

WHITE PAPER



Decontamination of healthcare equipment and surfaces

Importance of healthcare disinfectant selection and the material compatibility of healthcare equipment

Why should we clean?

A number of investigators have highlighted the importance of environmental contamination in the transmission of clinically relevant pathogens such as *C. difficile* and MRSA¹⁻⁷, and there is a body of evidence highlighting that improved infection control practices can help break the chain of transmission¹³. As such, surface disinfection is now a cornerstone of international infection control policies.

The use of pre-impregnated, combination detergent/disinfectant wet-wipes has a number of advantages over use of solutions and sprays. Dry wipes can interfere with the action of common hospital disinfectants¹⁴, chlorine solutions can be inactivated by organic matter¹⁵ and user error is associated with mixing solutions daily. Wet wipes deliver a consistent, stable dose of biocides that can be tested in situations accurately reflecting real world conditions. It is for these reasons that the use of wet wipes within healthcare settings is now more common than ever before.

How do you select the correct decontamination procedure?

The UK Microbiology Advisory Committee (MAC) manual notes that surfaces may become contaminated with biological material, presenting an HCAI risk¹⁶. The choice of decontamination procedure will depend on the infection risk associated with contact (both frequency and type of contact), the item in question and the class of microorganism likely to have contaminated the surfaces (Figure 1)¹⁷.

Improperly cleaned, disinfected, or sterilised surfaces are a critical cause of HCAIs¹⁸. Cleaning is a process which physically removes infectious agents and organic matter but does not necessarily destroy them. Disinfection reduces the number of viable microorganisms to a safe level, whilst some infectious agents – such as spores – remain active. High level disinfection is a process designed to kill bacteria, viruses and spores, however, it is only sporicidal under certain conditions. Sterilisation is defined as a process to make an object free from viable microorganisms¹⁶.

Historically, guidance recommends the use of detergent for cleaning and a disinfectant solution of either 1,000ppm or 10,000ppm available chlorine for surfaces contaminated with blood and body fluids¹⁶. Where the item cannot withstand chlorine releasing agents, the manufacturer's instructions should be consulted for a suitable alternative.

There is ongoing debate both for and against detergent and disinfectant use in healthcare^{4,20,21}. However, an inherent consideration of all disinfection strategies is elimination of the antibiotic

resistant microbial population.

Currently, a range of disinfectants are available – either as single substance products or in combination. Combination products minimise the risk of resistant organism survival as multiple mechanisms are used. Disinfectant choice will depend on intended efficacy: if the spores of *C. difficile* are the target, a product with proven sporicidal activity should be used. Suboptimal use can result in transference of microorganisms to clean surfaces²²⁻²⁵.

It is essential to ensure that any product used for cleaning and disinfecting is compatible with the target surface. In 2010 the UK MHRA issued an alert (MDA/2010/001⁸) indicating that failure to follow the device manufacturer's decontamination instructions may be considered to be 'off-label' use; only products recommended by the manufacturer and supplied by employers should be used. The use of hazardous products should be assessed in accordance with Control of Substances Hazardous to Health (COSHH) regulations^{18,26}.



The importance of surface-wipe compatibility

In 2013 the UK MHRA issued a further alert⁹ which identified that, as a result of incompatible detergent and disinfectant wipes degrading the plastic surfaces, damage had occurred to tympanic thermometers, patient monitors, infusion pumps, dialysis fluid filters, peritoneal dialysis transfer sets and infant warmers.

This alert highlighted that polymer damage can occur if the disinfectant or detergent is incompatible with the surface material, potentially compromising the ability to decontaminate the surface adequately and possibly interfering with device functionality. All staff involved in decontamination of healthcare surfaces were instructed that, if the manufacturer's decontamination instructions were inadequate, then they should report this to the MHRA and the manufacturer. The alert further requested identification of all device decontamination processes that include using a detergent or disinfectant wipe on a plastic surface and requested a compatible process in accordance with the device manufacturer's instructions. Subsequent to this, the UK MHRA have jointly targeted the wipe and device manufacturers regarding these points to ensure collaboration occurs.

