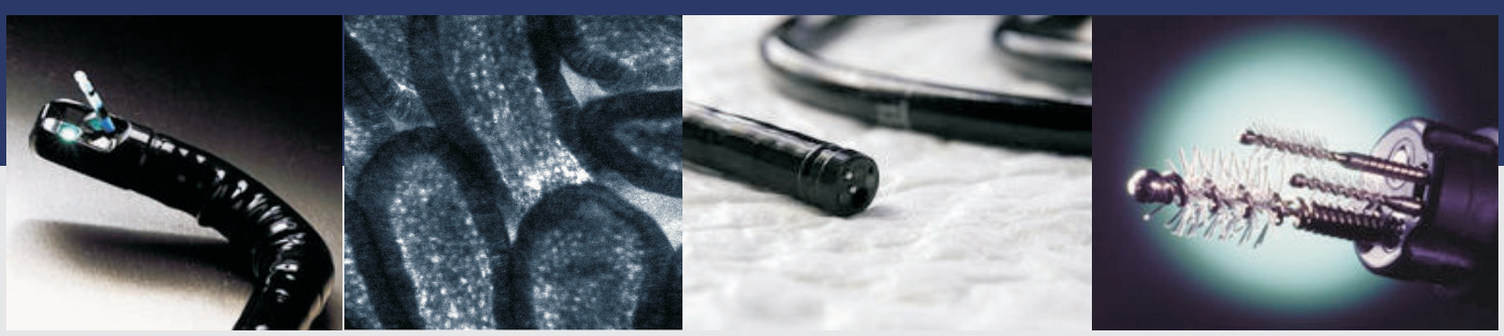
Professional Standard Handbook Cleaning and Disinfection Flexible Endoscopes

Version 3.1, 2014



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 Setting

PROFESSIONAL STANDARD HANDBOOK

FLEXIBLE ENDOSCOPES

Cleaning and Disinfection

Published on behalf of:
SVN
V&VN-MDL
VDSMH
VHIG
NVKF
VZI
WIBAZ

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

version 3.1, 17 September 2014

The SFERD welcomes your comments on this document; please mail the response form (appendix 20) to the SFERD secretary:
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INTRODUCTION

version 3.1, 17 September 2014

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, the NEN cleaning & disinfection working group and particularly the technical professional bodies for healthcare:

- Dutch Society for Medical Physics, NVKF
- Dutch Society of Clinical Engineers, VZI
- Taskgroup 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).

The SFERD hopes that with this update of the quality manual to version 3.0, 2013 that the manual will lay more emphasis on day to day practice. The revision of section 10 (process control) will certainly make a contribution to this.

In 2014, the Foundation for Training in Infection Prevention (STIP, www.STIPopleidingen.nl) sponsored SFERD with STIP's annual charity fee. This fee made it possible to publish this English version.

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.

On behalf of all the members of SFERD,

Federation for Medical Technology
Martijn Franken, clinical physicist, Franciscus hospital, Roosendaal and Lievensberg hospital, Bergen op Zoom

Sterilization Association of the Netherlands
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Kees Ballemans (chair), DSRD University Medical Center, Utrecht

As well as the professional associations listed above involved in the SFERD, we would like to thank the following associations and organisations for their critical review of the draft version 3.0 of the manual:

- Dutch anaesthesiology association (NVA)
- Netherlands Society of Cardiology (NVvC)
- Dutch association for Internal Medicine (NIV)
- Dutch association for ear, nose and throat medicine and head and neck medicine (KNO)
- Dutch association for pulmonary medicine and tuberculosis (NVALT)
- Dutch society for gastrointestinal and liver medicine (MDL)
- Radiological Society of the Netherlands (NVvR)
- 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)
- Health care inspectorate (IGZ)
- Working party on Infection Prevention (WIP)

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DEFINITIONS

Adverse event
An adverse event is an unforeseen occurrence, or in other words a deviation from protocols or operating instructions.

Compatibility
A combination of declarations concerning a medical resource to be reused, cleaning materials and disinfectants and an automatic cleaning and disinfection device, showing that the resources used in the cleaning and disinfection process can be used effectively.

Contact
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 exterior.

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

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.

Incident
A incident is any adverse event which leads to (possible) injury to a patient or staff.

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

Maintenance
All measures and preventive replacement of components specified by the manufacturer in the maintenance schedule to enable the endoscope disinfector to be used safely.

Manufacturer
The person or corporate body or the agent thereof, who:
1°. is responsible for the design, the manufacturing, the packaging and the labelling of a medical device with the intention of marketing it under their own name, regardless of whether these activities are carried out by the same party or under its responsible by a third party; or
2°. which assembles, packages, handles, renovates or labels one or more prefabricated products, or repurposes such products as medical devices with the intention of marketing them under their own name.

Owner
Board of directors or body responsible for the management of the institution, its representative(s), agent(s) and successor(s) that hold or own the endoscope disinfector.

Release, functional
A device 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 device 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 device (a flexible endoscope, endoscope disinfector or drying cabinet) is microbiologically released for use when the party responsible for it, in this manual the doctor/microbiologist, 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.

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

Storage cabinet
A storage cabinet is an enclosed dust-free cabinet, with or without overpressure at room temperature, inside which a dried flexible endoscope is stored. The difference between a drying cabinet and a storage cabinet is that in a storage cabinet the cannels of the endoscope cannot be connected.

Supplier
Any natural person or corporate body authorised by the manufacturer to supply, install and maintain endoscope disinfectors.

User
Trained member of staff authorised to use an endoscope disinfector.

Verification
Verification is the evaluation of the results of measurements, tests and checks carried out over a given period in order to ensure that the endoscope disinfector still complies with the specifications drawn up by the manufacturer. On the basis of the specifications the manufacturer has certified that the endoscope disinfector 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.).

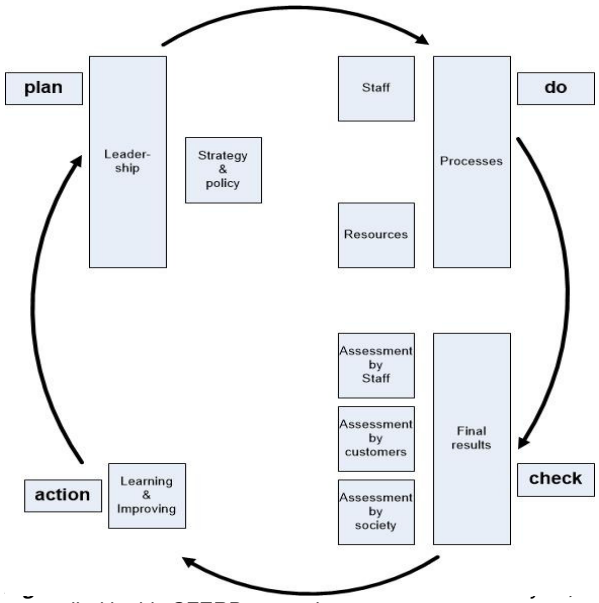
ABBREVIATIONS

ARBO	Working conditions (health and safety)
CSA	Central Sterilisation Section
CSD	Central Disinfection Section
DSMH	Expert in sterile medical devices
DSRD	Expert in cleaning and disinfection of scopes
IGZ	Health care inspectorate
INK	Dutch quality institute
MT/KF	Medical technology/clinical physics
NIAZ	Dutch institute for accreditation in healthcare institutions
PDCA	Plan-Do-Check-Act
SFERD	Steering group for flexible endoscope cleaning and disinfection
THT	Usable at least until
VMS	Safety management system
VWS	Ministry for public health, welfare and sport
WIP	Workingparty on infection prevention

DOCUMENT STRUCTURE

The INK model[1] is a useful tool for healthcare institutions and professionals and is enjoying increasing popularity in healthcare. 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":



as applied in this SFERD manual

PLAN:
Leadership
Strategy and policy
DO:
Staff
Resources
Processes

Connection to these are five 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 take 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 we wish to cause our patients no harm. 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 *'Reiniging en desinfectie van endoscopen'* issued by the infection prevention working party (WIP), the first version of which dates from 1992 and the current version from 2009 [ref 5].
In 2007 the inspector-general for health care Gerrit van der Wal presented the safety programme *'Prevent harm, work safely'* [ref 16] to the minister for public health, welfare and sport (VWS) Ab Klink. This safety programme proposed the

introduction of a Safety Management System (SMS) from 1 January 2008 and began with the reduction of hospital infections. The core of an SMS consists in a risk analysis, a system for the (safe) reporting of adverse events, a method for incident analysis and a system for managing the resulting recommendations and measures for improvement. The introduction of this system within the cleaning and disinfection of flexible endoscopes will have a positive impact on patient safety.
In 2012 the IGZ published its assessment framework for the oversight of safety in the cleaning and disinfection of flexible scopes, using the SFERD quality manual 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 a European 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.

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 (NVKF,VZI and WIBAZ).

The SFERD seeks to issue an updated version of the SFERD quality manual which will be valid for three years. In the future 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. The starting point, therefore, has been that the content of this quality manual must not conflict with the existing guidelines. Nonetheless, there are areas where the vision of the SFERD does not entirely correspond with that of the guidelines mentioned above.
In the view of the SFERD, mechanical cleaning and disinfection should be the first if not the only choice for all flexible endoscopes. Mechanical disinfection is a reproducible method of disinfection that ensures tracking and tracing. Manual disinfection should only be seen as an emergency procedure for endoscopes without channels.

The SFERD emphasises that endoscope disinfectors should not be used for other medical instruments for which the supplier of the endoscope disinfector has provided no compatibility declaration. This means that rigid endoscopes that are used in naturally-non-sterile body cavities can be disinfected in the endoscope disinfector only if the supplier so indicates. 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 qualified personnel. This is a matter of patient safety in line with the 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 also notes that the process of cleaning and disinfecting flexible endoscopes still offers many challenges for research and publications.

2. STRATEGY AND POLICY

2.1 Organisation of cleaning & 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, explicitly mentioning 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 to ensure a successful management plan [ref 4]. In practice, this responsibility is assumed by infection prevention experts, experts in sterile medical equipment, or the heads of the central sterilization department, the endoscopy department or the medical technology/clinical physics department.

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. These might be management teams from decentralised endoscope disinfecting and/or using departments. If an organisation has opted for centralised endoscope disinfection, the management may be part of the central sterilisation department or of a service company (support services). Hybrid approaches with precleaning at an outpatient department, followed by the appropriate logistics and central mechanical disinfection with the input of expert CSA employees, provide a safe structure for the cleaning and disinfection of endoscopes. As a result of outsourcing, responsibility for the disinfection of endoscopes can even be carried out entirely outside the organisation. However the process is organised, measures for documentation, process quality, tracking and tracing should be appropriately set up and periodically audited.

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 hygiene and infection prevention department contributes to good-quality patient care with its expertise in on cleaning and disinfecting, providing advice spntaneously and on request.

The cleaning and disinfection expert monitors operational conditions and procedures for the use of endoscopes, based on laws and guidelines. He also highlights possibilities for the improvement of patient care on behalf of the executive committee or board of the institution or its delegate. On acquisition of endoscopes, cleaning and disinfection equipment and process chemicals, the cleaning and disinfection expert checks the compatibility declarations with suppliers on behalf of the organization in compliance with EN-ISO 15883.

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	Additional logistics require transport and staff
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. 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 should be appointed. For the proper performance of his tasks, this officer needs the appropriate authority, for example the powers to halt processes. This expert 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.

The expert in the cleaning and disinfection of endoscopes

- 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;
- ensures that changes in policy are reflected in the procedures and operating instructions;
- is responsible for reporting and convening the policy team in the event of any adverse events involving endoscopes where patient safety is under threat;
- 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.

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;
- manages the quality documents;
- 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;
- reports adverse events/faults to the cleaning and disinfection expert;
- 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 or functional 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 checklists 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).

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;
- reports adverse events/faults to the cleaning and disinfection expert;
- 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;
- provides advice in the event of adverse events;
- advises on the acquisition of cleaning substances and disinfectants for the cleaning & disinfection of flexible endoscopes.

