Scope and performance of type test of washer-disinfectors used to reprocess thermolabile endoscopes as per standard series EN ISO 15883

H. Biering, B. Kampf[1], A. Rittich[2]*

Type testing of the washer-disinfectors used to reprocess thermolabile endoscopes (EWDs) serves as the basis for risk assessment during automated reprocessing of thermolabile endoscopes and as proof of EWD compliance with the normative requirements. In addition, any modifications or supplements based on national requirements and provisions must also be observed.
The relevant standards are highly complex, allowing a broad margin of latitude for both the EWD manufacturers and the accredited test centres. This results in widespread variability in the scope of the type test used for EWDs already on the market. A working group, the Type Test Working Group, has now reviewed the general as well as, in particular, the German requirements underlying the type test in order to reach a consensus on the requisite test scope and thus make it easier for users to compare EWD performances.

KEYWORDS
- instrument reprocessing
- thermolabile endoscopes
- cleaning
- disinfection
- type test
- EWD
- EN ISO 15883

Introduction

Responsibility for type testing a washer-disinfector for thermolabile endoscopes (EWDs) is taken by the EWD manufacturer. The type test serves as the basis for risk assessment during automated reprocessing of thermolabile endoscopes and as proof of EWD compliance with the requirements of EN ISO 15883-1 (1) and -4 (2), while applying the methods set out in ISO/TS 15883-5 (3). A successful type test outcome will reassure the operator that all the product features specified by the EWD manufacturer have been tested and confirmed and that the respective EWD fully meets the essential requirements of medical device legislation. The type test also serves as the basis for generation of reference data for subsequent tests, such as e.g. the works test at the manufacturer's premises as well as for validation and routine checks by the clinical service provider.
Pursuant to subclause 4.1.3 of EN ISO 15883-4, the type test must demonstrate that at the end of the EWD cycle the endoscope is free of vegetative bacteria (but not necessarily of spores) and other soils. The type test should be able to demonstrate this for all endoscope types to be reprocessed in the EWD. Any factors that could impact a successful reprocessing outcome, for example the design of connectors, must also be taken into account.
As required by EN ISO 15883-4, Section 8, and based on the type test results, the EWD manufacturer must provide the clinical service provider with the following information:

- A list of compatible endoscopes whose successful reprocessing in the EWD has been demonstrated,
- An operating manual for the specific EWD which, amongst others, describes the precautions or operating conditions for certain endoscopes,
- For each endoscope a description of the connectors needed to flush the channels,
- A list of detergents and disinfectants specified at the time of the type test.

The market experience gained in the years following the introduction of EN ISO 15883-4 has highlighted differences in the EWD type test with regard to:

- The nature and scope of the tests,
- Inclusion of representative endoscopes from different manufacturers.

This is largely the result of the different conflicting interests and dependencies:

- On the one hand, the interests of the EWD manufacturer, who for the type test is reliant on the information supplied by the manufacturers of the endoscopes and process chemicals, and the desire to keep the test scope within a reasonable limit,
- On the other hand, there is the EWD operator who wants to have maximum assurance of the safety of the endoscopes used and reprocessed on their premises.

Besides, the relevant standards are very complex, allowing a broad margin of interpretational latitude for both the manufacturers and the accredited test centres. Against that background and in the interest of all parties involved, the requisite scope of the type test needs to be defined, taking account of all relevant aspects of

* H. Biering,Gladiolenstrasse 19, 41516 Grevenbroich, Germany. E-mail: holger.biering@web.de
1 Pentax Europe GmbH, Hamburg, Germany
2 Olympus Europa SE & CO. KG, Hamburg, Germany

patient safety and keeping the test scope within a reasonable limit.

To that effect, at the time of compiling the Guideline for validation of automated cleaning and disinfection processes for reprocessing thermolabile endoscopes (4) an expert working group was formed, comprising the manufacturers of EWDs, endoscopes and process chemicals. The representatives of endoscope and process chemicals' manufacturers promoted the interests of their respective areas, engaged in continual conversations during meetings with other market participants and communicated their findings. Since until then there was no dedicated body representing the EWD manufacturers, all manufactures marketing EWD's in Germany at that time were contacted and invited to participate.

