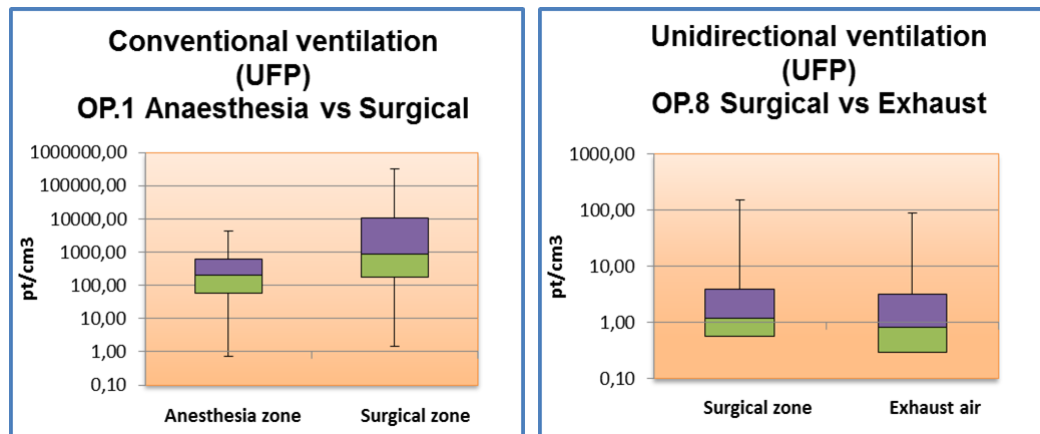


Figure 3.4. Ultrafine particle measurements in two operating rooms with two different ventilation systems. On the left, the particle concentrations with conventional ventilation. On the right, the particle concentrations with unidirectional ventilation.

The first plot is taken from the data related to conventional ventilation during a liver resection (operation n°1), and the second one from the data concerning unidirectional ventilation in the Hybrid operating room during a melanoma metastasis removal (operation n°8 ). However, both of the operations taken as example for the graphs are open surgeries where the electrosurgical instruments were used.

In the conventional ventilation system, the first clear outcome is that value distribution is different in relation to the measurement point. Obviously, the greater particle concentration is found in the surgical zone, near the surgical area. Moreover, the median of the concentration of the sample in the surgical zone is around  $1000 \text{ pt/cm}^3$ , that is bigger than the one in the anaesthesia zone, which corresponds to  $100 \text{ pt/cm}^3$ .

This discrepancy of one order of magnitude highlights a considerable variation in concentration between the surgical and the anaesthesia areas.

In contrast, from the second plot it is easily deducible that in the Hybrid OT with unidirectional ventilation the medians of the two populations of values are more or less the same. Such medians are approximately  $1 \text{ pt/cm}^3$ , which implies very low levels of particle concentration also in the surgical zone.

These statistical evaluations lead to two different considerations. Firstly, there is a noticeable difference between the medians of values in the two kinds of operating rooms taken into account, namely around  $100 \text{ pt/cm}^3$ , at the least, in the case of conventional ventilation, and  $1 \text{ pt/cm}^3$  with unidirectional ventilation. Secondly, it results evident that in hybrid operating rooms - equipped by unidirectional air flow – the people around the surgical zone and those far from it are exposed to the same levels of particle concentration.

To sum up, the analysis of these values makes it possible to state that unidirectional ventilation allows the surgical staff to breathe cleaner air independently of their position inside the operating room. On the other hand, with conventional ventilation the operating staff is exposed to higher particle concentration compared with unidirectional one; moreover, a significant increase in particle number is observed while moving from the anaesthesia to the surgical zone.

### *3.3.2 Mann-Whitney Test*

The statistical analysis continued with the Mann-Whitney test for non-parametric values. As defined by [29] “The Wilcoxon Mann-Whitney Test is one of the most powerful of the nonparametric tests for comparing two populations. It is used to test the null hypothesis that two populations have identical distribution functions against the alternative hypothesis that the two distribution functions differ only with respect to location (median), if at all. The Wilcoxon Mann-Whitney test does not require the assumption that the differences between the two samples are normally distributed. In many applications, the Wilcoxon Mann-Whitney Test is used in place of the two sample t-test when the normality assumption is questionable. This test can also be applied when the observations in a sample of data are ranks, that is, ordinal data rather than direct measurements.”

This new step consisted in the observation of data collected with P-track for ultrafine particles and the examination of the trend of values obtained with this test. Furthermore, it is necessary to point out that the populations of measurements were the same as the previous statistical study carried out with

the box plot since they were the most representative of all data. The P-value of the test was fixed at 0.05.

In operation n°1, which referred to the operating room with conventional ventilation, it was compared the two populations of 178 data coming from the measurements performed both in surgical zone and anaesthesia zone. This comparison, made with Mann-Whitney test, gave the result of 2.06E-11. This value was smaller than the P-value (0.05), thus implying that the null hypothesis can be rejected. The null hypothesis states that the distributions of data are identical. Due to rejection of the null hypothesis, the populations of data were distinct. It means that with conventional ventilation the particles dispersed by the use of the electrosurgical instruments don't follow a defined path from the surgical area to the anaesthesia zone. In addition, the result of this turbulent air mixing with particles decrease the average particle concentration without sweeping away all contaminants in the same direction.

On the other hand, in operation n°8, which concerned the unidirectional flow inside the Hybrid OT, it was considered the populations of 44 values taken from the surgical zone and the zone near the exhaust air grilles. The Mann-Whitney test gave the result of 0.131. Since this value is greater than the P-value, the null hypothesis cannot be rejected; therefore, populations are supposed to be identical. It means that all particles spread in the surgical zone are detected close to the exhaust grilles. This is an indicator of the fixed movement of all particles in accordance with the unidirectional air pattern within the environment.

In short, with upward ventilation populations are distinct and with unidirectional ventilation populations are identical. These results can be associated to the airflow dynamics. The former kind of ventilation works with a higher level of turbulence, so it is normal that the populations are different due to the mixing of the air. The latter, instead, works with a unidirectional airflow and all the particles generated move directly from the surgical area to the exhaust air grilles.



### 3.3.3 Spearman test of linearity

Spearman's correlation coefficient is a statistical measure of the strength of a monotonic relationship between paired data (linearity). The purpose of this statistical correlation is to compare the trends in the concentrations of particles of two different sizes. In other words, the comparison is between the trend of ultrafine particle concentration analysed with UPC (P-trak) and the trend of larger particles detected with the OPC (Climet).

Correlation is an effect size; therefore it is possible to describe the strength of the correlation using the following Table 3.1 [30] for the absolute value

*Table 3.1. Strength of the Spearman's correlation taking into account the absolute value of the statistical test.*

Absolute value of Spearman's correlation	Correlation Strength
0.00 - 0.19	very weak
0.20 - 0.39	weak
0.40 - 0.59	moderate
0.60 - 0.79	strong
0.80 - 1.0	very strong

As far as the use of Spearman's correlation is concerned, there is no requirement of normality and hence it is a nonparametric statistic.

Spearman's correlation makes it possible to verify if the trend of ultrafine particles (0.02  $\mu\text{m}$  – 1  $\mu\text{m}$ ) is the same as that of particles with a diameter  $\geq 0.5$   $\mu\text{m}$  or  $\geq 5$   $\mu\text{m}$ . The basic idea is to evaluate if the air movements inside the room lead differently sized particles to the same distribution.

Figure 3.5 describes the various instrument positions used in operation n°1.

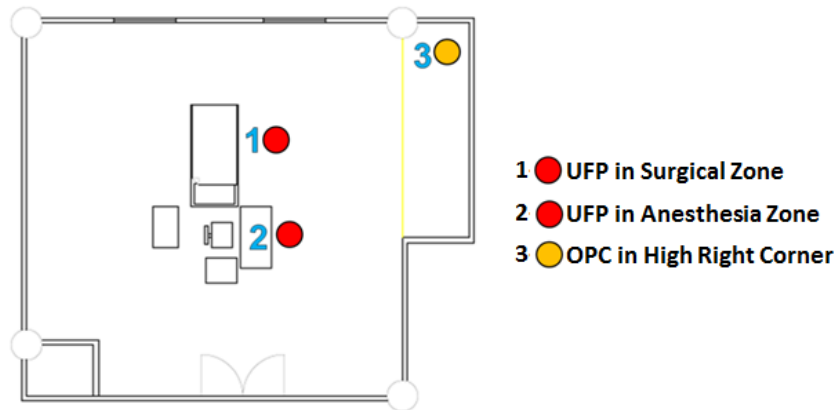


Figure 3.5. Instrument positions during operation n°1, inside the room equipped with conventional airflow.

The results listed in Table 3.2 highlight a moderate linearity between the ultrafine particles and the particles with the size respectively  $\geq 0.5 \mu\text{m}$  and  $\geq 5 \mu\text{m}$ . For this reason, it can be assumed that particles of different dimensions follow the same path inside the operating room.

Predictably, this outcome derives from the air mixing of the conventional airflow system, which ensures the same mean concentration level in all the areas of the operating room.

1 UFP = Ultrafine particles detected with the UPC (P-trak) in the surgical zone

2 UFP = Ultrafine particles detected with the UPC (P-trak) in the anesthesia zone

3 OPC  $0.5 \mu\text{m}$  = Cumulative data of OPC (Climet)  $\geq 0.5 \mu\text{m}$  detected in high right corner of the layout

3 OPC  $5 \mu\text{m}$  = Cumulative data of OPC (Climet)  $\geq 5 \mu\text{m}$  detected in high right corner of the layout

Table 3.2. Spearman's Coefficient related to measurements inside the room equipped with conventional airflow

	2 UFP / 3 OPC $0.5 \mu\text{m}$	2 UFP / 3 OPC $5 \mu\text{m}$	1 UFP / 3 OPC $0.5 \mu\text{m}$	1 UFP / 3 OPC $5 \mu\text{m}$
Spearman's Coefficient	<b>0.53</b>	<b>0.53</b>	<b>0.27</b>	<b>0.27</b>

Figure 3.6 describes the various instrument positions used in operation n°8.

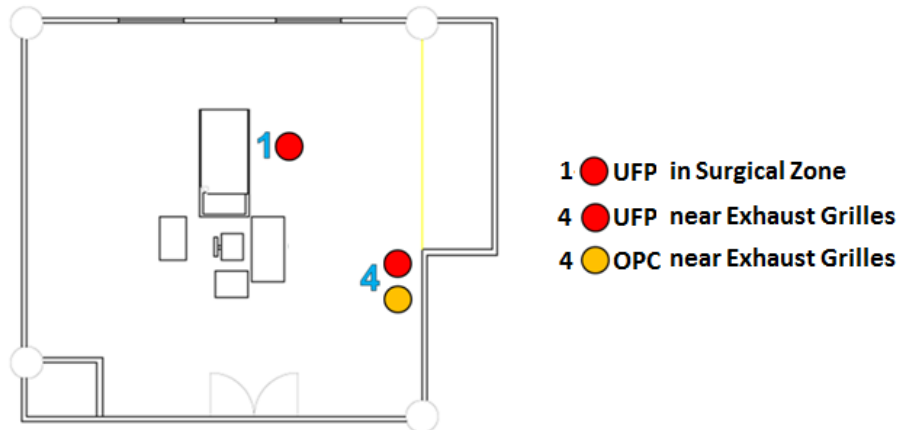


Figure 3.6. Instrument positions during operation n°8, inside the room equipped with unidirectional airflow

The results listed in Table 3.3 highlight a moderate linearity between the ultrafine particles and the particles with the size  $\geq 0.5 \mu\text{m}$ . The same linearity is not observed between the ultrafine particles and the particles with the size  $\geq 5 \mu\text{m}$ . As a consequence, it is possible to assert that the ultrafine particles follow a different path from that of the particles with an aerodynamic diameter  $\geq 5 \mu\text{m}$  inside the operating room. This result is likely to depend on the unidirectional air flow, which throws the larger contaminants out of the operating room leaving only the smaller particles inside.

1 UFP = Ultrafine particles detected with the UPC (P-trak) in the surgical zone

4 UFP = Ultrafine particles detected with the UPC (P-trak) near exhaust grilles

4 OPC  $0.5 \mu\text{m}$  = Cumulative data of OPC  $\geq 0.5 \mu\text{m}$  detected near exhaust grilles

4 OPC  $5 \mu\text{m}$  = Cumulative data of OPC  $\geq 5 \mu\text{m}$  detected near exhaust grilles

Table 3.3. Spearman's Coefficient of data related to measurements inside the room equipped with unidirectional airflow.

	1 UFP / 4 OPC $0.5 \mu\text{m}$	1 UFP / 4 OPC $5 \mu\text{m}$	4 UFP / 4 OPC $0.5 \mu\text{m}$	4 UFP / 4 OPC $5 \mu\text{m}$
Spearman's Coefficient	<b>0.49</b>	<b>0.02</b>	<b>0.59</b>	<b>0.15</b>

### *3.3.4 Important issues for the work*

Firstly, from the analysis of data, it is possible to confirm that unidirectional ventilation gives the surgical staff the possibility to air with a better quality independently of their position inside the operating room; on the contrary, with conventional ventilation the operating staff is exposed to higher particle concentration. Moreover, this study has shed light on the better air quality that is guaranteed by the use of the Hybrid OT provided with a unidirectional airflow system with HEPA filters. This outcome is completely in line with the conclusions already found by the previous work.

Secondly, the analysis with the Mann-Whitney test has highlighted that the unidirectional airflow makes the entire particles generated move directly from the surgical area to the exhaust air grilles. These results in the possibility to evaluate the particle concentration near the operating table with measurements carried out far from the surgical area. For instance, it can be sufficient to position the sampling instrument in a place between the surgical area and the exhaust grilles. This result is completely new in relation with the previous work, and it represents an important indication about the particle samplers positioning.

Finally, the analysis of the data with the Spearman test of linearity allows examining the different particle movements inside the room depending on their size. The outcomes of the test show a different air motion between UFP and larger particles with the unidirectional airflow that is the environment of the new measurement campaign. As a result, it is important to use for the same position two different sampling instruments, in order to detect the particle trend on a greater size range. In addition, the positioning of the ultrafine particle sampler as well as of the other for larger particles may offer the opportunity to continue the analysis comparing the trend of the two differently sized particles. This outcome, also, is completely new respect the previous work and it is an important issue to work.

### 3.4 Measurement strategy

The new measurement campaign will only focus on the particle contamination only inside the Hybrid OT. The following measurements are expected to be useful for the future design of a new operating room in the Sahlgrenska University Hospital, which will be projected and built thanks to the information collected during the research in this prototype room.

The first step for the new measurement campaign was to deal with the problems arose during the measurement campaign of the previous work [2]. For instance, the sampling time for instruments of the same typology needs to be identical. Furthermore, the outcomes of the statistical analysis represent an important support for the planning of the following measurements. For example, in order to obtain truthful particle concentration values, the sampling instrument is supposed to be placed between the surgical area and one of the exhaust grilles. In addition, the previous analysis highlighted different particle movements depending on their size. Therefore, the basic idea is to use two different sampling instruments in the same position inside the room in order to have a clear screenshot of the particle concentration values and their correlations with the different particle dimensions.

The particle sampling instruments used in this work were:

- 2 different UPCs (TSI P-TRAK™ 8525)
- An OPC (3313 by Metone)
- An OPC (CI-500 Innovation by Climet)

For both of the UPC, which provide a real-time concentration measurement of particles in the range between 0.02  $\mu\text{m}$  and 1  $\mu\text{m}$ , a sampling time of 5 seconds was chosen. The shortness of this sampling time allows to analyse an almost real-time value trend of the particle concentration as well as to reveal any connections between all the happenings in the operating room and changes in the particle concentration

The results of the OPC 3313 by Metone are given as a mean value over the time of 1 minute. This sampling time is the minimum possible to achieve good data registration and printing. The meaningful data taken into account derive from the cumulative count of particles larger or equal to 0.5  $\mu\text{m}$ , in one measurement sample, and  $\geq 5 \mu\text{m}$ , in the other.

The OPC (CI-500 Innovation by Climet) is characterized by the same sampling time as the Metone, that is 1 minute. Similarly, the representative values extracted for the purposes of research are the cumulative count of particles  $\geq 0.5$

$\mu\text{m}$ , in one measurement sample, and  $\geq 5 \mu\text{m}$ , in the other. The choice of the sampling time of one minute depends on the fact that Climet actually possesses the same technical characteristics as the abovementioned particle counter. In addition, these shared properties makes it easier to compare the two instruments, if necessary.

The limits for the sampling time of the two latter instruments imply the possibility to obtain only 1 mean value of the particle concentration per minute. Therefore, all the instant peaks of the measurements are decreased due to the output of an average value per minute.

During the surgeries selected for this study it was possible to record all the important data thanks to the Excel sheet showed in Figure 3.7.

Figure 3.7. The Excel sheet designed by Daniele Meda and Leonardo Claudio Amato for this measurement campaign for data collection.

This tool was designed by the author of this work and Leonardo Claudio Amato. The idea to design and use this tool was born from the necessity of registering all the events inside the operating room, which immediately highlighted the difficulty to do it only by writing on some tables or taking notes. The Excel sheet was designed ad hoc for this measurement campaign in order to collect as much as possible data at the same time with precision.

This tool was fundamental for the work. In effect, it offers the opportunity to record the time, the date and the kind of action taking place every time that the different actions take place and manually the button is pressed. In addition, depending on which button is pushed, the data are collected per type in different data sheets.

More precisely, the yellow section is related to the electrosurgical instruments, the green one is dedicated to the different operation times, the light blue area refers to the characteristics of the surgery and the blue one serves different purposes. For example, as can be noticed, the blue section permits the recording of the exact moment of the door opening, the use of the X-ray scanner and finally the number of surgeons, nurses, anaesthetists, visitors and X-ray nurses inside the room in every moment of the operation. In conclusion, this tool was designed ad hoc in order to have a clearer visualisation of the results as well as a precise overview of data. The important outcomes of this tool will be shown in the fourth Chapter resumed in some graphs.

An example of the obtained results collected in the OT with the Excel sheet is presented in Figure 3.8 which shows the records about the number of surgeons during the whole time of the orthopaedic surgery performed on the 28th of October 2013.

	A	B	C	D	E	F	G	H	I	J
1		28/10/13 08.46.12	1							
2		28/10/13 10.05.47	0							
3		28/10/13 10.05.53	1							
4		28/10/13 10.27.53	2							
5		28/10/13 10.27.54	1							
6		28/10/13 10.27.54	0							
7		28/10/13 10.28.08	1							
8		28/10/13 10.28.08	2							
9		28/10/13 10.45.40	1							
10		28/10/13 11.21.51	2							
11		28/10/13 11.21.51	3							
12		28/10/13 11.22.09	2							
13		28/10/13 11.22.09	1							
14		28/10/13 11.22.10	0							
15		28/10/13 11.22.25	1							
16		28/10/13 11.22.25	2							
17		28/10/13 11.22.26	3							
18		28/10/13 13.58.27	2							
19		28/10/13 14.30.11	3							
20		28/10/13 15.08.12	2							
21		28/10/13 15.09.27	1							
22										
23										
24										
25										
26										

Figure 3.8. Excel sheet concerning the orthopaedic surgery of the 28th of October 2013 related to the number of surgeons inside the Hybrid OT.

An important issue to discuss deals with instrument synchronization. Every time, before surgeries, the two different UPCs, the Metone and the Climet were

synchronised with the pc clock - in which the Excel sheet was installed - thus leading to perfect record conformity of all the instruments. This matter arose on the second measurement day when, after the time check, it appeared clear that all the instruments showed a discrepancy of some seconds, probably due to the shut-down period between two subsequent uses. Therefore, the instrument synchronization was supposed to be indispensable since the study clearly aimed at measurement precision and accuracy.

The data download from the particle samplers was done with different software. The two different TSI P-TRAKs had their own software TrackPro 4.6.1 TSI. On the other hand, the software used for the laser particle counter 3313 by Metone was Hyper Terminal from Hilgraeve and converted a signal from a RS-232 serial port. Consequently, after every measurement, the data were downloaded on the PC and the thermal papers were stored in a close box. Finally, after several trials it was impossible to find a software to download the data from CI-500 Innovation by Climet. As a result, the values were copied directly from the printed measurement papers.

The TSI P-TRAK™ 8525 Ultrafine Particle Counters are provided with a tubing sample made of Tygon, with a length of 1.5 m. Its length is the maximum allowed, so that to foster the greatest flexibility for the instruments positioning not so close to the sampling probe. At the top of the tubing a telescopic probe was fixed, even though it was usually employed without the complete extension, which means with a length of 15 cm. The positioning of the instruments was performed with the maximum precision, in order to maintain the tubing in a straight and stable position, thus avoiding a decrease in the efficiency of the counter due to the block of particles in the tubing. For the Metone and the Climet a tubing of the same material (Tygon) was used. The length of these pipes was 1.5 m each for the same purpose already mentioned for the P-track. At the top of the two different tubing, two isokinetic sampling probes were positioned.



