# 6 Years review and future outlook - The heater cooler unit for extracorporeal circulation as a source for bacterial infection in open heart surgery

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## Introduction

Heater-cooler units (HCU) are an integral component of cardiac surgery using cardiopulmonary bypass. Recently, they have been implicated in an airborne contamination scenario potentially causing prosthetic valve endocarditis (Sax et al. 2015). HCU used for managing temperature during cardiopulmonary bypass have been implicated with contamination by potentially pathogenic microorganisms that may be refractory to eradication (Sorin warning letter 06/2014).

## Methods

This review shows the 6 years of development in this area. It gives insights into the findings on the spread of the germs and shows how new cleaning protocols have had an effect and what problems users continue to face. In addition, an outlook on new device generations is given.

## Results

New cleaning protocols are effective but create more work and a hazard potential still exists for the person cleaning the HCU. The type and the size of laminar strom field determine whether airborne transmission is possible or not. We observe increasing maintenance and repair requirements and shorter overall usage times. Really new device are not on the market yet.

## Conclusion

In summary, the risk from airborne transmission in HCU appears overestimated. Nevertheless new devices without water or self cleaning mechanism would be desirable.

# Building an Effective Hygiene Management System

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## Introduction

The systematic management of hygiene is one of the key components in making health systems safer and more effective. Therefore, the aim of this study was to take a holistic approach in identifying and analysis of elements necessary to develop a Hygiene Management System. This comprises of the careful planning beginning at the stage of design of health care infrastructures, the adequate consideration and integration of health care personnel, patients and their relative in infection prevention, the development of customized standard operating procedures and appropriate training in hygiene processes.

## Methods

Our approach is based on the identification of potential challenges and barriers in the key measures of hygiene management: (1) Surveillance, (2) monitoring infrastructures, practices, processes, outcomes and providing data feedback, (3) outbreak investigation and management, (4) education and training, and (5) the communication and cooperation with key players. We are undertaking an analysis of the existing situation in a hospital of maximum care and select performance indicators for the underlaying processes.

## Results

A baseline review together with undertaking a risk assessment is a good starting point to assist with the development of a systematic hygiene management and prioritisation of how to best utilise resources. The results will determine priorities for improvement and for implementing new hygiene concepts which ideally form part of the quality management system of the medical organisation.

## Conclusion

As the scope of this analysis is limited it is clear that there is a necessity for a comprehensive Hygiene Management System that is constantly developing and open to innovative concepts considering the balance between cost, clinical outcomes, patient satisfaction, and economic impact.

# Proof of Concept for Ozone-Based Disinfection of Heater Cooler Units

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## Introduction

Heater Cooler Units (HCUs) are frequently used not only during heart surgery but also in ECMO therapy to regulate the blood temperature of patients. It is known from cardiac surgery that the water circuits of HCUs can be bacterially contaminated and under adverse conditions can lead to a nosocomial infection of the patient.
The addition of chemical disinfectants to the water of HCUs is problematic. In addition, it is an increasingly signigicant cost factor due to the required material and personnel input.

## Methods

The aim of this research project is both the development of an automated device for disinfecting water in HCUs and proof of its effectiveness. The device is based on ozone, a substance with known antimicrobial properties. To prevent ozone from coming into contact with the HCU components, the water is irradiated with UV light (254nm). Two bypasses and ozone sensors guarantee a complete elimination of residual ozone. The effectiveness of the device was tested by series of experiments with the surrogate germ, *Pseudomonas aeruginosa*.

## Results

The device allows a wide range of ozone concentrations and exposure times to be selected. In previous test series, it has been shown both that a reduction of the bacterial count to drinking water quality can be achieved with a treatment time of only one hour, and that self-cleaning can be carried out effectively before clinical use, and in standby mode.

## Conclusion

Attention must be paid to the water quality in HCUs as a potential source of infection, regardless of where they are used. The "proof of concept" showed an excellent disinfection effect with simultaneous elimination of excess ozone to drinking water levels. The number of indicator bacteria in the water tank of the dummy HCU was reduced by approx. 98% after only 30 minutes.

# VDI status report for the performance description of antimicrobial surface materials and active ingredients: Test procedures and regulatory framework

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## Introduction

In order to reduce the risk of spreading pathogenic agents over contact surfaces, among others antimicrobial technologies and materials are being used. Areas of application are e.g. surfaces of medical devices as well as commodities in medical facilities. Regulatory requirements may require a product- or application-specific proof of effectiveness including the evaluation of infection preventive efficacy.