The Type Test Working Group was active from 2010 to 2013 and was coordinated by the Working Group Instrument Reprocessing (AKI). Its members were as follows: Eike Bach (ASP), Markus Auly (Belimed), Assistant Prof. Dr. Holger Biering (AKI), Helmut Fromberger (Belimed), Markus Kamer (Dr. Weigert), Dr. Birgit Kampf (Pentax), Petra Labonte (BHT), Annette Rittich (Olympus), Anne Schlingmann (Olympus), Verona Schmidt (Dr. Weigert), Ronald Wassenburg (Wassenburg Medical).

Normative requirements to be met by the type test

The type test is performed with EWD prototypes which must be identical to the serial production machines in terms of the engineering elements, processes to be executed, process control as well as the safety and alarm functions. Retrospective alterations to EWDs already on the market and type tested must be evaluated in accordance with the Medical Devices Directive, Annex II subclause 3.2 (5) by carrying out risk analysis of factors influencing the type test results. If necessary, a repeat, partial or complete type test is needed, for example in the event of any:

- Constructional changes, including new connectors
- Replacement of materials and use of alternative components
- Changes to the process parameters
- Changes to the control software
- Changes to the process chemicals

Table 1a: Tests engineering elements of EWD according to EN ISO 15883-1:2009

Brief description of test	Requirements/ subclauses	Test/subclauses
Thermometric		6.8
Thermal disinfection		
Chamber walls	4.3.1.2, 4.3.1.3, 4.3.3.2 und 5.9.2	
Load carrier	4.3.1.2, 4.3.1.3	
Final rinse water tank	5.3.2.5	
Load (not applicable for thermolabile endoscopes)	4.3.1.1, 4.3.1.3, 4.3.3.1, 5.9.1	
Temperature control:		
Rate of rise	4.1.4	
Flushing stage	4.2.2	
Washing stage	4.2.3	
Over-temperature cut-out	5.8.3	
Chemical Disinfection:		
Chamber walls and load carrier	4.3.2	
Load	5.3.2.3, 4.3.2, 4.3.3	
Fluid emission		6.5
Chamber leak proof	5.1.7. 5.1.8	
Doors and interlocks		6.3
Cycle start	5.4.1.8	
Loading/unloading	5.4.3.1	
On fault condition	5.4.1.5	
Door interlock	5.4.3.2	
Air Quality	4.5.3, 4.5.4	6.11
Pipework		6.5
Dead volume	5.5.1.3	
Free draining	4.1.7	
Venting system	5.24.2	
Instrumentation		6.6
Legibility	5.12.3	
Calibration	5.11	
Load carriers – internal		6.7
Stability	5.27.1 a), b)	
Alignment	5.27.4	
Fitting	5.27.5	
Force to move	5.27.1 b)	
Trolleys		6.7
Alignment	5.28.2	
Operating cycle		6.3, 6.8, 6.10
Spray system	5.6	
Reproducibility	5.9.1 c)	
Fault indication	5.22.1	

The range of tests to be conducted during the type test is summarized in standard EN ISO 15883-1, Annex A as well as in standard EN ISO 15883-4, Annex C. In general, the tests can be subdivided as follows:

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

A. Testing the EWD engineering elements

Part 1 of the standard EN ISO 15883 "General requirements, terms and test methods" specifies the essential requirements to be met by washer-disinfectors and corresponding test methods. This includes engineering elements such as, for exam-

Table 1b: Tests engineering elements of EWD according to EN ISO 15883-4:2009

Brief description of test	Requirements/ subclauses	Test/ subclauses
Leak test failure alarm	4.2.3	6.5
Leak test	4.2.5	6.5
Leak test non-connection test	4.2.4, 4.2.5	6.5
Temperature of disinfectant stage	4.4.3	6.9
Channels non-obstruction test	5.2.2.1	6.6
Channels not conntected test	5.2.2.2	6.7
Temperature throughout process	5.4.2, 5.4.3	6.9.1
Minimum process temperature test	5.4.4	6.9