### 3.5 Measurements methodology

The routine carried out every day for the measurements was the following:

1. Zero count of the samplers
2. Synchronization of the instrument clock
3. Cleaning procedures regarding the instruments, trolleys, tubing and all the accessories needed
4. Preparation of the instruments on trolleys
5. Positioning of the instruments inside the Hybrid operating room followed by the turning on of them
6. Sampler measurements and records with Excel sheet
7. Measurements end
8. Data download
9. Final zero count of the samplers

Before beginning to sample with the particle counters, it was important to verify if the instruments were working properly. Therefore, the zero filter (HEPA) assembly needs to be attached to the instrument. The particle concentration should go to zero in approximately 5 to 10 seconds. In order to make sure the zero reading is stable, it was necessary to leave the zero filter attached to the instrument at least for 180 seconds.

As mentioned above, the achievement of the precision goal resulted in the development of a procedure for the synchronization of the instruments with the computer.

The next step refers to the instrument sanitization. These procedures took place in the sterilization room. First of all, during the cleaning phase, the operators wore gloves made of poly-isoprene powder-free. After that, they started to clean accurately all the accessories – such as telescopic instrument holder, probe holders, trolleys, tubing, isokinetic probes and also the instruments – with isopropyl alcohol, as showed in Figure 3.9.



Figure 3.9. Clean instruments. In order from left: P-trak, Tygon piping, telescopic probe, telescopic instrument holder , probe holder.

After the cleaning procedures the instruments and the sampling accessories were positioned on the trolleys. This operation allowed the instruments to be easily transported and placed inside the operating room.

Sometimes, the positioning of the instruments required a long time of waiting due to the need to ask the surgeon which could be the best location for the trolleys. The decision was taken considering both the urgency to measure the particle contamination in defined zones and the requirement to avoid interferences with the surgical procedures. Usually, the instruments were positioned during the phase of the preparation of the operating room with some minutes of delay between them. As a result, the starting time of the measurements was different. Nevertheless, the relevant data concerned the surgery phase, and the instruments were always working properly at that time.

During the operation, two operators dealt with measurements, one inside the operating room checking the good working of the instruments, and the other in the next office collecting the data while looking inside through the windows, as shown in Figure 3.10. The other operator ( Leonardo Claudio Amato) was inside the Hybrid OT in order to measure the air velocity in various positions of the chamber. His collected data will be the starting point for future computational fluid dynamic (CFD) simulations about the Hybrid OT air flow pattern for his Master Thesis work.



Figure 3.10. Office next to the Hybrid OT, position of the operator that used to work with the Excel sheet.

The office operator's job was to record the surgery thanks to the excel sheet. In addition, his work was simplified by the use of two real time cameras inside the Hybrid OT, which made it possible to follow the operations step by step and monitor the usage time of the instruments as well as the door openings. Moreover, the window allowed him to count the number of people inside the operating room.

After the end of the surgery, the routine was to download the data thanks to the above mentioned software. Finally, it was necessary to attach the zero filter assembly to the instruments in order to clean the particles from their internal channels.

### 3.6 Measurements performed

The measurement period within the Hybrid OT lasted from the 18th October 2013 to the 21<sup>st</sup> March 2014. During these months of work the possibilities to visit the Hybrid OT were several, thus serving different purposes. For this reason, it is useful to divide the various working days in five different categories depending on the type of surgery or on the different uses of the room:

- EVAR ( Endovascular Aortic Repair)
- Orthopedic surgery
- Liver resection
- Empty room
- Simulation

Table 3.4 outlines the date and the duration of all the measurements performed in the Hybrid OT as well as the goal of the Hybrid OT.

*Table 3.4. Summary of the measurements inside the Hybrid OT*

Operation N°	Date	Type of operation	Duration (hh.mm.ss)
1	18/10/2013	EMPTY ROOM	2.59.23
2	24/10/2013	EVAR	3.00.29
3	25/10/2013	EMPTY ROOM	3.50.05
4	28/10/2013	ORTHOPAEDIC SURGERY	4.39.43
5	29/10/2013	EVAR	2.31.00
6	31/10/2013	EVAR	2.46.34
7	04/11/2013	ORTHOPAEDIC SURGERY	1.19.28
8	05/11/2013	EVAR	7.28.34
9	07/11/2013	EVAR	4.54.00
10	08/11/2013	EMPTY ROOM	3.23.12
11	11/11/2013	ORTHOPAEDIC SURGERY	3.15.07
12	12/11/2013	EVAR	4.59.30
13	14/11/2013	LIVER RESECTION	6.06.05
14	18/11/2013	ORTHOPAEDIC SURGERY	2.46.45
15	19/11/2013	EVAR	3.14.56
16	21/11/2013	EVAR	2.43.57
17	22/11/2013	EMPTY ROOM	3.20.12
18	25/11/2013	ORTHOPAEDIC SURGERY	3.34.09
19	03/12/2013	EVAR	5.46.00
20	05/12/2013	EVAR	1.24.16
21	09/12/2013	ORTHOPAEDIC SURGERY	4.50.13
22	09/12/2013	SIMULATION	3.50.18
23	16/12/2013	ORTHOPAEDIC SURGERY	2.29.59
24	21/03/2014	SIMULATION	2.30.12
Total measurements duration			~ 90 hours

Out of 24 days, 10 of them were dedicated to a particular kind of surgery, the so called EVAR (EndoVascular Aneurysm Repair), as shown in Table 3.5.

*Table 3.5. Measurements days inside the Hybrid OT during EVAR surgery*

Operation N°	Date	Type of operation	Duration (hh.mm.ss)
2	24/10/2013	EVAR	3.00.29
5	29/10/2013	EVAR	2.31.00
6	31/10/2013	EVAR	2.46.34
8	05/11/2013	EVAR	7.28.34
9	07/11/2013	EVAR	4.54.00
12	12/11/2013	EVAR	4.59.30
15	19/11/2013	EVAR	3.14.56
16	21/11/2013	EVAR	2.43.57
19	03/12/2013	EVAR	5.46.00
20	05/12/2013	EVAR	1.24.16

The following description of this type of surgery is taken from the website Johns Hopkins Medicine [31], which devotes a special section to the diagnosis and treatment of most diseases: “EVAR is a minimally-invasive (without a large abdominal incision) procedure performed to repair an abdominal aortic aneurysm. EVAR may be performed in an operating room, radiology department, or a catheterization laboratory. The doctor may use general anaesthesia or regional anaesthesia (epidural or spinal anaesthesia). The doctor will make a small incision in each groin to visualize the femoral arteries in each leg. With the use of special endovascular instruments, along with X-ray images for guidance, a stent-graft will be inserted through the femoral artery and advanced up into the aorta to the site of the aneurysm. A stent-graft is a long cylinder-like tube made of a thin metal framework (stent), while the graft portion is made of various materials such as Dacron or polytetrafluoroethylene (PTFE) and may cover the stent. The stent helps to hold the graft in place. The stent-graft is inserted into the aorta in a collapsed position and placed at the aneurysm site. Once in place, the stent-graft will be expanded (in a spring-like fashion), attaching to the wall of the aorta to support the wall of the aorta. The aneurysm will eventually shrink down onto the stent-graft”.

In Figure 3.11 it is possible to see a sequence of 3-D images that use to help surgeons in the correct positioning of stunts during the intravascular procedures.

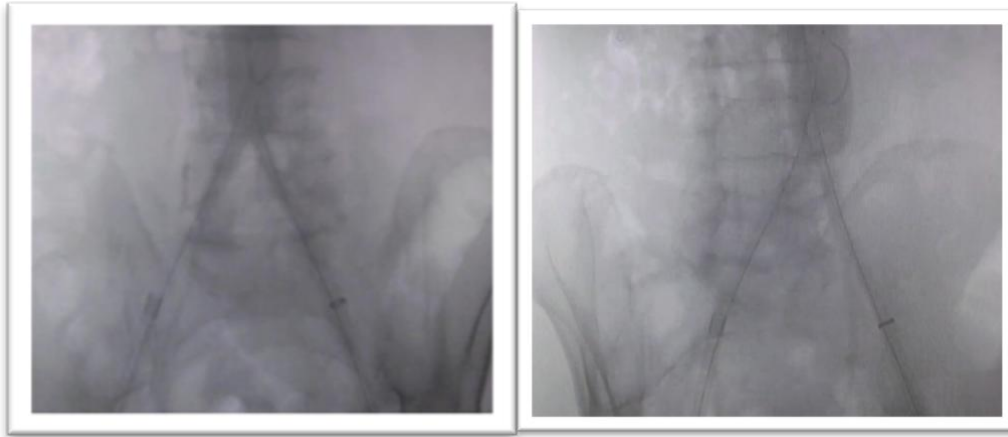


Figure 3.11. Sequence of pictures represents the rotational 3-D visualization recorded with the X-ray scanner with a standard angiography during an EVAR surgery. The two wires in the pictures are the catheters used for the introduction of the stunts through the femoral arteries.

As the description and the previous figure point out, during this kind of surgery the surgeon is required to use the X-ray scanner, which provides real time images of the position of the stent inside the patient's body during the operation.

This peculiarity makes it more likely to attend this kind of operations inside the Hybrid OT. The extract also focuses on the minimal- invasiveness of the procedures. As a result, surgeons very rarely resort to the electrosurgical instruments, as was clear from the first operation.

During EVAR surgery, the positioning of the instruments was:

- UPC (P-TRAK™) and OPC (Metone) outside the clean area, placed at the height of 1.50 m, in order to evaluate the particle concentration trend of the air breathed by nurses and visitors. This measuring point varies according to the kind of operation, since it aims at detecting any possible differences in the contamination level depending on the position in the room. This measurement point will not be relevant for the final aim of the work, so its data will not be taken into account.

- UPC (P-TRAK™) and OPC (Climet) placed in the surgical zone, as showed by Figure 3.12, between the operating table and one of the exhaust grilles in order to detect the particle concentration near the sterile zone. The sampling probes are positioned on the Mayo (trolley) at the height of 1.50 m and the distance between them is around 30 cm. It is worth noting that due to the rare use of the electrosurgical tools the particle concentration is generated directly by the surgical staff around the operative table.

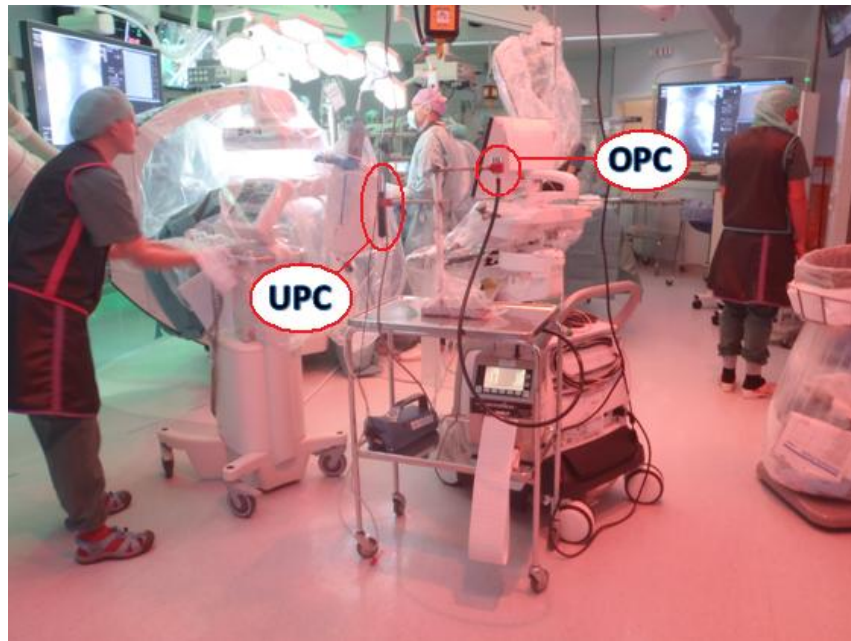


Figure 3.12. Probes of UPC (P-TRAK™) and OPC (Climet) are placed in the surgical zone. The sampling probes are positioned on the Mayo (trolley) at the height of 1.50 m and the distance between them is around 30 cm.

Out of 24 measuring days, 7 of them were devoted to orthopaedic surgery, as exposed in Table 3.6.

*Table 3.6. Measurement days in the Hybrid OT during orthopaedic surgeries*

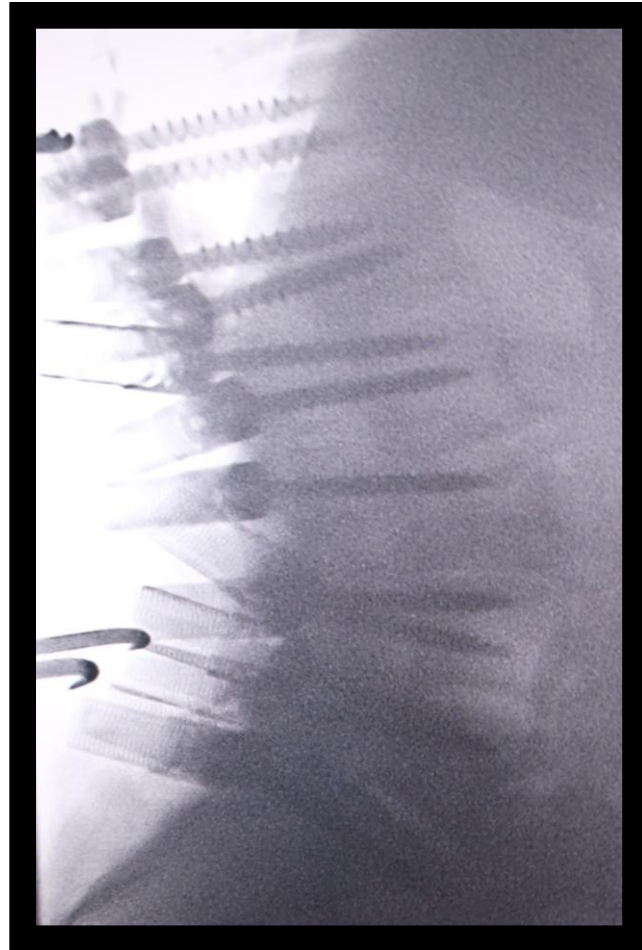
Operation N°	Date	Type of operation	Duration (hh.mm.ss)
4	28/10/2013	ORTHOPAEDIC SURGERY	4.39.43
7	04/11/2013	ORTHOPAEDIC SURGERY	1.19.28
11	11/11/2013	ORTHOPAEDIC SURGERY	3.15.07
14	18/11/2013	ORTHOPAEDIC SURGERY	2.46.45
18	25/11/2013	ORTHOPAEDIC SURGERY	3.34.09
21	09/12/2013	ORTHOPAEDIC SURGERY	4.50.13
23	16/12/2013	ORTHOPAEDIC SURGERY	2.29.59

The high air quality of the Hybrid OT is expected to make it the best place to perform this kind of open surgery. In addition, another key-concept to consider is the availability - inside the room - of the X-ray scanner, extremely useful for orthopaedic surgery.

The website Orthoinfo [32] – AAOS (American Academy of Orthopaedic Surgeons) – describes it as follows: “Spinal fusion is a surgical procedure used to correct problems with the small bones of the spine (vertebrae). It is essentially a "welding" process. The basic idea is to fuse together the painful vertebrae so that they heal into a single, solid bone. Spine surgery is usually recommended only when your doctor can pinpoint the source of your pain. To do this, your doctor may use imaging tests, such as x-rays, Computed Tomography (CT), and magnetic resonance imaging (MRI) scans”.



In Figure 3.13 is presented a typical X-ray image that helps the surgeon to check the correct positioning of the screws on the spinal column.



**Figure 3.13.** Typical image that permits the surgeon to control the correct positioning of screws on the spinal column during orthopaedic surgeries.

These operations cause the patient to have a big wound on his back and the air coming from the H14 HEPA filters goes directly toward it. This means that the air needs to be sterilized to the utmost degree, in order to limit the risk of infection.

In this case, the disposition of the particle samplers is quite different from the previous one:

- OPC (Metone) is usually located close to the exhaust grille, at the height of 1.50 m but these data will not be necessary for the evaluations of this work.
- UPC (P-TRAK™) and OPC (Climet) placed in the surgical zone, as showed by Figure 3.14, between the operating table and one of the exhaust grilles in order to detect the particle concentration near the sterile zone. The sampling probes are positioned on the Mayo (trolley) at the height of 1.50 m and the distance between them is around 30 cm. Unlike the former case, during orthopedic surgery the particle concentration is generated mainly by the massive use of electrosurgical tools.

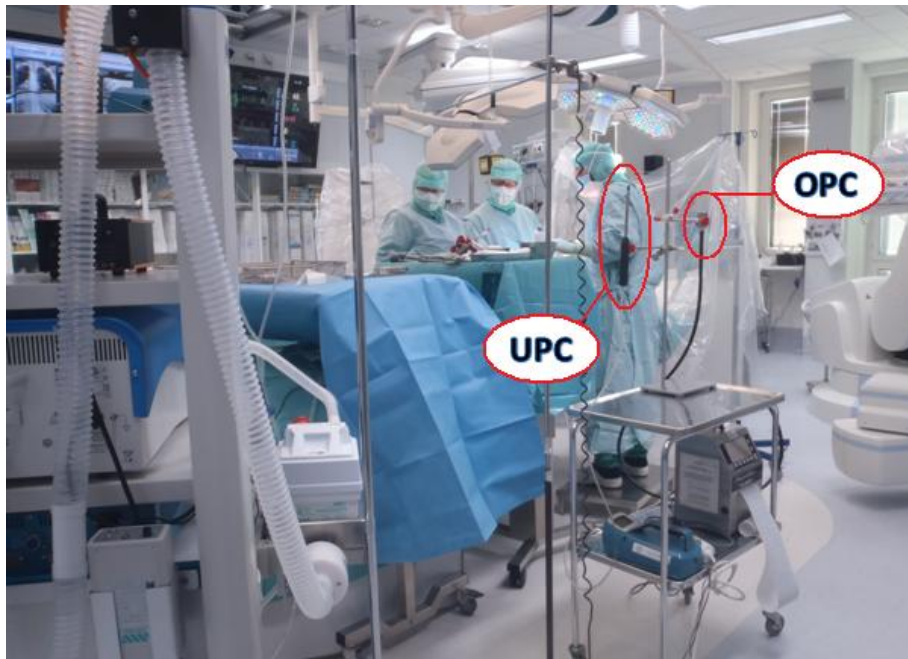


Figure 3.14. UPC (P-TRAK™) and OPC (Climet) placed in the surgical zone. The sampling probes are positioned on the Mayo (trolley) at the height of 1.50 m and the distance between them is around 30 cm.

- UPC (P-TRAK™) positioned in the clean area with the telescopic probe placed at the height of 2.80 m, which means at a distance of 20 cm below the HEPA filters, as possible to be seen in the red circle in Figure 3.15. The choice of this position is motivated by the crucial role played by this instrument in the analysis of the quality of the air coming from the AHU system, which provides 70% of recirculated air in this zone. The aim is to assess if the recirculated air that enters the room is contaminated by the surgical smoke produced by the electrosurgical instruments.



Figure 3.15. UPC (P-TRAK™) positioned in the clean area with the red circle that indicates the position of the telescopic probe placed at the height of 2.80 m, which means at a distance of 20 cm under the H14 HEPA filters.

Out of 24 measuring days, 1 was dedicated to liver resection, as exposed in Table 3.7.

*Table 3.7. Measurement day inside the Hybrid OT during liver resection surgery*

Operation N°	Date	Type of operation	Duration (hh.mm.ss)
13	14/11/2013	LIVER RESECTION	6.06.05

According to the website WebMD [33], “Liver resection is the surgical removal of part of the liver. This operation is for some types of liver cancer and for certain cases of metastatic colorectal cancer. Up to half of your liver can be removed as long as the rest is healthy. During a liver resection, the part of your liver that contains cancer is removed, along with some healthy liver tissue on either side. If the right side of your liver is removed, your gallbladder, which is attached to the liver, is also taken out”.

These operations are likely to provoke a big wound on the patient's belly and the air coming from the HEPA filters goes directly toward it. Therefore, also in this case maximum air sterilization is required in order to prevent patients from the risk of infection.

Some differences can be identified in the disposition of the particle samplers compared with the previous ones:

- UPC (P-TRAK™) and OPC (Climet) near the surgical zone, placed between the operative table and one of the exhaust grilles, at the height of 1.50 m, in order to detect the particle concentration near the sterile zone. As in the case of orthopedic surgery, the particle concentration is generated mainly by the massive use of electrosurgical tools.
- UPC (P-TRAK™) and OPC (Metone) positioned in the clean area; the former at the height of 2.80 m, the latter at 1.90 m. The choice of this positioning depends on the need to test the quality of the air coming from the AHU system, which provides 70% of recirculated air in this zone. This measurement helps to determine if the recirculated air that enters the room is contaminated by the surgical smoke produced by the electrosurgical instruments. The data from Metone were not relevant, so they will not be used for the work.

