Professional Standard Handbook Cleaning and Disinfection Flexible Endoscopes

Version 4.1, 2017

Published on behalf of:
- Federation for Medical Technology
- The Dutch Nurse Association: division Gastroenterology and Hepatology
- Sterilization Association of the Netherlands
- Dutch Society of Experts on Sterile Medical Devices
- Dutch Society for Infection Prevention and Control in the Health Care

PROFESSIONAL HANDBOOK
FLEXIBLE ENDOSCOPES
Cleaning and Disinfection

Published on behalf of:
Koepel-MT
SVN
V&VN-MDL
VDSMH
VHIG

by: the steering group for flexible endoscope cleaning and disinfection (SFERD)

version 4.1, September 2017

(translation of version 4.0, 2016)

This document is valid for 3 years. The SFERD welcomes your comments on this document; please mail the response form (appendix 21) to the SFERD secretary: J.C. van Bergen Henegouw, j.vbergenhenegouw@hagaziekenhuis.nl

INTRODUCTION

version 4.0, September 2016

The steering group for flexible endoscope cleaning and disinfection (SFERD) was set up in 2006 as a collaboration between four professional bodies:

- Sterilization Association of the Netherlands, SVN
- Dutch Nurse Association; division Gastroenterology and Hepatology, V&VN-MDL
- Dutch Society of Experts on Sterile Medical Devices, VDSMH
- Dutch Society for Infection Prevention and Control in the Health Care setting, VHIG

In 2009 this steering group published the first version of the flexible endoscope cleaning and disinfection quality manual, in which existing legislation concerning the cleaning and disinfection of flexible endoscopes was interpreted as a practical standard. The publication of this first version in 2009 led to more and stronger contacts with other professional groups. This in turn has led to a positive contribution from various scientific professional associations, the health care inspectorate, the infection prevention working group (WIP), the NEN cleaning & disinfection working group and the technical professional bodies for healthcare:

- Dutch Society for Medical Physics, NVKF
- Dutch Society of Clinical Engineers, VZI
- Task group Instrumentation Management University Hospitals, WIBAZ

These technical professional bodies have come together in the Federation for Medical Technology (Koepel MT) and have worked together as a member of the SFERD on the quality manual version 2.0, 2010. When this version appeared it was widely adopted as a standard for the field, as the following quotations bear out:

> "The quality manual for cleaning and disinfection of endoscopes of the flexible endoscope cleaning and disinfection steering group (SFERD) has been incorporated into the NIAZ's basic document collection." *Ms Beaard, NIAZ director*

> "The quality manual for cleaning and disinfection of endoscopes of the flexible endoscope cleaning and disinfection steering group (SFERD) has been incorporated into the HKZ standard for endoscopy." *Ms K. vd Haar, HKZ policy officer*

> "The quality manual for cleaning and disinfection of endoscopes of the flexible endoscope cleaning and disinfection steering group (SFERD). I am very happy to see that there is now a standard for the field which the Inspectorate is using as a supervisory standard."
> *Prof.dr. G. van der Wal, Inspector-general for healthcare, IGZ*

In 2011 the SFERD was awarded the VHIG Infection Prevention Prize; this made it possible to have the manual translated into English (version 2.1, 2011) and in 2014 the foundation for training on infection prevention (STIP), made it financially possible to translate version 3.0 into an English language version 3.1.

In January 2015, a revision of the WIP guideline 'Thermolabile, flexible endoscopes' was brought out. The amendments in the WIP guideline have been incorporated in this version of the Professional Handbook. In this way, the SFERD adheres to the vision of JGZ, that sees the WIP guideline as the professional standard on the basis of scientific literature and the SFERD manual provides the handles (the management plan) to be able to comply with the WIP guideline.
Alongside the amendments arising from the WIP guideline, the Professional Handbook 4.0 (Dutch version) had been textually edited, in particular chapter 5 and 8. Finally, chapter 10 has been extended with a practical translation of the NEN-EN 16442, the European guideline regarding drying cabinets.

The SFERD wishes to express its thanks to mr A. de Bruijn, scientific officer RIVM, who has made an essential contribution to this Professional Manual.
You are welcome to cast a critical eye and to carry on letting the SFERD know about your remarks and observations, additions and new developments.

Version management:
In 2015, the SFERD has introduced a new system in relation to participation and peer reviews; the procedure is as follows:

1. Date release concept SFERD professional Manual draft version 1st round (Embargo)
2. After 3 months closing reaction period 1st round draft
3. After 1 month assessment reactions to 1st draft
4. After 1 month: feedback of decision on the reactions received to draft (1st round)
5. After 1 month: release concept SFERD Professional Manual draft version 2nd round (Embargo)
6. After 2 months closing reaction period 2nd round draft (only discussion on amendments from the 1st round remains)
7. After 1 month assessment reactions on 2nd draft
8. After 2 weeks: feedback of decision on the reactions received on draft (2nd round)
9. After 1 month: release SFERD Professional Manual new version (Symposium)

On behalf of all the members of SFERD,

Federation for Medical Technology (Koepel MT)
Martijn Franken, clinical physicist, Bravis hospital, Roosendaal and Bergen op Zoom
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As well as the professional associations listed above involved in the SFERD, we would like to thank the following people who have reacted individually and the associations and organisations for their critical review of the draft version 4.0 of the manual:

- Dutch association for Internal Medicine (NIV)
- Dutch society for gastrointestinal and liver medicine (MDL)
- Dutch association for pulmonary medicine and tuberculosis (NVALT)
- Dutch association for ear, nose and throat medicine and head and neck medicine (KNO)
- Dutch society for gastrointestinal and liver medicine (MDL)
- Dutch association for radiotherapy and oncology (NVRO)
- Dutch urology association (NVU)
- Dutch association for medical microbiology (NVMM)
- Dutch association for technical facility management in health care (NVTG)
- National Institute for Public Health and the Environment (RIVM)
- Working party on infection prevention (WIP)
- Health care inspectorate (IGZ)
- Federation of Medical Specialists

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DEFINITIONS

Storage cabinet
A storage cabinet is a closed dust free cabinet, with or without overpressure at room temperature, in which a dried flexible endoscope can be stored. The difference between a drying cabinet and a storage cabinet is that the endoscope channels are dried using HEPA-filtered air in the drying cabinet.
Note: European standard EN16442 refers to 'storage cabinet'; however the equipment described in this standard is in line with the Dutch definition 'drying cabinet'.

Calamity
A calamity is any incident that leads to (possible) damage in a patient or member of staff.

Compatibility
A combination of declarations concerning a medical resource to be reused, about cleaning materials and disinfectants and about an automatic cleaning and disinfection device, showing that the combination results in an effective and replicable cleaning and disinfection process.

Contact person
Person in the department in which the endoscope disinfector is in service, with authority to have repairs, maintenance, measurements, tests and checks conducted and responsible for daily and weekly inspections, or head of department.

Drying cabinet
A drying cabinet is a cabinet in which a disinfected flexible endoscope can be hung up wet and in which the endoscope's channels can be connected so that HEPA filtered air can be blown through. A drying cabinet dries the entire endoscope; the channels and the outside.
Note: European standard EN16442 refers to 'storage cabinet'; however the equipment described in this standard is in line with the Dutch definition 'drying cabinet'. In this professional manual, the drying cabinet is treated as a medical aid.

Endoscope disinfector
Machine designed to clean and disinfect flexible endoscopes using an automatic process.

Owner
Board of Directors, Directors of the Institution, representative(s), authorised person(s) and legal successor(s) who own or have possession of the endoscope disinfector.

Manufacturer
The person, including legal entities, or his representative, who:
1°. is responsible for the design, the manufacture, the packaging and the labelling of a medical device with a view to bringing it to market under his own name, regardless of whether these actions are carried out by the same person or under his responsibility by a third party; or
2°. assembles, packages, handles, renews or labels one or more prefabricated products, or designated these products as medical devices with a view to bringing them to market in his own name.

Flexible endoscope
Medical device (with flexible shaft) used to view the interiors of body cavities for diagnostic purposes and/or to carry out therapeutic treatment.

User
Specifically trained employee who is competent and authorised to operate an endoscope disinfector.

Incident
A incident is any unforeseen event, in other words a deviation of protocols or work instructions.

Supplier
Any natural person or legal entity, who has been authorised by the manufacturer to supply, place and maintain endoscope disinfectors.

Log
Digital (or written) document in which all relevant data on inspections, maintenance, breakdowns and use is to be entered and retained.

Maintenance
All actions specified by the manufacturer in the maintenance programme and preventative replacements of components to enable the endoscope disinfector to function safely.

Process control
The evaluation of all measurements, tests and checks that have been carried out in a particular period in order to safeguard a replicable cleaning and disinfection process.

Repair
Any work carried out to rectify a fault or defect in the endoscope disinfector.

Target standard
A target standard means that this recommendation refers to (medium to) large alterations to buildings or spaces or the purchase of (expensive) material or equipment and that this recommendation will be included in a subsequent rebuilding or budget.

Verification
Verification is the evaluation of the results of measurements, tests and checks carried out over a given period in order to ensure that a flexible endoscope, endoscope disinfector or drying cabinet still complies with the specifications drawn up by the manufacturer, as for a medical device. On the basis of the specifications the manufacturer has certified that the medical device meets the basic requirements of the Medical Devices Decree. These specifications are the starting point for all subsequent measurements, tests and checks. The results of the measurements and the procedures followed are tested/evaluated using the standards and instructions in this manual and set out in a report together with the underlying data (test reports, measurements, declarations, etc.).

Release, functional
A flexible endoscope, endoscope disinfector or drying cabinet is functionally released for use when following technical release the party responsible for it, in this manual the DSRD, considers it also to be functional for working in a safe and appropriate manner.

Release, technical
A flexible endoscope, endoscope disinfector or drying cabinet is technically released when the responsible department, in this manual assumed to be medical technology/clinical physics, has given a technical release for the device to be used. In many cases a functional release is still required after this step.

Release, microbiological
A flexible endoscope, endoscope disinfector or drying cabinet is microbiologically released for use when the party responsible for it considers it to be in a condition for working in a safe and appropriate manner. In many cases the microbiological release forms part of the functional release.

ABBREVIATIONS

ARBO	Working conditions (health and safety)
BMTZ	Trade association for Biomedical Technicians in Healthcare
CSA	Central Sterilisation Section
DSMH	Expert in sterile medical devices
DSRD	Expert in cleaning and disinfection of scopes
ECRI	Emergency Care Research Institute
ERCP	Endoscopic Retrograde Cholangiopancreatography
IFU	Instructions for Use
IGZ	Health care inspectorate
INK	Dutch quality institute
JCI	Joint Commission International
KVE	Colony forming units
MT/KF	Medical technology/clinical physics
NFU	Dutch federation of university medical centres
NIAZ	Dutch institute for accreditation in healthcare institutions
NV-KFM	Dutch association of clinical physical staff
NVMM	Dutch association for medical microbiology
NVZ	Dutch association of hospitals
PDCA	Plan-Do-Check-Act
RIVM	National institute for public health and environment
SFERD	Steering group for flexible endoscope cleaning and disinfection
SVN	Sterilisation association of the Netherlands
THT	Usable at least until
VDSMH	Dutch Society of Experts on Sterile Medical Devices
VHIG	Dutch Society for Infection Prevention and Control in Health Care
SMS	Safety management system
V&VN-MDL	Dutch Nurse Association; division Gastroenterology and Hepatology
VWS	Ministry for public health, welfare and sport
VZI	Association of Hospital instrumentation technicians
WIBAZ	Task group Instrumentation Management University Hospitals
WIP	Working party on infection prevention
Wkkgz	Quality complaints and conflicts health care Act

DOCUMENT STRUCTURE

The structure of this document is based on the INK-model[1]. The model offers a structure within which to combine the interests of the patient with organisational goals in a balanced manner. The model also appears to work very well as a means of communication between management board, care professionals, managers, heads of department and staff because of the simple methodology and division into 9 fields and the improvement cycle; see the figure below:

It distinguishes between five interconnected "organisational fields":

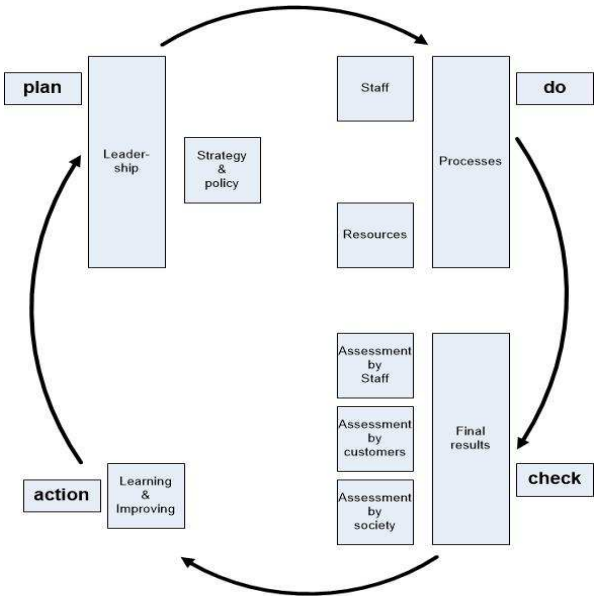


Figure 1 – *the INK model with the Plan-Do-Check-Act cycle, as applied in this SFERD manual*

PLAN:
Leadership
Strategy and policy
DO:
Staff
Resources
Processes

In connection to this are four defined result fields:
CHECK:
Assessment by customers
Assessment by staff
Assessment by society
End results

Testing and improving processes is shown in the final field:
ACT:
Learning and improving

The SFERD is grateful to have been able to make use of this model in its attempts to develop a guaranteed quality system. The PDCA cycle from the INK management model is expressed in full across the sections as follows:

PLAN:	section 1	Leadership : Vision and organisation
	section 2	Strategy and Policy
DO:	section 3	Management of Staff
	section 4	Management of Resources
	section 5	Management of Processes
CHECK:	section 6	Assessment by Customers
	section 7	Assessment by Staff
	section 8	Assessment by Society
	section 9	End results
ACT:	section 10	Process control

[1] The INK is an independent foundation established in 1991 at the initiative of the Ministry of economic affairs under the name Instituut Nederlandse Kwaliteit

1. LEADERSHIP: VISION AND ORGANISATION

1.1 Introduction

Flexible endoscopes are used for diagnostic and therapeutic purposes. Because the same endoscopes are used to treat different patients, it is important that cleaning, disinfection and sterilisation takes place appropriately. Inadequate cleaning and disinfection has adverse consequences such as:

Transmission of micro-organisms between patients

Endoscopy-related transmission of Gram-negative bacteria, mycobacteria, and fungi have frequently been described in the literature. Nor can the transmission of hepatitis B and C and HIV be excluded in the event of deficient cleaning and disinfection of endoscopes [ref 31-35].

Incorrect diagnosis

As well as the infection risk for patients, there is also a danger of incorrect diagnosis, with an inappropriate (antibiotic) treatment as a result. Patient material, in the form of fibres, can remain behind if endoscopes are inadequately cleaned and disinfected. This patient material can lead to a mistaken diagnosis during the diagnostic investigation of a subsequent patient. Alongside incorrect diagnosis with respect to mycobacteria for example, this could also concern malignant cells [ref 7-9, 36-38].

In several Dutch hospitals in recent years, adverse events have occurred involving flexible endoscopes which have caused hundreds of patients to be recalled to be tested for HBV, HCV and HIV. The Healthcare Inspectorate (IGZ) has repeatedly made the hospitals aware of their responsibilities [ref 6].

The goal of the Flexible Endoscope Cleaning and Disinfection Steering Group (SFERD) includes the development of this flexible endoscope quality manual in which the existing regulations for the cleaning and disinfection of flexible endoscopes is translated into a practical standard text. It includes a verification and release procedure, a complaints and recall procedure, and an audit and control system.

1.2 Starting points

Primum non nocere (first do no harm): with this memorable statement the medical world declares that no harm may be caused to patients. This means that we must avoid the occurrence of any exogenous contamination by micro-organisms during diagnosis or treatment using a flexible endoscope.

In its reports the IGZ has already drawn attention to omissions in the cleaning and disinfection of flexible endoscopes [ref 3,4,47]. The IGZ here refers to compliance with the directive *'Cleaning and disinfection of endoscopes'* issued by the infection prevention working party (WIP), the first version of which dates from 1992 and the current version from 2015 [ref 5].

In 2012 the IGZ published its assessment framework for the oversight of safety in the cleaning and disinfection of flexible scopes., The SFERD quality manual was included therein as a reference [ref 45]. In the same year the NVZ and the NFU published an 'agreement on the safe use of medical technology in the hospital' which explicitly stated that the hospital must have a procedure for the efficient cleaning, disinfection, sterilisation and storage of medical equipment [ref 48].

In an international context, attention was paid to ensuring the quality of endoscope disinfectors in the form of the directive EN-ISO-15883 [ref 10]. This directive establishes verification tests to obtain assurance as to the technical specifications.

Parts 1, 4 and 5 of EN 15883 summarise the test programme for endoscope disinfectors. The technical requirements and verification tests for drying cabinets are stated in the European NEN-EN 16442 [ref 26].

1.3 SFERD Organisation and Vision

The SFERD is a steering group with representatives from the following professional associations: SVN, V&VN-MDL, VDSMH, VHIG and Koepel MT (BMTZ, NVKF, NV-KFM, VZI and WIBAZ) and strives for a current version of the SFERD quality manual with a future-proofing of 3 years. The SFERD will ensure that relevant developments in the cleaning and disinfection of flexible endoscopes will be incorporated into new versions of this manual.

The SFERD has focused on current legislation and regulation, standards and guidelines. The starting point, therefore, has been that the content of this quality manual must not conflict with the existing guidelines. The SFERD wants to emphasise that endoscope disinfectors should not be used for other medical instruments for which the manufacturer of the endoscope disinfector has not provided a compatibility declaration. If single-use instruments become available for endoscopes or probes, these should be preferred.

The SFERD fully concurs with the IGZ's assumption that the cleaning and disinfection of endoscopes should be carried out by (verifiably competent and authorised) qualified personnel. This is a matter of patient safety in line with the Wkkgz (formerly: Healthcare Facilities Quality Act) [ref 40]. The feasibility of this goal will be enhanced if cleaning and disinfection is centralised as much as possible, so that these activities are carried out by as restricted a group as possible. In order to train this group adequately, the SFERD calls upon professional associations to develop appropriate training courses.

Despite the reliance on evidence-based guidelines, the SFERD concludes that the advice in this manual is mainly based on best practice and common sense. The SFERD notes that the process of cleaning and disinfecting flexible endoscopes still offers many challenges for research and publications and encourages professional associations to initiate and/or support research or publications.

2. STRATEGY & POLICY

2.1 Organisation of cleaning and disinfection

Safety management is only successful if responsibilities are clearly allocated. Both the VMS report and the IGZ reports mentioned above state as a condition that responsibilities must be clearly defined. They explicitly mention the commitment of executive committees or boards. The involvement of all healthcare providers and medical specialists is also crucial to the successful implementation of the SMS. The IGZ recommends the appointment of an expert on endoscope cleaning and disinfection (DSRD) to ensure a successful management plan [ref 4].

The Dutch Care Institutions Quality Act states that the executive committee or board is at all times responsible for the quality and continuity of operational management. Operational responsibility is delegated at a managerial level to the organisational managers or management teams appointed for the purpose. However the process is organised, measures for documentation, process quality, tracking and tracing should be appropriately set up and periodically audited. In this way the management complies with the policy framework, that has been set up by content specialists.

In the interest of the patient, organisational managers and professionals in departments which use or disinfect endoscopes must ensure the quality of care at their respective operational and medical levels when using medical equipment and must prevent inexpert use.

The medical technology/clinical physics department monitors the life cycle of medical equipment. The department also provides support and advice regarding the quality and safety of medical equipment from a technical point of view.

The infection prevention department advises on the area of infection prevention whether solicited or not during the cleaning and disinfection process of flexible endoscopes.

The cleaning and disinfection expert (DSRD) monitors operational conditions and procedures for the use of endoscopes, based on laws and guidelines. The DSRD also highlights possibilities for the improvement of patient care on behalf of the executive committee or board of the institution or its delegate. On the acquisition of endoscopes, cleaning and disinfection equipment and process chemicals, the DSRD collects the required compatibility declarations.

2.2 Central versus decentralised organisation

For the proper cleaning and disinfection of flexible endoscopes, the appropriate spatial facilities and equipment must be provided, and staff must have expertise in the cleaning and disinfection of endoscopes. The scope and design of the cleaning and disinfecting area should maintain a clear physical separation between the clean and contaminated areas. This being the case, a central cleaning and disinfection area is preferred to a decentralised area.

SCENARIO 1 - Central treatment areas and cleaning/disinfection
Endoscopy treatment areas of various specialisms adjacent to (or in the vicinity of) the cleaning and disinfection unit.

Advantage	Disadvantage
Spatial facilities and expertise are better used as the activities are carried out by a smaller group	Difficult to set up in existing buildings
Personnel and equipment can be used more efficiently. Stocks of materials can be reduced	Depending on the location in the hospital, additional transport costs and logistics problems
More uniformity	
Quality assurance is more easily controlled, so there are fewer patient risks	

N.B. Consultations regarding facilities are necessary between the various user specialisms.

SCENARIO 2 - Central cleaning/disinfection
Endoscopy treatment areas at a distance from the cleaning and disinfection unit.

Advantage	Disadvantage
Spatial facilities and expertise are better used as the activities are carried out by a smaller group	Extra logistics, requires transport methods and personnel
Personnel and equipment can be used more efficiently. Stocks of materials can be reduced	More flexible endoscopes may be necessary
More uniformity	
Quality assurance is more easily controlled, so there are fewer patient risks	

SCENARIO 3 - Decentralised cleaning/disinfection
A cleaning/disinfection unit per one or several endoscopy treatment areas

Advantage	Disadvantage
	Risk of limited staff knowledge and experience
Very short logistics chain, fast throughput and little transport required	Inefficient use of endoscope disinfector and staff.
Inefficient use of endoscopes	Absence of hospital-wide uniformity
	Quality assurance and documentation management are more difficult

Recommendations
From the point of view of patient safety, quality assurance, the better use of spatial facilities and the expertise of cleaning and disinfection staff, preference is for the central (organisation of) endoscope cleaning and disinfection. This ensures better allocation of responsibilities, clearer logistics and processes that can be planned.

In its 2004 report the IGZ stated that the hospitals it visited where disinfection took place centrally saw clear benefits in centralisation, including

- better spatial facilities;
- activities carried out by a smaller group, so that better use is made of expertise.

2.3 Quality system

The process of cleaning & disinfecting flexible endoscopes should be embedded in the hospital or departmental quality system. Guaranteeing the quality of this process should be based on a quality philosophy and quality circles (Plan-Do-Check-Act-cycles). The performance of controls, both during the acquisition and installation of equipment and during the cleaning and disinfection process itself, should be tested by frequent checks and audits, see table 3. Documents recorded in a document management system should carry the usual management data such as creation date, validity, author, authoriser, etc. It is essential that roles are properly allocated between the staff responsible. Documents for procedures with the same equipment used in different departments must carry identical instructions (standardisation).

3. STAFF MANAGEMENT

3.1 Responsibilities and authority

In an organisation where staff work with flexible endoscopes, responsibilities and authority must be established in respect of the cleaning and disinfection process. Every organisation will do this in a way which reflects its own management model.
Final responsibility for policy on flexible endoscopes rests with the management committee or the board, which, according to the advice of the IGZ, should ensure a clear allocation of responsibilities for the cleaning and disinfection process. The IGZ recommends that a flexible endoscope disinfection expert (DSRD) should be appointed. For the proper performance of his tasks, this officer needs the appropriate authority, for example the powers to halt processes. The DSRD is not a part of the management hierarchy but has an independent position vis-à-vis the departments working with flexible endoscopes. The expert's responsibilities can be further described as follows.

Expert in the cleaning and disinfection of endoscopes (DSRD)
- Advises on the drafting and implementation of the endoscope management plan;
- ensures that changes in policy are reflected in the procedures and operating instructions;
- is responsible for testing, guaranteeing and assessing process quality via internal audits;
- is responsible for the quality of the suggestions for improvement that arise from the audit;
- assesses observed discrepancies in regard to risks to patient safety and if required calls in a policy team and is responsible for reporting;
- has shared responsibility for the acquisition of flexible endoscopes and equipment;
- establishes the verification plan in consultation with the medical technology / clinical physics department and the supplier;
- has final responsibility for the functional release of the endoscope disinfector, the drying cabinet and flexible endoscope after acquisition, installation and maintenance;
- is empowered to halt the cleaning and disinfection in the event of any doubt regarding the effectiveness and reproducibility of the processes.
- is jointly responsible for the risk assessment of disorders as a consequence of adverse events.

Cleaning and disinfection department manager
- is responsible for the quality of processes for the cleaning, disinfection and storage of flexible endoscopes;
- is responsible for the introduction of new equipment;
- is responsible for providing training or retraining, and for keeping the knowledge of staff up to date;
- is responsible for reporting and documenting faults;
- is responsible for the drawing up of procedures and operational instructions;
- is responsible for the induction and support of new staff;
- is responsible for ensuring that he or she is appropriately informed regarding current procedures for the cleaning and disinfection of endoscopes and acts accordingly;
- notifies the DSRD of any incidents;
- is responsible for the exclusive use of approved equipment; in the event of any doubt as to the technical or functional status of equipment it must not be used.

Medical specialist / endoscopist
- is responsible for ensuring that he or she is appropriately informed regarding current procedures for endoscopy and acts accordingly;
- should report suspected abnormalities or failure of current procedures to the department manager;
- is responsible for the exclusive use of functioning equipment; in the event of any doubt as to the technical, functional or microbiological status of equipment it must not be used and must be reported to the department manager;
- is jointly responsible for the risk assessment of disorders as a consequence of adverse events.

Medical practitioner - microbiologist
- is responsible for the proper processing of microbiological cultures of rinse water and the endoscope;
- is responsible for interpreting the results of microbiological tests;
- is jointly responsible for the risk assessment of disorders as a consequence of adverse events.

Disinfection or Endoscopy assistant[2]
- is responsible for conducting current procedures for the cleaning and disinfection of flexible endoscopes, the endoscope disinfector, drying cabinet and associated equipment;
- is responsible for maintaining logbooks and check lists regarding the use of flexible endoscopes and associated equipment;
- is aware of the procedure in the event of faults or failure of current procedures;
- is responsible for the registration of patient, endoscope and endoscope disinfector data (patient tracking system).
- notifies the manager about incidents.

Medical technology/clinical physics department staff member
- is responsible for ensuring the quality and safety of medical equipment;
- is responsible for conducting current procedures for the maintenance and repair of flexible endoscopes and associated equipment including carrying out the verification plan;
- is responsible for recording malfunctions, repairs and maintenance of flexible endoscopes, loaned equipment and related items;
- has shared responsibility for the acquisition of new equipment for the cleaning and disinfection of flexible endoscopes;
- notifies the DSRD of any incidents;
- is responsible for the release of the endoscope disinfector and drying cabinet after maintenance and technical verification (technical release);
- is responsible for the installation, transfer and acceptance of the equipment.

Infection prevention expert
- takes part in audits of the cleaning and disinfection of endoscopes;
- provides advice and support in the development of hygiene procedures;
- advises in the event of incidents;
- advises on the acquisition of cleaning substances and disinfectants for the cleaning & disinfection of flexible endoscopes.
- has shared responsibility for the risk assessments
- has shared responsibility for the interpretation of cultivation results.

Purchaser
- coordinates commercial activities related to the acquisition of flexible endoscopes, endoscope disinfectors, chemicals, drying cabinets and associated flexible endoscope equipment.

[2] By endoscopy assistant we mean any assistant working in departments using endoscopes: GE, Urology, Lungs, and ENT. In the framework of the expertise it is recommended that a specially qualified expert be appointed for disinfection.

