Evolving technologies in decontamination

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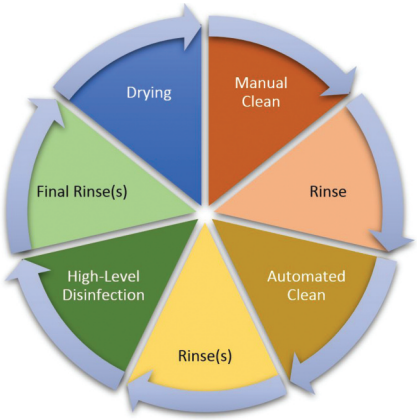
Since the early days of the 'HTM 2030' Department of Health guidance document in 1997, the process of decontaminating an endoscope has gone through significant changes fuelled by a demand for a faster, safer process that suits the requirements of the modern healthcare system. Endoscope Washer Disinfectors (EWDs) have had to keep pace with the increasing complexity of the devices and so too have the testing and validation requirements in order to ensure patient safety and reduce the risk of cross-contamination.

There have been many recent innovations such as capsule videoendoscopy and single use colonoscopes[1] and these, along with other technologies, may in the future replace the traditional flexible endoscope. For now automated high-level disinfection of these reusable instruments remains the most economical and rapid means to meet the ever-increasing demand for diagnostic procedures in the NHS.

To achieve high-level disinfection, it is critical that items are clean ie: free of protein and organic matter. Many recent developments have focused not on the disinfection process but rather ensuring thorough cleaning takes places beforehand.[2] The disinfection process itself has not changed significantly and contains the basic core components: wash; rinse; high-level disinfect; and final rinse. The high-level disinfection has always been a liquid chemical disinfection only now more commonly with peracetic acid rather than the aldehyde-based disinfectants that used to be prevalent. Peracetic acid, which works by oxidising bacterial components, filled the gap in the market as Glutaraldehyde was phased out in the UK - mainly due to protein fixation and concerns regarding health effects.



The flexible endoscope decontamination cycle has always retained the same key steps

After disinfection it is equally important to ensure that bacteria are not reintroduced or allowed to proliferate. After all, the endoscope is not guaranteed to be completely free of bacteria.

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Preventing protein drying

Starting almost immediately after patient use, the 'bedside clean' is now a recommended part of the process and ensures the decontamination process begins as early as possible. This presents an important opportunity for development and improvements to the process.

One of the most important aspects of soiling removal is to not allow the protein to dry as it becomes more difficult to remove afterwards. Reprocessing the endoscope within three hours of patient use has been the traditional means of preventing dried on soiling but this can be impractical or difficult to achieve - especially when procedures are happening out-of-hours or at a location remote from the procedure.[3] A means of prolonging this time-window is to supplement the humidity of the endoscopes' environment, so as to slow the drying process; increasing the relative humidity around the soiling will decrease the rate of evaporation. This can be achieved after the bedside clean with sealed transport bags and a moisture source, such as a wetted pad. The result will be an endoscope that is more easily cleanable and a much lesser challenge to the decontamination process.

The process of transporting dirty endoscopes is yet to be fully standardised and there are many unanswered questions, such as: the effect of temperature; the maximum time where bacterial proliferation may become an issue; and how well the humidity will be maintained in the endoscope channels. To date, the latter issue has not being given enough attention as the endoscope channels are much harder to decontaminate than the surface. This whole transport process is largely unmonitored which is an area for future technologies to ▶

be developed to provide further assurance that drying has been avoided, especially where extended transport distances and times are being used.

The bedside clean may also present some additional risk to operators as liquids that have a high level of potential pathogens are being generated and handled. A way to mitigate this risk and aid the decontamination processes may be to introduce a low-level non-toxic disinfectant to the bed-side process and provide a 'pre-disinfection' as well as a pre-clean.

