Original Article

Type testing washer-disinfectors for reprocessing thermolabile endoscopes (EWDs) in accordance with the revised EN ISO 15883 series of standards

Part 1: Scope and conduct of tests by the EWD manufacturer

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Abstract

The revised version of EN ISO 15883-4:2018 [1] contains important changes related to type testing of washer-disinfectors for reprocessing thermolabile endoscopes (EWDs). Already the previous version of this standard from 2009 stipulated that the type test should provide evidence that the endoscope was free of vegetative bacteria and other soils at the end of the entire reprocessing procedure in the EWD. However, no information was given how this requirement could be implemented by the EWD manufacturer considering the large number of different types of endoscopes provided by various manufacturers.

This gap was closed with the normative annex H Establishing endoscope type test groups in the revised standard from 2018.

The Type Testing EWDs 2.0 working group was set up for the purpose of arriving of at a uniform interpretation and implementation of these new requirements. Members of the working group were employees of manufacturing companies of EWDs, endoscopes and process chemicals. The results of the working group will be published divided in three parts. The present part contains the uniform interpretation of the standard related to the nature, requirements, conduct and scope of the tests to be performed for type testing EWDs. The implementation of these requirements can only be achieved in close cooperation between manufacturers of EWDs, endoscopes and process chemicals and requires considerable material and financial expenditure. However, this considerable commitment of expenditure is justified by the significant increase in the safety of patients undergoing endoscopic examinations and procedures.

Preface

Within the EN ISO 15883 series of standards, the revised version of Part 4 "Washer-disinfectors – Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes" [1] was published in 2018. This standard contains important changes and supplements compared to the previous version [2] from 2009. This applies in particular to the points listed in the national preface to the German version:

- Extensive revision of the performance requirements, e.g. requirements for challenge substances;
- More detailed specification of the requirements for process testing;
- Extensive revision of the requirements for the water used for the final rinse following disinfection;
- Extensive revision of the requirements for conducting type testing with the test load in conjunction with verification of the cleaning efficacy;
- Revision of the summary of the tests to be performed in addition to EN ISO 15883-1;
- Inclusion of normative Annex H regarding the definition of endoscope type test groups;

Keywords
- instrument reprocessing
- thermolabile (heat-sensitive) endoscopes
- type testing
- washer-disinfectors (WD)
- EN ISO 15883
- cleaning
- disinfection

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- Inclusion of informative Annex I regarding the definition of endoscope product families.

These changes have significant implications for the requirements, conduct and scope of type testing washer-disinfectors for reprocessing thermolabile endoscopes (EWDs), also known as automated endoscope reprocessors (AERs).

The *Type Testing EWDs 2.0* working group was set up for the purpose of arriving at a uniform interpretation of this complex standard, while taking account of the relevant parts of the EN ISO 15883 series of tests.

The working group's objective was to develop a uniform, common understanding of the nature, requirements, conduct and scope of the tests to be performed for type testing EWDs. It also aimed to formulate recommendations for testing components (e.g. process chemicals) not taken into account in the type test.

Employees of all the EWD manufacturing companies represented in the German market were invited to participate in the working group. The manufacturers of reprocessable endoscopes and process chemicals were each represented by employees from two different companies. The other manufacturers of process chemicals in Germany are kept informed about the status of the work and the findings by the German Industrial Association for Hygiene and Surface Protection (IHO), while other suppliers of endoscopes on the German market are updated by the existing working groups. Furthermore, continuous updates on the work progress are given by the *Validation of EWDs Guideline Group and the Instrument Preparation Working Group (AKI).*

The *Type Testing EWDs 2.0* working group was active in the period September 2020 to July 2022 and was coordinated by the AKI. Here a list of participants, in alphabetical order: Markus Auly (Belimed), Ilka Barteldes-Neubauer (Belimed), Priv.-Doz. Dr Holger Biering (coordinator), Francesco Calzavara (Steelco), Denys Dhiver (Steris), Dr Sascha Eschborn (Olympus), Vincent Evers (Wassenburg), Markus Fürg (MMM), Philipp Hergesell (Cantel), Markus Hoppe (Miele), Henny Knorth (Wassenburg), Aaron Papadopoulos (Ecolab), Kathrin Pechmann (MMM), Annette Rittich (Olympus), Verona Schmidt (Dr Weigert), Daniela Schricker (Dr Weigert), Ines Willam (Karl Storz).