In the UK and in Australia the manufacturer of healthcare equipment are legally obliged to follow 'state of the art' and provide validated cleaning and disinfection protocols appropriate for their device. Appropriate advice means that locally available disinfectants and cleaning agents for where they sell the product must be taken into consideration. This of course would not apply to manufacturers of equipment not generally considered to be a medical device however still used in a medical environment, such as plug sockets, light switches etc. Regulatory authorities should consider whether this is an area in which useful and much needed guidance could be given.

Design of medical equipment should capture the state of the art also, in that the available number of suitable disinfectants (bearing in mind that local environmental and industry requirements preclude many chemicals) should be included when the device/product is developed.

This issue is not unique to the UK: recently in Australia VMIA, who provide risk advice services for the Victorian Government²⁷, and the Therapeutic Goods Administration issued risk alerts and subsequent Medical Devices Safety updates^{10,11} which actioned a review of all decontamination processes that use a disinfectant wipe or detergent containing quaternary ammonium compounds on a plastic surface³. However, within neither the risk alert or the Medical Devices Safety Update, was there consideration given to the healthcare equipment selection and the polymers used within the construction of these surfaces.

The TGA's update¹⁰ concluded that if the cleaning agent is incompatible with the plastic surface, it may cause damage. It suggested disinfectants containing QACs should not be used on plastic surfaces.

However, following further investigation the TGA have subsequently re-issued their advice with several clarifications¹¹. The main clarification concluded that cleaning agents containing benzalkonium chloride at concentrations below 5-10% are safe for use on medical devices and are considered non-corrosive at 0.5% or less. These clarifications should provide reassurance and guidance to those using cleaning products containing QACs.

Both the TGA and the MHRA recognise the importance of the device manufacturer in the decontamination process and recommend the user consult the manufacturer's instructions for use regarding the type of disinfectant that should be used to ensure compatibility. Should no manufacturers advice be provided, this should be reported to the TGA and MHRA respectively.

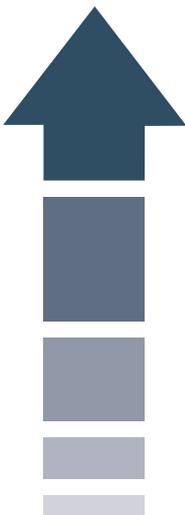
	MICROORGANISM	EXAMPLES	
	High Resistance	Prions	Creutzfeldt-Jakob Disease
	Bacterial spores	Bacillus spp., Clostridium spp.	
	Protozoal oocysts	Cryptosporidium	
	Mycobacteria	Mycobacterium tuberculosis	
	Small, non-enveloped viruses	Poliovirus, Papillomaviruses	
	Protozoal cysts	Giardia	
	Fungal spores	Aspergillus, Penicillium	
	Gram-negative bacteria	Pseudomonas spp., Escherichia coli	
	Vegetative fungi	Aspergillus, Candida	
	Vegetative protozoa	Giardia, Cryptosporidium	
Less Resistance	Large, non-enveloped viruses	Adenoviruses and Rotaviruses	
	Gram-positive bacteria	Staphylococcus spp., Enterococcus spp.	
	Enveloped viruses	Human Immunodeficiency Virus, Hepatitis B Virus	

Figure 1 – Classification of microorganisms by level of resistance to common disinfectants. Adapted from Russell, 1999¹⁷

Studies support the issues raised in these alerts: a growing trend worldwide is the cracking of polymer housings for electrical equipment used in the healthcare environment, known as environmental stress cracking²⁸. In some cases, the cracking can occur within three to four months of initial use in a healthcare environment. Research has shown that manufacturers have moved away from using durable metals and plastics to using cheaper polymers. These cheaper, less durable polymers are susceptible to environmental stress cracking, caused by repeated exposure to chemical disinfectants used to help prevent healthcare-associated infections^{29,30}.

Disinfectants are required to adhere to strict standards of efficacy, stability and safety before regulators will allow products to enter the market. These same standards do not apply to materials selected for construction of healthcare equipment – particularly of plastic surfaces commonly found in domestic environments like plugs and power sockets. American Standard Test Methods (ASTM) are not universally enforced – and there is no standard testing method to compare exposure to all surface disinfectants – allowing plastic manufacturers to set their own

success criteria³¹. Environmental stress cracking has been observed in a range of plastics, including those traditionally considered highly chemically resistant on exposure to a range of disinfectants³². These issues will not be resolved until standardised compatibility tests between plastics and healthcare disinfectants are developed and manufacturers of healthcare equipment act upon these data to improve material selection during product development.