Out of 24 measuring days, 4 were used to detect the particle contamination level inside the empty room, as exposed in Table 3.8. In other words, no operation was performed while the two operators inside were carrying out the measurements.

*Table 3.8. Measurement days inside the empty Hybrid OT*

Operation N°	Date	Type of operation	Duration (hh.mm.ss)
1	18/10/2013	EMPTY ROOM	2.59.23
3	25/10/2013	EMPTY ROOM	3.50.05
10	08/11/2013	EMPTY ROOM	3.23.12
17	22/11/2013	EMPTY ROOM	3.20.12

With this configuration, the instruments were moved several times in order to measure the particle contamination in almost every part of the room. The collected data provided a significant contribution in the development of the classification contained in Chapter 4.

The trolley (Mayo) was positioned in different places of the Hybrid OT in order to collect representative data for the air quality classification of the operating theatre.

The instruments were used in pairs, as in some cases during the operations:

- UPC (P-TRAK™) and OPC (Metone) without a fixed position, the sampling probes were positioned at the height of 1.50 m with a distance of 30 cm between them.

- UPC (P-TRAK™) and OPC (Climet) without a fixed position, the sampling probes were placed at the height of 1.50 m with a distance of 30 cm between them, as showed in Figure 3.16.

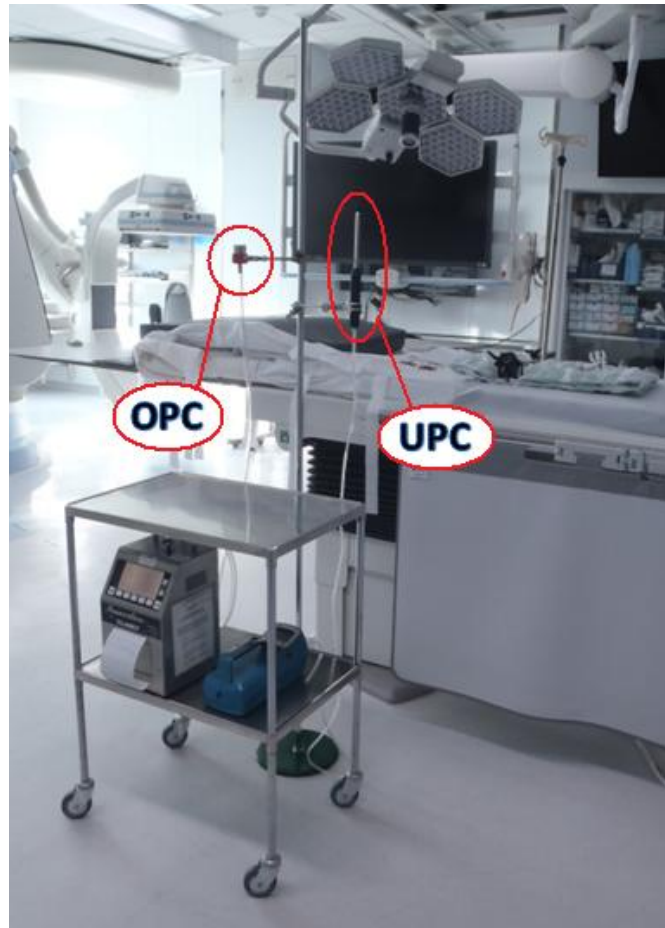


Figure 3 .16. UPC (P-TRAK™) and OPC (Climet) near the surgical table; the sampling probes were placed at the height of 1.50 m with a distance of 30 cm between them.

Only the data about the OPC (Climet) were used for this study.

Out of 24 measuring days, 2 were dedicated to simulated surgeries with a calf liver, as showed in Table 3.9.

*Table 3.9. Measurements days inside the Hybrid OT during the simulated surgeries*

Operation N°	Date	Type of operation	Duration (hh.mm.ss)
22	09/12/2013	SIMULATION	3.50.18
24	21/03/2014	SIMULATION	2.30.12

The first simulation was performed for two main reasons:

- to measure the different particle concentrations near the surgeon's nose while using the various electro-surgical instruments
- to detect the concentration of ultrafine particles in the air coming from the HEPA filters over the surgical area during the use of the different electro-surgical tools

The instruments were arranged as follows:

- UPC (P-TRAK™) and OPC (Climet) were positioned near the surgeon's nose; in Figure 3.17 it is possible to see the two sampling probes.

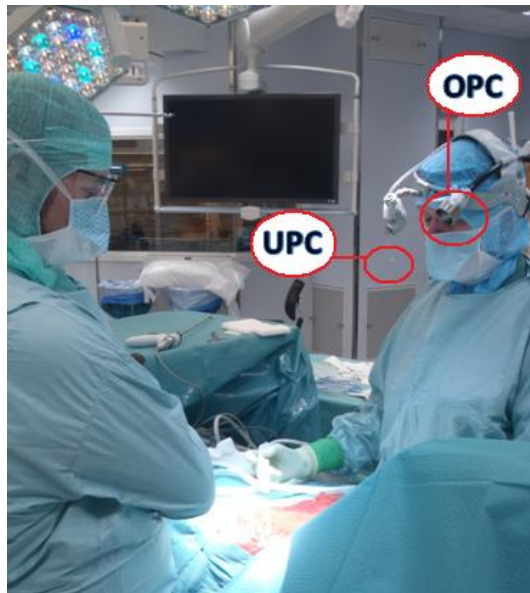


Figure 3.17. The two sampling probes of UPC (P-TRAK™) and OPC (Climet) positioned near the surgeon's nose during the simulated surgery (operation N°22).

- UPC (P-TRAK™) was located at the height of 2.80 m in the clean area that is at a distance of 20 cm below the HEPA filters.
- OPC (Metone) was placed close to the exhaust grille near the surgical area, at the height of 1.50 m. The data taken from this instrument were not useful for this work.

On the other hand, the second simulation was performed as the previous one on a calf liver. In this case, the purpose of the simulation was to measure the particle concentrations source near the surgical site. The measuring probe of the P-track was used at a distance of 5-8 cm in order to measure the local number of particles dispersed during the use of the different electrosurgical instruments. The electrosurgical tools used were the same utilized during standard open surgeries.

The working strategy for the two different simulations will be discussed in detail later thanks to the help of data and graphs.



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## 4 Measurement campaign

Chapter 3 was important not only to understand the specific preconditions and the resulting methodological strategy for this study, but also to highlight the work done before the actual measurements in order to optimize the relevance of results.

In this Chapter, at the beginning, it is shown how the air cleanliness classification of the Hybrid OT is defined. The aim of this first part is to demonstrate that particle concentrations in the Hybrid OT with the state of occupancy “at rest” are lower than the maximum level for operating rooms imposed by standard.

Afterwards, it will be possible to consider and evaluate the main data gathered from the measurement campaign in terms of typical characteristics of the different operations involved – such as the clothing system, the duration of surgeries, the average number of people inside the Hybrid OT and the frequency of door openings.

Furthermore, as it will be shown hereinafter, the hypotheses about particle concentrations were not confirmed, due to the massive use of electrosurgical instruments during open surgeries. For this reason, it is worth specifying that Chapter 5 will be focused only on the data related to such types of surgeries, in order to analyse the presence of ultrafine particles inside the Hybrid OT as well as the way they may affect the patient's health.

## 4.1 Classification of air cleanliness

### 4.1.1 Standards used

The useful standards to understand the characteristics of operating rooms are:

- SIS-TS 39:2012 [1] Microbiological cleanliness in the operating room – Preventing airborne contamination – Guidance and fundamental requirements
- UNI 11425:2011 [15] Surgery operating theatre, ventilation and air-conditioning system for contamination control (VCCC)
- ISO 14644-1:2001 [34] Cleanrooms and associated controlled environments. Classification of air cleanliness

The technical specification SIS-TS 39:2012 [1] underlines the importance of the ventilation inside operating rooms “to provide a safe and comfortable environment for patients and personnel working in the room”.

As described with the UNI 11425:2011 [15], the main purposes of the VCCC (Ventilation and air-Conditioning system for Contamination Control) are to maintain in the environment:

- Total concentration of the spread particulate, viable and non-viable, below fixed limits
- Thermo-hygrometric conditions suitable to guarantee the regular procedures
- Chemical concentration of contaminants below fixed limits
- Stable and detectable pressure gradients between rooms with different needs of contaminants protection
- Constant values of the fixed parameters

In addition, for every operating room it is important to specify:

- The needs of the surgical procedure
- The use variety and intensity
- The necessary cleanliness class and the measurement conditions
- The recovery time of the starting conditions
- The maximum number of people inside the room
- The prescribed behavior and clothing system for the authorized personnel
- The criteria to handle and dismiss the pollutant materials

- The entrance and exit criteria for materials, equipment, patients and personnel.

The Appendix B of the UNI 11425(2011) [15] highlights the better efficacy of the laminar airflow to maintain the cleanliness of the surgical area in all the operating rooms. In the case of the Hybrid room, it is compulsory to follow the rules defined for the operating rooms designed for specialized surgical procedures, like organs transplants or prosthesis implants and, in general, for complex operations with a duration higher than 60 minutes. The cleanliness class needs to be at least ISO 5 with the occupancy state “at rest”.

The specification about the cleanliness classes is available on the ISO 14644-1(2001) [34]. This standard is both for clean rooms and for rooms with a controlled environments. Moreover, the cleanliness classification by particle concentration can be applied to the operating rooms. The main objective of the ISO 14644-1(2001) is to define the correct procedures to classify the cleanliness level in these environments.

“In the clean room standard ISO 14644-1(2001) "Classification of Air Cleanliness" the classes are based on the equation:

$$C_n = 10^n \times \left(\frac{0.1}{D}\right)^{2.08} \quad (4.1)$$

Where

$C_n$  = maximum permitted number of particles per cubic meter equal to or greater than the specified particle size, rounded to whole number

$n$  = is the ISO class number, which must be a multiple of 0.1 and be 9 or less

$D$  = is the particle size in micrometre ”

The following Table 4.1 resumes all the calculations for the different particle sizes done using the equation 4.1.

*Table 4.1. The different airborne particle threshold limits for the nine ISO cleanliness classes*

ISO Class	Maximum Number of Particles in Air (particles in each cubic meter equal to or greater than the specified size)					
	Particle size					
	$\geq 0.1 \mu\text{m}$	$\geq 0.2 \mu\text{m}$	$\geq 0.3 \mu\text{m}$	$\geq 0.5 \mu\text{m}$	$\geq 1 \mu\text{m}$	$\geq 5 \mu\text{m}$
ISO Class 1	10	2				
ISO Class 2	100	24	10	4		
ISO Class 3	1000	237	102	35	8	
ISO Class 4	10,000	2,370	1,020	352	83	
ISO Class 5	100,000	23,700	10,200	3,520	832	29
ISO Class 6	1,000,000	237,000	102,000	35,200	8,320	293
ISO Class 7				352,000	83,200	2930
ISO Class 8				3,520,000	832,000	29,300
ISO Class 9				35,200,000	8,320,000	293,000

In order to define the cleanliness level of the room it is necessary to specify:

- The cleanliness classification number (Class ISO N)
- The occupancy states (as built, at rest, operational)
- The particle dimensions and the number of particles used for the classification.

Also following formulas revealed in Appendix C of the standard ISO 14644-1:2001 are relevant to define the cleanliness class of rooms.

The minimum sampling air volume is defined by the following formula:

$$V_s = \left(\frac{20}{C_n}\right) \times 1000 \quad (4.2)$$

Where

$V_s$  = minimum air volume of each sampling point, expressed in litres

$C_n$  = limit number of particles for the required class, defined for a specific dimension

20 = defined number of particles, that should be counted if the particle concentration would be the limit number for the class

The following formula refers to the mean particle concentration per each sampling point.

$$\bar{x}_i = \frac{x_{i,1} + x_{i,2} + \dots + x_{i,n}}{n} \quad (4.3)$$

Where

$\bar{x}_i$  = mean particle concentration per each sampling point in the point  $i$

from  $x_{i,1}$  to  $x_{i,n}$  = particle concentrations of the single sample in the point  $i$

$n$  = number of samples in the point  $i$

This procedure is relevant only if the number of sampling points is between 1 and 9.

It is possible to proceed with the calculation of the general average of the mean values.

$$\bar{\bar{x}}_i = \frac{(\bar{x}_{i,1} + \bar{x}_{i,2} + \dots + \bar{x}_{i,m})}{m} \quad (4.4)$$

Where

$\bar{\bar{x}}_i$  = general average of the mean values

from  $\bar{x}_{i,1}$  to  $\bar{x}_{i,m}$  = mean values per each sampling point

$m$  = number of mean values in the single points

Finally, it is possible to calculate the standard deviation of the mean values

$$s = \sqrt{\frac{(\bar{x}_{i,1} - \bar{x})^2 + (\bar{x}_{i,2} - \bar{x})^2 + \dots + (\bar{x}_{i,m} - \bar{x})^2}{(m-1)}} \quad (4.5)$$

Where

s = standard deviation of the mean values

Now it is possible to define the upper bounds of a 95% confidence interval of the general average:

$$95\% \text{ CI} = x'' + t_{0,95} * \left(\frac{s}{\sqrt{m}}\right) \quad (4.6)$$

Where

95% CI = upper bounds of a 95% confidence interval of the general average

$t_{0,95}$  = 95th percentile of the t-student distribution, with m-1 degrees of freedom which is defined in Table 4.2 in relation with the number of samples.

*Table 4.2.  $t_{0,95}$ , 95th percentile of the t-student distribution*

No. of individual averages (m)	2	3	4	5	6	7-9
t	6.3	2.9	2.4	2.1	2.0	1.9

### 4.1.2 Definition of the measurement conditions

The data collected in the empty Hybrid OT were initially thought to be compared with those gathered during the ongoing surgery. In fact, the data were collected in two different days. However, the idea is to follow the calculation from standards in order to evaluate the order of magnitude of the particle concentrations within the Hybrid OT. However, some further researches raised the possibility to use them for a sort of classification of the Hybrid OT with the occupancy state “at rest”. The definition of this occupational state according to ISO 14644-1(2001) [34] is: “the installation is complete with equipment installed and operating in a manner agreed upon by the customer and supplier, but with no personnel present”.

However, in the case of point the different condition is the presence of two operators inside the OT, working with the proper attention in order not to interfere with the measurements. Nevertheless, every time the operator turned on the particle sampler, he stood near the instrument, thus increasing the risk of altering the data collection. For this reason, the first five minutes of each measurement were deleted in order to use only the data gathered with steady conditions.

The measurements were carried out inside the Hybrid OT using the OPC (Climet CI-500). The particle sampler during the measurements was moved inside the room in different positions in order to detect the particle concentration in several points of the room.

The clothing system of the two operators was the common nurse uniform as defined in Chapter 2.

Moreover, as mentioned before, the data used for this sort of classification were acquired in two different days, but with the same occupancy state of the Hybrid OT. This choice depended on the need of enough sampling points in the right positions, in order to have an order of magnitude about the cleanliness class guaranteed in the environment.

### 4.1.3 Data and calculations

It is important to remind the two different areas inside the Hybrid OT that are considered separated in the classification:

- The clean zone (under the unidirectional air flow about  $3.6 \text{ m}^3/\text{s}$  or equally  $12960 \text{ m}^3/\text{h}$ , over the operating table)
- Peripheral zone of the clean zone (with an airflow around  $0.7 \text{ m}^3/\text{s}$  or equally  $2520 \text{ m}^3/\text{h}$ )

The data gathered could be used to understand if the minimum ISO 5 class for operating rooms is reached, but in this case the aim of the collection was not a complete classification; however, it can be considered a realistic screen shot of the particle contamination distribution inside the Hybrid OT.

#### 4.1.3.1 The clean zone

The area under the HEPA filters was about  $12.6 \text{ m}^2$  and the occupancy state was “at rest” with two people inside the operating room, due to two different and contemporary research studies in the Hybrid OT. The particle concentrations collected were selected in order to prevent the results from being altered by any interference from the two researchers. The sampling time of the OPC used is 1 minute and the data were collected for each point for around 10 minutes. Furthermore, only the constant values of the central 3 minutes were taken.

The particle dimensions selected for the class definition are the cumulative number of particles for two dimensions, respectively higher than  $0.5 \text{ }\mu\text{m}$  and  $5 \text{ }\mu\text{m}$ . The number of the sampling points is defined by ISO 14644-1(2001) as

$$N = \sqrt{A} = \sqrt{12.6} \sim 4$$

Consequently, as it can be seen, the number of the sampling points is lower than 10, so it is possible to calculate the 95% CI to verify if the requirements are satisfied.

For particles  $\geq 0.5 \text{ }\mu\text{m}$ , to reach the ISO 5 class, the maximum particle concentration is  $3520 \text{ pt}/\text{m}^3$  (Table 4.1)

For particles  $\geq 5 \text{ }\mu\text{m}$ , to reach the ISO 5 class, the maximum particle concentration is  $29 \text{ pt}/\text{m}^3$  (Table 4.1)

The minimum air volume is defined by the use of equation (4.2)



$$V_{s\ 0.5} = \left(\frac{20}{3520}\right) \times 1000 = 5.69\text{ L}$$

$$V_{s\ 5} = \left(\frac{20}{29}\right) \times 1000 = 690\text{ L}$$

The sampling air volume is 1 CFM (cubic feet per minute), that means approximately 28.3 L/min. The selected sampling data are 3 per each point (3 minutes), in other words 3 minutes, which means about 85 litres per each point.

$85\text{L} > 5.69\text{ L} = V_{s\ 0.5} \rightarrow$  This results in the possibility to proceed.

The needed air volume for the particle dimension of  $5\ \mu\text{m}$  is 690 l, that is around 24 minutes per each point. The data collected allow at most 10 minutes of good sampling. As a result, it is not possible to use the data related to the particles with a dimension of  $5\ \mu\text{m}$ .

Sampling point positions selected for this study are shown in Figure 4.1, the number indicated refers to the progressive measurement day and the letter to the progressive measurements during the same day.

Day . Progressive letter	Date
2.F	25/10/2013
3.A	08/11/2013
3.B	08/11/2013
3.C	08/11/2013

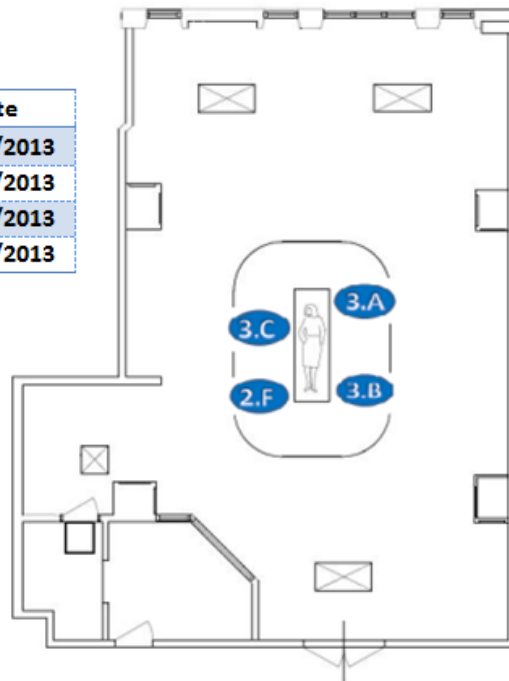


Figure 6.1. Positioning of the sampling probe of the OPC for the 4 different measuring points.

In addition, due to the original measurement unit of the data is in  $\text{pt}/\text{ft}^3$ , but the instrument converts automatically into  $\text{pt}/\text{m}^3$ . Because of the zero data, it is important to evaluate that these values represent an amount of less than  $35 \text{ pt}/\text{m}^3$  due to the adaptation. The zero data collected are on the left but the data used are showed on the right is showed in Table 4.3.

Table 4.3. Data of the different mean particle concentration measurements during the air cleanliness classification for the clean area

	$\bar{x}_i$ ( $\text{pt}/\text{m}^3$ )		$\bar{x}_i$ ( $\text{pt}/\text{m}^3$ )
Sample points	0.5 $\mu\text{m}$		0.5 $\mu\text{m}$
3.A	0		< 35
3.B	0		< 35
3.C	0		< 35
2.F	0		< 35

The equations used to calculate the values in Table 4.4 are 4.3, 4.4, 4.5 and 4.6.

Table 4.4 Calculations for the different measurements during the air cleanliness classification for the clean area. General average of the mean values, standard deviation of the mean values, 95th percentile of the t-student distribution, upper bounds of a 95% confidence interval of the general average.

	0.5 $\mu\text{m}$
$\bar{\bar{x}}_i$	35
S	0
$t_{0,95}$	1,9
95% CI	35

The following result is relevant for the study:

$$95\% \text{ CI } 0.5 \mu\text{m} = 35 \text{ pt/m}^3 < 3,520 \text{ pt/m}^3$$

Thanks to these calculations, the requirements are proven to be satisfied. Therefore, the clean zone of the Hybrid OT can be defined at least with the class ISO 5, bearing in mind the different conditions of the measurement process, with two operators in the OT and the collection of data taken over two different days. The particle dimension was  $0,5 \mu\text{m}$  and the value of particle concentration used for the classification was 35.

