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Laying-up of sterile instruments in the operation theatre; equal or superior protection by using a horizontal unidirectional air flow system

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Summary

Background: A system for the preparation of sterilized instruments with unidirectional horizontal air flow (UDHF) has several advantages over a unidirectional down-flow system (UDDF). The advantages are based on the installation of the system being more flexible and easier to use, no cooling of the air flow being necessary and less air being needed for circulation, resulting in reduced energy use.

Objectives: The objective of this study is to determine whether a system with a unidirectional horizontal air flow (UDHF) performs equal or superior to a system with a unidirectional vertical air flow (UDDF) in terms of prevention of contamination of the air (the presence of particles and micro-organisms) during the laying-up process.

Methods: The degree of protection (DP) offered by two UDHF system variants and two UDDF system variants was determined for several static set-ups and a dynamic simulation of the process. In addition to determining the level of protection for several categories of particle size, colony forming units (CFU's) were also measured during process simulations.

Results: When maximum protection (no particles present) is considered, the UDHF systems performed significantly better than the UDDF systems for particles ≥ 2.5 µm. When particles were present, there was no significant difference between systems for particles ≥ 0.3 µm and ≥ 0.5 µm. However, the performance of the UDHF system was superior to that of the UDDF system (DP) for particles ≥ 1.0 µm representing the bacteria carrying particles. During the process measurements, no CFUs were found with the UDDF system in 64% of the measurements, as compared to 90% for the UDHF system (p = .012).

Conclusions: The UDHF system offers equal or superior protection to the UDDF system against contamination of the clean area within which the laying up takes place. Despite our finding that the differences did not always reach statistical significance (due to low background concentrations), there is a clear trend, from the small-sized particles (≥ 1.0 µm) up to the largest sizes considered, including bacteria-carrying particles, that demonstrates the superiority of the horizontal flow system. The UDHF system offers a more robust solution than the UDDF system, provided good work instructions are given and the height of the table and height of the plenum are properly adjusted.

Keywords
Operation theatre, air quality, unidirectional flow system, horizontal flow, vertical flow, instruments, laying-up process, particles, contamination, protection

Introduction

Laying-up of sterile instruments in the operation theatre is an important quality process and should keep instruments sterile to be used for the procedure. There is an unresolved and ongoing debate which air treatment systems create the best conditions for this process. In the Netherlands, laying-up of sterile instruments is more and more frequently done in a separate and dedicated preparation room with a special ventilation system to provide an ultraclean environment for the lay-up process in order to reduce the number of surgical side infections as much as possible. These rooms are attached to an operation room or more centrally located in the operating department. Newly built lay-up systems in The Netherlands almost exclusively use unidirectional down-flow systems (UDDF systems), similar to the systems used in operating rooms. However, a system with horizontal flow (unidirectional horizontal flow system (UDHF system) would seem to offer advantages from a hygiene point of view. In the case of a down-flow system, the person doing the lay-up is (partially) located within the down flow. In the case of emission of particles by this person (the so-called spraying from the neck opening of the clothing), these particles – possibly contaminated with micro-organisms - are carried to the laying-up table by the down flow, creating a risk of contamination of the instruments. In contrast, in a system with a UDHF the falling particles are carried away from the instrument table, as long as the particles are not too heavy and the air flow is strong enough.
From an installation point of view, a UDHF system also has advantages for both new build and renovation of operating rooms. The advantages of a UDHF system compared to a UDDF system are threefold. First, the system is simpler because it requires no cooling (energy conservation and cost reduction). Because of this, it is easier to install and may even be mobile. Second, less air is needed to protect the same number of instrument tables (energy conservation) and third, the system set-up results in a less ambiguous process because of the location of sterile material between the air coming from the UDHF and the scrub nurse. P.N. Hoffman *et al*[1] pointed out that the air change rate in preparation rooms used for laying-up sterile instruments should be around 37 ACH; a greater air change rate than in theatres.[2]
Up until now, it is not clear whether the performance in terms of air quality achieved in the laying-up zone of a UDHF system equals or exceeds that of a UDDF system during the laying-up of instruments in a separate preparation room.
The objective of this experimental comparative study is to answer the following research question: "what is the difference in contamination (presence of particles and micro-organisms) of the clean area within which laying up takes place when a UDHF system is used versus when a UDDF system is used?"