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

Purchaser

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

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 is supported by a mentor who will monitor progress by means of part-qualification lists. 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 follow internal and external courses in:
    - cleaning methods and machines;
    - cleaning and disinfection materials;
    - relevant legislation;
    - quality systems;
    - safety, working conditions & environment;
- prepared to enter into peer learning and review with other cleaning and disinfection experts.

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 aspect	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 labour law.
Electricity	Compliant with NEN 1010, class 0 (technical quality requirements) [ref 14] of IEC 61010-2-040 [ref 46]
Air conditioning	Air conditioning can be installed in accordance with the “Central sterilisation section building standards” [ref 12] 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 materias as required under labour 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
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 finished, 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 be specified by the supplier. Take account of space for any water filters required.

Spatial design aspect	Requirements/standards
General	Facility to install emergency alarm.
Administrative workstations	If a PC is used, washable keyboard. 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 eyebath and provision to protect staff from splashing.
Drying and storage cabinets	Space separated from work on soiled material. Pass-through cabinets should be considered. Utliities: HEPA filtered air, electricity, data processing.
Endoscope disinfector	Enough space for number required, installation, loading/unloading, operation, maintenance and repairs. Pass-through equipment should be considered. Utliities: 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. Preferably mechanised Utliities 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 reproduceability, automatic dosaging is recommended. 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 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.

4.3 Package of requirements 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 checklist, split into the following main groups of requirements:

- Legal
- Verification
- Health, safety and environment
- Technical and technological
- Process
- Cleaning and disinfection
- 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 14 for endoscope disinfector package of requirements
See appendix 15 for flexible endoscope package of requirements
See appendix 16 for drying cabinet package of requirements

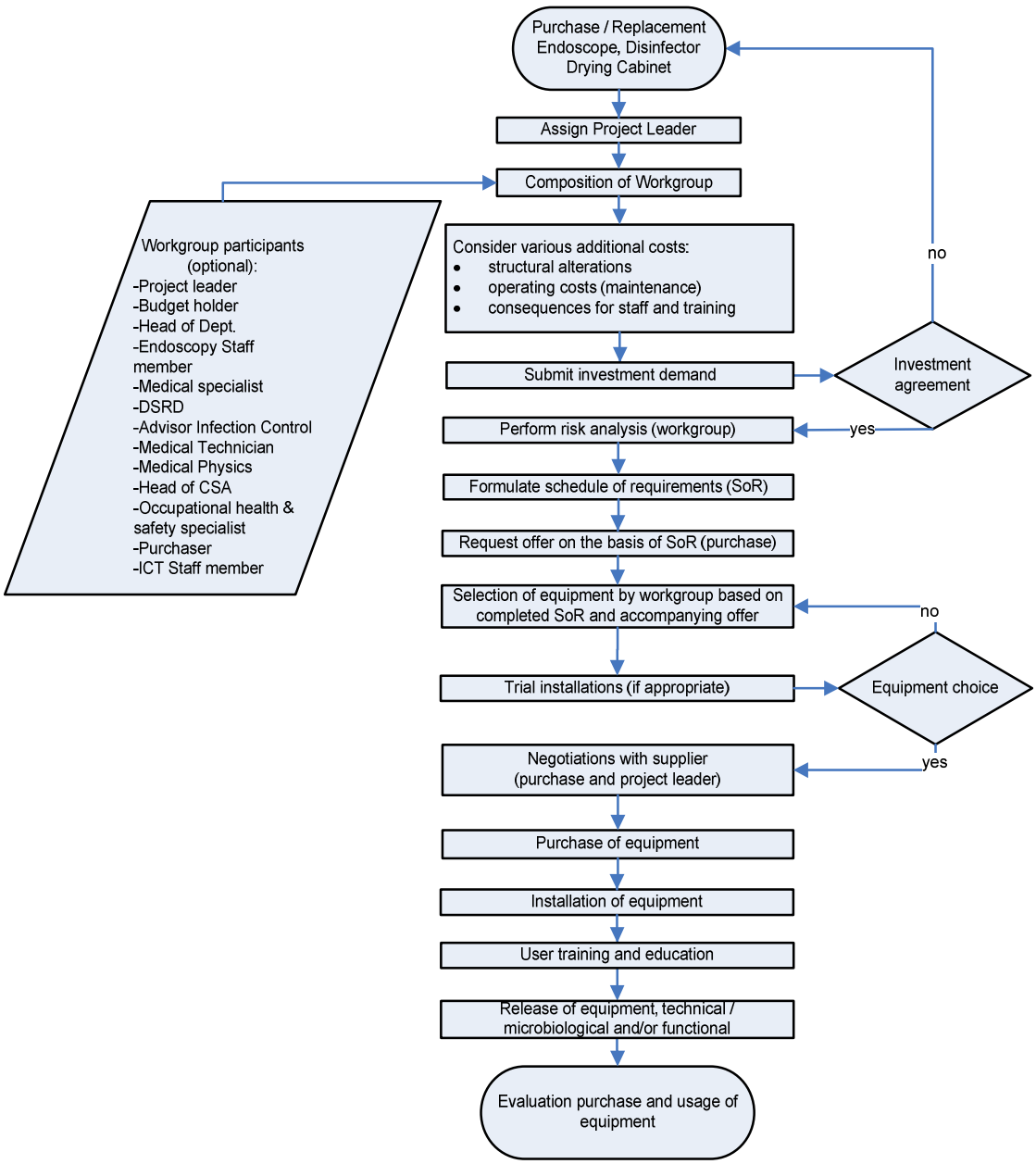


Figure 2 *- Flow chart for acquisition/replacement of endoscope, endoscope disinfector and/or drying cabinet (and any other equipment)*

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.

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 Making the endoscope ready for use
STEP 2 Transport of disinfected (dry) endoscope
STEP 3 Initial cleaning by user in the treatment room
STEP 4 Transport of used endoscope
STEP 5 Preparation, cleaning and disinfection of the endoscope
STEP 6 Testing the endoscope for leaks
STEP 7 Operating a defective endoscope
STEP 8 Preliminary hand cleaning of the endoscope
STEP 9 Mechanised cleaning and disinfection of the endoscope
STEP 10 Release of the flexible endoscope following disinfection
STEP 11 Flexible endoscope drying 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

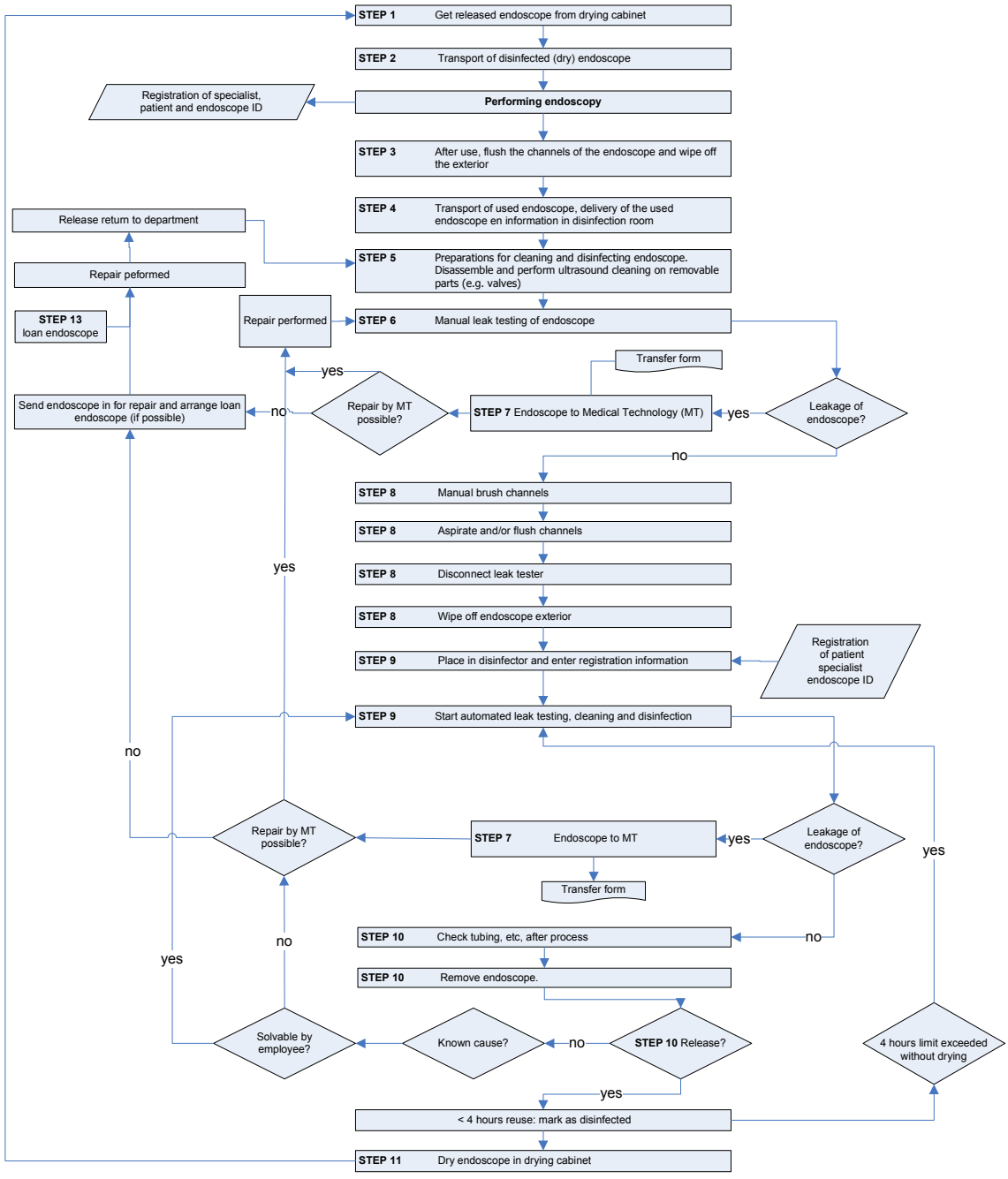


Figure 3 – Primary process for cleaning and disinfection of flexible endoscopes

STEP 1 - Making the endoscope ready for use

- All activities involving a disinfected endoscope must be carried out with disinfected hands and using gloves;
- Take the endoscope from the drying/storage cabinet or endoscope disinfector (if endoscope to be used within 4 hours). Release WARNING:
  - for a endoscope taken from the endoscope disinfector, the disinfector display must show that the endoscope was correctly disinfected;
  - when using an endoscope from the drying cabinet, the "use-by period" must not have expired.[4]
- Install appropriate covers and valves.

STEP 2 - Transport of disinfected endoscope

- Lay the endoscope on a new cellulose pad (or otherwise protected from damage while being moved) in a clean dust-free container which is enclosed (with a lid, dust cover/plastic sleeve or similar);
- The container must be clearly marked or sealed to show that the endoscope has been disinfected;
- 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.

While the endoscope is in use on the patient gloves must be worn. 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[5].

STEP 3 - Initial cleaning by user in the treatment room

Direct after the endoscopy the following steps should be taken while wearing gloves:

- draw cleaning agent (acqueous solution) through the suction and biopsy channel;[6]
- continue to draw fluid through until the used fluid is clear;
- flush and blow through he water/air channel (using valve);
- wipe the outer shell with an non-sterile gauze;
- set the endoscope friction controls to a neutral (free) position;
- disconnect the endoscope and take it to the disinfection space; if the disinfection space is not immediately adjacent to the treatment room, then the endoscope must be transported in a closed container (marked as dirty);
- immediately on concluding the examination, put on the protective cap;
- Deal with the (digital) recording of patient, medical specialist and endoscope.

[4] The WIP gives a "use-by period" of a year if the endoscope has been dried correctly. The SFERD considers that this may lead to risks which arise during the storage slipping through, with the opening and closing of doors to remove and replace endoscopes; the SFERD recommends a period of one month, in conjunction with the recommendation that the cabinet should be cleaned and disinfected monthly.

[5] In 1968 is 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, semicritical and non-critical. Critical means that a there is substantial risk of infection for the patient when the medical appliance is contaminated with microorganisms. In these cases sterilisation is necessary. Semicritical 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.

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

STEP 4 - Transport of used endoscope

- Lay the used endoscope back in the container on the cellulose pad (or otherwise protected against damage in transit);
- Clearly mark on the container that the endoscope has been used and could be contaminated, for example: the breakiong of the seal on the container marks the endoscope as contaminated;
- Take the container to the disinfection room;
- Offer the container up immediately for preliminary cleaning by hand and mechanised disinfection.