3.2 Training and education

Because the same endoscopes are used to treat different patients, it is important that cleaning and disinfection are carried out in a responsible manner. The quality of this cleaning and disinfection is largely determined by people. Staff should therefore be able to perform all these tasks appropriately. The aim of the training given to these employees is provide them with sufficient knowledge for the appropriate performance of their duties. Managers should be aware which staff members have had sufficient training. In the absence of relevant training courses offered by third parties, the organisation itself should provide training for staff.

Starting point
The training required by staff involved in cleaning and disinfection should be at least at intermediate vocational training level 3.

Subsequent training
To familiarise employees with the knowledge and skills required for cleaning and disinfection, and to maintain this level of knowledge, the minimum requirements are as follows:

New staff induction programme
Every new employee follows an induction programme which includes reading through all the procedures, studying the instructions for the use of the equipment used, cleaning and disinfecting endoscopes, handling equipment, reporting defects and working safely with materials. During this period, the employee will be paired up with a regular supervisor. After all aspects of the induction programme have been approved by the department head, the new employee may work independently.

Maintaining employee skills
Staff must maintain their skills and expertise in the field of cleaning and disinfection. To do so they should have regular practice in carrying out these processes, and should attend internal or external courses in the event of developments in areas such as:
- relevant legislation
- cleaning methods and machines;
- cleaning and disinfection materials;
- health and safety and environmental legislation.

A copy of the attendance certificate is kept on the employee's HR file.

Brief skills description
- vocational training certificate or equivalent level (level 3 apprenticeship training)
- fluent written and spoken Dutch, able to read and interpret instructions;
- knowledge of the contents of protocols and instructions;
- applied knowledge of and insight into the activities and practices of other departments and knowledge of the function of the flexible endoscopes used there;
- affinity with hygiene, technology and protocol-based approaches to work;
- applied knowledge of computerisation and automation.

Educational requirements of the cleaning and disinfection expert.
- can work and think at at least university level + appropriate training

Brief skills description
- an affinity with technology;
- knowledge of process management;
- knowledge of medical microbiology;
- knowledge of quality systems and the ability to apply them;
- able to transfer knowledge;
- alert to risks to patient safety;

- able to conduct risk assessments and act decisively;
- prepared to follow internal and external courses in:
    - cleaning methods and machines;
    - cleaning and disinfection materials;
    - relevant legislation
    - quality systems;
    - safety, working conditions & environment;
- prepared to consult with colleagues.

4. RESOURCE MANAGEMENT

4.1 Construction and design requirements

A prerequisite for satisfactory cleaning and disinfection of endoscopes is that the used endoscope must be routed so as to prevent any possibility of soiling of the cleaned and disinfected endoscope with microbiologically contaminated material (used endoscopes and accessories). This goal should be preferably be achieved by the physical separation of work activities. If circumstances do not permit this, then work carried out in the same space should be performed in a logical sequence to avoid contact between clean and soiled material. The size and design of the cleaning/disinfection space should be appropriate for this principle to be applied. To achieve this, the following construction and design requirements must be met.

Construction aspects	Requirements/standards
Waste	In accordance with hospital environment plan, enough space for separated waste
Disposal of disinfectants	In accordance with hazardous materials management plan/environmental permit. See also the safety data sheet for the chemicals
Doors and windows	Automatic sliding doors preferred. Alternatively, foot operated opening/closing. Windows compliant with employment laws.
Electricity	Compliant with NEN 1010, class 0 (technical quality requirements) [ref 14] of IEC 61010-2-040 [ref 46]
Air conditioning	Washer-disinfector extraction system, as per manufacturer's recommendations. Splashing from preliminary hand cleaning must not contaminate clean endoscopes.
Receiving area for soiled endoscopes	Enough space to take in and temporarily store soiled endoscopes including their means of transport
Supplies storage for the chemicals section	Liquids in drip tray, cleaning and disinfecting materials as required under employment law and by environmental permit, see also the safety data sheets for the materials
Ceiling	Ceiling in dust-free, moisture resistant material with adequate technical space above ceiling
Spatial separation	Floor area large enough to allow separate spaces for clean and soiled goods flows, to be achieved by: -separated spaces where the endoscope disinfector forms the separation (target standard) -in the absence of a pass-through system: min. 1.5m between area of pre-cleaning and endoscope disinfector (procedural separation)
Future	Take account of future developments in technology, data processing, equipment required and possible expansion
Distribution area for clean endoscopes	Enough space to store and distribute clean endoscopes including their means of transport (option: pass-through cabinet in the wall)
Lighting	In line with standards, no areas in shadow
Wall and floor covering	Smooth finish, shock-resistant and easy to clean, resistant against cleaning agents and disinfectants. Floor must not become slippery when wet
Water	Water from the used equipment must not be able to return into the water supply. The water quality required depends on the type of disinfector and the cleaning and disinfection agent and will be specified by the supplier. Take account of space for any water filters required. The use of water that has been treated with copper/silver to combat legionella is not recommended Experience has shown that these substances from the water form deposits on endoscopes and in the washing machine. The function of the water treatment installations can also be affected.

Spatial design aspect	Requirements/standards
General	Facility to install emergency alarm.
Administrative workstations	A PC with keyboard that can be cleaned. Network connection and good lighting.
Equipment	Should be marked clearly (e.g. a printed sticker) with information for users and technicians stating the time limits within which the equipment can be used in view of its maintenance and verification status.
Health and safety	Construction and design is consistent with health and safety policy. As a minimum there must be an eye bath and provision to protect staff from splashing.
Drying and storage cabinets	Spatially separated from work on soiled material. Pass-through cabinets should be considered. Utilities: HEPA filtered air, electricity, data processing.
Endoscope disinfector	Enough space for number required, installation, loading/unloading, operation, maintenance and repairs. Target standard: pass though equipment. Utilities: compressed air, water, electricity, suction, data, sewer connection
Hand hygiene	On “dirty” work side: - washstand with foot/elbow operated tap - elbow-operated soap and hand cleanser dispensers - hand towel dispenser On “clean” work side: -elbow-operated hand cleanser dispenser.
Leakage tester	Close to sink but located such that no there can be no contact between moisture and the internals of the (electric) leakage tester
Carrying bins and means of transport for cleaning and disinfection products	Requirement depending on centralised or decentralised working. Machine-operated preferred (target standard) Utilities for mechanised cleaning and disinfection: compressed air, water, electricity, suction, data and sewer connection
Clean/dirty transport	Requirement depending on centralised or decentralised working. Make a clear spatial separation between clean and dirty transport
Sinks and worktops	Sink (in easily cleaned material) with rounded corners, fitted with spray head. Size consistent with endoscope length. For the sake of reproducibility, automatic dosing is recommended. Consider point extraction and/or splash screen. Dirty worktop, adequate size for the work to be carried out. Smooth waterproof finish without seams. Rear wall of worktop smooth and easily cleaned, seamlessly attached to worktop. Storage space for materials required for pre-cleaning by hand Clean worktop, spatially separated from dirty worktop, including compressed air pistol or other provision for cleaning out canals. Storage space for clean endoscope accessories. Consider high-low worktops (health and safety)

4.2 Acquisition of endoscopes, endoscope disinfectors and accessories

The flow chart for the acquisition and replacement of equipment (figure 2) broadly outlines the cycle of acquisition and/or replacement for endoscopes, endoscope disinfectors and drying cabinets. The flow chart can used be as a guide to involve the relevant disciplines within the hospital in the final choice of equipment. The structure depends on the organisation.
Within a particular institution, when a given type of endoscope disinfector is used for scope cleaning and disinfection, it is preferable[3] that the same cleaning agents and disinfectants are used for the different phases of cleaning (by hand and/or mechanised) and disinfection (standardisation).

[3] Where all endoscopes are suitably compatible with the same chemicals.

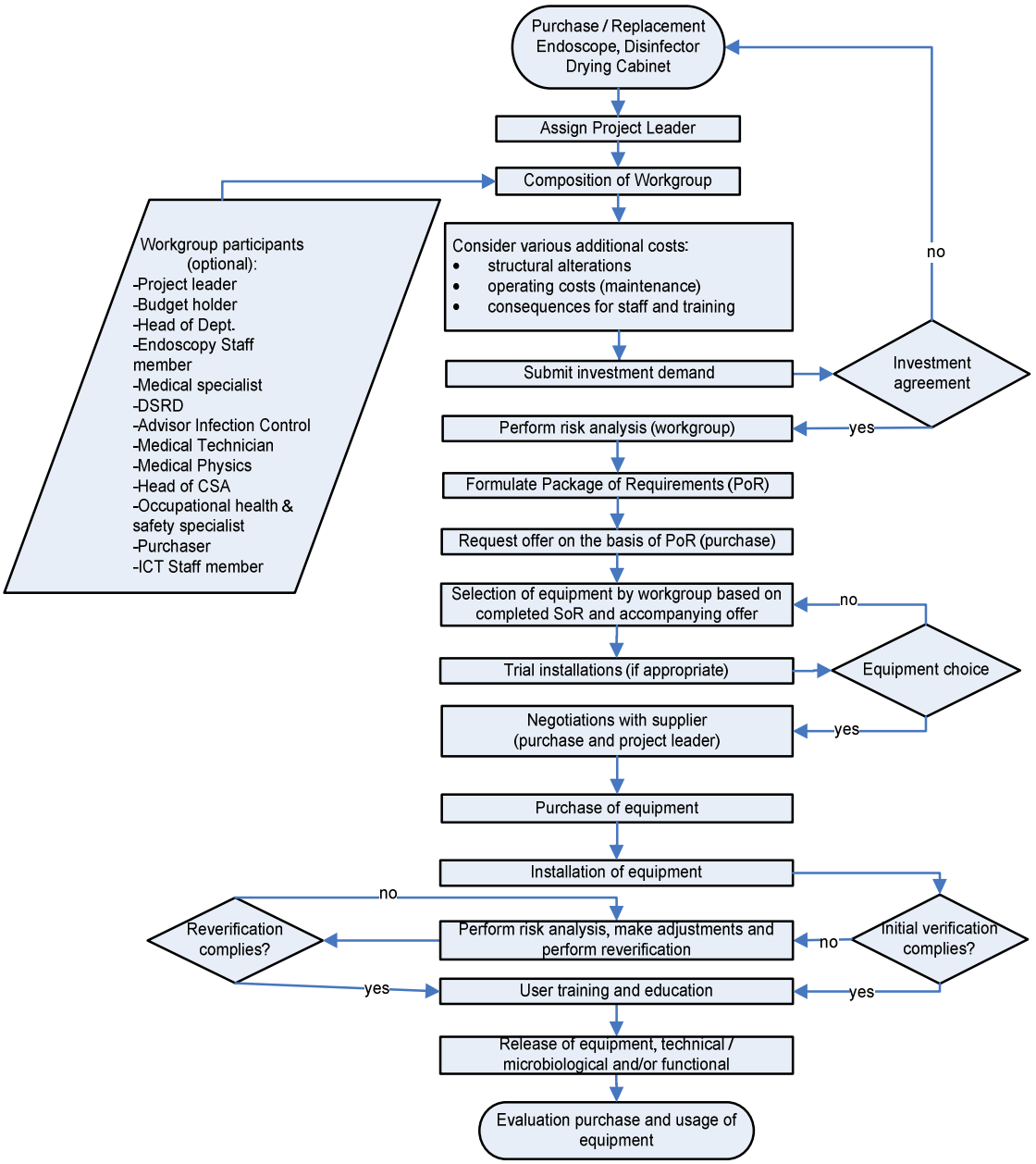


Figure 2 *- Flow chart for acquisition/replacement of endoscope, endoscope disinfector and/or drying cabinet (and any other equipment)*

4.3 Package of requirements (PoR) for endoscopes, endoscope disinfectors and drying cabinets

The package of requirements is a verification tool for market research for purchasing and is set out as a check list, split into the following main groups of requirements:

- Legal
- Verification
- Health, safety and environment
- Technical and technological
- Process
- Cleaning and disinfection
- Drying
- User-friendliness
- Traceability and recording
- Installation conditions
- Maintenance and service
- Support/training

These primary groups are made up of subgroups for which the supplier should indicate yes or no to show whether the specified criterion is met. It is also possible to add remarks and reference can be made to attached documents.
The package of requirements covers both statutory requirements and points for attention drawn up by the SFERD. It is the responsibility of hospital's working party to set a value for the points for attention or to seek clarification or other information.

A preliminary risk assessment, as recommended by bodies including the NVKF [ref 29], is necessary in order to be able to determine what points will require for attention in the follow-up to the acquisition and what specific input is required from officials.

The appendices give examples for programmes of requirements. Programmes of requirements cannot be copied and must be rewritten to suit the situation and the preferences of the hospital. The documents in the appendices can be used as a starting point.

See appendix 15 for endoscope disinfector package of requirements
See appendix 16 for flexible endoscope package of requirements
See appendix 17 for drying cabinet package of requirements

5. PROCESS MANAGEMENT

5.1 Primary process: cleaning, disinfecting and drying flexible endoscopes

Processes are the basis of every organisation. A process sets out the sequence and interactions of a series of activities which have to be carried out during a process. Having a clear overview of risks allows them to be minimised and processes can be organised efficiently and improved.
Risk management is used to optimise patient safety. This means that the risks which stem from human, technical and/or organisational inadequacies in the process of providing a service are as far as possible eliminated.

Where possible work must be carried out according to the manual (IFU) of the manufacturer.[4] In areas where this is not possible or desirable, the procedures from this handbook will be followed.[5]

The different stages of the process are described in the primary process flow chart (figure 3). The risks are shown in a risk table (paragraphs 5.4 and 8.2). This provides a clear overview for all those involved. The management measures for the most serious risks are described.

This section describes the following stages of the process:

STEP 1	Get ready for use the disinfected endoscope
STEP 2	Transport of used endoscope
STEP 3	Initial rinsing by user in the treatment room
STEP 4	Transport of used endoscope
STEP 5	Preparation, cleaning and disinfection of the endoscope
STEP 6	Manual leak test of the endoscope
STEP 7	Operating a defective endoscope/endoscope disinfector
STEP 8	Preliminary manual cleaning of the endoscope
STEP 9	Automated cleaning and disinfection of the endoscope
STEP 10	Release of the flexible endoscope following disinfection
STEP 11	Flexible endoscope drying and storage process
STEP 12	Cleaning and disinfecting outside normal working hours
STEP 13	Loaning out flexible endoscopes and/or accessories
STEP 14	Variations to primary process for endoscopes without channels
STEP 15	Replacing cleaning materials and disinfectants
STEP 16	Self-disinfection of endoscope disinfector
STEP 17	User maintenance of endoscope disinfector

[4] A manufacturer is required (as in ISO-17664) to align himself to the practical feasibility.
[5] Deviations from the manual must be set down in the institution's procedures.

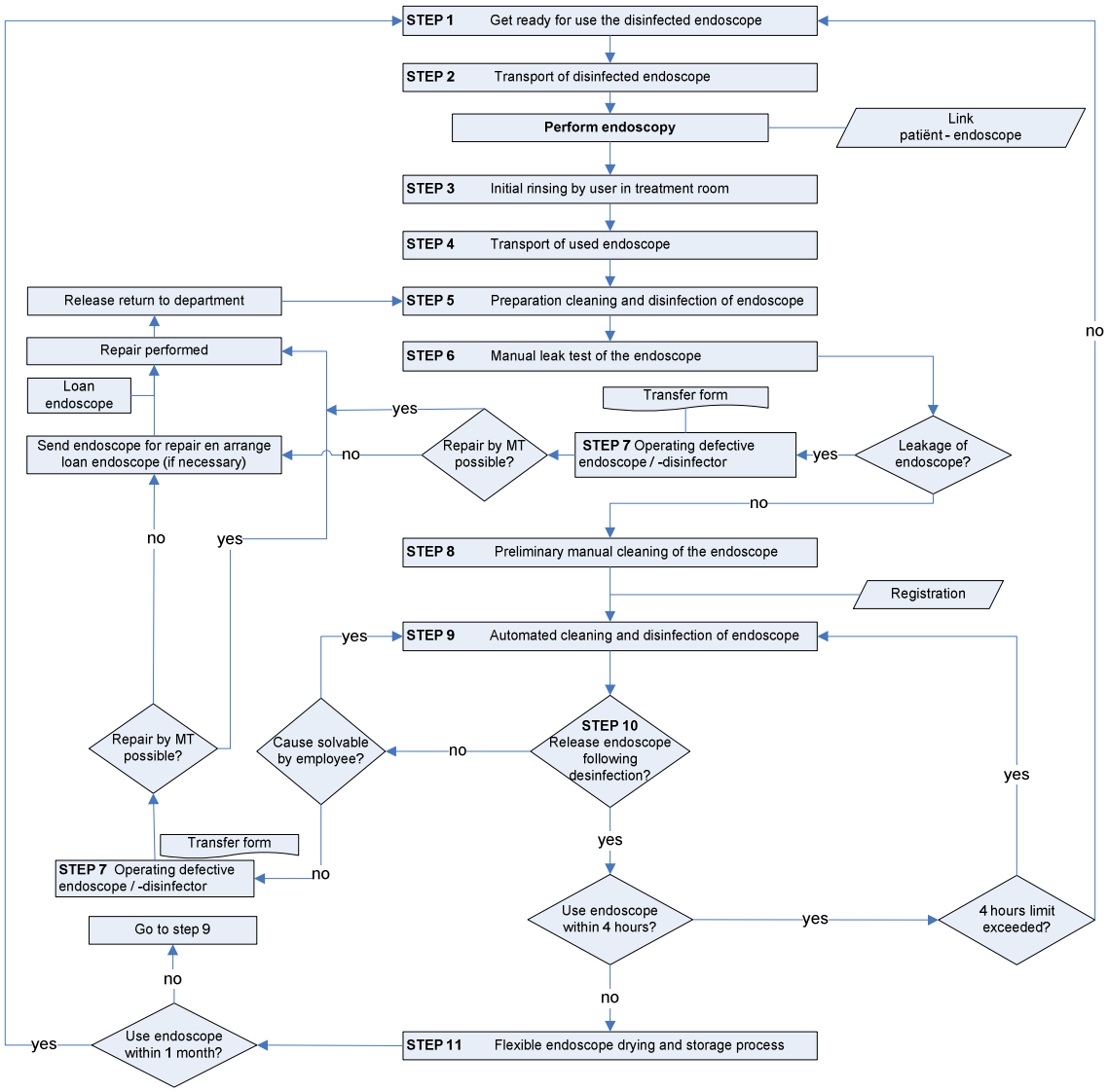


Figure 3 – Primary process for cleaning and disinfection of flexible endoscopes

STEP 1 – Get ready for use the disinfected endoscope

- All activities involving a disinfected endoscope must be carried out with disinfected hands;
- Take the endoscope from the drying/storage cabinet or endoscope disinfector (if endoscope is removed directly from endoscope disinfector, it must be used within 4 hours). For this reason, the time until when the endoscope may be used must be clearly indicated on the transport container. If this time limit is exceeded, the scope must be mechanically cleaned and disinfected again;
- Before the endoscope is taken from the endoscope disinfector it must be released (see step 10);
- For use of endoscope taken from drying/storage cabinet: check for any visible signs of water in the connection hoses, if this is the case the technician must be consulted to investigate the problem. Do not use endoscope while awaiting the findings of the technician;
- Affix accompanying single-use or disinfected valves and place a single-use biopsy cap on the biopsy channel.

STEP 2 - Transport of the disinfected endoscope

- lay the endoscope in a disinfected container/system, and cover it in such a way that it is clear that the endoscope is disinfected (with a lid, dust cover/plastic sleeve or similar); Ensure that the endoscope is protected from damage while being moved and that the cleanliness remains guaranteed.
- The container should show the use-by time, taking account of whether the endoscope has been properly dried and transported to the treatment/endoscopy room.

During endoscopy the general precautionary measures recommended by the WIP should be applied. Materials and liquids used should be applied in accordance with the Spaulding principle[6]. The used endoscope is also linked to the patient by registering it in the locally used system,

STEP 3 - Initial rinsing by user in the treatment room

Directly after the endoscopy the initial cleaning will be performed as follows while wearing gloves:
Note: the dirty gloves are removed (and hands disinfected) as soon as the dirty tasks have been completed.

- draw cleaning agent (aqueous solution), compatible with cleaning and disinfection materials used in the endoscope disinfector, through the suction and biopsy channel;[7]
- continue to draw fluid through until the used fluid is clear;
- flush and blow through the water/air channel (using valve);
- wipe the outer shell with an non-sterile damp gauze;
- set the endoscope controls knobs to a neutral (free) position;
- place the endoscope in the transport container;
- disconnect the water/air bottle and suction hose of the endoscope
- turn off the processor and light source; uncouple the endoscope and put the protective cap on the connector of the scope;
- deal with the (digital) recording of patient, medical specialist and endoscope. record this in the registration system

Note: if channel-free endoscopes without sheath are being used, the outside of the endoscope will be cleaned after use as preparation for mechanical cleaning and disinfection.

[6] In 1968 Spaulding drew up a cleaning, disinfection and sterilisation scheme for medical appliances, based on the risk of infection for the patient. Spaulding operated on the basis of 3 categories: critical, semi critical and non-critical. Critical means that a there is substantial risk of infection for the patient when the medical appliance is contaminated with micro-organisms. In these cases sterilisation is necessary. Semi critical means that the risk of infection for the patient is lower and disinfection of the medical appliance is enough, while for non-critical cases cleaning is sufficient.

[7] The cleaning fluid should be transparent in order that the clarity of the used fluid can be assessed.

STEP 4 - Transport of used endoscope

- seal the transport container;
- clearly mark on the container that the endoscope has been used;
- transport the contaminated endoscope (status: contaminated) in the sealed container directly to the disinfection area;
- Offer the container with the endoscope up immediately for preliminary cleaning by hand and mechanised disinfection.

STEP 5 - Preparation for cleaning and disinfection of the endoscope

Requirements:
For personal protection (see WIP[8] and locally applicable advice):

- waterproof smock with long sleeves;
- disposable gloves;
- surgical mouth/nose mask;
- eye protection (safety goggles, face shield, protective glasses or splash guard with a surgical mouth/nose mask).

For the cleaning and disinfection process:

- a suitable cleaning agent for preliminary cleaning by hand, compatible with the cleaning materials and disinfectants used in the endoscope disinfector. activation time, concentration and temperature are applied in accordance with manufacturer's instructions;
- caution: disinfectants in the endoscope disinfector must at a minimum be active against vegetative bacteria, mycobacteria, viruses, fungi and yeasts.
- gauze or cellulose cloths;
- various single-use brushes compatible with working channel diameter;
- tools to flush out or blow through channels, such as;
    - air/water spray gun or suction system;
    - Luer Lock connectors;
    - water jet channel tube (depending on type and make of endoscope);
    - elevation channel tube (depending on type and make of endoscope);
- leakage tester;
- (optional) cellulose mat or underlay;
- cleaning materials and disinfectants for transport containers or a container washing machine.

Execution:

- fill a large clean sink with cleaning fluid (concentration and temperature in accordance with manufacturer's instructions);
- place the cellulose pad or underlay used for the protection of the endoscope on the work surface;
- remove valves and distal caps, unless valves are required for endoscopes of which channels have to be flushed through rather than brushed (e.g. EUS/EBUS).
- clean the reusable valves and other accessories according to manufacturer's instructions;
- disinfect the transport container.

STEP 6 - Manual leak test of the endoscope[9]

- the endoscope is laid (on a cellulose pad or underlay) with the controls uppermost;
- connect the leak test hose to the leakage tester connector of the endoscope (check the pressure); check with endoscope supplier before setting the pressure
- connect the leakage tester and the shaft swells up slowly;
- immerse the endoscope completely in the sink with cleaning fluid in which the endoscope can lie stretched out;
- wait at least 1 minute, until full pressure has been reached;
- check the endoscope for leakage, being sure to agitate the tip thoroughly;
- if the endoscope leaks: see step 7;

[8] WIP guideline 'General precautions, personal protective equipment' Sept 2015
[9] Procedure depends on the type of leakage tester.

- if the endoscope does not leak, carry out preliminary cleaning: see step 8;
- carry out the preliminary cleaning under pressure of the leakage test pump.

STEP 7 - Operating a defective endoscope / endoscope disinfector

If the endoscope shows signs of leakage or one or more channels are blocked, the endoscope must be sent for repair to Medical technology / Clinical physics.
A leaking endoscope cannot be disinfected and may be contaminated with pathogenic micro-organisms. A blocked endoscope must be treated as if it is contaminated.
The endoscope should be handled as follows before it is sent for repair:

- clean the outside of the non-disinfected endoscope and after drying wipe it off with alcohol 70%;
- dry the channels as far as possible;
- place the defective endoscope in a sealed container;
- label the endoscope “contaminated”;
- the user completes the transfer form (see example in appendix 2);
- the technician handles the endoscope with gloves on, and if necessary with goggles and mouth and nose mask and protective clothing (according to local regulations);
- the technician covers the endoscope in film and takes it away in a transport case. the case is clearly labelled to show that the endoscope is contaminated;
- following repair and before use the endoscope must always be mechanically cleaned and disinfected.

Note: Defects can also occur as a result of defects in the endoscope disinfector, involve the MT to get this verified.

STEP 8 - Preliminary manual cleaning of the endoscope[10]

- before brushing ensure that the channels are full of cleaning solution and fully immerse the endoscope;
- use a single-use brush with the correct diameter for each endoscope;
- check in-between if brush is visually contaminated and if that is the case rinse it clean;
- brush the biopsy/suction channel (there are endoscopes where other channels must also be brushed):
  - from suction channel valve housing to connector;
  - from suction channel valve housing to distal;
  - from biopsy valve to distal;
- flush all channels through with cleaning solution;
- flush the jet channel through with cleaning solution;
- flush the CO_2 channel, if any, through with cleaning solution;
- flush the elevator channel, if applicable, through with a 1 or 2 ml spray of cleaning solution (following the instructions of the manufacturer);
- brush the back and sides of the elevator (if present) and/or flush through with cleaning solution. For this follow the endoscope manual and use the prescribed brush[11];
- wipe off the outside with a gauze;
- brush the knobs on the control housing and the distal end;
- brush out the valves (see paragraph 5.2);
- take the endoscope out of the sink;
- switch off the leakage tester and vent the endoscope;
- transport the endoscope (if required in a sealed container (marked as contaminated) if the disinfection area is elsewhere) to the disinfection area and place it in the endoscope disinfector.

[10] The manufacturer may recommend specific procedures for the endoscope; the manufacturer’s specifications are always to be taken as a guide
[11] ECRI Health Devices Alerts H0245 : Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes: Design May Impede Effective Cleaning

STEP 9 - Automated cleaning and disinfection of the endoscope[12]

- Open the endoscope disinfector preferably using the foot or knee switch;
- Using gloves, place the endoscope inside the endoscope disinfector;
- Connect the channels to the correct hoses as prescribed;
- Take note of specific remarks by the manufacturer in the endoscope manual, for instance about the position of the
- Check that there are no kinks in the hoses;
- Clean and disinfect the valves and distal caps, if they are not single-use (see paragraph 5.2);
- Take gloves off and disinfect hands;
- Close the door of the endoscope disinfector;
- Choose the correct programme, according to the supplier's instructions;
- Record (preferably automatically) the data required:
    - Date + time of the process;
    - identification number of the endoscope disinfector;
    - Patient details (if not linked during the endoscopy);
    - identification number of the endoscope;
    - R&D staff member responsible.
- Start the programme;
- If the endoscope disinfector interrupts the programme because of an error message, follow the manufacturer's instructions;
- In the event of repeated error messages, call in medical technology/clinical physics.