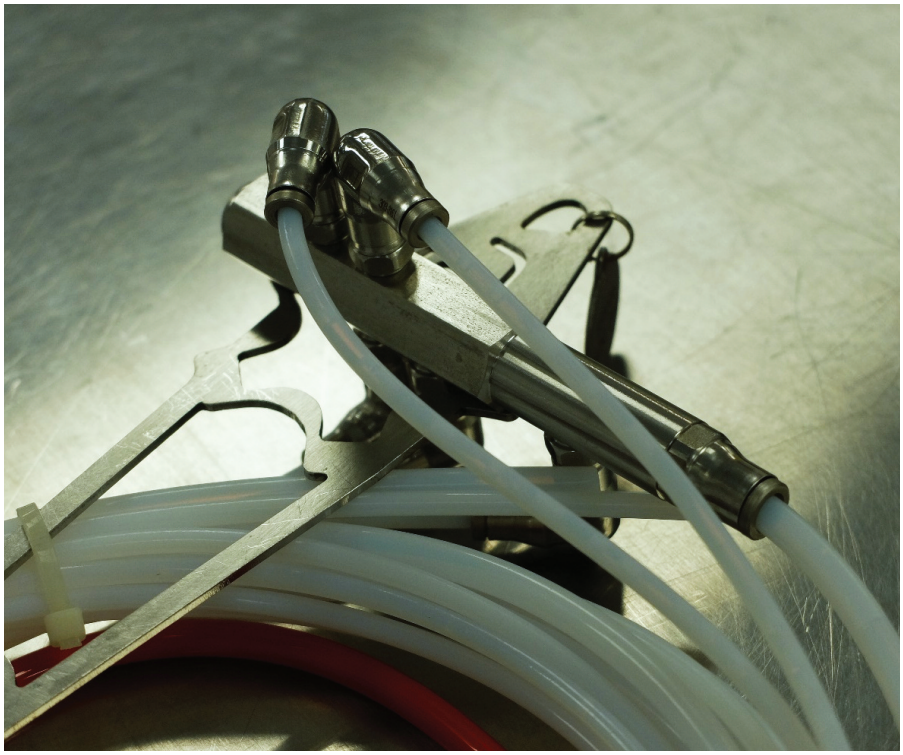
Improving the manual clean process

The only stage where the channels will be mechanically brushed is during the manual clean, hence it is a critical stage in the process. Carried out in a pre-cleaning sink, the manual clean with a sponge or lint-free cloth and flexible brush removes the majority of the organic contamination from the channels and outside of the endoscope. The channels must be flushed with a detergent solution as the lumen will be too long and complex to be cleaned simply by submersion. Manual processes, although potentially very effective, can vary from operator to operator so these are aided by automated flushing systems. These often wall-mounted units deliver pump-driven detergent to the channels to deliver a consistent and controlled cleaning action.

As is the case with any accessories, care should be taken to follow all manufacturers' disinfection instructions for the flushing equipment itself as equipment could act as a reservoir for bacteria and create additional risks - and a challenge for the disinfection process.

Delivering water to the endoscope washer disinfector

Since the introduction of automated machines for disinfection of endoscopes there have been recognised issues with contamination,[4] most notably in the final rinse water.[5] Filtration below 0.45 micron or 0.2 micron had always been the traditional way to ensure bacteria-free water and this may have worked well under laboratory conditions with single use equipment. In theory, the pore sizes of the filters were narrower than the smallest known bacteria. However, in practice, delivering consistent quality water over a long time-period with a complex water system network would be unachievable without further treatment. Furthermore, it has been discovered that there may be more species than previously thought that can pass through these filters including Spirochaete and Actinobacteria phyla.[6] Biofilms of multiple species can quickly take hold of treatment equipment, pipework and the EWD itself and become extremely difficult to remove.



Example of an ISO 15883-4 compliant surrogate device used to test endoscope drying cabinets

Many different treatment methods have evolved to tackle these issues, the current guidance lists six recommended methods[7]:

- Softening
- Deionisation
- Distillation
- Reverse osmosis
- Filtration
- Disinfectant addition.

None of these technologies are new. However, allowing for 'disinfectant addition' is a recent change in the Health Technical Memoranda and, as a result, there are new technologies to meet this new recommendation. Some products are combining these technologies for instance reverse osmosis (RO) purification with low level chlorine dioxide dosing to prevent bacterial proliferation within and after the filter.

Although it may be quite straightforward to filter water, it is more difficult to maintain this bacteria-free state though a long network of pipes and valves before it eventually enters the endoscope. Low doses of non-toxic disinfectant appear to be an important way forward to ensure the water microbiological quality is maintained in all areas the rinse water travels though. Technologies such as these fill a gap in the water treatment process where only more limited single-point technologies, such as ultraviolet, existed before.

The traditional idea of aiming for increasing purity of rinse water is being challenged as it is recognised that more than one method is needed to maintain and ensure patient safety. The current UK guidance states that even the traditional trusted indicator of water quality, electrical conductivity, is not important if biocides are present. As long as patient safety can be demonstrated, residual biocide can lower potential infection risks as bacteria proliferate in standard final rinse water.

