Advice from IHEEM Decontamination Technical Platform/IHEEM Registered Authorising Engineer (Decontamination) Group.

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Re: Change of supplier of process chemicals for surgical instrument and endoscope washer-disinfectors

1. Introduction

Surgical instrument washer-disinfectors (WDs) are used to clean and disinfect reusable medical devices, typically instruments, before assembly, packing and sterilization. Endoscope WDs, sometimes known as Automated Endoscope Reprocessors (AERs), are used to clean and disinfect endoscopes before their storage or clinical use, typically without further processing.

2. Concern

In a free market, users of such equipment are able to choose alternative sources of consumables, such as the process chemicals used for each processing cycle. This is appropriate and allows free trade and competition, potentially benefitting users and patients alike, as long as safety and performance considerations are appropriately addressed and mitigated by verification testing – a technical operation to verify conformity to a standard or specification, and to establish data for reference in subsequent tests, to be performed that demonstrate safety and performance. These clinical and patient safety risk considerations are significantly different for surgical instrument WDs, compared to endoscope WDs.

3. Surgical instrument WDs

Consideration of the use of alternative detergents for surgical instrument WDs may be considered, provided that verification testing, at the equipment installation location, of the alternative detergent demonstrates adequate cleaning performance, in accordance with HTM 01-01, Part D[1], BS EN ISO 15883-1[2], BS EN ISO 15883-2[3] and BS EN ISO 15883-5[4]. These considerations should include any potential material incompatibilities of the alternative detergent with the materials it may contact within the WD, as well as compatibility with the surgical instruments themselves. Material compatibility needs to be confirmed by the process chemical manufacturer, WD manufacturer and surgical instrument manufacturer to mitigate the risk to patients if surgical instruments are damaged or contaminated by process chemicals or their residues, and also the risk that any manufacturer warranty / guarantees from the WD or surgical instrument will not be valid. Correct dosing should also be verified, as changes in viscosity can affect detergent delivery volume. Human factor aspects should also be considered, such as the potential for misconnection or use of the wrong process chemical. In addition, there may be consequences for routine maintenance and test activities, including, but not limited to, calibration, when considering an alternative detergent.

4. Endoscope WDs

Endoscope WDs also use detergents to clean endoscopes, so the considerations described in (3) above for alternative detergents in surgical instrument WDs apply. However, due to the thermolabile nature

of many flexible endoscopes, endoscope WDs utilise chemical disinfection using a process chemical (rather than the thermal disinfection used in surgical instrument WDs). It must also be recognised that the endoscope WD process is typically the final step before patient use, unlike with surgical instrument WDs, where surgical instruments will likely be subsequently sterilized before patient use. This terminal step for endoscopes can introduce additional safety and efficacy issues. These can be summarised as follows:

4.1 Detergent residues. Detergent residues from the cleaning stage can interfere with the efficacy of the disinfectant. If alternative detergents and disinfectants are used, any potential effects should be known and quantified (see HTM 01-06, Part C[5], clause 4.2). This is likely to require extensive knowledge of the formulation of all process chemicals and detailed microbiological studies that would not be practical in a user setting, hence suitability of alternative detergents must be established and accepted by WD and endoscope manufacturers prior to implementation.

4.2 Disinfectant residues. Disinfectant residues on endoscopes and endoscope channels from the disinfection stage must be reduced to a level that is unlikely to cause harm to patients during endoscopy procedures (see HTM 01-06 Part B[6], clause 2 and HTM 01-06 Part C[5], clauses 4.7 & 4.54). This residue reduction typically takes place during the final rinse. Changes to disinfectants of associated buffer components may affect the efficacy of this reduction.

4.3 Microbiocidal efficacy of the disinfectant. The efficacy of disinfectants *in vitro* is potentially very different to their efficacy in use. Efficacy must be determined microbiologically, showing that the disinfectant has appropriate bactericidal, mycobactericidal, fungicidal and virucidal efficacy, using the correct temperature, exposure time and concentration ranges found in the particular endoscope WD, as specified in BS EN ISO 15883-1[2] (clause 4.6) and BS EN ISO 15883-4[7] (clause 4.4.2). When performing this microbiological testing, methods need to be provided to the user for how the process chemical(s) are to be neutralised, according to BS EN ISO 15883-4[7] (clause 5.5). This microbiological testing is extensive and would not be practical in a user setting, hence suitability of alternative disinfectants must be established and accepted by WD and endoscope manufacturers prior to implementation.