STEP 10 - Release of the flexible endoscope following disinfection

- Check that the disinfection process has been completed;
- Open the endoscope disinfector with disinfected hands or using a foot switch;
- Check that all hoses, caps and channel separators are still connected and that the endoscope is not visually contaminated; if necessary use a check list;
- If all conditions are met, then the endoscope can be released and the release recorded on the form 'flexible endoscopes user release' (see appendix 14) or automatically;
- If not all conditions are met, then the problem must be resolved and the disinfection procedure must be carried out anew;
- In cases of use within 4 hours of disinfection the transport container will be marked with a label indicating the maximum time of use. If the endoscope is not used within the set period, it must be returned for mechanical cleaning and disinfection again. Before transport the endoscope can be dried both inside and out using medicinal compressed air.

STEP 11 - Flexible endoscope drying and storage process

- Store endoscopes without channels in a storage cabinet and endoscopes with channels in a drying cabinet;
- If it is not for immediate use, place the endoscope in the drying cabinet;
- Close all channels of the endoscope in accordance with the supplier's instructions. Depending on the type of drying cabinet, drying takes between 30 and 120 minutes: (in accordance with information from supplier);
- Ensure that endoscopes are not hanging/lying on the bottom of the drying cabinet;
- Put the valves and other loose components in a wire basket in the drying cabinet;
- Set the drying time in in accordance with the supplier's instructions;
- When the drying process has finished and the process has been checked and agreement reached, the endoscope can be released;
- After the complete drying procedure the endoscope (and the valves and other loose components) can be stored for one month in the drying cabinet or dust-free storage cabinet, in accordance with the WIP.

Remarks:

- Where the endoscope has not undergone a complete drying process, if it is not used within four hours it should be returned for disinfection again.

[12] The procedures described depend on the type of endoscope disinfector

- If the drying cabinet is not working well or is faulty, contact should be made with medical technology/clinical physics and the (insufficiently dried) endoscope should not be kept for more than four hours before use.
- The drying cabinet should be validated as specified in section 10.

STEP 12 - Cleaning and disinfection outside normal working hours

- Immediately after use initial pretreatment is carried out in the treatment room as described in step 3;
- As soon as possible after pretreatment cleaning (within locally determined time-scale) manual precleaning and mechanical cleaning and disinfection will take place.

STEP 13 - Loaning flexible endoscopes and/or accessories [13]

- Principal places a loan order[14] with the appropriate department of the institution;
- When making the order, the supplier's conditions and documentation on technical data and cleaning and disinfection are required;
- The principal informs the departments in question (e.g: CSA, DSRD and MT/KF) about the endoscopes and equipment ordered and the dates and time period on which they will be supplied, used and returned;
- The medical specialist/endoscopist can only plan the intervention if the conditions for adequate cleaning and disinfection[15] are met;
- Reception and checking of endoscopes and/or equipment within the institution at the medical technology/clinical physics[16] department and then into the department for cleaning and disinfection;
- Loaned endoscopes should be "learned" in the endoscope disinfector, so that their correct specifications can be stored in the endoscope disinfector;
- Cleaning, disinfection and where necessary sterilisation by the relevant department;
- Delivery of the endoscopes and/or equipment to the user;
- After use, return as quickly as possible for cleaning and disinfection.

Explanation

Documentation by the supplier:

Offering an endoscope or equipment should always start on the presumption that it is being offered for the first time. If it is a repeat order it should be indicated that all documentation is already in the hands of the department in question.

Documentation to be supplied by the company:

- identification form for the endoscope;
- decontamination declaration;
- and in accordance with EN 17664 [ref 39]:
    - cleaning, disinfection and where necessary sterilisation protocol for loan supplies;
    - maintenance instructions and instructions for functional operating test.

Reception of endoscopes/equipment, routing and checks.

- The endoscope and/or equipment should be supplied to the medical technology/clinical physics department at least one working day before the planned intervention in a closed package for transport;
- The endoscope is recorded by medical technology/clinical physics in the institution's recording system;
- Medical technology/clinical physics is then responsible for transport to the relevant department;
- The supplier must keep a log for the endoscope in which the decontamination declarations are kept and the history of the equipment can be made available to the user on request;

[13] The same measures apply to a loaned endoscope as for a new endoscope;

[14] Loan/rental: for use with patients for a given period, via an order number submitted to organisation. For assessment: only for testing, not in combination with use on patients/trial placement, etc.

[15] Compatibility is determined.

[16] Records should be kept of endoscopes with serial number and period in service in the institution.

- The supplier declares to the institution on delivery of the endoscopes that the materials have been decontaminated. In this, the supplier cannot invoke a declaration made by an earlier user.

Return via medical technology/clinical physics
- At medical technology/clinical physics a record should be made of the loaned endoscope on return to the supplier.

STEP 14 - Variations to primary process for endoscopes without channels

Channel-less endoscopes that are being used with an intact sheath must, if not mechanically cleaned and disinfected, be disinfected after use with alcohol 70% or other disinfectants as described by the endoscope manufacturer, taking into account the prescribed contact period. At the end of the programme the channel-less endoscopes are transported to the (main) cleaning and disinfection area for mechanised disinfection. This means that after each endoscopy the channel-less endoscopes are automatically tested for any leaks using the leak test in the endoscope disinfector. Endoscopes should be transported in closed transport containers, which must be cleaned and disinfected. Since the chance of a look-back procedure is so slight and an endoscope leak will only affect one endoscopy programme, a track & trace recording is not necessarily required. Patients may be traced on the basis of surgery registration.
In the event of aseptic use of a CE-marked sheath there is no indication for cleaning during interim disinfection and after the sheath has been removed the endoscope can be disinfected with alcohol 70% or another disinfectant permitted for this purpose. Without the use of a sheath there is therefore always an indication for cleaning and disinfection which is always carried out mechanically.

After mechanical cleaning and disinfection the endoscope is stored dry in a storage cabinet or other dust-free storage facility according to the supplier's instructions. If, following mechanised disinfection the endoscope does not come dry out of the endoscope disinfector, the endoscope is dried in a drying cabinet or wiped off using a gauze with alcohol 70%, so that air-drying is promoted.

STEP 15 - Replacing cleaning materials and disinfectants

Required materials (if indicated on the safety data sheet):
- cleaning agent and/or disinfectant, CE-marked, permitted on the Netherlands market and compatible with endoscopes and endoscope disinfectors;
- gloves;
- mouth/nose mask;
- smock;
- safety goggles.

Method:
- Take account of the general safety measures as well as the personal protection measures (see endoscope disinfector guide and chemicals safety data sheet);
- When the message is received from the endoscope disinfector the container with cleaning agent/disinfectant is replaced;
- Ensure that you set out the correct replacement product. The types of containers with the various types of cleaning agent or disinfectant are recognisable, to ensure that only one type of cleaning agent or disinfectant is placed in the appropriate place in the endoscope disinfector. This will prevent confusion or mix-up of chemicals;
- Replace the container; check for the correct (colour) coding on the connector. Read the Dutch labelling closely;
- A second person must always check that the containers are fully connected before the endoscope disinfector is re-used, unless there is automatic control;
- Record in the log: date, time, name and serial number of the agent being replaced, name of endoscope disinfector, if not computerised then to be initialled by two people.

Remarks:

- Incorrect exchange of containers results in the endoscopes being inadequately cleaned and disinfected.
- Using incompatible chemicals can lead to damage to endoscopes and endoscope disinfector.
- The cleaning agents and disinfectants for hand and mechanised cleaning and disinfecting of endoscopes should be standardised across the entire organisation.
- Do not transfer residues for reuse.
- Containers with residues should be closed and processed in accordance with current hospital guidelines.

STEP 16 - Self-disinfection of endoscope disinfector

Endoscope disinfectors are equipped with a self-disinfection programme. This programme is executed to prevent a biofilm from forming.
The self-disinfection procedure reaches internal parts of the machine which are not touched by disinfectant during the standard process.

Method:
- Check that the endoscope disinfector does not contain an endoscope and start the self-disinfection program. The endoscope disinfector's self-disinfection program should be used in accordance with the supplier's instructions. At least weekly, preferably at the weekend or during the night;
- The self-disinfection programme is in any advent advised prior to an expected period of non-use that is longer than 24 hours. The aim is to arrive at a lower exit contamination for an endoscope disinfector of which it is expected that it may be out of use for a longer period. The self-disinfection programme is also recommended after a period of non-use that is longer than 24 hours.

Note:
The SFERD recommends that the manufacturer's advice should be followed. Variations to this procedure should only be made after due consideration with sufficient grounds. Changes to the recommended procedures will probably result in the manufacturer no longer being liable for any issues arising.
Following a thermal self-disinfection program the endoscope disinfector remains hot for long enough that a cooling period is necessary. No endoscope disinfection may take place in the interim. Account should be taken of this when scheduling thermal self-disinfection. Most endoscope disinfectors are fitted with a timer. This allows the (thermal self-disinfection to take place before the start of the working day.

STEP 17 - User maintenance of endoscope disinfector

in accordance with the instructions, Medical technology/clinical physics will decide jointly with the DSRD what maintenance is needed. Thereafter responsibilities for maintenance can be split between the DSRD and medical technology/clinical physics and possibly others. The supplier recommends that the owner carries out frequent checks and routine maintenance to the endoscope disinfector. Checks and maintenance carried out should be signed off; the template for a routine endoscope disinfector maintenance form (appendix 4) could be used for this purpose. The form for each endoscope disinfector must be stored in the log. Checks and maintenance should be considered to include:
- running the endoscope disinfector's self-disinfection program;
- checking that cleaning agent and disinfectant are correctly connected;
- checks on (defective) connecting hoses;
- checks on (defective) O-rings; (also on channel separator)
- cleaning the control panel and handles;
- cleaning (the outside of) the endoscope disinfector.
- remove and clean strainer (depends on brand);
- soften water for the endoscope disinfector in accordance with supplier's instructions (when the endoscope disinfector indicates this; the frequency depends on the hardness of the water used).

These check-items are also considered as an element of verification; see para [10.2.

5.2 Cleaning, disinfection and sterilisation of accessories

Accessories used in endoscopy may be divided into four groups:

1. Accessories used in endotherapy (intervention materials);
2. Rinsing systems;
3. Endoscope accessories;
4. Accessories used during cleaning process.

If during endoscopy the accessories come into direct with sterile tissue, they too must be sterile. The prescribed method for these four groups is described below.

Group 1: Accessories used in endotherapy

- These instruments come into direct contact with sterile tissue during endoscopy;
- Single-use accessories are preferred;
- Reusable accessories must be sterilised.

Group 2: Rinsing systems

- The sterile water bottle is filled with sterile water and must be replaced daily;
- Single-use bottles are preferred;
- Reusable bottles must be sterilised.

Group 3: Endoscope accessories

- These accessories do not come into direct contact with sterile tissue, but the likelihood of contamination with tissue and bodily fluids is high;
- Single-use accessories are preferred;
- Reusable accessories should preferably be sterilised, at a minimum mechanically cleaned and disinfected;
- Reusable valves should be brushed both in open and closed position. This removes as much contamination as possible. The valves are then preferably sterilised, at a minimum mechanically cleaned and disinfected.

Group 4: Accessories used during the cleaning process

- These accessories do not come into direct contact with the patient during endoscopy;
- These accessories are single-use.

Table1 – *Accessories and their respective methods of disinfection or sterilisation*

Group	Accessory types *	Mechanical disinfection	Sterilisation [17]	Single Use
1	Biopsy forceps, loops, ERCP materials and irrigation equipment		X	X
2	Rinsing water bottle and hose		X	X
3	Valves, caps and mouth pieces	X	X	X
4	Water jet channel hoses Brushes	X	X**	X X

Note: *- single-use are always preferred to reusable equipment.*
** = accessories which cannot withstand disinfection or sterilisation may be used once and then discarded.*
*** = if material withstands sterilisation*

[17] Sterilisation is always preceded by cleaning and mechanical disinfection

5.3 The installation of an endoscope disinfector

Before the endoscope disinfector is taken into use, the supplier checks the following aspects of the installation in consultation with the medical technology/clinical physics department. The endoscope disinfector must be verified prior to commissioning.

General utilities

The room must contain at least a water supply (including filters), an outlet to the sewage system, electricity, air extraction and a network connection.
Ensure that the existing air extraction has sufficient capacity to deal with the machines.

Instruments

- Testing and if necessary calibration of:
  - temperature, pressure and flow sensors;
  - disinfectant dosing system;
  - detergent dosing system.
- technical verification (see paragraph 10.1);
- provide a logbook for each endoscope disinfector; record with mention of process counter status:
  - machine inventory data;
  - preventive and corrective maintenance;
  - faults;
  - replacement of components;
  - interrupted processes;
  - replacement of detergent and disinfectant containers;
  - verification (refer to verification report);
  - release declaration.

Microbiological aspects

- Microbiological verification (see paragraph 10.3);
- These items are reported to the cleaning and disinfection expert (DSRD) by the department responsible;
- The DSRD is responsible for the assessment and functional release of the endoscope disinfector (see Appendix 5 for release form);
- The DSRD is also responsible for archiving the technical and microbiological installation reports.

5.4 Risk inventory and assessment

The cleaning and disinfection of endoscopes is carried out in order to prevent patient risks. However, these procedures may bring other risks with them. Both the supplier of the cleaning and disinfection equipment and the heads of the departments concerned must take this into account. Risks can be divided into categories:

- risks to staff;
- risks to endoscopes and endoscope disinfectors;
- environmental risks;
- chemical safety risks;
- microbiological risks

Risks can be minimised by using general precautionary measures or by circumstance-specific measures. The potential risks in each category and the measures required to minimise them are described below.
The hospital itself should conduct a risk assessment tailored to the location.

Risks to staff

Tasks	Risk	Risk-minimising measures
Transport of contaminated endoscopes	Injury, contamination, physical symptoms	Clear working instructions, protective clothing, vaccinations in accordance with hospital policy, appropriate body posture
Manual preliminary cleaning of contaminated endoscopes	Injury, microbiological and chemical contamination (via the skin, mucous membranes or inhalation; or caused by aerosols), physical symptoms	Clear operating instructions, protective clothing, extractor system, vaccinations in accordance with hospital policy, appropriate body posture
Loading and unloading the endoscope disinfector	Injury, contamination, contact with chemical fluids (via the skin, mucous membranes or inhalation) physical symptoms	Clear operating instructions, protective clothing, vaccinations in accordance with hospital policy, well ventilated work place, endoscope disinfector extractor, regular maintenance and appropriate body posture
Replacement of cleaning and disinfection materials	Contact with chemical fluids (via the skin, mucous membranes or inhalation)	Clear operating instructions, protective clothing, mask, goggles, well ventilated work place, appropriate body posture Storage in accordance with instructions

Risks to endoscopes and endoscope disinfectors

Tasks	Risk	Risk-minimising measures
Transport of (contaminated) endoscopes	Damage	Clear operating instructions, protective transport containers
Manual preliminary cleaning of contaminated endoscopes	Damage, leakage, corrosion, biofilm	Clear operating instructions, the right cleaning materials/equipment, mechanical cleaning
Loading, mechanical disinfection and unloading of the endoscope disinfector	Damage, defects and leaks, corrosion and biofilm to endoscopes and endoscope disinfectors	Compatibility checks, clear operating instructions, the right cleaning and disinfection materials, (thermal) self-disinfection, preventive maintenance
Storage of clean endoscopes	Damage	Protective transport containers, appropriate drying and storage cabinets

Environmental risks

Tasks	Environmental risks	Risk-minimising measures
Storage of chemicals	Leaks Explosive	Storage in accordance with supplier's instructions
Disposal of chemical waste	Improper disposal or leakage of chemical waste	Clear operating instructions, special containers and disposal procedures
Discharge to the sewer	Improper discharge of chemical waste	Clear operating instructions, discharge permit

Chemical risks

Tasks	Risk	Risk-minimising measures
Disposal of chemical waste	Improper disposal or leakage of chemical waste	Clear operating instructions, special containers and disposal procedures
Replacement of cleaning and disinfection materials in the endoscope disinfector	Unintentional spillage and leakage of detergents and disinfectants, improper disposal	Clear operating instructions, appropriate storage of cleaning and disinfection materials, special containers and disposal procedures
Ventilation of the area in which the endoscope disinfectors are set up	Unintentional leakage of harmful vapours	Thorough ventilation, sufficient capacity use and maintenance of appropriate filters

Microbiological risks

Tasks	Risk	Risk-minimising measures
Transport of contaminated endoscopes	Contamination of staff, cross-contamination with other equipment	Clear operating instructions, closed transport containers, sufficient working space, vaccination in accordance with hospital policy, good logistics organisation**
Disposal of contaminated material	Contamination of staff, cross-contamination with other equipment	Vaccination in accordance with hospital policy, clear operating instructions, appropriate use of waste containers, good logistics organisation

**including the separation of clean and contaminated equipment

5.5 The traceability of endoscopes and patients

The guidelines state that hospitals must use a traceability system which records which endoscope is used on which patient, and by whom and in which endoscope disinfector the endoscope is cleaned and disinfected and placed in the drying cabinet.

Track & Trace

Tracking and tracing is the recording of successive data that safeguard the effectiveness of the disinfection process. Endoscopy and disinfection processes are preferably recorded automatically (target standard).

Required measurement data and records

- Record the process number together with the date and time of the disinfection process;
- Record the serial number of the endoscope disinfector and the section (left or right container, position 1,2,3 or 4, etc.);
- Record the endoscope series number per section or position;
- Record the patient identification number for the used endoscope awaiting disinfection, per section or position;
- Treating medical specialist / endoscopist for the endoscopy, per section or position;
- Record the applicable chemical, reference and serial number;
- Cleaning & disinfection process per section or position; the person who places the endoscope in the endoscope disinfector and person who removes the endoscope from the endoscope disinfector after the cleaning and disinfection process (= person who releases the endoscope for safe reuse);

- Record the effective or interrupted cleaning & disinfection process, per section or position, along with measurement data including:
    - pressure measurement (including leak test and continuous pressure monitoring for connection controls and flow);
    - temperature measurements;
    - duration of the cleaning, disinfection and drying phases;
    - starting time, finishing time and duration of the process; if necessary, the duration of other phases of the process.

The data to be recorded per work process / work space is as follows:

- The execution of the endoscopy:
    - patient data;
    - practising medical specialist / endoscopist;
    - endoscope identification/charge number.
- loading and connecting the endoscope in the endoscope disinfector:
    - patient details (if not linked at the time of the endoscopy)
    - endoscope identification number;
    - endoscope disinfector identification number, including connection position (left/right, top/bottom);
    - name of operator.
- release of the endoscope:
    - endoscope identification number;
    - endoscope disinfector identification number;
    - name of operator.

Record storage period

There are no statutory storage periods for technical data on cleaning and disinfection. The decree on sterilised medical devices [ref 43] states that the records for a batch of sterilised medical equipment “shall be stored for at least six months”. In the case of sterilisation carried out for third parties, the storage period for sterilisation records is five years [ref 44].
In this profession, a storage period of six months is on the short side, since it is possible for the symptoms of infection resulting from patient treatment to become apparent after this time.
The SFERD advises maintaining the WIP directive. This states a storage period of at least 1 year for technical data on cleaning and disinfection. This enables an organisation to demonstrate with a probability bordering on certainty that any infections manifested in a patient could not have been caused by inadequate endoscope disinfection. This storage period includes the periods subject to lookback investigation in the event of incidents relating to inadequate cleaning and disinfection endoscope procedures.

It is recommended that all the available data is periodically backed up. Data should not only be stored locally on a work station; it must be managed centrally (on the network).

6. ASSESSMENT BY CUSTOMERS

6.1 Patient safety

Within the EFQM model, assessment by the partners, customers, and suppliers with which an organisation works is of great importance to its successful performance. Partners are external organisations with which there is a long-term or close working relationship. These may be suppliers or buyers, sometimes in changing roles. It is necessary to know how they assess products, services and cooperation. What is their opinion about these things? Does the organisation know why people decide whether or not to use its services? And what can the organisation expect from them in the future?

Patient satisfaction can be investigated. Research methods are available, including the use of questionnaires. To match the service to patient expectations, organisation-wide creative initiatives can lead to a rise in patient numbers. This can result in an increasing demand for investigations in which flexible endoscopes are used.
An attractive setting with an eye for colour and function, in combination with discreet and friendly treatment, gives patients the confidence that they are in good hands. Features indicating that the guidelines and standards are met can contribute to an understandable sense of patient safety.
Transparency in the form of information about the tests which patient must undergo reassures the patient and helps create a relaxed atmosphere for treatment.
Written and verbal means should be available to allow the expression of complaints, or suggestions about the patient experience. Patients should be confident that when they report complaints or suggestions their points are at least considered in the discussion of how to improve future patient care, audits or incident drills.

6.2 Throughput / availability of endoscopes

Within the endoscopy department team, the medical specialist should be regarded as the customer, with requirements, rights, and obligations. When treating a patient, the medical specialist / endoscopist must be able to assume that the right endoscopes will be available at the right time. The decontamination cycle should be so designed that the endoscope is quickly available again for patient use. The number of endoscopes required should be determined on the basis of the number of patients awaiting treatment and the speed of cleaning and disinfection.
It is for the specialist to satisfy himself that the endoscope presented to him has been properly cleaned and disinfected so that patient safety is not at put at risk, as set out in the Order of Medical Specialists' guidelines for medical equipment [ref 30].

7. ASSESSMENT BY STAFF

The EFQM model addresses the question of the extent to which the organisation delivers additional value to its staff. The staff assessment should be evaluated through staff satisfaction surveys. The results of such surveys can help an organisation to keep staff interested and committed to the institution.
New developments can lead to the expansion of tasks and to remuneration at a different rate after assessment using the heath care job evaluation system. Organisation and department managers must create a balance between work, pay, development and giving staff sufficient challenges. Good motivation leads to effective efforts and performance.

It is important for staff working with flexible endoscopes to feel satisfied and safe, both on their own behalf and on behalf of patients. Therefore, the tasks to be performed in the organisation should be described in an endoscopy quality manual.
When performing a task described in a quality manual, staff can be confident that they will carry out the procedures correctly and safely. Procedures are derived from guidelines and drawn up in protocols based on local circumstances. These protocols are established with the support of the team and provide instructions for day to day operations. This enables procedures to be standardised, audited and improved. The protocols should also ensure a safe working environment (Quality, Working conditions and the Environment.) They should ensure the statutory registration of dangerous substances, and establish a safe working environment, for example taking account of activities that involve noise and climatic conditions. To maintain the quality of working and labour conditions, an organisation must have access to a medical technology / clinical physics department, an infection protection department, an occupational health service and a cleaning and disinfection expert.
State-of-the-art equipment should be used, and staff should be suitably trained or retrained. This demands the preparedness of the board to invest appropriately.

8. ASSESSMENT BY SOCIETY

The assessment by society is important for the quality of healthcare. The development of performance indicators contributes to greater transparency. Incidents relating to the cleaning and disinfection of endoscopes attract a good deal of attention in the media. This can damage the image or reputation of the hospitals concerned. Transparent care leads to increasing social pressure. This finds expression in the Safety Management system (SMS) and the quality standards of the NIAZ or JCI. Patient safety is an important issue in contemporary hospital management.

Society requires hospitals to use endoscopes safely, and for hospitals to be fully accountable should safety be in any way at risk. This means that a hospital should have an appropriate incident management procedure, focusing both on preventing the recurrence of incidents and on providing clear explanations of such events and the potential risks to patients.

8.1 Incident management

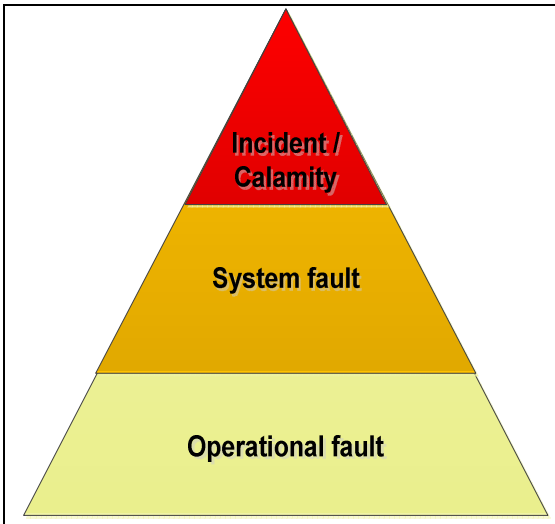
The purpose of incident management is:

- to take immediate measures in the event of incidents involving flexible endoscopes to prevent any transmission of micro-organisms through improperly cleaned and disinfected endoscopes or accessories.
- to implement measures to prevent an incident in the future;
- To implement measures to check if patients/staff may have been subjected to risk;
- To provide communication towards all relevant parties

The hospital's current incident procedure will be used in the event of an incident. The chairman of the incident committee will if necessary advise the board to appoint an expert team and which functionaries should be involved.

8.2 Criteria for the start of an incident management procedure

The incident procedure comes into action when a fault is reported in the endoscope cleaning and disinfection process. These faults are corrected where possible within the regular process and/or process checks, as displayed in the figure below:



If the event carries a risk of damage to a patient, the board will appoint a team of experts with a view to a recall.
If damage is detected in a patient, the event is classed as a calamity.

A system fault is a deviation of the process which is detected within the regular control measures / process checks and which does not directly lead to damage in patient and/or staff.
- ➢ Report to the DSRD and rectify the fault within the improvement process.

An operational fault is a deviation of the process which is detected within the daily process checks as part of the primary process.
- ➢ Staff member (CSD) rectifies the fault as part of the normal task setting; the fault is registered in the regular process registration.

Table 2 below gives examples of possible incidents; however, this table is not complete. The DSRD carries out a risk assessment of the incident based on the notification, if necessary in consultation with (a) medical specialist(s). The incident procedure can be started on the basis of these assessments.

Table 2 - *Examples of faults and incidents*

Examples of operational faults (rectified as part of the primary process)
▪ inadequate pre-cleaning (e.g. failure to brush channels or incomplete disinfection recorded on display)
▪ use of incorrect or expired chemicals
▪ lumens too small or inaccessible channels (not accessible to brushes)
▪ damage to endoscopes (with possible build-up of organic material)
▪ use of endoscopes that have been insufficiently dried after 4 hours
▪ observation of organic material in endoscope or endoscope disinfector
▪ improper storage of endoscopes (e.g. in transport containers)
Examples of system faults (rectified as part of the regular process checks)
▪ contamination of the last rinsing water
▪ use of incorrect concentrations, processing times or temperatures
▪ malfunctioning of channel connection/blocking safeguarding
▪ omissions due to inexpert staff
Examples of incidents (Incidents give rise to the setting up of a team of experts and possibly a recall of patients)
▪ contamination of tubes, containers, etc.
▪ biofilm in pipes, containers, etc.
▪ incorrect use of endoscope disinfector (e.g. incorrect programmes)
▪ technical faults (found on verification or maintenance).

8.3 Incident procedure stages

The following flow chart describes the different steps in the procedure. Some steps may be started and carried out in parallel.

The incident procedure of the organisation takes precedence

Steps 1 to 3 are part of the regular process checks. If an unacceptable risk is shown as a result of the risk analysis, the board will be notified and the incident procedure will be followed.