Research has shown that some equipment manufacturers may use less durable metals and plastics, preferring to use cheaper polymers³³. These less durable polymers become susceptible to environmental stress cracking caused by repeated exposure to chemical disinfectants used to decontaminate them.

These cheaper products are likely to be affected by any chemical disinfectants, and not just benzalkonium chloride. For example, chlorine has long been associated with damage to surfaces, alcohol has been shown to strip out chemicals within plastics, making them brittle over time, and the newer hydrogen peroxide wipes with very low pH levels are also associated with surface damage.

To counteract these negative effects, material suppliers have developed polymers with higher levels of chemical resistance specifically for medical device applications. Examples include Bayer's Makroblend EL4000 polycarbonate (PC) and polybutylene terephthalate (PET) blend, Eastman's Tritan MX811 copolyester, SABIC's VALOX polybutylene terephthalate (PBT) and NORYL polyphenylene ether (PPE) resins, and Daikin's Neoflon perfluoro alkoxy (PFA) copolymer. Thus it is quite possible for a manufacturer to incorporate a polymer that is tolerant of disinfectants into the design process. Responsible equipment manufacturers understand this, recognising the importance of using polymers that can be effectively cleaned and disinfected.



Quaternary ammonium compounds versus amines

The VMIA risk alert raised electrical outlets as an issue of concern²⁷. From our internal testing, we have seen that some healthcare environmental plastics, often electrical outlets, are now made from polycarbonates. Polycarbonates are easily damaged by amines³⁴ – through a mechanism called aminolysis – leading to cracking of the plastic. The ability of amines to breakdown polycarbonate is so great that they have been studied as a potential method for recycling plastics³⁵. Amines are hydrocarbon derivatives of ammonia, and are sub-classified as primary, secondary and tertiary based on the degree of hydrocarbon substitution; it is this substitution that interacts with plastic surfaces. This issue is not

limited to polycarbonates: amines have been found to cause chemical weakening of PET, PVC and rubber³⁶.

Amines with four hydrocarbon substituents are positively charged and exist as 'permanent cations' – referred to as quaternary ammonium compounds (QACs) – this makes QACs morphologically and functionally distinct from primary, secondary and tertiary amines. The reactivity of amines depends upon the presence of a free electron pair on the nitrogen; QACs do not have this and therefore do not undergo aminolysis reactions in the same way.

Quaternary Ammonium Compounds are comparatively unreactive and have good surface compatibility compared with other disinfectants³⁷.

Additionally, because QACs exist as permanent cations, they act as cationic surfactants as well as disinfectants, and do not diffuse readily across biological membranes³⁸ – making them ideal for human and animal disinfection.

The most likely source of amines in a hospital environment is not from the use of QACs, but from chlorine-based disinfectants; reactions between chlorine-based disinfectants and organic matter produce, amongst other things, chloramines^{39,40}. Chloramines are highly reactive amines which can be responsible for aminolysis of plastic surfaces.

Why is it important to consider wipe selection?

Wipes are routinely used to clean and disinfect patient equipment and environmental surfaces; they are a convenient and rapid means of cleaning and disinfection. In the UK, in the absence of national guidance on wipe selection and use, the Royal College of Nursing (RCN) issued guidance on the selection and use of wipes⁴⁰. A key recommendation was that a collaboration between all stakeholders should take place to develop standard test methods that reflect real-life applications of wipe products in order to support wipe selection and purchase in health care. MDA/2013/019⁹ highlights that this collaboration between

the wipe and medical device manufacturers was not happening.

Three categories of wipes currently exist: detergent wipes, for cleaning of visibly soiled areas; disinfectant-only wipes, for disinfection after cleaning and combination disinfectant/detergent wipes, for one-step removal/reduction of microorganisms. Disinfectant-only wipes, such as alcohol wipes, are now rarely used, as they have no cleaning action and are therefore open to misuse if cleaning does not take place. They are not sporicidal and can damage some equipment (rubbers and plastics), particularly with prolonged use⁴¹.

