Validation of the OspreyDeepclean Steam Cleaning Technology in the Healthcare Environment

TNO Food and Nutrition

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CONFIDENTIAL

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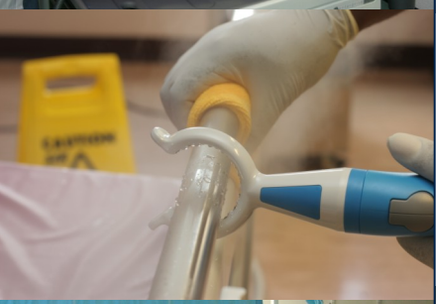
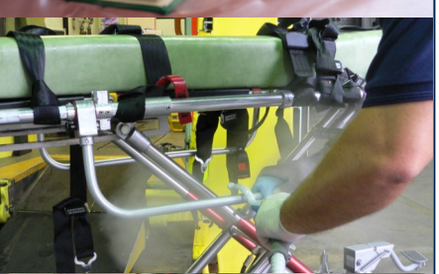





The physical act of 'cleaning' removes soil including contamination by micro-organisms. The efficiency with which soil and microbes are removed from common healthcare environment surfaces has been studied utilising microbiological measures to investigate the efficacy of novel technology based on the application of controlled superheated Dry Steam Vapour.

OspreyDeepclean has developed Dry Steam Vapour (DSV) cleaning technology for the cleaning and disinfection of medical devices like patient beds, mattresses, privacy curtains, seats and other common hand contact surfaces (plastic laminate, stainless steel, vinyl, wood) typically found in healthcare environments. The technology is based on the application of controlled superheated dry steam vapour by purpose-designed steam vapour delivery tools.

The 12 month study assessed disinfection efficacy of eleven challenge micro-organisms associated with Healthcare Associated Infections (HCAIs) including MRSA,VRE, *Clostridium difficile* and *Acinetobacter calcoaceticus-baumannii* (ACCB).

The decontamination challenge tests were performed on a number of representative 'risk' surfaces associated with cross-contamination potential in the patient environment (*plastics, stainless steel, vinyl, ceramic tile, paint finishes, curtain textiles*).

The study investigated the context of how the tools would be practically used within the healthcare environment in typical cleaning tasks. This included critical assessment of patient safety and comfort. As well as a comprehensive evaluation of operator safety, ergonomics, productivity and cleaning results. Standards of cleanliness were assessed and validated by microbiological measures.

The evaluation of cleaning performance for each type of surface and material has established the basis for validation of a standard operating procedure (SOP) for manual steam vapour cleaning of each component of the patient environment and furnishings.

The SOP is incorporated within the operator training manual and specifies tool selection, technique and timing for each cleaning procedure.
Through competency based training, consistent standards of cleaning, decontamination and productivity has been demonstrated.

The study was undertaken in two parts in two locations.

- TNO Zeist Netherlands: Controlled Clean room laboratory conditions to evaluate the potential for formation and intensity of aerosol of the prototype design tool set.
- UCLH London, UK: Decommissioned ward environment populated as a four bed bay with typical furnishings and equipment. Surfaces were purposely contaminated, allowed to dry, and then cleaned, using the prototype steam tools, by trained domestic cleaning staff (blinded to contamination sites). Microbiological measures were taken for both aerosolisation and surface decontamination.

TNO, Netherlands Organisation for Applied Scientific Research was consulted by OspreyDeepclean (ODC) to provide its expertise in the design and specification of robust test methods and validation standards to demonstrate the safety, suitability and efficacy of the steam cleaning system and tools in a hospital environment.

Besides TNO, ODC chartered the expertise of the Department of Microbiology at the University College of London Hospitals (UCLH), Environmental research unit, represented by Project Manager Michael Rollins and Neghat Lakadawalla who conducted the testing at UCLH. Consultant Microbiologist Kees Ballemans from Unic Medical Services, Nieuwegein, Netherlands, provided guidance on European standards for Infection prevention & control.

In close cooperation between TNO, UCLH and OspreyDeepclean design engineers, the study was designed to investigate and validate the safety, suitability and efficacy of the system in the daily and periodic cleaning practice within a hospital environment.

The study focussed on the efficacy and removal of bio-film and microbiological decontamination of the 'risk' contact surfaces for patients and clinical staff in a hospital environment like beds, patient's furniture, wheelchairs, commodes, bedside clinical equipment, privacy curtains and so on.

The two study workstreams;

In work program 'A' the formation and intensity of aerosols (aerosolisation) produced by the application tools were studied under controlled laboratorial conditions by TNO in their clean room facilities. The initial results from this testing aided the design development and refinement of the steam delivery prototype tools.