STEP 5 - Preparation for cleaning and disinfection of the endoscope

Requirements

for personal protection:

- waterproof smock;
- gloves;
- mouth/nose mask;
- protective goggles or splash guard.

for the cleaning 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;
- Gauzes or cellulose cloths;
- Various brushes (compatible with working channel diameter; preferably single-use)[7];
- Tools to flush out or blow through channels, such as:
- air/water spraygun or suction system;
- Luer Lock connectors;
- waterjet channel tube (depending on type and make of endoscope);
- elevation channel tube (depending on type and make of endoscope);
- Leakage tester;
- Transport containers clearly marked for clean and dirty;
- 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);
- Lay the cellulose mat on the worktop;
- Remove valves and distal caps, unless valves are required for endoscopes which channels have to be flushed through rather than brushed (e.g. EUS/EBUS).

[7] The SFERD strongly recommends the use of single-use brushes selected to match the appropriate channel diameter; the brushes can be used for a shift for multiple channels of the same diameter. The SFERD offers this advise with the intention of ensuring adequate preliminary cleaning, with better reach through he use of good quality brushes, rather than the sterility of the brushes used.

STEP 6 - Testing the endoscope for leaks[8]

- The endoscope is laid on a cellulose pad, with the controls uppermost;
- Turn on the leakage tester;
- Connect the leak test cable to the connector on the light guide plug of the endoscope (check the pressure);
- The shaft swells up slowly;
- Immerse the endoscope completely in the sink with cleaning fluid in which the endoscope can lie;
- 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;
- If the endoscope does not leak, carry out preliminary cleaning: see step 8;
- The endoscope should always be removed from the fluid with the leak testing pump still active and laid on a cellulose pad;
- Turn off the leak tester and pull the connector slightly clear of the device to depressurise the endoscope;
- Wait at least 1 minute, until the pressure is fully released;
- Disconnect the leak tester.

STEP 7 - Operating a defective endoscope

If an endoscope does not function to requirements, but is not leaking, it can be disinfected and dried normally. Thereafter the fault should be reported to Medical technology/clinical physics A leaking endoscope cannot be disinfected and may be contaminated with pathogenic microorganisms. The endoscope should be handled as follows before it is sent for repair:

- Clean the outside of the non-disinfected endoscope and wipe it off with alcohol 70%;
- Dry the channels (by hand using air and adequate personal protection). If the endoscope is transported “wet” this can cause major damage to it;
- Label the endoscope “contaminated”;
- The user completes the transfer form (see example: appendix 2);
- The technician handles the endoscope with gloves on, and if necessary with goggles and mouth and nose mask;
- 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.

STEP 8 - Preliminary hand cleaning of the endoscope[9]

- Before brushing ensure that the channels are full of cleaning solution;
- 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;

[8] Procedure depends on the type of leakage tester.
[9] The manufacturer may recommend specific proecdures for the endoscope; the manufacturer’s specifications are always to be taken as a guide

- Flush the elevation channel, if any, through with a 2 ml spray of cleaning solution;
- 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;
- Lay the endoscope on the cellulose pad;

STEP 9 - Mechanised cleaning and disinfection of the endoscope[10]

- Open the endoscope disinfector preferably using the foot or knee switch;
- Using gloves, place the endoscope inside the endoscope disinfector;
- Connect the leakage tester;
- Connect the inlet hoses onto the channels of the endoscope (follow the endoscope disinfector supplier's instructions). Use the correct hose set for the endoscope;
- Check the extra channels and connect them;
- Check that there are no cuts in the hoses;
- If necessary, remove the unused hoses, see the supplier's instructions;
- If the valves, distal caps and suchlike are not single-use, they should preferably be cleaned and disinfected by the CSA (see paragraph 5.2);
- Take gloves off and disinfect hands;
- Close the door of the endoscope disinfector;
- Choose the correct program. Follow the supplier's instructions;
- Record (automatically or manually) the data required:
    - date + time;
    - identification number of the endoscope disinfector;
    - patient data;
    - identification number of the endoscope;
    - medical specialist;
    - R&D staff member responsible.
- Start the program;
- If the endoscope disinfector interrupts the program 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 without faults;
- Open the endoscope disinfector with disinfected hands (optionally with gloves) or using a foot switch;
- Check that all hoses, caps and channel separators are still connected;
- If all conditions are met, then the endoscope can be released be and the release recorded on the form 'flexible endoscopes user release' (see appendix 13) or automatically;
- If not all conditions are met, then the problem must be resolved and the disinfection procedure 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 period set, it must be returned for disinfection again. Before transport the endoscope can be dried both inside and out using compressed air.

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

STEP 11 - Flexible endoscope drying process

- If it is not for immediate use, close 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);
- 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 an indeterminate time in the drying cabinet or dust-free storage cabinet, in accordance with the WIP. Because the frequent opening of the drying or storage cabinet is linked to an increased risk of contamination, a maximum storage time of one month for the endoscopes is recommended; it is also recommended that the cabinet should be cleaned monthly.[11]

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.
- 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 the Verification section.

STEP 12 - clean and disinfect outside normal working hours

- Immediately after use initial preliminary cleaning is carried out in the treatment room as described in step 3;
- this is followed by preliminary cleaning as described in step 8;
- Preliminary cleaning is followed by as soon as possible by mechanised cleaning and disinfection.

Suggestion

If qualified staff are present, the endoscope can be mechanically disinfected. The endoscope remains in the endoscope disinfector until the following working day. Before the endoscope is removed from the endoscope disinfector the following day, it is disinfected once again.
WARNING: this is not possible if there is a preset for thermal disinfection using a timeswitch!

[11]The supplier can advise on any variations in frequency (e.g daily maintenance)

STEP 13 - Loaning flexible endoscopes and/or accessories [12]

- Principal places a loan order[13] 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 endoscopist can only plan the intervention if the conditions for adequate cleaning and disinfection[14] are met;
- Reception and checking of endoscopes and/or equipment within the institution at the medical technology/clinical physics[15] 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 decontamination.[16]

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 for 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;

[12] The same measures applie for a loaned disinfector as for a new disinfector

[13] 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.

[14] Compatibility is determined.

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

[16] Decontaminatie: adequate cleaning and disinfection with a validated process that results in a medical tool which can continue to be used safely. If it is not possible to meet these conditions, a meeting with the supplier will be necessary.

The supplier must keep a log for the endoscope in which the decontamination declarations are kept and the history of the tool can be made available to the user on request;
The supplier declares to the institution on delivery of the endoscopes that the materials have been decontaminated. In this it cannot invoke a declaration made by an earlier user.

Return via medical technology/clinical physics
if the endoscope was cleaned and disinfected immediately after the intervention, this takes place within one working day, including issuing the decontamination declaration (see example: appendix 3), ready for dispatch to the supplier;
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

The risk of transfer of microorganisms during the use of endoscopes with channels is considerably greater than with channel-less endoscopes. This does not mean that channel-less endoscopes can be reused without adequate cleaning and disinfection. For channel-less endoscopes the WIP has expressed a preference for a mechanical cleaning and disinfection process. IN the evnet of aseptic use of a CE-marked sheath there is no indication for cleaning 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 which is always carried out mechanically. A major exception for cleaning by hand is the failure of equipment because of a power cut.

In short, this means that channel-less endoscopes, which are used with an intact sheath, can be disinfected after use with alcohol 70% with a contact time of at least 30 seconds. At the end of the program the channel-less endoscopes are transported to the (main) establishment for mechanised disinfection. This means that after each endoscopy the 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.

After disinfection the endoscope is stored dry in a storage cabinet or other dust-free storage facility. 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 on removal from the disinfector 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 specified safety measures; see endoscope guide and chemicals safety data sheet;
- When the message is received from the endoscope disinfector the cleaning agent/disinfectant is replaced;
- Take a new container out of the supplies cabinet. The types of containers used should be identifiable in such a way that only a single type of cleaning agent or disinfectant is contained in a specific shaped or coloured container. This will prevent confusion of chemicals from suppliers with a major delivery program using the same containers;
- Replace the container; check for the correct colour coding on the connector. Read the Dutch labelling closely;
- Second person checks that the containers are fully connected, in the case of automatical control;
- Record in the log: date, time, name of the agent being replaced, name of endoscope disinfector, if not computerised then to be initialled by two people.

Remarks:

- Changing 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 pass residues on for reuse.
- Containers with residual disinfectants should be closed and processed in accordance with current hospital guidelines.

STEP 16 - Self-disinfection of endoscope disinfector

Most endoscope disinfectors are provided with a self-disinfection program. This program 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 after the weekend (if consultation hours start on Monday);

NB:
The SFERD recommends that the disinfector 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's 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.

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 carry 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 is stored in the log for each endoscope disinfector. 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;
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. When using an irrigation system, sterile water should be used.

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;
- Reusable valves should be brushed both in open and closed position. This removes as much contamination as possible. The valves are then transferred to the central sterilisation department for further treatment.

Group 4: Accessories used during the cleaning process

- These instruments do not come into direct contact with the patient during endoscopy;
- Single-use accessories are preferred;

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

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

NB: - 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

5.3 The installation of a 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.

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.

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

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 by the department responsible;
The cleaning and disinfection expert is responsible for the assessment and functional release of the endoscope disinfector (see Appendix 5 for release form);
He 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 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 attitude to work
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 working instructions, protective clothing, extractor system, vaccinations in accordance with hospital policy, appropriate attitude to work
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 attitude to work
Replacement of cleaning and disinfection materials	Contact with chemical fluids (via the skin or inhalation)	Clear operating instructions, protective clothing, mask, well ventilated work place, appropriate attitude to work Storage in accordance with instructions
Storage of clean endoscopes	Injuries, physical symptoms	Gloves, appropriate attitude to work

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, 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 IGZ requires hospitals to use a traceability system which records which endoscope is used on which patient by whom, and in which endoscope disinfector the endoscope is cleaned and disinfected.

Tracking & Tracing

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.

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 for the endoscopy, per section or position;
- Persons carrying out the 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:

- endoscopy:
    - patient data;
    - treating medical specialist;
    - endoscope identification/charge number.
- loading and connecting the endoscope in the endoscope disinfector:
    - patient data;
    - 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 recommends a storage period of five years 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 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

Assessment by society is a significant factor in the quality of care in Dutch hospitals. The development of performance indicators contributes to greater transparency of care. Media attention to the quality of healthcare is an important incentive encouraging hospitals to keep the quality of care high on the agenda. Incidents relating to the cleaning and disinfection of endoscopes attract a good deal of attention in the media. This can damage the reputation of the hospitals concerned. Transparent care leads to increasing social pressure. This finds expression in official government targets, as set out in the Safety Management system (SMS). Patient safety is a important issue in contemporary hospital management.

Society requires hospitals to use endoscopes safely, and 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

Despite every care in the proper cleaning and disinfection of flexible endoscopes, an incident may still occur.
The steps to be followed in incident management are based on a risk assessment; in other words, on an estimate of the likelihood that an incident can cause an emergency. The aim 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. It also aims to take steps to prevent a repetition of the incident and to investigate whether patients or staff have been put at any risk of the transmission of micro-organisms.

The hospital's current 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 consisting of the cleaning and disinfection expert, a medical microbiologist or virologist and representatives of the infection prevention department, the management committee or board, the medical technology/clinical physics department and the endoscopy department(s) involved. 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 management of the findings;
- advising the management 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;
- determining whether an incident has actually occurred on the basis of all the available information;
- advising the management about the (temporary) measures that should be taken to guarantee patient safety, including the suspension of endoscopic examinations.

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. The table below gives examples of possible incidents; however, this table is not complete. The cleaning and disinfection expert carries out a risk assessment of the incident, and if necessary a risk assessment for the patient risk in consultation with a medical specialist and a medical microbiologist. The procedure below can be started on the basis of these assessments.