#### 4.1.3.2 Periphery of the clean zone

The area outside the clean zone is about  $78.4 \text{ m}^2$  and the occupancy state is “at rest” with two people inside the operating room, for the same scientific reasons as explained above. Similarly, it is necessary to underline again that the data collected were selected to avoid any kind of interference brought about by the presence of the two researchers. It was used the same sampling modality of the previous case.

The particle dimensions selected for the class definition are the cumulative number of particles for two dimensions, respectively higher than  $0.5 \mu\text{m}$  and  $5 \mu\text{m}$ . The number of the sampling points is calculated as

$$N = \sqrt{A} = \sqrt{78.4} \sim 9$$

Consequently, according to this calculation, the number of the sampling points is lower than 10, therefore it is possible to calculate the 95% CI to verify if the requirements are satisfied.

For particles  $\geq 0.5 \mu\text{m}$ , to reach the ISO 5 class, the maximum particle concentration is  $3520 \text{ pt/m}^3$  (Table 4.1)

For particles  $\geq 5 \mu\text{m}$ , to reach the ISO 5 class, the maximum particle concentration is  $29 \text{ pt/m}^3$  (Table 4.1)

The minimum air volume is defined thanks to the equation (2.2)

$$V_{s 0.5} = \left( \frac{20}{3520} \right) \times 1000 = 5.69 \text{ L}$$

$$V_{s 5} = \left( \frac{20}{29} \right) \times 1000 = 690 \text{ L}$$

The sampling air volume is 1 CFM (cubic feet per minute), which corresponds to approximately 28.3 L/min. The selected sampling data are 3 per each point, in other words 3 minutes, which means about 85 litres per each point.

85L > 5.69L → This results in the possibility to proceed.

The needed air volume for the particle dimension of 5 µm is 690 L, that is around 24 minutes per each point. The data collected allow at most 10 minutes of good sampling. As a result, it is not possible to use the data related to the particles with a dimension of 5 µm.

Sampling point positions selected for this study are showed in Figure 4.2, the number indicated refers to the progressive measurement day and the letter to the progressive measurements.

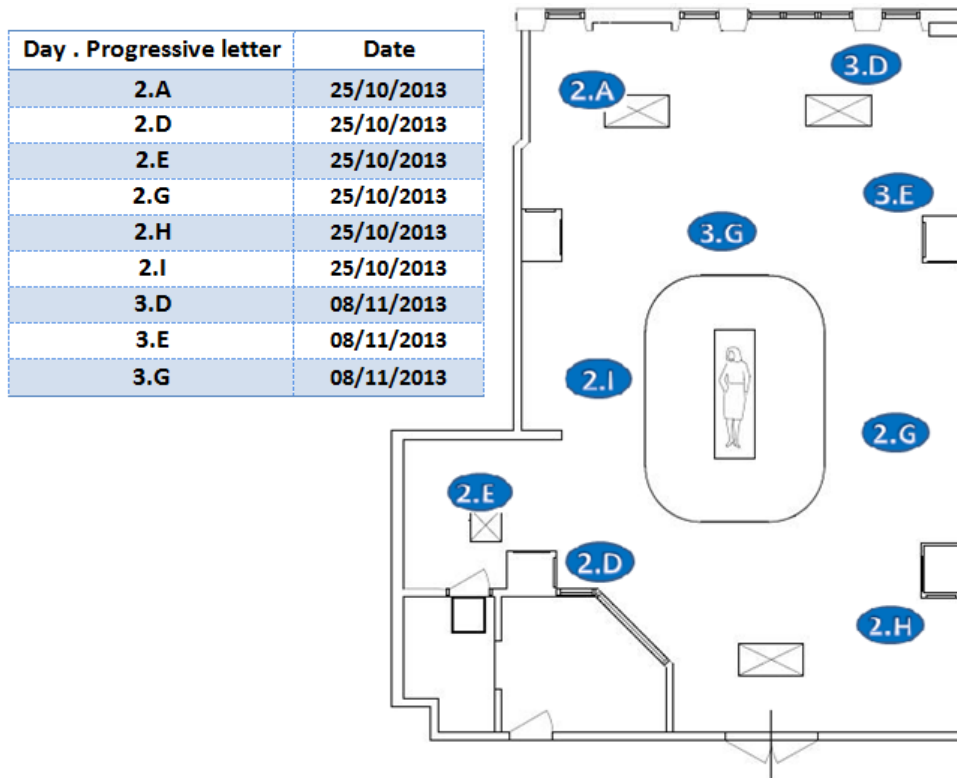


Figure 4.2. Positioning of the sampling probe of the OPC for the 9 different measuring points.

In addition, due to the original measurement unit of the data is in  $\text{pt}/\text{ft}^3$ , but the instrument converts automatically into  $\text{pt}/\text{m}^3$ . Because of the zero data, it is

important to evaluate that these values represent an amount of less than  $35 \text{ pt/m}^3$  due to the adaptation. Also the values of  $12 \text{ pt/m}^3$  are rounded up to the value of  $35 \text{ pt/m}^3$ . The zero data collected are on the left but the data used are showed on the right is showed in Table 4.5.

*Table 4.5. Data of the different mean particle concentration measurements during the air cleanliness classification for the periphery of the clean area*

	$\bar{x}_i \text{ (pt/m}^3\text{)}$		$\bar{x}_i \text{ (pt/m}^3\text{)}$
Sample points	0.5 $\mu\text{m}$	Sample points	0.5 $\mu\text{m}$
2.A	12	2.A	< 35
2.D	0	2.D	< 35
2.E	0	2.E	< 35
2.G	12	2.G	< 35
2.H	0	2.H	< 35
2.I	0	2.I	< 35
3.D	0	3.D	< 35
3.E	12	3.E	< 35
3.G	0	3.G	< 35

The equations used to calculate the values in Table 4.6 are 4.3, 4.4, 4.5 and 4.6.

*Table 4.6. Calculations for the different measurements during the air cleanliness classification for the periphery of the clean area. General average of the mean values, standard deviation of the mean values, 95th percentile of the t-student distribution, upper bounds of a 95% confidence interval of the general average.*

	0.5 $\mu\text{m}$
$\bar{\bar{x}}_i$	35
S	0
$t_{0,95}$	1,9
95% CI	35

The following result is relevant for the study:

$$95\% \text{ CI } 0.5 \mu\text{m} = 35 \text{ pt/m}^3 < 3,520 \text{ pt/m}^3$$

Thanks to these calculations, the requirements are proven to be satisfied also for the peripheral zone. Thereby, the space outside the clean zone of the Hybrid OT can be defined at least with the class ISO 5.

## 4.2 Activity characterization

The air cleanliness classification was useful in order to highlight that the standard conditions about particle contamination are fulfilled. The focus of this new section is to characterize the activities inside the Hybrid OT. It is possible to describe the various operations performed inside the Hybrid operating room from different points of view. As mentioned in chapter 3, the three distinct surgery types have different needs and characteristics. Therefore, this section aims at pointing out the differences observed among EVAR, liver resection and orthopaedic surgeries at several levels.

The definition of EVAR (EndoVascular Aortic Repair) surgery provided by UCSF Medical Center [35] describes it as “an innovative, less invasive procedure used to treat problems affecting the blood vessels, such as an aneurysm, which is a swelling or "ballooning" of the blood vessel. The surgery involves making a small incision near each hip to access the blood vessels”. It then highlights that “In the past, this condition was treated by open surgery, involving an incision in the side of the chest or breastbone and a long recovery period”. However, the small incision mentioned above allows the patient to be less vulnerable to infections than in the case of open surgery. For this reason, the working conditions of the personnel vary considerably from those concerning the open surgeries like orthopaedic operations and liver resections.

In the description given by Laser Spine Institute [36] the orthopaedic spine surgery is depicted as follow “During open back surgery or traditional back surgery, a long incision (usually 5 to 6 inches) is made through the muscles and soft tissues to access the affected part of the spine. The surgeon then removes any bone matter or tissue causing nerve or spinal cord pressure”. It is clear from this description that due to the big wound on the patient’s back, this kind of operation needs more attention and cure of the environmental conditions than EVAR procedures to limit the risk of infection. Furthermore, as mentioned by [37] about Liver resection surgery “Surgeons make an incision across the right upper abdomen, below the ribcage, to remove the tumor”, it means also in this case that because of the presence of a big wound the attention level need to be higher, especially about the cleanliness of the procedures. These two last groups of procedures – orthopaedic and liver resection – during the work are treated as similar due the similar nature of the open surgeries in relation to the big wound in the patient’s body. This choice was done in order to compare this open procedures with the percutaneous procedures of the EVAR surgeries.

The data collected and resumed in the following paragraphs will provide a detailed contrastive analysis of these surgical procedures. Furthermore, these data are supposed to form the basis for the following analysis of particle concentration, also considering the way it is affected by the use of diathermy during orthopaedic surgery. The focus will be at first on the clothing system - followed by an evaluation of the main staff number - then on the frequency of door openings and finally on the average particle concentration in the surgical zone. All these data were collected during the 18 real surgeries referred to this work.

### 4.2.1 Clothing system

The clothing system used during EVAR operations is the same for all the personnel inside the operating room and there are no distinctions compared with the ordinary hospital uniform which - as specified in Chapter 2.

In the case of orthopaedic surgery and liver resection some differences occur as specified in Chapter 2. The clothes for open surgeries have another manufacture which allows a higher level of cleanliness; but they are also more expensive.

The different choices for the clothing system in the two different kind of surgeries are resumed in Table 4.7.

*Table 4.7. Different choices for the clothing system for EVAR surgeries and open surgeries.*

	EVAR	Open Surgeries
<b>Blouse &amp; trousers</b>	50% poliestere 50% cotton	30% nylon 70% cotton
<b>Shoes</b>	Standard	Standard
<b>Head cover</b>	Standard	Helmet
<b>Face mask</b>	NO	YES

The cost increase is worth due to the patient's sensitivity to infections during orthopaedic surgery and liver resection. It is also important to remember that the main objective is to preserve the patient's health, but also the safety of the personnel and the surgical staff.



## 4.2.2 Surgery duration

The collection of data by means of the Excel sheet makes it possible to measure the length of the surgeries examined. As far as surgery duration is concerned, it is worth to specify that it refers to the time between the end of the preparation procedures and the moment in which the wound of the patient is completely closed after the suture.

As can be easily noticed in Figure 4.3, the different surgery durations are completely independent from the operation type.

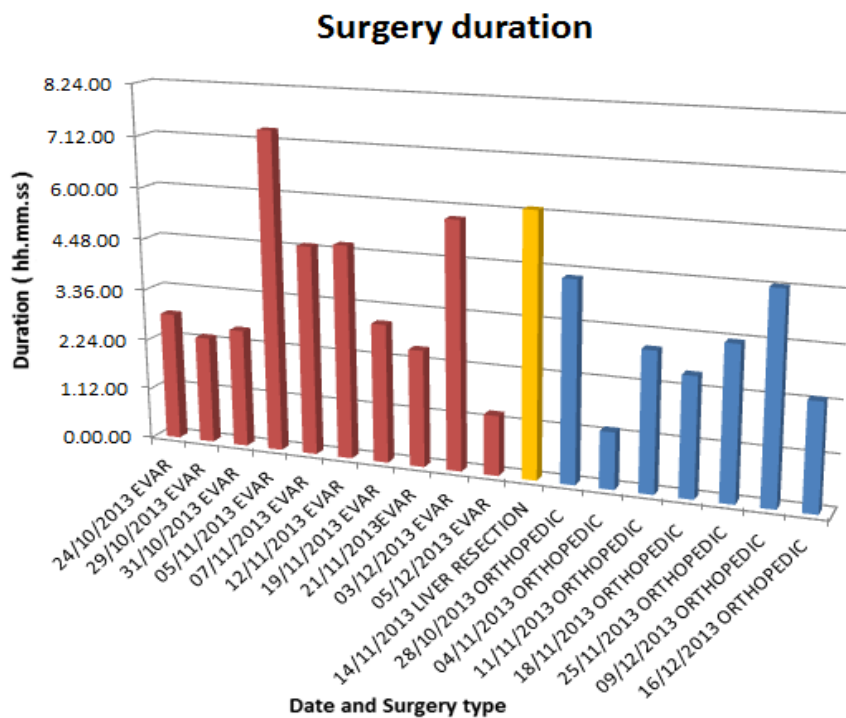


Figure 4.3. Surgery duration related to the different types of operations observed

The three different type of surgeries - EVAR, orthopaedic and liver resection- respectively, have not a characteristic duration. As a result, this point of view cannot be taken as an indicator of the way of working during different types of surgeries. The longest surgeries are expected to coincide with the most complex, since such operations need more time to complete the medical procedures properly.

As stated by Smith et al [38], the operative time is kept short as much as possible to decrease the infection risk. However, some surgical procedures demand more time than usual due to the complexity of the operation. In the case of the Hybrid OT, for example, the most innovative procedures performed, as shown in Figure 4.3, require sometimes more than 3 hours for all the three types of surgery taken into account.

### 4.2.3 The average number of people

As mentioned in Chapter 2, the maximum number of people inside the Hybrid OT is between 15 and 20. Usually, in a conventional OT there are approximately 6 - 8 people, but the greater space available in the Hybrid OT allows twice the number of people inside.

Thanks to the data collected with the Excel sheet, it is possible to analyse the number of people present during the different operations in an extremely precise and accurate manner. Afterward, the data were elaborated considering the mean values of the number of staff in the time interval of 1 minute, in order to adjust them to the sampling time used for the particle counters and provide a more intuitive data visualisation.

At a first glance, Figure 4.4 reveals that during the three kinds of operations the average numbers of personnel present in the OT vary considerably. For instance, during EVAR surgeries the number of people inside the operating room is higher than the other two types. However, within the same group of the EVAR operations significant discrepancies are reported to occur in terms of staff presence, due the complexity of operations, which implies the joint work of a wider team of experts and medical specialists, as well as the presence of a greater number of visitors inside the operating room.

Moreover, it is important to underline that the new approach to EVAR surgery triggered by the use of real-time imaging visualization has gained increasing prominence and attention among surgeons from other hospitals and students. In addition, because of the use of new particular types of stents, technicians supplied by the selling companies are required to help surgeons handle the new tools properly during the operations. All that, explains the higher number of people inside the OT attending some of the EVAR surgeries.

Comparing the three types of surgery considered in terms of average of the number of people – as illustrated in Figure 4.4 – the substantial difference between non-invasive operations (EVAR) and open surgeries (liver resection and orthopaedic) appears immediately clear.

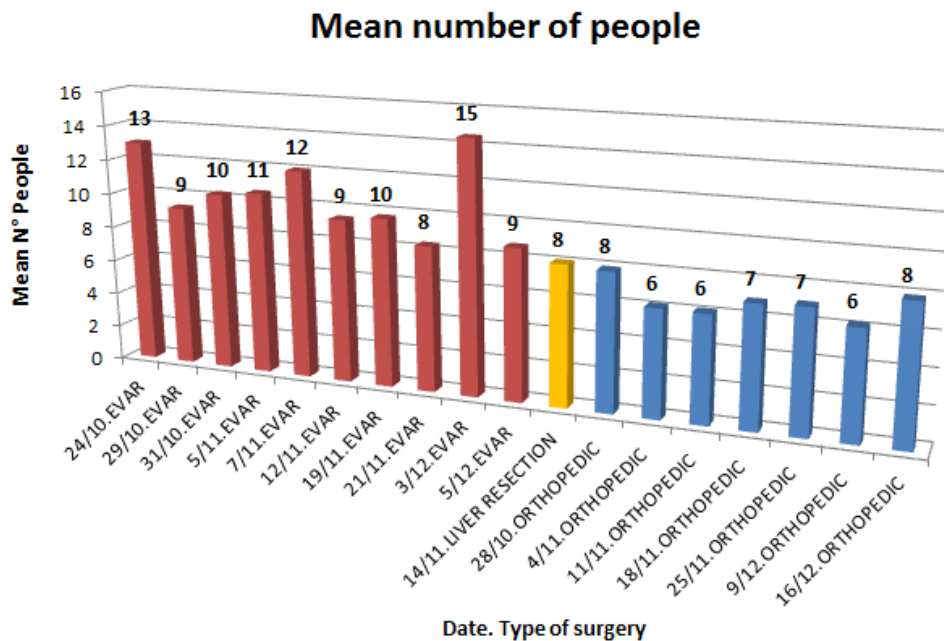


Figure 4.4. The mean number of people recorded during the various operations inspected

During EVAR a larger staff is needed due to the complexity of the operation as well as the crucial interaction of surgeons, nurses, X-ray nurses, anaesthetists, visitors and technicians. Furthermore, non-invasive procedures allow more people to stay inside the OT since they are likely to lead to a lower risk of infection for the patient.

On the other hand, in the case of open surgeries, the staff's presence is supposed to be reduced at most, since the microbial level in an operating room is proportional to the number of people inside it, as was fully explained in Chapter 1.

Moreover, the personnel movements may cause skin debris, lint and respiratory droplets to disperse inside the room. As a result, during open surgeries the staff should move as least as possible in order to prevent the spread of particles and the consequent higher risk of SSI (Surgical Site Infection) [3].

To confirm what has been said so far, a valuable example is provided by the trends shown in Figure 4.5, which describes the personnel presence during the EVAR operation performed on the 7th of November 2013 (operation n° 9).

By observing the diagram, in Figure 4.5, it is possible to infer the significant influence exerted by the occurrence of visitors on the total number of people inside the OT during the operation. This category includes technicians, surgeons from other hospitals and one operator appointed to carry out the measurements necessary for this study.

In addition, the number of surgeons remains almost constant throughout the operation, whereas the number of nurses is variable. Another aspect worth noting is the presence of X-ray nurses, who are the only able to drive the X-ray scanner – particularly useful for this kind of surgery – in all its movements.

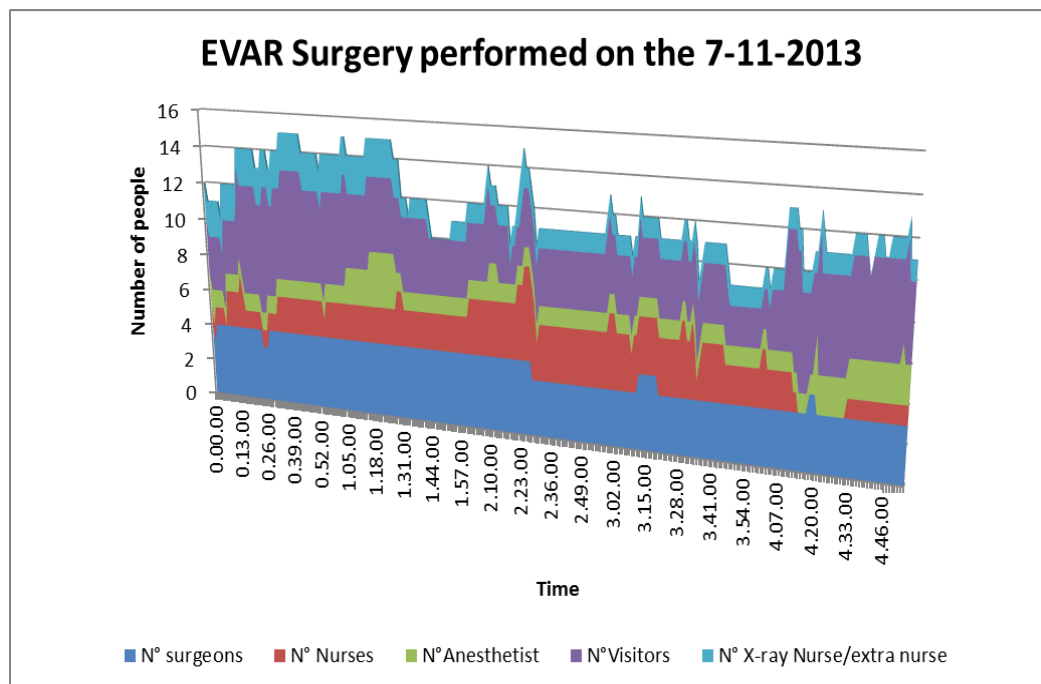


Figure 4.5. Number of people recorded during the EVAR operation performed on the 7-11-2013 (operation N°9).

In Figure 4.6 it is possible to observe the trends related to the presence of the medical staff during the orthopaedic operation performed on the 9th of December 2013 (operation n°21), as representative for open surgeries.

