ESGE/ESGENA guideline for process validation and routine testing for reprocessing endoscopes in washer-disinfectors, according to the European Standard prEN ISO 15883 parts 1, 4 and 5

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Institutions Institutions are listed at the end of article.

Bibliography
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Contents

1. Scope of this guideline

Validation is an important quality assurance tool in hygiene and infection control, whether endoscopy procedures are performed in hospitals, in private clinics, or in doctors' offices. Up till now, the clinical service provider (see Appendix **1**: Glossary) has had to rely on the correct functioning of automated washer-disinfectors according to the manufacturer's specifications. The current tools for regular quality control are routine maintenance and microbiological surveillance.

Validation procedures have long been common practice in the monitoring of sterilization devices, for example in central sterilization units. The implementation of validation of reprocessing procedures for flexible endoscopes will be an important step for systematic quality assurance and patient safety.

This guideline, from the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA), is based on the European standard, prEN ISO 15883, which describes in detail the design and function requirements for washer-disinfectors. This ESGE/ESGENA guideline addresses the need to validate the entire reprocessing cycle for flexible endoscopes and their accessories, because such validation:

- ensures the transparency of reprocessing procedures
- supports the early detection of weaknesses and defects in washer-disinfectors
- is based on dedicated and proven test methods for benchmarking

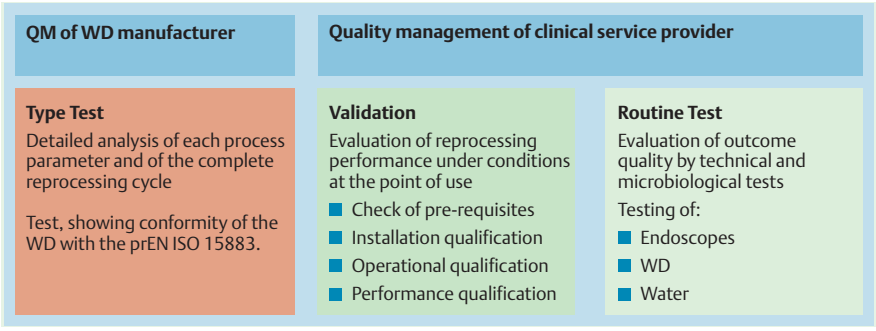

Figure 1 Quality Management for reprocessing of flexible endoscopes.

- has the potential to reduce the amount of routine testing

This guideline is an expert opinion and provides practical information about and guidance through the validation of the entire procedure of reprocessing with washer-disinfectors. Example checklists are provided to support the implementation of validation at each individual endoscopy unit.

Aims of this guideline

These are:

- To support individual endoscopy departments and clinical service providers in establishing local standards and protocols for validation processes for endoscope reprocessing with washer-disinfectors
- To support national societies and official bodies in developing national recommendations for the validation of procedures for reprocessing flexible endoscopes

Target groups

This guideline provides practical guidance through the validation process for the following groups:

- Clinical service providers, as they have the responsibility to meet structural and organizational requirements and to provide educated staff, for the safe use of washer-disinfectors
- Endoscopists, endoscopy nurses, and other users of washer-disinfectors, who use flexible endoscopes and who are responsible for the safe reprocessing of endoscopy equipment
- Hospital hygienists, microbiological personnel, microbiologists, and authorized agencies, who perform regular microbiological quality control in endoscopy units
- Manufacturers, suppliers, and authorized third parties who sell, install, and maintain flexible endoscopes and washer-disinfectors for gastrointestinal endoscopy
- Institutions, companies, and other qualified agencies that are authorized to perform validation of washer-disinfectors

2. Quality management: the roles of validation and routine testing

The European standard prEN ISO 15 883 consists of five parts, of which three are relevant to endoscopy:

- Part 1 states the general requirements and definitions for all washer-disinfectors.
- Part 4 defines the special requirements for the design of washer-disinfectors and for reprocessing of heat-sensitive instruments such as thermolabile, flexible endoscopes. In addition, prEN ISO 15 883 – 4 requires a check on whether the correct reprocessing results are obtained with all endoscope types to be reprocessed under the particular circumstances obtaining at the service provider's location (water quality, power supply etc.). This process is called validation.
- Part 5 provides test soils and methods for demonstrating the cleaning efficacy of washer-disinfectors.

Quality assurance systems for washer-disinfectors comprise three parts (see **Figure 1**), type testing, validation, and routine testing.