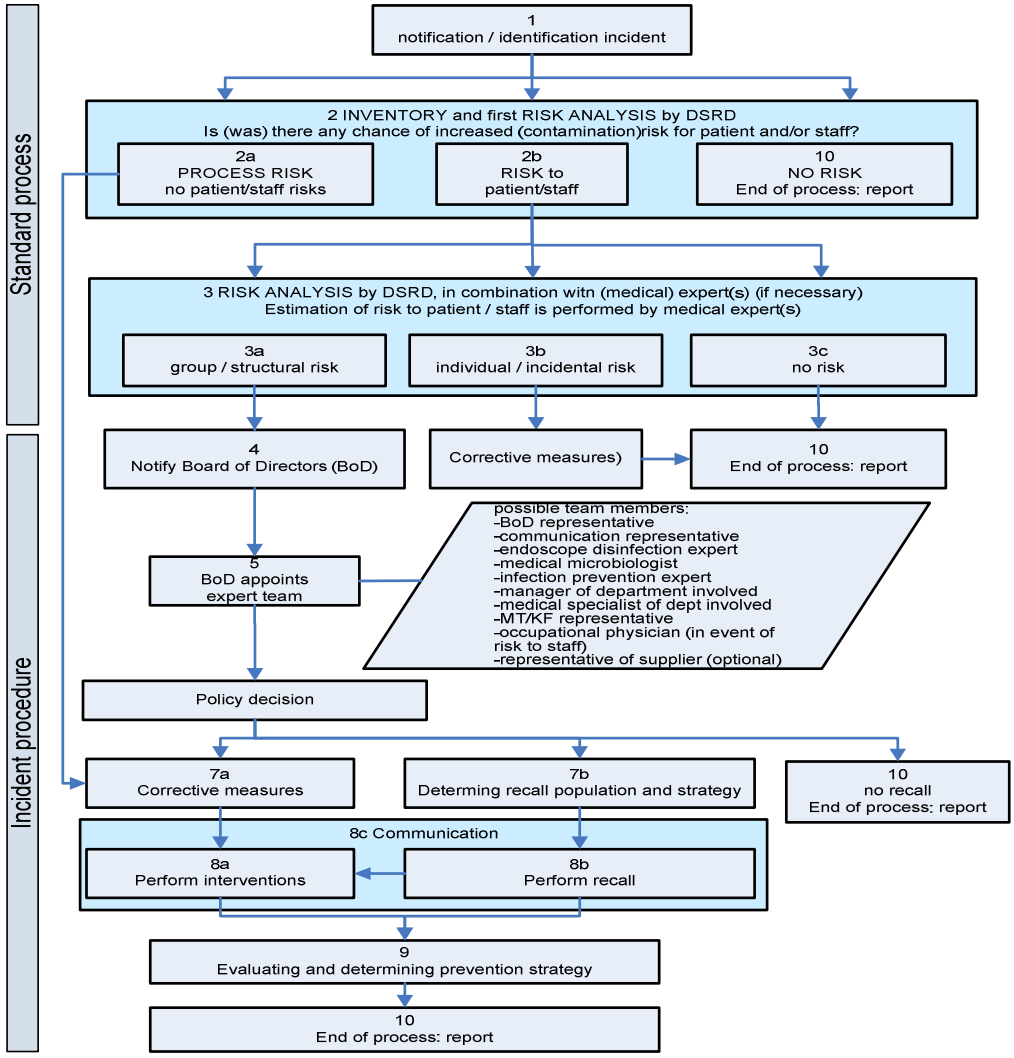


Figure4 – *Incident procedure action plan*

8.4 Incident procedure stages: process description

STEP 1: - Notification

The DSRD receives a notification based on:
- signals from MT staff, medical specialist / endoscopist;
- Notifications from suppliers/manufacturers;
- findings (results) of regular controls (maintenance, verification, cultures);
- anomalous process parameters in the automated cleaning and disinfection process;
- production registration findings via tracking & tracing.
- Other notifications.

STEP 2- Inventory and 1st analysis

The DSRD identifies and analyses the notifications (see examples in table 2) and performs the first risk analysis. If the notification appears to be 'only' a deviation from daily practice, the procedure will not be continued. Exceptions can be made if there is a structural divergence from day to day procedures. Based on the inventory and analysis, the DSRD estimates whether there is or has been:

SCENARIO 2a: Process risk
Any omissions in the work process can lead to a long-term risk to patients and staff. These omissions should be included and safeguarded in protocols or work instructions. If patients or staff have run no increased risks due to these omissions, a recall is unnecessary.

SCENARIO 2b: Risk to patient or staff
In the event of a suspected or demonstrated risk to patients or staff, the DSRD contacts (a) medical specialist(s) directly to further assess the risk (see step 3). Note: the risk does not always have to be microbiological; there may be chemical risks.

SCENARIO 2c: No risk to patient and/or staff
On analysis, it appears that the notification carries no risk to the process, patients or staff. The procedure is terminated, though the notification is still reported.

STEP 3 Risk inventory

The medical expert(s) assess the risk in combination with the DSRD. This assessment may have three possible outcomes:

a. There is a structural risk whereby several patients or staff have been at risk. In this event the procedure will continue.

b. There is an incidental risk for one patient/employee. The anomaly may have been present for longer, but on the basis of the inventory and analysis, the risk assessment can be limited to one individual. In this event, improvement measures will be put in place to prevent a recurrence of the anomaly. Possible measure relating to relevant patient / employee will be dealt with at individual level. The incident procedure is terminated, though the notification is still reported.

c. Mutual consultations show that there is or was no risk to patients or staff. The procedure is terminated, though the notification is still reported.

STEP 4- Notifying the board

The DSRD reports the findings to the board and advises the chairman of the board to appoint an expert team.

STEP 5 - Board appoints expert team

The representative of the board appoints an expert term, the members of which are selected in consultation with the DSRD and the medical expert(s). The size of the team will reflect the

scope of the risk. If staff have been put at risk, the occupational physician will join the team. The expert team is responsible for:

- conducting a further analysis of the nature and extent of the incident and an assessment of the risks to patients and staff;
- informing the board;
- advising the board about the steps and measures to be taken to ensure patient and staff safety;
- drafting an evaluation report and if necessary establishing a prevention strategy to prevent recurrence;
- delivering internal – and if necessary external – reports (including a report to the IGZ);
- identifying and analysing all necessary information;
- advising the board about the implementation of (temporary) measures to ensure patient and staff safety;
- the temporary halting of endoscopic examinations;
- coordinating the recall of patients in the event that this is required;
- streamlining internal and external communication.

STEP 6 - Policy decision

The expert team decides on the policy to be conducted and advises the board. The following aspects must be addressed:

- can endoscopic examinations proceed without increased risk to patients and/or staff;
- should patients be recalled for examination; if so which diagnostic is to be used;
- must the incident be reported to the IGZ;
- should there be a press release.

If the incident is caused by malfunctioning equipment, the supplier will be contacted so that it can be involved in determining further investigation and strategy.

STEP 7 - Implementing the decision

A. *Corrective measures*
Establish measures to ensure that there is no further risk and establish measures to prevent incidents in the future. This may include taking the equipment (temporarily) out of use until the cause has been rectified.

B. *Determining the recall population and strategy*
   - the risk period and risk population are determined on the basis of the inventoried data;
   - which investigations will be conducted and when is determined on the basis of the risk assessment;
   - the strategy for communication to patients, staff and media is determined on the basis of the decision.

C. *No recall*
If the expert team decides a recall is not necessary, the procedure is terminated here; however, the notification, assessment and decision should all be reported.

STEP 8 - Implementing policy

A. *Interventions*
The corrective measures identified are put into action. The manager of the department is responsible for carrying them out and reports to the group of experts.

B. *Recall*
The recall is carried as determined. The DSRD and the medical specialist / endoscopist are responsible for the progress of the recall process. The medical specialist / endoscopist concerned is responsible for contacting the patient(s). The occupational physician is responsible for contacting staff (if they have been exposed to risk).

C. *Communications*
The board and/or the PR & information department is responsible for communication both internally and externally.

STEP 9 - Evaluating and determining prevention strategy

The progress of the procedure is evaluated and reported to all the parties concerned. Any improvements to prevent a future recurrence of the incident are identified on the basis of this assessment. These improvements may be included in the endoscope management plan. If necessary, procedures will be adapted.

STEP 10 - Conclusion of the process: reporting

The DSRD draws up a final report of the procedure. This report is sent to the board, the infection prevention committee and members of the expert team. It is also sent to the IGZ by the appointed functionary if relevant (depending on organisational policy).

8.5 Damage to the image of the institution

An organisation does not just deliver services to society; it is also a part of that society. An organisation can demonstrate that it has learned lessons from an incident, and in this way can distance itself from the from the problems existing before the incident. This new standard comes about after the demonstrable implementation of adapted or even new equipment, increased expertise among practitioners, improved support within the organisation or from the supplier of the equipment concerned, or changed procedures.

Tell both the internal and external media that you can explain the necessary changes. Mention the marginal likelihood of the risk now compared with the time before the incident and explain that this has been reduced to a level accepted by the authorities (IGZ / infection prevention working party). Point out the effect of your quality assurance system and the role of audits in the short and longer term.

When managing patient reactions, the involvement of a confidential patient counsellor or contact person may be helpful. Patients may enter a claim against the organisation because of suffering in the form of uncertainty or indeed certainty about damage (such as infection) caused by the incident. Any such claims should be handled in accordance with arrangements with the institution's insurers.

Dealing with the media takes place according to the procedure of the organisation.

9. FINAL RESULTS

Guaranteed safety for both the patient and staff. The patient must be justifiably confident of responsible care (IGZ principle). Such care comes about through:

- the existence of an operational quality system for the management of the process of cleaning and disinfecting endoscopes;
- the existence of a structural process of quality assurance that means that points for improvement noted will be acted upon;
- taking account of the following starting points: applicable legislation and regulation covering quality assurance for cleaning and disinfecting endoscopes, such as the Wkkgz (formerly: healthcare institutions quality law [ref 40], the BIG law [ref 41], the law on medical resources.

To assess the testing of the cleaning and disinfecting endoscopes, the IGZ uses the guidelines of the infection prevention working group.
These should be considered as guidelines in a path of continuous improvement, particularly where new construction or rebuilding is concerned.
The staff should have the skills required and be able to meet these requirements in safe (healthy) working conditions, a stimulating working atmosphere with due professional concern for the environment.

10. PROCESS VERIFICATION

In this quality manual process verification is defined as the evaluation of the results of measurements, tests and checks that have been performed in a particular time period to ensure that the cleaning and disinfection process meets the current standards and regulations.
The manager of the department where the cleaning and disinfection of the flexible endoscopes takes place is responsible for the process. The procedures for cleaning and disinfection as well as the results from measurements, tests and checks are periodically evaluated under the responsibility of the DSRD. The steps and actions that are part of this system of process verification are given in table 3.

The four parts of process verification are:

Part 1	Technical verification
Part 2	Functional tests and checks
Part 3	Microbial test
Part 4	Audit & Control

Detailed guidance on each part is given in the clauses below. The sum of all actions gives the assurance that the cleaning and disinfection process is effective and reproducible. The hospital bears the final responsibility for ensuring that all the actions are properly performed. The actual work however, may be outsourced to various third parties.

The verification of the specifications of the WD and the processes is performed annually, but daily, monthly and quarterly functional tests must also be carried out. Part of the functional tests and checks are the verification of the channel non-connection and channel blockage alarms, channel cleaning tests and micro biological testing of the final rinse water.

All control measures described in table 3 must include process verification in order to ensure process safeguarding.

Table 3 *– System of process verification*

Clause	Action	At purchase	Daily	Monthly	Quarterly	Yearly	At incidents	After process altering repairs**	After maintenance / repairs	Facultative
10.1	**Technical verification**									
10.1.1	Verification of the system specification of the disinfector	X				X		X*	X*	
10.1.2	Verification of the system specification of the drying cabinet	X				X		X*	X*	
10.1.3	Endoscope inspection	X				X			X	
10.1.4	Compatibility establishment	X								
10.2	**Functional tests and checks**									
10.2.1	Check of the channel separators	X	X							
10.2.2	Check of the connectors	X	X							
10.2.3	Check of the connection tubes	X	X							
10.2.4	Channel obstruction test	X			X			X*		
10.2.5	Channel non-connection test	X			X			X*		
10.2.6	Cleaning test	X			X		X	X*	X	
10.2.7	Testing the efficacy of the self-disinfection cycle	X				X				
10.2.8	Testing the cleanliness of the external surfaces of the endoscope									X*
10.3	**Microbiological checks**									
10.3.1	Microbial quality of the final rinse water	X			X		X	X		
10.3.2	Microbial testing of endoscopes						X			X*
10.3.3	Microbial status of loan endoscopes						X			X*
10.4	**Audit & Control**									
10.4.1	Audit of the primary process					X				
10.4.2	Audit of technology and maintenance					X				
10.4.3	Audit of incident procedure					X				
10.4.4	Audit of the processing persons' expertise					X				
10.4.5	Audit of the registration of the replacement of cans of chemicals			X						
10.4.6	Audit of logs					X				
10.4.7	Audit of registration for traceability					X				
10.4.8	Audit omission of protocols					X				
10.4.9	Audit of management plan					X				

* To be decided by the DSRD
**Interventions which influence the process are anomalies that have (had) effect on process parameters, temperature, flow, pressure, dosing, alarms, contact time, water and air quality. For examples see: annex 6a

10.1 Technical verification

Periodic technical verification of the WD is necessary to ensure reproducible cleaning and disinfection of the endoscopes. The technical verification as described in this quality manual is expressly not intended to demonstrate that the equipment meets the requirements of the Medical Devices Directive. This has already been established by the manufacturer and the CE-mark shows that the requirements are met.

This quality manual provides guidance for organisation of the technical verification of endoscope disinfectors and drying cabinets and the periodic checks of flexible endoscopes that are used in the hospital.

The manufacturer has declared on basis of the specifications that the equipment meets the essential requirements of the Medical Devices Directive. These technical specifications form the criteria for all measurements, tests and checks. This quality manual gives guidance for the periodic verification of the measurements, test and checks and the evaluation of the procedures, the results of which are collated into a report and completed with the available test reports, measurement data, manufacturer statements, etc.

SFERD is of the opinion that patient safety is served by meticulously documenting all checks and maintenance of medical equipment. Apart from the technical measurements and micro biological tests, the machine safety aspects of the disinfector should also be periodically verified.

After work has been completed on the equipment (maintenance, repairs, or verification tests which may have influenced the functioning of the equipment), the MT/ clinical physic must assess afterwards if the equipment still complies with the specifications and provide a technical release. The equipment must then be functionally released by the DSRD before use.

To the question ‘who should perform the measurements to verify that the equipment works within its technical specifications’, SFERD is of the opinion that the DSRD has the responsibility to perform (or outsource), in collaboration with the manufacturer, periodically all necessary measurements, tests and checks and to verify the technical specifications as provided by the manufacturer are met. The DSRD, as the responsible person, decides who will perform the measurements, tests and checks. Where possible the measurements, test and checks could coincide with periodic preventive maintenance. This will save time, thus increasing the availability of the equipment. It is unnecessary and uneconomical to repeat measurements, tests and checks by another party, where these have already been performed during maintenance. It is the task of the DSRD to make detailed agreements with the involved parties about which verifications will be carried out, according to which method and with which level of precision. Possible partners are the supplier, the Medical Technology department / Clinical Physics of the hospital and validation companies. The DSRD verifies that the parties involved have the necessary expertise[18] and that the procedures that are used are endorsed by the manufacturer of the endoscope disinfector or the drying cabinet.

WARNING: No (temporary) modification of the endoscope disinfector and/or drying cabinet shall be made for the performance of the verification. E.g. disconnection of internal tubing the in equipment to connect sensors, disconnection of sensors to test alarm systems or modification of process parameters. There is a risk that the modifications are not fully restored after the measurements. In that case the equipment may not perform as designed by the manufacturer, resulting in ineffective processes. Thus the verification measurements and checks become a patient hazard! Modifications to the equipment are only allowed by the manufacturer/supplier, if only to maintain the validity of the CE-mark and through that the product liability of the manufacturer. Where the manufacturer prescribes that temporal modifications to the WD shall be made to facilitate particular measurements, he shall provide a clear protocol.

[18] A party is competent when it is acquainted with all the technical details of the endoscope disinfector and how it operates according to a quality assurance management system.

10.1.1 Verification of the system specification endoscope disinfector

The endoscope disinfectors shall meet the requirements of the Medical Devices Directive [ref 27] and shall be CE-marked.
The efficacy of the cleaning and disinfection process is determined by the use of the process chemicals that have been validated by the WD manufacture, the washing principle, the manner of channel connection and irrigation and the process parameters of the cleaning and disinfection process. Technical verification of the equipment is performed by measuring the process parameters. Establishment of the efficacy of the cleaning, disinfection and final rinse to remove the residues of the disinfectant, is part of the type testing and has not to be repeated by hospital.
At least annually the technical system parameters (see 10.1) are verified. Where necessary corrections to the automatic controller are made (e.g. calibration of sensors) during maintenance. The DSRD ensures that the verification of the system parameters is performed according a protocol that is suitable for the particular endoscope disinfector.
Before commencement of the system verification the logs of the endoscope disinfector are checked for any particulars that should be taken into account when doing the system verification.

Compatibility establishment

The manufacturer of the endoscope disinfector shall declare which endoscopes it is able to clean and disinfect (declaration of compatibility, see EN-ISO 15883-4 §4.1.3.[19] and §8.a.[20])
By including an endoscope in the list, the manufacturer declares factually that the endoscope is suitable to be cleaned and disinfected in the endoscope disinfector. This is provided that the correct connectors are being used to connect the endoscope in the endoscope disinfector, the prescribed chemicals are being used and that the preliminary treatment of the endoscope is carried out as prescribed by the manufacturer, see NEN EN ISO 15883-4 §4.1.4.[21]
Most manufacturers have a list available of the endoscopes that can be cleaned and disinfected in the endoscope disinfector. Owners are advised to check whether their endoscopes are on the list of compatible endoscopes of the WD manufacturer before purchase of the endoscope disinfector. This check should also be done when a new endoscope is purchased or a loan endoscope is going to be used.
When the endoscope is on the list of compatible endoscopes there is no need for the hospital to test whether the endoscope can be effectively reprocessed in the endoscope disinfector.
Where the supplier/manufacturer is not able to give a declaration of compatibility, the hospital should not purchase the particular endoscope, unless the hospital or the endoscope supplier performs the necessary tests themselves.

Task to perform at initial verification is to check whether:
- the endoscopes that are in use, are on the list of compatible endoscopes of the manufacturer;
- the correct channel connectors, channel separators and port closures are available;
- the necessary preparations as prescribed by the endoscope manufacturer (e.g. the brushing of channels) are incorporated into the operator's SOP.

[19] After the complete process in the disinfector, the endoscope shall be free from vegetative bacteria (but not necessarily spores) and other contamination. The combination of the cleaning process and the disinfection process shall be designed to achieve this condition, recognising the high level of bacterial contamination that may exist. It shall be necessary to take into account other factors such as the design of connectors. The endoscope disinfector manufacturer shall demonstrate this capability during type testing for all the types of endoscope that the disinfector is designed to process.

[20] In addition to the information specified in ISO 15883-1:2006, Clause 8 the endoscope disinfector manufacturer shall provide the following information: the devices and/or device families for which the manufacturer has evidence that they can be processed satisfactorily and any precautions necessary for particular devices or operational conditions

[21] The endoscope disinfector manufacturer's instructions shall recommend that any requirements, e.g. for manual cleaning and or disassembly of the endoscope, prior to processing in the disinfector provided by the device manufacturer should be followed.

Task to perform at re-verification is to check whether:
- new endoscopes or loan endoscopes are on the list of compatible endoscopes of the endoscope disinfector manufacturer. If necessary the disinfector manufacturer shall establish whether the endoscope can be effectively cleaned and disinfected in the endoscope disinfector;
- the correct connectors are available for the new endoscope;
- any new preparations as prescribed by the manufacturer are incorporated into the operator's SOP.

The results of measurements, tests and checks are recorded. Whenever corrections to sensors or measuring systems are made, the condition of these before the corrections are also recorded, e.g. If a temperature sensor shows a too low value the sensor must be adjusted so that it shows the correct value. In this case also the deviation before the adjustment shall be recorded. The DSRD shall establish whether the deviation had a negative impact on process efficacy to an extend that patient safety was at risk. Where necessary patient 'look back' shall be considered.

When there is doubt about the efficacy of the disinfection phase of the process, one should verify whether the disinfectant that is used is prescribed by the manufacturer and the process parameters that influence the disinfection efficacy shall be verified. In addition the concentration of the active ingredients(s) of the disinfectant could be verified. Possibly the concentration of the active ingredients are not as manifested on the label.

Normative references

The performance requirements and test methods for endoscopes disinfectors are given in the following international standards.[ref 10.] :

NEN-EN-ISO 15883-1:2009	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests
NEN-EN-ISO 15883-4:2009	Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
NPR-CEN-ISO/TS 15883-5:2005	Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy

Where in this document reference is made to 'the standard' the conjunction of the above standards is meant.

Requirements and responsibilities

In this clause the persons are mentioned who have a role in the verification of endoscope disinfectors. These persons have responsibilities and need particular expertise.

Contact person

Ensures that the endoscope disinfector is used in accordance with the user manual, the endoscopes are correctly prepared for automated reprocessing as prescribed in the standard operating procedure, the daily and weekly inspections are performed and that the log is kept. Whenever the contact person has doubts about the performance of the endoscope disinfector, they shall contact the DSRD.

Owner

The owner ensures that sufficient means are available for the cleaning and disinfection of flexible endoscopes in a responsible manner. The owner also ensure timely maintenance of the equipment and education of personnel.

Manufacturer/supplier

The manufacturer/supplier delivers an endoscope disinfector that fulfils the requirements of the sales agreement. This includes the requirements of the Medical Devices Directive [ref 27] and the international standard NEN-EN-ISO 15883, parts 1, 4 and 5.

The manufacturer shall clearly identify the endoscopes (brands, types, series) that can be reprocessed in the endoscope disinfector, the necessary connectors for each endoscope and the preparations that are necessary before the endoscope can be placed in the machine. Before the endoscope is put into service it shall be established that this information is incorporated in the SOPs. Where needed the SOP shall be updated and the employees instructed.
The manufacturer specifies all process parameters and demonstrates how these can be verified. The manufacturer shall also specify the user maintenance.

User
The user shall use the endoscope disinfector as instructed by the manufacturer and prescribed in the SOPs, for the purpose identified by the manufacturer of the endoscope disinfector. The user shall have up to date expertise and shall be instructed in the operation of the endoscope disinfector. This should be instruction by the manufacturer/supplier including the technical functioning of the endoscope disinfector with emphasis on the limitations of the endoscope disinfector and its processes. The user shall be capable of recognising simple fault conditions and malfunctions and be able to correct these. Malfunctions that cannot be corrected by the user shall be reported to the Medical Technology / Clinical Physics Department. The Medical Technology / Clinical Physics Department records the notification and follow-up actions in the log and informs the DSRD. The user and technicians must be able to recognise anomalies in the functioning of the equipment.

Performer of measurements, tests and checks
The persons who conduct measurements, checks and test shall be specifically trained and shall be familiar with the design, use and maintenance of the endoscope disinfector. The system specifications provided by the manufacturer are the reference to which the results are judged. Third parties that conduct maintenance, measurements, tests and checks shall work within a quality assurance system, e.g. ISO 13485. To assure the professional integrity of the personnel, all work shall be performed and reported as prescribed in SOPs. The DSRD monitors the work and reporting of the activities.

Planning of technical verification of the endoscope disinfector

In the following clauses give the steps of the verification procedure. The DSRD ensures that all steps are performed according to plan. Verification of the endoscope disinfector is performed at least annually. Maintenance and repair, depending on the nature of it, shall be followed by verification measurements, tests and checks. In any event a release test must be performed. The manufacturer shall explain whether maintenance or repair has a possible detrimental effect on the performance, the Medical Technology / Clinical Physics Department together with the DSRD evaluate the explanation of the manufacturer. Together they establish the nature and extent of the release tests.

Log
Logs shall contain all data in relation to the use of the endoscope disinfector. Every endoscope disinfector shall have its own log. The log must be kept by the endoscope disinfector or it will consist of an electronic log that can be viewed and amended by the DSRD or the user close to the workplace. The following information shall be recorded:
- name, site and address of the owner/contact person
- serial number and type number;
- brand and type/model of the endoscope disinfector
- year of manufacturing of the endoscope disinfector.

The following information shall be recorded in the log:
- exchange of chemical containers, employee(s), date and lot numbers of the containers;
- summary of measurements, tests and checks with the names of the persons that conducted and verified the results (with reference to protocols and other documents);
- overview of daily, weekly and quarterly inspections including the name of the person that conducted these;
- overview of the routine cleaning of the equipment, including the name of the person that conducted these

- overview of maintenance and the results from the release tests, including the name of the person that conducted these;
- overview of malfunctions and corrections/repairs and the results from the release tests, including the name of the person that conducted these;
- overview of maintenance of water treatment systems and the results from the release tests, including the name of the person that conducted these;
- overview of the compatible endoscopes and accessories;
- details of the exchange of water filters, preliminary filters and bacterial filters.

Note: The exchange of process chemical containers may be recorded in the log, however this is often recorded on separate sheet, outside the log.

System specifications

The values for the process parameters (including upper and lower limits) for the endoscope disinfector shall be stated, to allow verification, through measurements, that the machine is still operating within the manufacturer's specifications. The values of the process parameters shall be specified by manufacturer of the endoscope disinfector, including the detergent and disinfectant to be used and the concentrations and temperatures to be used for these process chemicals. All specifications have to be stated in measurable units, allowing verification of the attainment of these parameters through measurements.

The parameters for the different process stages are listed in Appendix 6. Depending on the age, the brand and the type of endoscope disinfector, additional process parameters can be applicable, or not all process parameter may be applicable. For all process parameters, the values and allowed tolerances shall be specified. The reason for a process parameter not being applicable, shall be provided.

Changes made by the manufacturer/supplier

As a consequence of a corrective action of the manufacturer, changes can be made to the endoscope disinfector. The Medical Technology / Clinical Physics department shall assess these issues together with the manufacturer, whereby reasons must be specified by the manufacturer and tested by the DSRD.

- The changes are entered into the log (by the manufacturer);
- The influence on the efficacy of the cleaning and disinfection for every type of endoscopes that can be processed in the endoscope disinfector;
- The influence on the reproducibility of the processes.
- The influence on the quality of the final rinse water;
- The influence on the efficacy of the self-disinfection process.

The results of these evaluations are documented by the DSRD. If the DSRD concludes that the efficacy and reproducibility of the endoscope disinfector are no longer guaranteed following the changes, he can decide to suspend the use of the endoscope disinfector. In the latter case, it is likely that the changes to the endoscope disinfector are such, that the type tests as once performed by the manufacturer are no longer valid. The manufacturer shall re-perform part of the type tests and hand the results over to the DSRD. For examples see annex 6a Interventions that influence the process.

10.1.2 Verification of the system specification of the drying cabinet

The drying cabinets must confirm to the requirements as stated in the standard NEN EN 16442 [ref 26]. Drying cabinets are not medical devices and are therefore not fitted with a CE-mark according to the Medical Device Directive.
The drying capacity of a drying cabinet is largely determined by the way of connecting the endoscope and the parameters of the drying process. Technical verification of the equipment is performed by measuring the process parameters. Establishment of the efficacy of the drying and the protection of the endoscope is part of the type testing and does not have to be repeated by hospital at the verification stage.
All the technical system parameters (see 10.1) are verified at least annually. Where necessary corrections to the automatic controller are made (e.g. calibration of sensors)

during maintenance. The DSRD ensures that the verification of the system parameters is performed according a protocol that is suitable for the particular drying cabinet.
Before commencement of the system verification the logs of the drying cabinet are checked for any particulars that should be taken into account when doing the system verification.