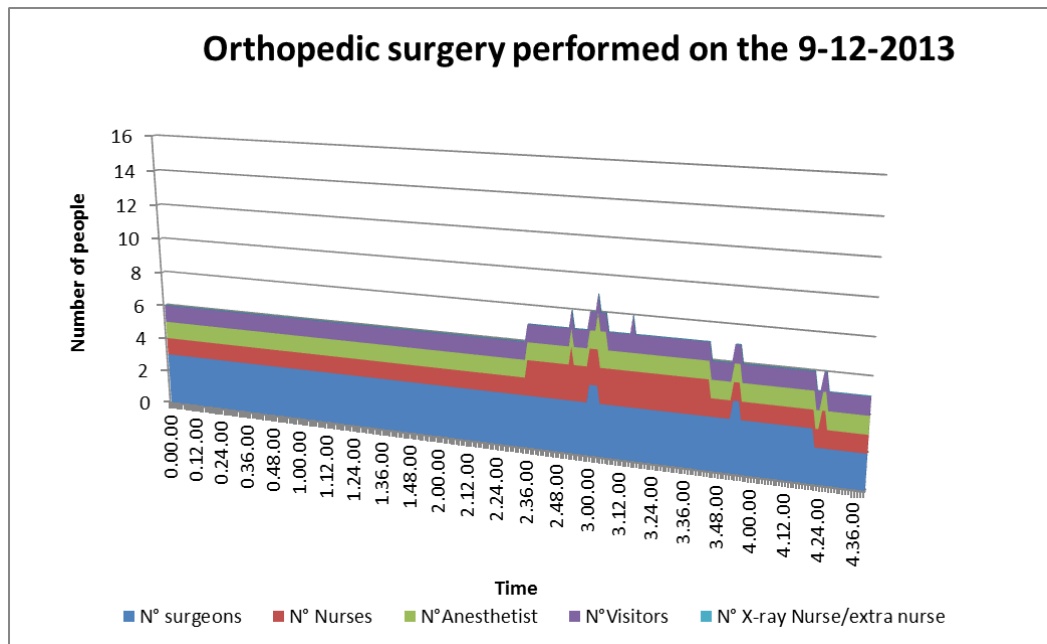


Figure 4.6. Number of people recorded during the orthopedic operation performed on the 9-12-2013 (operation N° 21).

Unlike the previous case, here it is noticeable that the analysis of all the categories of people involved in terms of occurrence inside the OT has highlighted rather constant values, which are also generally lower than those concerning the EVAR operation (Figure 4.5).

Furthermore, since orthopaedic surgery allows the X-ray scanner to be moved with greater ease, the instrument is entrusted directly to the surgeon and these results in the absence of X-ray nurses during such operations.

#### 4.2.4 Frequency of door openings

After the evaluation of the number of personnel inside the operating room, for the purposes of this study, it is important to focus on the frequency of door openings during ongoing surgeries.

The impact of the number of door opening need to be evaluated in detail, but the general aim is to reduce this number to preserve the air cleanliness of the operating room in order to reduce the risk for infections.

During the measuring campaign, it was possible to count the door openings and record their timings using the Excel sheet designed ad hoc for this work. As can be easily observed in Figure 4.7, higher frequency of door openings per minute is reported to occur during EVAR and liver resection operations. On the other hand, measurements have revealed lower frequency values in the case of orthopaedic surgeries.

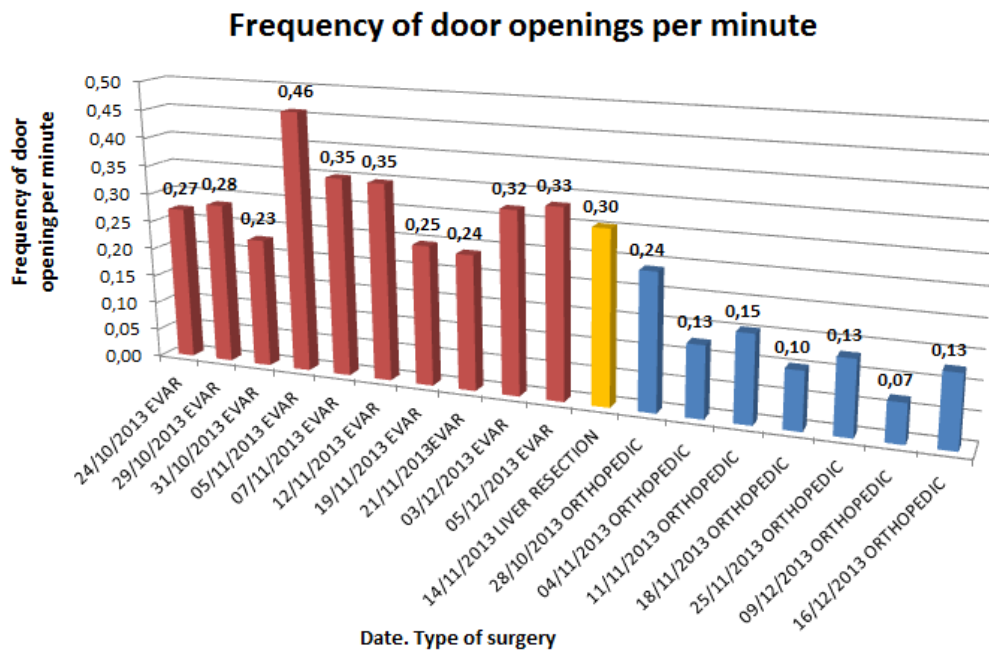


Figure 4.7. Frequency of door openings per minute recorded during the different types of operations

This discrepancy in the results can be associated to the higher level of cleanliness required for open surgeries, which causes the medical staff to exit rarely from the operating room, thus reducing the frequency of door openings. Nevertheless, as far as liver resection is concerned, the frequency level is high mostly due to the need of specialized personnel for the different phases of the operation, given the complexity of the surgical procedures that requires special equipment to be taken from other rooms.

To sum up, the lower frequency values recorded during orthopaedic operations confirm a greater attention to the cleanliness of the OT in the case of open surgeries in general than EVAR surgeries.

As pointed out by previous analyses, every time the door opens, air is supposed to flow out of the OT to the corridor due to the overpressure maintained between the two zones. This difference in pressure – equal to around 10 Pa – is brought about by the ventilation system, which is designed with a higher supplied air volume ( $4.3 \text{ m}^3/\text{s}$ ) than the exhaust one ( $4.2 \text{ m}^3/\text{s}$ ) for this aim. On the other hand, there is several air driving forces that lets the air income from the corridor to the OT due to the door openings with a negative effect on the air quality. For example, it worth to be mentioned that the vortexes creation due to the sliding movement of the door can probably originate a reintroduction of particles for the corridor to the OT. In addition, as Ljungqvist et al [39] state, one of these negative air driving forces is the temperature gradient between the corridor and the operating room which could create some reintroduction of air inside the same operating room. Moreover, their work underlines the importance to minimize the number of door openings and the hold on time of the door opened in order to limit the air infiltration.

Furthermore, the occurrence of door openings is strictly connected with the flow of people moving between the Hybrid room and the adjacent corridor. However, as a matter of fact, the door openings themselves represent a risk for the air quality inside the OT, since they are likely to introduce contaminants from outside. As stated by Smith et al [38] during their research they noticed a correlation between an increasingly higher level of contamination in the OT and the greater frequency of door openings. More specifically, they highlighted that this kind of contamination depends mainly on two different factors:

- The increase in foot traffic
- The decrease in the pressure gradient between the protected zone and the periphery, which leads to a faster spread of bacteria in the surgical field

Therefore, it is clear that a reduction in the number of door openings makes it possible for the staff to stay in an environment more protected from contaminants. In addition, the personnel, avoiding passing through the corridor –

which is obviously less clean than the operating room – prevents both cloth contamination and the consequent risk of infection for the patient.

To summarize, different driving forces can influence the air motion in relation with the door openings. For instance, the pressure difference lets the air going out the OT without any contamination problems for the surgical room. In contrast, other opposite driving forces lead the less clean air of the corridor inside the operating room increasing the risk for infections.

Unfortunately, during the measurement campaign it was not possible to measure the temperature gradient between the Hybrid OT and the corridor or doing some smoke tests to check the airflow in relation with the door openings because the attention was focused on other measurements. Nevertheless, the theoretical approach already mentioned can be considered satisfactory in order to understand the problems related to the air motion during the door openings.

In conclusion, it is always better to reduce as much as possible the number of door openings to avoid a possible contamination of the operating room. As a result, during open surgeries due to the higher risk for infections the frequency of door openings is lower than EVAR surgeries which can probably result in a better air quality inside the Hybrid operating room.



### 4.2.5 Mean values of particle concentration

During all the 18 surgeries followed in the Hybrid OT at Sahlgrenska University Hospital two of the four particle samplers were positioned in the surgical area in order to collect the data useful for this study. Due to the different types of operations and the various needs of the surgical staff the position of the measuring instruments was defined from time to time but, in any case, they were placed more or less near the zone indicated by the red point in Figure 4.8. This position can be associated with position 2 described in the next chapter.

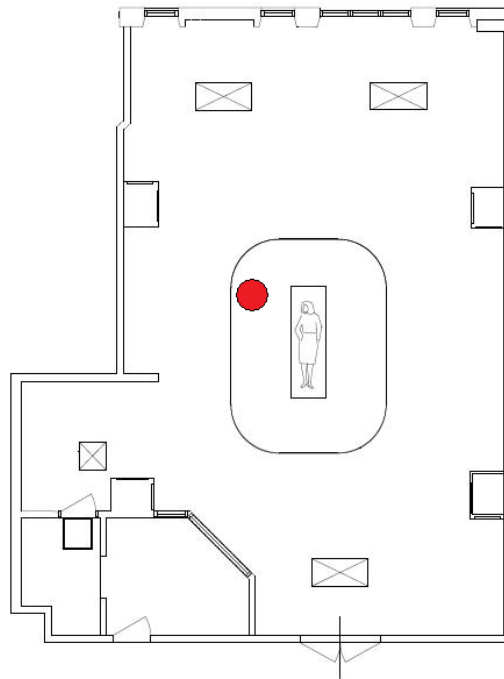


Figure 4.8. Position of the particle sampling probe during the different ongoing surgeries, indicated by the red point.

The instruments used in this zone of the OT were:

- OPC (CI-500 Innovation by Climet)
- One of the two UPC (TSI P-TRAK™ 8525)

The OPC is a laser particle counter with a flow rate of 1.0 cubic foot per minute. The data selected as representative of this instrument are the cumulative counts of particles respectively  $\geq$  than 0.5  $\mu\text{m}$  and 5.0  $\mu\text{m}$ . The unit of measurement is particles per cubic foot ( $\text{pt}/\text{ft}^3$ ) but it is automatically converted in  $\text{pt}/\text{m}^3$ .

The P-TRAK™ is an Ultrafine Particle Counter (UPC) and its flow rate is around  $100 \text{ cm}^3/\text{min}$ . This instrument gives the concentration values of ultrafine particles in the range between  $0.02 \text{ }\mu\text{m}$  and  $1 \text{ }\mu\text{m}$ . The unit of measurement is particles per cubic centimetre ( $\text{pt}/\text{cm}^3$ ).

The main purpose of positioning two instruments in the same place is to detect the concentrations of particles in all the range between  $0.02 \text{ }\mu\text{m}$  and  $25 \text{ }\mu\text{m}$  as well as their trends. This paragraph aims at providing an analysis of the average values of particle concentrations in order to compare them according to the three different kinds of operations, even though in the Chapter 5 the same data will be used for other evaluations.

The OPC data, obtained with cumulative counts of particles larger or equal than  $0.5 \text{ }\mu\text{m}$ , are summarized in Figure 4.9. It is clear from the bar graph that the higher particle concentration rate in the surgical area is measured during orthopaedic operations, followed by the one related to the liver resection surgery. The smallest particle concentration is detected during EVAR surgeries.

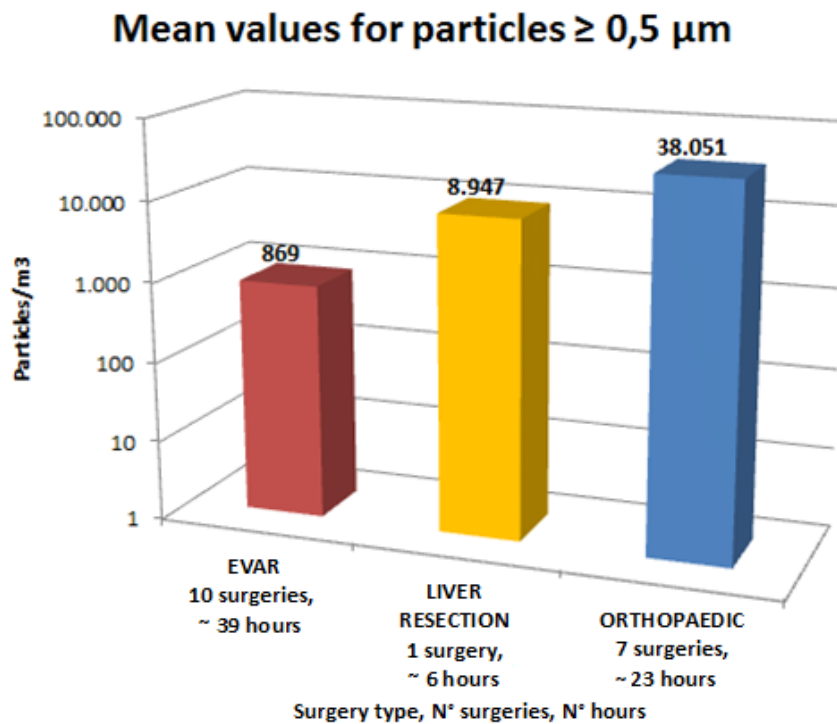


Figure 4.9. Mean concentration values related to particles  $\geq 0.5 \text{ }\mu\text{m}$ , recorded near the surgical area during the different types of operations (18 surgeries for a total of 68 hours).

These results may appear in contrast with the data already shown about the number of people and the door openings, especially with reference to what has been said about open surgeries. In other words, according to the analyses previously described, the greater emphasis put on the cleanliness and sterilization in the surgical area were expected to result in a reduction in the level of particle concentration during liver resection and orthopaedic operations.

The reason for this surprisingly high concentration value related to particles  $\geq 0.5 \mu\text{m}$  has to be found in the use of electrosurgical instruments. Although the dimensions of the particles spread by the most adopted instruments (monopolar and bipolar) are reported to be between  $0.007 \mu\text{m}$  and  $0.42 \mu\text{m}$  – that is smaller than those currently detected – it is, however, an undeniable fact that the use of electrosurgical tools affect most significantly the increase in particle concentration.

Moreover, it is important to underline that both the surgeons' clothing system and the preparation routine for the three different types of operations are identical; therefore, no other reason can explain the results illustrated in Figure 4.9. The existing correlations between the use of the electrosurgical instruments and the increasing number of particles spread inside the OT will be discussed in Chapter 5.

The OPC data, obtained with cumulative counts of particles  $\geq 5 \mu\text{m}$ , are summarized in Figure 4.10.

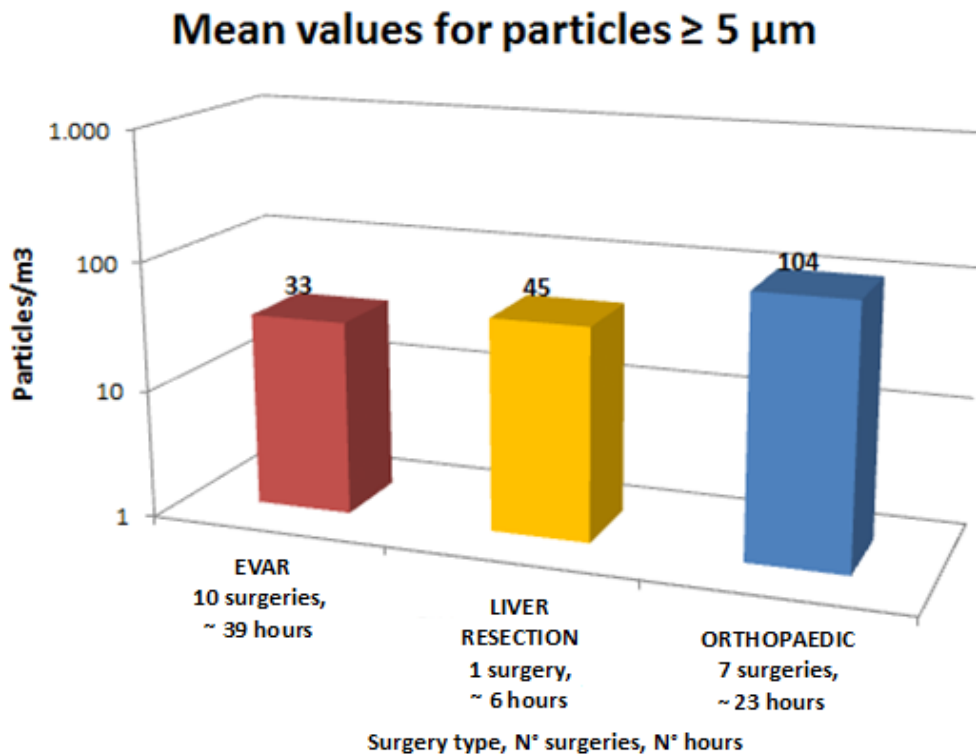


Figure 4.10. Mean concentration values related to particles  $\geq 5 \mu\text{m}$ , recorded near the surgical area during the different types of operations (18 surgeries for a total of 68 hours).

It reports the same trends pointed out by the previous graph, but with a considerably lower order of magnitude. In the surgical area, the particle concentration referred to the orthopaedic operations is – also in this case – higher than that measured during the EVAR surgeries. The liver resection operation presents a medium level of particle concentration.

The generally lower levels of particles  $\geq 5 \mu\text{m}$  – compared with those related to particles  $\geq 0.5 \mu\text{m}$  – need to be associated to the successful filtration work of the HEPA filters, which blow clean air with a unidirectional flow from the ceiling above the surgical table. More precisely, these HEPA filters actually remove 99.995% of particulate matter greater in size than  $0.3 \mu\text{m}$  [13].

In general, it is important to remember that the analyses of the clothing system, the number of people and the door openings revealed higher strict rules followed

during open surgeries than the less-invasive EVAR surgeries. The use of a different clothing system during orthopaedic and liver resection surgeries reveals an important strategy choosing particular garments for the personnel in order to limit the particle spread from the same clothes. Moreover, during EVAR procedures the number of people accepted inside the Hybrid OT was higher due to the lower risk of infection than orthopaedic and liver resection surgeries. Finally, the higher frequency of the door opening during EVAR surgeries could be a cause for a potential introduction of particles inside the operating room due to the air infiltration and for the cloth contamination of the personnel during the passage through the corridor.

Owing to this, the expected highest level of particle concentration should be about EVAR surgeries. However, the highest levels of particle concentration are detected during the two types of open surgeries. The cause of the higher concentrations measured need to be found in the use of electrosurgical instruments. In effect, these instruments are not used during EVAR operations due to the different technique performed, but only during orthopaedic and EVAR surgeries.

Similarly, the measurements performed with the UPC have led to analogous results, as can be seen in Figure 4.11.

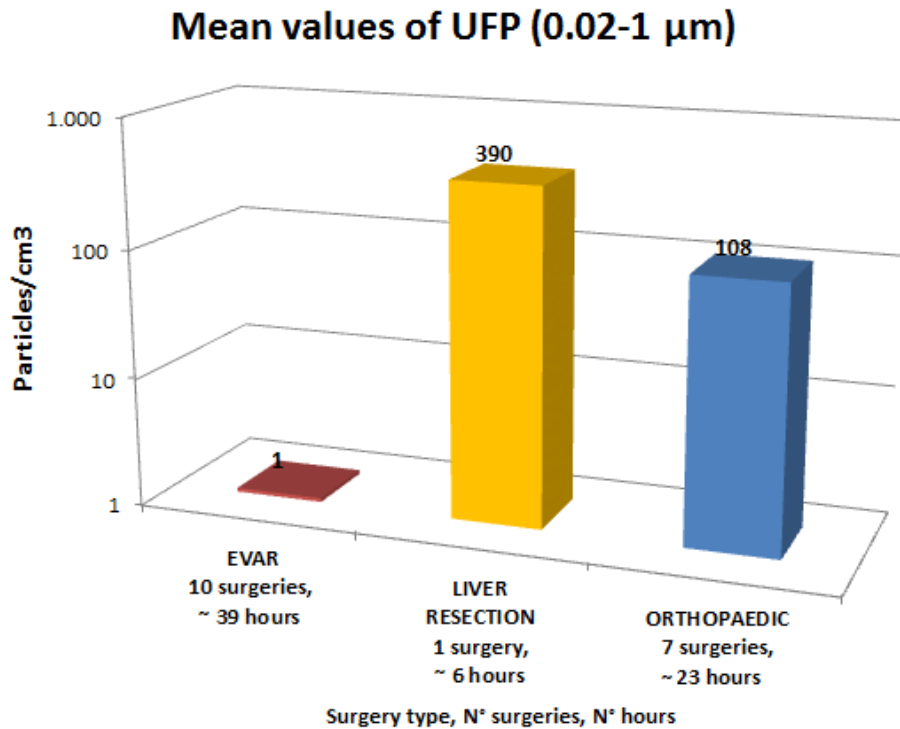


Figure 4.11. Mean concentration values related to particles of 0.02- 1  $\mu\text{m}$  (ultrafine particles), recorded in the surgical area during the different types of operations (18 surgeries for a total of 68 hours).