Going mobile

The requirement for endoscopy in the NHS has massively increased in recent years due, in part, to programmes such as the NHS Bowel Cancer Screening Programme (BCSP).[8] To meet the required targets and reduce procedure waiting times hospitals are turning to mobile endoscopy suites with built-in decontamination facilities. This is much more cost effective compared to redevelopment and rebuilding, which may take years to complete. These often privately run trailer type units are equipped with the full range of decontamination equipment including manual cleaning sinks, washer-disinfectors and drying cabinets. Such self-supporting systems can include the patient treatment rooms, recovery wards and consulting rooms. Although a stop-gap solution, some of these units offer a fully compliant process and can have faster turn-

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around compared to transport to another hospital.

Decontamination units in the future will undoubtedly change further still as the demands for an adaptable and cost-efficient solution increase.

The 'use-by' date

To cut costs and waste, the shelf-life of the processed endoscope is being extended by various products and technologies. Decontamination units no longer need to put the disinfected endoscope back into the washer after three hours because of concerns of bacterial growth; the endoscopes may be dried and packed in a preserved state.

Drying cabinets have been around for a decade or more and evolved from the endoscope storage cupboards of-old to create a system that actively dries and maintains the internal and external microbial quality for often up to 30 days. These were never described in the original HTM 2030 document and only in 2015 an international standard became officially available to dictate their design and testing requirements.[9] The principle of the storage aspect is similar to what people consider to be a 'cleanroom' environment with positive pressure and HEPA filtration. Drying can help to reduce the risk of biofilm developing inside the endoscope as the desiccation will prevent the formation or growth of biofilms from any microorganisms that remain.

In some situations, where the patient need is not immediate, or perhaps further afield, transport of the processed endoscope is necessary. Endoscope packing systems have become increasingly commonplace, mostly due to the stated maximum storage time which may save costs in reprocessing due to expiring the traditional three hour time window. As in the early days of drying cabinets, the international standards are not yet developed to fully cover their use and testing, therefore we see a variety of systems and methods on the market.

Various gases, liquids and vacuum methods are employed in this area to preserve and protect the state of the endoscope after drying. But, without fully defined testing and validation standards, users can be left without independent reassurance. Users should seek advice from their Authorising Engineer for Decontamination before putting such equipment into use.

With these additional stages being added to the process it is more important than ever that all the links in the decontamination 'chain' are secure. Each step is reliant on the previous stages being effective and validated otherwise the whole process will fall apart and potentially endanger patient safety. Storage methods cannot by their nature 'disinfect', only maintain the state hence they are reliant on highly disinfected and dry endoscopes as a starting point.

The complexity and number of steps in the process means that staff are more reliant on tracking systems to work out the 'where, when, who and how'.

Traceability - following the steps

Endoscope tracking and traceability has been one of the areas that would not have been possible with the computer systems from 20 years ago. Now a unit manager has the ability to instantly assess where an endoscope has been reprocessed, all patients it was ever used on and its current location. This is a critical tool for infection control if patients need to be recalled due to faulty equipment or processes and makes traceability fast and more straight-forward than paper-based systems.

A new definition for 'clean'

Testing methods for EWDs have been adapted over the years to accommodate the practical difficulties of maintaining and managing a high-level disinfection process for endoscopes. A lot of the tests described in the 1997 memorandum were based around pharmaceutical specifications that were simply not achievable using treated mains tap water. Users who were not able to stick to the strict specifications were left in the dark because the guidance lacked any interpretation for bacterial and endotoxin levels and no advice on remediation was given. Specifications for test methods, particularly microbiological tests, are less prescriptive and more advisory, putting the onus back to the end-user to risk-assess and decide the best outcomes for the patients, infection control and budgets.

Final rinse water microbiological counts are carried out weekly and now allowed up to 10 cfu (Colony Forming Units) per 100mL with colour coded guidance and action levels beyond this. The endotoxin maximum limit is now 120x higher than previous guidance ▶

and the chemical purity specifications have been removed and rely on drinking water specifications.

When taking into consideration that most flexible endoscopy procedures are not performed in a sterile cavity and the endoscope retains very little residual rinse water, the justifications for these changes become apparent. Compared to other decontamination processes such as steam sterilisation, EWDs have seen the most changes in their testing and standards in recent years. The quality of testing is vital, users should ensure samples are sent to UKAS accredited testing laboratories for assurance of quality management and to ensure methods are validated and carried out by proficient laboratory staff.

One area that has received a lot of attention in recent years is residual protein after reprocessing. Not specific to endoscopy but for all medical instruments, the ADCP-TSE subgroup determined that current protein detection methods were not sensitive enough and highlighted a requirement for new technologies to reliably and quantifiably detect to the microgram level. This has spurred suppliers to produce a new range of protein detection products and tests, none of which are yet standardised in the guidance.