Methods

Principles
By emitting particles in the lay-up area and evaluating whether these particles land on the instrument table one determines whether there is a risk of contamination and whether the system offers protection from these environmental conditions. If the number of particles found is the same or less with a UDHF system as with a UDDF system, we conclude that it gives at least the same level of protection against airborne contamination as the UDDF system.
Because it is impossible to maintain the background concentration of particles (C_{ref}, see below) at exactly the same level for both systems, we chose to make use of the degree of protection (DP) concept described in DIN 1946 part 4 annex C. [3] The degree of protection is derived according to the following formula.[3]

$DP_x = -\log (C_x/C_{ref})$
DP_x = Degree of protection in the “clean” area x
C_x = Concentration of particles in the “clean” area x
C_{ref} = Concentration of particles outside the “clean” area, i.e. the background

The degree of protection in our analysis was limited to a factor of 7 (i.e. a 10^7-fold reduction in counts) for the situation in which no particles were found at a given measuring point (x).
A range of particle sizes was used including the range of particles containing bacteria.[4] The sizes were divided into six categories: ≥ 0.30 µm, ≥ 0.50 µm, ≥ 1.0 µm, ≥ 2.5 µm, ≥ 5.0 µm and ≥ 10.0 µm.

Systems

The two systems (UDHF and UDDF), were subjected to the same experimental procedures. The experiments with the UDHF system were carried out with a nominal air velocity of 0.45 m/s (UDHF) and a lowered air velocity “Low Flow” (UDHF_LF; 0.3 m/s). The experiments with the UDDF system were carried out at an air velocity of 0.3 m/s with air cooling (UDDF) and without air cooling "No Cooling" (UDDF_NC). The temperature of the cooled air was roughly 2-3 K lower than the ambient temperature. The systems were installed and tested in the same room, one after the other, so that the environmental factors during the experiments (air flow, temperature, number of people present, etc.) were as similar as possible.

Experiments

Particles were emitted into the room so that the background concentration (C_{ref}) in the room was kept at a relatively high level. The particle concentration in the background was created by the vaporization of tap water with an ultrasonic fogger (Lighthouse Volcano P6). The small (2 to 4 µm) water droplets emitted by the machine vaporize very fast (a few seconds) and the mineral residues from the evaporated tap water remain as solid particles airborne in the air flow in the room.[5, 6, 7] Two emission positions A and B were used one at a time (figure 1). The particles in this study were emitted at a height of 1.5 meters (average neck height). Airborne particles were measured using three particle counters (Lighthouse 3016-IAQ, Fremont, CA, USA).

Set-up

The experiment set-up used was placed in a general purpose room with no special air ventilation in the hospital.

The UDHF and UDDF systems were supplied with air by two ventilator boxes connected to the plenum with tubes. The plenum was supplied with air using two filter boxes fitted with HEPA grade 14 (H 14) filters.[8] A homogeneous air velocity over the outlet surface of the plenum was created by fitting the plenum chambers with an air distributor consisting of two layers of air distribution cloth that were approximately 1 cm apart.

Particle measurement

Airborne particles were measured on the instrument table ($M_{2,P}$), the Mayo stand ($M_{1,P}$), and in the background ($M_{3,P,CFU}$,) see figure 1. At 30-second intervals, particles in the size categories of $\geq$ 0.3 micrometer, $\geq$ 0.5 micrometer, $\geq$ 1.0 micrometer, $\geq$ 2.5 micrometer, $\geq$ 5.0 micrometer, and $\geq$ 10.0 micrometer were read online via a computer. The airflow through the instrument was 2.8 dm^3/minute. Each measurement had a duration of at least 10 minutes, so a total amount of at least 28 dm^3 of air was sampled. Outcome parameter was the degree of protection at the instrument table and the Mayo stand, determined on the basis of the reduction in particle counts at these measuring points compared to the background measurement.

CFU measurement

The number of micro-organisms was determined using an active air sampler, sampling at a volume flow of 200 dm^3/min. Two Biotest Diagnostics’ RCS Plus Centrifugal Air Samplers were used for this purpose. One of these air samplers measured the background concentration ($M_{3,P,CFU}$), just as with the particle measurement (figure 1), and the other air sampler was placed between the instrument table and the Mayo stand at a height level with the top of the tables ($M_{4,CFU}$). At least 200 dm^3 of air were passed over the strips per sample. The strips contained Tryptone Soya Agar, and were incubated for 48 hours at 30 °C.
All CFU’s were counted but speciation was not performed.

Measurement 1 (Experiments carried out without instruments or Mayo stand)

The size and quality of the clean area for the given configuration of the systems was determined by using a grid. No instrument table or Mayo stand was present in the clean area when these measurements were conducted; particles were only emitted from position A (figure 1).

Measurement 2 (Experiments carried out with instruments and Mayo stand)
Measurement 2 was carried out with the instrument table and Mayo stand in place and covered with a sheet. By carrying out measurements with and without a heated dummy, the effect of the presence of a "person" on the protective function of the system during emission from positions A and B was determined. The convective air stream that is created by the heat effect of this person will cause particles to move upwards into the unidirectional air stream. The dummy was a 1.80 m high cylindrical body with a uniform heat emission of 120 W. It was fitted with clothing customary for scrub nurses and placed in the working position of the scrub nurse (figure 1).

