Original Article

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

Part 2: Challenges faced by the manufacturers of EWDs and endoscopes when establishing endoscope type test groups in accordance with EN ISO 15883-4:2018, Annex H

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Abstract

The EN ISO 15883-4:2018 standard version [1] features, in addition to a description of the scope of type testing of washer-disinfectors for reprocessing thermolabile endoscopes (EWDs), the important new normative Annex H "Establishing endoscope type test groups", which specifies how the test endoscopes to be used for type testing are to be selected.

While in the previous version of this standard from 2009 [2] endoscopes had also to be used for the individual tests described, no information was given on what basis these endoscopes were to be selected. The newly published Annex H attempts to close that gap in that it describes a systematic selection procedure based on various design characteristics of the endoscopes to be declared compatible.

To achieve uniform interpretation and implementation of the revised provisions of EN ISO 15883-4:2018 [1], the Type Testing EWDs working group was set up, comprising employees of manufacturing companies of EWDs, flexible endoscopes and process chemicals. The findings of the working group are being published in three parts. This second part now focuses, in particular, on Annex H by interpreting, and using examples to explain, the selection criteria used therin.

A flow chart describes in detail all the steps needed for this selection procedure and gives tips on which individual endoscope design characteristics are to be used and how these can be set in relation to each other. In addition to drawing up a new list of representative test endoscopes, the publication also explains how further endoscopes from a new or already considered manufacturer are to be added to a machine that has already undergone type testing.

This evaluation requires comprehensive information, which the manufacturers of the flexible endoscopes must make available to the EWD manufacturers. Therefore, this selection calls for close cooperation between the parties involved.

Keywords
- type testing EWDs
- endoscope type test groups
- assignment endoscopes to a block
- challenges for manufacturers

Introduction

With the publication of the revised Part 4 of the EN ISO 15883 series of standards in 2018, compared with the previous version from 2009, very extensive tests were defined for type testing the washer-disinfectors used to reprocess thermolabile endoscopes (EWDs) and for the reprocessing process [1, 2]. An important new addition is a guide in the normative Annex H to classifying endoscopes into endoscope type test groups, which allows comprehensive testing of a large number of endoscope types in interaction with the EWDs, reprocessed thermolabile endoscopes and process chemicals, while limiting the number of tests to a feasible scope. The aim is

to define and demonstrate which endoscopes can be reprocessed with which process chemicals in which EWD. These tests make a significant contribution to improving the reprocessing quality and thus to patient safety.

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 [3].

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

The guide given in the normative Annex H to establishing type test groups can be viewed as a kind of "recipe" for grouping endoscopes. The aim of this procedure is to define a required number of endoscopes to be tested using a reproducible and standardized method. In this way, the evidence provided to confirm reprocessability can be extrapolated to all flexible endoscopes of the corresponding type test group.

In addition to the already described use of Annex H, another procedure describes how to add further endoscopes to a compatible endoscope list. In such cases a check must be made to ascertain whether the new endoscope is already covered by the currently defined "relevant endoscope type test groups (RTTG)". If that is not the case, a new relevant endoscope type test group must be defined and the requisite tests performed.

This publication now describes the procedure used to classify endoscopes, including how such a list can be initially compiled. From the data available for the flexible endoscopes and the respective EWD, the endoscopes of relevance for the tests are selected.

Classification of endoscopes in accordance with Annex H

Classification of compatible endoscopes into type test groups in accordance with Annex H and definition of the test endoscopes are carried out as per the flow chart in Figure 1.

Sections 1 to 7 of this publication describe in detail the individual steps and make suggestions for the implementation of the requirements of Annex H. Subsequently, Section 8 describes a procedure for adding further endoscopes.