The working group's findings on the various aspects of EWD type testing will be published in the following parts:

Part 1: Scope and conduct of tests by the EWD manufacturer.
Part 2: Challenges faced by the manufacturers of EWDs and endoscopes when defining endoscope type test groups in accordance with EN ISO 15883-4:2018, Annex H.
Part 3: Scope and conduct of tests for process chemicals not taken into account by the EWD manufacturer in the type test.

Introduction

Already Point 4.1.3 of the EN ISO 15883-4 version of the standard from 2009 stipulated that the type test should provide evidence that the endoscope was free of vegetative bacteria (but not necessarily spores) and other soils at the end of the entire reprocessing process in the EWD. Moreover, as set out in Section 8, the EWD manufacturer should provide the economic operator (clinical service provider) with a list of compatible endoscopes that can demonstrably be reprocessed in accordance with the requirements of this standard [2]. However, no information was given on how this requirement could be implemented by the EWD manufacturer within the framework of an acceptable test scope, bearing in mind the large number of different endoscopes from various manufacturers being used.

For that reason the *Type Testing EWDs 1.0* working group recommended [3] that testing of the entire process be carried out with two endoscopes each with, if necessary, corresponding connectors per endoscope family in accordance with the ESGENA definition [4].

With the current version of the EN ISO 15883-4 standard from 2018 this gap was closed. Annex H, which is a normative part of that standard, gives a guide to classifying endoscopes into type test groups. This limits the scope of type testing to a feasible scale. This approach can only be implemented in close cooperation between the manufacturers of the EWDs and endoscopes.

Details of how to use this guide to form type test groups in accordance with Annex H will be given in Part 2 of the publication series on the findings of the Type Testing EWDs 2.0 working group.

Normative requirements

The requirements and tests set out in Parts 1, 4 and 5 of the EN ISO 15883 series of standards must be taken into account in the type test. At the time of compiling the recommendations of the *Type Testing EWDs 2.0* working group, Part 1 of the EN ISO 15883 standard was undergoing revision and Part 5 was published just in 2021. The following standards were used as a basis for the recommendations given below for conduct of EWD type testing:

- prEN ISO 15883-1:2020: Washer-disinfectors – Part 1: General requirements, terms and definitions and tests [5]
- EN ISO 15883-4:2018: Washer-disinfectors – Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes [1]
- EN ISO 15883-5:2021: Washer-disinfectors – Part 5: Performance requirements and test method criteria for demonstration of cleaning efficacy [6].

The following overview does not take account of farther reaching requirements stemming from other European standards and which have to be considered within the framework of the conformity assessment procedure for obtaining a CE mark for the EWD (e.g. electrical safety of EWD). In the interest of transparency, the working group deems the following grouping of the requirements and tests to be useful:

A. Testing the EWD engineering elements
B. Testing the water and process chemicals
C. Testing the EWD in combination with process chemicals
D. Test the EWD in combination with process chemicals and endoscopes.

Conduct of testing

A. Testing the EWD engineering elements

The essential requirements for a washer-disinfector (WD) and the corresponding tests for their implementation are described in Part 1 of the EN ISO 15883 series of standards [5]. For EWDs the main focus of type testing is on the requirements to be met by the doors and their locks, leak tightness and the machine dead volume, readability of the display instruments as well as calibration of measurement instruments. The requirements addressed to the loading rack relate to its stability and