Measurement 3 (Experiments carried out with a simulated process)
Measurement 3 was carried out during a simulated laying-up process. In addition to measuring the number of particles the number of CFUs was also determined, both in the background and between the instrument table and the Mayo stand. The simulated process was executed by two scrub nurses (one sterile scrub nurse and one pathway scrub nurse). Both scrub nurses wore scrub suits, the sterile scrub nurse was additionally equipped with a sterile gown and gloves, surgical mask and cap, protective equipment usually worn during these activities. The simulated process involved laying up one instrument table and one Mayo stand with a basic surgical kit, and involved the following process steps:
1) Preparing materials; 2) Placing sterile cloth over instrument table + opening packet by the non-sterile staff; 3) Putting on sterile overcoat and gloves by sterile scrub nurse (handing the coat and closing it on the back by non-sterile scrub nurse); 4) Placing cover on the Mayo stand by sterile scrub nurse; 5) Laying up by sterile scrub nurse; 6) Cleaning up by sterile scrub nurse.
The simulated process followed an actual laying up protocol. The measurements started at step 2 and ended after step 5.

Statistical analysis
For most particle sizes, the distribution of degree of protection was negatively skewed, with a high peak at the value of 7 (indicating maximal protection; values > 7 were not possible). Therefore, we split per particle size the variable degree of protection into two outcome variables. The first outcome variable was maximum protection (yes or no), where “yes” equaled a degree of protection value of 7, and “no” equaled a value below 7. The second outcome variable was degree of protection (value < 7) and was only applicable for the situations without maximal protection (i.e., value of 7 removed). The latter outcome was approximately normally distributed. Consequently, for each particle size, we analyzed the data to answer the following research questions: First, do the systems differ in their percentages of maximal protection? (i.e., “no particles present”); and second, in the situations without maximal protection: do the systems differ in their mean degree of protection? The difference between the systems in percentages maximal protection was analyzed by using Chi-square tests.

Whether the difference in percentages depended on the type of table (“instrument table” or “Mayo stand”) or the dummy variable (“present” or “not present”), was analyzed using logistic regression analysis. The outcome variable in this analysis was maximal protection (yes or no); the predictor variables were type of system (categorical variable with four categories: UDDF, UDHF, UDDF_NC, UDHF_LF), type of table and the interaction effect between type of system and type of table (i.e., cross-product). The same type of analysis was repeated with, instead of type of table, either the dummy variable (with dummy or no dummy) or the emission variable (position A or B).

The difference between the systems in mean DP (for the situations without maximal protection) was tested with Analysis of Variance. The outcome variable in this analysis was degree of protection, and the independent factor was type of system. Whether the differences between the systems in mean DP depended on type of table or dummy or emission, was also investigated with Analysis of Variance. Type of table (or dummy or emission) was included as an extra factor, and a full-factorial design was used (including the interaction effect). Again, a significant interaction effect indicated that the difference between the systems in mean DP depended on, for example, type of table. For all analyses, we used a two-sided α of 0.05 as significance level. The analyses were performed using SPSS, version 20.

Results

Measurement 1 (Experiments carried out without instruments or Mayo stand)
As indicated, these experiments were carried out without instruments or Mayo stand. The DP offered by the UDDF system without cooling at 1.0 m was found to be 2 or less at 70 cm from the back wall and 1 or less at 105 cm. Both sides of the system showed a similar rapid decrease in DP (constriction). At 69 cm from the sides and 70 cm from the back wall, a DP of 2 was reached. The DP of this area was not symmetrical relative to the central line. This is due to the fact that the air on the left side cannot flow out freely.
Cooling the air emitted by the UDDF system to 2-3 K lower than the ambient temperature, was found to increase the size of the clean area at 1 m above the ground. At 105 cm from the back wall, the DP was still maximal (no particles found). At 117 cm from the back wall, the DP had dropped to below 1. Substantial improvement was also measured along the sides of the system. At 70 cm from the back wall and 56 cm from the side, the DP was still maximal. At 43 cm from the side a DP of 1.0 was measured. In conclusion, the area with a DP of 2 or better with a UDDF system with cooling was found to be substantially larger (1.281 m^2 versus 0.672 m^2 of usable clean area, DP ≥ 2) than with a UDDF system without cooling (UDDF_NC).
The experiments with a UDHF system resulted in an area with a DP greater than 2 reaching to 110 cm from the plenum. Measured at a height of 30 cm above the bottom of the plenum (at half height) and at a distance of 80 cm from the plenum and 30 cm to the side, the DP was still maximal. Thus the breadth and depth of this area (1.914 m^2) exceeded that of the UDDF system with cooling. At a lower air velocity (UDHF_LF, reduced from 0.45 m/s to 0.30 m/s), the size of the equivalent area measured at 30 cm above the bottom of the plenum hardly changes in comparison with the UDHF system. A higher air velocity was found to have positive effects (less constriction) for the outer area. Compared to the UDHF system the size of the usable clean area (DP ≥ 2) of the UDDF system was 49% smaller (1.281 versus 1.914 m^2).