1. Type testing according to prEN ISO 15883, is the responsibility of the manufacturer and checks that the washer-disinfector complies with the prEN ISO 15 883 standard. During type testing, each individual step of the reprocessing cycle is separately analyzed (e. g. cleaning efficacy, disinfection efficacy, water quality, chemicals), followed by evaluation of the reprocessing cycle as a whole. In addition, type testing provides reference data for further validation and use of the washer-disinfectors.

2. Validation is the responsibility of the clinical service provider. It demonstrates that the entire reprocessing procedure gives reproducible results at the point of use as required. Single parameters can be defined as indicators. The validation process for washer-disinfectors includes the following steps:

- Installation qualification (IQ), to check that the equipment is received as specified, that it is correctly installed, and that the particular location is suitable for the use of the washer-disinfector
- Operational qualification (OQ), to check that the washer-disinfector will operate as specified in the endoscopy unit concerned
- Performance qualification (PQ), to check that the washer-disinfector consistently performs according to the specification for routine use

Validation must be repeated (**revalidation**):

- on a regular basis (according to national requirements),
- after each major change of the reprocessing cycle, or
- after major repair.

This is in order to document that the reprocessing process still achieves the same required, reproducible results.

3. Routine testing is the responsibility of the clinical service provider. Based on the validation results, routine tests are established in order to prove that the washer-disinfector works within the defined limits for dedicated parameters and to prove the outcome quality of the complete reprocessing cycle. Routine testing may include tests of endoscopes, washer-disinfectors, and the water used in the particular department. An appropriate sampling plan has to be established for each type of washer-disinfector.

This guideline focuses on the validation process (including installation, operational, and performance qualification) and on the routine testing.

Validation	Responsibility	Option for Execution	Qualification
Prerequisites	Clinical Service Provider	Manufacturer Authorised Supplier Authorised third party	Expertise in regulatory issues technical and electrical issues of WD, chemicals, flexible endoscopes and special equipment
IQ	Clinical Service Provider		
OQ	Clinical Service Provider		
PQ	Clinical Service Provider	Manufacturer Authorised Supplier Authorised third party, Endoscopy staff Microbiological institutes Microbiological staff Hygienists Infection control nurses	Microbiological expertise Technical understanding of the WD
Routine tests	Clinical Service Provider		

Table 1 Responsibilities and Qualification in Quality management of validation

3. Responsibilities and qualifications

It is the responsibility of the clinical service provider to ensure that validation is carried out. Validation must be done at the location where the washer-disinfector is being used. A qualified company/person may carry out validation on behalf of the clinical service provider. It is strongly recommended that the company or persons performing such validation have expert knowledge in all relevant areas such as microbiology, hygiene and infection control, technical and electrical issues relating to washer-disinfectors, chemicals, flexible endoscopes, and regulatory issues.

The clinical service provider must document all the relevant validation data for the washer-disinfector, and the use of standard checklists is recommended. This guideline provides examples of checklists [1] which can be adapted to local structures and the requirements of particular clinical settings (see section 8, Appendices 2 – 6.)

Installation qualification is usually performed by the manufacturer, the supplier, or authorized third parties.

Operational qualification is the responsibility of the clinical service provider. Specialized knowledge will be required about: technical and electrical issues relating to washer-disinfectors; chemicals; flexible endoscopes; regulatory issues; and special equipment. Therefore it is recommended that authorized and specially trained persons perform this validation. The manufacturer of the washer-disinfectors must provide instructions on how to test the various process parameters and functions of each washer-disinfector. The manufacturer may also need to supply appropriate specialized test equipment.

Performance qualification is the responsibility of the clinical service provider. Only persons or organizations with appropriate microbiological expertise should carry out these tests. Additionally, such persons or organizations should have a thorough understanding of the structure and function of the tested washer-disinfectors and endoscopes.

Routine testing is the responsibility of the clinical service provider. The tests may cover technical and microbiological parameters, and should therefore be performed by appropriate trained persons. Collection, culturing, and the interpretation of test results should be done in close cooperation with endoscopy staff, the hospital hygienist, appropriate microbiology personnel, and the microbiologist, in line with national requirements.

An example of the procedures and expertise required for validation and routine testing has been published recently [2]; **Table 1** shows these, linked with the appropriate organizations and personnel needed to carry out the procedures.