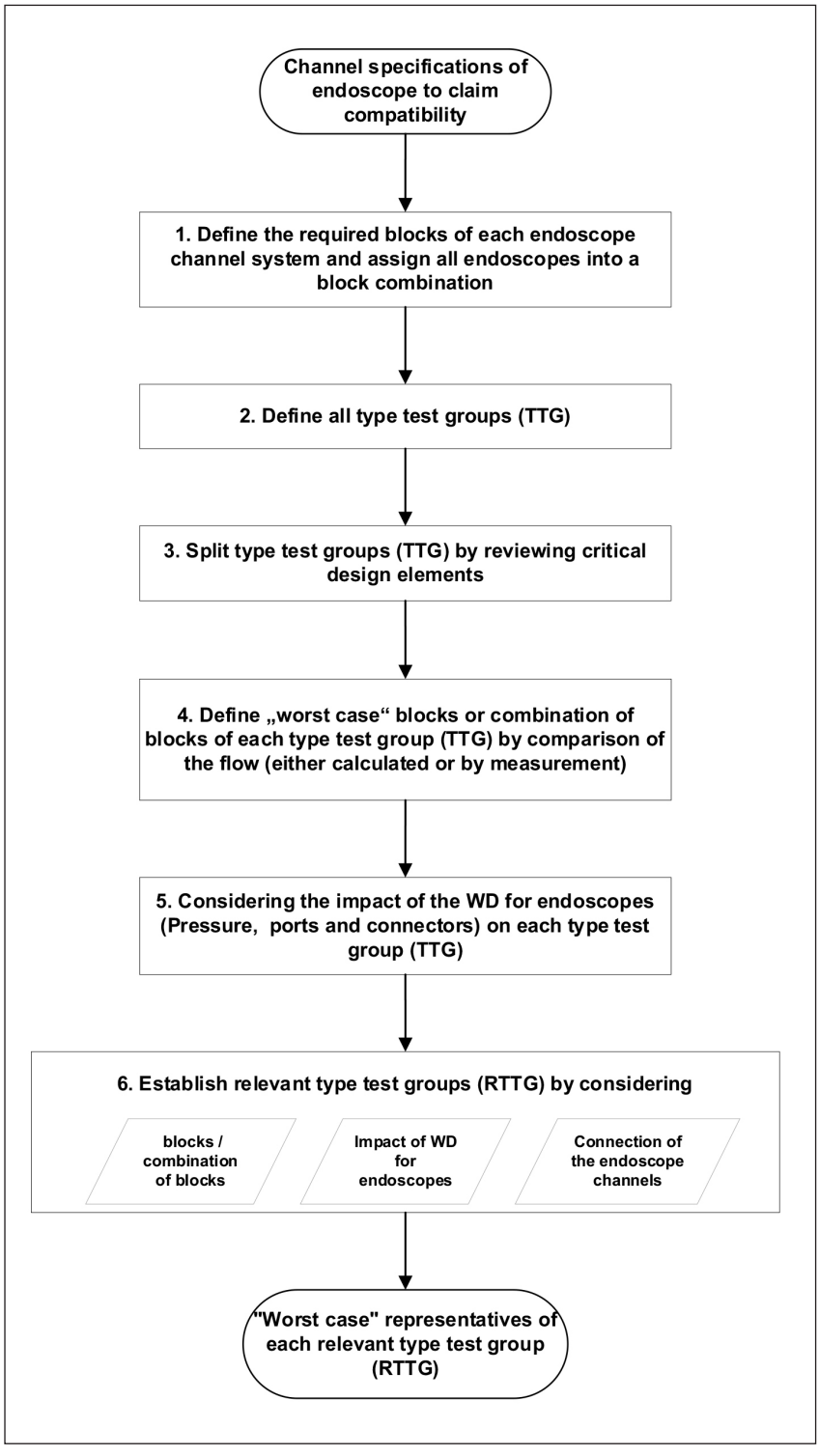


Figure 1: Flow chart for classification of endoscopes according to Annex H

1. Define the required blocks for each endoscope channel system and assign all endoscopes to a block combination

Table H.2 "Examples for specified endoscope blocks" of Annex H contains suggestions for the various channel systems, including their lengths and diameters, in the form of endoscope blocks. Each channel system of a flexible endoscope is assigned to individual blocks or their combinations. If the channel system cannot be assembled from these proposed blocks, other blocks can be added and parameters for lengths and diameters can be specified and documented.

Table H.2 of Annex H currently features proposals for assembly of the following, in all cases mutually independent, channel systems [1]:

- Blocks with designation A: air/water systems
- Blocks with designation B: biopsy/suction channel systems
- Blocks with designation C: water jet as well as (double) balloon channels
- Blocks with designation D: elevator channel, or in colloquial terms known as the "albarran channel"
- Blocks with designation E: channel systems of small diameter endoscopes (such as cystoscopes or bronchoscopes)

As a first classification step, the channel geometries as well as the channel lengths and diameters are considered (Figure 2). Other critical design elements of the endoscopes, which must be taken into account in the final selection, are considered in a subsequent step (see Section 3).