Before starting measurement 2 and 3, experiments were conducted to determine the optimal positioning of air supply and tables. Initially, the bottom of the air supply surface was positioned at a level that was nearly the same as the top of the tables. This set-up did not offer any protection because contaminated air was entrained from the environment. The horizontal flow attracted air containing particles from under the table, “sucking” the particles into the "clean area" (figure 2, left). By lowering the air supply surface, the air flow split into a flow over the table with covering material and one under the table (figure 2, right), creating a clean area above the table. All experiments were carried out with tables that were 99 cm high and with the bottom of the air supply surface located 79 cm above the floor, that is, 20 cm below the surface of the table. The distance between the air supply surface and the tables turned out to be an important parameter. Positioning the air supply surface so that there was a 20 cm distance to the tables led to an increase of entrained air from under the table. At a distance of approximately 5 cm between the air supply surface and the tables, the UDHF system functioned properly. This is the distance that was used during all experiments with the tables.

Measurement 2 (Experiments carried out with instruments and Mayo stand)
Table I gives an overview per system showing that the percentage of observations in which no particles were found on the tables (maximal protection) increases with the size of the particles. The percentage is especially low for the two lowest particle categories (≥ 0.3 µm and ≥ 0.5 µm). There is a significant difference between the systems for all particle categories except for the ≥ 0.3 µm category. If only the UDDF and UDHF systems are compared, the UDHF systems performs significantly better than the UDDF systems for the particle categories ≥ 2.5 µm, ≥ 5.0 µm and ≥ 10.0 µm ($p < 0.01$), whereas for particle size ≥ 0.5 µm, the UDDF system performs better. For the ≥ 5.0 µm and ≥ 10.0 µm particle categories almost no particles were found (≥ 99% of the observations) at the UDHF system. The UDDF system shows that in 68% of the observations no particles are encountered.

The difference in the percentage of observations in which no particles were found between the four systems does not depend on the type of table (instrument table or Mayo stand) except for the case of the ≥ 5.0 µm particle category. The difference between the two most important system types (UDDF, UDHF) does not depend on the type of table either. In addition, the difference between UDDF and UDHF depends on the

presence of a dummy only in the case of the ≥ 1.0 µm particle category. The difference between UDDF and UDHF does not depend on the emission position (position A or B).

Table II shows the mean DP per system for the observations in which particles were found (DP < 7) for the UDDF and UDHF system. Only the particle categories ≥ 0.3 µm, ≥ 0.5 µm, ≥ 1.0 µm and ≥ 2.5 µm are displayed. The number of observations where particles are found for the UDHF system particle categories ≥ 5.0 and ≥ 10.0 µm (n ≤ 1) was too low for statistical analyses.

Results of Analysis of Variance indicated that there was no significant difference between the performance of the two systems for the ≥ 0.3 µm and ≥ 0.5 µm particle categories. In the case of the ≥ 1.0 µm and ≥ 2.5 µm particle categories, the UDHF system performs significantly better than the UDDF system ($p < 0.01$). The difference in performance of the two systems was slightly influenced by "type of table" (instrument table or Mayo stand). Only for the ≥ 0.5 µm particle category a significant interaction effect between Table and Type of system was found ($p < .01$). In this situation the DP of UDHF system on the Mayo stand was higher.

The presence or absence of a heated dummy has an effect on all particle categories. There was a significant interaction effect for the ≥ 0.3 and ≥ 0.5 µm particle categories. For these particle sizes, the UDDF system performs better than the UDHF system when the dummy was present.
The mean values in Table II show that there is a remarkable difference between the performance of the UDDF system with and without a dummy, while there was hardly any difference between the performance of the UDHF system with and without a dummy.

If the position from which the particles are emitted (position A or B) is taken into consideration, the emission position only had an effect on the difference in performance of the systems for the ≥ 0.5 µm and ≥ 1.0 µm particle categories.

Measurement 3 (Experiments carried out with a simulated process)
Table III shows that during the process measurements, no CFUs were found with the UDDF system in 64% of the measurements, as compared to 90% for the UDHF system ($p = .012$). When CFUs were found, the mean number of CFUs for the UDDF system was 19.2 CFU/m^3 compared to 5.0 CFU/m^3 for the UDHF system ($p = .05$). The difference in background concentrations was not significant ($p = .96$) for the different experiments at 91.4 CFU/m^3 for the UDDF system, and at 90.7 CFU/m^3 for the UDHF system.

Based on the Analysis of Variance of the mean DP for the laying-up process (process steps 2 through 5) the difference in performance (DP) between the two main systems was not significant for any of the particle categories. If "type of table" (instrument table or Mayo stand) was taken into consideration, there was a limited and not significant influence ($p > .05$) on performance of the different systems.

