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Focus Ultra Clean Ventilation (UCV) Systems for Operating Theatres

<table>
<thead>
<tr>
<th>Model</th>
<th>*Purpose</th>
<th>Diffusion Size (mm)</th>
<th>Overall Size (mm sq)</th>
<th>Nominal Airflow (L/s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Focus 1000</td>
<td>ST/DP</td>
<td>1900 x 1900</td>
<td>2200-2800</td>
<td>1500-1750</td>
</tr>
<tr>
<td>Focus 2000</td>
<td>GS/O</td>
<td>2400 x 2400</td>
<td>2800-3300</td>
<td>2200</td>
</tr>
<tr>
<td>Focus 3000</td>
<td>O/NS</td>
<td>2800 x 2800 / 3200</td>
<td>3200-3420</td>
<td>2980</td>
</tr>
</tbody>
</table>

*Purpose Legend: ST=Small Theatre, DP=Day Procedure, GS=General Surgery, O=Orthopedic, MS=Major Surgery

CFD modelling diagram for Focus 3000 with integrated perimeter lighting and return air grilles.

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- Laminar Flow / Class II / Class I / Isolators
- Clean Room Certification
- Particle Counting / Air Change Rates / Room Pressure Differentials / Fumigation
- Indoor Air Quality
- Fume Cupboard Certification
PART 2
INTRODUCTION

The cost of construction and maintenance of health care facilities is substantial and the cost effectiveness of procedures systems and facilities is under constant review. Reduction in hospital acquired infections can have a significant impact on improved patient outcomes and minimising the cost to the health care facility for the delivery of clinical services. Strategies to improve outcomes are both clinical and engineering. One area of ongoing discussion is the role of operating theatre ventilations systems and system design to assist in the reduction of surgical site infections (SSIs).

Development in microbiology has made surgery safer, but the overall instance of associated infections remains high and represents a substantial burden of disease. [1]

This section Part 2 completed the Part 1 of the paper previously published.

LAMINAR AIR SYSTEMS

Operating Theatre Ventilation Systems should provide a reduction of potential contaminants in the operating theatre by conveying air with low levels of potential pathogens to the surgical site and provide good environmental control.

Laminar air-flow units are generally two types; ceiling-mounted (vertical flow) or wall-mounted (horizontal flow). There are inconveniences associated with both types. Generally the major problem associated with laminar air-flow is flow disruption. With vertical laminar flow, it is the heat generated by surgical lamps creates air turbulence while with horizontal laminar flow it is the surgical team that disrupt the air-flow [17].

Although with the introduction of LED surgical lights the thermal influence on turbulence due to surgical lighting has been negated in modern vertical laminar flow systems.

Laminar air-flow systems are mainly used in implant surgeries where even a small number of microorganisms can cause infection. In joint replacement surgeries, one of the main causes of early (within 3 months) and delayed (within 18 months to 2 years) deep prosthetic infections was found to be colonisation which occurred during surgery [18].

• Most modern operating theatres have conventional ventilation with filtered air and HEPA filters to remove airborne particles of 0.3 μm and above with an efficiency of 99.97%. The arrangement of diffusers in a typical theatre with large gaps for light troffers and other components ultimately create turbulence in the space and would be unacceptable by ISO Class 1 to Class 4 clean room standards,

• HEPA-filtered laminar air-flow supplied by ceiling-mounted (vertical flow) units.

• Vertical laminar air-flow generates fewer bacteria at the operating site and they are 3 to 8 times more effective than the horizontal systems [16]. Laminar airflow is desirable to minimise turbulence and produce predictable movement of particles away from the sterile field.

• UCV systems installed in operating rooms are claimed to reduce the joint sepsis rate after total joint replacement surgery to approximately half that found in a conventionally-ventilated operating room.

• In a study by Bosanquet DC et al (Ann R Coll Surg Engl [2013] Jan; 95(1):15-9), 170 procedures overall were analysed. The study suggests that laminar flow may reduce incidences of SSI, especially in the subgroup of patients receiving arterial grafts.

• Turbulence is undesirable because particles are allowed to float undirected, eliminating any ability to predict where they may settle.