Table 2 - *Examples of incidents*

Inadequate cleaning & disinfection of endoscopes or accessories
▪ inadequate pre-cleaning (e.g. failure to brush channels) ▪ use of incorrect or expired chemicals ▪ use of incorrect concentrations, processing times or temperatures ▪ contamination of the last rinsing water or endoscope culture medium ▪ observation of organic material in endoscope or endoscope disinfector ▪ use of non-sterile accessories for invasive diagnosis/treatment
inadequate transport and/or storage of endoscopes
▪ insufficient drying of endoscopes ▪ improper storage of endoscopes (e.g. in transport containers)
contaminated or defective endoscope disinfector
▪ contamination of tubes, containers, etc. ▪ contamination of the last rinsing water ▪ biofilm in pipes, containers, etc. ▪ incorrect use of endoscope disinfector (e.g. incorrect programmes) ▪ technical faults (found on verification or maintenance).
design limitations or damage to the endoscope
▪ lumens too small or inaccessible channels (not accessible to brushes) ▪ damage to endoscopes (with possible build-up of organic material)
incomplete implementation of the cleaning & disinfection process
▪ omissions due to inexpert staff ▪ incomplete process due to excessive throughput/pressure of work
inappropriate use of loan endoscope
▪ loan endoscope taken into use with notification and testing

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.

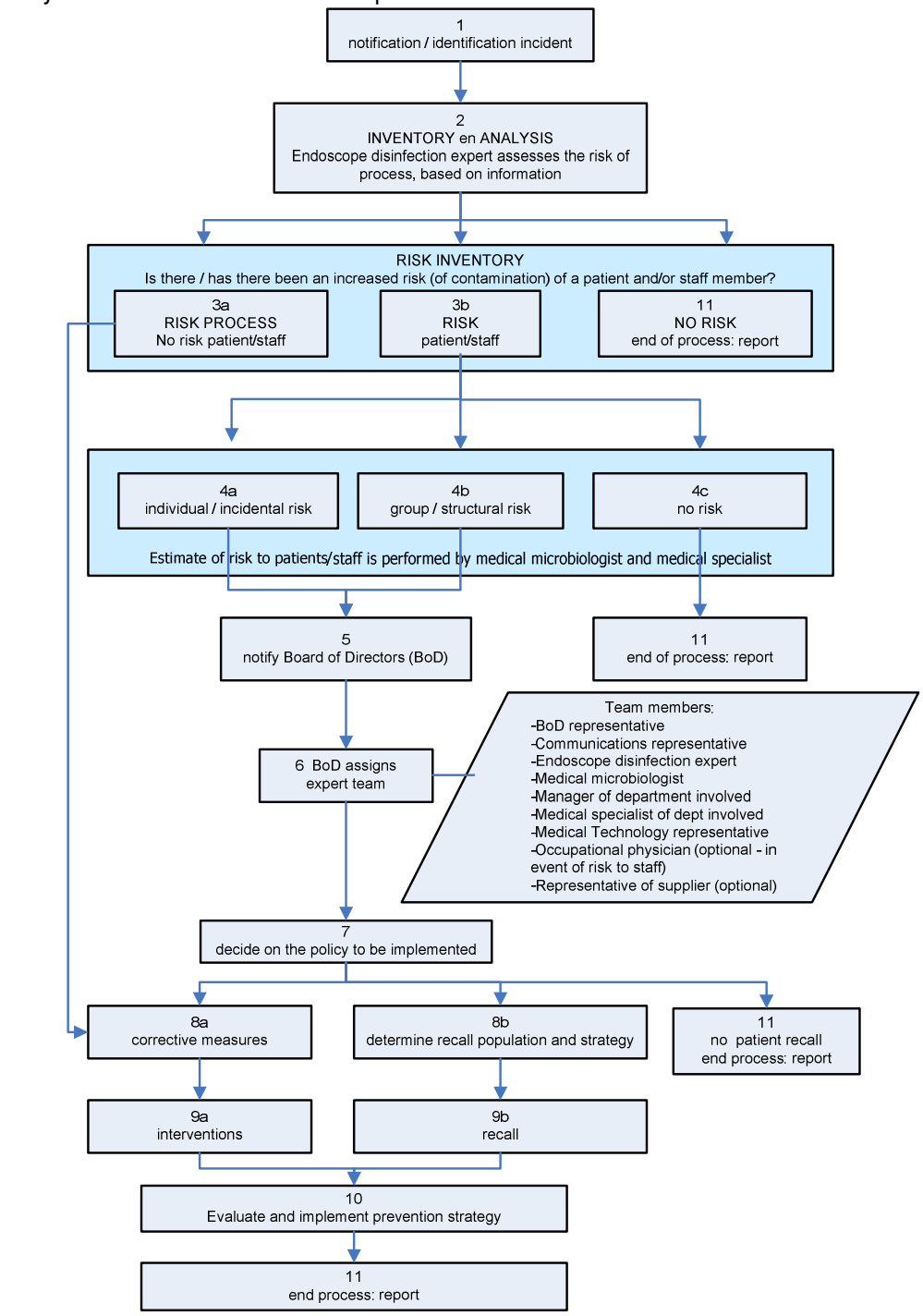


Figure4 – *Incident procedure action plan*

8.4 Incident procedure stages: process description

STEP 1: - Notification

The cleaning and disinfection expert receives a notification based on:

- signals from staff, medical specialist;
- findings of regular controls (maintenance, verification, cultures);
- anomalous process parameters in the automated cleaning and disinfection process;
- production registration findings via tracking & tracing.

STEP 2- Inventory and analysis

The cleaning and disinfection expert identifies and analyses the notifications. The table in paragraph 8.2 (Incident examples) can be used as a guide. If the notification appears to be 'only' a deviation from daily practice, the procedure will not be continued, unless there is a structural divergence from day to day procedures.

STEP 3 Risk inventory

Based on the inventory and analysis, the cleaning and disinfection expert estimates whether there is or has been:

SCENARIO 1 : 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 2: Patient or staff risk

In the event of a suspected or demonstrated risk to patients or staff, the cleaning and disinfection expert contacts the medical microbiologist directly to further assess the risk (see step 4). Note that the risk does not always have to be microbiological; for example, there may be chemical risks. In this event a pharmacist / toxicologist or safety expert can be involved.

SCENARIO 3: No patient or staff risk

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 4- Risk assessment

The medical microbiologist, pharmacist / toxicologist and safety expert assess the risk together with the cleaning and disinfection expert. This assessment may have three possible outcomes:

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

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

STEP 6 - Board appoints expert team

The representative of the board appoints an expert term, the members of which are selected in consultation with the cleaning and disinfection expert and the medical microbiologist. The size of the team will reflect whether the risk is individual (step 4a) or affects a group (step 4b). If staff have been put at risk, the occupational physician will join the team.

STEP 7 - 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 to patients or staff;
- must patients be recalled for examination, if the risk of hepatitis B, hepatitis C or HIV cannot be excluded;
- must the incident be reported to the IGZ;
- must 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 8 - Implementing the decision

A. *Corrective measures*
   Establish measures to ensure that there is no further risk and to prevent incidents in the future.
B. *Determining the recall population and strategy*
   - the risk period and risk population are determined on the basis of the inventorised 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 9 - Implementing policy

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

B. *Recall*
   The recall is carried as determined. In conjunction with the assessment of the risk of blood-borne diseases, the medical microbiologist is responsible for the recall process. The medical specialist concerned is responsible for contacting patients. 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 with the media.

STEP 10 - 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 11 - Conclusion of the process: reporting

The cleaning and disinfection expert 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 if relevant.

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. In the interests of healthcare, treatment should be resumed in accordance with the new quality standard. 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. Unreasonable social expectations should be avoided: explain what you do and how you do it.
The cleaning and disinfection of flexible endoscopes involves a high standard of disinfection in line with the type of instruments and their applications. The casually use of the term “sterility” should be avoided.
Tell both the internal and external media that you can explain the necessary changes. Mention the marginal likelihood 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 an infection caused by the incident. Any such claims should be handled in accordance with arrangements with the institution’s insurers.

The management or board can at least partially delegate media dealings to the PT or communication department.

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 healthcare institutions quality law [ref 40], the BIG law[ref 41], the law on medical resources.

To assess the testing of the state of quality assurance for cleaning and disinfecting endoscopes, the IGZ uses the guidelines of the infection prevention working group. monitoring and implementing new technological developments. 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 and 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 department manager is responsible for the cleaning and disinfection of the flexible endoscopes and accessories. 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. As a whole these steps and action encompass the 'validation' of the endoscope WD and the related procedures.
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 the 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. A range of functional tests and checks is performed on a daily, monthly or quarterly bases. 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.

Table 3 *– System of process verification*

Clause	Action	At purchase	Daily	Monthly	Quarterly	Yearly	At incidents	After process altering repairs	After maintenance	Facultative
10.1	**Technical verification**									
10.1.1	Verification of the system specification of the endoscope WD	X				X		X*	X*	
10.1.2	Verification of the system specification of the drying cabinet	X				X		X*	X*	
10.1.3	Inspection of endoscopes	X				X				
10.1.4	Compatibility establishment	X								
10.2	**Functional test and checks**									
10.2.1	Check of channel separators	X	X							
10.2.2	Check of 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								X*
10.3	**Microbial tests**									
10.3.1	Microbial quality of the final rinse water	X			X		X	X		
10.3.2	Microbial status of endoscopes						X			X*
10.3.3	Microbial status of loan endoscopes						X			X*
10.4	**Audit & Control**									
10.4.1	Audit primary process					X				
10.4.2	Audit technology and maintenance					X				
10.4.3	Audit incident handling procedure					X				
10.4.4	Audit expertise of the reprocessing persons					X				
10.4.5	Audit records of exchange of process chemicals containers			X						
10.4.6	Audit logs					X				
10.4.7	Audit track-and-trace					X				
10.4.8	Audit omissions in SOPs					X				
10.4.9	Audit endoscope management plan					X				

* To be decided by the DSRD

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 not intended to demonstrate that the WD meets the requirements of the international standard ISO 15883 or the Medical Devices Directive. This has already been established by the manufacturer and the CE-mark on the WD shows that the requirements are met.

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

The technical specifications of the WD and its processes are designed by the manufacturer to fulfil 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 has the opinion 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 WD should also be periodically verified.

To the question ‘who should perform the measurements to verify that the WD works within its technical specifications’, SFERD is of the opinion that the DSRD has the responsibility to perform (or outsource), in collaboration with the supplier of the WD, periodically all necessary measurements, tests and checks and to verify that the technical specifications as provided by the WD manufacturer are met.

The DSRD, as the responsible person decided who will perform the measurements, tests and checks. Where possible the measurements, test and checks could coincide with period preventive maintenance. This will safe time, thus increasing the availability of the WD. 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 the work that is outsourced. Possible partners are the supplier of the WD, the Medical Technology department / Clinical Physics of the hospital and validation companies.

10.1.1 Verification of technical specifications of the WD

The endoscope WDs 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. Technical verification of the WD 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 WD. Before commencement of the system verification the logs of the WD are checked for any particulars that should be taken into account when doing the system verification.

Verification of the system parameters may be performed by any competent party[18] (supplier of the WD, the Medical Technology department / Clinical Physics of the hospital, validation company), but could be, for the sake of efficiency be combined with routine maintenance. Many of the process parameters are already verified during maintenance. The parameters that are verified, the procedures that are used and the necessary accuracy should be agreed upon with the party that performs the verification. For those system specifications that are not verified by the maintenance party, the DSD will contract another party. The DSRD verifies that the parties involved have the necessary expertise and that the procedures that are used are endorsed by the WD manufacturer.

WARNING: No (temporary) modification of the WD shall be made for the performance of the verification. E.g. disconnection of internal tubing the in WD to connect sensors, disconnection of WD 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 WD may not perform as designed by the manufacturer, resulting in ineffective processes. Thus the verification measurements become a patient hazard!
Modifications to the WD are only allowed by the WD supplier, if only to maintain the validity of the CE-mark and 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.

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. when a temperature sensor indicates a value that is lower than the real temperature, the sensor should be adjusted. 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 WD 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.

[18] A party is competent when it is acquainted with all the technical details of the WD and how it operates. A competent party shall use a maintain a quality assurance management system, e.g. ISO 9000.

Normative references

The performance requirements and test methods for endoscopes WDs are given the 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 thermo labile 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 standards is meant.