## Methods

The current status of microbiological, biotechnological and material-based processes for the management of hygienically relevant surfaces was put together from literature and research practice. Technologies and test methods for infection prevention measures have been assessed regarding practical relevance and infection preventive performance.

## Results

Normative requirements for assessing the effectiveness of antimicrobial surfaces are not sufficient from a clinical infectiological point of view with regards to assessment of infection chains and risk-benefit analysis. Current test set-up does not account sufficiently for practical applications (dirty surfaces, drying out, mixed populations, environmental organisms, longevity (VBNC). Based on new test approaches first recommendations for manufacturers and operators were developed in order to allow selection of suitable practice-relevant test methods. However, test approaches require a scientific assessment to determine limitations and areas of application of technologies and test methods, materials and active ingredients, practical test procedures and regulatory framework conditions were therefore compared in the report in a matrix and recommendations for action were derived.

## Conclusion

The VDI technical committee "Management of hygienically relevant surfaces in medical facilities" has comprehensively put together the available information in a status report for the first time. The report provides a line of argumentation for internal decisions regarding hygienically-optimized equipment and contributes to the socio-political discussion in order to initiate funding and launch further, urgently needed research projects.

# Integration of antimicrobial substances in 3-D printed plastics

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## Introduction

The risk of healthcare associated infections (HAI) is rising with the utilization of more complex medical devices. Cleaning and disinfecting measures of such devices are often insufficient leading to an increased microbiological contamination on these devices. Recent studies imply that antimicrobial coatings could present a solution for this topic. Unfortunately there are few publications that deal with the durability and stability of such coatings. In this work a novel approach for the introduction of an antimicrobial technology into plastic granulate was tested. After 3-D printing the antimicrobial activity of the test samples was analysed.

## Methods

In previous studies we could already demonstrate a strong antimicrobial activity of the TiTANO coating (HECOSOL GmBH, Bamberg). Different approaches (mixing, heating, compounding) were performed to combine an ABS plastic granulate with the antimicrobial substance. After each step standardized test samples were 3-D printed by using the freeformer 3-D printer system (ARBURG GmBH, Loßburg). The samples were then tested for their antimicrobial activity with a standardized test procedure (JIS Z 2801/ISO 22196).

## Results

Our results show that the integration of an antimicrobial substance to ABS plastic is feasible only with sophisticated plastic processing technologies. Simple heating or mixing of the substance did not allow integration of the antimicrobial substance into the 3-D printed sample, but it was possible to integrate the antimicrobial ingredient into the raw material by compounding. The printed test samples showed strong antimicrobial activity in the standardized test procedures.

## Conclusion

Contaminated Medical devices can contribute to an increased risk of HAI. Recent studies already proved that antimicrobial coatings can reduce bacterial contamination of these surfaces reducing infection risks. We could demonstrate that introduction of antimicrobially active substances into 3-D printing material is feasible and enables production of antimicrobially active plastic components for nearly every purpose and application. Further studies are needed to assess the clinical impact of such devices for the risk reduction and prevention of HAI.

# Durability and stability of antimicrobial coated surfaces

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## Introduction

Antimicrobial surface coating of i.e. medical devices could contribute to infection prevention and reduction of hospital acquired infections (HAI). Recent studies showed a significant reduction in the microbial contamination of antimicrobial coated surfaces in clinical setups. Nevertheless, there are only few publications available that deal with the durability and stability of these coatings under routine clinical conditions. In this work different antimicrobial coating compositions were tested on different surfaces for their durability and remaining antimicrobial activity.

## Methods

In previous studies we could already show strong antimicrobial activity of the TiTANO coating (HECOSOL GmBH, Bamberg). Different compositions of this antimicrobial technology were formulated and applied on underlying test samples (glass, plastic, metal) by electrospray technique. Furthermore, the antimicrobial substance was introduced into 3-D printed ABS plastic samples. Subsequently durability of the antimicrobial activity was assessed after abrasion tests with the test samples using a standardized test protocol and device (Elcometer 1720, Elcometer Instruments GmBH, Aalen, JIS Z 2801/ISO 22196).