4. Validation

4.1. Prerequisites

The endoscopy department or unit must fulfil technical and organizational prerequisites. A purpose-designed room for cleaning and disinfection that is separate from procedure rooms is recommended, to minimize patient and staff exposure to:

- chemicals used in cleaning and disinfection procedures (e.g. because of toxic/allergic reactions, glutaraldehyde vapour)
- the risk of infection and contamination with potentially infectious material, blood and other body fluids.

The manufacturer must provide information about the structure and function of the washer-disinfector. The validation can be performed when the washer-disinfector is installed according to the manufacturer's instructions and local safety regulations, and when all components and utilities are available.

The checklist in Appendix **2** is an example of what should be considered. It is based on the recommendations of the ESGE Guidelines Committee and relevant European guidelines [3,4].

4.2. Installation qualification (IQ)

Installation qualification is the process of obtaining and documenting evidence that the washer-disinfector has been supplied and installed in accordance with its specifications. Checks need to be carried out that all ordered items have been received and that the location of the washer-disinfector correctly fulfils specifications (e.g. with regard to water quality, power supply, etc.). An example of a checklist is shown in Appendix **3**.

4.3. Operational qualification (OQ)

Operational qualification is the process of obtaining and documenting evidence that the installed washer-disinfector operates within predetermined limits when used in accordance with its operational procedures. For example, checks are needed to show whether:

- the leak test and the flow control function in accordance within their specifications,

- the temperature profile is in line with specifications, and
- the dosage pumps for the chemicals deliver the right quantities.

A standardized checklist is available in Appendix **4**.

4.4. Performance qualification (PQ)

Performance qualification is the process of obtaining and documenting evidence that the washer-disinfector, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields reprocessed instruments according to the specifications.

Performance qualification focuses on the testing of the washer-disinfector in operational conditions. The efficacy of the cleaning and disinfection steps should be evaluated as a combined test procedure.

The prEN ISO 15 883 – 5 standard offers a variety of test soils and methods for demonstrating cleaning efficacy, but there is currently no consensus in the relevant working group of the CEN (Comité Européen de Normalisation/European Committee for Standardization) regarding preferred test soils and methods. Therefore, the present guideline only recommends that they should be carried out on endoscopes that are routinely used in clinical practice and should include representative samples of all types of endoscopes used and reprocessed in the particular department.

The endoscopes employed in the performance qualification procedure should be used in clinical practice and should be reprocessed following the everyday standardized reprocessing protocol, including pre-cleaning by brushing manually and cleaning and disinfection in the washer-disinfector. This will ensure that potential negative side effects of incompatible chemicals are identified.

National guidelines and laws on validation and hygiene in endoscopy vary from country to country [5,6]. Test procedures for performance qualification have to be modified according to national regulations. This guideline includes suggestions for testing important process parameters.

Test condition procedures for evaluating the results and to achieving limits are available in Appendix **5**.

5. Routine testing

Routine testing ensures that the required performance standard is delivered consistently at all times.

Based on the individual risk assessment and the results of the validation of each individual machine, the extent of the routine testing has to be defined, based on national recommendations and prEN 15 883/4 Annex C. These routine tests cover technical and microbiological parameters.

Routine checks of technical parameters (such as leakage testing and channel non-obstruction testing, and of temperature, water quality, etc.) can reduce the required number of microbiological tests on endoscopes, as the technical tests demonstrate that the washer-disinfector is working within its specifications. In addition paper print-outs document that the particular reprocessing cycle has been completed within the required process parameters. Daily check-ups of single machine parameters document that the washer-disinfector operates within its specifications. These daily check-ups may be defined by the manufacturer or the service provider.

For performance of microbiological tests on endoscopes, it is recommended that the ESGE–ESGENA guideline on microbiological surveillance testing in endoscopy is followed [7].

If any routine test result breaches the specification (because it is out of the predetermined range of the technical parameters or because of contamination), it is the responsibility of the clinical service provider to take the suspect device out of service (e.g. washer-disinfector, endoscope), until corrective actions have been taken and satisfactory results have been achieved.

Examples of possible test options are given in Appendix **6**.

6. Frequency

6.1. Frequency of validation and revalidation

A complete validation is necessary before routine use. This first validation is a baseline assessment of the adequacy of effectiveness (prEN ISO 15883-4).

A revalidation is necessary after any major repair, change, or both of the reprocessing cycle (e.g. in temperatures, process chemicals).

Regular maintenance of washer-disinfectors is part of quality management and is a prerequisite for their safe use. It ensures the early detection of possible weaknesses and defects in washer-disinfectors.