The data collected with the UPC show the highest mean particle concentration during the liver resection surgery, followed by that recorded throughout orthopaedic operations. The lowest mean particle concentration, again, refers to EVAR surgery. The values related to the UPC cannot be compared with those achieved with the OPC due to their difference in terms of flow rate and unit of measurement.

Moreover, it is important to underline that the particles spread have a mean aerodynamic size around 0.07  $\mu\text{m}$  during the use of diathermy, and between 0.35  $\mu\text{m}$  and 6.5  $\mu\text{m}$  during the use of ultrasonic devices. In the time of EVAR surgeries any kind of these instruments is used, except for some unusual cases in which they are used to open the small wound. In contrast, during liver resection operations all diathermy and ultrasonic instruments are used, and for orthopaedic spine surgeries only diathermy instruments are needed.

The absence of ultrafine particles (0.02-1  $\mu\text{m}$ ) during the EVAR procedures is given by the avoided utilization of electrosurgical instruments which are, probably, the unique source of ultrafine particles inside the operating room. On the other hand, the high level of ultrafine particles for liver resection surgery can be associated to the use of all the instruments to perform the operation. Lower level of these particles is detected during orthopaedic surgeries than liver resection, probably as consequence of the use of only monopolar and bipolar diathermy. Nevertheless, the mean value related to orthopaedic surgeries is bigger than the almost zero value of liver resection.

These outcomes related to liver resection could be associated to the fact that the clothing system, the number of people and the door opening don't influence the ultrafine particle concentration in the surgical zone and the only responsible of the presence of them during open surgeries is the use of electrosurgical instruments.

To sum up, based on this analysis the dominant difference in particle levels is due to the use of electrosurgical instruments which hide the probable effect of the different clothing system or the number of people or the door openings. In the Chapter 5 will be highlighted the influence of the use of these tools on the concentration of ultrafine particles in different characteristic positions of the Hybrid OT.





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## 5 Consequences of diathermy

In Chapter 4, the data analysis highlighted that, in relation to the particle concentration measured inside the Hybrid OT, the use of electrosurgical instruments seems to nullify the effect of some devices adopted by the medical staff to prevent the room from being contaminated. In fact, during open surgeries – namely orthopaedic surgery or liver resection – particle levels are significantly higher than during EVAR surgeries, despite the greater attention given in order to limit both the door openings and the number of people inside the operating room, as well as to use a specific clothing system.

Due to the considerable influence exerted by the use of these electrosurgical tools on the cleanliness of the air inside the Hybrid OT, the main topic of Chapter 5 is the analysis and evaluation of the actual changes they brought about in terms of particle concentrations during the different types of open surgery considered.

As mentioned in Chapter 1, the potentially hazardous smoke spread while using electrosurgical tools is reported to contain particles whose size ranges is between 0.1  $\mu\text{m}$  and 6.5  $\mu\text{m}$ . In detail, the particles generated during the use of diathermy instruments have a dimension of about 0.1 - 0.8  $\mu\text{m}$ , whereas in the case of ultrasonic devices particle size tends to vary between 0.35  $\mu\text{m}$  and 6.5  $\mu\text{m}$ . Moreover, it is important to notice that the mostly used tools during open surgeries are monopolar and bipolar diathermy, which cause the smallest particles to be released. Owing to this, only the data related to ultrafine particles (0.02 – 1  $\mu\text{m}$ ) – measured by the two UPCs – are taken into account for the analysis presented in Chapter 5.

In Chapter 5 it is presented the typical unidirectional air flow pattern inside operating rooms. This description is followed by the test of the real air motion inside the Hybrid OT thanks to the smoke test performed. The knowledge of the air movement inside the environment lead to the understanding of surgical smoke motion which is swept away from the supply air.

Moreover, thanks to the evaluation of the H14 HEPA filters efficiency curve it was possible to define that for these filters the critical value of the MPPS (Most Penetrating Particle Size) is around 0.16  $\mu\text{m}$ . In this case, this value - in which the efficiency is at the lowest level - is in correspondence with the characteristic range of dimension of the surgical smoke spread during the burning of tissues due to the use of electrosurgical tools.

As a result, looking also at the airflow pattern and the recirculation system, one of the sampling probe place defined was exactly under the H14 HEPA filters in order to detect if some ultrafine particles spread as surgical smoke return from the recirculation system and pass through the filters. Another sampling positions used was between the surgical area and the exhaust grilles, in order to reveal the typical ultrafine concentration in the peripheral zone. The third measuring point was over the surgical table, used only during the simulated surgeries performed. This last point, was useful to detect the particle concentrations near the surgeon's nose or to measure the local source of particles dispersed.

The measurements of the local particle source during operation N°24 (simulated surgery on a calf liver) revealed higher ultrafine concentrations during the use of monopolar diathermy, argon diathermy and ultrasonic device than bipolar diathermy. These high values are confirmed during operation N°22 (simulated surgery on a calf liver) due to the presence of ultrafine particles coming out from the H14 HEPA filters during the use of the same surgical instrument of the previous case. It was also defined that the ultrafine particles breathed by surgeons comes only from the recirculation system.

The data about the reintroduction of ultrafine particles were also confirmed by some measurements during real open surgeries. It is also important to underline that during some open surgeries was not revealed a reintroduction of ultrafine particles from the air system, probably due to the different procedural technique and the consequent lower number of particles spread during the use of same electro surgical instruments.

Due to the small size of ultrafine particles, emitted during the use of electro surgical tools makes them impossible to be filtered by ordinary surgical masks. The reintroduction of the surgical smoke by the recirculation system represents so a health hazard for anyone working inside it.

Some possible solutions will be delineated in the end of the work, followed by the possible future works useful to try to solve this occupational problem for the surgical team.

## 5.1 Particle samplers positioning

Certainly, the first step is to understand which is the air motion inside the Hybrid OT, in order to define the right positions for the ultrafine particle samplers. For this reason, the following Figure 5.1 describes an example of a typical pattern of the air inside an operating room supplied by a vertical unidirectional airflow from the ceiling provided by exhaust grilles at the corners.

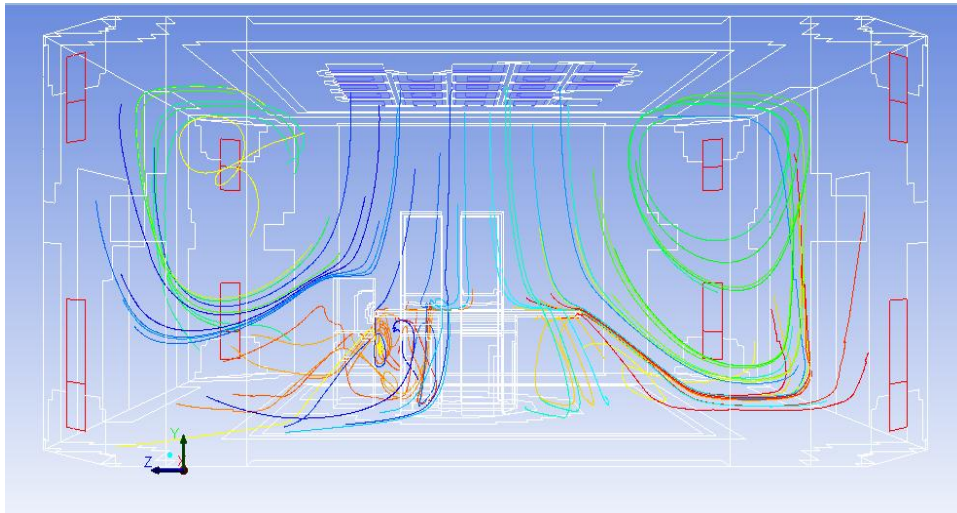


Figure 5.1. Illustration of air pattern inside an operating room, produced by a vertical unidirectional airflow from the ceiling.

The air is supplied by the ceiling and goes down toward the operating table in the central zone. The same air after the contact with personnel, operating table and floor changes its direction towards the exhaust grilles positioned in the operating room corners on the walls near the floor. Moreover, one part of this air is directly drawn into the exhaust grilles, whereas the other part remains inside the periphery of the inner zone.

The air movement in the peripheral zone is mainly directed toward the ceiling, thus creating big vortices on the two sides of the outer zone under the ceiling as it can be noticed in Figure 5.1. The typical air pattern for a vertical unidirectional airflow from the ceiling represented schematically in the previous Figure 5.1 can be assumed realistic for the understanding of the air motion inside the Hybrid OT due to the use of a similar air supply principles.

## 5.2 Smoke test

In order to verify the assumptions about the air flow pattern within the Hybrid OT, it was necessary to perform a smoke test. The knowledge of the air motion is a basic tool to define the following relevant positions of the particle sampling probes.

During the so called operation N°23 a smoke test was carried out in the Hybrid OT thanks to the use of smoke generators called “Dräger Air Flow Testers”, of which an example is illustrated in Figure 5.2.



Figure 5.2. Dräger Air Flow Tester

As described on the website Dräger [40], “Smoking sulfuric acid is located in the tubes. When the top of the tube is opened, a small rubber ball is used to pump air through the tube. This creates visible white smoke, which is carried on any existing air flows [...] with the air flow test tubes, the source, direction and speed of the air flow are visible immediately”. In order to have a better distribution of the smoke, a pipe with some aligned holes was attached to the Dräger Tester.

The initial idea of this trial was to verify the actual air movement inside the OT – so far discussed only at theoretical level – and it was confirmed. More precisely, the air goes down from the central part of the ceiling in correspondence of the clean area. Then, after the impact with the operating table, the air changes direction and moves to the lateral sides of the room, toward the floor and the exhaust grilles. After touching the floor, the air movement outside the protected zone follows another direction and goes toward the ceiling, thus creating big vortexes on the two sides of the OT next to the walls, immediately below the ceiling.

The vertical air flow in the central part of the operating room prevents the air contained in the lateral big vortexes from entering the clean zone.

The essential outcomes achieved through this test were:

- The confirmation that the clean zone is preserved from the air coming from the lateral sides of the OT, thanks to the central flow which – like an air-barrier – hinders any contamination
- The proof that the air, once outside the clean area, flows directly towards the exhaust grilles.

The former consideration plays an important role in giving evidence that all the air supplied by the ceiling in the clean area comes from the AHU, without any contamination from the air moving inside the room itself.

In conclusion, it is possible to definitely state that the achievement about the direction of the air, on the other hand, proves to be in line with the statistical data presented in Chapter 3, thus confirming that the air coming out of the surgical area flows directly toward the exhaust grilles, while a part is thrown out.

In Figure 5.3 it is possible to observe a sequence of pictures taken during the smoke test. As can be easily noticed, the air moves from the surgical area to the sides of the operating table. The black bags were positioned on the wall to facilitate the visualization of the white smoke pattern in pictures.

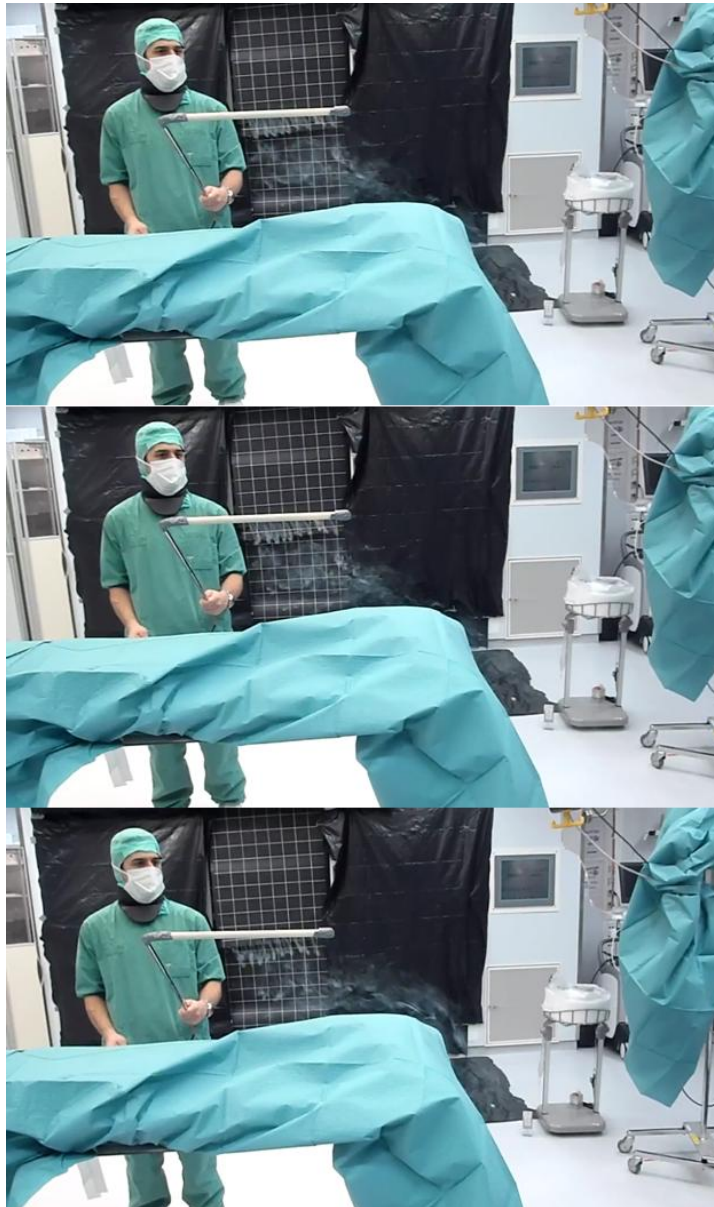


Figure 5.3. Pictures sequence about the smoke test performed on the 16th December 2013 (operation N° 23) in the Hybrid OT.

### 5.3 Evaluations on H14 HEPA filters

The prerequisites to get clean air, regarding particles is that the supply air to the room is clean. Therefore, the efficiency of the air supply HEPA filters should be a guarantee for the air cleanliness. The Figure 5.4 taken from the standard EN 1822-3:2009 [24], shows a real example where the MPPS (Most Particle Penetrating Size) for an H14 HEPA filter is about  $0.16 \mu\text{m}$  and it is in correspondence of the lowest mean local efficiency value about 99.9975%. Accordingly, for particles larger and smaller in size, the filter efficiency is supposed to increase.

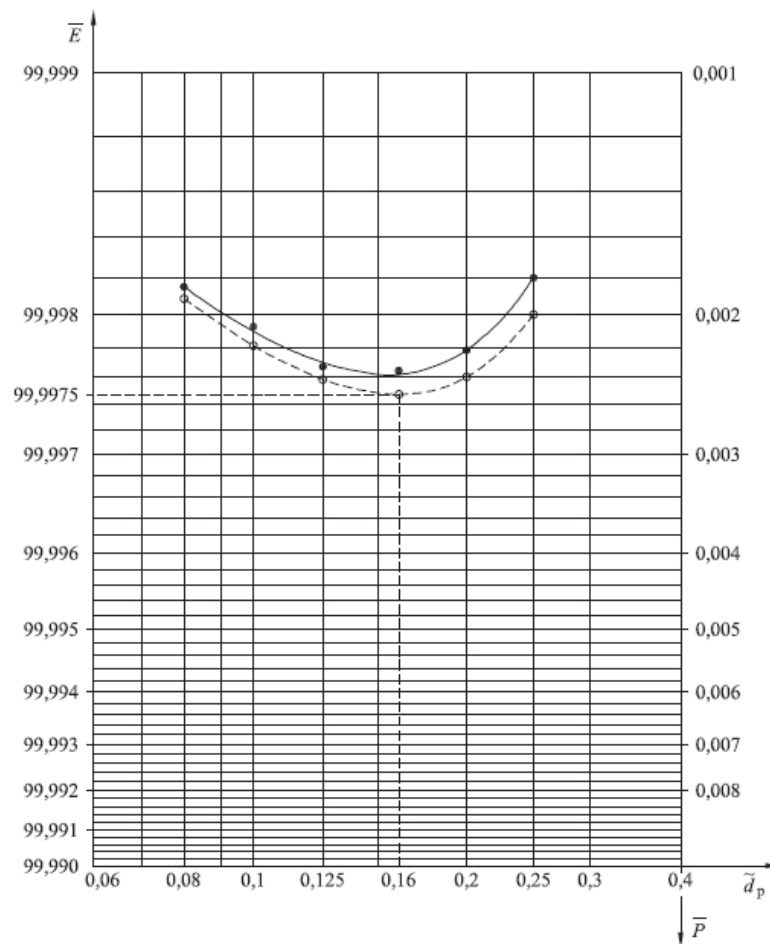


Figure 5.4. Mean efficiency  $\bar{E}$  (-) and  $\bar{E}_{(95\%)}$  (---) (calculated as the lower limit value for the 95 % confidence) as a function of the particle diameter  $\bar{d}_p$  (EN 1822-3:2009) for H14 HEPA filters.

The filters installed in the Hybrid OT have the same characteristics as for the one showed in Figure 5.4. In this case, the critical value has a similar value to the typical dimensional range of the surgical smoke spread by electro-surgical tools.

Thanks to Figure 5.5 it is possible to compare the dimensional ranges for particles spread by electro-surgical instruments and the MPPS of H14 HEPA filters. Owing to this, the highest level of ultrafine particles is in the same dimensional range of the MPPS of filters, which means that for this dimension the filter efficiency is the low, but more studies need to confirm that. It leads in the possibility to have the passage of part of the surgical smoke through the H14 HEPA filters

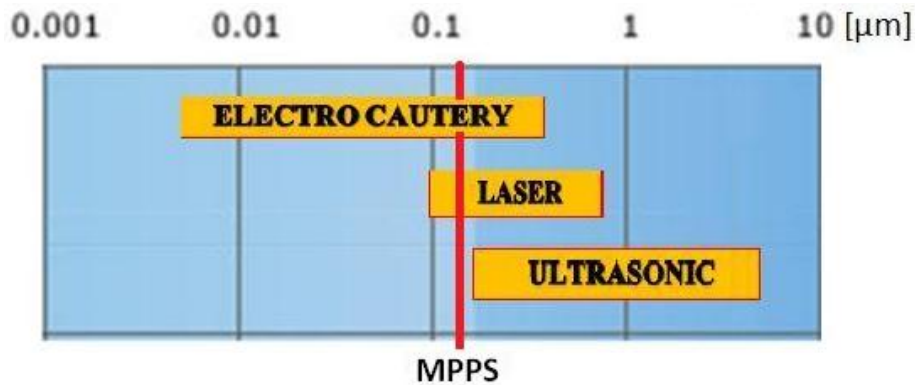


Figure 5.5. Comparison of the dimensional ranges for particles spread by electro-surgical instruments and the MPPS of H14 HEPA filters.



## 5.4 Sampling probes positions

The positions defined inside the Hybrid OT for the measurements are shown in Figure 5.6 and they are:

- Position 1 is 20 cm under the HEPA filters in the inner zone
- Position 2 is between the surgeon's position and the exhaust grille between the inner and the outer zone
- Position 3 is above the surgical table

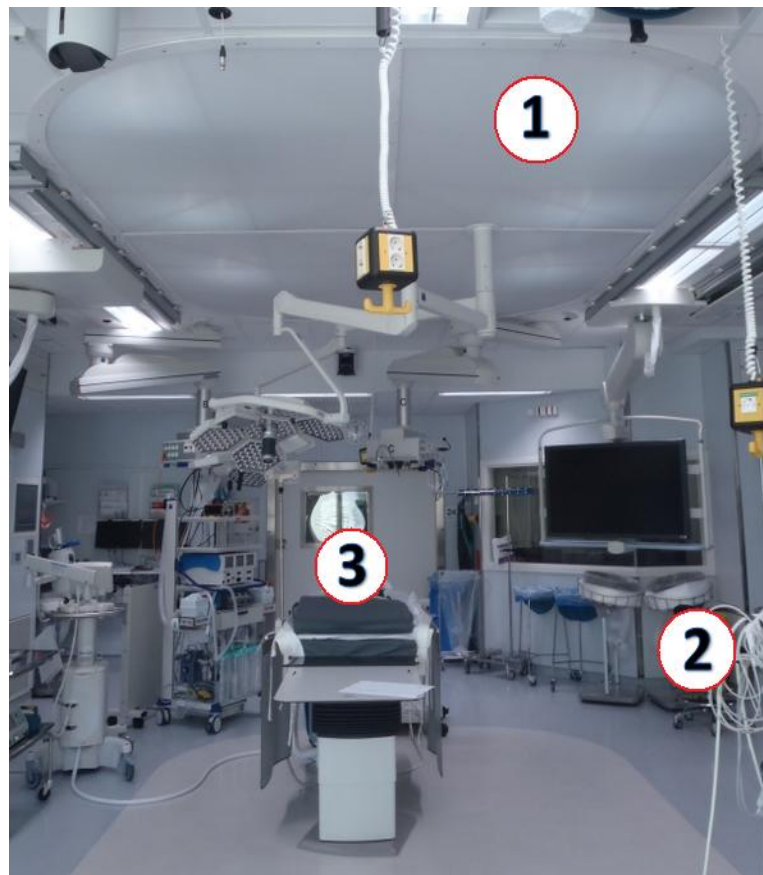


Figure 5.6. Positions of the sampling probes monitoring during open surgeries.