Discussion
This study has partially answered the research question whether the UDHF system equals or performs better than a UDDF system in controlling contamination (presence of particles and micro-organisms) of the clean area within which laying up takes place. On the one hand, there is a significant difference in the percentage of observations where no particles were found for the higher particle categories (≥ 2.5 µm, ≥ 5.0 µm and ≥ 10.0 µm), clearly favoring the UDHF system. On the other hand, for the ≥ 0.5 µm, there is a significant difference favoring the UDDF system. For the ≥ 5.0 µm and ≥ 10.0 µm particle categories, almost no particles were found (≥ 99% of the observations) using the UDHF system. The UDDF system yielded a no particles result in only 68% of the observations. If particles were detected, there was no significant difference in the performance of the UDDF system and the UDHF system for the small particles (≥ 0.3 µm and ≥ 0.5 µm), although the results point in the direction of better performance with the UDHF system. The performance of the UDHF system is better than the performance of the UDDF system for the larger particles (≥ 1.0 µm and ≥ 2.5 µm).
However, the reliability of observations for the ≥ 5.0 µm and ≥ 10.0 µm particle categories is low due to the relatively low background concentration (Figure 3). ISO 14644-1 Annex B.4.2 indicates that, for a

statistically reliable measurement, it should be possible to detect a minimum of 20 particles at the class limit.[9] This research took a similar approach and used this minimum number of particles that would be acceptable to find, given the background concentration and DP, to check if the measurements were reliable. At the sample volume used (28.8 litres per measurement), a DP of 5.0, 4.0, 3.0 and 2.5 could be determined to be statistically reliable for the particle categories ≥ 0.3 µm, ≥ 0.5 µm, ≥ 1.0 µm and ≥ 2.5 µm, respectively. No statistically reliable degrees of protection could be determined for the ≥ 5.0 µm and ≥ 10.0 µm particles due to the low background concentration for these particle sizes.

It must be noted that the presence or absence of a dummy has an influence on the performance of the systems for the 0.3 and 0.5 µm particle categories. The UDDF system performs better with a dummy than without a heated dummy. For the UDHF system there is hardly any difference in performance with or without a heated dummy. This is probably because the static dummy guides the UDDF air stream over the instrument table. This effect is not likely to occur if a moving person is present. The difference in performance with and without a dummy is much larger for the UDDF system than for the UDHF system, leading to the conclusion that the UDDF system is less robust than the UDHF system. The position from which the particles were emitted is of importance because of the unusual behavior these particles have in the air stream.[10] In order to have these experiments reflect the actual situation in the operating room as closely as possible, particles needed to be emitted from the position they would come from in practice. We chose to emit the particles at a height of 1.5 meters (average neck height), on the assumption that when dressed in operation clothing with cuffs and a sterile overcoat and gloves, particles (flakes of skin) are mainly released from the neck area. This release of particles is caused by the presence of a gap between the clothing and the body at the neck, and the convection effect (upward flow of air around the body).
The percentage of observations for which no CFUs were found is significantly higher for the UDHF system. When CFUs are found, their number is higher for the UDDF system than for the UDHF system (p = .05).
The DP during the process does not vary significantly between a UDDF and UDHF system.
Taking both systems into consideration, based on the bigger difference in performance of the UDDF system for the design factors table, dummy and location (table II), we conclude that the UDHF system offers a more robust solution than the UDDF system, provided good work instructions are given and the height of the table and height of the plenum are correctly adjusted. A UDHF system could easily be made mobile because cooling is not necessary. However, whether a mobile system would also offer a more robust solution needs to be carefully considered.

The DP offered by the different systems is influenced by environmental factors and human behavior. For instance, the differences in measurements with the UDHF system on the left and right side shows that the distance of the plenum to the side wall or other obstructions is of influence. It is clear from our experiments that the height of the instrument tables relative to the height of the UDHF system is also critical. If the tables are too low in relation to the UDHF system, the non-filtered air below the table is sucked along by the air flow from the UDHF system, possibly leading to contamination of the instruments. To function properly, the UDHF system needs to be set up in such a way that the air flow from it gets split into a flow above and below the table.

We predicated our research method on the fact that the presence of particles has been shown to be a good proxy of the risk of the instruments being contaminated with micro-organisms.[11] Bacteria are part of particles with a mean equivalent diameter of 12.3 µm, with a distribution of between 4 and 18 µm. Research in a hospital in Korea has shown that most airborne bacteria occur in the range between 1.1 and 2.1 µm.[12] There is also proof of a good correlation between particles sized 5-7 µm and the number of micro-organisms found in air samples in ultra-clean operating theaters.[12] Hambraeus at al. (1980) show that 7.9% of the measured bacteria carrying particles in an operating room have a diameter from 1.1 µm up to 2.1 µm, 12,7% from 2.1 µm up to 3.3 µm, 17.9% from 3.3 µm up to 4.7 µm, 23,7% from 4.7 µm up to 7.0 µm and 35.7% > 7.0 µm.4 Based on these studies it can be stated that smaller particles (1.1 – 5.0 µm) can carry bacteria as well as larger ones. Very small-sized particles (< 1.0 µm) are seen as “indicator” particles for larger particles which potentially carry bacteria. Counting of these particles is considered a good approximation of the relative presence of larger particles. Since they are more frequently present in higher numbers they can be measured more reliably than the larger bacteria-carrying particles. Particles with sizes