Table 2: Tests of water and process chemicals

Brief description of test	EN ISO 15883-1:2009	
	Requirements/ subclauses	Test/ subclauses
Water quality	4.4.1	6.4
Rinse water	4.4.2, 4.4.3, 4.2.1.2	
Brief description of test	**EN ISO 15883-4:2009**	
	Requirements/ subclauses	**Test/ subclauses**
In vitro efficacy of disinfectant suspension tests acc. to EU standards (phase 2; step 1 and step 2 [if applicable]) in the relevant process time, temperature and concentration under consideration of carry over of residues (process chemicals and soiling) between cleaning and disinfection stage; process chemicals at the end of the shelf life	4.4.2 4.3.4	6.12.1 6.12.2
European test methods:		
Bactericidal efficacy (EN 13727, EN 14561) Fungicidal efficacy (EN 13624, EN 14562) Mycobactericial efficacy (EN 14348, EN 14563) Virucidal efficacy (EN 14476, phase 2/step 2 test is not available at the moment) Sporicidal efficacy (EN 13704, phase 2/step 2 test is not available at the moment) **optional, not mandatory** Define most resistant microorganism of *in-vitro* test		
Further tests recommended by Working Group		
Influence of process chemicals on biocompatibility of endoscopes Responsible: chemical manufacturer		

ple, the doors, chamber, pipework or spray system, the control system, safety features such as alarm functions, access to the load in the event of faults as well as temperature control of the various process steps (Table 1a).

In addition to this, Part 4 of standard EN ISO 15883 sets out specific requirements and test methods for washer-disinfectors used to reprocess thermolabile endoscopes. With regard to engineering and safety features, this refers to, as applicable, endoscope leak tests and alarm generation in the event of faults, indication of non-connection of channels or channel obstruction (Table 1b).

Testing the combination of EWD with endoscopes is particularly important in view of the different endoscope engineering elements, such as for example internal volumes, channel lengths or diameters, but also because of the importance of using connectors of the right fit. These factors can have a major impact on EWD functionality and compromise effective endoscope reprocessing.

B. Testing the water and process chemicals

For automated reprocessing of thermolabile endoscopes water and, as process chemicals, detergents and disinfectants as well as, if applicable, rinse aids are used. Before it is used in the EWD the quality of the process water must be defined in accordance with EN ISO 15883-1, and the microbicidal efficacy of the disinfectant must be tested independently of the EWD in accordance with EN ISO 15883-4 (Table 2). No independent tests are specified in EN ISO 15883 for detergents and rinse aids. Hence, these are only tested in combination with the EWD, as described in Section D of that publication.

The EWD manufacturer must specify the physical/chemical and microbiological quality of the water to be used for the various process steps, which must at least be of drinking water quality. If no value has been defined for the water hardness, type testing must be performed with water of standardized hardness for diluting detergents and disinfectants in accordance with EN ISO 15883-4, subclause 6.4 (2).

The microbicidal efficacy of the disinfectant is verified in *in vitro* tests under conditions relevant to the process such as the temperature, exposure time and concentration of relevance for the process. For these tests disinfectants at the end of their shelf life are used. The European test methods demonstrating bactericidal efficacy, fungicidal efficacy, mycobactericidal efficacy, virucidal efficacy and, as applicable, sporicidal efficacy are employed. In cases where the national requirements are more stringent than their European counterparts, additional tests are needed. For these tests the most resistant microorganism is also ascertained and should be used for subsequent process efficacy tests. Other tests are performed to demonstrate that through the use of an appropriate "dead volume" (see also EN ISO 15883-1, 5.5) the expected carry-over of process chemicals and soils from the cleaning to the disinfection step, taking account of the intermediate rinse step, will not impact disinfectant efficacy.