• In Orthopedics Today, January 2009 an article by David Backstein, MD, MEd, FRCSC; Yona Kosashvili, MD, MHA, they discuss the Interposition of the head between the air source and the wound causes contamination that can be reduced significantly if hats, masks and occlusive gowns are worn. Of the facial areas left exposed when wearing standard theatre hats and masks with visors, the ears shed the most bacteria.

• Knobben [18] reported that behavioural changes, including use of body coverage and new guidelines for patient workup, as well as restricting activity in the operating theatre combined with enhancing the technical properties of their laminar flow system, lowered the incidence of intraoperative...
contamination and deep wound infections in postarthroplasty surgeries.

- A recent study conducted by Kakwani [22] found that laminar air-flow systems are effective in reducing the reoperation rate in Austin-Moore hemiarthroplasty.

- Their study compared the reoperation rate between theatres with laminar air-flow and theatres without laminar air-flow systems. A cohort of 435 patients who had Austin-Moore hemiarthroplasties at Good Hope Hospital in Birmingham between August 2000 and July 2004 were selected for this study. Of those 435 patients, 212 had operation in laminar air-flow theatres and 223 had operation in non-laminar air-flow theatres. Data was collected by reviewing case notes and radiographs.

For all cases antibiotics were administrated and water impervious surgical gowns and drapes were used. In the non-laminar air-flow group it was found that the re-operation rate for all indications in the first year after hemiarthroplasties was 5.8 % (13/223), while in the laminar air-flow group it was 1.4 % (3/212). Analysis found that there was no statistically significant relationship between the re-operation rate and water impervious gowns and drapes (p=0.15), while the use of laminar air-flow found a statistically significant drop (p=0.0285) in the re-operation rate within the first year after hemiarthroplasties. They found that the re-operation rate in non-laminar air-flow theatres was four times greater than that in laminar airflow theatres.

- In their study Brandt [23] found that the infection rate was substantially higher in theatres with laminar air-flow system. This was a retrospective cohort study based on routine surveillance data from German national nosocomial infections surveillance system (KISS - Krankenhaus Infektions Surveillance System).

Hospitals which had performed at least 100 operations between the years 2000 and 2004 were selected for this study. The type of ventilation technology installed in the operation rooms of the selected hospitals was collected separately through questionnaires from infection control teams in the participating hospitals. Surgical departments were grouped into categories according to the type of ventilation system installed.

Departments using artificial operating room (OR) ventilation with either turbulent or laminar airflow was included in this study. A total of 63 surgical departments from 55 hospitals was included in this study. Analysis was performed on the data set created by merging the questionnaire data on OR ventilation and surveillance data from the KISS data base. The data set analysed contained 99,230 operations with 1,901 single site infections (SSIs). Age and gender of the patient was found to be a significant risk factor of SSIs in most procedures. Univariate analysis conducted found that the rate of SSIs was high in departments with laminar air flow ventilation. Multivariate analysis also confirmed this finding. The Authors note that, horizontal laminar air-flow systems enclosed by walls, or semi enclosed systems with partial walls are not recommended by German National Guidelines and have not been routinely used.

- Benefiting fully from Laminar Airflow requires proper design and adoption of more stringent requirements, similar to those used in clean room environments that are inclusive of contamination control. However, the debate over laminar airflow systems illustrates how difficult this process can be without the benefit of similar design guidelines and standards.

- Utilisation of a laminar flow diffuser does not necessarily guarantee the desired results of a laminar flow system in a critical environment. Proper laminar flow design requires that a strict set of rules be followed to optimise its effectiveness.

The authors comment that:

- The unexpected findings require further discussion and noted that the department based factors analysed, such as academic status of the hospital and bed number, have been shown to be significant factors for some operative procedures.

- This may be because operative severity is not yet exhaustively considered in the patient based risk index variables.

- Due to surveillance-induced infection control activities, lower infection rates have been described in departments with long-term participation in the surveillance system.

- A confounding factor was whether prophylaxis was administered was not documented individually for each patient in the surveillance data analysed in the study.

- Patient-based factors such as smoking and obesity are missing in the database.

- Details of perioperative management that may influence surgical site infection were not considered and may have influenced the results.

- Improper positioning of surgical personnel may also increase the risk of infection.

- The work concentrated on patient outcome and did not consider any data on OR air quality or other infection reduction schemes (occlusive clothing).