## Results

Our results show that the durability and stability of a subsequent applied antimicrobial coating is strongly dependent on the chemical formulation of the coating and also the underlying surface condition. Whereas we could still detect remaining antimicrobial coating and activity on some samples after repeated abrasion testing, some other samples lost their coating and activity after only a few abrasion cycles. Interestingly the integrated antimicrobial substance in the 3-D printed samples showed strong antimicrobial activity even after rough treatment of the surfaces (brushing, scratching).

## Conclusion

Antimicrobial coating of surfaces in medical facilities and of medical devices could be an additional option for infection prevention. Our findings suggest that special attention should be payed to the formulation of the coating, the surface material and the application procedure. Whereas some applications show more durable properties others are not resistant to standard cleaning and disinfecting measures and thus not effective and robust in the clinical routine.

# Clinical validation and efficacy of a temperature-controlled ventilation system (TcAF) in the OR to reduce surgical site infections

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## Introduction

Microbiological burden of room-air in operating theatres is a known risk factor for surgical site infections. However, it is unclear how to best evaluate efficacy and efficiency under routine clinical conditions. Moreover, there still is a lack of data to assess the impact on infection rates. The aim of this study was to evaluate a temperature-controlled ventilation system (TcAF) under routine clinical conditions and assess its impact on infection rates.

## Methods

10 clinical installations of the TcAF system Opragon (Avidcare AB, Sweden) were assessed during live surgeries according to the Swedish SIS TS 39: 2015 standard. Furthermore, a retrospective analysis of 1,000 consecutive cases of primary total joint arthroplasty (hip, knee) before and 1000 after installation of the TcAF system was performed. Endpoints for clinical outcome were length of stay and infection rates.

## Results

Clinical installations showed measurement of median 0 cfu/m³ over all measuring points in the room, mean value 1.8 cfu/m³, standard deviation 4.5 cfu/m³. Intraoperative airborne contamination in the retrospective analysis was always within the limits of to the Swedish SIS standard for ultraclean air in operating theatres. The use of the TcAF system was associated with a decrease in mean postoperative hospital stay from 11.0 to 8.64 days, a decrease in percentage of hospital length of stay over 14 days after surgery from 7.3 to 2.2 %, and a decrease of surgical site infections from 3.3 to 1.1 %.

## Conclusion

Our results show that requirements of the Swedish standard were met or significantly exceeded by the TcAF system reliably and robustly ensuring "ultra-clean" air in the entire operating theatre and demonstrating the capability to reduce the risk of airborne microbial transmission under routine clinical conditions. The study shows positive impact on key clinical outcome parameters in line with previous research by Charnley and Lidwell.

# Relevance and implications of positioning analysis for infection-preventive effectiveness of ventilation systems with low-turbulence displacement flow

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## Introduction

Ventilation technology in German operating rooms is regulated by DIN 1946-4. Since the release of the latest version in 2018, a positioning analysis (worst-case scenario with the largest space requirement) for determining the required protected area in class 1a operating rooms is mandatory. The aim of this investigation was to use typical workflow scenarios to assess existing installations regarding the match of the required and the built size of the protected area.

## Methods

Positioning analyses were carried out together with the on-site staff for various clinical procedures in 2 hospitals to assess the built versus required protected areas. For this purpose, the built protected area was marked and then the room was prepared according to the usual clinical procedures on site for comparison. Any differences between the existing and actually required protected area were recorded and measured, as well as the effects on room size and ventilation system.

## Results

In all cases, the positioning analysis revealed that required protected areas need to be significantly larger than provided by the existing setup. Typically, an average of approximately 4.00 m x 4.00 m is required to ensure appropriate protected areas for most interventions.

## Conclusion

The size of the protected area that is actually required can only be determined by individual positioning analysis. Most existing installations of low turbulence displacement flow systems (TAV) are likely to be too small. The larger protected areas actually require significantly larger rooms in order to maintain proper thermodynamics. Furthermore, significantly higher volumetric flow rates are required (approx. 15,800 $m^3$ / h, equalling approx. 60% more volumetric flow). Finally, the current mismatch between actual and necessary protected area would be a possible explanation for the controversial data situation regarding the infection preventive effects of TAV systems.