C. Testing the EWD in combination with process chemicals

When testing the EWD in combination with process chemicals, general technical preconditions are investigated and the initial tests run without endoscopes (Table 3). The technical prerequisites include, in particular, testing of the dosage accuracy

Table 3: Tests of EWD in combination with process chemicals

Brief description of test	EN ISO 15883-1:2009	
	Requirements/ subclauses	Test/subclauses
Cleaning efficacy		**6.10**
Chamber	4.2.1.1	
Load carrier	5.1.10	
Process residuals	**4.4.1, 4.4.2**	**6.10.4**
Chemical dosing		**6.9**
Accuracy and repeatability	5.7.5	
Low level indicator	5.7.6	
Brief description of test	**EN ISO 15883-4:2009**	
	Requirements/ subclauses	**Test/subclauses**
Self-Disinfection Test	**4.8.7**	**6.12.3.1**
Method acc. to EN ISO 15883 Part 5: Annex F (biofilm)		
thermal		
chemical		
with process chemicals		
with different than process chemicals		
Disinfection of liquid transport system following failure	**4.8.5**	**6.12.5.1**
acc. to EN ISO 15883-4, D. 5.2.1		
acc. to EN ISO 15883-4, D. 5.2.2		
Disinfection of water treatment equipment	**4.9.2**	**6.12.4**
Final rinse water treatment – microbial quality	**4.5.2**	**6.12.4**
Chemical dosing test (single container) – if applicable	**5.7**	**6.10**
Further tests recommended by Working Group		
Material compatibility of process chemicals with EWD Responsible: chemical manufacturer, EWD manufacturer		

of the water, detergent, disinfectant and, as applicable, rinse aid and definition of the respective tolerance limits. Likewise, the EDW's ability to indicate an inadequate amount of the respective process chemical in the storage tank for an entire process cycle must also be tested.

In addition, separate tests are needed to demonstrate cleanliness of the chamber walls and load carrier, self-disinfection, disinfection of the liquid transport system as well as, where applicable, the integrated water treatment equipment with regard to the microbiological quality of the rinse water.

- To investigate cleanliness of the chamber walls and load carrier the test methods and test soils specified in ISO/TS 15883-5 (3) should be used. It is possible to use different test soils for the chamber walls and load carrier.
- Self-disinfection can be carried out either by thermal or chemical process. For chemical self-disinfection either the disinfectant used in the disinfection cycle or another disinfectant can be used. In general, preference is given to thermal self-disinfection. The method chosen by the EWD manufacturer needs to be tested in accordance with the methods described in ISO/TS 15883-5, Annex F (3).
- Self-disinfection can also be used to disinfect the liquid transport system after failure of the water treatment equipment. In such cases the effectiveness of that process should be tested in accordance with EN ISO 15883-4, Annex D (2).
- If the EWD has an integrated water treatment equipment, such as for example softener, filter, etc., it should be disinfected at regular intervals. The self-disinfection process described above can be used but in such a case it must in addition meet the requirements set out in EN ISO 15883-4, 6.12.4 (2).

For EWDs with single-dose containers the type test must be able to demonstrate that the specified dosage quantity is delivered. For discrepancies of more than 10% an automated error message should be generated.

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

Testing of the EWD in combination with process chemicals and endoscopes is conducted with surrogate devices and/or real endoscopes, while focusing on the cleaning and disinfecting efficacy or on the efficacy of the entire process in accordance with EN ISO 15883-4 (Table 4):

- The cleaning efficacy as well as the efficacy of the entire process is tested with surrogate devices (e.g. tube model, dummy) and real endoscopes. To reflect the latter, the EWD manufacturer should select endoscopes with engineering elements representing all types of endoscopes to be reprocessed in that EWD.
- All tests of the disinfecting efficacy are performed with surrogate devices.

Part 1 of EN ISO 15883 (1) calls for general testing of the cleanliness of the load. Further details of these tests are given in Part 4 (2) for EWDs.

Testing of the cleaning efficacy is conducted for all programme cycles run in the EWD before the disinfection cycle.