In addition to the growing evidence that use of disinfectants should be more widely considered, there is now evidence of the benefits of using disinfectants and detergents in a ready-to-use wet wipe^{37,42,43}. Combination disinfectant/detergent wipes are three times more effective at reducing bacterial burden than detergent wipes⁴⁴ and detergent wipes have been demonstrated to transfer microorganisms to multiple surfaces⁴⁵.

Ready-to-use disinfectant wet wipes have been proven to significantly increase cleaning compliance, with associated cost savings in terms of staff time⁴⁶.



The importance of selecting the right wipe

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Standard efficacy tests for disinfectants can be inconsistent because they are not designed for wet wipes. Efficacy information for a product can usually only be derived from laboratory tests, conducted by manufacturers, using non-standard tests. This can lead to the use of wipes that may be inappropriate for applications in the healthcare environment⁴⁷.

Peter Hoffman (Consultant Clinical Scientist at the Antimicrobial Resistance and Healthcare Infections Reference Unit of Public Health England) provided a practical set of recommendations for how best to select disinfectant wipes in his presentation at the Infection Prevention Society Conference 2013 in London. Hoffman suggested that a wipe manufacturer should be able to:

- Adequately explain how the formula works by describing the active compounds and outline their relationship with target microorganisms
- Ensure that efficacy tests are undertaken on liquid expressed from the wipe, not on solution added to the wipe – as some materials may retain the disinfectant
- Present efficacy data that reflects achievable contact times and conditions. A disinfectant that only achieves a satisfactory kill after 30 minutes contact is unlikely to be of any practical use in a clinical setting
- Provide an experienced and reputable microbiologist who can explain the importance of all aspects of the formula and relevant testing
- Deliver comprehensive training on correct use and best practice
- Undertake and publish practical user results for their products
- Comply with current product safety regulations and occupational health considerations and guidelines

Wipe selection is critical, as infection prevention efforts may be compromised if a product is not fit

for the intended purpose. The choice of an appropriate product can be a complex process that includes the consideration of scientific information and the interpretation of laboratory test data. Cleaning and disinfection are a fundamental component of any Infection Prevention and Control Strategy. Education and training for all healthcare personnel that perform environmental cleaning is integral to wipe selection: there is now a growing collection of studies that demonstrate the effectiveness of training in improving environmental decontamination^{20,48}.

In summary

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Your wipe selection is just as important as the healthcare equipment you have chosen; infection prevention efforts and patient safety may be compromised if both are not considered in conjunction. The Medical Device Regulation (EU) 2017/745 and the Therapeutic Goods (Medical Devices) Regulations 2002 stipulate that the onus is on the equipment manufacturer to provide a validated cleaning/disinfection program for their reusable surface. Whilst some manufacturers of healthcare equipment are addressing these issues^{49,50}, compatibility data – particularly for domestic surfaces – remains lacking.

The implementation of an effective IPC policy, based on high quality evidence, should remain the goal of healthcare providers. Simply switching disinfectant will not be an adequate measure to resolve this ongoing issue; bleach, chlorine and hydrogen peroxide are all capable of causing environmental stress cracking in high-performance resins traditionally considered chemically resistant³². Over time, equipment used in healthcare settings may be subject to a variety of disinfectants as priorities change and newer agents become available. Compatibility checks should always be done before using any disinfectant on a surface. It is essential that healthcare equipment is constructed from materials proven robust enough to tolerate regular disinfection. Ultimately, both manufacturers of wipes and of equipment used in healthcare settings should have a shared vision: to provide healthcare professionals with the products and equipment that are fit for purpose in terms of functionality and ability to be effectively decontaminated in order to protect patients.

Manufacturers confirmed approval matrix

As a proactive disinfectant manufacturer, at GAMA Healthcare, we collaborate with equipment manufacturers to create a 'Manufacturers Approval' matrix for our products. We have worked with many manufacturers of medical devices including Welch Allyn, Philips, Carefusion and others to test compatibility, produce disinfection regimes, and work collaboratively on disinfectant compatibility and polymer choice for new devices.