Requirements and responsibilities

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

Contact person

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

Owner

The owner ensures that sufficient means are available for the cleaning and disinfection of flexible endoscopes. The owner also ensure timely maintenance of the equipment and education of personal.

Manufacturer/supplier

The manufacturer/supplier delivers a WD that fulfils the requirements of the sales agreement. This includes the requirements of the Medical Devices Directive and the international standard ISO 15883, parts 1, 4 and 5.
The manufacture shall clearly identify the endoscopes (brands, types, series) that can be reprocessed in the WD, the necessary connectors for each endoscope and the preparations that are necessary before the endoscope can be placed in the WD. 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 reprocessing technicians instructed. The manufacture specifies all process parameters and how to verify these, as well as instruction for user maintenance.

User

The user shall use the endoscope WD as instructed by the manufacturer and prescribed in the SOPs, for the purpose identified by the manufacturer. The user shall have up to date expertise and shall be instructed in the operation of the WD. This should be instruction by the manufacturer/supplier including the technical functioning of the WD with emphasis on the limitations of the WD and its processes.
The user shall be capable to recognise fault conditions and malfunctions and 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 report and the subsequent actions in the WD's log and informs the DSRD about the event.

Performer of measurements, tests and checks

The persons that conducts measurements, checks and test shall be specifically trained and shall be familiar with design, use and maintenance of the endoscope WD. The system specifications provided by the manufacturer are the reference to which the results from measurements, checks and tests are judged.
Third parties that conduct maintenance, measurements, tests and checks shall work within a quality assurance system, e.g. ISO 9000. 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.

Planning of technical verification of the endoscope WD

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 WD is performed at least annually. Maintenance and repair, depending on the nature of it, shall be followed by verification measurements, tests and checks. At least a release test shall be done. The manufacturer/supplier shall explain whether maintenance or repair has a possible detrimental effect on the performance of the WD, the Medical Technology / Clinical Physics Department together with the DSRD evaluate the explanation of the manufacturer/supplier and establish the nature and extent of the release tests.

Logs

In the log all data about the endoscope WD shall be recorded. Every WD has its own log that kept with the WD. Electronic logs shall be accessible by the user, DSRD and hospital technicians from their respective work places. The records shall contain at least:

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

The following information shall be recorded in the log:

- date of the exchange of process chemical containers, the lot numbers of the containers and the names of the persons that conducted and verified the exchange;
- overview and results (by reference to SOPs, reports and other documents) of measurements, tests and checks, including the name of the person that conducted these;
- overview of daily, weekly and quarterly inspections including the name of the person that conducted these;
- overview of the routine cleaning of the WD, 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 a the compatible endoscopes and accessories;
- date of the exchange of water filters (pre filters and bacterial grade filters) the lot numbers of the filters and the name of the person that conducted the exchange.

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 WD 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 endoscopes WD, 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 manufacturer and the type of endoscope WD, additional process parameters can be applicable or not all process parameter are 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/distributor

As a consequence of a corrective action of the manufacturer, changes can be made to the endoscope WD. The DSRD shall, in cooperation with the manufacturer, assess these changes. This shall include the arguments given of the manufacturer and an evaluation by the DSRD of:

- 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 WD;
- 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 WD are no longer guaranteed following the changes, he can decide to suspend the use of the endoscope WD. In the latter case, it is likely that the changes to the endoscope WD are such, that the type tests as once performed by the manufacturer are no longer valid. The manufacturer shall redo part of the type tests and hand the results over to the DSRD.

10.1.2 Verification of the system specification of the drying 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.
The verification of drying cabinets is derived from CEN/TC102 N784 NWIP STORAGE CABINETS-heat-sensitive endoscopes (version January 2008) and is focused on the Dutch market. This document is only the first draft of a European standard. The publication of the final version will take considerable time. With this, SFERD tries to get the verification of drying cabinets moving in the right directions. 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.

Difference between drying cabinet and storage cabinet

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. The difference between a drying and storage cabinet is that the endoscope channels are dried using HEPA-filtered air in the drying cabinet. For endoscopes without channels, a drying cabinet is not required.

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 schedule of requirements
- process specifications as stated by the manufacturer
- safety equipment
- type test declaration
- connection drawings/information for pipework, computer networks etc.
- compatibility declaration for endoscopes that can be dried in the cabinet
- channel connection protocol for each type of endoscope
- loading and unloading protocol
- user's manual
- maintenance protocol
- cleaning protocol
- technical manual

The following needs to specified as well:

- environmental conditions:
  - temperature, humidity and rate of air changes in the room where the cabinet is installed
- power supply:
  - voltage and current
- pressurized air:
  - capacity, static and dynamic pressures
  - quality, particulate matter, humidity, oil content.

System verification of the drying/storage cabinet

- Are all documents present?
- Is the responsibility set for release of the drying/storage cabinet after installation, routine maintenance and repairs?
- Are all channel connectors and connecting tubes in good order?
- Are all channels of every endoscope actually flushed with air?
- Are the endoscope hangers in good working order?

- Is all routine maintenance performed as required by the manufacturer?
- Is the drying/storage cabinet cleaned as required by the manufacturer?
- Does the drying/storage cabinet work within its specifications, are the (critical)[19] parameters within the limits specified by the manufacturer?
- Does the drying cabinet indicate an alarm when faults occur in the drying process?
- Does the drying cabinet indicate an alarm when the maximum storage time is exceeded?
- Does the drying cabinet indicate an alarm when a door is not closed?
- Does the drying cabinet indicate an alarm when the power fails?
- Are the environmental conditions changed?

Track records

It should be possible to connect the drying cabinet to the endoscope tracking system that is used in the hospital.

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 type 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 to inspect these items 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 third party. The (visual) inspections should focus on the following hygiene related items:

- visual defects;
- 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, type and series number or other identifier;
- condition of the connectors to the light source, water bottle, air source and suction bottle;
- function of the RFID chip;
- correlation of the RFID chip data and the logs of the endoscope;
- manual leakage test of the endoscope, while the distal end is wagging.

10.1.4 Compatibility establishment

The manufacturer of the WD shall declare which endoscopes the WD is able to clean and disinfect (declaration of compatibility, see EN-ISO 15883-4 §4.1.3.[20] en §8.a.[21])

[19] Where applicable, e.g. temperature, relative humidity, flow through the channels, flow in the cabinet, status of HEPA filter.
[20] After the complete process in the WD 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 WD manufacturer shall demonstrate this capability during type testing for all the types of endoscope that the WD is designed to process.

By adding an endoscope to the list of compatible endoscopes the manufacturer actually states that the endoscope can be effectively cleaned and disinfected in the WD, under the condition that the correct channel connectors and channel separators as well as the prescribed cleaning and disinfection agents are used, and that the endoscope is prepared for automated processing as prescribed by the manufacturer of the WD; see EN-ISO 15883-4 §4.1.4.[22].
Most manufacturers of endoscope WDs have a list available of the endoscopes that can be cleaned and disinfected in the WD. Owners are advised to check whether their endoscopes are on the list of compatible endoscopes of the WD manufacturer before purchase of the WD. 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 WD. This has already been established by the WD manufacturer.
Where the WD manufacturer is no able to give a declaration of compatibility, the hospital should not purchase the particular endoscope, unless the hospital 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 WD manufacturer;
- the correct channel connectors, channel separators and port closures are available;
- the necessary preparations as prescribed by the WD manufacturer (e.g. the brushing of 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 WD manufacturer. If necessary the WD manufacturer or the endoscope manufacturer shall establish whether the endoscope can be effectively cleaned and disinfected in the WD;
- the correct channel connectors, channel separators and port closures are available for the new or loaned endoscope;
- de juiste connectoren voor de nieuwe endoscoop aanwezig zijn;
- any new or special preparations as prescribed by the WD or endoscope manufacturer (e.g. the brushing of channels) are incorporated into the operator's SOP.

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

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

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 WD 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) draw up a dedicated program of inspections, verifications and checks , and have this program carried out.

Daily checks[23]

User maintenance on the endoscope WD, like the replacement of filters, cleaning and disinfection agents and the self disinfection of the endoscope WD, shall be carried out by the department responsible for the decontamination of the endoscopes. The 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 WD 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 WD can require additional checks.

10.2.1 Check of the channel separators

The channel separator shall not impair the operation of the machine caused by 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 machine and the endoscope shall not impair the operation of the machine as a consequence of leaks, flow restrictions or other limitations
The check of the connectors as a consequence of leaks, flow restrictions of other limitations:

- state of O-rings and interface with the endoscope;
- damage of the connector and the tubes attached to it.

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

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 performed using a commercially available surrogate endoscope and/or a comparable test endoscope (as specified in NEN EN ISO 15883).

10.2.4 Channel obstruction test

The surrogate endoscope has the option to restrict the flow in every channel. The endoscope WD shall give an alarm for every obstructed channel.

10.2.5 Channel non-connection test

The channels of the endoscope are connected. One of the channels is disconnected and the process is started. The WD shall indicate a fault. The test is repeated for each channel. The WD shall 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 WD. By comparing the test results over a period of time, insight can be gained into the reproducibility of the endoscope WD. 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 WD, 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 shall be paid to a negative trend in the results. This can indicate wear of parts of the WD, that could eventually lead to break down 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.

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. This sample shall be test for the presence of bacteria. To do this, the procedure as presented in appendix 7 can be used.

NB: 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 is not 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 WD or water supply system, it is necessary to run a routine process following the self-disinfection process and then 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 11) residual protein on the swab can be stained and using TMB (see Appendix 12), residual hemoglobin 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. Information on research and acceptance criteria, to effectively use this method, are lacking.

10.3 Microbial testing

Processes and systems are guaranteed through technical verification. Microbiological controls can be considered as additional control to this. Microbiological controls can be considered as valuable trend analysis and to a lesser degree as a critical value, since no growth from microbiological tests is no guarantee for a successful process.

10.3.1 Microbial quality of the final rinse water

Following installation of the endoscope WD 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 Willes), it is sufficient to test the microbiological quality of the water quarterly. The protocol for these tests is given in Appendix 7.
An acceptable result is not only achieved when there are no microorganisms detected in the final rinse water. The following table specified how the results of the microbiological tests shall be interpreted and which actions have to be taken, if necessary. The type of microorganism (pathogenicity) determines the interpretation and acceptability see Appendix 10.

***Tabel 4** – Acceptance criteria of Willes for a microbiological test of the final rinse water [ref 28.]*

Aerobe colonies per 100ml	Interpretation and possibile action
0	Acceptable.
1-9	Acceptable. Consistent low number of bacteria indicates that a water treatment system is under control.
10-100	Questionable. Find the cause of the problem, see Appendix 9 and 10.
>100	Unacceptable. Decommission the endoscope WD until the water quality has improved.

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 WD. 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 microbiologically tested following a specific defect of the endoscope, endoscope WD, 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 microbiologically tested by flushing the channels with sterile saline solution, the method is described in Appendix 7.

Loboratory method
See Appendix 7.

Interpretation of positive cultures
See flow chart and assessment list in Appendix 8 and 10.

10.3.3 Microbiological testing of loan endoscopes

Apart from the compatibility declaration, as described in paragraph 10.1.4, loan endoscopes can be tested microbiologically 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 microbiological 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 WD used, it is advised to ask for a declaration that the endoscope has only been used on human subjects.

10.4 Audit & Control

10.4.1 Audit of the primary process

Apart from the regular organization-focused audits (eg NIAZ), every department where scopes are cleaned and disinfected shall be audited by the DSRD, together with the department for infection prevention. These audits, as recommended by the Dutch Healthcare Inspectorate, shall focus on rooms, facilities, equipment, logs and procedures. These audits can have a general of thematic approach. An example of a general audit is included in Appendices 17 and 18. The results and any proposals for improvement are reported to the responsible manager.

10.4.2 Audit of Department of medical technology/Clinical Physics 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 WD's, 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 19. The results and possible proposals for improvement are reported to the responsible manager.

10.4.3 Audit of incident procedure

Apart from the requirement to perform yearly audit on the activities done according to general procedures related to endoscope disinfection, the Healthcare Inspectorate promotes the yearly evaluation of the effectiveness of the 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. The actions taken, findings related to handling the practice incident and the points for improvement need to be documented.

