FINEMAN
MEDICAL

The effectiveness of design relating to hygiene control?

A quantified analysis of bedside mounting solutions.

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CIMmed

Content

Background information on healthcare-acquired infections

Healthcare-acquired infections (HAIs) are a major problem in the healthcare sector as they contribute to increased morbidity and mortality in hospitalised patients. Every year HAIs affect millions of patients worldwide (1; 2). In the European Union (EU) alone the number of HAIs is 4,544,100 per year, leading directly to approximately 37,000 deaths and 16 million extra days of hospital stays (3). In the United States the number of HAI cases is approximately 1,700,000 per year and 99,000 HAI-associated deaths. About 30 % of all patients in intensive care units (ICU) are affected by HAIs.

Infection control and adequate hygienic routines are vital in the clinical environment in order to prevent HAIs in critical care areas. The often unanswered question is "What was the transmission pathway that led to the HAI?".

The most common sources of microbial contaminations are patients' permanent or transient flora, pathogens from the environment, antibiotic multi-resistant microorganisms which have very well adapted to the hospital environment, transmission between patients or healthcare staff (4) and contaminated surfaces. Clinicians' hands touch contaminated surfaces of medical equipment, devices and monitors during patient care. Hygiene regimes and cleaning processes are often not consistent during a clinical day. As a result microbial contamination of those surfaces causes microbial colonisation and transmit pathogens (5; 6).
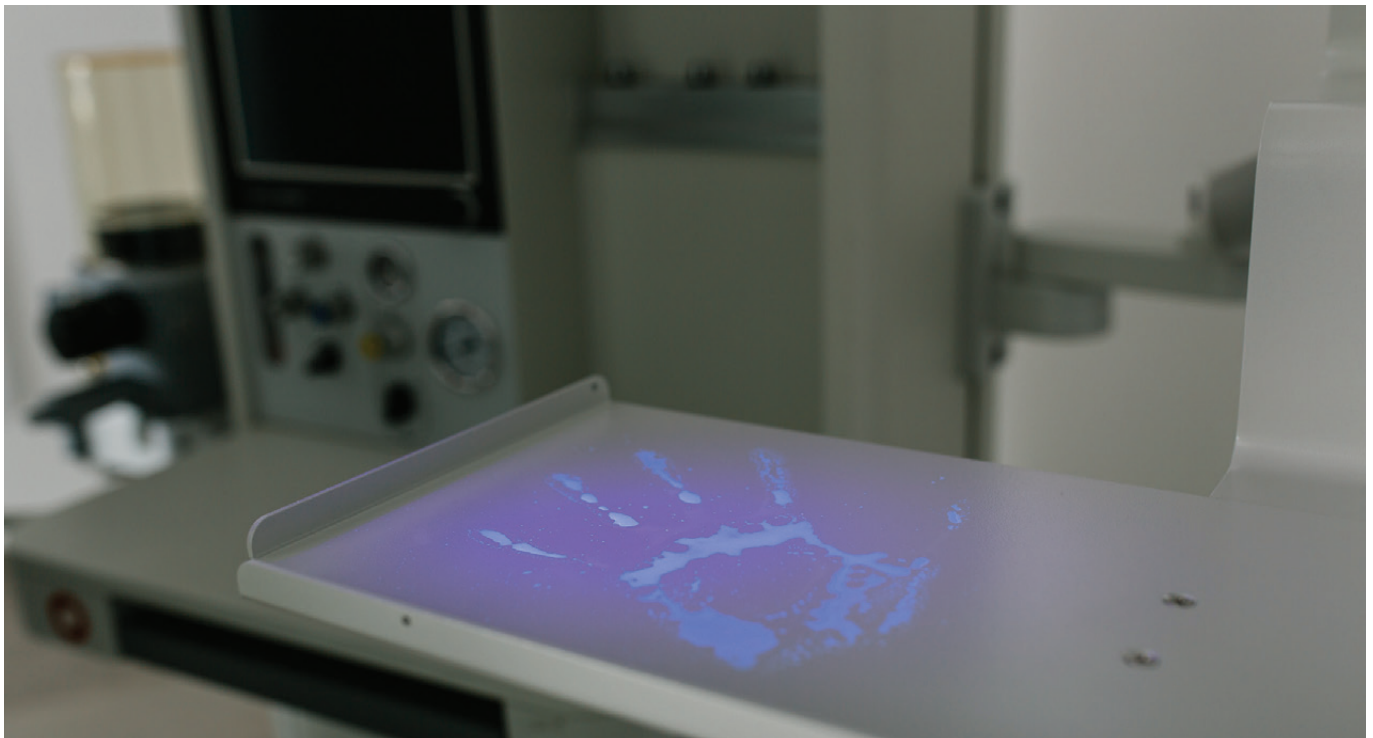
General information on supportive device equipment

Supportive device equipment such as mounting systems is often not considered as "medical product" although used in critical care areas. Mounting systems in operating theatres, intensive care units, recovery and emergency departments hold medical monitors, devices, keyboards or other electrotechnical equipment. Optimal ergonomic positioning of devices in the patient vicinity requires mounting arms to have 3-dimensional adjustment. This manoeuvrability requires many articulating parts. This coupled with the many cables transmitting power and data to and from the device being held creates a plethora of opportunities for microbial havens. As mounting systems are touched numerous times every day this is a transmission pathway to be investigated.