< 4.5 µm are also considered to be completely airborne .[13] They pretty much behave like a gas ("Brownian motion"), and will follow the air stream they are in.[14] Skin particles released by staff are a potentially greater source of contamination because they may carry more micro-organisms than other particles and these micro-organisms come directly from humans.[15] These skin particles measuring 10-25 µm and roughly 1 µm thick [2] especially have a lot of staphylococci many people are carriers of.[16, 17, 18, 19] This group of microorganisms is responsible for post-operative wound infections especially in implantation surgery.[15] We didn't find other research related to contamination of sterile instruments during the laying-up process with different air systems or the air quality provided by different systems during this process to compare our study with.

Apart from the choice UDDF or UDHD, other procedures are also important to protect instruments from contamination. It was shown that the contamination rate of surgical instruments exposed to the air in an operating theater was 1.18 times higher than that of instruments which had been covered with sterile guard.[20, 21] The exposure time also had a positive correlation with the bacterial contamination rate. Chosky et al. (1996) concluded that setting up instruments in the ultra-clean air theater and covering them until the patient was transferred onto the operating table produced an overall 28-fold reduction compared to instruments set up in the conventional plenum-ventilated preparation room in instrument contamination.[22] By contrast, covering the instruments after setting them up in the preparation room produced only an overall fourfold reduction compared to not covering them.

Conclusions

The UDHF system offers at least as well or better protection against contamination (the presence of particles and microorganisms) of the clean area within which the laying up takes place compared to the UDDF system. For large particles, the UDHF system offers superior protection. However, for the ≥ 5.0 µm and ≥ 10.0 µm particles the difference is not statistically reliable due to the low background concentration for these particle sizes. The results based on the measurements of particles (DP) and the measured number of CFU's both show that the UDHF system offers at least as well or better protection against contamination. Although the differences between the two systems did not always reach statistical significance, there is a clear trend, from small-sized particles up to the largest sizes considered, including bacteria-carrying particles (≥ 1.1 µm), that demonstrates the superiority of the horizontal flow system. The UDHF system offers a more robust solution than the UDDF system, provided good work instructions are given and the height of the table and height of the plenum are properly adjusted.

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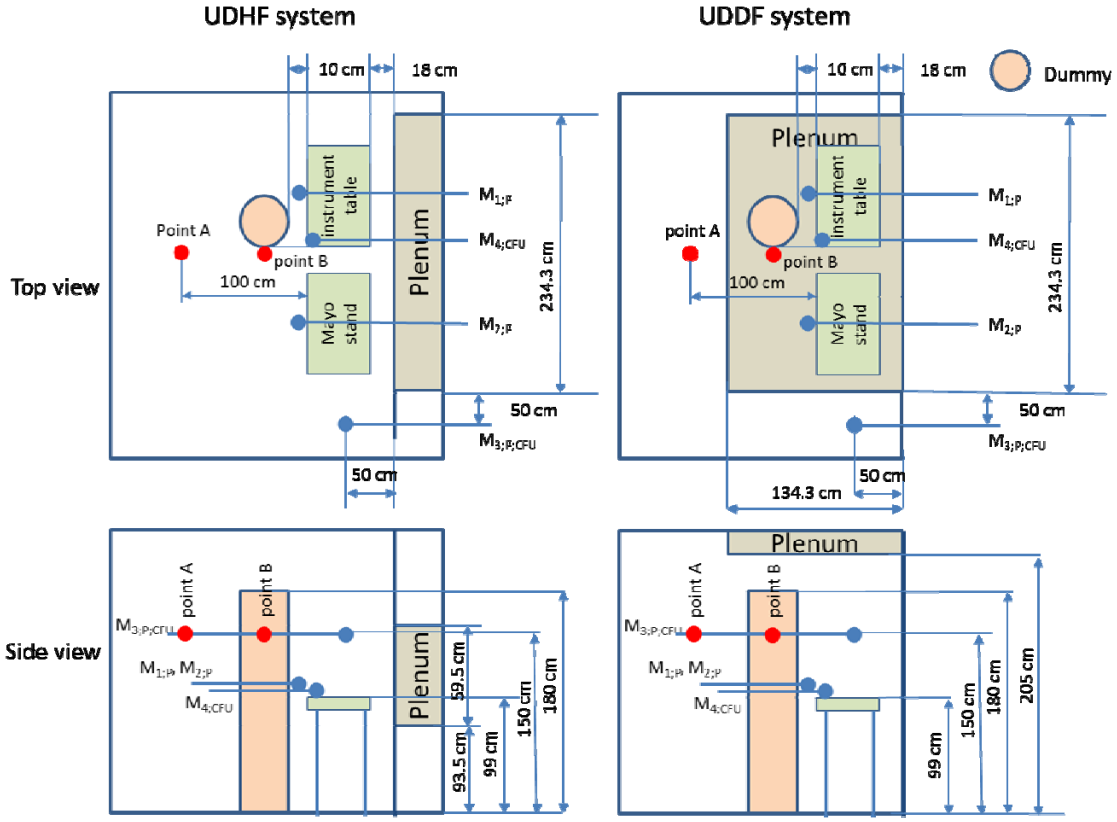
Figures