In particular, this means:
- thinking up the incident;
- analyzing the risk on equipment level/procedure/microbiological risk;
- acting on deviations, preventing the occurrence of subsequent risks;
- analyzing 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 reprocessing persons' expertise

The workers that operate the endoscope WD, 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

In cast 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 shall be documented. It shall be checked 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 en 10.1.2). It shall be checked that logs are correctly and completely filled in.

10.4.7 Audit of registration for traceability

Check if the relation between patient, medical practitioner, 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 organization 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. Is one or more aspects are not sufficient, the DSRD assesses the severity of the deviation and the DSRD shall decide which improvement measures are necessary. If the deviation could result in risks for patient safety, the DSRD can decide to (temporarily) stop the process.

When a WD it put into operation following purchase, maintenance or verification activities, the user shall be attentive to possible deviation in the functioning of the endoscope WD. 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 endoscope WD

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 het endoscope WD is safe to use, this shall be clearly marked on the endoscope WD 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 het endoscope WD is not safe to use, the endoscope WD shall be decommissioned. This shall be clearly marked on the endoscope WD using a decommissioned sticker. This sticker shall be red and include the decommissioning date. Decommissioning occurs when e.g. damage to the endoscope WD prevents it to be 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 het conclusion “not to be used”. The decommissioning has to be done in manner that prevents the endoscope WD from being used.

10.5.2 Functional release of endoscope WD

Following technical release by the department of Medical Technology /Clinical Physics , the endoscope WD 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, microbiological or functional tests performed.

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[43.] Decree sterilised medical accessories in hospitals, Article 7 paragraph 3 (1983)

[44.] Decree sterilisation companies medical accessories, Article 6 paragraph 3 (1989)

Appendix 2 – Form for transport of a damaged or leaking endoscope

Checklist for user

The exterior of the endoscope has been wiped off with alcohol

The channels have been dried
Note: If an endoscope is sent in "wet", this can lead to major damage to it.

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:
- wiped off with alcohol
- manually cleaned
- mechanically disinfected

Inventory code for the washer-disinfector

Checklist 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 to the 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

I the undersigned hereby declare 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.

The flexible endoscope was last processed for cleaning and disinfection in:
[WD brand] **Machine number 1** ☐
Machine number 2 ☐
Machine number 3 ☐
WD 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 en check of the endoscope WD
Month …… Year 20……
Endoscope WD identification number ……..

Date	Every 1st day of the week Self-disinfection	Check amount of detergent and disinfectant Daily	Check O-seals of channel connectors and separators Daily	Check channel connecting tubes Daily	Cleaning of control panel and handles Daily	Exchange of detergent container 2x autograph	Exchange of disinfectant container 2x autograph	Descaling Weekly	Cleaning of the drain + WD Weekly		Malfunctions

Appendix 5 – Release form for flexible endoscopy after maintenance

☐ Release Washer-disinfector specification: ……..

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

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

☐ Release Flexible Endoscope specification: ……..

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

☐ Microbiological validation 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 WD

Parameter	*Manufacturer specified value and tolerances*	*Measured value*	*Conforming: Yes/No/ Remarks*
I Pre-rinse			
Number of rinses			
Amount of water taken in			
Quality of the water that is taken in (see VI)			
Temperature of the water that is supplied to the WD			
The time required for the WD to heat the water to rinse temperature			
The temperature of the water during rinsing			
The duration of the rinse (the time interval after the rinse temperature is attained)			
II Cleaning			
Amount of water taken in			
Quality of the water that is taken in (see VI)			
Dosing of detergent			
The time required for the WD to heat the detergent solution to cleaning temperature			
The temperature of the detergent solution 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 cleaning temperature is attained)			
The pressure delivered by the circulation pump			
The flow of cleaning solution through the channels of a worst case endoscope as identified by the WD manufacturer or the pressure at the connection to the endoscope channels: • Suction • Biopsy • Biopsy 2 • Water • Air • Jet • CO_2 • Elevator • Balloon filling • Balloon emptying			
Rotation speed of washing arms			
III Intermediate rinse (between cleaning and disinfection)			
Number of rinses			
Amount of water taken in			
Quality of the water that is taken in (see VI)			
Temperature of the water that is supplied to the WD			
The time required for the WD to heat the water to rinse temperature			
The temperature of the water during rinsing			
The duration of the rinse (the time interval after the rinse temperature is attained)			

Parameter	*Manufacturer specified value and tolerances*	*Measured value*	*Conforming: Yes/No/ Remarks*
The pressure delivered by the circulation pump			
IV Disinfection			
Amount of water taken in			
Quality of the water that is taken in (see VI)			
Dosing of disinfectant			
The time required for the WD to heat the disinfectant solution to disinfection temperature			
The temperature of the disinfectant solution during the disinfection phase			
The temperature of the chamber walls during the disinfection phase			
The duration of the disinfection phase (the time interval after the disinfection temperature is attained)			
The pressure delivered by the circulation pump			
The flow of disinfectant solution through the channels of a worst case endoscope as identified by the WD manufacturer or the pressure at the connection to the endoscope channels: • Suction • Biopsy • Biopsy 2 • Water • Air • Jet • CO_2 • Elevator • Balloon filling • Balloon emptying			
V Post-rinse			
Number of rinses			
Amount of water taken in			
Quality of the water that is taken in (see VI)			
Temperature of the water that is supplied to the WD			
The time required for the WD to heat the water to rinse temperature			
The temperature of the water during rinsing			
The duration of the rinse (the time interval after the rinse temperature is attained)			
VI Quality of the water used in the WD			
Temperature			
Hardness			
Mineral content, other than water hardness			
Number and type of micro organisms			
Details of built in water softeners, ion exchangers, RO-membranes, etc.:			
• Maintained as required			
• Disinfected as required			
Built in filters			
• Prescribed filter type installed			
• Maintained as required			
• Disinfected as required			

Parameter	*Manufacturer specified value and tolerances*	*Measured value*	*Conforming: Yes/No/ Remarks*
Note: The specified water qualities may be different for the process phases.			
VII Self-disinfection			
Amount of water taken in			
Quality of the water that is taken in (see VI)			
Temperature of the water that is supplied to the WD			
Where applicable; dosing of disinfectant			
The time required for the WD to heat the water solution to self-disinfection temperature			
The temperature of the water solution during the self-disinfection phase			
The temperature of the chamber walls during the self-disinfection phase			
The duration of the disinfection phase (the time interval after the disinfection temperature is attained)			
The pressure delivered by the circulation pump			
VIII Purging of the channels at the end of the cycle			
Quality of the air that is used for the purging of the channels			
Air pressure			
Air temperature			
Settings of the pressure limiter (to prevent damage to the endoscope)			
Duration of the purging			
IX Leak test			
Note: The parameters of the leak test have no direct influence on the effectivity of the cleaning and disinfection of the endoscopes. However, the leak test is an important part of the cycle and the parameters are easily verified.			
Pressure (at which the test is conducted)			
Settings of the pressure limiter (to prevent damage to the endoscope)			
Setting of the pressure decline during the test that should raise an alarm.			
Maximum allowed temperature change of the endoscope during the test.			
X Monitoring, recording and fault indication systems, set limits and allowed tolerances			
Limits of the flow reduction or pressure increase (or the change of any other relevant parameter) during the channel non obstruction test, that will cause the indication of a fault.			
Limits of the flow increase or pressure reduction (or the change of any other relevant parameter) during the channel non connection test, that will cause the indication of a fault.			
The limit of the maximum pressure that may occur in the endoscope channels before a fault is indicated.			
Limits of the min/max temperature that will cause the indication of a fault.			
Limits to the min/max dose of detergent and disinfectant that will cause the indication of a fault.			
Maximum duration or maximum number of cycles for which a			

Parameter	*Manufacturer specified value and tolerances*	*Measured value*	*Conforming: Yes/No/ Remarks*
disinfectant may be reused.			
For monitoring systems that check the nature of the detergent and/or disinfectant (e.g. viscosity, refraction index, colour, pH) in order to detect whether the correct product is placed in the WD, the limits of the measured parameter, that will cause the indication of a fault. .			
The parameters that are recorded during the cycle.			
The accuracy of every system that records a parameter.			
The specifications of any safety devices for the particular WD.			

Appendix 7 – 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 ^{o}C
Incubation time	5 days
Acceptance criterion	<10 CFU/100ml. See annex 10 Checklist 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 whether this is done before doing any microbial tests.

- Carry out a normal operating cycle, especially when samples are taken after self-disinfection of the WD;
- 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 WD manufacturer[24]. 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 neutralizing agent shall be added to the sample immediately after collection. The WD manufacturer shall identify suitable neutralizing agents.

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

Procedure for the microbial study:

- Filtrate the water sample through a 0,22-0,45 µm membrane and transfer the membrane to a R_2A-agarplate[25].
  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 ºC
- 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 WD is used for the cleaning and disinfection of bronchoscopes, the test shall be repeated for *Mycobacteria* and/or *Legionellae* whenever there growth. This requires specific culture media and incubation periods[26]. The water shall be free from these species.

Acceptance criteria:

- See acceptance criteria Willes, clause 10.3.1
- See annex 9 Flowchart Culture of final rinse water
- See annex 10 Checklist positive cultures from endoscopes or WD

Endoscope channels

Materials for sampling	Remark
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 mobilize biofilm
sterile channel separator	to ensure that the correct channel is sampled
laboratory form for tests	

[25] NEN EN ISO 15883-1:2006 §6.4.2.4

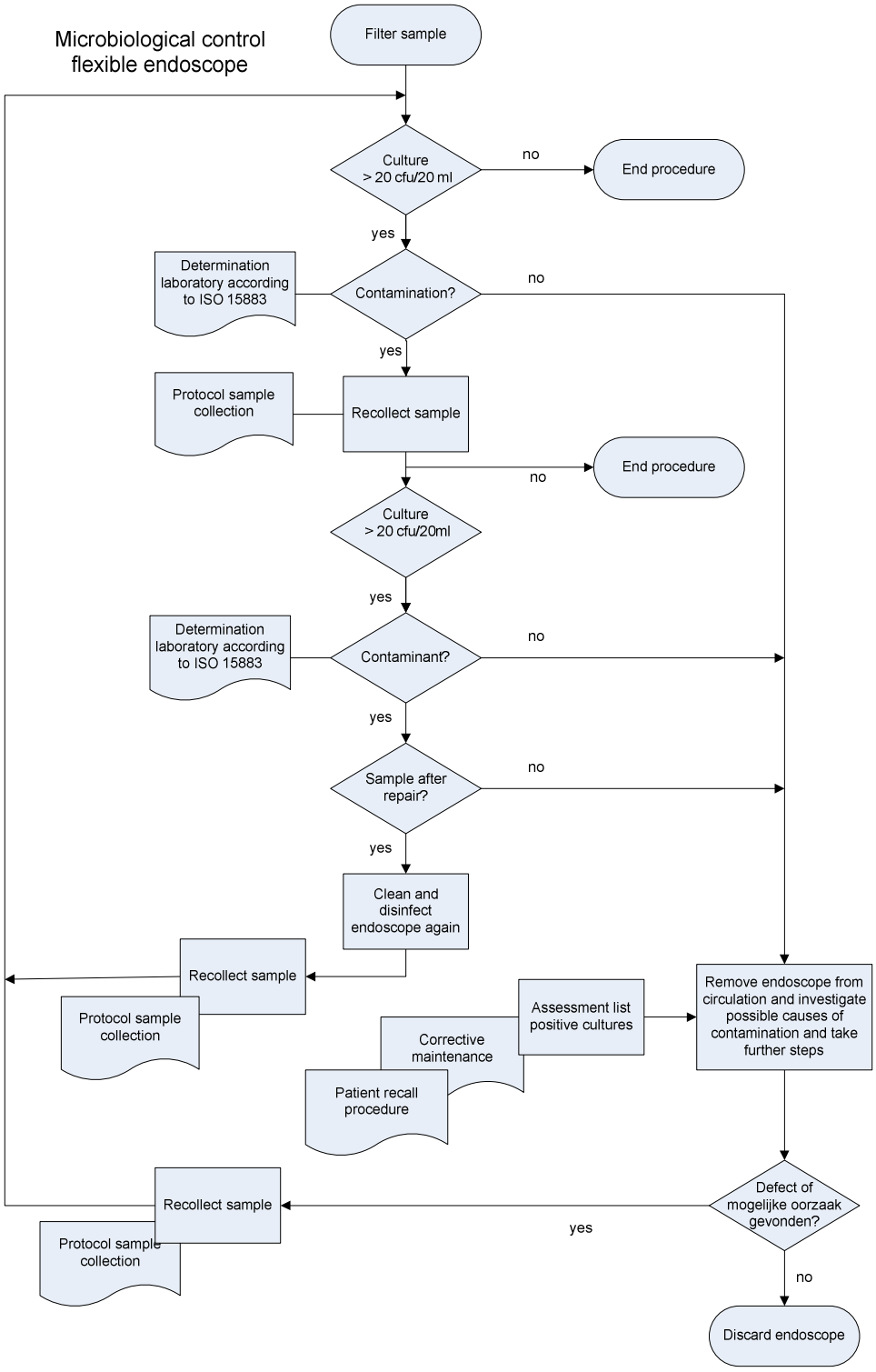
[26] NEN EN ISO 15883-4 Annex B3 en B4

Sample collection[27]