Clinical hygiene standards relating to equipment such as implants, instruments and medical devices directly linked to patients (e.g. vital sign monitors) are rigorously applied. However, peripheral and supporting device equipment in critical areas often escape such scrutiny, yet they are installed at the same time as the devices they hold and remain there for many years. The recommended features including smooth, one-wipe easy-to-clean surfaces, resistance to all common detergents and disinfectants as well as even and closed structures without gaps often remain unconsidered when selecting mounting equipment for critical care areas.

Purpose of the investigation

The investigation was carried out to evaluate the effectiveness of wipe disinfection of mounting systems after controlled contamination. We sought to identify "hot spots" which are difficult to clean by routine wipe disinfection. Such areas increase the risk of pathogen transmission and consequently elevate the risk of secondary infection. A major aspect of the investigation was to evaluate the benefit of integrated cable management compared to external cable management, as these are features available in the market.

Test subjects

Seven mounting arms of six manufacturers have been tested. All seven arms were like-for-like products with the same and/ or similar functions, purposes and intended use. The arms were produced by the following renowned manufacturers (in alphabetical order):

- Amico
- CIM med
- Ergotron
- GCX (2 Tragarme)
- ITD
- Strong Arm (unter der Marke Cleanmount)

Test Procedure

Two test series have been carried out:

a) Microbial control after wipe disinfection:
An artificial microbial contamination was applied prior to wipe disinfection. The microbial burden on complex geometries was investigated by swab sampling.

b) Black light investigation:
Identification of potential microbial design related "hot spots" under black light, after wipe disinfection.Test set-up for microbial control after wipe disinfection in an aerosol chamber.

The contamination was carried out with a mixture of 3 different, clinically relevant pathogens. The contamination mixture contained a gram-positive bacteria strain Staphylococcus aureus, a gram-negative bacteria strain Escherichia coli and a yeast strain Candida albicans. The number of each species was adjusted to achieve a microbial contamination of 10 CFU (colony forming units)/cm^2 in an aerosol chamber after nebulisation of the microbial solution for 5 minutes. After contamination the mounting arms were disinfected with a wipe disinfection cloth containing 70% ethanol. Subsequent smear tests were performed over a period of 8 hrs. after contamination using sterile cotton swabs which were streaked out on plate count-agar (PCA) plates to quantify surface associated microorganisms.

Test procedure cont.

Test set-up for microbial black light investigation.
The black light solution was applied to the mounting arm by aerosol nebulisation. After drying the black light colour for one hour to prevent liquid colour dispersion during handling systemic wipe disinfection was performed on the arm's surface. Traces of remaining black light colour were identified under UV light.

Results:
Swab samples is usually associated with test-immanent and biological variations. Therefore the average CFU values from all 6 tested time points for each mounting arm has been verified. The data were normalised to 100% for the mounting arm with the lowest microbiological contamination. Figure 1 and table 1 show the mounting arm from CIM med with the lowest microbial contamination compared to all 7 tested mounting arms.
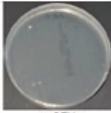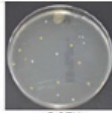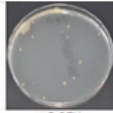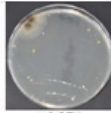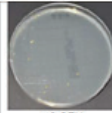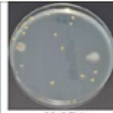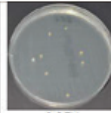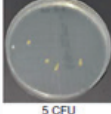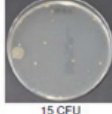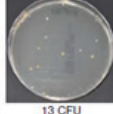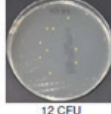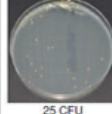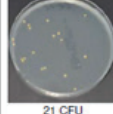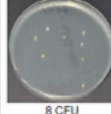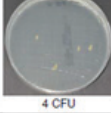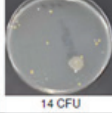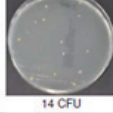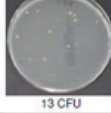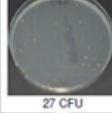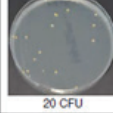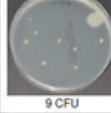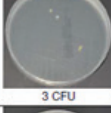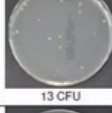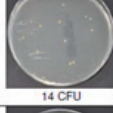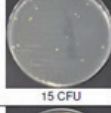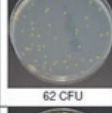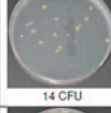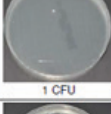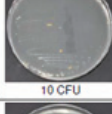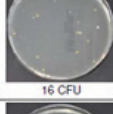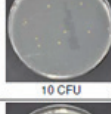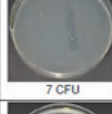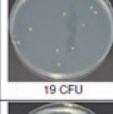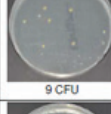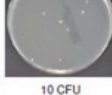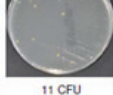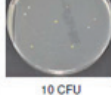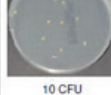
Time	CIM med	Comp. 1	Comp. 2	Comp. 3	Comp. 4	Comp. 5	Comp. 6
0	1 CFU	15 CFU	15 CFU	10 CFU	10 CFU	22 CFU	8 CFU
0.5	5 CFU	15 CFU	13 CFU	12 CFU	25 CFU	21 CFU	8 CFU
1	4 CFU	14 CFU	14 CFU	13 CFU	27 CFU	20 CFU	9 CFU
2	3 CFU	13 CFU	14 CFU	15 CFU	62 CFU	20 CFU	14 CFU
4	1 CFU	10 CFU	16 CFU	10 CFU	7 CFU	19 CFU	9 CFU
8	0 CFU	10 CFU	11 CFU	10 CFU	33 CFU	17 CFU	10 CFU