- To investigate cleanliness of surrogate devices and real endoscopes the test methods and test soils described in ISO/TS 15883-5 are used. The only source mentioned in EN ISO 15883-4, 6.11.3 (2) for determination of the cleaning efficacy during the type test is the French biofilm method (ISO/TS 15883-5, Annex F [3]).
- For placement of the EWDs on the German market, the tests specified in ISO/TS 15883-5 Annex I (3) must be conducted additionally. The test soil should be chosen in relation to the internal diameters of the test piece: for an internal diameter of 1 mm non-reactive sheep blood, and for an internal diameter of 2 mm, heparinised and reactivated sheep blood are used as test soil, in all cases with *Enterococcus faecium* as test organism. The test is passed if the test organism is reduced by at least 4 log steps and if, in the case of surrogate devices, these are visibly clean.
- As a first step, 2 m long transparent PTFE tubes with an internal diameter of 2 mm and 1 mm are investigated as surrogate devices. Only after the EWD efficacy has been successfully tested with these surrogate devices further tests are carried out with at least two representative real endoscopes. Based on ISO/TS 15883-5 Annex I (3), the test soil is applied only to the working channel. The standard does not give any further details of the criteria applied for selection of representative endoscopes.

The efficacy of the disinfection stage can be tested according to EN ISO 15883-4 Annex B (2) exclusively with surrogate devices, taking account of several microorganisms.

Pursuant to EN ISO 15883-4, subclause 4.1.3, the efficacy of the entire process must also be demonstrated for all endoscope types which, as per the EWD manufacturer's declaration, can be reprocessed. The reference sources cited in this standard (6, 7, 8) describe a maximum bacterial bioburden of up to 10^9 colony forming units per endoscope. Based on Note 1 (2), the method specified in ISO/TS 15883-5, Annex I (3) using *Enterococcus faecium* or another heat-resistant microorganism as test organism can be applied. Alternatively or additionally, a modified method based on Annex B (2) using real endoscopes can be employed; the current literature does not feature any method to that effect.

If the EWD has a load-drying function, the drying results are recorded. To that effect, the individual channels are flushed with medical compressed air and the residual humidity visually inspected using the crepe paper technique.

Discussion

The tests to be conducted for type testing EWDs are summarized in standard EN ISO 15883, Part 1, Annex A (1) and Part 4, Annex C (2). Both annexes have an "informative" character since not all tests are necessarily of relevance for a particular EWD and national regulations may necessitate modified tests. This can result in different interpretations of the scope and nature of the type test. A successful type test result based on the regulations of one country opens the door to unrestricted marketing throughout Europe. It is therefore in the interest of the national authorities as well as of the individual operator to enquire at the time of EWD procurement whether the national requirements of the specific country have been taken into consideration.

The Working Group dealt primarily with the requirements for type testing EWDs for the German market. The debates in this Type Test Working Group were very open and constructive, and focused on type testing as applied for EWDs already on the market at that time and whose manufacturers were represented in this Working Group.