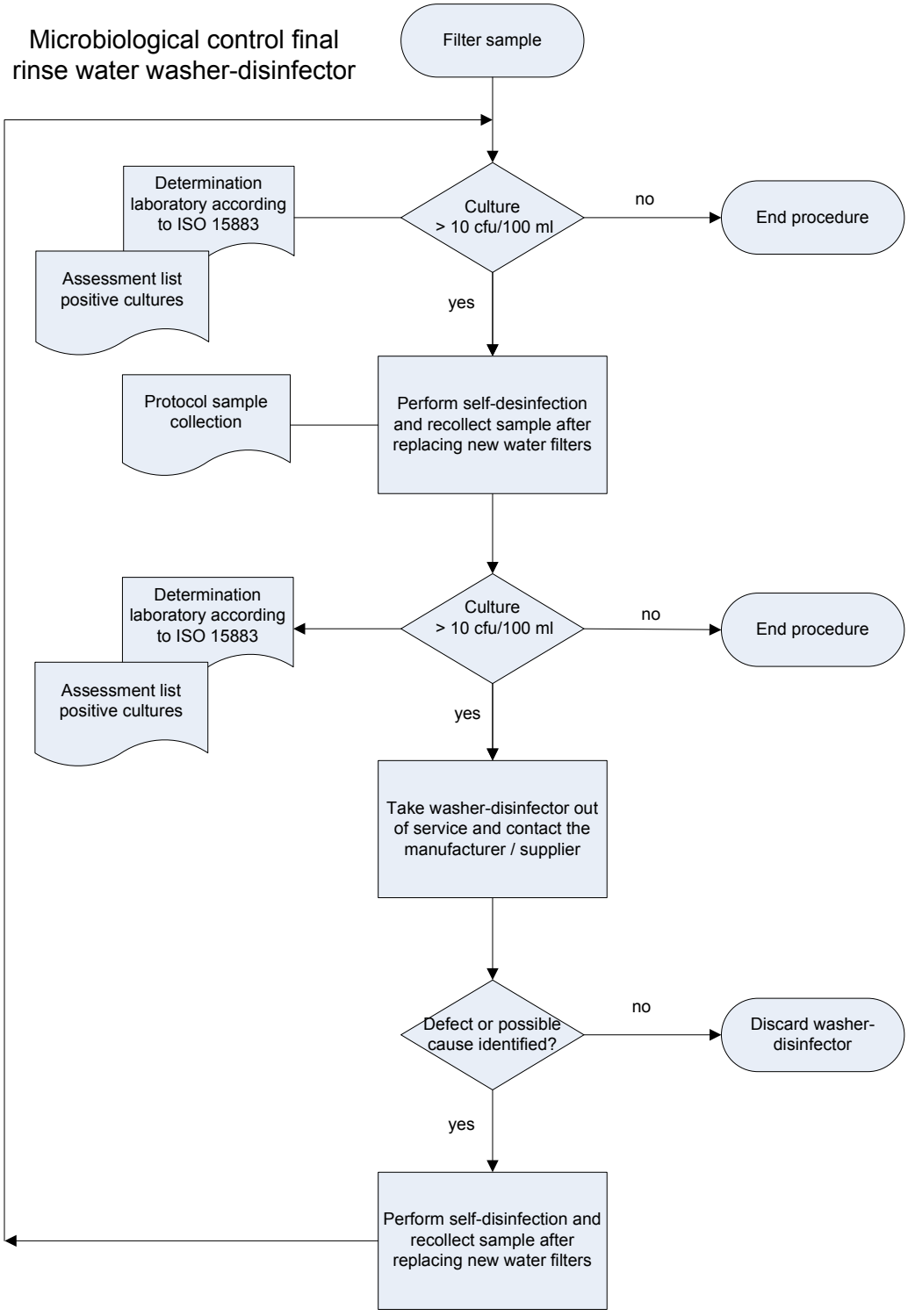
- It takes two persons to aseptically sample an endoscope
- Both persons disinfected their hands and don gloves
- After the operating cycle disconnect the endoscope from the WD (see manufacturer's instructions
- Where possible leave the endoscope in the WD, or position the endoscope on a sterile workbench
- Position a channel separator
- Ensure that all of the endoscope's channels are sampled: suction/biopsy channel, water/air channel, elevator channel (ERCP endoscope), jet channel, etc.
- Where necessary use a sterile tube to connect the syringe to the endoscope channel.
- Close/cap the biopsy port. Flush the suction channel with 20 ml sterile physiological saline solution and collect the fluid from the distal end into a sterile container. While keeping the distal end submerged in the collected fluid, suck and press the fluid strongly through the channel for three times. Use the syringe to purge the channel with air, until all liquid is expelled and collected.
- Close/cap the suction channel. 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. While keeping the distal end submerged in the collected fluid, suck and press the fluid strongly through the channel for three times. Use the syringe to purge the channel with air, until all liquid is expelled and collected.
- 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.
- Flush the air/water channels with 20 ml sterile physiological saline solution and collect the fluid from the distal end into a sterile container.
- Flush the elevator channel with 20 ml sterile physiological saline solution, if necessary in two portions of 10 ml each, and collect the fluid from the distal end into a sterile container.
- Flush any other channels with 20 ml sterile physiological saline solution and collect the fluid from the distal end into a sterile container.
- Mark and date all samples.
- Complete the lab form with all required information 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.

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

Appendix 8 – Flowchart flexible endoscope culture



Appendix 9 – Flowchart Final rinse water culture



Appendix 10 – Checklist 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 WD or defective endoscope	– complete maintenance of the WD – culture the final rinse water – re-culture the endoscope that tested positive
Pseudomonas and other non-fermenting Gram-negative rods	– insufficient rinsing – contamination of rinsing water – contamination of the WD due o mechanical or electronic malfunctions – contamination of filters – defective endoscope	– verify water supply and audit the procedures for manual and/or automated rinsing – complete maintenance of the WD and the filters – re-culture the endoscope that tested positive – culture the rinse water
	– insufficient drying of the endoscope during storage – defective endoscope	– verify the performance of the drying cabinet – re-culture the endoscope that tested positive
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-culture 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-culture the endoscope that tested positive
	– in-effective drying cycle	– audit the drying procedure and verify the ventilation in storage – re-culture the endoscope that tested positive
Atypical Mycobacteria Legionella (special culture technique)	– contamination of the – contamination of the water supply	– verify the (drinking)water supply system and audit the procedures for manual and/or automated rinsing – complete maintenance of the WD and the filters – re-culture the endoscope that tested positive – culture the rinse water

Appendix 11 - 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.[28]

Materials

- Swabs; simple cotton swabs with a plastic handle.
- Incubator set to 220 ℃
- 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 (ordernr. N4876, Sigma, Netherlands) 2 % in 70 % isopropanol (ordernr. 1.09634.1000, Merck, Netherlands) in water, used within 3 weeks after preparation.
- 2 pipets to dispense 50 µl liquid.

Method

- Select an endoscope that is clearly visibly contaminated with blood and/or other debri after use.
- 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 observation.
- 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 colorations that indicate the presence of protein was present.

[28] See A.C.P. de Bruijn, T.H.J. Orzechowski, C. Wassenaar "Validation of the ninhydrin swab test to monitor cleaning of medical instruments". Zentralsterilisation 4/2001.

Appendix 12 – Hemoglobin swab test

By using the pseudo-peroxidases activity of van hemoglobin, 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 peroxidases activity of hemoglobin 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 peroxidases 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 peroxidases (verify!);
- 1 ml pipets;
- 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 pipet or a saturated swab, to visualise blood residues in situ.

Swab method
Verify that the swab itself does not give a colour reaction by performing a negative control.
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.

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 hemoglobin 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 hemoglobin per microliter eluent, 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 13 – Release form for flexible endoscopes

Release form for flexible endoscopes

Washer-disinfector:

Date:

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

Appendix 14 – Schedule of requirements for washer-disinfector

I	**Purpose of the washer-disinfector**				
	Cleaning and disinfection of flexible endoscopes and their accessories.				
II	**Interaction with endoscopes and their accessories**				
	It must be possible to clean all types of flexible endoscope and accessories in accordance with the required procedure				
III	**Patient categories**				
	N/A				
IV	**Users**				
	Staff in CSA, inpatient or outpatient examination departments.				
		Requirement/ Demand			**Explanation**
1. Legal requirements			**Yes**	**No**	
Medical Devices Directive	***1.1***	The washer-disinfector has a CE label under the Medical Devices Directive 93/42/EC.			
EN standard	***1.2***	The washer-disinfector complies with EN ISO 15883-1 and EN ISO 15883-4			
EN 60601	***1.3***	The washer-disinfector meets the electrical safety standard (EN 60601).			
NEN-EN-IEC 61010-2-040:2005	***1.4***	The washer-disinfector meets the safety requirements for electronic equipment - Part 2-040: Special requirements for sterilisers and washer-disinfectors used to treat medical supplies.			
EN 1717	***1.5***	The connections of the washer-disinfector meet the requirements of the water supply company (EN 1717)			
WIP directives	***1.6***	The washer-disinfector complies with the WIP directive "Cleaning and disinfection of endoscopes", (www.wip.nl).			
Occupational health, safety and environment	***1.7***	The washer-disinfector complies with the occupational health and safety law (www.arbo.nl).			
2. Validation			**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 program/protocol (provide programme/protocol).			
	2.3	There is a qualification programme/protocol for the release for the process (provide programme/protocol).			
	2.4	The supplier has a list of critical process parameters (including criteria) that can/should be validated (enclose list)			
	2.5	The supplier provides training for external validators (certificate is issued).			
	2.6	Supplier indicates how the training is structured and which validators have attended it (enclose list of validators).			
	2.7	The supplier makes a dummy endoscope available for validation			
	2,8	The supplier provides documentation showiing how validation should be carried out and what form the validation should take.			
	2,9	The supplier indicates how the last rinse water from the machine can be sampled for micr			
3. Occupational health and safety and environment			**Yes**	**No**	
	3.1	Supplier indicates the water consumption (specify consumption).			
	3.2	Supplier indicates energy consumption (specify consumption).			
	3.3	The supplier/ manufacturer accepts returns of washer-disinfectors which need to be replaced			
	3.4	The substances contained in the cleaning agent and disinfectant are permitted under the disposal permit			
	3.5	The detergent and disinfectant are deliverer in an appropriate UN approved package.			
	3.6	A safety sheet for the detergent and disinfectant is present.			
	3.7	Indicate the average quantity of residual liquid in the storage tank			
	3.8	The washer-disinfector is equipped with facilities to prevent - substances from being released into the environment; - substances remaining in the user-accessible areas of the units; - substances remaining on the treated endoscopes?			
	3.9	The working height complies with occupational health standards (**state specified working height**)			
	3.10	There is an extraction system on the washer-disinfector (specify size).			
	3.11	During the entire process the noise level remains at or below 65dB (A) (provide test report).			