Table 1: Tests engineering elements of EWD

Brief description of test	prEN ISO 15883-1:2020	
	Requirements/subclauses	Test/subclauses
Thermometric		
Thermal disinfection:		
Final rinse water tank	5.3.5	6.8.4
Temperature control:		
Over-temperature cut-out	5.8.3	6.8.5
Fluid emission		
Chamber leak proof	5.1.2.6; 5.1.2.7	6.5.2
Doors and interlocks		
Cycle start	5.4.1.8	6.3.1
Loading/unloading	5.4.3.1	6.3.2; 6.3.3; 6.3.4
On fault condition	5.4.1.5	6.3.5; 6.3.7
Door interlock	5.4.3.2	6.3.7
Air Quality	4.5.3; 4.5.4	6.11
Pipework		
Dead volume	5.5.1.2	6.5.1
Free draining	4.1.7	6.5.3; 6.5.4
Leakage	5.1.2.6; 5.1.2.7	6.5.2
Venting system	5.24.2; 5.24.5	6.5.5; 6.5.6
Instrumentation		
Legibility	5.12.3	6.6.2
Calibration	5.11.1; 5.11.2; 5.11.3; 5.11.4 c)	6.6
Load carriers – internal		
Stability	5.27.1 a) + b)	6.7.1
Alignment	5.1.3.2	6.7.1
Fitting	5.1.3.5	6.7.1
Force to move	5.27.1 c)	6.7.1
Trolleys		
Alignment	5.28.2	6.7.2
Operating cycle		
Fault indication	5.22.1	6.3.5; 6.3.6; 6.3.8
Automatic control	5.19.5	6.13
Brief description of test	**EN ISO 15883-4:2018**	
	Requirements/subclauses	**Test/subclauses**
Leak tester fault and pass condition	4.2.3	6.5.3.3
Leak test	4.2.4	6.5.3.2
Leak test non-connection test	4.2.5	6.5.3.4
Temperature throughout process	4.3.3; 4.4.3; 5.4.2; 5.4.3	6.9.1
Channels non-obstruction test	5.2.2.1	6.6
Channels non-connection test	5.2.2.2	6.7
Minimum process temperature test	5.4.4	6.9.2

alignment as well as to rack insertion into the EWD and the force needed to move the rack.

Part 4 of the EN ISO 15883 series of standards sets out the specific technical requirements and tests for reprocessing thermolabile endoscopes in washer-disinfectors [1]. This includes issues around leakage tests and failed tests, testing for channel blockages as well as testing for non-connection of channels. Besides, maintenance of the defined temperatures during the entire process is checked (Table 1).

B. Testing the water and process chemicals

In automated reprocessing of thermolabile endoscopes, detergents and disinfectants are used as process chemicals in addition to water.

As part of the type test, the physicochemical and microbiological quality of the water used must be checked and defined for the different process steps [Table 2].

The detergents and disinfectants used in Europe for automated reprocessing of thermolabile endoscopes are tested and manufactured in accordance with the Medical Device Regulation (MDR) [7].

Pursuant to MDR, process chemicals devoid of antimicrobial efficacy, such as e.g. detergents, are classified as Class I medical devices and identified by a CE mark on the label.

Process chemicals with antimicrobial efficacy, which are used e.g. for automated terminal disinfection at room temperature or high temperature (instrument disinfectants), are classified as Class II b medical devices. These are identified by a CE mark together with a four-digit number denoting the competent Notified Body.

To obtain a CE mark the efficacy and safety of the process chemicals must be tested by the manufacturer and confirmed in a conformity assessment procedure.

Pursuant to MDR, the manufacturer must guarantee the performance and safety of their products. The composition of the process chemicals must be tested and demonstrated with regard to the application properties to be achieved, such as e.g. the cleaning performance, disinfectant efficacy and material compatibility vis-a-vis the medical devices to be reprocessed and the recommended washer-disinfectors. Furthermore, evidence must be provided of the biocompatibility of the process chemical residues, and threshold values and methods for monitoring them must be defined according to EN ISO 15883-5:2021 [6].

For the water quality in the cleaning step in the EWD the interaction between the water constituents and components of the detergent are determining factors elucidated while developing the detergent. However, if no specific requirements, for example as regards the water hardness, have been stipulated for the cleaning step in the EWD, conduct the type tests with water of standardized hardness [1].

Microbiological *in vitro* tests of disinfectants are carried out in accordance with the European test methods for testing the bactericidal, fungicidal, mycobactericidal, virucidal and, possibly, sporicidal efficacy as set out in Table 2. Both EN ISO 15883-4 [1] and EN 14885 [8] stipulate phase 2, step 1 and phase 2, step 2 tests (if available) for testing the disinfectants used for instrument disinfection. As a result of the *in vitro* tests the disinfectant efficacy is confirmed under process conditions (concentration, exposure time, temperature) and the most resistant microorganisms identified for further tests.