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

Brief description of test	EN ISO 15883-1:2009	
	Requirements / subclauses	Test / subclauses
Cleaning efficacy		**6.10**
Load	4.2.1.1	
Load dryness	**4.5.1, 4.5.2**	**6.12**
Brief description of test	**EN ISO 15883-4:2009**	
	Requirements / subclauses	**Test / subclauses**
Cleaning efficacy	**4.3.5**	**6.11**
Method acc. to EN ISO 15883 Part 1: Annex C		
Method acc. to ISO/TS 15883 Part 5: Annex F		
Additional test for German market: Method acc. to ISO/TS 15883 Part 5: Annex I		
Test body: PTFE tube (2 m, 2 mm) Soiling: reactivated, heparinized sheep blood, Test microorganism: *Enterecoccus faecium*		
Test body: PTFE tube (2 m, 1 mm) Soiling: non-reactivated, heparinized sheep blood Test microorganism: *Enterecoccus faecium*		
Evaluation of results: Pass criterion: visual cleanliness and 4 log step reduction		
Test with representative devices/device families (min. 2 endoscopes), contamination of working channel only Soiling: non-reactivated (< 2 mm) and/or reactivated (≥ 2 mm) heparinized sheep blood depending on channel diameter Test microorganism: *Enterococcus faecium*		
Evaluation of results: Pass criterion: 4 log step reduction		
Disinfection efficacy (disinfection only, no cleaning step)	**4.4.1**	**6.12.6.1**
Method acc. to EN ISO 15883 Part 4: Annex B		
Evaluation of results: $\log_{10}$ 6 inactivation of vegetative bacteria and yeast $\log_{10}$ 5 inactivation of mycobacteria $\log_{10}$ 4 inactivation of fungal spores and viruses	4.4.2.4	
Efficacy of total process (cleaning + disinfection step)	**4.1.3**	**4.1.3**
Method acc. to ISO/TS 15883 Part 5: Annex I		
Test body: PTFE tube (2 m, 2 mm diameter) Soiling: reactivated, heparinized sheep blood, Test microorganism: *Enterococcus faecium*		
Test body: PTFE tube (2 m, 1 mm diameter) Soiling: non-reactivated, heparinized sheep blood, Test microorganism: *Enterococcus faecium*		
Evaluation of results: Pass criterion: visual cleanliness and 9 log step reduction		
Tests with endoscopes (contamination of working channel): Soiling: non-reactivated (<2mm diameter) and/or reactivated (≥2mm diameter) heparinized sheep blood depending on channel diameter, Test microorganism: *Enterococcus faecium*		
Evaluation of results: Pass criterion: 9 log step reduction If 9 log step reduction technically not feasible, separate evaluation of cleaning and disinfection phase and achieved log reduction from total process		
Drying	**4.7**	**6.8**
Further tests recommended by Working Group		
Material compatibility of process chemicals with endoscopes Responsible: chemical manufacturer, endoscope manufacturer		
Influence on biocompatibility of endoscopes after reprocessing Responsible: chemical manufacturer, EWD manufacturer		

The results of this debate are now presented below.

A. Testing the EWD engineering elements

The scope of testing for the engineering elements in accordance with Parts 1 and 4 of standard series EN ISO 15883 was interpreted similarly by all manufacturers.

B. Testing the water and process chemicals

Likewise, there was also unanimity on testing of the process chemicals, in particular, the in vitro tests for the disinfectant efficacy. The majority of microbiology tests were performed as per the European test standards phase 2, step 1, using the criteria stipulated by the respective standard for bactericidal, mycobactericidal, fungicidal and virucidal efficacy.

For testing instrument disinfectants both EN ISO 15883-4 (2) and EN 14885 (9) specify phase 2, step 1 as well as testing as per phase 2, step 2 (if available).

In summary, the following standards have to be applied:

- Bactericidal efficacy EN 13727 (10) and EN 14561 (11)
- Fungicidal efficacy EN 13624 (12) and EN 14562 (13)
- Mycobactericidal efficacy EN 14348 (14) and EN 14563 (15)
- Virucidal efficacy EN 14476 (16) (phase 2 step 2 test currently not available)

As applicable, national differences have to be taken into account. For example, in Germany virucidal efficacy has to be tested in accordance with the requirements of the DVV/RKI. These differ from the European requirements (17, 18), especially with regard to the choice of test organisms and organic test soil.

The minimum requirements to be met by the spectrum of activity of disinfectants used for reprocessing flexible endoscopes in Germany comprise bactericidal efficacy, fungicidal, mycobactericidal and virucidal efficacy (19). Sporicidal efficacy may be required in certain justified cases (4). Therefore the Working Group recommends that the clinical service provider evaluates the requisite spectrum of activity of the disinfectants used based on endoscope application.

Based on the *in vitro* test results the disinfectant efficacy is confirmed under process conditions (concentration, exposure time, temperature) and the most resistant microorganism identified for further testing as per Annex B (2).

The note in Part 4 (2) of the standard indicating that the disinfectant efficacy could be affected by "carry-over" of detergents and organic soils was interpreted differently by the various manufacturers during the type test.