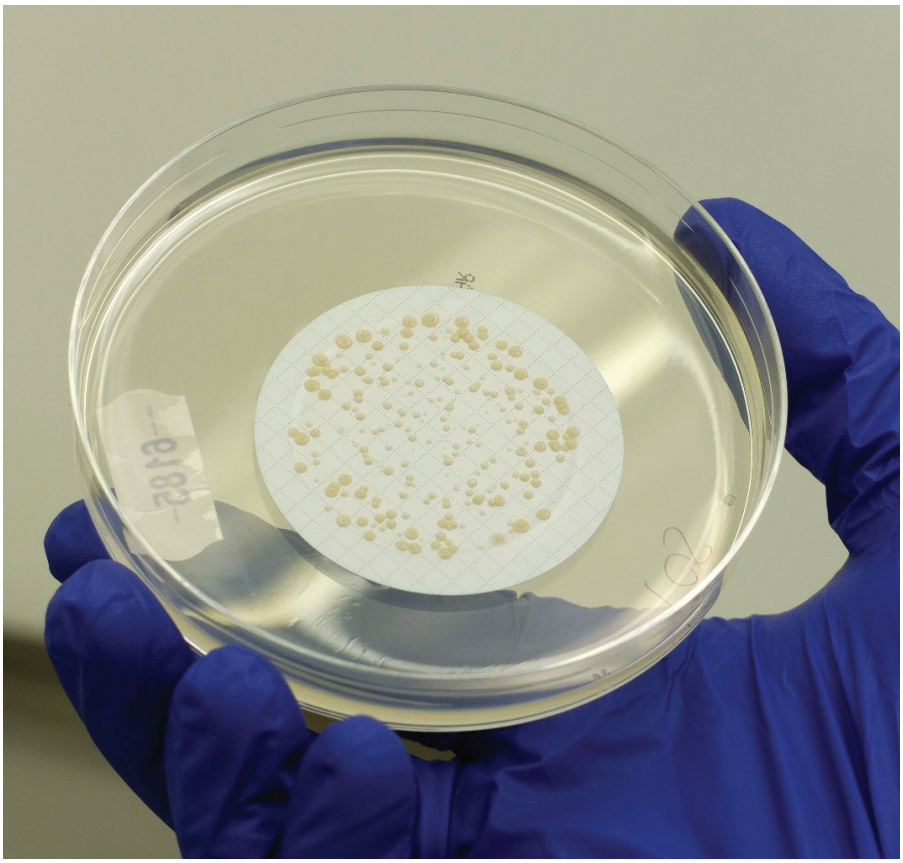
Despite revisions to the testing methods, improvements EWD design and other technological innovations, studies are being released indicating that biofilms within flexible endoscopes are still a cause for concern.[10] Disinfectant resistant biofilms may need routine, intensive treatment from alternative chemistry as they build up resistance from the routine processes. The direction of development of the endoscope always tends to be focused in the diagnostic and imaging direction, whereas considerations of disinfection and cleaning have received little attention.

Is sterilisation the answer?

Due to the nature of the design and material compatibility, the endoscope cannot be simply steam sterilised and must go through low temperature processes. High-level disinfection is not enough assurance for some sensitive procedures and endoscope types, such as choledochoscopes. In these cases, sterilisation is required either by plasma (Low Temperature Hydrogen Peroxide) or ethylene oxide. These sterilisation methods are never as fast as automated washer disinfectors, some of which can complete in less than 20 minutes. Sterilisation usually requires degassing over the course of several hours and the sterile barrier system needs to be maintained through any transport process. Faster sterilisation technologies will undoubtedly become available in the near future and potentially all flexible endoscopes could be sterilised. Protein removal in the washing stages will always need to be an important step in the processing of reusable instruments, therefore sterilisation can never be the panacea for all problems in decontamination.

In conclusion, the decontamination process still follows the familiar basic steps but will look very different from the processes and equipment 20 years ago. Protein removal and disinfection will be more effective thanks to recent innovation and technologies.

Our greater understanding of the chemical and biological aspects of the process is constantly changing how we define and monitor the whole system. The pace of change is increasingly rapid and testing and validation requirements are yet to be fully defined for some areas, so it is now more important than ever for users to seek advice and verify. Complacency with endoscope decontamination risks endangering patients so we must actively prepare and anticipate risks. CSJ



Testing for Environmental Mycobacteria in rinse water

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