If the design of an endoscope is too complicated to be classified in different blocks, i.e. if the endoscope channels are interconnected as, for example, may be seen in the case of ultrasound endoscopes, these channel systems can be defined as one block system according to the suggestions of Table H.3 of Annex H "Examples for endoscopes that cannot be divided in endoscope blocks because of interconnections" [1].

2. Define all type test groups

After the respective channel blocks have been defined for all endoscopes to be declared compatible, they are arranged in a table. Each type of endoscope is given a single row and in the columns of the table the blocks of the channel systems that make up this type are entered (see examples A2, B1, C2 in row 4 of Table 1). Each of these rows forms a separate endoscope type test group (TTG). If two endoscope types have an identical block classification, they are combined into one endoscope type test group (see TTG 5 in Table 1). It should be noted that endoscopes without a channel system are also included in this table, so that they are not forgotten in the further procedure.

Table 1 shows an example of a selection of endoscope types as well as of endoscope type test groups.

3. Split type test groups by reviewing critical design elements

The endoscopes are inspected for design elements that could impact the reprocessing results.

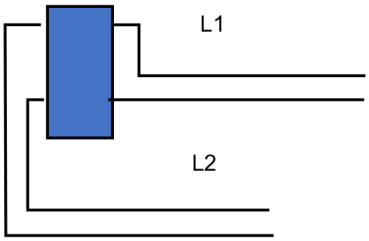
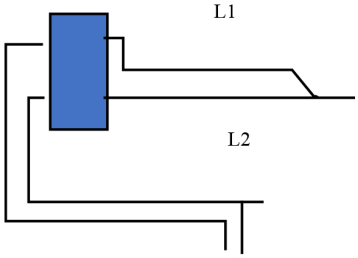
Examples of critical design elements include the following:

- Change of channel diameter (e.g. channel tapering)
- Tapering position
- Branching or channel merging
- Internal connections between channels
- Diameter of the nozzle at the distal end of the channel (e.g. air/water nozzle)
- Albarran lever
- Volume of entire channel system
- EWD ports and channel separators

If such elements are identified it may be necessary to split the type test groups in order to be able to depict and evaluate the different designs.

Critical design elements can include, for example, nozzles at the outlet

Figure 2: Examples of endoscope blocks according to Table H.2 of EN ISO 15883-4:2018 [1]

#	Endoscope block	Specification	Diameter / mm	Channel length / mm
A1		Separate air channel and water channel: not combined	0.7 < d < 1,7	600 < L1 < 2600 800 < L2 < 2000
A2		Separate air channel and water channel: combined	0,8 ≤ d ≤ 2,4	900 < L1 < 2900 1400 < L2 < 2000

of the air/water channel of block A2. This means that block A2 presents a greater challenge compared with other A blocks that do not have such a nozzle.

Furthermore, different endoscope types assigned to block A2 may have nozzles of different diameter size at the outlet of the merged air/water channel. These differences in design must also be taken into account when defining the endoscope type test groups; hence, TTG 5 in the example in Table 2 must be split because of two nozzle geometries. Therefore, TTG 5 is split into the two endoscope type test groups TTG 5 and TTG 5a with nozzle geometry A and B (see Table 2).

4. Define worst-case block or combination of blocks for each type test group by comparing the flow

If several endoscopes can be assigned to one type test group, from/to ranges are possible in the channel dimensions of the blocks concerned. In the example TTG 5 in Table 1, channel C1 of Colo2 type has a channel length of 2 m with a diameter of 1.5 mm, whereas by contrast Colo3 type has a channel length of only 1.6 m with a smaller diameter of 1.1 mm.

These variations in lengths and diameters impact the flow through the block concerned. The resulting volume flow rate through the respective channel system has a significant impact on the reprocessing results. These volume flow rates can be either measured or calculated.