Compatibility establishment

The manufacturer of the drying cabinet shall declare which endoscopes it is able dry (declaration of compatibility, see NEN EN 16442 §4.1.1.[22] and §8.2a.[23]) By including an endoscope in the list, the manufacturer declares factually that the endoscope is suitable to be dried in the cabinet. This is provided that the correct connectors and possible channel separators are being used to connect the endoscope in the drying cabinet, the prescribed pressurised air is being used and that the preliminary treatment of the endoscope is carried out as prescribed by the manufacturer of the drying cabinet, see NEN EN 16442 §8.2.j.[24]
Most manufacturers have a list available of the endoscopes that can be dried and stored in the drying cabinet. Owners are advised to check whether their endoscopes are on the list of compatible endoscopes of the manufacturer before purchase of the drying cabinet. This check should also be done when a new endoscope is purchased or a loan endoscope is going to be used.
When the endoscope is on the list of compatible endoscopes there is no need for the hospital to test whether the endoscope can be effectively dried or stored in the drying cabinet.
Where the supplier/manufacturer is not able to give a declaration of compatibility, the hospital should not purchase the particular endoscope, unless the hospital or the endoscope supplier demonstrates the compatibility themselves.

Task to perform at initial verification is to check whether:
- the endoscopes that are in use, are on the list of compatible endoscopes of the manufacturer of the drying cabinet;
- the correct channel connectors, channel separators and port closures are available;
- the necessary preparations (e.g. the throughput of the channels) are incorporated into the operator's SOP.

Task to perform at re-verification is to check whether:
- new endoscopes or loan endoscopes are on the list of compatible endoscopes of the drying cabinet manufacturer. If necessary the drying cabinet manufacturer or the endoscope manufacturer shall establish whether the endoscope can be effectively dried and stored in the drying cabinet;
- the correct connectors are available for the new endoscope;
- any new preparations as prescribed by the manufacturer are incorporated into the operator's SOP.

The results of measurements, tests and checks are recorded. Whenever corrections to sensors or measuring systems are made, the condition of these before the corrections is also recorded. E.g. when a temperature or flow sensor indicates a value that is too low, the sensor should be adjusted so it records the correct value again. In this case also the deviation before the adjustment shall be recorded. The DSRD shall establish whether the

[22] Storage cabinets are designed to provide a controlled environment for storage of endoscopes (with or without channels). The controlled environment provided by the cabinet shall ensure that during storage there is no deterioration of the microbial quality of the endoscope. An optional drying function is intended to supplement, if necessary, any drying provided as part of the automated or manual processing cycle.
[23] Before delivery of the storage cabinet and for installation qualification, the following information shall be provided to the purchaser:
a) list of endoscopes that can be stored in the storage cabinet;
d2) list of endoscopes that can be dried in the storage cabinet (if applicable);
[24] Before delivery of the storage cabinet and for installation qualification, the following information shall be provided to the purchaser:
j) the operations to be carried out on the processed endoscope before it can be stored in the storage cabinet, during storage and before the endoscope can be reused once it has been removed from the storage cabinet (e.g. extensively air-flushing of channels, etc.)

deviation had a negative impact on process efficacy to an extend that patient safety was at risk. Where necessary patient 'look back' shall be considered.

In the event of doubt about the efficacy of the drying process, the process parameters that may influence the efficacy of the drying process must be verified.

Normative references

The performance requirements and test methods for drying cabinets are given in the following international standards [ref 26.] : NEN-EN 16442:2015 Controlled environment storage cabinet for processed thermolabile endoscopes.

Requirements and responsibilities

In this clause, the persons are mentioned who have a role in the verification of drying cabinets. These persons have responsibilities and need particular expertise.

Contact person

Ensures that the drying cabinet is used in accordance with the user manual, the endoscopes are correctly prepared for automated reprocessing as prescribed in the standard operating procedure, the daily and weekly inspections are performed and that the log is kept. Whenever the contact person has doubts about the performance of the drying cabinet, they shall contact the DSRD.

Owner

The owner ensures that sufficient means are available for the cleaning, disinfection and drying of flexible endoscopes in a responsible manner. The owner also ensures timely maintenance of the equipment and education of personnel.

Manufacturer/supplier

The manufacturer/supplier delivers a drying cabinet that fulfils the requirements of the sales agreement. This means that the drying cabinet must meet the NEN-EN 16442 standard. The manufacturer shall clearly identify the endoscopes (brands, types, series) that can be dried and stored in the drying cabinet, the necessary connectors for each endoscope and the preparations that are necessary before the endoscope can be placed in the drying cabinet. Before the endoscope is put into service it shall be established that this information is incorporated in the SOPs. Where needed the SOP shall be updated and the employees instructed.
The manufacturer specifies all process parameters and demonstrates how these can be verified. The manufacturer shall also specify the user maintenance.

User

The user shall use the drying cabinet as instructed by the manufacturer and prescribed in the SOPs, for the purpose identified by the manufacturer of the drying cabinet. The user shall have up to date expertise and shall be instructed in the operation of the drying cabinet. This should be instruction by the manufacturer/supplier including the technical functioning of the drying cabinet with emphasis on the limitations of the drying cabinet. The user shall be capable of recognising simple fault conditions and malfunctions and be able to correct these. Malfunctions that cannot be corrected by the user shall be reported to the Medical Technology / Clinical Physics Department. The Medical Technology / Clinical Physics Department records the notification and follow-up actions in the log and informs the DSRD. The user and technicians must be able to recognise anomalies in the functioning of the equipment.

Performer of measurements, tests and checks

The persons who conduct measurements, checks and test shall be specifically trained and shall be familiar with the design, use and maintenance of the drying cabinet. The system specifications provided by the manufacturer are the reference to which the results are judged. Third parties that conduct maintenance, measurements, tests and checks shall work within a quality assurance system, e.g. ISO 13485. To assure the professional integrity of the personnel, all work shall be performed and reported as prescribed in SOPs. The DSRD monitors the work and reporting of the activities.

Planning of technical verification of the drying cabinet

In the following clauses give the steps of the verification procedure. The DSRD ensures that all steps are performed according to plan. Verification of the drying cabinet is performed at least annually. Maintenance and repair, depending on the nature of the work carried out on the drying cabinet, shall be followed by verification measurements, tests and checks. In any event a release test must be performed. The manufacturer shall explain whether maintenance or repair has a possible detrimental effect on the performance, the Medical Technology / Clinical Physics Department together with the DSRD evaluate the explanation of the manufacturer. Together they establish the nature and extent of the release tests.

Log

Logs shall contain all data in relation to the use of the drying cabinet. Drying cabinet shall have its own log. The log must be kept by the drying cabinet or it will consist of an electronic log that can be viewed and amended by the DSRD or the user close to the workplace. The following information shall be recorded:

- name, site and address of the owner/contact person
- serial number and type number;
- brand and type/model of the drying cabinet;
- year of manufacturing of the drying cabinet;

The following information shall be recorded in the log:

- summary of measurements, tests and checks with the names of the persons that conducted and verified the results (with reference to protocols and other documents);
- overview of daily, weekly and quarterly inspections including the name of the person that conducted these;
- overview of the routine cleaning of the drying cabinet, including the name of the person that conducted these activities;
- overview of maintenance and the results from the release tests, including the name of the person that conducted these;
- overview of malfunctions and corrections/repairs and the results from the release tests, including the name of the person that conducted these;
- overview of maintenance of air filters, air dryers and possible compressor and the results from the release tests, including the name of the person that conducted these;
- overview of the compatible endoscopes and accessories;
- details of the exchange of air filters and drying patterns.

System specifications

The values for the process parameters (including upper and lower limits) for the drying cabinet shall be stated, to allow verification, through measurements, that the machine is still operating within the manufacturer's specifications. The target values of the process parameters must be specified by the manufacturer of the drying cabinet, including the compressed air to be used. All specifications have to be stated in measurable units, allowing verification of the attainment of these parameters through measurements.

The parameters are listed in Appendix 7. Depending on the age, the brand and the type of drying cabinet additional process parameters can be applicable, or not all process parameter may be applicable. For all process parameters, the values and allowed tolerances shall be specified. The reason for a process parameter not being applicable, shall be provided.

Changes made by the manufacturer/supplier

As a consequence of a corrective action of the manufacturer, changes can be made to the drying cabinet. The DSRD shall assess these issues together with the manufacturer, whereby reasons must be specified by the manufacturer and tested by the DSRD.

- the changes are entered into the log (by the manufacturer);
- the influence on the efficacy of the cleaning and disinfection for every type of endoscopes that can be dried and stored in the drying cabinet;
- the influence on the reproducibility of the processes;
- the influence on the quality of the air that is being used to dry the endoscopes.

The results of these tests are documented by the DSRD. If the DSRD concludes that the efficacy and reproducibility of the drying cabinet are no longer guaranteed following the changes, he can decide to suspend the use of the drying cabinet. In the latter case, it is likely that the changes to the drying cabinet are such, that the type tests as once performed by the manufacturer are no longer valid. The manufacturer shall re-perform part of the type tests and hand the results over to the DSRD.

Verification of the system specifications
The verification of drying cabinets is derived from the NEN EN 16442:2015 and is targeted at the Dutch market. Due to the large variety in drying cabinets, the current drying cabinets will be unable to partially or fully comply with these requirements. For the purchase or replacement of drying cabinets it is advised to include the feasibility of performing verification for the drying cabinets in the purchasing requirements.

Starting points
The manufacturer of the drying cabinet must specify which endoscopes can be dried in the drying cabinet. Before the purchase of the drying cabinet it must be established if the endoscopes in use in the hospital can be dried in the drying cabinet that is being considered for purchase and which connection materials are required. In the case of new endoscopes or loaned endoscopes it must be also be established before use if these can be dried in the drying cabinet and whether specific connectors have to be purchased. By adding an endoscope to the list of compatible endoscopes, the manufacturer factually declares that the particular endoscope will be effectively dried and can be stored for a longer period of time. The instructions of the manufacturer must be taken into account and the prescribed connection materials must be used. If the relevant endoscope does not appear in the compatibility listing, the endoscope may not be dried in the particular drying cabinet.

NEN-EN-16442 describes the number of microbiological tests with which the operation of the drying cabinet can be verified. The correct operation of the drying cabinet can also be determined by physical measurements, such as recorded in Appendix 7a, provided that:
a) the endoscopes that are being dried and stored are listed as compatible endoscopes;
b) the right connectors as prescribed by the manufacturer of the drying cabinet are used for every endoscope;
c) the connectors are being maintained as prescribed;
d) the air that flows through the endoscope channels is HEPA filtered and that it can be shown that the filters have been replaced at the correct time;
e) the air that flows through the clear space in the drying cabinet is HEPA filtered and that can be shown that the filters have been replaced at the correct time;
f) It has been determined that the (internal) surfaces of the clear space of the drying cabinet are being cleaned and disinfected regularly, according to the directions of the manufacturer and with the prescribed materials.

Documentation
As part of the purchase process for a drying/storage cabinet, a (digital) log shall be made available. In this log, the following data and documents need to be included:
- date of installation on site;
- product specifications as stated in the package of requirements;
- process specifications as stated by the manufacturer;
- safety equipment;
- type test declaration;
- connections of pipework, automation etc.;
- technical manual;
- compatibility declaration for endoscopes that can be dried in the cabinet;
- maintenance schedule;
- channel connection protocol for each type of endoscope;
- user manual;

In addition, the following environmental factors must be recorded and checked to see if they agree with the prescriptions of the manufacturer of the drying cabinet:

- environmental conditions:
    - temperature, humidity and rate of air changes;
- electrical specifications:
    - voltage and current.
- pressurised air specifications;
    - capacity, static and dynamic pressures;
    - quality (particulate matter, humidity, oil content).

Automation

It is desirable for the drying cabinet to be connected to the endoscope tracking system that is used in the hospital.

Difference between drying cabinet and storage cabinet

Reliable storage of disinfected flexible endoscopes in drying cabinets is of utmost importance to guarantee the quality of the endoscope following storage periods longer than 4 hours.
A drying cabinet is a cabinet in which a wet disinfected flexible endoscope can be placed and in which the channels of the endoscope can be connected to blow HEPA-filtered air, warm and/or dry, through these channels. A drying cabinet dries the entire endoscope; the channels and the outside. The drying cabinet can be connected to a track/registration system, allowing to check how long every endoscope has been in the cabinet.
A storage cabinet is a closed dust free cabinet, with or without overpressure at room temperature, in which a dried flexible endoscope can be stored.

10.1.3 Endoscope inspection

When the endoscope is damaged (e.g. crack in the biopsy channel, torn distal end rubber), it is possible that a cleaned and disinfected endoscope is still contaminated despite the flawless cleaning and disinfection process. These types of defects are not always detected with the air leakage test. To enable an effective cleaning and disinfection process and subsequent drying in the drying cabinet, the channel connectors, connecting tubes and the channel separators shall be in good working order. SFERD proposes that the endoscopes, connectors and channel separators be inspected annually.

Annual inspection of endoscopes and accessories

The endoscope shall be inspected at least annually. This may be done by the medical devices technician of the hospital, the endoscope supplier or a specialised third party. The (visual) inspections should focus on the following hygiene related items:
- visual faults and defects that can be spotted easily;
- corrosion and other deposits;
- cleanliness of the outside of the endoscope, including the control section and light source connector;
- wear of coatings, readability of insertion depth indicator marks;
- condition of the connectors to the light source, water bottle, air source and suction bottle;
- readability of the type and serial number or other unique Id number;
- functioning of the RFID chip;
- correlation of the RFID chip data and the logs of the endoscope;
- leaks (manual leakage test, whereby the shaft is manipulated).

10.2 Functional tests and checks

The following inspections and checks are usually conducted according to the yearly schedule as described in table 3. When an incident occurs, it is required to investigate the cause of the incident. Following the correction of the problem, it shall be verified in the endoscope disinfector or drying cabinet is again operating within specifications. The nature and extent of the activities required to be performed will depend on the nature of the incident

and the problem that caused the incident. The DSRD shall (let another) draw up a dedicated program of inspections, verifications and checks, and have this program carried out.

Daily checks[25]

a) Endoscope disinfectors:
User maintenance on the endoscope disinfector, like the replacement of filters, cleaning and disinfection agents and the self-disinfection of the endoscope disinfector, shall be carried out by the department responsible for the decontamination of the endoscopes. These activities shall be part of the procedures of the department and have to be entered in the log (see Appendix 4 for an example).

On every working day, the endoscope disinfector shall be visually inspected before it is used. The visual inspection consists of:
- sufficient amount of chemicals in the containers;
- the containers are in the correct location and are correctly connected;
- control of the expiry date of the solutions;
- inspection of defects, faults and other inadequacies that can be visibly detected;
- inspection for leaks;
- inspection for corrosions and other deposits that can be indications of leaks;
- check that the use period/maintenance interval mentioned on the equipment has not expired.

The manufacturer of the endoscope disinfector can require additional checks.

b) Drying cabinets:
User maintenance on the dryer cabinets, like the visual checks and the cleaning and disinfection of the storage compartment shall be carried out by the department responsible for the decontamination of the endoscopes. These activities shall be part of the procedures of the department and have to be entered in the log (see Appendix 4 for an example).

The drying cabinet shall be visually inspected at the start of each working day. The visual inspection consists of:
- cleanliness of the bottom of the drying cabinet / check if any dirt has dripped out of the endoscope;
- inspection of defects, faults and other inadequacies that can be visibly detected;
- if the drying cabinet is fitted with visible flow indicators, check if airflow can be detected;
- if the drying cabinet is fitted with a visible pressure gauge (manometer) to indicate air pressure, check that it is showing the correct value;
- check that the use period/maintenance interval mentioned on the drying cabinet has not expired;
- check if any faults have occurred since the previous working day.

The manufacturer of the drying cabinet may require additional checks.

10.2.1 Check of the channel separators

The channel separator shall not impair the operation of the endoscope disinfector or drying cabinet as a result of leaks, flow restrictions or other limitations.
The check of the channel separators consists of inspection of:
- the mechanical operation of movable parts: do parts move smoothly?;
- attachment of fixed parts; are parts that need to be attached indeed attached?;
- completeness of the channel separator; are parts missing?;
- state of O-rings and interface with the endoscope;
- damage, scratches, bending of parts.

10.2.2 Check of the connectors

The connection between the endoscope disinfector or the drying cabinet and the endoscope shall not impair the operation of the machine as a result of leaks, flow restrictions or other limitations.

[25] These daily checks have to be considered as a routine alertness that has to be performed for each process.

The check of the connectors consists of an inspection of:
- state of O-rings and interface with the endoscope;
- damage of the connector and the tubes attached to it.

10.2.3 Check of the connection tubes

The connection tubes shall not be damaged and shall not be blocked by bending or twisting.

Quarterly inspection

Using a surrogate endoscope, the performance of the channel irrigation control system (channel obstruction test), the channel connection control system and the cleaning shall be checked. The tests are carried out by using a test endoscope according to NEN EN ISO 15883-4; this must be calibrated at least annually.

10.2.4 Channel obstruction test

The surrogate endoscope has the option to restrict/block the flow in every channel. The endoscope WD shall give an alarm for every obstructed channel.
Note: For this test, it is essential that the construction of the surrogate endoscope complies with the demands in the standard. The y-connection between the water and the air channel must be present.

10.2.5 Channel non-connection test

For this test, an endoscope must be used in which the channels provide relatively little resistance to the flow through the channels; channels with a large diameter.
The channels of the endoscope are connected. One of the channels is disconnected and the process is started. The endoscope disinfector should indicate a fault. The test is repeated for each channel. The endoscope disinfector should give an alarm for every disconnected channel.

10.2.6 Cleaning test

The cleaning test is performed using a (commercially available) indicator. Such a test provides a quick insight into the performance of the endoscope disinfector. By comparing the test results over a period of time, insight can be gained into the reproducibility of the endoscope disinfector. Following the post-washing rinse between the cleaning stage and the disinfection stage, the process is interrupted and the surrogate endoscope is taken from the disinfector, unless the manufacturer of the indicator states that the process can be completed including the disinfection stage.
The result of the test is recorded and compared to the results of the previous tests. Attention must be paid to a negative trend in the results. This can indicate wear of parts of the endoscope disinfector that could eventually lead to a breakdown of the machine or to an unacceptable deterioration of the efficacy of the cleaning and disinfection process.
The cleaning test is also used as a release test following installation, maintenance and repair. Anomalies in the process-influencing parameters (water quality, temperature, dosage, contact period, flow) should have visible results on the test contamination.

10.2.6.1 *Criteria for the cleaning indicator*

The value of the cleaning tests is partly determined by the quality of the cleaning indicator. The indicator must give a realistic picture of the efficacy of the cleaning process. This means on the one hand that the test contamination should not be able to be rinsed off too easily, but also that this should be washed away (largely) in a correctly performed process. There is no standard test for the evaluation of cleaning indicators, but by following the procedure below it is possible to estimate the quality of the indicator.

Test 1: with indicator and cut off after the pre-rinse stage;
Test 2: with indicator and cut off after the cleaning stage;
Test 3: with indicator and cut off after the cleaning stage; without the use of a cleaning agent.

During test 1, hardly any of the indicator should have been removed.

During test 2 the indicator may be completely clean, but a small residue (smaller than at test 3) makes it possible to evaluate changes in the efficacy of the cleaning.
During test 3 some of the indicator may be removed, but the residue should be clearly visible.

10.2.7 Testing the efficacy of the self-disinfection cycle

The self-disinfection of the endoscope WD is intended to prevent contamination of the endoscope WD itself. The self-disinfection is performed according to the instructions of the manufacturer. During the self-disinfection process, most of the parts of the system of the endoscope WD, that are not disinfected during routine processes, are disinfected. For example, these can be parts of the water supply or water treatment systems (filters).
The microbiological quality of the final rinse water is actually also an indication of the absence of bacteria in the machine. When a machine is contaminated with a biofilm, bacteria can be found when the final rinse water is tested. If bacteria are found when the final rinse water is tested, a water sample shall be taken after the self-disinfection. In a subsequent regular process the last rinse water shall be tested again for the presence of bacteria. To do this, the procedure as presented in appendix 8 can be used.

Note: *The self-disinfection is often a thermal process. The temperature of the final rinse water can be high, or was high shortly before a sample was taken. As a consequence, it is highly likely that thermally disinfected water shall not be contaminated. For some systems, chemical self-disinfection is performed using a higher concentration of chemicals, which could lead to a higher level of residue in the rinse water. When a sample still contains disinfectant, a possible contamination risk might not be detected. To identify a contaminated endoscope disinfector or water supply system, it is necessary to run a routine process following the self-disinfection process and then to determine if the final rinse water of this routine process is free of bacteria.*

10.2.8 Testing the cleanliness of the external surfaces of the endoscope

Test the cleanliness of the external surfaces of the endoscope, including the control section and the light source connector. The test is performed visually. Residual contamination can be made clearly visibly by swabbing the surface with a moist swab. Using ninhydrin, (see Appendix 12) residual protein on the swab can be stained and using TMB (see Appendix 13), residual haemoglobin is detected.

NB. ATP measurements are used in the food industry to get a quick and rough indication of the bacterial contamination on the surfaces. ATP measurements are not sufficiently developed as a control method for endoscopes. Research information and acceptance criteria to apply this method effectively are not yet provided.

10.3 Microbiological checks[26]

Processes and systems are guaranteed through technical verification. Microbiological controls can be considered as additional control to this, as valuable trend analysis and in a lesser way as a critical standard. Negative culture results are never a guarantee of a safeguarded process.

10.3.1 Microbial quality of the final rinse water

Following installation of the endoscope disinfector and/or a water treatment system, the microbial quality of rinse water shall be tested. It is recommended to repeat this test twice with a week between measurements. Afterwards, a final test shall be performed a month after the last measurement. If all results are acceptable (see acceptance criteria of Willis), it is sufficient to test the microbial quality of the water quarterly. The protocol for these tests is given in Appendix 8.

[26] The NVMM is in the process of developing a guideline for the microbiological checks of endoscopes. As soon as this guideline is published, the SFERD will include any possible changes in this paragraph.

An acceptable result is not only achieved when there are no micro-organisms detected in the final rinse water. The following table specifies how the results of the microbial tests shall be interpreted and which actions have to be taken, if necessary. The type of micro-organism (pathogenicity) determines the interpretation and acceptability see Appendix 11.

Table *4 – Adapted acceptance criteria of Willis for a microbial test of the final rinse water [ref 28.]*

Aerobe colonies per 100ml	Interpretation and possible action
0	Acceptable.
1-10	Acceptable. Consistent low number of bacteria indicates that a water treatment system is under control.
11-100	Questionable. Find the cause of the problem, see Appendix 10 and 11.
>100	Depending on the type of micro-organism the endoscope disinfector is taken out of use until the water quality has been improved; see Appendix 11

10.3.2 Microbial testing of endoscopes

Microbial testing of flexible endoscopes, as described in this paragraph, is not intended to demonstrate adequate performance of the endoscope disinfector. Therefore, there is no point in periodically testing endoscopes. However, the SFERD has decided to include these tests in the handbook, as there can be occasions where it is useful to verify if the endoscopes could be the source of infections. Endoscopes are only microbially tested following a specific defect of the endoscope, endoscope disinfector, water treatment system or drying cabinet and a possible outbreak of endoscope related infections.
The procedures described are general, which means that for each (type of) endoscope it has to be assessed which channels and other risk items have to be tested.
The channels of the endoscope can be microbially tested by flushing the channels with sterile saline solution, the method is described in Appendix 8.

Laboratory method
See Appendix 8.

Interpretation of positive cultures
See flow chart and assessment list in Appendix 9 and 11.

10.3.3 Microbial testing of loan endoscopes

Apart from the compatibility declaration, as described in paragraph 10.1.4, loan endoscopes can be tested microbially as described in 10.3.2. However, in practice, loan endoscopes are to be used immediately, which does not allow waiting for the results of the culturing of microbial samples taken.
Apart from the compatibility declaration of the distributor of the endoscope stating that the endoscope can be safely cleaned and disinfected in the endoscope disinfector used, it is advised to ask for a declaration that the endoscope has only been used on human subjects and that there are no data showing that the endoscope has been used on a patient with a prion disease.

10.4 Audit & Control

10.4.1 Audit of the primary process

Apart from the regular organisation-focused audits (eg NIAZ), IGZ advice is that every (endoscopy) department where scopes are cleaned and disinfected shall be audited annually by the DSRD, together with the department for infection prevention, in order to test spaces, equipment, logs and procedures. These audits can have a general or a thematic approach. An example of a general audit is included in Appendices 18 and 19. The results and any proposals for improvement are reported to the responsible manager.

10.4.2 Audit of technology and maintenance

In accordance with the advice of the Dutch Healthcare Inspectorate, a yearly audit is performed by the DSRD to verify the maintenance, verification and registration of the endoscope disinfectors, endoscopes and drying cabinets, which is done by the Department of medical technology/Clinical Physics. An example of such an audit is included in Appendix 20. The results and any proposals for improvement are reported to the responsible manager.

10.4.3 Audit of incident procedure

Apart from the requirement to perform a yearly audit on the performance of general procedures related to endoscope disinfection, the Healthcare Inspectorate promotes the yearly evaluation of the effectiveness of incident handling, together with tracking and tracing. To do this, the DSRD has to think up a possible incident and assess if all patients involved can be traced using the look back procedure. The effectiveness of the agreements within the institution on this for the available expertise at infection prevention, technical and management level have to be visibly evaluated. By means of reporting of the steps taken and the findings related to handling of the practice incident, the process and the points for improvement defined therein need to be documented.

In particular, this means:
- thinking up the incident;
- analysing the risk on equipment level/procedure/microbial risk;
- acting on deviations, preventing the occurrence of subsequent risks;
- Analysis of the patients involved that were exposed to the risky agent;
- involving the required expertise to identify the risk for patients;
- evaluating the risk for the current group of patients (track and trace);
- Involving the relevant practitioners and formulating the strategy, formulating an approach for at least patient information/patient treatment and communications.

Following all these activities, the incident has to be evaluated to be able to improve this type of procedures or evaluations. Possibly, new ideas for a practice incident can be generated.

10.4.4 Audit of the processing persons' expertise

The workers that operate the endoscope disinfector shall be qualified and competent. For every worker, there has to be a portfolio, demonstrating the education, in-service training and refresher courses. Check that the portfolios are available.

10.4.5 Audit of the registration of the replacement of cans of chemicals

If the process of replacing the chemical is not guaranteed by automation (e.g. using RFID) or incorrect replacement isn't prevented by technical means (e.g. using guards), the replacement of a can shall be verified by another worker and shall be documented. Check that this list is correctly and completely filled in.

10.4.6 Audit of logs

Several aspects shall be recorded in logs (see 10.1.1 and 10.1.2). Check that logs are correctly and completely filled in.

10.4.7 Audit of registration for traceability

Check if the relation between patient, medical specialist / endoscopist, endoscope, cleaning process and drying cabinet is being recorded. Verify that the incident procedure has been assessed in accordance with 10.4.3.

10.4.8 Audit omission of protocols

All protocols shall be available, clear and up-to-date. Test at random if this is the case.

10.4.9 Audit of management plan

The management plan shall be present and up-to-date and every relevant officer within the organisation shall be aware of it. Check if this is the case by asking relevant officers.

10.5 Release of the primary process

Every year, all results of the management measures (10.1-10.4) are verified by the DSRD. In the event that one or more aspects are found lacking, the DSRD will assess the level of deviation and decide which improvement measures are required. If the deviation could result in risks for patient safety, the DSRD can decide to (temporarily) stop the process.

At the time of use after purchase, maintenance and/or verification activities, the user must be alert for potential deviations in the working of the endoscope disinfector. The department of Medical Technology /Clinical Physics or the DSRD shall always be involved in case of unexpected results. Attention of workers involved in disinfection can reveal possible failures and reduce risks.

10.5.1 Technical release of endoscopes, endoscope disinfector and drying cabinet

Technical approval/release of equipment is performed by the department of Medical Technology/Clinical Physics if all requirement form paragraph 10.1 are fulfilled.
Rejection occurs when one or more requirements are not fulfilled. The DSRD assesses the severity of the deviation and decides, in consultation with the department of Medical Technology /Clinical Physics if the endoscope WD is to be decommissioned.

Approval marking

If the verification indicates that the equipment is safe to use, this shall be clearly marked on the equipment using an approval sticker issued by the department of Medical Technology /Clinical Physics. The validity until the next scheduled date of maintenance is to be mentioned on the sticker.