National requirements may mandate further tests.

C. Testing the EWD in combination with process chemicals

When testing the EWD with process chemicals, the EWD functions are tested in interaction with the detergents, disinfectants as well as with the water and EWD. This entails ascertainment and definition of tolerance limits for the water volume of each process step as well as the dosage precision of the detergent and disinfectant process chemicals. The displays must also be checked for any

Table 2: Tests water and process chemicals

Brief description of test	prEN ISO 15883-1:2020	
	Requirements/ subclauses	Test/subclauses
Definition of water quality for each process stage	5.23.1	6.4
Brief description of test	**EN ISO 15883-4:2018**	
	Requirements/ subclauses	**Test/subclauses**
In vitro efficacy of disinfectant		
Applicable European test methods:		
Bactericidal efficacy (EN 13727, EN 14561)	4.4.1; 4.4.2	6.12.1; 6.12.2
Yeasticidal efficacy (EN 13624, EN 14562)	4.4.1; 4.4.2	6.12.1; 6.12.2
Mycobactericidal efficacy (EN 14348, EN 14563)	4.4.1; 4.4.2	6.12.1; 6.12.2
Virucidal efficacy (EN 14476, EN 17111)	4.4.1; 4.4.2	6.12.1; 6.12.2
Sporicidal efficacy (EN 17126) (optional – modified to detect 6 $\log_{10}$ reduction)	4.4.1; 4.4.2	6.12.1; 6.12.2

indication of insufficient amounts of these process chemicals in the respective storage containers for the next reprocessing cycle.

If applicable, national regulations, such as backflow protection for the drinking water system, must be observed and verified.

Other tests involve self-disinfection, disinfection of the liquid transport system after failure of the water treatment system, disinfection of the water treatment system in the EWD (if present) as well as the water quality for the final rinse (Table 3). The chemical and microbiological water quality for the final rinse must not adversely impact the extent of cleaning and disinfection achieved in the preceding process steps [5].

D. Testing the EWD in combination with process chemicals and endoscopes

The requirements from Part 1 of the EN ISO 15883 series of standards in this test step relate to the final rinse step and the drying of endoscopes (Table 4). The last rinse step in the EWD must be designed such that residual contaminants are removed from the reprocessed supplies and the remaining amounts of detergent and disinfectant process chemicals will not negatively affect the use of the endoscope on the patient or the subsequent process steps (for example sterilization).

The performance of the cleaning step, disinfection step and overall process in the EWD is tested with surrogates and endoscopes.

Pursuant to MDR, flexible endoscopes are classified as invasive medical devices [7]. Hence, to test the cleaning performance in accordance with the provisions of EN ISO 15883-5:2021, quantitative determination of the residual protein amount as well as of another analyte is required, in addition to visible cleanliness [6].

Basic cleaning tests must be performed with a surrogate defined in the standard and contaminated with biofilm. Before conducting any further tests of the cleaning performance with surrogates and endoscopes, the endoscopes recommended by the EWD manufacturers for reprocessing must be classified into relevant type test groups and the most representative endoscope defined with the respective surrogate for each of these groups.

The biofilm soil is used as an obligatory test soil. Besides, other clinically relevant soils must be considered. Examples of such soils are given in Part 5 of the ISO 15883 series of standards, Annex A1 [6]. For the tests with biofilm at least one surrogate must be used with the B2 block. The tests with at least one clinically relevant soil are carried out with surrogates for all relevant type test groups. Following the tests, the tubing systems must be visually evaluated. Furthermore, the amount of residual protein as well as, if applicable, of another analyte is determined [6].

If the surrogates can be adequately cleaned, extend the tests to the inner

Table 3: Tests of EWD in combination with process chemicals

Brief description of test	prEN ISO 15883-1:2020	
	Requirements/	Test/subclauses
Water		
Volume of water used per stage	8.2 b)	6.4.3
Backflow protection for porable water system	5.23.3 note	no test discribed
Final rinse water quality	4.4.3	6.4.2 exeption 6.4.2.1
Prior to IQ, OQ and PQ	8.2 b)	6.4.4
Chemical Dosing		
Accuracy and repeatability	5.7.5	6.9
Low level indicator	5.7.6	6.9
Brief description of test	**EN ISO 15883-4:2018**	
	Requirements/ subclauses	**Test/subclauses**
Self-Disinfection Test		
thermal	4.8; 4.8.6	no test discribed
chemical	4.8; 4.8.7	6.12.3
Disinfection of liquid transport system following failure	4.8.5	6.12.5; Annex D
Test of microbial quality of final rinse water treatment equipment	4.5.2; 4.9.2.3	6.12.4
Water quality used for final rinsing	4.5; 4.9.2.3	6.3; Annex E
Chemical dosing test (single container) – if applicable	5.7	6.10