Following the debate in the Working Group the following approach was recommended:

- It is difficult to estimate the effects of "carry-over" of organic soils to the disinfection stage because of the contamination expected following use on the patient and the baseline bioburden. Against that background, to meet the requirements from EN ISO 15883-4, 4.3.4 and 4.4.2.6 (2) risk assessment should therefore be conducted with regard to organic contamination in the disinfection cycle. This in turn serves as a basis for deciding whether the disinfectant *in vitro* tests should be carried out with the most resistant microorganism, while also using challenge substances (dirty conditions).
- Furthermore, the calculated "carry-over" of detergent should be taken into account for the *in vitro* tests. The amount of residual process chemicals persisting on the endoscope after the reprocessing process should not present any risk to the patient. Different approaches were taken to biocompatibility testing for determination of the tolerable residual amounts. Based on these findings, in addition to the method for determination of the tolerable residual amounts of glutaraldehyde on endoscopes (20, 21) a uniform test method was also devised and published by the manufacturers of process chemicals (22).

C. Testing the EWD in combination with process chemicals

Testing of the technical prerequisites for the combination of EWD with process chemicals was conducted largely similarly by all manufacturers. However, the Working Group discussed the following points:

- If the EWD has its own water treatment equipment, that facility must be disinfected at regular intervals. Based on the type test results, the EWD manufacturer must specify the minimum disinfection frequency for the water treatment equipment. Taking account of seasonal fluctuations in the water composition of the in-house water supply and the experiences gathered from operation of the water treatment equipment, the operator then defines the disinfection intervals.
- In addition to the tests stipulated in standard EN ISO 15883, the Working Group believes there is an urgent need for material compatibility testing of process chemicals in respect of all relevant EWD elements in order to meet the requirements of the Medical Devices Directive Annex I Item 7.3 and 9.1 (5). Examples can include, in particular, material incompatibility with EWD elements leading to particle detachment which can cause endoscope damage and put the patient at risk.

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

EN ISO 15883-4 (2) stipulates that evidence of the process efficacy be demonstrated during the type test. From that can be concluded that all process cycles used in everyday practice should be tested for the predefined load. To limit the test scope to an acceptable level, based on risk assessment the EWD manufacturer can define the process cycles that make the most stringent requirements on the efficacy of the entire process, thus also covering other cycles.

The Working Group debate revealed that while all EWD manufacturers used surrogate devices, they did not always use real endoscopes for testing in accordance with the normative provisions. For testing the cleaning efficacy and, as applicable, the efficacy of the entire process the criteria for selection of representative endoscopes and grouping of endoscope families have not been adequately defined in EN ISO 15883-4. On the other hand, it is not possible to test all endoscopes of different manufacturers on the market. To limit the test scope to an acceptable level, the Working Group decided by way of compromise to test for each endoscope family two representative endoscopes with, as applicable, the corresponding connection pieces, in accordance with the ESGENA definition (23). Discussions taking place in the currently ongoing revision of EN ISO 15883-4 (2) focus on the choice of test endoscopes and the use of test pieces.

If tests are conducted with real endoscopes, based on Annex I of ISO/TS 15883-5 (3), the test soil is applied only to the working channel. The Working Group de-

bated whether restricting contamination (to only one part of a channel) sufficed to demonstrate that all other channels used for patient examination could also be effectively reprocessed. Such considerations should also include application of the test soil to the external surfaces of endoscopes and surrogate devices. The initial experiences from the field indicate that the test soil described in Annex I is not suitable for all channel designs (length, diameter, cable winch, etc.) or external surfaces. Due to their complexity, it was not possible to resolve these issues in the Working Group.
For the German market the cleaning efficacy tests should be conducted with surrogate devices and real endoscopes in accordance with ISO/TS 15883-5 Annex I (3). By contrast, for validation of EWDs in accordance with the guideline (4), Annex 8, it is the residual protein amount that is determined. Therefore the Working Group recommends that for the type test additional tests should be carried out in accordance with Annex 8 of the guideline (24).
Testing of the disinfectant efficacy is performed in accordance with EN ISO 15883-4, Annex B. Here, in addition to *Enterococcus faecium*, a number of organisms which during preliminary tests had proved most resistant to the disinfectants is used.
The entire process must be tested in accordance with EN ISO 15883-4, Item 4.1.3 (2). To that effect, the standard specifies two different reference processes which, however, are subject to interpretational and practical limitations. The Working Group discussions revealed that in Germany current testing is carried out in accordance with ISO/TS 15883-5, Annex I (3) with *Enterococcus faecium* as test organism and using both surrogate endoscopes and real endoscopes. However, at the time the Working Group activity was launched testing of the entire process was performed by very few manufacturers, regardless of whether surrogate devices or real endoscopes were used.
With regard to biocompatibility of the process chemicals, type testing should demonstrate that the EWD process cycles ensure compliance with the acceptable minimum quantities of process chemicals on the endoscope surfaces.
Standard EN ISO 15883 does not stipulate any tests for the material compatibility of the process chemicals with all the relevant elements of the endoscopes. But the Working Group believes such tests are urgently needed since, for example, material incompatibility can detract from endoscope functionality, in turn posing a risk to the patient. It is therefore recommended that the operator obtain such confirmation from the manufacturers of the endoscopes or process chemicals in use.