Disapproval marking

If the verification indicates that the equipment is not safe to use, the equipment shall be decommissioned. This shall be clearly marked on the equipment using a decommissioned sticker. This sticker shall be red and include the decommissioning date. Decommissioning occurs when e.g. damage to the equipment prevents it from being used safely, maintenance/repair is no longer possible or when this is a clear conclusion from the verification.

The data shall be recorded in the log, including the conclusion “not to be used”. The decommissioning has to be done in manner that actually prevents the equipment from being used.

10.5.2 Functional release of endoscopes, endoscope disinfector and drying cabinet

Following technical release by the department of Medical Technology /Clinical Physics, the equipment is functionally released by the DSRD. On the basis of functional requirements, the DSRD can decide not to release the system functionally and/or to have additional technical, microbial or functional tests performed.

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Appendix 2 – Transfer form for faulty endoscopes

Check list for user

The exterior of the endoscope has been wiped off with alcohol
The channels have been dried.
Note: If the endoscope is transported "wet" this can cause major damage to the endoscope.

Label indicating "disinfected yes/no" attached to the endoscope

Failure reported to department of Medical Technology/Clinical Physics

To be completed by the user

Inventory code for the endoscope	
Description of the problem	

The endoscope has been …. by the user:

☐ manually cleaned
☐ wiped with alcohol 70%
☐ mechanically disinfected

Inventory code for the endoscope disinfector	

Check list for the technician

Handle the endoscope while wearing gloves. If necessary wear safety goggles and a mouth mask.
Wrap the endoscope in foil and take it in a transportation case.
Indicate both on the inside and outside of the case whether manual pre-cleaning and/or disinfection has been performed.

Appendix 3 – Sample decontamination declaration

The undersigned hereby declares that the flexible endoscope:

Number…… **Type……**

Institution name: …… **Department……**

has been decontaminated (completely cleaned and disinfected) and not used on animals, cadavers and/or in a pathological anatomy laboratory.
No presence of prion diseases in patients on whom this has been used has been recorded.

The flexible endoscope was last processed for cleaning and disinfection in:
[Disinfector brand] **Machine number 1** ☐
Machine number 2 ☐
Machine number 3 ☐
Disinfector no ☐

Sent for repair to company: .....

Checking and assessment of complaint handled by (MID) :

Name: .....

Date sent: .....

Place: ……

Signature: ……..
*** fill form in completely.**

Appendix 4 – Users maintenance of the endoscope WD

Form: Start and check of the endoscope WD
Month …… Year 20……
Endoscope disinfector identification number .....

Date	Every 1st day of the week Self-disinfection	Daily Check amount of detergent and disinfectants	Daily Check O-seals	Daily Check hoses	Daily Cleaning of control panel and handles	Change detergents 2x signature	Exchange of disinfectant container 2x signature	Weekly Water softening	Weekly Cleaning of the drain + polish machines		Malfunctions

Appendix 5 – Release form Endoscopy

☐ Release Endoscopy disinfector specification: ……..

☐ Technical validation correct dated ……. by: ……

☐ Microbial tests correct dated ……. by: ……

☐ Release Flexible Endoscope specification: ……..

☐ Technical validation correct dated ……. by: ……

☐ Microbial tests correct dated ……. by: ……

☐ Release Drying Cabinet specification: ……..

☐ Technical validation correct dated ……. by: .....

The aforementioned instrument is hereby released for responsible use for up to one year after the date of signature. The release is no longer valid if the instrument / equipment has been repaired/subjected to radical maintenance during that period.

Date of release: …….

Signature of Expert on Endoscope Cleaning & Disinfection (DSRD): ……

This release statement is filed by the DSRD and a copy of this statement will be sent to the head of Medical Technology/Clinical Physics and the head of the endoscopy department.

Appendix 6 – System specifications of the endoscope disinfector

Parameter	*Endoscope disinfector manufacturer specified value and tolerances*	*Measured value*	*Conforming Yes/No: Remarks*
1 pre rinse			
Number of rinses			
The temperature of the water during rinsing			
The duration of the rinse (the time interval after the rinse temperature is attained)			
2 Cleaning			
Concentration of the detergent			
• Quantity of detergent dosage			
• Quantity of water taken in			
The temperature of the endoscope and the channels during the cleaning phase			
The temperature of the chamber walls during the cleaning phase			
The duration of the cleaning phase (the time interval after the wash temperature is attained)			
3 Intermediate rinse (between cleaning and disinfection)			
Number of rinses			
The temperature of the water during rinsing			
The duration of the rinse (the time interval after the rinse temperature is attained)			
4 Disinfection			
Concentration of the disinfectant			
• Quantity of disinfectant dosage			
• Quantity of water dosage (if applicable)			
• Quantity of water taken in			
The temperature of the disinfectant solution during the disinfection phase			
The temperature of the chamber walls during the disinfection phase			
The duration of the disinfectant phase (the time interval after the disinfection temperature has been attained as long as the disinfectant is in contact with the endoscope and the channels)[27]			
5 Final rinse			
Number of rinses			
The temperature of the water during rinsing			
The duration of each rinse step (the time interval after the rinse temperature has been attained)			
6 Flow through the channels of the endoscope			
The flow of through the channels of a worst case endoscope as identified by the manufacturer or a surrogate scope. Instead of the flow through the channels, the pressure at the connection point of each channel can be specified and measured*: - Suction - Biopsy - Biopsy 2 - Water			

[27] The temperature as measured in the channel of an endoscope is not always suitable to determine the duration of the disinfection period. Another parameter may be needed, for instance conductivity or pressure. The temperature may lag behind while the disinfectant has been pumped out. This may appear to show a longer disinfection phase than is actually the case.

Parameter	*Endoscope disinfector manufacturer specified value and tolerances*	*Measured value*	*Conforming Yes/No: Remarks*
- Air - Jet - CO2 - Elevator - Balloon filling - Balloon emptying * in the event that the target values are not known, the measuring details can be used to make an assessment about the reproducibility of the processes. For instance between the various phases of the process, between the various washing chambers in the disinfector and/or between disinfectors of a similar type.			
7 Self-disinfection			
For chemical self-disinfection, the concentration of the disinfectant.			
• Quantity of disinfectant dosage			
• Quantity of water dosage (if applicable)			
• Quantity of water taken in			
The temperature of the chamber walls during the self-disinfection phase			
The duration of the disinfection phase			
8 Leak test			
Note: The parameters of the leak test have no direct influence on the efficacy of the cleaning and disinfection of the endoscopes. However, the leak test is an important part of the process and is therefore included in the verification process.			
Proposed pressure at start of test			
Duration of the test			
Setting of the alarm limit for pressure decline during the test			
9 Quality of the water used in the disinfector Note: The manufacturer's specified water qualities may be different for various process phases.			
Temperature of the water entering the disinfector			
Hardness			
Other mineral content			
Number and type of micro organisms			
Details of built in water softeners, ion exchangers, RO-membranes, etc.: • Maintained as required • Disinfected as required			
Details regarding built-in filters • Prescribed filter type installed • Maintained as required • Disinfected as required			

Appendix 6a - process-influencing interventions

Process-influencing intervention, type of test required
Any deviation to the endoscope disinfector that results in the process progressing differently after the alteration when compared to beforehand. In SFERD terms, any deviation that results in the system specifications as listed in appendix 6 of the SFERD quality manual needing to be adjusted.
Deviations in the system parameters can influence the validity of the CE-marking and must therefore be carried out by the manufacturer or at least be authorised by him. The manufacturer must check if the type tests performed are still valid and whether additional investigation is required. It must also be checked if the list of compatible endoscopes is still valid.
Process-influencing interventions can include deviations to:

- The types of process chemicals and/or dosage;
- Process parameters such as temperature, duration, pressure;
- The process sequence, the number of process steps and the speed with which the process steps are performed;
- The water quality and/or quantity.

Process-influencing intervention	*Action (examples, may not be complete)*
Other type of detergent	Perform cleaning tests according to ISO15883, determining compatibility with endoscopes, the endoscope disinfector and the disinfectant, determining the safety of the detergent residue at the end of the process.
Other type of disinfectant	Perform disinfection tests according to ISO15883, determining compatibility with endoscopes, the endoscope disinfector and the disinfectant, determining the safety of the detergent residue at the end of the process.
Lower dosage of the detergent or, lower temperature during the cleaning phase or, shortening the warm-up time or, shortening the cleaning phase.	In accordance with ISO15883 performance of cleaning tests
Lower dosage of the disinfectant or, lower temperature during the disinfection phase or, shortening of the warm-up time or, Shortening of the disinfection phase	In accordance with ISO15883 performance of disinfection tests
Higher dosage of the detergent or, higher temperature during the cleaning phase or, lengthening of the warm-up time or, lengthening of the cleaning phase	In accordance with ISO15883 determining the compatibility with endoscopes, the endoscope disinfector and the disinfectant, determining the safety of the detergent residue at the end of the process
Higher dosage disinfectant or, higher temperature during the disinfection phase, or Lengthening of the warm-up time or, lengthening of the disinfection phase	According to ISO15883, determining compatibility with the endoscope disinfector and the disinfectant, determining the safety of the disinfectant residue at the end of the process.
Changing of pressure on the connectors with the endoscope, changing the amount of flow through the channels	In accordance with ISO15883 performance of cleaning tests, disinfection tests and determining the compatibility of the endoscopes.
Modification of the connection material for endoscopes that are already listed on the compatibility list.	Perform flow measurements confirm ISO 15883 which demonstrate equivalence of the connection materials or, performance of cleaning and disinfection tests
Deviations to the water quality	In accordance with ISO15883 performance of cleaning tests, determining the compatibility with endoscopes, the endoscope disinfector

	and the disinfectant, determining the safety of the detergent residue at the end of the process
Other adjustment	On the basis of the risk analysis, check how the process can be influenced and which tests must be repeated to determine if the endoscope disinfector still meets the standard.

No process-influencing interventions, but performing verification
Any deviation to the endoscope disinfector that *can* result in the process progressing differently after the alteration when compared to beforehand. In SFERD terms, any deviation that *can* result in the system specifications as listed in appendix 6 of the SFERD quality manual needing to be adjusted. At every maintenance cycle, repair or recall action by the manufacturer in which components of the endoscope disinfector are replaced or adjusted and during a software update/upgrade, it is recommended to check if this may result in one or more alterations of the system specifications. If this is the case, it must be checked if these system specification are still compatible with the specification by the manufacturer after the work has been carried out. Often it may not be necessary to perform a complete verification of all system specifications, but a partial verification may suffice.

Interventions that are not in principle process-influencing, but will require verification, include:
- software update;
- software upgrade;
- Replacement or adjustment of components such as:
  - sensors;
  - dosage pumps;
  - channel pumps;
  - valves;
  - circulation pump;
  - heating element;

The requirement to perform verification may be dependent on the specific design of the endoscope disinfector. Also, the source of the replacement component may be a factor. If a component is replaced by a technician of the manufacturer/supplier by an original component of the same manufacturer, verification may not be required. The decision to perform verification rests with the DSRD.

Retrospectively it must be checked if the malfunction in the defect component has resulted in possible deviations to the process, which may have affected the efficacy or put patients at risk. It may be necessary to implement a look-back. For instance, when cleaning and disinfection has been carried out at a too low temperature, or with a too low concentration of chemicals, or with insufficient flow through the channels. If it is still possible to determine what the actual temperature, dosage or flow was while the defective component was in place, it can be determined in consultation with the endoscope manufacturer and/or chemical manufacturer whether the relevant parameter was still above the acceptable lower limit. If possible, a cleaning test should be carried out in the “defect condition” to see if this shows a deviation to the results.

In some cases, no external measuring equipment has to be used for the verification. For instance, after a software update the process registration will show if the process remains unaltered.
After an intervention into the endoscope disinfector, a cleaning test is performed with the surrogate endoscope, to verify that the result of this test matches that of earlier tests.

No process-influencing intervention	*Action (examples, may not be complete)*
Software update; i.e. a new version of the system software of the endoscope disinfector, in which faults in the software are being remedied (bug fixes), but which do not influence the cleaning or disinfection process.	Check after the installation of the software if: • the machine starts normally after switching on, • the access codes still work, • the same cleaning and disinfection programmes are available, • the processes progress in the same way, with the same dosage, and the same temperature • process details are being registered correctly, • etc. etc. In addition, it must be checked if the faults in the earlier software version have had any negative effect on the functioning of the endoscope disinfector and if this has put patients at risk.
Software update; i.e. a new version of the system software of the endoscope disinfector, in which the functionality is extended, but which does not influence the cleaning or disinfection process.	Alongside the points for software update, it must also be checked that the extra functionality functions correctly.
Replacing a sensor	After replacement of a sensor it must be checked that it is correctly calibrated, regulates the process correctly (i.e. temperature control) or displays the correct value, or registers that an alarm will sound at the correct moment.
Replacing a dosage pump	After replacement of a dosage pump it must be checked if the correct quantity of the relevant product is being dispensed.
Replacing a channel pump	After replacement of a channel pump it must be checked if the pump delivers the correct pressure and/or discharge.
Replacing the circulation pump	After replacement of the circulation pump it must be checked if the pump delivers the correct pressure,
Replacing a valve	After replacement of a proportionally regulating valve it must be checked if the relevant parameters are regulated within the specified tolerances.
Replacing a heating element	After replacement of a heating element it must be checked if the warm-up time for the cleaning and/or disinfection remains within the specified tolerances.
Replacement of other components	On the basis of the risk analysis, check how the process can be influenced and which tests must be repeated to determine if the endoscope disinfector still meets the standard.
Repairs of leaks, fixing of connections in pipework or the replacement of hoses	None Retrospectively it must be checked if the process may have performed outside of the specifications because of leaks in the relevant component which may have affected the efficacy or may have put patients at risk.

Appendix 7 – System specifications of drying cabinet

Parameter	*Drying cabinet manufacturer specified value and tolerances*	*Measured value*	*Conforming Yes/No: Remarks*
I Air (channels)			
Temperature (in the event that the air that flows through the endoscope channels is being heated)			
Humidity (in the event that the air in the drying cabinet is being dried or if the manufacturer provides requirements for the extreme pressurised air)			
Oil content (in the event that the compressed air is derived from an oil-based compressor)			
II Air (clear space)			
Particle levels			
Overpressure			
Air circulation levels (number of cycles per hour)			
III Endoscope connector point			
Air pressure: - If an endoscope is connected with low flow resistance - If an endoscope is connected with high flow resistance			
Flow: - If an endoscope is connected with low flow resistance - If an endoscope is connected with high flow resistance			

Appendix 7a - Verification measurements and tests on the drying cabinet

D.1	**Temperature** (applicable if the temperature of the air is controlled or limited)
D.1.1	**Materials, procedure and acceptance criteria**
	See NEN-EN-16442 par.6.9
D.2	**Overpressure in the drying cabinet**
D.2.1	**Materials, procedure and acceptance criteria**
	See NEN-EN-16442 par.6.9
D.3	**Relative humidity** (applicable if the temperature of the air is controlled or limited)
D.3.1	***Materials***
D.3.1.1	Relative humidity (RH) detector, such as a RH sensor and readout equipment or, dew point meter or, detector tube, suitable for the specified humidity range.
D.3.2	***Procedure:***
D.3.2.1	Position the RH detector in the storage compartment.
D.3.2.2	Wait for the RH value to stabilize.
D.3.2.3	Read the RH value or calculate this from the measured dew point.
D.3.2.4	For measuring the RH in the air that is provided to the endoscope channels, connect the RH sensor or detector tube to the ESC connector in the storage cabinet.
D.3.2.5	When a dew point meter is used it can be necessary to position the measuring device in a suitable container that has a connection for a tube and an outlet at the opposite side. The container is connected to the ESC connector in the storage cabinet, enabling the air from the ESC connector to replace the air in the container.
D.3.2.6	Wait for the RH to stabilize.
D.3.2.7	Read the RH value or calculate this from the measured dew point.
D.3.3	**Acceptance**
	The result is acceptable when the measured %RH is within the specifications.
D.4	**Oil content of the air that flows through the channels** (Applicable if the air is derived from a source that may add oil to the air)
D.4.1	***Materials***
D.4.1.1	Detector tube or oil impactor, suitable to determine that the oil content is below 0,1 mg/m^3.
D.4.1.2	A tube to connect the detector tube or oil impactor to the ESC connector in the storage cabinet.
D.4.2	***Procedure:***
	Follow the instructions of the supplier of the detector tube or oil impactor.
D.4.3	**Acceptance**
	The result is acceptable when the measured concentration of oil is below 0,1 mg/m^3
D.5	**Air volume**
D.5.1	***Materials***
D.5.1.1	In-line velocity meter or volume displacement meter suitable to measure ten times the volume of the storage compartment in one hour, with an accuracy of at least 10 %.
D.5.1.2	A suitable accessory to position the meter in front of the air inlet to the fan that supplies the air to the storage compartment.

D.5.2	***Procedure:***
	Follow the instructions of the manufacturer of the meter to determine the velocity of the in-flowing air or the volume per time interval. From this measurement, calculate the volume of air flowing into the storage compartment per hour.
	NOTE: If the air outlet is well defined this measurement can be done determining the volume of the outflowing air.
D.5.3	**Acceptance**
	The result is acceptable when the calculated volume per hour is at least ten times the volume of the storage compartment.
D.6	**Particulate contamination**
D.6.1	***Materials***
D.6.1.1	Particle counter capable of sampling air and able to count particles in the sampled air that are ≥ 0,5 µm and that are ≥ 5 µm, simultaneously. The counter is required to count up to 4×10^6 particles/m^3 of 0,5 µm and larger and up to $3,5 \times 10^4$ particles/m^3 of 5 µm and larger.
D.6.1.2	The isokinetic sampling pipe that is intended to be used with the particle counter.
D.6.2	***Procedure:***
D.6.2.1	Follow the instructions from the manufacturer of the particle counter.
D.6.2.2	Position the isokinetic sampling pipe in the storage compartment to sample air at the geometric centre of the storage compartment.
D.6.2.3	Record the reading after 15 min to 20 min.
D.6.3	**Acceptance**
	The result is acceptable when the calculated number of particles of both size ranges is below the specified value.
D.7	**Pressure on the endoscope connection point**
D.7.1	***Materials***
D.7.1.1	Pressure indicator suitable for the specified range, with an accuracy of at least 5 %.
D.7.1.2	Tubing to connect the pressure indicator between the ESC connector and the endoscope.This tubing is required to be able to connect with the ESC connector at one end and the connector to the endoscope at the other end (T-connector).
D.7.1.3	Endoscope, from the list of compatible endoscopes and that is used by the user, that has the highest air demand (least resistance to air flow) including the connectors and tubing that are to be used to connect this endoscope to the storage cabinet.
D.7.1.4	Endoscope, from the list of compatible endoscopes and that is used by the user, that has the lowest air demand (highest resistance to air flow) including the connectors and tubing that are to be used to connect this endoscope to the storage cabinet.
D.7.2	***Procedure:***
D.7.2.1	Connect the pressure indicator tubing to the storage cabinet.
D.7.2.2	Connect the endoscope channel or group of channels to the pressure indicator tubing.
D.7.2.3	Wait for steady reading on the pressure indicator.
D.7.2.4	Record the indicated pressure.
D.7.2.5	Repeat this procedure for every connection from the storage cabinet to this endoscope (when more than one connection point is offered).
D.7.2.6	Repeat both procedures with the other endoscope.
D.7.3	**Acceptance**
	The results are acceptable when the recorded pressures are within the specified limits [see 8.2 e) 4) of EN16442] for the particular endoscopes.

D.8	**Air flow rates**
D.8.1	***Materials***
D.8.1.1	Flow meter suitable for the specified range with an accuracy of at least 5 %.
D.8.1.2	Tubing to connect the flow meter between the ESC connector and the endoscope.This tubing is required to be able to connect with the ESC connector at one end and the connector to the endoscope at the other end.
D.8.1.3	The endoscopes identified in D.7.1.3 and D.7.1.4, including the connectors and tubing that are to be used to connect these endoscopes to the storage cabinet.
D.8.2	***Procedure:***
D.8.2.1	Connect the flow meter to the storage cabinet.
D.8.2.2	Connect the endoscope channel or group of channels to the flow meter.
D.8.2.3	Wait for steady reading on the flow meter.
D.8.2.4	Record the indicated flow rate.
D.8.2.5	Repeat this procedure for every connection from the storage cabinet to this endoscope (when more than one connection point is offered).
D.8.2.6	Repeat both procedures with the other endoscope identified in D.7.1..
D.8.3	**Acceptance**
	The results are acceptable when the recorded flow rates are within the specified limits [see 8.2 e) 4) of EN 16442] for the particular endoscopes.
D.9	**Drying time** (Applicable if the drying cabinet has a specific drying phase, that varies from the storage phase)
D.9.1	***Materials***
	Chronometer.
D.9.2	***Procedure:***
D.9.2.1	Position an endoscope in the storage cabinet.
D.9.2.2	Record the identification of the endoscope.
D.9.2.3	Start the drying cycle and record the time.
D.9.2.4	Observe when the storage cabinet indicates that the drying cycle ends.
D.9.2.5	Record the time.
D.9.2.6	Calculate the length of the drying cycle.
D.9.3	**Acceptance**
	The result is acceptable when the calculated length of the drying time is within the specified limits for the particular endoscope.
D.10	**Automatic control of channel aeration (if fitted)**
D.10.1	***Materials***
D.10.1.1	The two endoscopes identified in D.7.1.3 and D.7.1.4 and the connectors and tubing that are to be used to connect these endoscopes to the storage cabinet.
D.10.1.2	Means to block the flow of air from the storage cabinet to the channels of the endoscope,e.g. artery clamp.
D.10.2	***Procedure:***
D.10.2.1	Block the flow of air in each tubing of the ESC connector one by one.
D.10.2.2	Record the moment the storage cabinet indicates a fault.
D.10.3	**Acceptance**
	Verify that the moment the fault is indicated corresponds to the setting of the channel aeration control.

Appendix 8 – Microbial quality

Final rinse water

Test for aerobic mesophilic bacteria	
Frequency	Quarterly, at verification and after repairs that may influence the water quality
Sample size	100cc
Method	0.22 – 0.45 µm filter
Growth medium	Filter on R_2A ager plate
Incubation temperature	28-32 °C
Incubation time	5 days
Acceptance criterion	<10 CFU/100ml. See annex 10 Check list positive cultures from endoscopes or WD
Test for environmental Mycobacteria	
Frequency	Per event, e.g. proven inadequate cleaning phase or increasing number of patients with (atypical) Mycobacteria
Sample size	Refer to the sampling method and culture method prescribed by the laboratory that performs the test.
Method	
Growth medium	
Incubation temperature	
Incubation time	
Acceptance criterion	No Mycobacteria
Test for Legionella	
Frequency	The (drinking)water supply in the hospital is monitored in line with the Legionella-control measures
Method	No further tests are indicate for the quality assurance of endoscope reprocessing.

The water treatment system shall be maintained and disinfected as instructed by the manufacturer. Check if this has been done before carrying out microbial tests.

- carry out a normal operating cycle with an endoscope in the wash chamber, especially when samples are taken after self-disinfection of the endoscope disinfector;
- where the manufacturer prescribes a specific sampling method this method shall be used. The protocol should be based on a real-time process and fulfil the requirements of EN-ISO 15883-4;
- Aseptically take a sample from the final rinse water. Use the sampling procedure provided by the endoscope disinfector manufacturer[28]. The sample should be at least 100 ml and be collected in a sterile container;
- Where the final rinse water is disinfected by the addition of disinfectant in the final rinse water, a neutralising agent shall be added to the sample immediately after collection. The endoscope manufacturer shall identify suitable neutralising agents.

Procedure for the microbial study:

- filtrate the water sample through a 0.22-0.45 µm membrane and transfer the membrane to a R2A-agarplate[29];

[28] NEN EN ISO15883-4:2008 §8 Information to be supplied by the manufacturer

[29] NEN EN ISO 15883-1:2006 §6.4.2.4

Warning: The technique of 'sample plating' using an 'inoculation eye' is unsuitable to detect small amounts of bacteria.
- incubate for at least 5 days, at 28 to 32 º C
- check for growth and count CFUs.
- there shall be less than 10 CFU/100 ml (see annex 9).
- in case of growth (> 10 KVE/100 ml) determinate the bacteria species.
- where the disinfector is used for the cleaning and disinfection of bronchoscopes, the test shall be repeated for *Mycobacteria* and/or *Legionellae* whenever there is growth (above the standard). This requires specific culture media and incubation periods[30]. The water shall be free from these micro-organisms.