and outer surfaces of the endoscope. Here, too, the cleanliness of the outer endoscope surfaces is visually evaluated. In addition, the amount of residual protein as well as, if applicable, of another analyte is determined [6].

The disinfection performance is tested with a surrogate representing each of the type test groups and contaminated with the most resistant mycobacteria species. The process is deemed effective if a reduction of 6 log levels has been achieved. National authorities may impose different requirements.

The overall process performance is tested with surrogates using the test method given in Annex B of Part 4, but with additional test soil and with endoscopes and the most resistant microorganism determined in previous tests. The results are evaluated in accordance with the criteria specified for the individual test organisms in Section 4.1.4 of Part 4. If provision has been made for a drying step in the EWD, the elimination of residual moisture on the inner and outer surfaces of endoscopes at the end of the reprocessing process must be checked. The requirements and tests from Parts 1 and 4 of the EN ISO 15883 series of standards must also be taken into account (Table 4).

Table 4: Tests of EWD in combination with process chemicals and endoscopes

Brief description of test	prEN ISO 15883-1:2020	
	Requirements/ subclauses	Test/ subclauses
Performance final rines stage ; Process residuals	4.4.1 ; 4.4.2	6.10.4
Load dryness	4.5.1 ; 4.5.2	6.12
Brief description of test	**EN ISO 15883-4:2018**	
	Requirements/ subclauses	**Test/ subclauses**
Cleaning efficacy		
Method acc. to EN ISO 15883-5:2021, Annex A – see Table A.1 "Flexible endoscopy – Biofilm test soil" Using surrogate acc. Annex H incl. Block B2	4.3.5	6.11.3.2 a)
Tests using surrogates acc. Annex H definition define test soils and analytes using EN ISO 15883-5:2021, 4.4 and Annex A – see Table A.1 "Flexible endoscopy"	4.3.5	6.11.3.2 b)
Tests using endoscopes acc. Annex H definition define test soil and analytes using EN ISO 15883-5:2021, 4.4 and Annex A see Table A.1 "Flexible endoscopy"	4.3.5	6.11.3.2. c)
Evaluation of results acc. to EN ISO 15883-5:2021 Pass critera: - visually clean (according to 4.4.2) and - residual protein < 3 µg/cm2 (acc. to 4.4.3.2) and - at least one other analyte (acc. to 4.4.3.3)		
Disinfection efficacy (disinfection only, no cleaning stage)		
Tests using surrogates acc. Annex H definition Test organism: worst case *Mycobacterium sp.* Pass criteria: 6 log	4.4.2.5	6.12.6.1
Efficacy of total process (cleaning + disinfection stage)		
Tests using endoscopes acc. Annex H definition	4.1.3	Annex C, Table C1, annotation C
Representative surrogate with block A2 and B2 acc. to Annex H Soiling and test microorganism acc. to 4.1.3	4.1.3	Annex C, Table C1, annotation F
Evaluation of results	4.1.3	4.1.3
Drying – if applicable	4.7	6.8

Discussion

The requirements and tests applicable to EWD type testing are summarized in the EN ISO 15883 series of standards, in Part 1 in Annex A and in Part 4 in Annex C. In prEN ISO 15883-1:2021 this information has an *informative* character [5]. In the EN ISO 15883-4:2018 standard this summary in Annex C compared with the previous version has been changed from *informative to normative*. Therefore, these requirements and tests must be successfully implemented [1]. It should also be noted that certain requirements from Part 1 in Section 4.1.1 of Part 4 have been excluded from the EWD type test.

National regulations on the scope, conduct and acceptance criteria of the tests are still possible; hence, there may be different interpretations depending on the country. The working group focused on the type test requirements applicable to the German market, while taking account of the national provisions in other European countries, but without claim to completeness.