- The Brandt [23] study splits, conventional turbulent ventilated (with HEPA filtered air) and laminar airflow ventilated theatres (from HEPA filtered supply air diffusers). The article does not provide a description on the conventional turbulent ventilated or laminar air flow ventilated theatre either technical or descriptive, so we are not sure how the German laminar flow system compares with the design standards. We are aware that some laminar flow systems imported into Australia have considerably lower supply air velocities at the operating theatre table level compared to the Australian health care facility design standards for laminar flow ventilation systems.

- Sample size was 99,230 operations (of various types), the general outcome was that there was no advantage and possible a slightly higher risk.

- There was no reference to laminar ceilings.

- It is based on German facilities that only recommend vertical laminar flows, and do not include the use of body suits/exhaust.

- The was no reference to the prevailing environmental conditions in the theatres, for example supply
air temperature relative to room temperature and the potential influence of buoyancy effects, or the use or otherwise of warming blankets.

- Whether, Prophylaxis PAP was administered was not documented for each patient. The assumption is made that guidelines are generally followed and that about +98% of patients receive PAP.

- Conclusions suggested that Laminar flow did not provide a benefit of reduced infections (SSIs), but had the tendency toward a greater number of infections. SSIs however need to be investigated further to examine why. Further studies are suggested to include PAP, external risk factors such as obesity and smoking and surgical technique. Hirsch [33] commented on the Brandt Study [4] that neither an effectiveness control of the load turbulence displacement airflow system was made, primary comorbidities such as pre-existing acute or chronic disease, intake of immunosuppressive medication, abuse of nicotine and alcohol or obesity, were considered, and therefore the results are only restrictedly usable.

- Medical Research Council Trials [19] have shown the ineffectiveness of horizontal laminar flow systems and note in many cases the incidence of wound sepsis was significantly higher with horizontal flow system compared to conventional systems in adjacent theatres (also ref. Hospital for Special Surgery New York).

- Knobben [18] conducted an experimental study to evaluate how systemic changes together with behavioural changes can decreases intra-operative contamination. This study was conducted in the university Medical Centre Groningen, The Netherlands. A random sample of 207 surgical procedures which involved total knee or hip prosthesis from July 2001 to January 2004 was selected for this study. Two sequential series of behavioural and systemic changes were introduced to ascertain their role in reducing intra-operative contamination. The control group consisted of 70 cases. Behavioural changes (correct use of plenum) were introduced to the first intervention group (Group 1) of 67 operations. Intense behavioural and systemic changes were introduced to a second intervention group (Group 2) of 70 operations.

The systemic changes introduced were the installation of new laminar flow with improved airflow from 2,700m3/h to 8,100m3/h. Two samples each were taken from used instruments, unused instruments and removed bones. Control swabs were also collected to make sure that contamination had not occurred during transport and culturing. Early and late intra-operative contamination was also checked. All patients were monitored for any wound discharge while in hospital and followed-up for 18 months to check whether intra-operative contamination affects post-operative infection.

Among the control group contamination was found in 32.9% while in intervention Group 1 it was 34.3% and in intervention Group 2 it was 8.6%. Except in Group 1 (p=0.022) late phase contamination was not significantly higher than early phase contamination.

During the control period wound discharge was found in 22.9% of patients and 11.4% of them had wound infection later. Deep periprosthetic infection had been found in 7.1% of them in the follow-up period. Deep periprosthetic infection was found in 4.5% of cases of first intervention group and in 1.4% of cases in second intervention group in the follow-up period. But none of these decreases were found statistically significant. Contamination, prolonged wound discharge and superficial surgical site infections were found to have decreased after both first and second intervention.

But a statistically significant reduction was found only in second intervention (contamination p=0.001, wound discharge p=0.002 and superficialSSI p=0.004). This study concluded that behaviour modifications together with improved air flow system can reduce intra-operative contamination substantially.

• It is found that laminar airflow is more effective when used in conjunction with occlusive clothing Charnley, 1969 cited in Sandiford and Skinner [12].

- Scaltriti [20] conducted a study in Italy to examine effectiveness of well-designed ventilation systems on air quality in operation theatres. They selected the operation theatres of a newly built 300 beds community hospital which has ventilation systems designed to achieve 15 complete outdoor air changes per hour and are equipped with 0.3 µm, 99.97% HEPA filters.