Point A: Emission particles position A
Point B: Emission particles position B
$M_{1;P}$: Measuring point 1, particles
$M_{2;P}$: Measuring point 2, particles
$M_{3;P;CFU}$: Measuring point 3, particles and CFU
$M_{4;CFU}$: Measuring point 4, CFU
Dummy: 120 Watt

Figure 1. Layout of the measuring set-up UDHF and UDDF system.

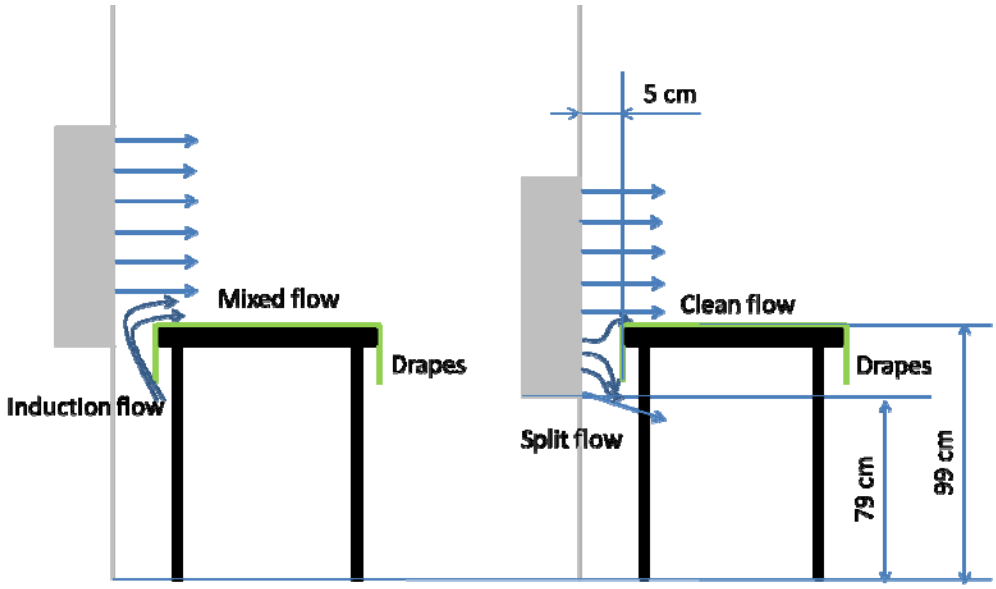


Figure 2. Air flow for too high positioning and proper positioning of the air supply surface for a UDHF system.