Also, as a sub-part of this work package the temperature and conditions of the steam leaving the system at the exit of the application tools were checked and validated on theoretical grounds using extended steam tables.

The second work program (work program 'B') undertaken by UCLH, focussed on dispersion and aerosolisation measurement and surface decontamination challenge tests with several hospital pathogenic micro-organisms strains, using the new design tool prototypes. These tests were conducted in a simulated hospital 4 -bed bay patient environment setup within a decommissioned hospital ward.

The initial results from the TNO studies showed that the potential for aerosolisation of test micro-organisms is considerable. The design of the tool and delivery of steam to the target surface, including operator technique was identified to be critical with a tolerance for error.

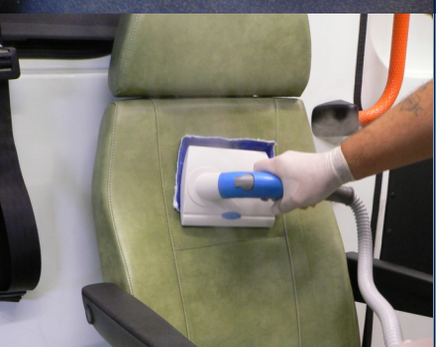
Within the scope of the study we evaluated the practical application of the steam cleaning method and its application through the various tools and specified tasks. (Standard Operating Procedures – SOPs).

In addition to conducting measures of microbiological performance, the issues of patient safety, user safety and ergonomics of use were all critical factors specifically considered in the tool design, test protocol and challenge method.

It was recognised from the outset that should any individual discipline fail, then the likely conclusion would be that steam cleaning, as a cleaning / disinfection method, would not be acceptable for use in general healthcare settings, particularly in close proximity to patients.

The specified cleaning procedure for each surface test within the study was undertaken by a member of University College London Hospitals domestic cleaning staff. Wherever possible, the operator was blinded to the study and instructed to disregard visual markers on the test materials and to clean the total surface using the trained technique and standard time allocated for cleaning each respective piece of equipment. Aerosol testing was based on a timed duration of cleaning activity.




In the decontamination challenge test the technique employed in cleaning each surface was designed to be representative of typical cleaning activity. Each challenge surface was cleaned using a typical side to side or 'figure-of-eight' wiping motion.

The experiments were designed to observe measure and validate the effectiveness of the application of purpose-designed dry steam vapour cleaning tools, under a specified operating procedure, in the removal of micro-organisms from a number of different surfaces commonly found in the patient's hospital environment.

The study considered not only the design of the tool, but also the method by which it is employed (Steam volume, temperature settings, cleaning technique, coverage, surface type and characteristics, suitability for practical purpose - *productivity*). The test protocols were designed to provide validation of each tool design based on both practical and microbiological evidence.

The definition of cleaning / disinfection performance, within the context of this study, is stated as the successful removal of measured contaminant from the target surfaces using a combination of steam vapour and mechanical cleaning methods.

Cleaning and decontamination is achieved through vapour penetration, soil release and physical removal by vacuum extraction and or microfibre adsorption. In some instances thermal disinfection and elimination of susceptible micro-organisms was achieved.

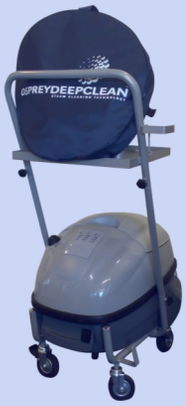
It should be noted that all methods of disinfection require a period of contact time for the disinfectant to act and kill the micro-organism. Alternately, effective decontamination can be the successful removal of foreign matter from the surface without necessarily killing microbes.

Steam vapour does not always kill micro-organisms in normal cleaning use, particularly robust spores such as *Clostridium difficile.* However, the performance characteristics of steam result in vapour penetration of surface soiling and dried-on residues, detergency and mechanical action. The resulting effect is a rapid break down of the soil into a water soluble solution which can then be effectively removed by adsorption or vacuum extraction.

Surfaces tested

The following ten materials' surfaces were involved in the testing:

1. Treatment Trolley	Stainless steel
2. Bed Head board	Plastic laminated surface (smooth)
3. Ceramic Tile	Gloss finish
4. Work top	Plastic laminate
5. Mattress	Nylon twill with polyurethane finish
6. Chair seat Cushion	Textured Vinyl seat cover
7. Flooring	Linoleum type floor covering (smooth)
8. Curtain	Polypropylene (disposable)
9. Curtain	Polycotton
10. Steel tubing	Chromium coated steel (dripstand pole, cot side rails)



Steam tools tested

Five tools were involved in the testing:

1. Squeegee Tool with vacuum
2. Flat surface & mattress tool (MultiTool) with microfibre
3. Floor steam mop with microfibre
4. Tube tool (specified technique with microfibre)
5. Curtain Tool with microfibre.