Acceptance criteria:
- See acceptance criteria Willis, clause 10.3.1
- See annex 9 Flowchart Culture of final rinse water
- See annex 10 Check list positive cultures from endoscopes and/or endoscope disinfectors

Endoscope channels

Materials for sampling	Remarks
gloves	
sterile luer syringes 25 ml	number needed depends on the number of channels
if necessary sterile needles	
100 ml sterile physiological saline solution	20 ml per channel (elevator channel to be rinsed twice with 10ml if necessary)
sterile tubes	number needed depends on the number of channels
sterile containers	number needed depends on the number of channels
sterile brush or sponge	to mobilise biofilm
sterile channel separator	to ensure that the correct channel is sampled
laboratory form for bacteriological tests	

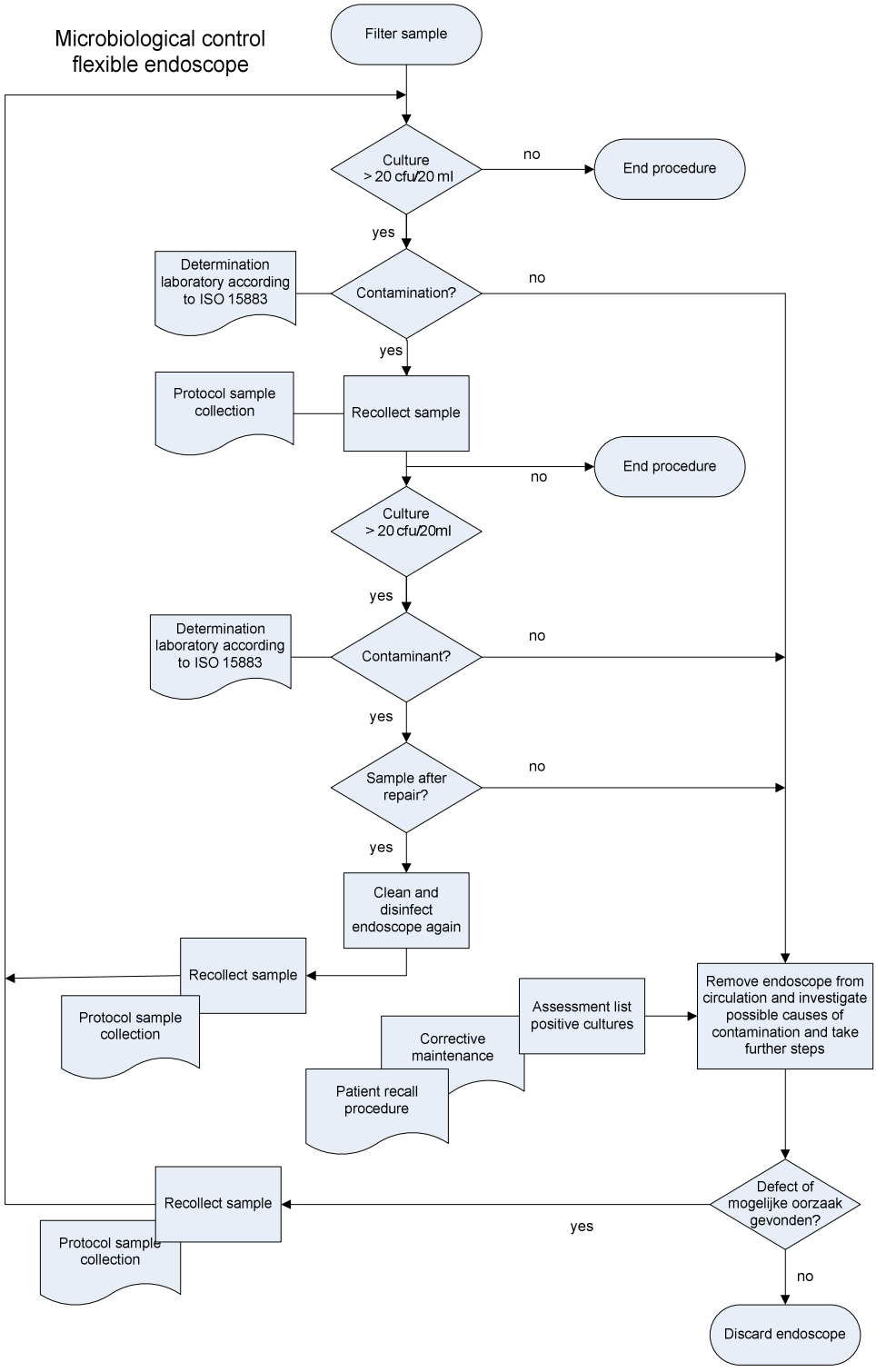
[30] NEN EN ISO 15883-4 Annex B3 and B4

Sample collection[31]

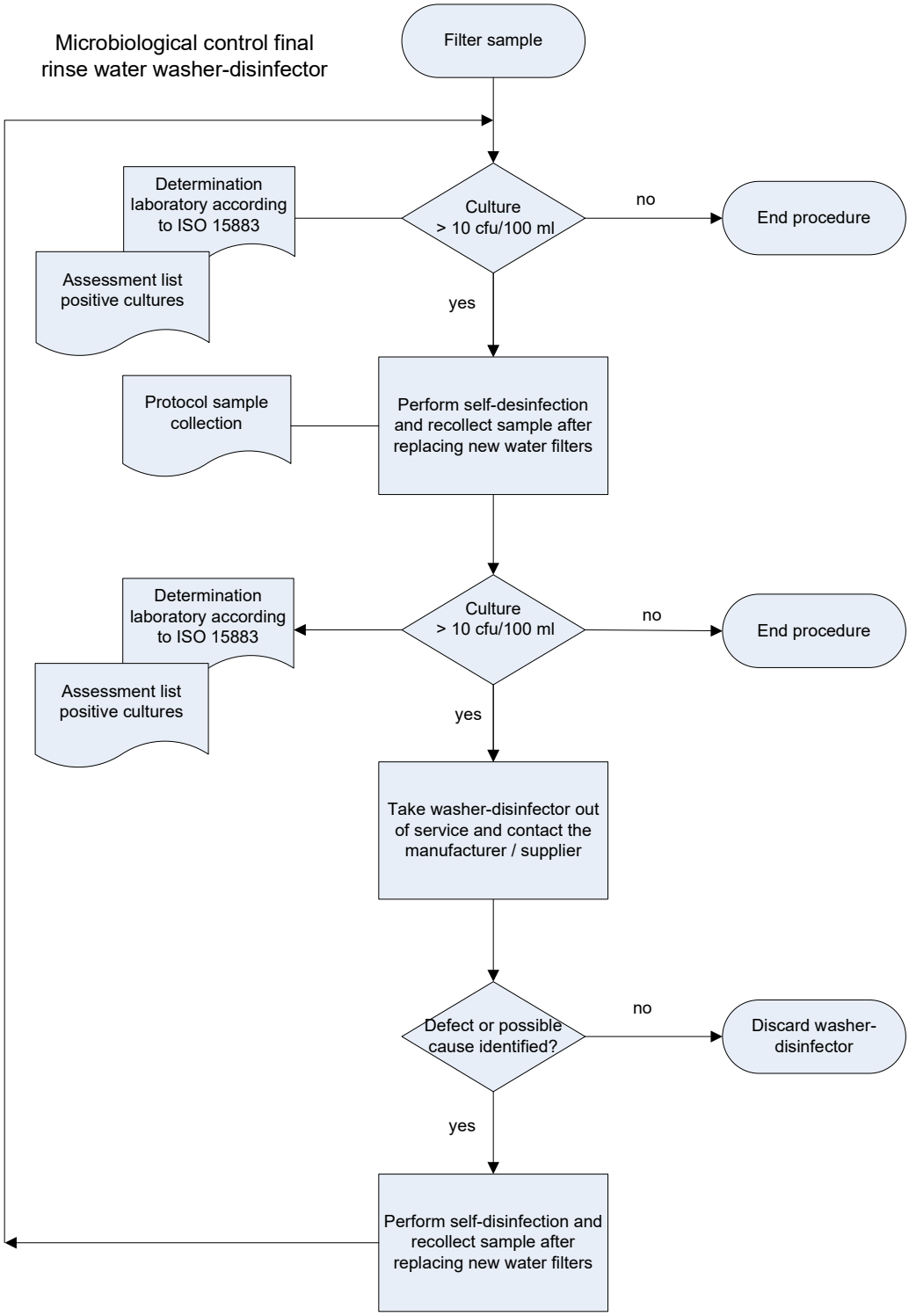
- depending of the purpose of the sample, the sample moment is selected (i.e. directly after disinfection, directly after drying or before the expiration of the final storage period)
- it takes two persons to aseptically sample an endoscope
- both persons disinfect their hands prior to taking a sample
- both persons wear gloves
- place the endoscope on a sterile surface;
- position a channel separator;
- ensure that all channels are sampled; suction/biopsy channel, water/air channel, elevator channel (ERCP-scope), jet channel etc.
- where necessary use a sterile tube to connect the syringe to the endoscope channel.
- flush the suction channel with 20 ml sterile physiological saline solution, temporarily closing the biopsy entrance and collecting the fluid from the distal end into a sterile container. Suck and press the fluid strongly through the channel three times. Use the syringe to purge the channel with air, until all liquid is expelled and collected (keeping the biopsy entrance closed)
- flush the biopsy channel from the biopsy port down to the distal end, with 20 ml sterile physiological saline solution and collect the fluid from the distal end into a sterile container. Suck and press the fluid strongly through the channel three times. Use the syringe to purge the channel with air, until all liquid is expelled and collected in container.
- using a well-fitting sterile brush or sponge brush the suction and biopsy channel. Shake the brush in the container with rinsing liquid or when using a single use brush, cut it off. Mark the sample with the date and origin of the sample;
- flush the air/water channels with 20 ml sterile physiological saline solution and collect the fluid from the distal end into a sterile container. (Mark origin of sample on container)
- flush any other channels with 20 ml sterile physiological saline solution.
- flush the elevator channel with 20 ml sterile physiological saline solution, if needed in portions of 2x10 ml. While flushing, agitate the elevator up and down.
- complete the lab form with all required information like origin of sample, date and time, and the reason of sampling (periodic monitoring / post repair / post purchase / repeated sampling after positive culture).
- transfer all samples to the lab as soon as possible. Where it takes more than 4 hours to get the samples to the laboratory additional precautions may be necessary as indicated by the laboratory.

[31] A retrograde sampling technique can also be used; see [ref 42]

Appendix 9 – Flowchart flexible endoscope culture



Appendix 10 – Flowchart final rinse water culture



Appendix 11 – Check list positive cultures form endoscopes and/or WDs

MICRO-ORGANISMS	POSSIBLE CAUSES	ACTION
Escherichia coli, other Enterobacteriaceae Enterococcus	– inadequate cleaning and/or disinfection procedure (especially in case of manual cleaning)	– verify the reprocessing cycle, with special attention for the manual cleaning – re-culture the endoscope that tested positive
	– mechanical or electronic malfunctions of the disinfection machine or defective endoscope	– complete maintenance of the machine – Take a culture of the final rinse water – re-sample the endoscope that tested positive
Pseudomonas and other non-fermenting Gram-negative rods	– insufficient rinsing – contamination of rinsing water – contamination of the disinfector due to mechanical or electronic malfunctions – contamination of filters – defective endoscope	– Check the water inlet and the procedures; -Manual and/or mechanical rinse – complete maintenance of the machine and the filters – re-sample the endoscope that tested positive – sample the rinse water
	– insufficient drying of the endoscope during storage – defective endoscope	– verify the performance of the drying cabinet – re-sample the endoscope that tested positive
(Possible contaminants) *Staphylococcus aureus*, *Coagulase Neg Staphylococci Micrococcus Bacillus species*	– re-contamination of the endoscope as the result of: • inadequate storage and transport • inadequate hand hygiene	– audit the procedures for storage and transport – re-sample the endoscope that tested positive
	– contamination of the sample as the result of faulty sampling technique or faults during culturing	– audit the procedures for sampling and culturing – re-sample the endoscope that tested positive
	– ineffective drying cycle	– audit the drying procedure and verify the ventilation in storage – re-sample the endoscope that tested positive
Atypical Mycobacteria Legionella (special culture technique)	– contamination of the disinfector – contamination of the water supply	– Check the water inlet and the procedures; • Manual and/or mechanical rinse • complete maintenance of the machine and the filters – re-sample the endoscope that tested positive – sample the rinse water

Appendix 12 - Ninhydrin swab test

Note: This provides the basic procedure, the amounts of liquids and the incubation time need to be quantified for the particular swabs that are used.[32]

Materials
- Swabs; simple cotton swabs with a plastic handle.
- Incubator set to 220°C
- If necessary injection needles (0.9 x 70) inserted into the hollow plastic handles of the swabs, to prevent them from bending during incubation.
- Water for injection.
- Ninhydrin (order no. N4876, Sigma, Netherlands) 2% in 70% isopropanol (order no 1.09634.1000, Merck, Netherlands) in water, used within 3 weeks after preparation.
- 2 pipettes to dispense 50 µl liquid.

Method
- Selection of the endoscope to be sampled
- Select an endoscope that is visibly contaminated with blood.
- Label the endoscope.
- Clean the endoscope as usual.

Assessment of the cleaned endoscope
- Assess the cleanliness of the endoscope by visual observation. Observe the presence of stains, colour deviations, foreign materials, water marks, etc. Note the observations.
- Apply 50µl of water on a swab and strongly rub the surface of the endoscope.
- Check the cleanliness of the swab and observe whether the surface has given off any visible material to the swab. Note the observations.
- Apply additional 50µl ninhydrin solution to the swab and incubate the swab for 3.5 minutes.
- Observe the swab and check for the presence of purple colourations that indicate the presence of protein was present. Note the observation.

[32] See Magazine for hygiene and Infection prevention, no, 1 February 2003. page 9-14

Appendix 13 – Haemoglobin swab test

By using the pseudo-peroxidase activity of haemoglobin, traces of blood residues can be detected. An amount of blood as small as 0.1 µg will give a colour reaction that the clearly visible even when the blood is dried or denatured. The peroxidase activity of haemoglobin works in the presence of hydrogen peroxide as a catalyst in the oxidation of chromogen, resulting in a clearly visible colour reaction. Blood residues turn into an intense blue colour within seconds.

This peroxidase activity in blood will even render a positive result after treatment with heat, alkaline or aldehydes. Oxidizing process chemicals such as hydrogen peroxide, can influence the test negatively. This test method is therefore not suitable to demonstrate the presence of blood on items that have been treated with such chemicals.

Materials
TMB-test, consisting of:
- 0,1 % tetramethyl benzidine (TMB) in 5 % acetic acid;
- 3 % hydrogen peroxide solution;
- 1 % SDS solution, for the sampling of lumen.

Activate 1 ml of TMB solution by adding four drops of the 3 % hydrogen peroxide solution. The activated solution is now ready for use.
Note: TMB may be purchased ready for use from the laboratory suppliers.

Equipment
- Glass tubes;
- Cottons swabs, free form peroxidase (verify!);
- 1 ml pipettes;
- Syringes, 10 ml, for the flushing of lumen.

Selection of the endoscope to be sampled
- Select an endoscope that is visibly contaminated with blood.
- Label the endoscope.
- Clean the endoscope as usual.

Sampling method
Direct method
The activated TMB solution may be applied to the surface of the endoscope using a pipette or a saturated swab, to visualise blood residues in situ.

Swab method
Fill a glass tube with 1 ml of activated TMB solution. Use a swab to sample the outer surfaces of the endoscope. When the surfaces are dry, moisten the swab with a drop of water of 1% SDS solution. Insert the swab into the activated TMB solution. Check in advance that the swab itself does not provide a colour reaction by performing a blank test.

Flushing method for hollow instruments
Blood residues in lumen can be detected by flushing the lumen with several millilitres of 1 % SDS solution. The presence of haemoglobin can be demonstrated with micro-haematuria dipsticks.

Acceptance criteria
The result of the cleaning process is acceptable when none of the samples show presence of blood residues. When the use of micro-haematuria dipsticks demonstrates the presence of more than 10 molecules haemoglobin per micro litre eluate, this indicates the presence of blood residues.

Safety

Handling reagents

The information that is provided by the manufacturer of the reagents, e.g. safety data sheets, shall be followed. Where necessary protective clothing, gloves and goggles shall be worn.

Waste removal

All reagent wastes need to discarded in conformance with the in-house rules. Medical devices that have been in contact with activated TMB solution or SDS solution shall be reprocessed before further use.

Appendix 14 – Release form for flexible endoscopes

Release form for flexible endoscopes

Endoscope disinfector:

Date:

Time	Endoscope number	Tubes connected	Channel separator present	End caps present	visually clean	Entire programme completed	Control by

Appendix 15 PoR Endoscope disinfector - Important points for set up

I	**Purpose of the endoscope disinfector**				
	Cleaning and disinfection of flexible endoscopes and their accessories.				
II	**Interaction with endoscopes and their accessories**				
	It must be possible to disinfect all types of flexible endoscopes and their accessories according to prescribed procedures.				
III	**Patient categories**				
	N/A				
IV	**Users**				
	Staff in CSA, employees in outpatient or inpatient departments, medical technicians.				
		Requirement/Demand			**Explanation**
1. Legal requirements			**Yes**	**No**	
Medical Directive	***1.1***	The endoscope disinfector has a CE-mark according to the Medical Devices Directive			
EN standard	***1.2***	The endoscope disinfector complies with the EN ISO 15883-1and EN ISO 15883-4			
EN 60601	***1.3***	The endoscope disinfector meets the electrical safety standard (EN 60601)			
NEN-EN-IEC 61010-2-040:2005	***1.4***	Safety requirements for electrical materials - Part 2-040 Special requirements for sterilisers and disinfecting washing machines used for the treatment of medical supplies.			
EN 1717	***1.5***	The endoscope disinfector meets requirements of the water company (EN 1717)			
WIP Directives	***1.6***	The endoscope disinfector complies with WIP Directive 'Thermolabile, flexible endoscopes', (www.wip.nl).			
Occupational health and safety and Environment	***1.7***	The endoscope disinfector complies with the occupational health and safety act (www.arbo.nl)			
2. Verification			**Yes**	**No**	
	2.1	The cleaning and disinfection processes have been validated and a validation report is present (supply copy).			
	2.2	There is an installation qualification programme/protocol **(supply programme/protocol)**			
	2.3	There is a qualification programme/protocol for the release of the process **(supply programme/protocol)**			
	2.4	The supplier has a list of critical process parameters (including criteria) that can/must be validated **(supply list)**			
	2.5	The supplier provides training for external validators (certificate supplied)			
	2.6	The supplier indicates how the training is structured and which validators have followed it (enclose list).			
	2.7	The supplier supplies a dummy scope for the purpose of validation.			
	2.8	The supplier supplies documentation to show how the validation should be performed and what the validation needs to consist of.			
	2.9	The supplier indicates how the last rinse water of the machine can be sampled for microbial investigation.			

3. Occupational health and safety and Environment			Yes	No	
	3.1	Supplier indicates water consumption (specify use)			
	3.2	Supplier indicates energy consumption (specify use)			
	3.3	Supplier/manufacturer accepts returns of endoscope disinfectors that must be replaced.			
	3.4	The substances used in the detergent and disinfectant are permitted under the disposal permit.			
	3.5	The detergent and disinfectant is supplied in appropriate UN approved packaging.			
	3.6	A safety sheet in relation to the detergent and disinfection materials is present.			
	3.7	Indicate the average quantity of residual fluid in the storage tank.			
	3.8	The endoscope disinfector is equipped with facilities to prevent: - that substances will be released into the environment; - that substances will remain in the user-accessible areas of the units; - that substances remain on the treated endoscopes.			
	3.9	The working height complies with occupational health and safety standards **(state specified working height).**			
	3.10	An extraction system is present on the endoscope disinfector (specify size)			
	3.11	The noise level during the whole process remains below < 65dB(A) **(supply test report).**			
4. Technical requirements			**Yes**	**No**	
Technical aspects	***4.1***	The endoscope disinfector should be suitable for all types of flexible endoscopes used in the hospital (provide declaration)			
	4.2	Defects or incomplete processes are indicated by and optical and acoustic signal.			
	4.3	The endoscope is monitored for leak tightness during the whole cleaning and disinfection process.			
	4.4	The endoscope disinfector is equipped with an automatic system to identify blockages during the process. Specify in which phase testing takes place and the percentage at which a blockage is detected.			
	4.5	The endoscope disinfector features a continuous channel connection check for each connected channel. State the maximum number of channels that is being monitored and specify in which phase testing takes place.			
	4.6	The endoscope disinfector indicates in good time when preventative maintenance is required.			
	4.7	It is not possible to switch/interconnect detergent and disinfectant.			
	4.8	There is a leak tray for detergent and disinfectant.			
	4.9	All parts are easily accessible for maintenance and repair.			
	4.10	All parts are resistant to the chemicals and water type used (such as RO water)			
	4.11	A 'no-break' facility is provided for data storage.			
	4.12	The endoscope disinfector is resistant to power failures. (Specify).			

	4.13	There is provision for the prevention of water flowing back from the water compartment to the water supply.			
	4.14	*Can the following processes be halted independently by authorised staff?* *-Cleaning:* *-Rinsing;* *-Disinfection;* *-Discharging disinfectant;* *-Flushing microbiologically safe water;* *-Producing microbiologically safe water;* *-Drying.*			
	4.15	The endoscope disinfector must be constructed in such a way that the contact surface with the endoscope is minimal.			
	4.16	The machine features an outlet for water testing.			
	4.17	The machine features a monitor for bacterial filters.			
	4.18	The manufacturer has drawn up a filtration plan for the water supply and gives advice on the installation of filters.			
	4.19	The machine is able to communicate with the data management system in use at the time of purchase. Specify which communication is possible and in which reference locations this has been delivered.			
	4.20	The supplier of the endoscope disinfector undertakes to provide the compatibility declaration for the endoscopes acquired by the purchaser during the life cycle of the endoscope disinfector.			
5. Process requirements			**Yes**	**No**	
	5.1	The endoscope disinfector operates according to the pass-through principle (clean/dirty separated)			
	5.2	The programme cannot be continued after the process has been interrupted.			
	5.3	The endoscope is not released if the process has not been fully completed.			
	5.4	The process consists of at least the phases: leak testing, cleaning, flushing, disinfecting, rinsing.			
	5.5	The current phase of the process is shown on the display.			
	5.6	Process parameters can only be adjusted by authorised personnel.			
6. Cleaning and disinfection			**Yes**	**No**	
	6.1	Cleaning and disinfection materials should feature a CE-mark.			
	6.2	Disinfectants must at a minimum be active against vegetative bacteria, mycobacteria, viruses, fungi and yeasts			
	6.3	The endoscope disinfector is suitable for generic detergents and disinfectants.			
	6.4	State the consumption of detergents and disinfectants per process (process cost).			
	6.5	The product information for the machine states the temperatures at which cleaning and disinfection takes place.			
	6.6	An information sheet showing usable materials, concentration, contact time and temperature is present.			
	6.7	The machine features a self-disinfection procedure.			
	6.8	The endoscope disinfector features a warning display if the disinfectant container is empty.			
	6.9	The endoscope disinfector features a warning display if the detergent container is empty.			

	6.10	There is a check on the dosage of: -disinfectant; -detergent.			
	6.11	Dosage, exposure time and temperature of the detergent and disinfectant are established in the programme.			
	6.12	The equipment runs an adequate rinse cycle with bacteria free water to avoid residues of detergent and disinfectant.			
7. Support/training requirements			**Yes**	**No**	
	7.1	An English instruction manual is available.			
	7.2	English language operating and loading instructions are available.			
	7.3	There is a protocol for corrective, preventative and inspective maintenance available for technicians **(certificate issued)**			
	7.4	Technicians are trained in corrective, preventative and inspective maintenance.			
	7.5	A technical manual is supplied.			
	7.6	The supplier can provide a Dutch or English speaking technical help desk.			
	7.7	The supplier provides training for users (certificate supplied)			
	7.8	The supplier provides connection diagrams for all types of flexible endoscopes used in the hospital.			
8. Usability requirements			**Yes**	**No**	
	8.1	The operation of the endoscope disinfector is ergonomic.			
	8.2	In the event of an alarm or warning, the machine provides a clear description of the problem and gives instructions suitable for users to solve the problem.			
	8.3	The loading and unloading doors can be opened hygienically.			
	8.4	The machine assists users with clear on-screen instructions displayed during operation.			
	8.5	Replacing the detergent and disinfectant can be done ergonomically.			
9. Traceability and registration requirements			**Yes**	**No**	
	9.1	Functionality for the registration of endoscope, charge, process data, date and time, patient and user is available.			
	9.2	Data including on machine, patient, scope, specialist and process flow are able to be registered centrally and decentrally and stored digitally per disinfection cycle.			
	9.3	The endoscope disinfector can communicate with the management system (specify).			
	9.4	The endoscope disinfector offers the possibility to generate management data (specify).			
10. Installation conditions			**Yes**	**No**	
	10.1	Drawings and measurements of facilities required for installation are provided. (Extraction, ventilation, suction, water).			
	10.2	Specific requirements for water quality are provided.			

11. Maintenance requirements			Yes	No	
	11.1	The supplier offers maintenance contracts.			
	11.2	The supplier offers a price list listing the most commonly used parts.			
	11.3	The company accepts the Standard Service Agreement (SSO) of the FHI.			
	11.4	All required parts can be supplied within 24 hours.			
	11.5	The supplier provides passwords and codes for repair and maintenance of hardware, software or mechanical components.			
	11.6	A technician can be provided by the supplier within 24 hours.			
	11.7	A loan endoscope disinfector can be provided within two days.			
	11.8	In the event of software and hardware problems the maximum downtime is 24 hours.			
	11.9	Software licences shall be valid for the duration of the life time cycle of the equipment.			
	11.10	Software and hardware updates and the provisions for these can be provided for at least 10 years for procedural and control purposes.			

Appendix 16 PoR Flexible Endoscope - Important points for set up

I	**Purpose of the Flexible Endoscope**				
	For non-invasive diagnostic and therapeutic investigations				
II	**Interaction with endoscope disinfector, drying cabinet and medical devices**				
	It must be possible to disinfect all types of flexible endoscopes and their accessories according to prescribed procedures.				
III	**Patient categories**				
	Various				
IV	**Users**				
	Staff in CSA, employees in outpatient or inpatient departments, medical technicians.				
		Requirement/Demand			**Explanation**
1. Legal requirements			**Yes**	**No**	
Medical Directive	***1.1***	The endoscope disinfector has a CE-mark according to the Medical Devices Directive			
EN 60601	***1.2***	The endoscope disinfector meets the electrical safety standard (EN 60601)			
2. Technical requirements			**Yes**	**No**	
Technical aspects	**2.1**	The endoscope can be mechanically cleaned and disinfected, in all endoscope disinfectors in the hospital **(compatibility detergents and disinfectants).**			
	2.2	All parts are resistant to the chemicals used			
	2.3	The endoscope must be constructed in such a way that it is easy to clean both manually and mechanically, and to disinfect.			
	2.4	The machine is recognised by the data management system in use at the time of purchase.			
	2.5	The manual features a list of the compatible devices and accessories (for examination and cleaning/disinfection).			
	2.6	The endoscope is resistant against medication, bodily fluids and agents used during the examination			
	2.7	The endoscope can be positioned and connected in all drying cabinets present.			
	2.8	Specification for maximum pressure and pressure differences in the channels is given.			
3. **Cleaning, disinfection and sterilisation**			**Yes**	**No**	
	3.1	The product information of the endoscope shows at which temperatures cleaning, disinfection and sterilisation can take place.			
	3.2	The product information shows which detergents, disinfectants and sterilisation fluids can be used on the endoscope.			
	3.3	The manual states which preliminary cleaning is required in advance of mechanical cleaning and disinfection.			
	3.4	Connecting equipment for leak tester, endoscope disinfector and drying cabinet is supplied. Specify which connection equipment has to be ordered separately.			
	3.5	The endoscope can be steam sterilised (121gr.).			
	3.6	The endoscope can be steam sterilised (134gr.).			
	3.7	The endoscope can be sterilised with Formaldehyde			

	3.8	The endoscope can be sterilised with Ethylene oxide			
	3.9	The endoscope can be sterilised with Plasma			
4. Requirements for support/training			**Yes**	**No**	
	4.1	An English instruction manual is available			
	4.2	An English operating manual is available			
	4.3	There is a protocol for corrective, preventative and inspective maintenance available for technicians			
	4.4	Technicians are trained in corrective, preventative and inspective maintenance.			
5. Usability requirements			**Yes**	**No**	
	5.1	(Assessment following trial installation(s)			
6. Traceability and registration requirements			**Yes**	**No**	
	6.1	The endoscope is fitted with a means of identification that can be read by the recording software at the hospital.			
7. Installation conditions			**Yes**	**No**	
	7.1	The endoscope is compatible with the processor and light source that are present.			
8. Maintenance requirements			**Yes**	**No**	
	8.1	The supplier offers maintenance contracts.			
	8.2	The supplier offers a price list listing the most commonly used parts.			
	8.3	The company accepts the Standard Service Agreement (SSO) of the FHI.			
	8.4	All required parts can be supplied within 24 hours.			
	8.5	Defective endoscopes will be repaired within a previously agreed time period. During this period a loan endoscope will be available.			
	8.6	Parts will be available for at least 10 years.			
	8.7	A technician can be provided by the supplier within 24			
	8.8	Maintenance and repairs can be carried out by medical technicians. (Special tools can be supplied)			

Appendix 17 PoR Endoscope disinfector - Important points for set up

I	**Purpose of the Drying cabinet**				
	(Drying both exterior as well as channels) and storage of flexible endoscopes and their accessories.				
II	**Interaction with endoscopes and their accessories**				
	It must be possible to dry all types of flexible endoscopes and their accessories according to prescribed procedures.				
III	**Patient categories**				
	Various				
IV	**Users**				
	Staff in CSA, employees in outpatient or inpatient departments, medical technicians.				
		Requirement/Demand			**Explanation**
1. Legal requirements			**Yes**	**No**	
Medical Directive	***1.1***	The drying cabinet complies with the Medical Device Directive			
EN standard	***1.2***	The cabinet complies with the NEN EN 16442:2014			
EN 60601	***1.3***	The Drying cabinet meets the electrical safety standard (EN 60601)			
WIP Directives	***1.4***	The drying cabinet meets the WIP directive 'Thermolabile flexible endoscopes' (www.wip.nl)			
Occupational health and safety and Environment	***1.5***	The drying cabinet complies with the occupational health and safety act (www.arbo.nl)			
2. Verification			**Yes**	**No**	
	2.1	The drying process has been validated and a validation report is present (supply copy).			
	2.2	The supplier supplies documentation to show how the validation should be performed and what the validation needs to consist of, with reference to 10.1.2. and EN16442,			
	2.3	The supplier provides training for external validators (certificate supplied)			
	2.4	The supplier indicates how the training is structured and which validators have followed it (enclose list).			
	2.5	There is a qualification programme/protocol for the release of the drying cabinet after installation **(supply programme/protocol)**			
	2.6	There is a qualification programme/protocol for the release of the process **(supply programme/protocol)**			
3. Occupational health and safety and Environment			**Yes**	**No**	
	3.1	Supplier indicates compressed air consumption (specify use)			
	3.2	Supplier indicates energy consumption (specify use)			
	3.3	Supplier/manufacturer accepts returns of drying cabinets that must be replaced			
	3.4	The working height complies with occupational health and safety standards **(state specified working height)**			
	3.5	The noise level during the whole process remains below < 65dB(A) **(supply test report)**			