The outcomes of discussions in the *Type Testing EWD 2.0* working group are described below.

A. Testing the EWD engineering elements

The requirements and tests of the engineering elements (Table 1) were uniformly interpreted by all EWD manufacturers represented in the working group and implemented when type testing their EWD.

B. Testing the water and process chemicals

The requirements for the water quality (Table 2) were uniformly interpreted by all EWD manufacturers represented in the working group and implemented when type testing their EWD. Only process chemicals that met the MDR requirements and displayed a CE mark were used.

The microbiological *in vitro* efficacy tests of disinfectants were performed as per the European test standards. The activity spectrum required for endoscope reprocessing comprised bactericidal, fungicidal, mycobactericidal and virucidal efficacy (Table 2).

As specified by EN ISO 15883-4 [1], the chosen disinfectant must also be active against bacterial endospores. The disinfectant should be able to reduce the population of bacterial endospores under application conditions (concentration, temperature) within 5 h by at least 6 $\log_{10}$ levels or by an equivalent rate.

This means that when observing the exposure time in the disinfection step, disinfectant sporicidal efficacy is generally not required. However, this may be necessary in justified cases e.g. against hygienically relevant spore formers such as *Clostridoides difficile*.

National differences are permitted in the microbiology disinfectant tests used for EWD type testing [1]. In Germany, for example, for testing the virucidal activity the requirements specified by the German Association for Control of Viral Diseases (DVV)/Robert Koch Institute (RKI) are used [9, 10].

The EN ISO 15883-4 standard [1], Sections 4.3 and 4.4, points out that disinfectant efficacy can be affected by the entrainment ("carry-over") of detergents and organic challenge to the disinfection step. Therefore, a general intermediate rinse step is required between the cleaning and disinfection steps. An intermediate rinse step can be omitted only if it can be demonstrated that no undesirable reactions can occur between process chemicals and no undesirable reactions between suspended or residual contaminants and the disinfectants (see Section 4.3.4).

As a result of discussions in the working group, the following procedure is recommended in the event of omission of the intermediate rinse step:

It is difficult to estimate the effects of entrainment of organic challenge in the disinfection step because of the contamination expected after patient use and the resulting baseline challenge. For that reason risk assessment of the organic challenge in the disinfection step should be carried out to meet the requirements. This should include all manual cleaning steps prior to automated reprocessing in the EWD. Risk analysis also serves as a basis for deciding whether the disinfectant *in vitro* tests can be carried out with a low organic challenge in accordance with the European test standards.

In addition, the calculated entrainment of detergents from the cleaning step to the disinfection step in the in vitro tests in accordance with Section 4.4.2.4.2 of the EN ISO 15883-4 [1] standard should be taken into account.

C. Testing the EWD in combination with process chemicals

The precision of the water volume in each process step, the corresponding dosage of detergents and disinfectants and thus the concentration of process chemicals in the cleaning as well as the disinfection step are of decisive importance. The quality of the water is specified by the EWD manufacturer. The economic operator is responsible for monitoring the water quality, which is usually carried out externally within water supply system.

Measures to protect the drinking water against contaminants from backflow from the EWD in accordance with DIN EN 1717:2011 [11] are mandated for the German market as well as for a number of other European countries.

Whether testing of disinfection of the liquid transport system within the EWD after failure of the water treatment system is done with or without connected endoscopes is not specified in the EN ISO 15883-4 standard. In the discussion it was noted that this was interpreted differently by the manufacturers during the type tests. The group saw no factual basis for defining a preference for one or the other variant.

D. Testing the EWD in combination with process chemicals and endoscopes

Implementation of the revised Part 4 of the EN ISO 15883 series of standards requires more intensive cooperation between the manufacturers of EWDs, endoscopes and process chemicals. This is also stipulated in Annex A of this standard and applies in particular to implementation of the classification of endoscopes into type test groups in accordance with the *normative* Annex H [1]. In the working group it was noted that this higher intensity of collaboration during EWD type testing was largely achieved after the conclusion of corresponding non-disclosure agreements. Part 2 of the publication series on the findings of the *Type Testing EWD 2.0* working group will report in detail on this as well as on implementation of the provisions of Annex H.