6.2. Frequency of routine testing

In order to confirm the correct functioning of the washer-disinfectors, routine testing on a regular basis according to national requirements is recommended. The frequency of routine microbiological tests can be reduced if the machine consistently shows reliable technical results on routine tests. It is the responsibility of the clinical service provider to decide on the intervals between microbiological tests.

The frequency of routine microbiological testing varies across Europe [7]. This guideline therefore will have to be modified locally to comply with the relevant national regulations. As a point of reference, the ESGE–ESGENA Guideline Committee recommends routine testing every 3 months at least.

Institutions

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[6] ESGE Guidelines Commitee chairman, Institute A. Tzanck, Saint Laurent du Var, France

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8. Appendices

The tables and checklists in Appendices 2 – 6 are based on the German Guideline for alidation of automated reprocessing processes or thermostable medical devices [6].

Appendix 1: Glossary

Clinical service provider: An organization, person, or persons legally responsible for the provision of a clinical service. Could be an institution (such as the health service), hospital or department, or a doctor working in his own premises.

User: Person or department using equipment; organization(s) or persons within those organization(s) who operate and/or use the equipment

Process chemicals: All chemicals used during the reprocessing procedures, including detergents, disinfectants, alcohol, etc.

Appendix 2: Example of a checklist to evaluate the prerequisites for installation of a washer-disinfector

Part 1 Environmental and structural prerequisites for the clinical service provider

Requirement	Available	Countermeasure, Comments
Purpose-designed reprocessing room, separate from procedure rooms		
Separation of contaminated and clean working areas		
Information about water quality (e. g. hardness and microbiological status)		
Trap (U-bend) in drainpipe		
Ventilation of reprocessing room		
Room temperature conditions defined		
Isolating valve and dirt arrester for cold water		
Isolating valve and dirt arrester for warm water		
Isolating valve for demineralised water		
Mains switch for electrical power supply		
Device for hand disinfection		
Storage for process chemicals, safe supply		
Health and safety requirements		

Part 2 Organizational prerequisites for the clinical service provider

Requirement	Available	Countermeasure, Comments
Reprocessing instructions for each medical device		
Risk analysis for reusable medical devices (with respect to hygiene)		
Medical device file and manual for WD, including description of the entire reprocessing procedure		
Maintenance and service schedule for washer-disinfectors		
Safety data sheets for all process chemicals		
Definition of test load for performance qualification		
Definition of person responsible for performance qualification		
Certification of reprocessing staff (training courses, competency assessment)		
Hygiene plan and reprocessing protocols		
Compatibility of WD, endoscopes and process chemicals		

Appendix 3: Example of checklist for installation qualification

General Information about the washer-disinfector

Installation location	
Person responsible for validation	
Further responsible persons	
Date of validation	
Type of device	
Manufacturer	
Serial number	
Year of production	

Part 1 Delivery contens

Products ordered	Article number	Amount	received products	Damage (Yes/No)

Process chemicals		Applicable (Yes/No)	
No.	Product name	Manufacturer	Function
1			

Part 2 Documentation

Type/Title	Delivered (Yes/No)	Docu-ment no.	To be filed at:
Installation plan			
Circuit diagrams			
Instruction manual			
Other manuals (i. e. Maintenance)			
Safety data sheets of che-micals			
Reports and certificates			
Declaration of conformity MDD 93/ 42			

Type of installation and installation task	Department/Company	Date of Installation
Electrical power supply		
Water supply		
Drainage		
Air ventilation		

Part 3 Responsible Departments/Companies. All internal departments and external companiesin charge of preparation of the installation site and maintenance shall be listed

Appendix 4: Example of a checklist for operational qualification

General information about the washer-disinfector

Device	
Location of installation	
Person responsible for validation	
Date of validation	

Part 1 Basic functions

Requirement	Applicable	OK	Not OK	Comments, Countermeasure
Check all water supply pipes in leakage concerned				
Check drainage pipes for buckling				
Check power supply; connectors available				
Check all door seals for leakage				
Check all sieves and filters (outside washer-disinfector), sterile filters for availability and leakage				
Check all sieves and filters (inside washer-disinfector) for availability and dirt				
Check spray arm for availability, check rpm*				
Check liquid level sensor				
Check function of scope identification				
Check functionality of documentation (printer or network connection)				
Check all adapters (position and function)				
Check leak test adapters (position and function) and endoscope connection				
Check external ventilation (if required)				
Check door lock of washer-disinfector, function, seals				
Check whether START of process is blocked if washer-disinfector door is still open				
Check filter efficacy (chemicals, vapour etc)				