Passive and active samples of microbiological air counts were collected as well as air borne particle counts. Details of the surgery, number of people in the room, door opening rate and estimated total use of the electrocautery unit were also collected.

The study concluded that there was a positive correlation between particle contamination, surgical technique (higher risk from general conventional surgery), electrocauterisation and operation length. Researchers suggest that human movement rather than human presence is the factor that determines airborne microbial contamination. It was found that average particle concentration in the theatres did not exceed the European ISO 14 644 standard limits for ISO 7 clean room, and so concluded that a well-designed ventilation system is effective in limiting particulate contamination.

- Clarke [21] conducted a quantitative study to examine the effectiveness of ultra-clean (vertical laminar flow) theatres in preventing infections by unidentified organisms.

They used the molecular technique, Polymerase Chain Reaction (PCR), to detect bacteria presence. Their study compared the wound contamination during primary total hip replacement (THR) performed in standard and ultra clean operation theatres. 20 patients were recruited for this study and underwent primary THR from 1999 to 2001. Patients with previous incidents of joint surgery or infection were excluded.
The standard operation theatres had 20 air changes per hour and CFU count was 50 CFU/m³, while ultramodern theatres had 530 air changes per hour and CFU count was 3 CFU/m³.

The contamination rate in the standard theatre at the end of the surgery was significantly greater than at the beginning. The contamination rate in the ultra-clean theatre at the end of the surgery had 530 air changes per hour and CFU count was 3 CFU/m³.

• Further reading indicated that laminar flow ventilation systems were beneficial and suggests possible factors that may have influenced the Brandt [23] study results.

• There is a lack of consistency in the classification and analysis of ultra-clean air system data used in the study of the influence on surgical site infections.

• Clean air/laminar flows had a greater impact prior to the use of antibiotics and in particular, PAP.

• The greater the air change rate, the faster the response on the number of particles in the room (laminar flow theatres typically had higher airflow rates)

• Memarzadeh [24] comments: “It appears that the main factor in the design of the ventilation system is the control of the central region of the operating room.”

• Backstein [25] comments: “In a study of 435 patients undergoing Austin Moore hemiarthroplasty, the rate of reoperation for all indications in the non-laminar air flow theatre group was four times greater than in the laminar air flow group. Similarly the use of laminar air flow has shown reduced infection rates after posterior spinal fusion.”

• Bosanquet [26] study conclusion: “This study suggests that laminar flow may reduce the incidence of SSIs, especially in the sub group of patients receiving arterial grafts.”

• Scaltriti [20] study concluded that there was a positive correlation between particle contamination, surgical technique, electrocauterisation and operation length.

• Kakwani [22] found that the reoperation rate in non-laminar air flow theatres was four times greater than that in laminar airflow theatres.

• The number of people in the theatre did have a substantial effect on infection rates; rather the activities they were doing did.

• Training of the personnel using laminar flow hoods bears the correct operational procedures reduced infection rates (Knobben [18]).

• Laminar airflow is more effective when used with occlusive clothing. (Charney 1969 and cited Sandiford and Skinner [12]).

• The wearing of exhausted body suits was more effective than laminar flow at reducing infection, [27] reduced infection.

The last two items above, may suggest that the issue is the theatre staff are introducing the infection to the patient (occlusion clothing removes it at the source, laminar flow attempts to keep it away, leaning over the patient causes entrainment of infection carrying particles and hence higher infection levels).

OPERATING THEATRE STANDARDS

Few countries have set bacterial threshold limits in conventionally-ventilated operating theatres, although most recommend 20 Air Changes per Hour (ACH).

In the UK, the limit is 3.5 cfu/m³ for an empty operating theatre and in activity it should not exceed 180 cfu/m³ for an average 5 minute period in an ultra-clean air operating theatre the limit is set at less than 10 cfu/m³ sampled within 30cm of the wound using conventional clothing. The limit is set at less than 1 cfu/m³ of air when total body exhaust gowns are used [16]. Most countries have set their own standards.