4.1 Calculating the volume flow rate

To calculate the volume flow rate, the resistance R is first calculated according to the following formula from the fluid mechanics for each individual section of a channel system:

$$R = \frac{\lambda \cdot \rho \cdot l \cdot 8}{d^5 \cdot \pi^2} \quad \rightarrow R \sim \frac{l}{d^5}$$

In addition to the channel length l and channel diameter d, this formula also includes the density ρ of the flowing fluid as well as the pipe friction coefficient λ, which is a measure of the obstruction of the flow through the endoscope channel. Assuming that the density of the cleaning and disinfection fluid (solution) per machine and process

Table 1: Example of the formation of type test groups

Endoscope	Block					
	A	B	C	D	E	TTG
Type Cysto1	N/A	N/A	N/A	N/A	N/A	1
Type Gastro1	A1	B1	N/A	N/A	N/A	2
Type Gastro2	A1	B1	N/A	N/A	N/A	
Type Gastro3	A1	B1	C2	N/A	N/A	3
Type Colo1	A2	B2	N/A	N/A	N/A	4
Type Colo2	A2	B3	C1	N/A	N/A	5
Type Colo3	A2	B3	C1	N/A	N/A	
Type Duodoeno1	A3	B3	N/A	D	N/A	6
Type Broncho1	N/A	N/A	N/A	N/A	E1	7

Table 2: Example of block assignment with inclusion of critical design elements

Endoscope	Block					
	A	B	C	D	E	TTG
Type Cysto1	N/A	N/A	N/A	N/A	N/A	1
Type Gastro1	A1	B1	N/A	N/A	N/A	2
Type Gastro2	A1	B1	N/A	N/A	N/A	
Type Gastro3	A1	B1	C2	N/A	N/A	3
Type Colo1 Nozzle A	A2	B2	N/A	N/A	N/A	4
Type Colo2 Nozzle A	A2	B3	C1	N/A	N/A	5
Type Colo3 Nozzle A	A2	B3	C1	N/A	N/A	
Type Colo4 Nozzle B	A2	B3	C1	N/A	N/A	5a
Type Duodeno1	A3	B3	N/A	D	N/A	6
Type Broncho1	N/A	N/A	N/A	N/A	E1	7

does not vary and that the materials of the endoscope channels of interest are identical, the parameters density and friction coefficient can be disregarded.

Thus, the resistance R of a channel section is proportional to the quotient of the length and diameter of the channel system concerned.

The volume flow V in an endoscope channel is proportional to the square root of the quotient of the pressure difference Δp and thus the EWD pump output, and the channel resistance R according to the following formula:

$$V = \sqrt{\frac{\Delta p}{R}}$$

If the cleaning pressure in the EWD of interest is constant, the flow through the channel is inversely proportional to the square root of the channel resistance:

$$V = \sqrt{\frac{1}{R}}$$

With these calculations, it is now possible to determine the approximate volume flow for each section of a block on the basis of the channel data based on lengths and diameters.

Likewise, for a block its total resistance or its volume flow can be calculated by combining the individual subsections. Provided that the volume flows through these blocks occur independently in the EWD, they can be considered separately from each other. If that is not the case, the total flow through all connected blocks must alternatively be considered together.

In this way, all endoscopes of a block with various combinations of lengths and diameters can be compared by taking account of the volume flow calculated.

4.2 Measuring the volume flow rate

In addition to calculating the volume flow rates through the channel systems of interest, these can also be measured. This can be done both within an EWD and outside the EWD using a specially designed device. It is important that the respective independent channel systems be flushed by the pump at a constant pressure or volume flow. The fluid (cleaning solution) at the outlet of the endoscope channel system to be measured can either be collected and determined volumetrically or gravimetrically or it can be measured directly using a specially attached sensor before or after the endoscope.

The drawback of this method is that the respective endoscopes must be physically present in order to conduct the measurement. For that reason the calculation method described in Chapter 4.1 is a feasible method for the EWD manufacturer. However, the calculation results should be confirmed by reference measurements and, if necessary, adjusted.

5. Reviewing the impact of the EWD on each type test group

The previous sections did not take account of any the EWD characteristics or their possible impact on the volume flow.

In particular, the cleaning pressure used in the EWD must be evaluated: Is it possible to assure a constant volume flow within the tolerances independently of the channel system of connected endoscopes or does the volume flow change for certain combinations of blocks? It may be necessary to split the TTG.

Likewise, the EWD adapter points and channel connectors (adapters) must be taken into account. If similar endoscope channel systems are fitted with adapters of different geometry and/or diameter, this must also be taken into account in the evaluation. If the adapters do not have any implications for the flow through the channel systems present, there is no need to further consider this feature. Alternatively, the TTG must be split.