Conclusions

The Working Group recommends that EWD manufacturers critically appraise the scope of their type tests with regard to:

- The possibility of carry-over of the cleaning solution into the disinfection cycle
- Biocompatibility testing for determination of the residual amounts of active substances on the endoscopes and the need to make process adaptations (rinse steps)
- Investigation of the material compatibility of the type-tested process chemicals with the EWD engineering elements and its implications for the scope and intervals of EWD servicing
- Give consideration to using real endoscopes for the type test to ensure that the results can be extrapolated to the real endoscopes reprocessed in the respective EWD cycle

Besides, the clinical service provider should pay attention to the following points, in particular with regard to safe operation of the EWD on their premises and patient safety:

- The need for reprocessing cycles with sporicidal efficacy depending on where the endoscopes are used
- Definition of the disinfection intervals for the water treatment equipment while taking into consideration local fluctuations in the water quality.

In the interest of patient safety, the clinical service provider should proactively request details of the type test for their EWD, including an explanation of any gaps or deviations.
The Working Group debates showed that standard EN ISO 15883 permitted broad latitude of interpretation and that the specified methods were not easy to implement in practice, e.g.

- The number and nature of the artificial test soils to be applied to the endoscope channels and external surfaces. Currently, only contamination of the working channel is stipulated, but that does not pay adequate attention to the complexity of the endoscope design;
- The choice of representative endoscopes or endoscope families. The latter terms are not further defined in the standard, thus causing widespread uncertainty and making it impossible to compare tests;
- The choice of relevant test organisms for testing the entire process.

These aspects will be debated when revising, on a rotational basis, the various parts of the standards.

Outlook

Resolving the conflict of interests arising from the desire to assure a cost effective approach while at the same time providing comprehensive evidence of patient safety is extremely complex. Priority should always be given to patient safety, which should not be neglected because of the cost and time investment needed. The findings of the Working Group have demonstrated that type testing can be successfully implemented if cooperation is assured between all participants, i.e. the manufacturers the EWD, of the process chemicals and endoscopes.
The recommendations of the Working Group focused primarily on the requirements of the German market. In an age in which EWDs are type tested and marketed not just in the context of a particular country, consideration must be given to whether the type test findings are also able to meet the test requirements of other countries. This relates, among other things, to the following:

- Deviations in testing of the cleaning efficacy
- Deviations in testing of the disinfectant efficacy.

The Working Group discussions have also shown that this present article can serve as an important guide to type testing. But in practice different processes are used which are not covered by the type test as conducted by the EWD manufacturer. These deviations relate, in particular, to the use of different process chemicals as well as connectors and endoscopes not featured on the EWD manufacturer's list of compatible items. Such deviations can

give rise to complex legal situations since at present responsibilities/liabilities are not legally clarified. These aspects have already been debated in the Working Group and will be addressed in a separate article. ■

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Kreuzberger Ring 46
65205 Wiesbaden
Germany

Fon 0611 50593-31
Fax 0611 50593-79

info@mhp-medien.de
www.mhp-medien.de

mhp_medien