The cleaning performance is tested with surrogates as well as with endoscopes. First, a cleaning test is performed with at least one surrogate consisting at least of block B2. Biofilm was used as test soil.

The working group recommends that tests to verify biofilm elimination be carried out with the method given in Annex F of ISO/TS 15883-5:2005 because this contains a practicable description [12]. Evaluation is based on the quantitative determination of protein and polysaccharides following appropriate elution. As a further analyte, TOC can be determined instead of polysaccharides.

The working group recommends contaminating the surrogates and endoscopes of each relevant type test group with the test soil "coagulated blood", proposed for flexible endoscopes in Table A.1 of the ISO 15883-5:2021 standard and to use the method specified there for conducting the tests with endoscopes [6, 13].

The results are evaluated through visual inspection and quantitative analysis of the protein amount.

The acceptance criteria for the different analytes are described in chapter 4.4.3.3, Part 5 of the ISO 15883 series of standards 6].

The working group is of the opinion that quantitative determination of polysaccharides and/or TOC in the biofilm test serves to meet the requirement specified in the EN ISO 15883-5:2021 standard that evidence of another analyte be provided in addition to protein as analyte [6].

The disinfection performance is tested with surrogates from each type test group and the most resistant mycobacteria species. In these tests the influence of the proceeding process steps (in particular rinse effects) must be borne in mind as specified by the provisions of Annex F of Part and considered when evaluating the results.

For testing the overall process, Part 4 of the EN ISO 15883 series of standards requires testing with the most resistant microorganism determined by *in vitro* testing with surrogates and endoscopes. The soiling methods may be those described in Annex B of Part 4, but with additional test soil, or elements from Annex I of ISO/TS 15883-5:2005 [12].

The EN ISO 15883-4 standard does not clearly specify whether testing of the overall process must be carried out with one or several of the most resistant microorganisms. In the discussion it was noted that this was interpreted differently by the manufacturers during type testing. The group saw no factual basis for defining a preference for one or the other variant.

The tests on surrogates must be conducted with at least one surrogate from blocks A2 and B2 as per Annex H (Table C1, footnote F) [1].

Moreover, tests with representative endoscopes are required. For conduct of these tests, the announcement by the German Society of Hospital Hygiene (DGKH) on adaptation of the method from Annex I of the ISO/TS 15883-5:2005 standard to a revised ISO format [13] has proved useful, because neither a method nor a reference source is given for this in the standard. As regards the soiling of channels apart from the instrument channel, there is no uniform interpretation of the requirements set out in the standard.

The final rinse process step must be interpreted such that the remaining residues of process chemicals do not present any risk to the patient when the endoscope is used. This can be demonstrated when type testing the EWD

- by determining the amount of process chemical residues on the surface of representative surrogates or endoscopes and demonstrating that this amount is below the biocompatibility threshold value identified by the manufacturer of the process chemicals (see chapter on Test Conduct, Sect. B) or
- by checking the biocompatibility of the endoscopes after the reprocessing process in accordance with the EN ISO 10993-1:2021 [14] standard.

The EWD manufacturer is responsible for carrying out these investigations. Additional tests to investigate the influence of repeated reprocessing of endoscopes on their biocompatibility must be performed as per MDR by the endoscope manufacturers as part of the conformity assessment procedure for the endoscopes. The endoscope manufacturers are also responsible for choosing the reprocessing processes to be used, based on risk analysis.

Conclusion

Extensive studies carried out in the past have revealed that not all endoscope types from all manufacturers can be reprocessed in all EWD processes with equally satisfactory results [15]. With the updated version of Part 4 of the EN ISO 15883 series of standards, guidance is now available for conduct of performance tests of the individual processes in the EWD for specific endoscopes or endoscope groups.

Within the framework of the working group's activities a largely uniform understanding was reached for interpretation and implementation of the requirements set out in the standards for EWD type testing. For certain partial aspects, each EWD manufacturer's individual decision is still needed.

The EWD manufacturers are collaborating with the manufacturers of the endoscopes and process chemicals while committing considerable material and financial expenditure to implement these requirements. However, this considerable commitment of expenditure is justified by the significant increase in the safety of patients undergoing endoscopy examinations and procedures.

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