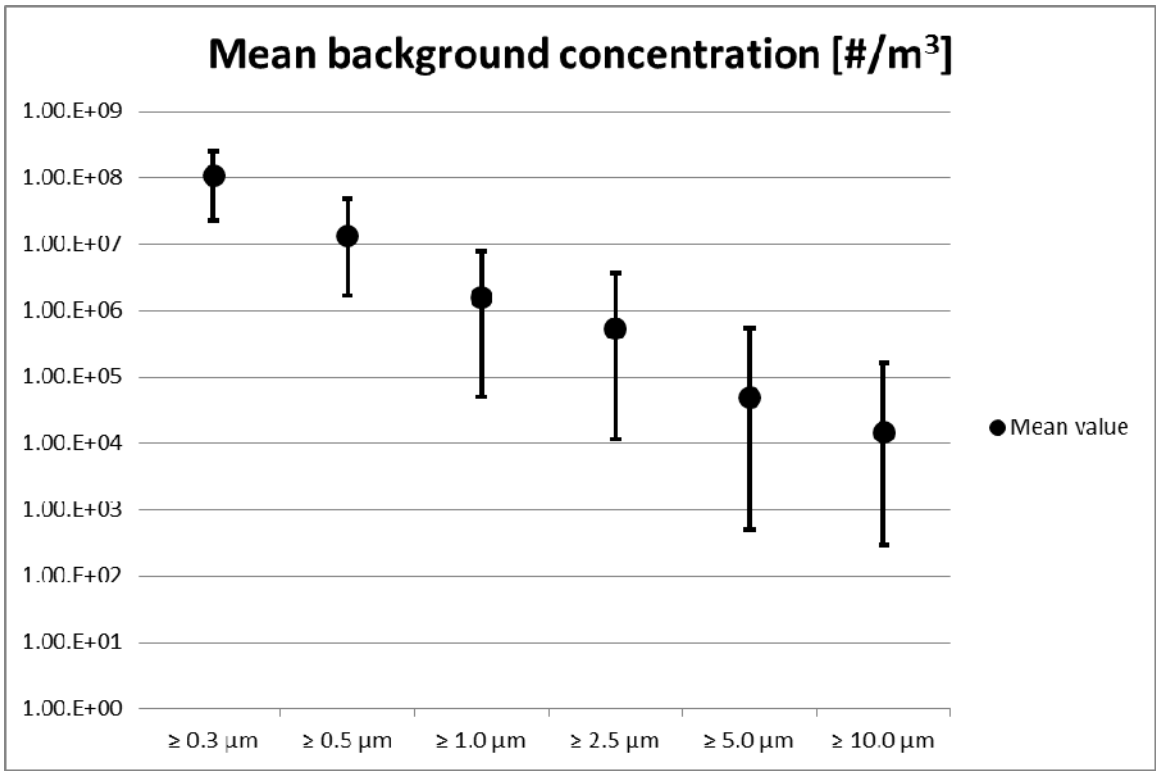


Figure 3. Mean background concentration during the measurements.

Tables

Table I. Percentage of observations with maximal protection (DP = 7) per type of system

	≥ 0.3 µm	≥ 0.5 µm	≥ 1.0 µm	≥ 2.5 µm	≥ 5.0 µm	≥ 10.0 µm
UDDF n=84	1%	24%	52%	57%	68%	68%
UDHF n=86	0%	0%	58%	91%	99%	100%
UDDF_NC n=80	1%	19%	36%	48%	54%	63%
UDHF_LF n=40	0%	0%	18%	30%	65%	85%
P-value[1]	.66	< .01	< .01	< .01	< .01	< .01
P-value[1,2]	.49	< .01	.45	< .01	< .01	< .01

UDDF: Unidirectional down flow; UDHF: Unidirectional horizontal flow; UDDF_NC: Unidirectional down flow without cooling the supply air; UDHF_LF: Unidirectional horizontal flow with a lower air velocity

1. Results from chi-square tests are given for differences between the systems in maximal protection (yes or no) for particle sizes ≥ 1.0 µm, and ≥ 2.5 µm. Results from Fisher Exact tests are reported for particle sizes ≥ 0.3 µm, ≥ 0.5 µm, ≥ 5.0 µm, and ≥ 10.0 µm due to frequencies smaller than 5.
2. Comparison between the UDDF and UDHF only.

Table II. Differences between the two main systems in mean degree of protection (DP) for different particle sizes and different design factors. Observations with maximal protection were disregarded. Results from univariate analyses-of-variance are reported.

Design factor	Levels	≥ 0.3 µm			≥ 0.5 µm			≥ 1.0 µm			≥ 2.5 µm		
		UDDF (n=83)	UDHF (n=86)		UDDF (n=64)	UDHF (n=86)		UDDF (n=40)	UDHF (n=36)		UDDF (n=36)	UDHF (n=8)	
		Mean DP	Mean DP	P-value	Mean DP	Mean DP	P-value	Mean DP	Mean DP	P-value	Mean DP	Mean DP	P-value
Total	-	4.10	3.99	.58	3.81	4.11	.14	2.59	3.92	<.01	2.32	4.13	<.01
Table	Instrument table	4.17	4.01		4.49	4.18		2.82	3.93		1.94	3.99	
	Mayo stand	4.03	3.98	.78*	2.89	4.03	<.01*	2.44	3.91	.49*	2.51	4.26	.79*
Dummy	Without dummy	3.75	3.97		3.63	4.09		2.49	3.76		2.15	4.06	
	With dummy	5.19	4.02	<.01*	4.70	4.13	.03*	3.29	4.05	.45*	3.35	4.17	.36*
Location	A	4.37	3.97		4.20	4.05		3.19	3.88		2.93	3.85	
	B	3.83	4.01	.13*	3.43	4.17	.02*	2.00	3.96	.01*	1.77	4.29	.13*

UDDF: Unidirectional down flow; UDHF: Unidirectional horizontal flow.

* P-value of interaction effect System(UDDF, UDHF)*Design factor.

Table III. Percentage of observations for which no CFU was observed at the table and mean CFU counts if CFUs were detected.

	CFUs between the tables		CFUs back ground
	Percentage of observations without CFU	Mean [CFU/m^3] if CFUs were observed	Mean [CFU/m^3]
UDDF	64% (n=21)	19.2 (n=12)	91.4 (n=17)
UDHF	90% (n=28)	5.0 (n=3)	90.7 (n=19)
P-value	.01	.05	.96

UDDF: Unidirectional down flow; UDHF: Unidirectional horizontal flow.