BRAND	EQUIPMENT	APPROVED PRODUCT
1st Call Mobility	Mattresses	Clinell Universal
Abbott	FreeGo Pump	Clinell Universal
Abecca	Positioning Supports & Mattresses	Clinell Universal Clinell Detergent Clinell Peracetic Acid Wipes*
Active Key GmbH & Co. KG	All Active Key MedicalKey™ products, including: AK-C4112, AK-C4412 AK-C7012 & AK-C7412	Clinell Universal Clinell Detergent Clinell Peracetic Acid Wipes* Clinell Alcohol
AGFA	DX-D products	Clinell Universal Clinell Peracetic Acid Wipes*
Agile Medical	All products	Clinell Universal Clinell Detergent Clinell Peracetic Acid Wipes*
AKV International	Upholstery Vinyl	Clinell Universal
Albyn Medical	Hermes Urodynamic (do not use wipes on monitor)	Clinell Universal
Align Technology	iTero Element	Clinell Universal
All Modul	Trolley Range	Clinell Universal
Arcomed	Pumps	Clinell Universal Clinell Detergent
ArjoHuntleigh	Mattresses Reliant IS2 Cover (this is a mattress cover)	Clinell Universal
ASep Healthcare	Tournistretch	Clinell Universal
BD (Bard)	CareFusion Jaeger Spirometry Cabinet Alaris Syringe Pump Alaris GW Volumetric Pump Site-Rite® 8 Ultrasound System and Probe	Clinell Universal Clinell Universal Clinell Peracetic Acid Wipes*
Bedfont	Smokerlyzer, ToxCO (Not suitable with Gastrolyzer)	Clinell Universal
Brandon Medical	Astralite Treatment Lights Astramax Minor Surgical Lights Quasar Elite Operating Theatre Lights	Clinell Universal
Braun	Thermoscans	Clinell Universal

Carrflex	Mattress Covers, Upholstery Tops & Associated Equipment	Clinell Universal Clinell Detergent Clinell Peracetic Acid Wipes*
Carr Plastics	Techmaflex	Clinell Universal Clinell Detergent Clinell Peracetic Acid Wipes*
Central Medical	Swabsafe Stands	Clinell Universal
Covidien	Genius 2 Tympanic Thermometer	Clinell Universal Clinell Detergent
Dartex Coating	Mattresses (with polyurethane face)	Clinell Universal Clinell Peracetic Acid Wipes*
De Smit Medical	CubeScan Bladder Scanners	Clinell Universal
Direct Healthcare	Dartex Mattress Covers	Clinell Universal
Echosens	FibroScan	Clinell Universal
Elekta	IBeam Evo Couch Top	Clinell Universal
Fresenius Kabi - Agilia range	VP MC volumetric infusion pump SP MC syringe infusion pump SP TIVA TCI syringe infusion pump SP PCA syringe infusion pump	Clinell Universal Clinell Detergent Clinell Peracetic Acid Wipes*
Fritz Stephen	Pediatric Ventilation Systems	Clinell Universal Clinell Detergent
Fujifilm Sonosite	Ultrasound Equipment (Edge, NanoMaxx, MicroMaxx, TITAN) iViz devices and C60v, L25v, L38v & P21v probe	Clinell Universal Clinell Peracetic Acid Wipes*
GE Healthcare	Ultrasound Transducers (Please email info@gamahealthcare.com for full list of compatible transducers) Probe Holders, User interface, Touch panel, OLED Monitor Display and the Housing of Voluson Expert BT15, BT16, BT17, BT18 and BT19 consoles. Note: LCD Monitor Display can only be cleaned with IPA (70%) solution Voluson Ultrasound Consoles Expert Series (E6, E8 and E10) Signature Series (S8 and S10) Performance Series (P8) MAC VU360™ Resting ECG	Clinell Universal
Haines Medica Australia	Haines MediCurtains (Full range) Haines Wipeclean Waterproof Pillows Haines Reusable Tourniquets Haines PVC Wipedown Mattress Covers Haines PVC Mackintosh Rolls Haines Reusable Pillow Cases	Clinell Universal
Hospedia	Patient Entertainment Unit	Clinell Universal
Hospira	Sapphire Pump	Clinell Universal