A special calculation is performed for those adapters that prior to connection to an endoscope split the flow, in that one adapter is connected to two endoscope channels. This fact must be taken into account by additionally reviewing the adapter and endoscope blocks, including the effects on the ensuing flow rates. If necessary, provision must be made for additional type test groups containing these special adapters.

Priority must be given to these effects generated by the EWD, which is taken into account in the further analysis of the endoscope type test groups. It should be noted here that such prioritization is never possible on the basis of the endoscope alone, but only in conjunction with the characteristics of the EWD, and therefore cannot be based exclusively on the endoscope manufacturer's specifications.

6. Establish relevant endoscope type test groups

Based on the calculated or measured flow rates and possibly critical design elements, the endoscopes belonging to each type test group are evaluated against each other and the endoscope with the most critical elements is identified.

In the next step, the relevant type test groups (RTTG) for the subsequent tests must be defined from these type test groups. Here, the individual blocks of the endoscopes with the critical elements are subjected to risk assessment to establish whether there are reasonable arguments for combining certain blocks. It must be noted that this combination can only be done by taking account of the interplay between endoscope block (see Sections 3 and 4) and EWD (see Section 5).

With this restriction the influence of each individual design element as well as its combination must be evaluated, while taking account of the EWD characteristics.

The following examples show an approach that may possibly be used to select the relevant type test groups:

Example 1: Nozzle at the outlet of the air/water channel

A nozzle at the end of the air/water channel system can reduce the volume flow in a type test group 5 endoscope (see Table 2) to such an extent that the endoscope block A2 with nozzle compared with blocks A1 and A3 without nozzle has the worst-case features.

Example 2: Combining long channels without branching

Pursuant to Annex H there are blocks which, despite different diameters and lengths, are otherwise composed of a long channel with one fluid inlet and one fluid outlet, with no other branching or channel constrictions. These are block B, block C, as well as blocks E1 and E2 in Table H.2. All these blocks

can be combined for evaluation on the basis of the calculated flow rates (see Section 4).

Example 3: Standardization of blocks with instrumentation/suction channel systems

Blocks B1, B2, B3, B5 and the connected instrumentation/suction channel system of block B6 have a similar channel structure but with different lengths and diameters of the individual channels. Therefore, blocks B1, B2, B3 and B5 can be jointly evaluated by taking account of the flow rates as well as other design elements.

If, additionally, the instrumentation/suction channel is separated from the balloon channel by the adapter used, the instrumentation/suction channel of B6 can be evaluated together with systems B1, B2, B3 and B5.

Table 3 shows an example of how the TTG can possibly be reduced to a few RTTG. Based on the discussions in the previous sections, it was possible to apply the following simplifications:

- Gastro3 type is identified as the worst-case representative of all type test groups containing B and C blocks because, due to the described resistance calculations, these have the lowest volume flow rates through the respective channel systems B1 and C2 (see RTTG 1* in Table 3).
- Because E blocks can also be depicted, based on their shape, like certain B and all C blocks according to example 2, the Broncho1 type channel system can be evaluated, showing that this is covered by the channel system C2 of RTTG 1*.
- Colo4 type with the smallest nozzle at the outlet of the air/water channel is identified as the worst-case representative of all type test groups containing A blocks, and the relevant type test group 2* is established. Here, channel system A2 with nozzle B covers all the other A channel systems such as A1 and A3 as well as channel systems A2 with nozzle A.
- The duodenoscopes in this example establish a third group of their own (RTTG 3* in Table 3). If there are several types of endoscopes with albarran channel, here too the worst-case representative can be identified on the basis of the flow rate.

Tabelle 3: Example of the selection of relevant type test groups / RTTG

Endoscope	Block					TTG No.	RTTG
	A	B	C	D	E		
Type Cysto1	N/A	N/A	N/A	N/A	N/A	1	Covered by endoscopes with channel system
Type Gastro1	A1	B1	N/A	N/A	N/A	2	Covered by RTTG 1* & RTTG 2*
Type Gastro2	A1	B1	N/A	N/A	N/A		
Type Gastro3	A1	B1	C2	N/A	N/A	3	RTTG 1* for all B and C blocks
Type Colo1 Nozzle A	A2	B2	N/A	N/A	N/A	4	Covered by RTTG 1* & RTTG 2*
Type Colo2 Nozzle A	A2	B3	C1	N/A	N/A	5	Covered by RTTG 1* & RTTG 2*
Type Colo3 Nozzle A	A2	B3	C1	N/A	N/A		
Type Colo4 Nozzle B	A2	B3	C1	N/A	N/A	5a	RTTG 2* for all A blocks
Type Duodeno1	A3	B3	N/A	D	N/A	6	RTTG 3* for D blocks
Type Broncho1	N/A	N/A	N/A	N/A	E1	7	Covered by RTTG 1*