4.4 Material compatibility. By their very nature, disinfectants have to be aggressive chemicals. The material compatibility of these chemicals is a function of concentration, temperature, time, and the presence of buffers that can lessen, and to a large degree, mitigate, any material compatibility. This material compatibility can affect not only the materials of construction of the WD, but also the materials of construction of the endoscopes to be processed (see HTM 01-06 Part C[5]). By way of example, peracetic acid (PAA) is a common disinfectant, but without the use of other chemicals such as buffers, can be very corrosive to many common materials used in the construction of WDs and endoscopes. The studies required would not be practical in a user setting, hence suitability of alternative disinfectants must be established and accepted by WD and endoscope manufacturers prior to implementation.

4.5 Human factors

Many endoscope WDs have dedicated cabinets that are purposefully designed to house the multiple process chemicals. These process chemicals need to be readily identified such that the wrong process chemical cannot be connected accidentally. Additional means are required according to BS EN ISO 15883-4[7] (clause 4.1.8) to ensure that means other than labelling and/or colour coding alone i.e. using dedicated connectors and/or tubing to ensure that the different process chemicals cannot easily be misconnected.

5. Summary

The use of alternative detergents in a surgical instrument WD may be appropriate if suitable validation tests are considered (see 3). The use of alternative detergents and disinfectants to those validated by the endoscope WD manufacturer in endoscope WDs are different in so much as the classification II B of an endoscope WD as a final process within the MDR raises concerns of performance and safety (see 4). The changing of chemicals to alternatives to those within the IFUs results in transferring the WD manufacturer's liabilities to the healthcare organisation[8]. Claims to conformity to relevant parts of BS EN ISO 15883[2,3,4,7] may be compromised. It is therefore strongly recommended that prior to any change of process chemicals within a WD the following are established as part of a formal risk assessment by the healthcare organisation:

5.1 The healthcare organisation is formally accepting of the responsibilities that will be transferring from the manufacturer of the WD to them because of the change in relation to the medical device regulations

5.2 The healthcare organisation has reviewed the validation testing of the proposed chemicals both individually and in conjunction with the specific WD type it is to be fitted to. This is to ensure conformance to BS EN ISO 15883[2,3,4,7], HTM 01-01[1] and HTM 01-06[5,6].

5.3 The chemical compatibility with the proposed chemicals and surgical instruments, endoscopes and WD are formally established.

5.4 The healthcare organisation acknowledges that the manufacturer warranties and guarantees may no longer be valid. This may apply to the WD manufacturer, the surgical instrument manufacturer or the endoscope manufacturer if process chemicals that are specified in the IFU are not used.

5.5 Consideration should be made whether any cycle programme changes are required for the use of alternative chemicals, and who will effect this change, since the WD manufacturer may be unwilling to modify their programme to accommodate process chemicals not specified in the IFU. There are significant risks inherent to any programme changes or cycle development if not carried out by the WD manufacturer.

6 References

1. HTM 01-01 Part D, Management and decontamination of surgical instruments (medical devices) used in acute care Part D: Washer-disinfectors
2. BS EN ISO 15883-1:2025, Washer-disinfectors - General requirements, terms and definitions and tests
3. BS EN ISO 15883-2:2025, Washer-disinfectors — Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices
4. BS EN ISO 15883-5:2021, Washer-disinfectors — Performance requirements and test method criteria for demonstrating cleaning efficacy
5. HTM 01-06 Part C, Decontamination of flexible endoscopes Part C: Operational management
6. HTM 01-06 Part B, Decontamination of flexible endoscopes Part B: Design and installation
7. BS EN ISO 15883-4:2018, Washer-disinfectors — Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
8. MHRA Guidance Off-label use of a medical device, 1 July 2023 https://www.gov.uk/government/publications/medical-devices-off-label-use/off-label-use-of-a-medical-device

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