4. Technical requirements			Yes	No	
Technical aspects	***4.1***	The drying cabinet should be suitable for all types of flexible endoscopes used in the hospital (**provide declaration)**			
	4.2	The supplier provides a written declaration that the drying cabinet is compatible with all the endoscopes present. The supplier states any limitations there may be. E.g. if control systems for certain types of endoscopes or for certain channels are not operational.			
	4.3	Defects or incomplete processes are indicated by and optical and acoustic signal.			
	4.4	The drying cabinet features a continuous endoscope connection check.			
	4.5	The drying cabinet features a continuous flow monitor for each connected endoscope.			
	4.6	The supplier states how the flow can be checked through the channels.			
	4.7	The drying cabinet indicates when preventative maintenance is required.			
	4.8	All parts are easily accessible for maintenance and repair.			
	4.9	A 'no-break' facility provided for data storage.			
	4.10	The drying cabinet is resistant to power failures(Specify)			
	4.11	The drying cabinet must be constructed in such a way that the contact surface with the endoscope is minimal.			
	4.12	The programme cannot be continued after the process has been interrupted.			
	4.13	The drying cabinet is able to communicate with the data management system in use at the time of purchase or in the future.			
5. Drying process			**Yes**	**No**	
	5.1	The product information of the drying cabinet includes the process parameters (time/temperature/pressure)			
	5.2	The drying cabinet features continuous monitoring of the process parameters.			
	5.3	Drying times are specified in the programme.			
	5.4	The equipment runs an adequate drying cycle with bacteria free pressurised air to avoid contamination of the scope. After the drying cycle, air continues to flow through the channels.			
	5.5	Overpressure is maintained in the cabinet.			
6. Support/training requirements			**Yes**	**No**	
	6.1	An English instruction manual is available.			
	6.2	English language operating and loading instructions are available.			
	6.3	There is a protocol for corrective, preventative and inspective maintenance available for technicians.			
	6.4	Technicians are trained in corrective, preventative and inspective maintenance.			
	6.5	A technical manual is supplied.			
	6.6	The supplier can provide a Dutch or English speaking technical help desk.			
	6.7	The supplier provides training for users			

7. Usability requirements			Yes	No	
	7.1	The drying cabinet is easy to operate (provide description)			
	7.2	In the event of an alarm or warning, the drying cabinet provides a clear description of the problem and gives instructions suitable for users to solve the problem.			
	7.3	The doors can be opened hygienically.			
	7.4	The drying cabinet assists users with clear on-screen instructions displayed during operation.			
	7.5	The drying cabinet features a maximum storage time setting and an alarm sounds if the maximum storage time is exceeded.			
8. Traceability and registration requirements			**Yes**	**No**	
	8.1	Functionality for the registration of endoscope, charge, process data, date and time, patient and user is available.			
	8.2	Data including on drying cabinet, patient, scope, specialist and process flow are able to be registered centrally and decentrally and stored digitally per drying cycle.			
	8.3	The drying cabinet is able to communicate with the management system, so that issues lie exceeding storage are visible in the treatment area.			
9. Installation conditions			**Yes**	**No**	
	9.1	Drawings and measurements of facilities required for installation are provided (ventilation, extraction, pressurised air).			
	9.2	Specific requirements for quality of pressurised air are provided.			
10. Maintenance requirements			**Yes**	**No**	
	11.1	The supplier offers maintenance contracts.			
	11.2	The company accepts the Standard Service Agreement (SSO) of the FHI.			
	11.3	All required parts can be supplied within 24 hours.			
	11.4	The supplier provides passwords and codes for repair and maintenance of hardware, software or mechanical components.			
	11.5	A technician can be provided by the supplier within 24 hours.			
	11.6	A loan drying cabinet can be provided within two days.			
	11.7	In the event of software and hardware problems the maximum downtime is 24 hours.			
	11.8	Software licences shall be valid for the duration of the life time cycle of the equipment.			
	11.9	Software and hardware updates and the provisions for these can be provided for at least 15 years for procedural and control purposes.			
	11.10	Faults in the software (bugs) that become apparent during the life cycle will be rectified free of charge by means of updates.			

Appendix 18 - Endoscopy R&D audit form

Questionnaire on behalf of endoscopy disinfection departments

Department……
Audited:.....
Date:.....
Auditors:.....

Definition for provision of criteria for the recommendations or points for improvement in the audit report for each department:

1. A non-permissible occurrence concerning cleaning or disinfection that must be remedied immediately.
2. An occurrence which has policy-level impact on the effectiveness of endoscopy cleaning and disinfection processes, to be carried out within 3 months.
3. Lowest priority: to be carried out within 6 months.

N.a. = not assessed.

1.	Endoscope cleaning and disinfection policy	Yes	No	N.a.	Notes / comments
1.1	Endoscopes and accessories, used in non-sterile body cavities, are mechanically cleaned and disinfected				
1.2	Endoscopes and accessories, used in sterile body cavities, are sterilised				
1.3	Used biopsy tools are sterilised or disposable items are used.				
	The correct principles are being applies, as follows:				
1.4	-Leak test				
1.5	- Preliminary cleaning				
	Process steps in the disinfector				
1.6	-Leak test				
1.7	-Cleaning				
	-(Possibly) flushing				
1.8	-Disinfecting				
1.9	-Rinsing				
1.10	-Drying				

	Recommendation/point for improvement	Priority
1		
2		

2	Execution preliminary cleaning endoscopes	Yes	No	N.a.	Notes / comments
2.1	The procedure for cleaning has been recorded in a protocol				
2.2	The protocol is kept near the washbasin and readily accessible to everyone..				
2.3	During the preliminary cleaning, non-sterile gloves are worn.				
2.4	Before cleaning a solution of compatible cleaner in hand-warm water is used.				Used product:
2.5	The concentration of the solution is in accordance with prescription.				Used concentration:
2.6	This solution is refreshed after every preliminary cleaning.				
2.7	Before immersion, a leak test is carried out.				
2.8	The scope is placed in the sink immediately after the examination				
2.9	The exterior of the scope is cleaned with a gauze or cloth.				
2.10	The suction cap is dismantled, flushed through with water, brushed, immersed in cleaning solution and then rinsed with water.				
2.11	Rings, caps and other possible loose components (if not disposable) are brushed, drenched in cleaning solution and then rinsed with water.				

	Recommendation/point for improvement	Priority
1		
2		

3	Ultrasonic bath N/A	Yes	No	N.a.	Notes / comments

4	Loading of the endoscope disinfector	Yes	No	N.a.	Notes / comments
4.1	There is a loading manual				Type of disinfector:
4.2	This is kept near the machine and readily accessible to everyone.				Date of manual:
	The loading manual contains the following actions:				
4.3	The rings, suction cap and any other loose components are put in a basket in the washing machine.				
4.4	The scope is placed in the machine, whereby the whole distal part is “free” (e.g, in the aperture of the treatment container)				
4.5	There is a system to prevent connection errors and this is explained.				
4.6	In the connection procedure is listed which tubes should be connected to which channels. This is the way operation takes place.				

Recommendation/point for improvement		Priority
1		
2		
....		

5	Operation of the disinfector	Yes	No	N.a.	Notes / comments
5.1	The general (including technical) operation of the machine is known to staff.				
5.2	Operating instructions are available close to the machine and readily accessible to everyone.				Date of instructions:
5.3	A written procedure has been drawn up on how to act in the event of malfunctions, close at hand an easily visible.				Date of procedure:
5.4	The process parameters and process programmes can only be altered by authorised personnel.				Authorised persons:
5.5	The endoscope compartment is locked throughout the whole process. If the process is interrupted, continuation of the same process is not possible.				
5.6	The washing machine features an automated leak test.				
5.7	The washing machine monitors the pressure in all channels, which signals obstructions.				
5.8	The washing machine is disinfected at least weekly and any time it is expected to be out of service for more than 24 hours by means of a self-disinfection programme.				
5.9	The washing machine is regularly descaled.				
5.10	Recording of the descaling takes place in a log.				Last date recorded:
5.11	The washing machine has a system for preventing recontamination during the final rinse (bacteria free water).				Means:
5.12	The washing machine features a process counter to determine periodic maintenance.				
5.13	The washing machine has a facility to allow patient tracking data to be entered.				
5.14	The washing machine undergoes preventative maintenance by an external or internal technician once a year.				Carried out by:

5.15	Checks and release after periodic major maintenance and after large repairs is set down in a protocol for verification and release of endoscope disinfectors.				Date of protocol: Verification by: Release by:

Recommendation/point for improvement		Priority
1		
2		
....		

6	Detergent and disinfectant endoscope disinfector	Yes	No	N.a.	Notes / comments
6.1	The disinfector has a system for the monitoring of dosage of detergent and disinfectant.				Which system:
6.2	The disinfector is fitted with connectors that prevent detergent and disinfectant from being interchanged.				
6.3	Detergent and disinfectant are kept in a closed cabinet following the FIFO principle.				How much stock:
6.4	The method for replacing of the containers of detergent and disinfectant are described in a protocol.				
6.5	This protocol is kept near the machine and readily accessible to everyone.				
6.6	Replacing the containers of detergent and disinfectant is done in accordance with this protocol.				

Recommendation/point for improvement		Priority
1		
2		
....		

7	Drying an endoscope in the drying cabinet	Yes	No	N.a.	Notes / comments
7.1	The drying method is recorded in a protocol.				Date of protocol:
7.2	The protocol is kept near the drying cabinet and readily accessible to everyone.				
7.3	Endoscopes which are not used within 4 hours of disinfection, are dried for at least 30 minutes in the drying cabinet.				Set drying time:
7.4	Endoscopes which are not used within 4 hours of disinfection without being dried, will be disinfected again prior to being used.				Applied storage time:
7.5	There is a written policy on how long endoscopes may be hung in the drying cabinet.				
7.6	The drying cabinet is given general cleaning once a month. The cleaning schedule is present and signed.				
7.7	Periodic maintenance and frequency of changing filters is recorded in a protocol.				Date of protocol: Frequency of replacement:

Recommendation/point for improvement		Priority
1		
2		
....		

8	Transport of Endoscopes	Yes	No	N.a.	Notes / comments
8.1	The method of transport of (contaminated and clean) endoscopes is recorded in a protocol.				Date of protocol:
8.2	The protocol is kept near the drying cabinet and readily accessible to everyone.				
8.3	Transport of endoscopes is limited from the disinfection area to the adjoining treatment or storage area.				
	If the answer at 8.3 is not "yes", the following questions must be answered.				Describe transport
8.4	Transport of endoscopes takes place in sealed containers.				System:
8.5	When endoscopes are transported, it is clear if they are clean or contaminated.				
8.6	The transport system is cleaned and disinfected after the transport of contaminated endoscopes.				Method:

	Recommendation/point for improvement	Priority
1		
2		
....		

9	Recording of data	Yes	No	N.a.	Notes / comments
	For each disinfector a log is maintained (automated or manual) in which the following information is registered:				System:
9.1	-Date				
9.2	-Patient number				
9.3	-Endoscope number				
9.4	-Name/code of staff member responsible for loading				
9.5	-Name/code of operating endoscopy specialist				
9.6	-Name/code of staff member responsible for unloading				
	When replacing detergent or disinfectant, the following details are recorded:				System:
9.7	-Date of replacement				
9.8	-Batch number detergent/disinfectant				
9.9	Machine number				
9.10	Signature of staff member who replaced container(s)				
9.11	Signature for check by colleague				

	Recommendation/point for improvement	Priority
1		
2		
....		

10	Hygiene and Infection prevention	Yes	No	N.a.	Notes / comments
	Hygienic endoscopy working methods				
10.1	Clean and contaminated components follow separate paths				
10.2	No rings, wrist watches or bracelets are worn				
10.3	After every endoscopy, the endoscopist washes or disinfects the hands before touching anything else.				
10.4	After every endoscopy, the assistant washes or disinfects the hands before touching anything else.				
10.5	After every endoscopy, hands are washed or disinfected after taking off of gloves.				

	Disinfector hygiene				
10.6	At the end of the day the top of the lid, the edges and the control panel are routine cleaned and disinfected.				Disinfectant: Check list present:
	The endoscopist wears:				
10.7	Gloves				
10.8	Protective coat				
10.9	Mask (if pulmonary tuberculosis is suspected)				
10.10	Protective glasses or splash goggles				
	The assistant wears:				
10.11	Gloves				
10.12	Protective coat				
10.13	Mask (if pulmonary tuberculosis is suspected)				
10.14	Protective glasses or splash goggles				
	Facilities:				
10.15	Adequate hand washing facilities are available				
10.16	The tap can be operated by foot or elbow				
10.17	Alcohol dispenser available				
10.18	Soap dispenser available				
10.19	Hand towel dispenser with paper towels available				
10.20	Pedal bin (or other hands-free) bin available				

Recommendation/point for improvement		Priority
1		
2		
....		

11	Staff expertise	Yes	No	N.a.	Notes / comments
11.1	*Which staff members carry out the disinfection?*				Function:
11.2	At least vocational secondary level (nurse)				
	Employees are specially trained?				
11.3	Complete training programme				
11.4	Training from disinfector supplier				
11.5	Training from scope supplier				
11.6	Endoscopy training				Explanation:
	Employees receive regular additional in-service training				
11.7	Annual endoscopy conference				
11.8	Annual training internally or from supplier				

Recommendation/point for improvement		Priority
1		
2		
....		

12	Quality assurance	Yes	No	N.a.	Notes / comments
12.1	Protocols are updated at predetermined regular intervals				
12.2	It is clear who is responsible for authorisation				
	The machine is verified at predetermined regular intervals				Externally/internally Who:
12.3	-technical				Frequency
12.4	-Functional verification				Frequency
12.5	-Microbiological				Frequency
12.6	-Use (audit)				Frequency
	The endoscopes are verified at predetermined regular intervals				Externally/internally Who:
12.7	-technical				Frequency
12.8	-Functional verification				Frequency
12.9	-Microbiological				Frequency
12.10	-Use (audit)				Frequency
12.11	The endoscope management plan is evaluated annually				

	Recommendation/point for improvement	Priority
1		
2		
....		

13	Area	Yes	No	N.a.	Notes / comments
13.1	There is a separate area for the cleaning and disinfection of endoscopes				
13.2	Work surface is large enough to allow for (spacial) separation of clean and soiled endoscopes				
13.3	Is there adequate technical provision for health and safety, such as splash guards, air treatment, extraction etc.				Air/Extraction: Splash guards:
13.4	Is there sufficient work space for the preliminary cleaning of contaminated scopes and the assembly of clean scopes?				Enlarged sink: Separate worktops:
13.5	Is there a separate administrative workspace				
13.6	Is there is a separate area for the drying and storage of endoscopes(pass through system?)				
13.7	The finish of floors, walls, edges and ceilings is in accordance with building standards for healthcare institutions (smooth, impact resistant, chemical resistant etc)				

	Recommendation/point for improvement	Priority
1		
2		
....		

Appendix 19 - Endoscopy Department audit form

Questionnaire on behalf of Endoscopy Depts
Department……
Audited:.....
Date:.....
Auditors:.....

Definition for provision of criteria for the recommendations or points for improvement in the audit report for each department:

1. A non-permissible occurrence concerning cleaning or disinfection that must be remedied immediately.
2. An occurrence which has policy-level impact on the effectiveness of endoscopy cleaning and disinfection processes, to be carried out within 3 months.
3. Lowest priority: to be carried out within 6 months.

N.a. = not assessed.

1.	Endoscope cleaning and disinfection policy	Yes	No	N.a.	Notes / comments
1.1	The endoscopy management plan is known to employees				
1.2	Endoscopy management is determined at departmental level and is known to employees (protocols, operating instructions)				
1.3	Endoscopes are disinfected mechanically				
1.4	All accessories, used in sterile body cavities, are sterilised				
1.5	It is clear where the responsibilities for cleaning and disinfecting endoscopes lie.				
1.6	Is the role and function of DMSH and H&I in these processes known?				
1.7	These are recorded in writing				
1.8	There is a separate path for articles that have to be cleaned and disinfected via the CSA or the CSD.				
1.9	Are number and variety of scopes adequate for the current CSD and transport process?				
1.10	Are accessories cleaned in the department (and disinfected if needed)				

	Recommendation/point for improvement	Priority
1		
2		

2	Handling flexible endoscopes	Yes	No	N.a.	Notes / comments
2.1	Disinfected flexible endoscopes are handled with disinfected hands				
2.2	Endoscope is used immediately in prepared room				
2.3	Attention is paid about what is happening with the tip				

	Recommendation/point for improvement	Priority
1		
2		

3	Execution preliminary cleaning endoscopes	Yes	No	N.a.	Notes / comments
3.1	The procedure for preliminary cleaning has been recorded in a protocol: “Returning contaminated endoscope to CSD”				
3.2	The protocol is available and readily accessible to everyone.				
3.3	Scopes are flushed through/aspirated by the department that used them to remove the worst of the contamination.				

Recommendation/point for improvement		Priority
1		
2		
....		

4	Transport/Logistics	Yes	No	N.a.	Notes / comments
4.1	Transport containers are always locked.				
4.3	Disinfected containers are stored in such a way that there is no risk of contamination.				
4.4	If applicable for wet transport: How long does container with wet scope remain/is en route from CSD and user location?				
4.6	Transport containers with disinfected scopes are delivered to a set location. It is ensured that they are not left without supervision. In locked cabinet/area.				
4.7	Transport containers with contaminated scopes Is it ensured that they are not left without supervision? In locked cabinet/area.				
4.8	Cabinets and trolleys for storage of scopes have clearly visible separation clean/contaminated				
4.9	The cabinets look clean				
4.10	Scopes are used according to FIFO				
4.11	Scopes are kept stored until used (in locked container or drying cabinet)				
4.12	Is it clear who must be approached if transports are not run as they should be?				

Recommendation/point for improvement		Priority
1		
2		
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5	Drying and storing endoscopes in drying cabinet	Yes	No	N.a.	Notes / comments
5.1	The drying method for endoscopes is recorded in a protocol..				
5.2	The protocol is available and readily accessible to everyone.				
5.3	Endoscopes that are not used within 4 hours of disinfection, will be at a minimum: Dried in a drying cabinet for 2 hours*				
5.4	Endoscopes which are not used within 4 hours of disinfection without being dried, will be disinfected again prior to being used..				
5.5	It is clear how long endoscopes may be kept in the drying cabinet..				
5.6	The bottom of the drying cabinet (leak tray) is cleaned and disinfected daily according to protocol.				
5.7	The drying cabinet is given general cleaning and disinfection once a month. The cleaning schedule is present and signed..				
5.8	The protocol for cleaning and disinfection of the drying cabinet is present and is followed.				
5.9	How is the scope handled? With disinfected hands?				
5.10	Every drying cabinet has a log close by				
** depending on drying cabinet 2 hours or 30 minutes*					

Recommendation/point for improvement		Priority
1		
2		
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6	Recording of data	Yes	No	N.a.	Notes / comments
6.1	Use is made of an automatic track and trace system for the cleaning, disinfection and drying process, as well as to link the patient data to the scope used.				
6.2	Use: overruling does not occur. Explain how notifications are handled				

	Recommendation/point for improvement	Priority
1		
2		
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7	Hygiene and Infection prevention	Yes	No	N.a.	Notes / comments
7.1	Staff are aware of how they operate (in relation to hand disinfection, handling (disinfected) endoscopes etc.)				
7.2	Clean and contaminated components follow separate paths				
7.3	Work is carried out aseptically				
7.4	Clothing instructions are complied with				
7.5	No rings, wrist watches or bracelets are worn				
7.6	After taking off gloves, hands are disinfected.				
7.7	The endoscope is only placed in the drying cabinet in a clean state				
7.8	Between operations, is the equipment and furniture cleaned and if needed disinfected				
Facilities in surgery/consulting room?					
7.9	Adequate hand washing facilities are available.				
7.10	The tap can be operated by foot or elbow.				
7.11	Alcohol dispenser available				
7.12	Soap dispenser available				
7.13	Hand towel dispenser with paper towels available				
7.14	Foot-operated waste bin is present				
7.15	Glove dispensers with gloves are available (various sizes)				

	Recommendation/point for improvement	Priority
1		
2		
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8	Staff expertise	Yes	No	N.a.	Notes / comments
8.1	Have employees been trained in handling flexible endoscopes?				
8.2	Employees have free access to protocols, manuals, procedures etc.				
8.3	Employees receive regular additional in-service training				
8.4	Are staff given individual assessments?				

	Recommendation/point for improvement	Priority
1		
2		

9	Quality assurance	Yes	No	N.a.	Notes / comments
9.1	Staff members are aware of protocols.				
9.2	The procedure for handling a defective endoscope is described in a protocol.				
9.3	The protocol is available and readily accessible to everyone.				
9.4	Agreements have been reached on duties and responsibilities in relation to maintenance of equipment, resources and materials.				
9.5	Agreements have been reached on procedures for requesting maintenance (corrective/preventative).				
9.6	Is the incident procedure known?				
9.7	Agreements have been reached on cleaning/disinfecting of scopes outside of regular working hours.				
9.8	Is it known how a request should be made for a hire/loan endoscope?				

Recommendation/point for improvement		Priority
1		
2		
....		

Appendix 20 - Endoscope technology & maintenance Audit Form

Questionnaire on behalf of department for technology and maintenance of endoscopes and accessories
Department……
Audited:.....
Date:.....
Auditors:.....

Definition for provision of criteria for the recommendations or points for improvement in the audit report for each department:

1. A non-permissible occurrence concerning cleaning or disinfection that must be remedied immediately.
2. An occurrence which has policy-level impact on the effectiveness of endoscopy cleaning and disinfection processes, to be carried out within 3 months.
3. Lowest priority: to be carried out within 6 months.

1	Technical verification	Yes	No	N.a.	Notes / comments
1.1	The endoscope disinfectors are technically verified:				
1.2.1	• Before use/ on acquisition				
1.2.2	• After repairs				
1.2.3	• After maintenance				
1.2.4	• When a new type of endoscope is used in the disinfector				
1.3	There is a release procedure before an endoscope disinfector is taken into service				
1.4	There is an up-to-date technical log for every endoscope disinfector				
1.5	There is a procedure for the planning and execution of preventative maintenance of the endoscope disinfector				

	Recommendation/point for improvement	Priority
1		
2		

2	Using the endoscope disinfector				
2.1	The process parameters and process programmes can only be altered by authorised personnel.				
2.2	The endoscope compartment is locked throughout the whole process. If the process is interrupted, continuation of the same process is not possible.				
2.3	The endoscope disinfector monitors the pressure in all channels which signals obstructions				
2.4	The endoscope disinfector has a system for preventing decontamination during the final rinse (bacteria free water).				
2.5	The endoscope disinfector features a process counter to determine periodic maintenance.				
2.6	The endoscope disinfector has a facility to allow patient tracking data to be entered.				
2.7	The endoscope disinfector received preventative maintenance at least annually by an internal or external technical expert.				
2.8	Checks and release after periodic major maintenance and after large repairs is set down in a procedure for verification and release of endoscope disinfectors.				
2.9	The endoscope disinfector has a system for the monitoring of dosage of detergent and disinfectant.				
2.10	The endoscope disinfector is fitted with connectors that prevent detergent and disinfectant from being interchanged				

Recommendation/point for improvement	Priority

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3	User maintenance of the endoscope disinfector				
3.1	The water softener is frequently regenerated				
3.2	The coarse filter of the drying unit is replaced every xxx operating hours				
3.3	The fine filter (sterile filter) is replaced every xxx operating hours.				
3.4	The UV unit is maintained at predetermined intervals				
3.5	The filters in the rinsing area are checked regularly				
3.6	The filters in the water supply are checked regularly				
3.7	The nozzles on the spray arm are regularly checked for blockages				
3.8	The sealing rings of the leak tester are regularly checked and replaced if necessary.				
3.9	The nozzles and tubes of the inset trolley are regularly checked and cleaned.				
3.10	The O-rings of the connector sets are regularly checked and replaced if necessary.				

	Recommendation/point for improvement	Priority
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4	Drying cabinets				
4.1	The drying cabinets are maintained regularly				
4.2	The filters of the drying cabinet are replaced regularly				
4.3	The drying cabinets use filtered, dust-free air				
4.4	The drying cabinets have a predetermined minimum drying time.				
4.5	The extraction channel from the drying cabinet vents outside.				
4.6	There is an up-to-date technical log for every drying cabinet.				
4.7	This technical log is up to date and contains useful data.				

	Recommendation/point for improvement	Priority
1		
2		

5	Ultrasound				

6	Endoscopes				
6.1	Endoscopes are checked technically at the following times:				
6.1.1	* at purchase				
6.1.2	* after repairs (external)				
6.1.3	* after maintenance (annual major)				
6.2	There is a release procedure before an endoscope is taken into service				
6.3	There is an up-to-date technical log for every endoscope.				
6.4	The endoscope has a unique code to enable automatic tracking and tracing.				
6.5	The endoscope receives preventative maintenance at least annually by an internal or external technical expert.				

	Recommendation/point for improvement	Priority
1		

2		
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7	Quality assurance				
7.1	Protocols are updated at predetermined regular intervals.				
7.2	It is clear who is responsible for authorisation.				
7.3	Staff members are aware of protocols. They are signed for.				
7.4	The method of handling a defective endoscope is recorded in a protocol.				
7.5	The protocol is known to MT staff members.				
7.6	Agreements have been reached on duties and responsibilities in relation to maintenance of equipment, resources and materials.				
7.7	This is recorded in a protocol.				
7.8	Agreements have been reached on procedures for requesting maintenance (corrective/preventative).				
7.9	This is recorded in a protocol.				
7.10	Contact about defective equipment/endoscopes is always via AT/MT, i.e. no direct contact between company and CSD staff				
7.11	There are no omissions in the current procedures / no additional procedures are needed.				

	Recommendation/point for improvement	Priority
1		
2		
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8	Hygiene and Infection prevention				
8.1	MT staff members know how to handle a contaminated scope.				
8.2	This is recorded in a protocol..				
8.3	It is clear when a scope is contaminated.				
8.4	A transport case is available to transport a contaminated endoscope.				

	Recommendation/point for improvement	Priority
1		
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Appendix 21 - Response form SFERD handbook version 2016

Feedback Professional Standard Handbook Flexible Endoscopes Cleaning and Disinfection:, version 4.0:

Page	Paragraph / Line	Remark	Request or suggestion for alteration / modification

Date:
Submitter:
Organisation:
Email address:

You can email your reaction to the secretary of the SFERD:
J.vbergenhenegouw@hagaziekenhuis.nl

Procedure:
1. Date release concept SFERD professional Manual draft version 1st round (Embargo)
2. After 3 months closing reaction period 1st round draft
3. After 1 month assessment reactions to 1st draft
4. After 1 month: feedback of decision on the reactions received to draft (1st round)
5. After 1 month: release concept SFERD Professional Manual draft version 2nd round (Embargo)
6. After 2 months closing reaction period 2nd round draft (only discussion on amendments from the 1st round remains)
7. After 1 month assessment reactions on 2nd draft
8. After 2 weeks: feedback of decision on the reactions received on draft (2nd round)
9. After 1 month: release SFERD Professional Manual new version (Symposium)

Stichting Trainingen Infectie Preventie

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