Test organisms

The following eleven organisms were used during testing. The selection criteria were based on micro-organisms of greatest concern to clinicians, being associated with Healthcare associated infection. Current clinical isolates of these were sourced from UCLH, Dept of Microbiology London. Other included test organisms are specified within Standard test methods for validation of chemical disinfection, were sourced from the National Collection of Type Cultures, PHLS Central Public Health Laboratory (NCTC), Colindale, UK.

Methicillin resistant *Staphylococcus aureus* (MRSA), UCLH clinical isolate

Acinetobacter calcoaceticus-baumannii (ACCB), UCLH clinical isolate

Staphylococcus aureus, NCTC 10788

Pseudomonas aeruginosa, NCTC 13359

Bacillus subtilis, NCTC 10400

Candida albicans, NCTC 90628

Aspergillus niger, UCLH clinical isolate

Vancomycin resistant Enterococcus (VRE), UCLH clinical isolate

Enterococcus faecalis, ATCC 29212

Clostridium difficile spores (010 strain) UCLH clinical isolate

Enterococcus hirae, NCTC 12368.

Test equipment

Prototype ProVap 7 Vac

2,600 watts max 7 bar g

Boiler pressure temperature nominal 175°C

Temperature measured at tool connector outlet 131°C

Three steam volume settings, three vacuum settings

Steam & Vac Professional – Digital

3200 watts max 5.5 bar g.

Boiler pressure temperature nominal 162°C

Temperature measured at tool connector outlet 133°C

Three steam volume settings, three vacuum settings

Temperatures of steam at point of exit of each steam cleaning tool used in this study were measured using a thermocouple probe and a digital thermometer.

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Testing methods

Surface decontamination Challenge

Preparations of the micro-organisms were made to replicate typical biological spills (bacterial load and difficulty with removal of dried-on soil). The inoculum was spread onto the test sites and allowed to dry. Testing was performed, using contact plates to detect viable organisms on the test surface before and after steam cleaning. The experiments were replicated six times for each tool, on each surface for each of the test micro-organisms. The purpose for replicating each test six times was to evaluate the consistency of results. Hard Surfaces tested resulted in consistent PASS results.

Test surfaces were contaminated, allowed to dry and the cleaned using the Standard Operating Procedure. Each surface test was repeated six times. The average recovery of viable microbes, over six repeat experiments, from all surfaces following DSV cleaning, is tabulated below. All results are less than 10 colony forming units (cfus) per contact plate sample which represents a 6 fold reduction or 99.9999% removal rate.

Surface Decontamination Challenge

	Stainless Steel Brushed	Plastic Laminate Head	Ceramic Tile (Gloss)	Plastic Laminate Trolley	Nylon Mattress	Vinyl Cushion (Textured)
S. Aureus	1.17	0.78	0.39	1.94	0.44	0.28
E. hirea	2.44	1.67	1.17	5.28	1.11	3.72
VRE	0.83	0.28	0.61	2.17	0.94	0.56
MRSA	0.33	0.17	0.28	0.72	0.33	0.22
ACCB	0.44	0.72	0.94	7.33	7.28	0.22
B. Subtilis	0.06	0	0.56	0	0	0
C. Albicans	0.83	0.78	0.06	0.67	0.28	0.44
P. Aeruqinosa	2.88	0.44	1.11	0.33	0.56	2.0
A. niger	0.33	0	0	0.28	0	0

Average post clean counts CFUs (Inoculum concentration approx 10^8 cfu/ml)

Flexible surfaces present an additional challenge to maintain consistent cleaning action with a rigid tool over a flexible surface. With the addition of microfibre to the tool contact surface, the microfibre conforms to the surface and provides consistent cleaning and adsorption action.

Results

- The final test results are equal to or better than standard chemical disinfection practices, using detergent and chlorine based compounds
- The Dry Steam Vapour method of surface cleaning and decontamination demonstrates pass results without the risk to health or environmental damage or impact on microbiological sensitivity or resistance associated with inappropriate antimicrobial / disinfectant use
- The use of Dry Steam Vapour in cleaning technology is environmentally friendly
- It is concluded that – with correct tool selection and application of the Standard Operating Procedure, DSV cleaning using the OspreyDeepclean healthcare tools stated – no aerosol hazard is expected within a hospital environment
- With competency based operator training DSV delivers effective deep cleaning and soil removal without the use of ecologically damaging biocides
- It is recommended that original equipment manufacturers review the OspreyDeepclean SOPs for cleaning and decontamination and publish specific validated standards for DSV cleaning of their respective equipment where appropriate