7. Select the test endoscopes, worst-case representative for each relevant type test group

From the defined number of relevant type test groups, the test endoscopes serving as worst-case representative for the tests specified in EN 15883-4 are now selected.

In the example from Table 3, it was possible to reduce the identified eight type test groups (TTG) to three relevant type test groups (RTTG) through risk assessment.

Taking account of the considerations in Section 4, the endoscope that is most difficult to reprocess is selected from each RTTG and is used for all further tests.

8. Procedure for adding further endoscopes

After completing type testing of an EWD, the issue arises as to how to add other endoscopes to the list of endoscopes that can be reprocessed in the EWD. This applies, for example, to new developments or modifications of existing models from one manufacturer or the range of endoscopes from another manufacturer. This is done in the same way as described in Sections 1–7 (see flow chart in Figure 1).

First, the blocks/block combinations are determined for the channel system of the new endoscope to be added and are classified in a type test group (TTG). If there is no TTG available yet for this special block combination, a new TTG must be established and documented. Besides, this new endoscope must be inspected with regard to its critical design elements and, as applicable, the influence exerted by the EWD on reprocessing this endoscope must be determined. Based on these insights, the risk assessment must be adapted to determine the relevant type test group (RTTG) and the results documented.

In many cases the RTTG selection as well as the worst-case endoscope representative remains unaffected and the new endoscope can be added to the compatibility list without further tests. However, if it turns out that this endoscope establishes an additional RTTG or the representative of an existing RTTG must be changed, the corresponding tests must be performed in accordance with the provisions of EN 15883-4 [1, 3].

Summary and outlook

The method described in Annex H of EN ISO 15883-4:2018 [1] serves as a systematic guide to classification of reprocessed flexible endoscopes.

The previous version of EN ISO 15883-4:2009 [2] already set out the reprocessing requirements in Chapters 4.1.3 and 8. However, no details were given of the basis on which the test endoscopes were to be selected or of whether these tests were to be carried out with endoscopes, surrogates or a combination of both.

The greatest problem was that the large number of endoscopes of different designs from various manufacturers could not be comprehensively tested by the EWD manufacturer with a reasonable investment.

Nonetheless, to define minimum requirements as well as a common understanding of testing the combination of EWD, endoscope and process chemicals, the Type Testing EWDs 1.0 working group formulated recommendations for selection of endoscopes on the basis of endoscope product families in accordance with the ESGENA definition [4,5]. It emerged that these recommendations were not being uniformly interpreted.

This gap has been closed with the newly published Annex H in EN ISO 15883-4:2018 [1]. For the first time a systematic guide is available for selection of representative endoscopes and surrogates for type testing an EWD, making it possible to meet the normative requirements. This guidance now available for the EWD manufacturer is conducive to standardization of the tests. However, this guidance is not self-explanatory, which is why in this publication the procedure to be used for selection of an endoscope was presented as a flow chart (see Figure 1) and illustrated with examples.

The assignment of the endoscopes to individual blocks, while taking account of special design elements, calls for comprehensive information, which the manufacturer of the flexible endoscopes must make available to the manufacturers of the EWDs. This requires close cooperation between the parties involved.

Compared with the recommendations of the Type Testing EWDs 1.0 working group, the implementation of Annex H has significantly increased the manpower and financial investment for conduct of type testing. The Type Testing EWDs 2.0 working group believes this is justified because now, by systematically selecting worst-case test endoscopes, testing can be performed representing the range of endoscopes that can be reproducibly declared as reprocessable in the respective EWD by its manufacturer. This makes a significant contribution to improving patient safety.

This stringent approach to type testing helps to reduce to a feasible and reasonable level the test scope in the EWD at the site of use at the time of validation and requalification and to also dispense with repetition of parts of the type test.

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