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

V6 1st August 2025

Re: Surrogate devices for use in endoscope reprocessing validation

1. Introduction

Surrogate devices are used to replicate some of the challenges of reprocessing endoscopes during manufacturer's type testing, during periodic validation and during routine monitoring; they are generally transparent to allow visible inspection of the effectiveness of cleaning or drying. They also allow testing for process chemical residues, testing for partial and complete blockage alarms, drying efficacy and microbiological type testing for disinfection efficacy of the wash disinfect process. They also have applications in the testing of the maintenance of quality of an endoscope in controlled environment storage/drying cabinets. Surrogate devices have the added benefit of being relatively inexpensive when compared to the cost of an actual endoscope.

2. Concern

Type testing (typically performed by the washer-disinfector manufacturer) according to BS EN ISO 15883-4, Annex C, requires a combination of endoscope surrogates and actual endoscopes. These endoscope surrogates and endoscopes are intended to represent the endoscope product families (BS EN ISO 15883-4, Annex I) that can be adequately processed in a washer-disinfector.

Periodic validation on site is not intended to go into the complexity of the manufacturers type testing, but endoscope surrogates should be representative of the endoscopes being reprocessed. Use of overly simplified surrogate devices consisting of straight tubes of, for example, length 1 500 mm does not necessarily replicate the dimensions, complexities or intended connection method of actual endoscopes being reprocessed. For example, colonoscopes with an auxiliary port and an insertion length of 2 000 mm is typical of an endoscope available in most endoscopy departments. The effective length for washing, disinfecting and if required, drying this endoscope would be a cumulative length of 2 000 mm (insertion), 200mm (control) and 1 200 mm (connection), giving a total effective length of 3 400 mm.

Routine monitoring of endoscope washer-disinfector cleaning performance using surrogate devices (referred to as process challenge devices [PCDs] in HTM 01-06), for example with channels of 1 500 mm in length, are appropriate for daily or weekly verification of washer-disinfector performance but are not suitable for type testing nor periodic validation activities.

3. Standards and guidance documents

BS EN ISO 15883-4, *endoscope washer-disinfectors*, gives examples of the range of channel lengths either side of the trumpet valves - approximately mid-point of the effective channel length needed to be cleaned and disinfected in a washer disinfector; some of these combined channel lengths are up to 3 400 mm. A surrogate device of 1 500 mm is therefore not reasonable as most manufacturers connect the endoscope to a washer-disinfector via the connectors at the stack end of the endoscope with through connectors in the trumpet valves, making the trumpet valve approximately the mid-point of an effective length. The auxiliary channel is direct from the stack to the distal end, so is an effective length of the full length of the endoscope.

Endoscope surrogates are specified in BS EN ISO 15883-4, Annex C, for cleaning efficacy tests, disinfection efficacy tests, channel non-obstruction (lumen patency or disconnection) tests and tests of the complete process, possibly including drying efficacy tests. The design of the surrogate needs to replicate the endoscopes in use and the connection methods. Different surrogates will be needed to replicate more complex endoscopes such as duodenoscopes with elevator channels.

BS EN 16442 *Controlled environment storage cabinet for processed thermolabile endoscopes*, there is no reference to a specific channel length. There is, however, detailed information on the suitable design for endoscope surrogates for different types of endoscopes. The connection method to the cabinet may alter the effective length to shorten it if drying from the trumpet valve. This will complicate the piping arrangement to replicate the different lumens connecting into the trumpet valve. Endoscope surrogates that were used during type testing should be verified to ensure that they adequately represent the type of endoscopes that are being used. These endoscope surrogates are then used to show during commissioning and periodic validation that both drying efficacy and the microbiological quality of endoscopes is maintained. The design of the endoscope surrogate needs to replicate the endoscopes in use, and the connection method also to replicate the intended use, i.e. connected and hung in the cabinet as a normal endoscope without additional wrapping or being tightly coiled.

HTM 01-06, part D (4.22) and part E (16.2), make reference to process challenge devices (PCDs) that are used daily or weekly to establish satisfactory washer-disinfector cleaning efficacy. HTM 01–06-part D describes the use of endoscope surrogates (4.27 – 4.30) that are to be used during periodic validation and highlights that they should be similar in characteristics to endoscopes. HTM 01–06-part E (16.4) describes the need for a reference load or endoscope surrogate of demonstrated relevance for periodic validation. Unfortunately, HTM 01–06-part E (16.20) then goes on to describe a surrogate device of 1 500 mm length, which is potentially contradictory to the earlier clause (16.4).

4. Environment

With consideration for the environment and reducing the volumes of materials and plastics being disposed, endoscope surrogates should, wherever possible, be reused. To enable reuse the surrogates must be stored disinfected and dried between uses.

5. Recommendations

5.1 When procuring either an endoscope washer-disinfector or endoscope drying cabinet, request that the endoscope washer-disinfector manufacturer supplies technical drawings of the surrogate devices (or actual endoscopes) used by the manufacturer during type testing to represent each family of endoscopes. This is a reasonable expectation in alignment with the above standards' requirements for information to be supplied by the manufacturer (including a list of the special tools necessary for maintaining and testing).

5.2 These technical drawings should define bore diameter, length, valve arrangements, connection points and materials of construction.

5.3 The technical drawings should be reviewed by the user and the Authorising Engineer (Decontamination) to ensure they adequately cover the endoscopes intended to be reprocessed on site.

5.4 Prior to the procurement of an endoscope washer-disinfector, agreement is established on the endoscope surrogate device design that will be used for commissioning and subsequent periodic validation. Agreement on ownership of this surrogate should be made clear.

6. References

6.1 BS EN 16442:2015 Controlled environment storage cabinet for processed thermolabile endoscopes

6.2 BS EN ISO 15883-4:2018 Washer-disinfectors Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

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