Figure 1: Summary of microbial contamination recovered by swab sampling from complex design structures (hinges, cable duct inlets and outlets, gaps and any other uneven surfaces).

Test procedure cont.

Sample	Average CFU/sample KBE/Probe	Normalization to HV Arm with lowest CFU	Difference factor
CIM med Arm	2.3	100%	1.0
Competitor 1	12.8	550%	5.5
Competitor 2	13.8	592.9%	5.9
Competitor 3	11.7	500%	5.0
Competitor 4	27.3	1171.4%	11.7
Competitor 5	19.8	850.0%	8.5
Competitor 6	9.7	414.3%	4.1

Table 1:   Summary of the microbial contamination of swab sampling. The date were normalised to the mounting arm with the lowest contamination to allow direct comparison of the biological results
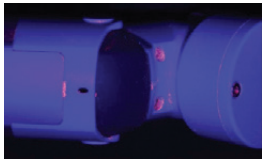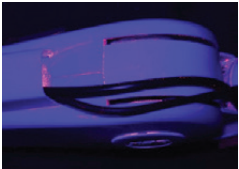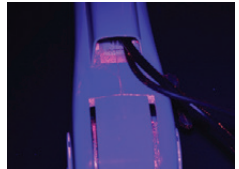
Test procedure cont.
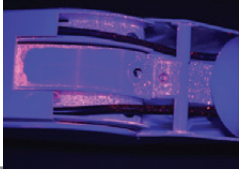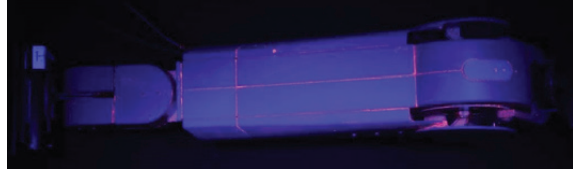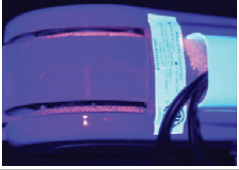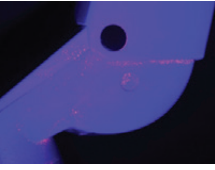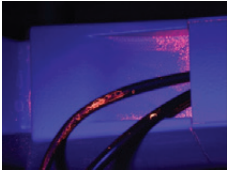
Sample	Mounting arm under UV Picture 1	Mounting arm under UV Picture 2
CIM med Arm		
Competitor 1		
Competitor 2		
Competitor 3		
Competitor 4		
Competitor 5		
Competitor 6		

Figure 2:   Summary of black light testing after wipe disinfection to identify critical design-related „hot spots" which are difficult to disinfect by wipe disinfection

Test procedure cont.

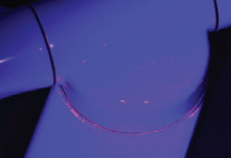The black light colour investigation reveals that the construction of mounting arms is crucial for efficient superficial disinfection and cleaning of the mounting arm. All structured surfaces or complex 3-dimensional components, such as hinges, external cable ducts, inlets and outlets of cable ducts are difficult to disinfect by wipe disinfection if possible at all and pose the highest risk of bacterial contamination.

Comparing all 7 tested mounting arms product 1 - HV arm CIM med - shows the lowest degree of black light traces.

Conclusion

This comparative investigation shows that the construction of mounting arms is a critical factor when it comes to microbial control in hygiene-sensitive environments. The experimental data clearly show that especially the internal cable duct has a major impact on the cleaning efficiency of mounting arms. Therefore an elaborated constructional design is a crucial and essential aspect to avoid and/ or reduce microbial contamination in a clinical environment, especially in highly sensitive areas and to lower the risk of microbial transmission during handling.

The mounting arm from CIM med was proven to be the best amongst all tested mounting arms and is the recommended product as far as hygiene control and infection prevention is concerned.

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