Howard Wright	Mattresses	Clinell Universal Clinell Detergent Clinell Peracetic Acid Wipes*
HP	IPAQ HP EliteBook 840 G6 Healthcare Edition HP EliteOne 800 G5 Healthcare Edition All-in-One HP Healthcare Edition HC270cr Clinical Review Display HP Healthcare Edition HC241 Clinical Review Monitor HP Healthcare Edition HC241p Clinical Review Monitor HP Healthcare Edition HC271 Clinical Review Monitor HP Healthcare Edition HC271p Clinical Review Monitor	Clinell Universal Clinell Universal Clinell Peracetic Acid Wipes*
Huntleigh Healthcare	Foetal Monitors	Clinell Universal Clinell Detergent
International Light Technologies	IL1350	Clinell Universal
Karomed	Mattresses	Clinell Universal
Konica Minolta	SONOVISTA FX Ultrasound Device (premium edition)	Clinell Universal
Laerdal	Suction Units	Clinell Universal Clinell Detergent
MePACS	Duress Alarms	Clinell Universal
Mindray	N Series Monitor	Clinell Universal Clinell Peracetic Acid Wipes*
Modsel	All product ranges	Clinell Universal Clinell Detergent Clinell Peracetic Acid Wipes*
OES Medical	Pressure Monitor and UAM Anaesthetic Machine	Clinell Universal Clinell Detergent Clinell Peracetic Acid Wipes*
Orfit Industries	All related types of AIO 3.0 Medium Density Blue Head Support Low Density Blue Head Support All related types of SBRT cushions	Clinell Universal Clinell Detergent Clinell Peracetic Acid Wipes* Clinell Universal Clinell Detergent Clinell Peracetic Acid Wipes* Clinell Detergent Clinell Peracetic Acid Wipes* Clinell Detergent
OxyLitre	All equipment	Clinell Universal Clinell Detergent

Panaz	Cadet Furniture	Clinell Universal Clinell Peracetic Acid Wipes*
Parity Medical	Mobile Computer Carts	Clinell Universal Clinell Peracetic Acid Wipes*
Park House	Healthcare Mattress Covers	Clinell Universal
Phantom Laboratory	Catphan 500	Clinell Universal
Philips	Ultrasound Equipment Intellivue Monitor (remaining residue must be wiped off)	Clinell Detergent Clinell Universal
	Ultrasound Transducers (Please email info@gamahealthcare.com for full list of compatible transducers)	Clinell Universal Clinell Peracetic Acid Wipes*
Plinth Medical	Vinyl Couches	Clinell Universal
Recticel	Mattresses	Clinell Universal Clinell Peracetic Acid Wipes*
Seca	All equipment	Clinell Universal
Sapura	Sapura TETRA products	Clinell Universal
Sidhil	IQ Bed Frame	Clinell Universal Clinell Peracetic Acid Wipes*
Siemens	Siemens RapidPoint Systems Mammomat Inspiration	Clinell Peracetic Acid Wipes* Clinell Universal
Smiths Medical	Pressure Infuser	Clinell Universal
Toshiba	Ultrasound Equipment	Clinell Universal Clinell Peracetic Acid Wipes*
Tough-PAC	iPad Covers	All Clinell products
Triton Electronics Systems Ltd	Multigas Analyser-AMG-06	Clinell Universal Clinell Detergent
Universal Ferrule Remover	Ferrule Remover	Clinell Universal Clinell Peracetic Acid Wipes*
Verathon	GlideScope cables BladderScan Prime	Clinell Universal Clinell Universal
Visionflex	Thinklabs One Digital Stethoscope	Clinell Universal
Welch Allyn	Connex Spot Monitor Caretemp Thermometers Pro6000 Thermometers Pocket Plus LED Diagnostic Set - Ophthalmoscope	Clinell Universal
Zebra	Zebra Healthcare Mobile Computers	Clinell Universal
Zoll	AED	Clinell Universal Clinell Peracetic Acid Wipes*

*Previously Clinell Sporidical Wipes.

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