Part 2 Operational functions

Water supply: **Applicable (Yes/No)**

Name/No. of process _____

Water Supply	Process cycle	Specified volume range*, L	Measured volume, L	Comment
	Pre-cleaning			
	Cleaning			
	Rinsing			
	Disinfection			
	Rinse 1			
	Rinse 2			
	Rinse 3			

* As specified in type testing of each individual washer-disinfector

Temperature:			**Applicable (Yes/No)**	
Name/No. of process: _____				
Temperature	**Process cycle**	**Specified temperature range*, °C**	**Measured temperature, °C**	**Comment**
	Pre-cleaning			
	Cleaning			
	Rinsing			
	Disinfection			
	Rinse 1			
	Rinse 2			
	Rinse 3			
	Drying			

* As specified in type testing for each individual washer-disinfector

Dosage process chemicals:			**Applicable (Yes/No)**	
Dosage	**Product no./name of product**	**Specified range of volume*, ml, tolerance**	**Measured volume, ml**	**Comment**
	1			
	2			
	3			

* As specified in type testing for each individual washer-disinfector

Part 3: Machine and alarm functions

Requirement	**Applicable**	**Ok**	**Not Ok**	**Comments, Countermeasure**
Alarm function: Leak test NOK (simulation leak)				
Alarm function: channel non-obstruction test				
Alarm function: Insufficient dosage				
Alarm function: No process chemicals				
Alarm function: Water supply				
Alarm function: Temperature				
Documentation (process print-out)				
Cycle completion 1 (pass function); Cycle completion 1 (fail function); Documentation of temperature profile				Name Prog. 1
Cycle completion 2 (pass function); Cycle completion 2 (fail function); Documentation of temperature profile				Name Prog. 2
Cycle completion 3 (pass function); Cycle completion 3 (fail function); Documentation of temperature profile				Name Prog. 3

Appendix 5: Example of a checklist for performance qualification

General information	
Location of installation	
Person responsible for validation	
Date of validation	
Persons collecting the test samples	
Institution and persons performing culturing	
Type/Article of tested endoscope	
Serial number of tested endoscope	
Date of last reprocessing cycle	
Washer-disinfector used for last reprocessing cycle (article, serial number)	
Type/Article of tested washer-disinfector	

Part 1: Microbiological tests

	Sample number	Volume of sterile saline used	Results – Specification of micro-organisms found – Number of cfu*
1. Test of Endoscope 1.1. Endoscope channels – Suction/instrument channel – Air-water-channel – Elevator channel – Separate flushing channels			
1.2. Swabs from endoscopes surfaces – Control part – Distal end – Channel openings – Elevator on duodenoscopes			
2. Test of washer-disinfector – Sample from last rinsing water from washer-disinfector			

* cfu, colony-forming units

Appendix 6: Routine testing-checklist

General information	
Installation place	
Person responsible for validation	
Date of validation	

Part 1: Technical tests (examples of possible test parameters):

Name/No. of washer-disinfector and process: _____

Temperature	Process cycle	Specified temperature range*, °C	Measured temperature, °C	Comment
	Cleaning			
	Disinfection			
	Drying			

* As specified in type testing of each individual washer-disinfector

Part 2 Machine and alarm functions (examples of possible alarm functions):

Requirement	Applicable	Ok	Not Ok	Comments, Countermeasure
Alarm function: Leak Test NOK (simulation leak)				
Alarm function: channel non-obstruction test				
Alarm function: Insufficient dosage				
Alarm function: Water supply				
Documentation (process print-out)				

Part 3 Microbiological tests

Persons collecting the test samples			
Institute and persons performing culturing			
Type/Article of tested endoscope			
Serial number of tested endoscope			
Date of last reprocessing cycle			
Washer-disinfector used for last reprocessing cycle (article, serial number)			
Type/Article of tested washer-disinfector			
Serial number of tested washer-disinfector			
	Sample number	**Volume of sterile saline used**	**Results – Specification of germs founded – Number of cfu***
1. Test of Endoscope 1.1. Endoscope channels – Suction/instrument channel – Air/water channel – Elevator channel – Separate flushing channels			
1.2. Swabs from endoscopes surfaces – Control part – Distal end – Channel openings – Elevator on duodenoscopes			
1.4. Water bottle – Water sample from used bottle			
2. Test of washer-disinfector Sample of final rinsing water from washer-disinfector			

* cfu, colony-forming units