The choice of the position 1 is motivated by the intention to check the particle concentration of the air that supplies the operating zone which goes directly towards the patient's wound and the surgeons' head. In effect, the air is coming

directly from the H14 HEPA filters and the particle concentration represents the air before the contact with the surgical procedure. In relation to the position 1, the MPPS (Most Penetrating Particle Size) of the H14 HEPA filters is in the range of 0.12-0.25  $\mu\text{m}$  and in accordance with the specifications the filter efficiency the presumed number of particles detected by the instrument in this position would be around zero.

To sum up, the main idea is to check if some particles spread by the diathermy tools are reintroduced in the Hybrid OT through the recirculation system.

On the other hand, it is important to underline that the concentrations detected in position 2 refer to the air that is going out of the critical area. As hinted before, this choice depends on the typical aerodynamics of unidirectional airflow systems, which also makes it possible to infer that the air is blowing out of the clean area to the peripheral zone via a down path after the contact with the surgical procedure. In addition, the smoke test – already shown - demonstrated that the position chosen for the OPC (Climet) and UPC (P-trak) – that is between the surgical table and the exhaust grilles – was perfectly fit for the purpose.

Therefore, the data concerning the assessments made in position 2 can be considered representative of the particle concentration of the air inside the peripheral zone, where nurses and visitors regularly attend the surgery.

Position 3 was chosen for two purposes, the first is to measure the particle concentration of the air breathes by surgeons, the second is to detect the particle source concentration close to the zone of the dispersion of surgical smoke due to the use of electro surgical instruments. Because of the critical position of the measuring point a special measurement program has been developed in order to get the particle level in this place. In effect, this position 3 was adopted only during the two simulated operations that will be presented later in this Chapter 5.

## 5.5 Measurement of particle source

Operation N°24 was a simulated surgery on a calf liver, it was performed in order to detect the ultrafine particle source generation during the use of the different electrosurgical instruments. The detection of these values was defined in order to understand which was the difference in term of particles spread by the different tools.

The data were carried out on a calf liver with the UPC in order to measure the concentration of the ultrafine particles depending on the different electro surgical instruments in use. The simulation was based on the local measure of the particle concentrations spread, keeping the sampling probe at a distance of 5-8 cm from the working instrument on the liver, and in direction of the stream of surgical smoke.

The electro surgical instruments used were in order: monopolar diathermy, bipolar pincers, bipolar scissors, argon diathermy and ultrasonic device. Due to the local measure of particle concentration it was not necessary the reproduce the same conditions of a real surgery about the clothing system or the number of people. The mean values about ultrafine particles are shown in Table 5.1.

*Table 5.1. Mean concentrations about ultrafine particles detected during a simulated operation on a calf liver. The sampling probe were positioned at 5-8 cm from the working instrument. The instruments used were monopolar, bipolar pincers, bipolar scissors, argon and ultrasonic device.*

Electro surgical tool	Concentration [pt/cm <sup>3</sup> ]
Monopolar	193377
Bipolar pincers	49447
Bipolar scissors	69610
Argon	370846
Ultrasonic	222944

The data collected reveal that the highest mean ultrafine particle concentration is in connection with the use of argon diathermy, followed by ultrasonic device and monopolar diathermy. The lowest levels are for bipolar pincers and bipolar scissors.

## 5.6 Results of simulated surgery on a calf liver

This section deals with the results of the simulated surgery on a calf liver. The outcomes showed the reintroduction of particles inside the Hybrid OT from the recirculation system through the HEPA filters can be confirmed by the data about the simulated operation performed. In addition, during the simulated operation was possible to detect the particle concentration near the surgeon's head (position 3 shown in Figure 5.8). This measuring position was not used during real surgeries due to the frequent surgeon movements which cannot be limited by the presence of the measuring probe on his head.

During the simulation (operation N°22), all the conditions of a real surgery were reproduced inside the Hybrid OT.

In the course of the simulated surgery, the operating staff was composed of 2 surgeons and a nurse, along with 4 visitors inside the room. All the personnel inside was dressed as usual during surgeries, with a pair of trousers (50% polyester and 50% cotton), a blouse (50% polyester and 50% cotton), a pair of ordinary shoes used only inside the hospital and a single-use head cover.

In addition, only the 2 surgeons, who stand in the protected zone, wore the surgical gown, the face mask and double gloves.

The surgery simulation – performed on a calf liver – aimed at:

- Measuring the different particle concentrations near the surgeon's nose while using the various electrosurgical instruments
- Detecting the concentration of ultrafine particles in the air coming down from the HEPA filters over the surgical area during the use of the different electrosurgical tools.

The instruments were arranged as follows:

- UPC (P-TRAK™) was located at the height of 2.80 m in the clean area, that is at a distance of 20 cm below the H14 HEPA filters, corresponding to the position 1 in Figure 5.7.
- UPC (P-TRAK™) and OPC (Climet) were positioned near the surgeon's nose, the position 3 of the sampling probes is shown in Figure 5.7.



Figure 5.7. The two instrument positions defined for the measurements performed during the simulated surgery (operation N°22). Position 1 indicates the sampling probe position of UPC that measures the UFP under H14 HEPA filters. In position 3 the UPC and OPC were placed to detect the airborne particle concentrations close to the surgeon's nose.

The disposition of the measuring probes near the surgeon's nose is clarified by Figure 5.8, in which is possible to see the sampling tube of the UPC sampling probe on the left and the isokinetic probe of the OPC on the right.



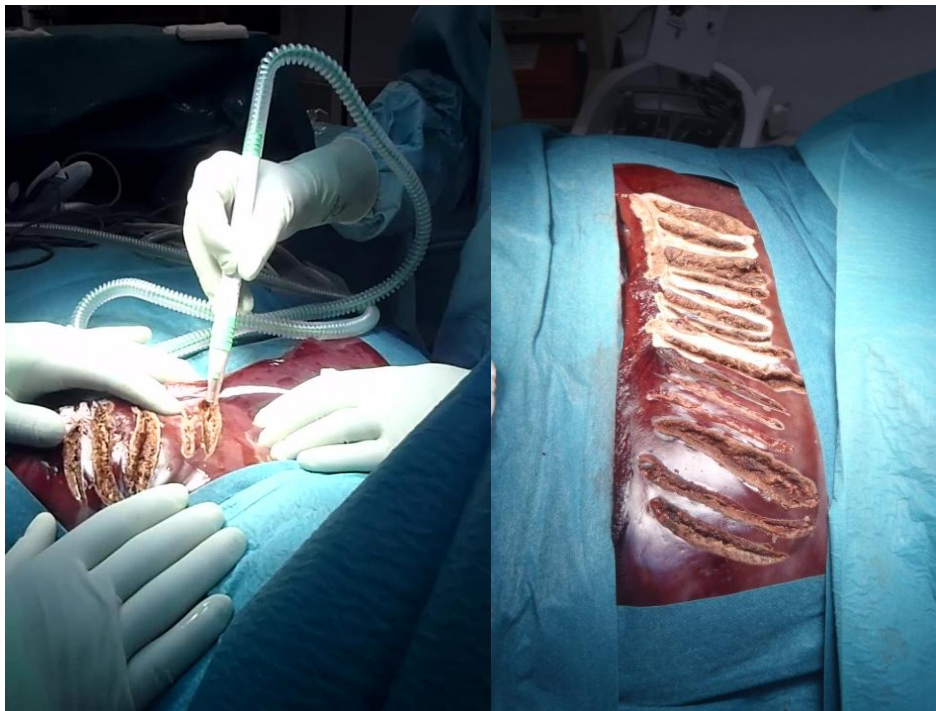
Figure 5.8. The disposition of the two measuring probes near the surgeon's nose in position 3. UPC sampling probe on the left and the isokinetic probe of the OPC on the right.

Only the results related to the 2 different UPCs are considered useful for this study, since they refer to the measurements of ultrafine particle concentrations (0.02 -1  $\mu\text{m}$ ).

Furthermore, it is worth noting that the data were collected continuously, and the various electrosurgical instruments were used for a period of one minute each, waiting around 5 minutes between the tests.

The instruments utilized to burn the calf liver tissues were in order: monopolar diathermy, bipolar diathermy (pincers type), bipolar diathermy (scissors type), argon diathermy and ultrasonic device.

In Figure 5.9 it is possible to see on the left an example of the use of monopolar diathermy and on the right there is the calf liver at the end of the simulation, signed by all the cuttings during the use of the instruments. The entire simulated operation lasted in total around 4 hours, but the useful data taken for this study were only about 1 hour of measurements.



**Figure 5.9.** Example of the procedure during the simulation with monopolar diathermy (on the left) and the calf liver at the end of the simulation (on the right).

Figure 5.10 represents the data collected during the simulated surgery on the calf liver. The first graph shows the UFP concentrations in position 1 (red) and in position 3 (blue). In the second graph, the bars indicate the moments in which the different electro-surgical instruments were turned on. The analysis of the values reveals that the two measurements are strictly correlated.

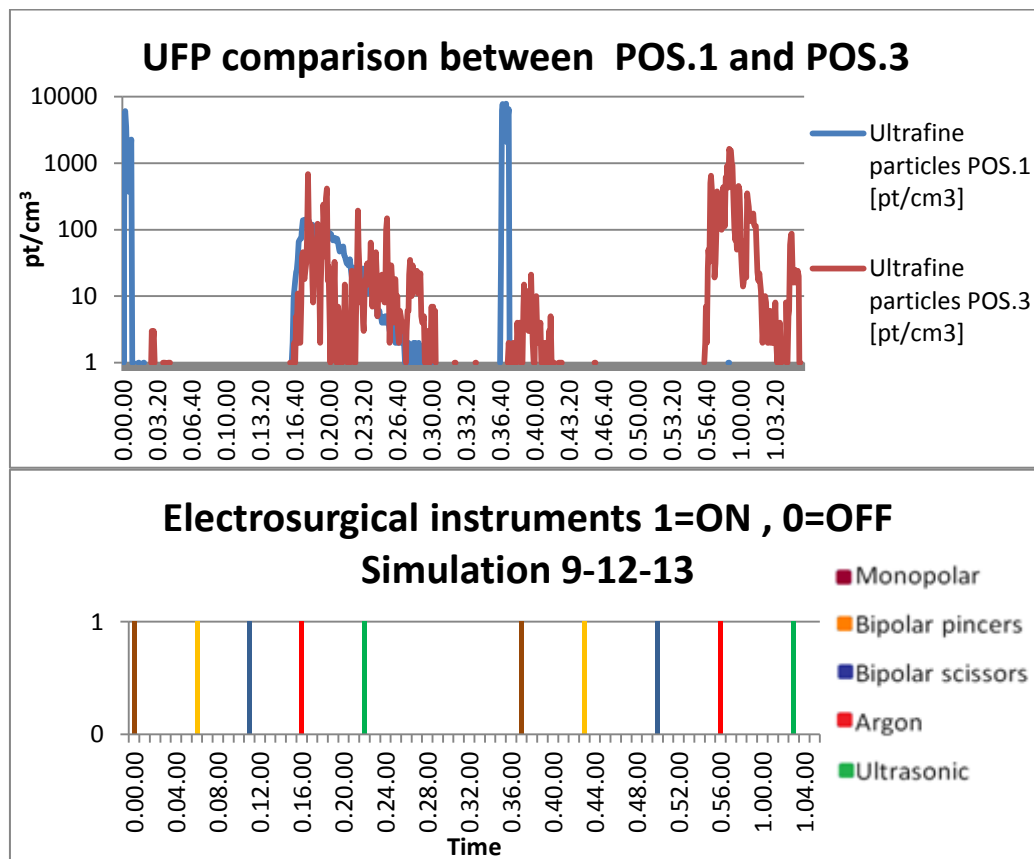


Figure 5.10. Data related to the simulated surgery on a calf liver performed on the 9th of December 2013. Comparison of UFP measurements carried out in position 1 and position 3 in relation to the moments in which the different electro-surgical instruments were turned on.

More in detail, the peaks in terms of particle concentration are noticeable in correspondence with the use of monopolar diathermy, argon diathermy and ultrasonic device as it can be seen in Figure 5.10. On the other hand, the particle



levels are reported to remain constant during the use of both of the two bipolar diathermy instruments.

As far as the particle concentration measured 20 cm below the HEPA filters (position 1) is concerned, the highest peaks occur during the use of monopolar diathermy, whereas lower values are connected with the argon diathermy and ultrasonic device utilization.

On the contrary, the greatest increases in particles detected in position 3 are affected by the use of argon diathermy and ultrasonic device, while monopolar diathermy seems to exert only little influence on them.

According to the available data and the previous considerations, it is possible to infer that the particle concentrations detected by the sampler of position 3 come directly from the ceiling with the supplied air. In fact, due to the descending unidirectional air flow pattern, the concentration levels are supposed to be associated only to the ventilation system, thus making highly unlikely any direct influence of the electrosurgical instruments on the quality of the air breathed by surgeons.

These data support the ones of the previous simulation. In fact, the reintroduction of ultrafine particles were detected during the use of the same instruments that in the previous simulation revealed the highest levels of particles spread.

To sum up, all the ultrafine particles that reach the operating table come from the air recirculation system. These possibly harmful particles may affect both the patient's and the surgeon's health. In particular, the patients might be exposed to an increasingly higher risk of infection due to the presence of these ultrafine particles; surgeons, instead, is not adequately protected against their inhalation, since the small size of ultrafine particles makes them impossible to be filtered by the common surgical face masks [41]. On this topic, it would be extremely interesting to verify if the concentration levels measured in this study are actually harmful for surgeons.

Furthermore, it is important to notice that the particle concentrations detected during the real operations are lower than those registered throughout the simulation. The common measurement point for both the surgeries and the

simulated operation is below the filters in position 1 and the following comparison refers, indeed, to the surveys undertaken in that position.

The highest peak measured during real open surgeries is about  $64 \text{ pt/cm}^3$ , whereas, in the case of the simulation, it reaches the value of around  $7876 \text{ pt/cm}^3$ . It is worth noting that the simulation consisted in burning calf liver cells and, in contrast, the tissues involved during open surgeries were different. As a result, the remarkable discrepancy in terms of amount of particles detected is supposed to depend on the different tissues that are burnt.

However, it is a given that the H14 HEPA filters and the recirculation system allow the reintroduction of these particles. The problem seems to be strictly related to the use of this recirculated air to supply the protected zone over the operating table and the surgeon's head.

To sum up, thanks to the simulated surgery it was shown the strict connection between the use of electro surgical instruments and the recirculation system.

### 5.7 Comparison between ultrafine particles concentrations in position 1 and 2

This section shows the main important results of the work. The data shown in the figures are related to UFP concentrations detected in position 1, UFP concentration in position 2 and the bars indicate the moments in which electro surgical tools are turned on. The information about the electro surgical instruments was collected thanks to the use of the Excel sheet depicted in Chapter 3.

To this end, Figure 5.11 below, related to the orthopaedic surgery performed on the 4th of November 2013 (operation N°7), provides a valuable example which allows, on one hand, to notice that during some open surgeries the amount of ultrafine particles coming out from H14 HEPA filters is around zero(position 1).

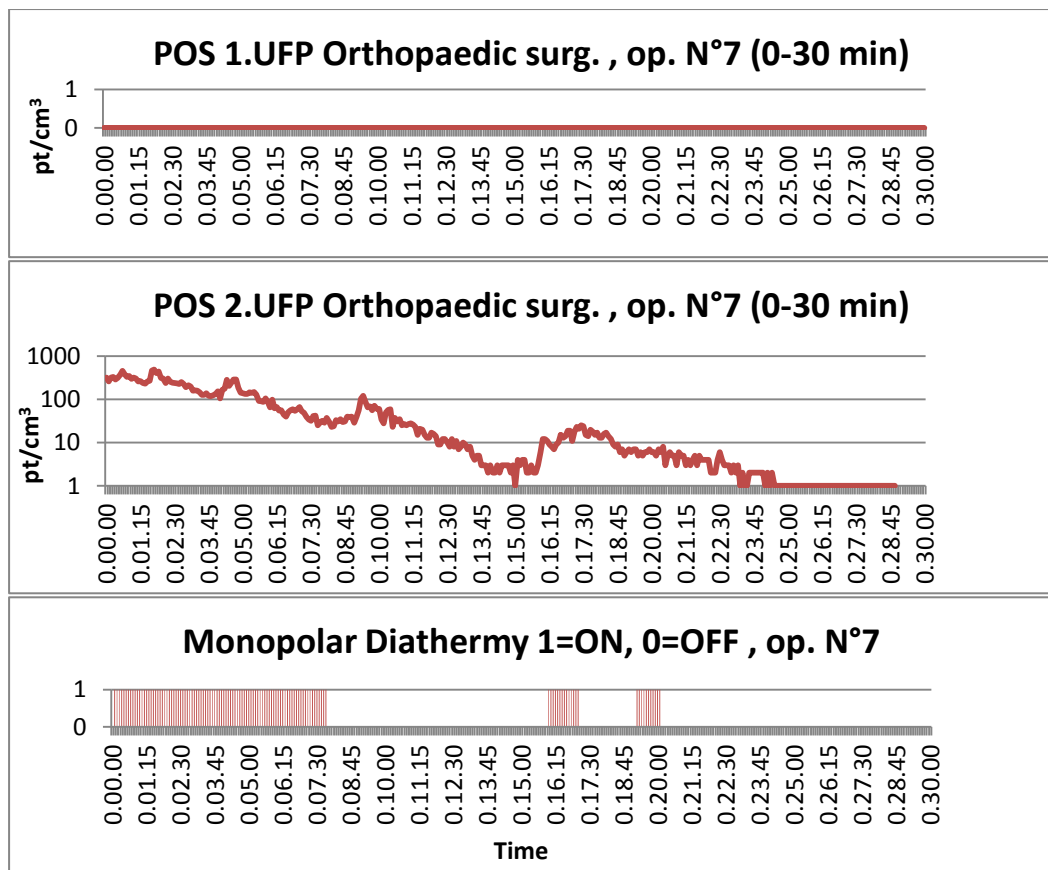


Figure 5.11. Data related to the first 30 minutes of the orthopedic surgery (operation N° 7) on the 4th of November 2013. In descending order: UFP measured in position 1, UFP in position 2 and moments in which monopolar diathermy was turned on.

The diagram shows also that the measurements of the ultrafine particles spread during the use of electro-surgical instruments – carried out by the UPC in position 2 – showed increasing values. In effect, Figure 5.11 highlights the clear correlation between the use of the monopolar diathermy and the increase in ultrafine particles in position 2, as demonstrated by the concentration peaks in correspondence of the switching-on of the electro-surgical instrument.

Similar values are reported in Figure 5.12, data are related to the Liver resection (operation N°13) performed on the 14-11-13.