The table above summarises the study by Hirsch [33] which assessed the bacterial contamination adjacent to the surgical site for a number of ventilation systems. The results indicated a relationship between mean bacterial burden and the operating theatre ventilation system installed with the higher velocity systems producing the highest efficiency.

### Ventilation System

<table>
<thead>
<tr>
<th>Description</th>
<th>Supply air Volume</th>
<th>Diffuser face velocity (average)</th>
<th>Results Mean Bacterial Burden</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR A</td>
<td>Open able Windows</td>
<td>-</td>
<td>13.3 CFU/h</td>
</tr>
<tr>
<td>OR B</td>
<td>Canopy 3mx3m</td>
<td>3,000 m³/hr (833 l/s)</td>
<td>0.093 m/s 6.4 CFU/h</td>
</tr>
<tr>
<td>OR C</td>
<td>Canopy 3mx3m</td>
<td>3,000 m³/hr (833 l/s)</td>
<td>0.093 m/s 3.9 CFU/h</td>
</tr>
<tr>
<td>OR D</td>
<td>Canopy 2.4mx2.8m</td>
<td>3,600 m³/hr (1,000 l/s)</td>
<td>0.15 m/s 3.4 CFU/h</td>
</tr>
<tr>
<td>OR E</td>
<td>Canopy 2.4mx2.4m</td>
<td>4,500 m³/hr (1,250 l/s)</td>
<td>0.217 0.8 CFU/h</td>
</tr>
<tr>
<td>OR F</td>
<td>Laminar flow Canopy 3.2mx3.2m</td>
<td>9,000 m³/hr (2,500 l/s)</td>
<td>0.244 0.7 CFU/h</td>
</tr>
</tbody>
</table>

### HYBRID OPERATING THEATRES

A variety of factors have lead to widespread interest in the development of Hybrid Operating Theatres which
incorporates conventional operating room capability with state of the art imaging. Hybrid Theatres require planning and foresight to allow a broad spectrum of conventional surgery and state of the art imaging and allow for more complex procedures to become commonplace where the imaging is essential. The design and implementation of hybrid operating rooms is a multi-disciplinary process. The significant investment in the operating theatre suites requires productive and efficient utilisation to improve the efficiency and quality of care for complex patients.

SUMMARY

- Reviews of current research shows that there is a lack of consistency in the classification and analysis of ultra clean air system design data used in the studies of the influence on SSIs.
- Katwani [22] found that the re-operation rate in non-laminar air-flow theatres were four times greater than that in laminar airflow theatres.
- Brandt [23] found the SSI rate was high in hospitals with laminar flow although further studies have been suggested to determine why this unexpected result occurred.

The work concentrated on patient outcome and did not consider any data on OR air quality.

The author suggests further clinical trials using defined case finding methods for risk factors, medical treatment and surgical technique. Further study and data may enable a comparison with the Laminar flow ventilation system performance parameter adopted by TS11 and AHFG.

German Standards DIN 1946-4 (E.5.2) recommends a mean velocity between 0.23 and 0.25 at 1.2m above the floor level which is a lower velocity than that recommended by the DHS - Vic Design Guidelines [6.84.00] and AHFG - TS11 (6.22.30) guidelines which recommend 0.3m/s at the working height.

- The study by Knobben [18] concluded that behaviour modifications together with improved air flow system can reduce intra-operative contamination substantially.
- The study by Scaltriti [20] concluded that a well-designed ventilation system is effective in limiting particulate contamination.
- The work by Clarke [21] found that the contamination rate in the standard theatre at the end of the surgery was significantly greater than at the beginning. The contamination rate in the ultra-clean theatre at the end of the surgery was not significantly different than at the beginning.
- Current literature suggests that understanding the source of contamination in an operating theatre and knowing the relationship between bacterial virulence, patient immune status and wound environment will help in improving the infection rates [28].
- The activities in the operating theatre including non-adherence to the principle of asepsis by a surgical team has been identified as a significant risk factor of infections. Hectic movement of surgical team members in the operating room and the presence of one or more visitors were also found as major causes of SSIs [29].
- The study by Creedon [30] argues that infections can reduce up to one third if staff follow best practice principles.
- To further progress our understanding and reduction of SSIs, continued quality improvement is needed and it should be based on evidence based research and on-going assessment of information [31].

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