# Constructional requirements of medical devices for hygienic design

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## Introduction

The procedure for reprocessing medical devices that are used sterile or low in germs is specified. This does not yet apply to non-sterile medical devices. These medical devices, some of which are insufficiently reprocessed, pose a risk of infection for medical staff and patients. This risk of infection via contaminated surfaces has already been shown by several publications. To minimize the risk of pathogen transmission from insufficiently reprocessed medical devices, the hygienic design of medical devices can be determined and optimized by different test procedures.

## Methods

The GlowCheck test uses ultraviolet light (UV light) to optically determine how effective the cleaning and disinfection measures are for the examined medical device. Medical devices are contaminated with a UV dye and cleaned according to a standard protocol. Under UV light, the effectiveness of cleaning and disinfection measures can be determined by the residual fluorescence on the surfaces.
In a second step, the effectiveness of reprocessing measures is examined microbiologically. For this purpose, defined surfaces of the medical device are contaminated with a bacterial suspensions (Staphylococcus aureus, Escherichia coli) of defined concentrations. After drying, contact and swab samples are taken before and after the cleaning measures. The germ growth can be documented and quantitatively evaluated to get an impression of the possible germ reduction.

## Conclusion

Especially due to the large number of medical devices, together with insufficient or not feasible processing instructions, microbial contamination can often not be reduced sufficiently. Therefore, a greater focus on hygienic design should be placed right from the start of the development of medical devices. While the food industry already has explicit specifications for hygienic design of equipment in DIN EN 1672-2, there are no precise specifications in the medical sector. By examining the hygienic design of such medical devices, strategies can be developed to identify and avoid possible hygienically problematic areas already during the development and design of these products.

# Konstruktive Anforderungen von Medizinprodukten für hygienisches Design

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## Einleitung

Für steril bzw. keimarm zur Anwendung kommende Medizinprodukte ist das Vorgehen für die Aufbereitung festgelegt. Dies gilt bisher noch nicht für nicht-steril zur Anwendung kommende Medizingeräte. Von diesen teils unzureichend aufbereiteten Medizinprodukten geht eine Infektionsgefahr für medizinisches Personal und Patienten aus. Diese Gefahr durch eine Infektion über kontaminierte Oberflächen wurde bereits durch verschiedene Publikationen gezeigt. Um das Risiko einer Erregerübertragung von unzureichend aufbereiteten Medizinprodukten zu minimieren, kann das hygienische Design von Medizinprodukten mittels Testverfahren bestimmt und optimiert werden.

## Methodik

Mit dem GlowCheck Test wird durch ultraviolettes Licht (UV-Licht) optisch überprüft, wie wirksam die Reinigungs- und Desinfektionsmaßnahmen bei der Aufbereitung eines zu testenden Medizinprodukts sind. Medizintechnische Produkte werden hierbei mit einem UV-Farbstoff angeschmutzt und nach Protokoll gereinigt. Unter UV-Licht zeigt sich die Effektivität von Reinigungs- und Desinfektionsmaßnahmen anhand der Restfluoreszenz auf den Oberflächen.
In einem zweiten Schritt wird die Effektivität einer Aufbereitung mikrobiologisch untersucht. Dafür werden festgelegte Oberflächen des Medizinprodukts mit einer Bakteriensuspension (Staphylococcus aureus, Escherichia coli) mit definierter Keimzahl kontaminiert. Nach Antrocknung werden Abklatsch- und Abstrichproben vor und nach den Reinigungsmaßnahmen abgenommen. Das Keimwachstum kann dokumentiert und quantitativ ausgewertet werden, um einen Eindruck über die mögliche Keimreduktion zu erhalten.

## Zusammenfassung

Vor allem durch die große Zahl der medizintechnischen Geräte, zusammen mit unzureichenden oder nicht umsetzbaren Aufbereitungsanweisungen, können mikrobielle Kontaminationen oftmals nicht ausreichend reduziert werden. Hier sollte schon zu Beginn der Entwicklung medizintechnischer Geräte ein größerer Focus auf hygienegerechtes Design gelegt werden. Während es in der Lebensmittelindustrie mit der DIN EN 1672-2 bereits explizite Vorgaben für ein hygienegerechtes Design von Geräten gibt, fehlen genaue Festlegungen im medizinischen Sektor. Durch die Überprüfung des hygienischen Designs solcher Medizinprodukte können Strategien entwickelt werden, um bereits bei Entwicklung und Konstruktion mögliche hygienische Problemstellen zu erkennen und zu umgehen.