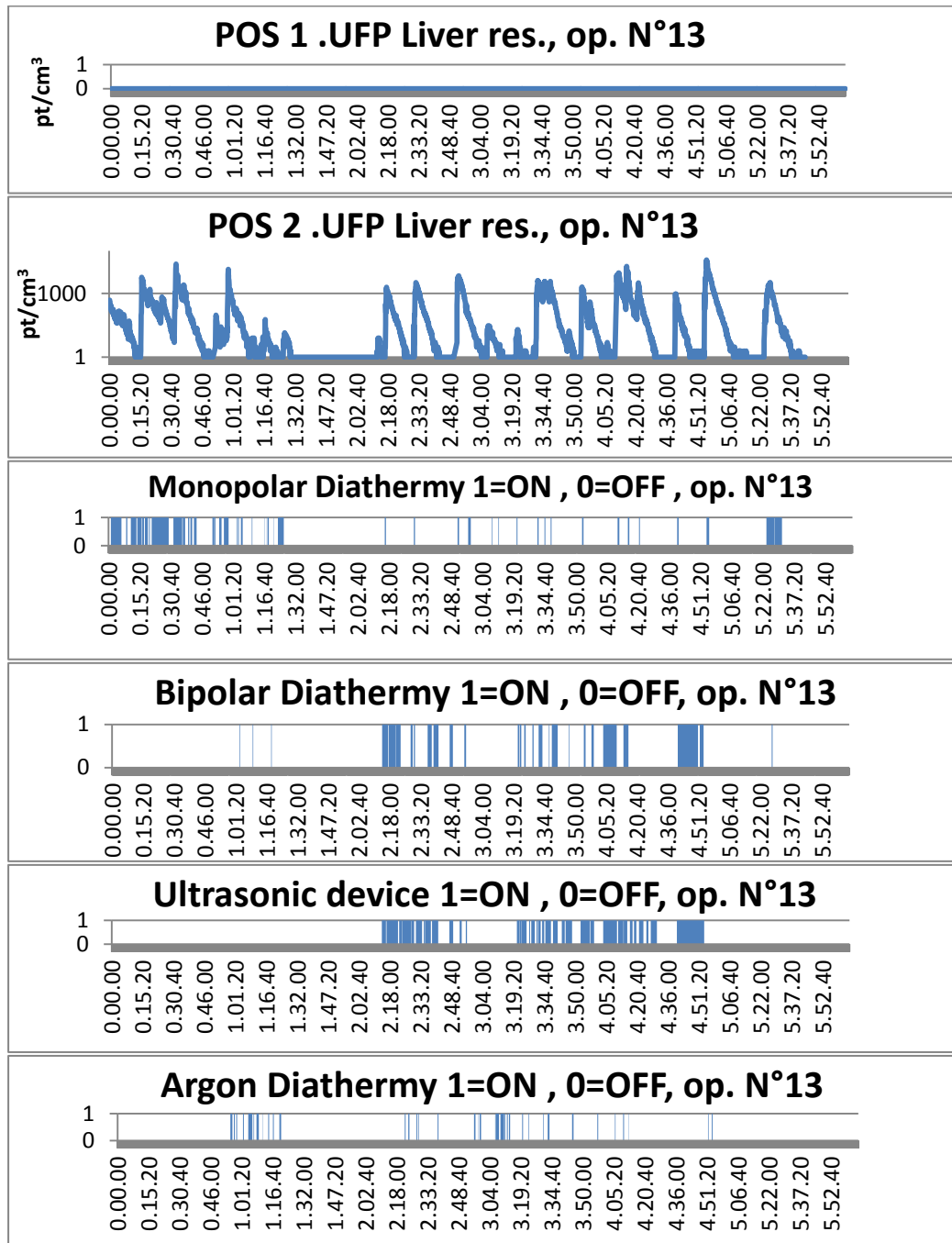


Figure 5.12. Data related to the liver resection (operation N° 13) on the 14th of November 2013. In order: UFP about position 1, UFP about position 2 and moments in which monopolar diathermy, bipolar diathermy, ultrasonic device and argon diathermy were turned on.

In these cases, the air coming out of the filters - detected in position 1- seems to be nearly completely clean from ultrafine particles. As a result, the air that goes directly toward the patient's wound and the surgeons' head is reported to contain an almost zero contamination level of particles. On the other hand, the values related to position 2 revealed high values in connection with the use of electro-surgical instruments.

The data related the position 2 were predictable, due to the direct measure of the ultrafine particles spread in the form of surgical smoke. In contrast, despite the massive use of electro-surgical instruments the air going out the H14 HEPA filters results completely lacking of ultrafine particles.

The possible presence of particles could depend on both the use of electro-surgical instruments and the recirculation system, which causes 70% of the exhaust air to flow again in the Hybrid OT. This recirculated air – mixed with the fresh one – is filtered again in the AHU and handled, before being reintroduced inside the OT through the HEPA filters positioned above the surgical table.

However, in other circumstances, as the following example (Figure 5.13) illustrates, the reintroduction of particles is detected also through the measurements carried out in position 1. In such a case, the particle concentration is supposed to be similar in both the sampling points, obviously maintaining a certain distinction in terms of concentration levels, due to the different positions of the instruments. Figure 5.13 allows to visually comparing the results obtained by means of the two above-mentioned types of measurements: in fact, the former graph represents the particle concentration in the air exiting from the filters, whereas the latter describes the particle trend near the surgical area while using the electro-surgical instruments, which spread surgical smoke. On the other hand, the massive use of monopolar diathermy makes it impossible to point out a direct correlation between the electro-surgical tools in general and the increase in particle concentrations. Nevertheless, since the data collected in all the operations prove it; this strict relation is likely to occur also in this case.

Furthermore, the massive use of monopolar diathermia may offer an explanation for the reintroduction of particles through the HEPA filters, due to the higher number of particles spread in a longer time. It has to be specified that no evidence is provided regarding the harm produced by these particles moving from the HEPA filters toward the patient's open wound. Anyway, the air is supposed to be clean due to a 99.9975% local efficient filtration as illustrated before in Figure 5.4. Nevertheless, in this case, the particles emitted when using the monopolar instrument have a diameter which approaches the value of the MPPS – in the range of 0.12-0.25  $\mu\text{m}$  – and this causes them to pass through filters.

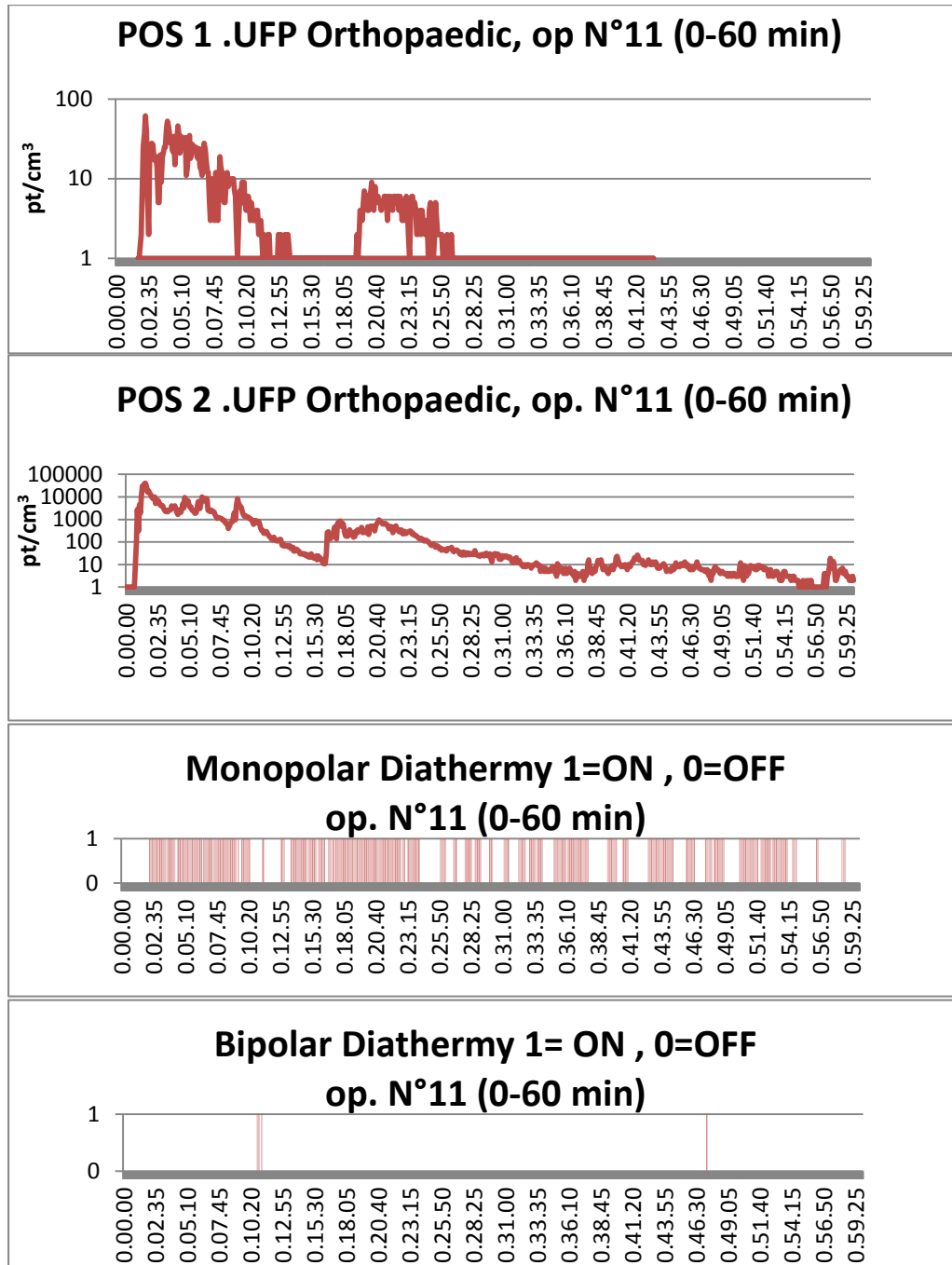


Figure 5.13. Data related to the first 60 minutes of the orthopaedic surgery (operation N° 11) on the 11th of November 2013. In descending order: UFP about position 1, UFP detected in position 2 and switching-on moments of monopolar and bipolar diathermy.

As can be observed in Figure 5.14, the analysis of the data related to the orthopaedic surgery (operation N°14) of the 18-11-2013 leads to similar conclusions.

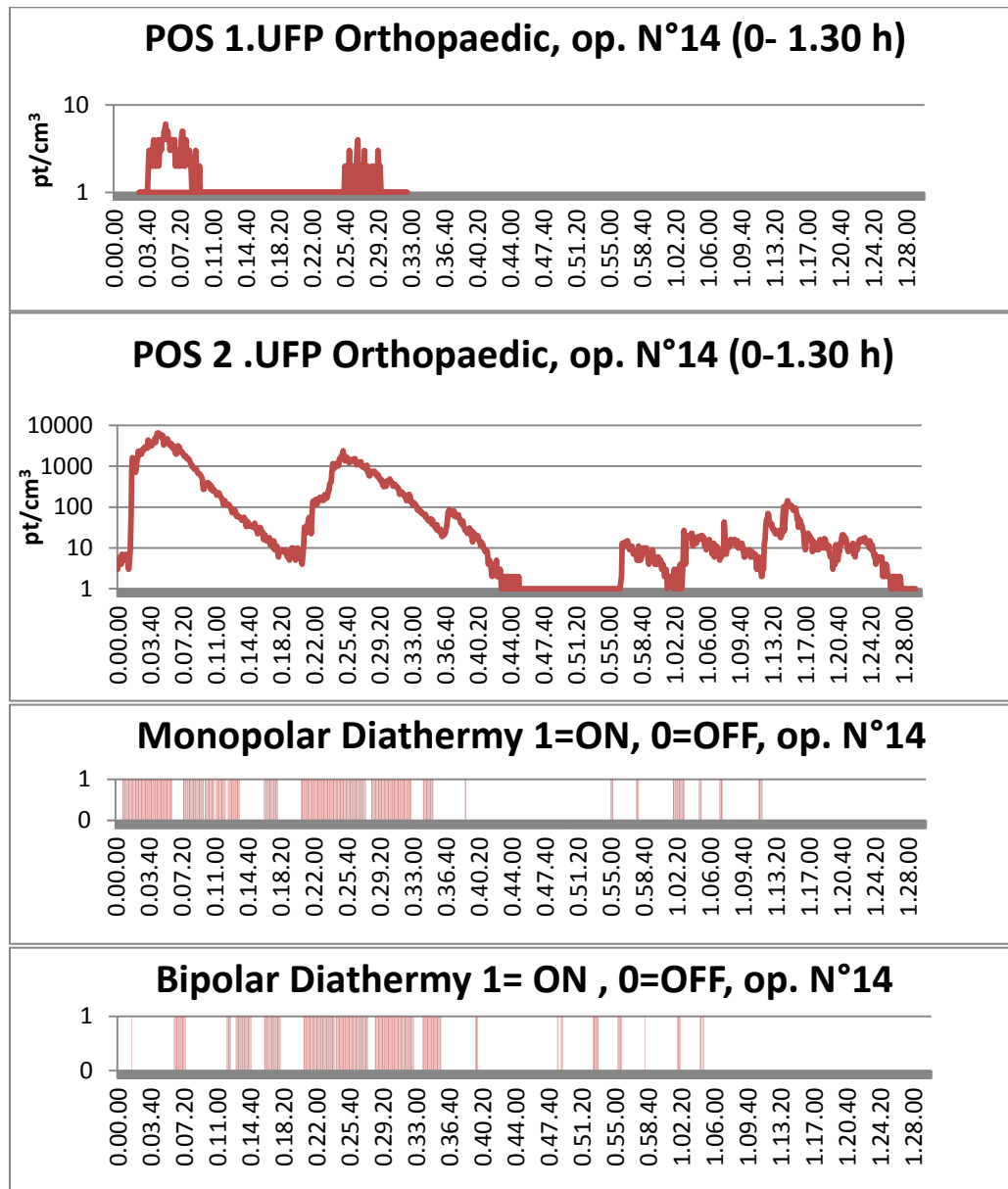


Figure 5.14. Data related to the first 1 hour and a half of the orthopaedic surgery on the 18th of November 2013. In descending order: UFP about position 1, UFP detected in position 2 and switching-on moments of monopolar and bipolar diathermy.



As already mentioned, in Figures 5.13 and 5.14 the graphs related to the ultrafine particles spotted respectively in positions 1 and 2 show similar trends. Owing to this, it can be stated that the peaks of particle concentration are detected in the same periods of time during the operation. Again, the massive use of the electrosurgical instruments can be assumed to be the reason for the reintroduction of particles through the HEPA filters.

A significant difference between the two compared operations emerges, in terms of height of the particle peaks, from the data concerning the measurements carried out in position 1. In fact, in Figure 5.13 the maximum particle concentration is about  $64 \text{ pt/cm}^3$ , whereas in Figure 5.14 the highest value is approximately  $6 \text{ pt/cm}^3$ . In other words, the former peak is around eleven times higher than the latter but the important result is the founding of these particles in the air that is going out from HEPA filters.

The first graphs in Figures 5.11 and 5.12 reveal a zero value due to the less particles spread during these surgeries probably in relation with the different use of the electro surgical tools during these open surgeries.

In conclusion, the data so far considered reveal that in some cases the air that comes out of the HEPA (H14) filters is completely free from ultrafine particles, whereas in other cases a certain concentration is present in the same air.

As mentioned before, the evaluation of the harm caused by these particles mainly appertains to medical studies, although also some further studies may deal with this issue.

## 5.8 Conclusions

The primary role to guarantee a good cleanliness in operating rooms belongs to the ventilation system but its efficiency can be jeopardized by the use of electro surgical instruments.

During open surgeries like orthopaedic surgery or liver resection the particle levels are higher than during EVAR surgeries despite of the more attention dedicated to limit the door openings, the number of people and to use a particular clothing system.

The cause of the higher concentrations measured during open surgeries need to be found only in the use of electrosurgical instruments. In effect, these instruments are not usually used during EVAR operations due to the different techniques performed, but only during orthopaedic and liver resection surgeries. The main affected particle results to be ultrafine particles in the form of surgical smoke.

Moreover, ordinary surgical masks are inadequate at filtering these ultrafine particles - emitted when using electrosurgical tools - due to their small size.

Surgeons and personnel are affected by indoor surgical smoke contamination which lead to health problems and diseases that need to be taken into account. As a result, the maintenance of good occupational working conditions is the primary goal together with the safety of patients. The aim of the measurement campaign was to evaluate which is the amount of particles spread and which are their motion and concentrations inside the Hybrid OT in different critical positions.

During the use of electro surgical instruments, thanks to the air recirculation system and the weak filtration efficiency of HEPA filters for a small range size for ultrafine particles, there is an introduction of ultrafine particles over the clean area from the filter ceiling diffuser.

A reintroduction of ultrafine particles is detected through the measurements carried out in the air exiting from the HEPA H14 filters. It has to be specified that no evidence is provided regarding the harm produced by these particles moving from the HEPA filters toward the patient's open wound.

The reason of the presence of ultrafine particles could not be found in the production process or the installation procedures. The integrity of H14 HEPA filters is proven. Installation procedures need to be verified with the constructor company which surely followed the standard procedures for the installation of the filters.

The evidence is the passage of ultrafine particles through the filters and it is important to think about the applicable solutions for this problem, due to the critical influence of this ultrafine particles on the surgical personnel's health.

The possible solutions for the problem are:

- Use of local exhaust systems suction piping
- Reduction of recirculation rate
- Use of ULPA filters or filter for the abatement of UFPs.

During the open surgeries observed from October 2013 to March 2014 there was in use a local air suction system only for the monopolar diathermy tool, because it was integrated in the same instrument. On the contrary, for all the others instruments any kind of local extraction for the surgical smoke was utilized, due to the design of the instruments and the shape itself. It could be possible to think the use for all the instruments of extra local air suction duct, which can be positioned in direction of the smoke stream in order to extract locally the surgical smoke. The function of this tool is too limit the particle spread in the operating room, thanks to a local extraction of the surgical smoke. This suction duct need to be produced with adequate materials in order to avoid itself to contaminate the surgical zone near the patient's wound. In addition, it needs to be positioned near the surgical site, avoiding any kind of interferences with the procedures.

On the other hand, a reduction of the recirculation rate could decrease the reintroduction of ultrafine particles through the system. In effect, using more air coming directly from outside could diminish the presence of surgical smoke in the supply air. The negative aspect of this choice is the increasing costs about the energy supply in order to handle high air volume of air from outside instead of recirculation air. This solution can be evaluated in the case of a new construction, because of changing the air flows in the system bring to an imbalance of the system about air velocities in the ducts, functioning of the fans, wrong dimension of heat exchanger and other problems related to the HVAC system.

It is possible to state that if the Hybrid OT would be in use only for EVAR surgeries, the recirculation system would not create any kind of reintroduction of particles. In fact, during EVAR surgeries electro surgical instruments are not usually in use, that means the absence of ultrafine particles due to the spread of surgical smoke within the Hybrid OT. On the other hand, the problem of high concentrations of ultrafine particles exists only during open surgeries due to the use of electro surgical tools.

Finally, the reintroduction of ultrafine particles could be associated to the inappropriate choice - in this specific case - of the kind of filters for this Hybrid OT due to the typical use of electro surgical instruments. In fact, after a detailed observation of the data collected, maybe the best choice could be the use of ULPA (Ultra-Low Penetration Air filters), in order to have higher filtration efficiency for the critical size around 0.16  $\mu\text{m}$ .

As a result, the overall efficiency of ULPA filters is higher in relation to a smaller characteristic MPPS. It means a complete filtration of the surgical smoke spread by electro surgical instruments.

More studies could support this suggestion in order to define which could be the best technology to guarantee a better air filtration that means a lower risk for infections for patients and a lower surgeon's and staff's exposure to this surgical smoke impossible to be filtered by traditional face masks.

To sum up, all the data taken into account bring to a clear outcome. Every kind of systems need to be designed for the specific use, depending on the features of the application. This work permits to have the confirmation about the strict interference and connection among the air recirculation system, the air flow distribution in the surgical area and the ultrafine particles dispersed by electro surgical instruments during surgical activities.

## 5.9 Future works

Due to the topics evaluated during the work there is the necessity of more comparative studies. It is fundamental the importance of future microbiological measurements for the air supplied by the plenum in the clean area of the Hybrid OT. The number of colony forming units per cubic meter (CFU/m<sup>3</sup>) could be an important value of the harmfulness of the ultrafine particles reintroduced by the recirculation system in order to evaluate the possible risk for infection for patients.

In addition, medical evaluations could be useful to understand the real influence of the surgical smoke on the personnel's and patient's health in relation with the ultrafine particle concentrations detected in this work.

Laboratory tests about ULPA filters could be important to check their real filtration efficiency for the ultrafine particles spread by electro surgical instruments.

Finally, for studies similar at this work it is fundamental to perform a preliminary smoke test inside the operating room before the start of the particle measurements. However, it could be also interesting to evaluate the airflow path and airborne particle spread also via computational fluid dynamic studies, which are less invasive than real measurements. The aim is to understand the real air flow pattern inside the operating room for the best positioning of the samplers probe during new on field measurements campaign.









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## Acronyms

AAOS	American Academy of Orthopaedic Surgeons
ACH	Air Changes per Hour
AHU	Air Handling Unit
AORN	Association of periOperative Registered Nurses
CFM	Cubic Feet per Minute
CFU	Colony Forming Units
CNC	Condensation Nuclei Counter
CT	Computed Tomography
DEHS	Di-Ethyl-Hexyl-Sebacat
EVAR	EndoVascular Aneurism Repair
HEPA	High-Efficiency Particulate Air filter
HVAC	Heating, Ventilation and Air Conditioning
ISO	International Organization for Standardization
IT	Information Technology
LAF	Laminar Air Flow
MPPS	Most Penetrating Particle Size
MRI	Magnetic Resonance Imaging
OPC	Optical Particle Counter
OR	Operating Room
OT	Operating Theatre
PC	Personal Computer
SSI	Surgical Site Infection

UDF	UniDirectional air Flow
UFP	UltraFine Particles
ULPA	Ultra Low Penetration Air
UPC	Ultrafine Particle Counter
VCCC	Ventilation and air-Conditioning system for Contamination Control

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