4. Technical requirements			Yes	No	
Technical aspects	4.1	The washer-disinfector should be suitable for all types of flexible endoscope used in the hospital (provide declaration).			
	4.2	Malfunctions or incomplete processes are indicated by both a visible and an audible signal.			
	4.3	The endoscope is monitored for leak tightness throughout the whole process.			
	4.4	The washer-disinfector is equipped with an automatic mechanism to identify blockages during the process.			
	4.5	The washer-disinfector features a continuous channel connection check for each connected channel (enter maximum number of channels that are monitored).			
	4.6	The washer-disinfector indicates in good time when preventive maintenance is required			
	4.7	It is not possible to switch or interconnect the detergent and disinfectant.			
	4.8	There is leak tray for the 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 to be used (eg RO water).			
	4.11	A"no-break" facility is provided for data storage.			
	4.12	The washer-disinfector is resistant to power failures. (Specify).			
	4.13	There is a facility to prevent water from flowing back from the water compartment into the water supply system.			
	4.14	*Can the following processes be halted independently by authorized staff?-cleaning;* *- flushing* *- disinfection;* *- discharge-disinfectant;* *- flushing microbiologically safe water;* *- production microbiologically safe water;* *- drying.*			
	4.15	The washer-disinfrector should be constructed such that the contact surface with the endoscope is minimal.			
	4,16	The machine has an outlet for water for testing.			
	4.17	The manchine has a monitor for the bacteria filter			
	4.18	The manufacturer has drawn up a filtration plan for the water supply and provides advice on installing filters.			
	4.19	The washer-disinfector can communicate with data management systems in place at the time of purchase. Indicate the forms of communication which are possible and the			
	4.20	The supplier of the washer-disinfector undertakes to provide declarations of compatibility for endoscopes to be acquired by the purchaser throughout the service life of the			
Process requirements			**Yes**	**No**	
	5.1	The washer-disinfector operates in accordance with the pass-through principle (clean/contaminated materials separated).			
	5.2	The program cannot be continued after interruption of the process.			
	5.3	The endoscope is not released if the process has not been entirely completed.			
	5.4	The process consists of at least the following phases: pre-cleaning, cleaning, flushing, disinfecting, rinsing.			
	5.5	The current phase of the process is shown on the display			
	5.6	Process parameters can be changed only by authorised staff			
6. Cleaning and disinfection			**Yes**	**No**	
	6.1	Detergent and disinfectant should be CE marked			
	6.2	The washer-disinfector is suitable for generic detergents and disinfectants.			
	6.3	State the consumption of detergents and disinfectants used for each process (process cost)			
	6.4	The product information for the machine states the temperatures used for cleaning and disinfecting.			
	6.5	A product information sheet showing usable materials, concetration, contact time and temperature is present			
	6.6	The machine has a self-disinfection procedure.			
	6.7	The washer-disinfector displays a warning if the disinfectant container is empty.			
	6.8	The washer-disinfector displays a warning if the detergent container is empty.			
	6.9	There is a check on the dosage of: -disinfectant; -detergent			
	6.10	Dosage, exposure time and temperature of the detergent and disinfectant should be established in the programs.			
	6,11	The equipment runs a rinse cycle with bacteria-free water to eliminate residues of detergent and disinfectant.			

7.	**Support/training requirements**		**Yes**	**No**	
	7.1	An English instruction manual is available.			
	7.2	English operating and loading instructions are available.			
	7.3	There is a protocol for corrective, preventive and inspective maintenance available to technicians (certificate issued).			
	7.4	The technicians are trained for both corrective and preventative maintenance and inspections.			
	7.5	A technical manual is supplied with the machine			
	7.6	The supplier has access to an English speaking technical helpdesk.			
	7.7	The supplier provides user training (certificate issued).			
	7.8	The supplier provides connection diagrams for all types of flexible endoscope used in the hospital.			
8.	**Usability requirements**		**Yes**	**No**	
	8.1	Washer-disinfector operation is ergonomic.			
	8.2	In the event of an alarm or warning, the machine gives a clear description of the problem and gives instructions for resolving it suitable for users.			
	8.3	The loading and unloading doors can be opened hygienically.			
	8.4	The machine assists users with clear on-screen instructions during operation.			
	8,5	Detergents and disinfectants can be topped up ergonomically			
9.	**Traceability and recording requirements**		**Yes**	**No**	
	9.1	Functionality is available to record data on the endoscope, load, process, date and time, patient and operator.			
	9.2	Data (eg on machine, patient, endoscope, specialist and process flow) is recorded digitally and stored locally and remotely for each disinfection cycle			
	9.3	The washer-disinfector can communicate with management systems (specify).			
	9,4	The washer-disinfector offers the option to generate management data (specify).			
10.	**Installation requirements**		**Yes**	**No**	
	10.1	Drawings and measurements of the facilities required for installation (drainage, ventilation, extraction, water) are supplied			
	10.2	Specific requirements for water quality are supplied.			
11.	**Requirements regarding maintenance**		**Yes**	**No**	
	11.1	The supplier offers maintenance contracts, .			
	11.2	The supplier provides a price list for the most commonly used parts.			
	11.3	The company accepts the Standard Service Agreement (SSO) of the FHI.			
	11.4	All required components can be supplied within 24 hours.			
	11.5	The supplier provides passwords and codes for repair and maintenance of hardware and software or mechanical components			
	11.6	A supplier's technician can attend within 24 hours.			
	11.7	A loan washer-disinfector can be made available within 2 days			
	11.8	The maximum downtime for software and hardware problems is 24 hours.			
	11.9	Software licenses should be valid for the service life of the machine.			
	11.10	Software and hardware updates and features for software and hardware updates can be provided for at least 10 year for procedural and control purposes.			

Appendix 15 - Schedule of requirements for flexible endoscopes

I	**Purpose of the flexible endoscopes.**					
	For non-invasive diagnostic and therapeutic examinations					
II	**Interaction with washer-disinfector, drying cabinet, and medical supplies.**					
	All types of flexible endoscope and accessories must be disinfected in accordance with the prescribed procedure					
III	**Patient categories**					
	Various					
IV	**Users**					
	Staff in CSA, inpatient or outpatient examination departments.					
			Requirement/ Demand			**Explanation**
1. Legal requirements				**Yes**	**No**	
	Medical Directive	***1.1***	The endoscope has a CE mark as per the Medical Devices Directive 93/42/EC.			
	NEN 10601	***1.2***	The endoscope meets the electrical safety standard (NEN 10601).			
2. Technical requirements				**Yes**	**No**	
	Technical aspects	***2.1***	The endoscope can be cleaned and disinfected automatically in all washer-disinfectors present in the hospital. **(compatibility with detergents and disinfectants).**			
		2.2	All parts are resistant to the chemicals to be used.			
		2.3	The endoscope should be designed in such a way that it can be properly cleaned, both manually and automatically, and disinfected.			
		2.4	The endoscope can communicate with the data management systems in use at the time of purchase.			
		2.5	The manual provides a list of compatible devices and accessories (for research and cleaning / disinfection).			
		2.6	The endoscope is resistant to medications, bodily fluids and agents used during the examination.			
		2.7	The endoscope can be positioned and connected in the currently used drying cabinets			
		2.8	Specifications for maximum pressure and pressure differences in the channels are given			
3. Cleaning, disinfection, and sterilisation				**Yes**	**no**	
		3.1	The temperatures for cleaning, disinfection, and sterilisation are given in the product information for the endoscope			
		3.2	The product information states to which detergents, disinfectants, and sterilisation agents the endoscope is resistant.			
		3.3	The manual describes the preliminary cleaning required as preparation for machine cleaning and disinfection.			
		3.4	Connecting equipment for leakage testers, washer-disinfectors and drying cabinets are supplied. Specify what connecting equipment			
		3.5	The endoscope is steam sterilisable (121gr.).			
		3.6	The endoscope is steam sterilisable (134gr.).			
		3.7	The endoscope is formaldehyde sterilisable.			
		3.8	The endoscope is ethylene oxide sterilisable.			
		3.9	The endoscope is plasma sterilisable.			
4. Support/training requirements				**Yes**	**no**	
		4.1	An English instruction manual is available.			
		4.2	English operating instructions are available.			
		4.3	There is a protocol for corrective and preventive maintenance and inspection available for technicians			
		4.4	Technicans are trained in corrective and preventive maintenance and inspections			

5. Usability requirements			**Yes**	**no**	
	5.1	Assessment following trial installations			
6. Traceability and recording requirements			**Yes**	**no**	
	6.1	The endoscope includes an identifier which can be read by the recording software in use at the hospital.			
7. Installation requirements			**Yes**	**no**	
	7.1	The endoscope is compatible with the processor and light source present.			
8. Maintenance requirements			**Yes**	**no**	
	8.1	The supplier offers maintenance contracts, .			
	8.2	The supplier provides a price list for the most commonly used parts.			
	8.3	The company accepts the Standard Service Agreement (SSO) of the FHI.			
	8.4	All required components can be supplied within 24 hours.			
	8.5	Defective endoscopes can be repaired within an agreed time. A loan endoscope will be available during that time.			
	8.6	Parts are available for at least 10 years.			
	8.7	A supplier's technician can attend within 24 hours.			
	8.8	Maintenance and repairs can be carried out by medical technicians (special tools can be supplied)			

Appendix 16 - Schedule of requirements for drying cabinet

I Purpose of drying cabinet

Drying and storage of flexible endoscopes and their accessories (both exterior and channels).

II Interaction with endoscopes and their accessories

All types of flexible endoscopes and accessories must be able to be dried in accordance with the prescribed procedure.

III Patient categories

Various

IV Users

Staff in CSA, inpatient or outpatient examination departments

		Requirement/ Demand			Explanation
1. Legal requirements			**yes**	**no**	
Medical Directive	1.1	The drying cabinet has a CE label under the Medical Devices Directive 93/42/EC.			
EN standard	1.2	Not yet available			
EN 60601	1.3	The drying cabinet complies with electrical safety standard (EN 60601).			
WIP guidelines	1.4	The drying cabinet complies with the WIP directive "Cleaning and disinfection of endoscopes " (www.wip.nl).			
Occupational health, safety and environment	1.5	The drying cabinet complies with the occupational health and safety law (www.arbo.nl).			
2. Validation			**yes**	**no**	
	2.1	The drying process has been validated and the validation report is available (provide copy).			
	2.2	The supplier provides training on the required validation procedure and what the validation should comprise			
	2.3	The supplier provides training to external validators (certificate awarded)			
	2.4	The supplier invidates how the training is supervised and which validators have taken it.			
	2.5	There is an installation qualification programme/protocol (provide programme/protocol).			
	2.6	There is a qualification programme/protocol for the release for the process (provide programme/protocol).			
3. Occupational health and safety and environment			**yes**	**no**	
	3.1	Supplier indicates compressed air consumption (specify consumption).			
	3.2	Supplier indicates energy consumption (specify consumption).			
	3.3	The supplier/manufacturer accepts returns of drying cabinets which need to be			
	3.4	The working height is appropriate in accordance with occupational health and safety standards **(state specified working heights).**			
	3.5	The noise level remains below 65dB(A) throughout the process (provide test report).			
4. Technical requirements			**yes**	**no**	
Technical aspects	4.1	The drying cabinet should be suitable for all types of flexible endoscope used in the hospital (provide declaration).			
	4.2	The supplier has issued a written declaration that the drying cabinet is compatible with the endoscopes in use.			
	4.3	Malfunctions or incomplete processes are indicated by both a visible and an audible signal.			
	4.4	The drying cabinet features a continuous channel connection check.			
	4.5	The drying cabinet features a continuous flow monitor for each connected channel.			
	4.6	The drying cabinet gives a signal when preventive maintenance is required.			
	4.7	All components for maintenance and repair are readily accessible.			
	4.8	A no-break facility is provided for data storage.			
	4.9	The drying cabinet is resistant to power failures (specify)			
	4.10	The drying cabinet should be constructed in such a way that the contact surface with the endoscope is minimal.			

5. Drying process			**yes**	**no**
	5.1	The process parameters (time/temperature/pressure) are shown in the product information for the drying cabinet.		
	5.2	The drying cabinet features continuous temperature monitoring.		
	5.3	Drying times must be determined by the programs.		
	5.4	The device uses an appropriate drying cycle with bacteria-free compressed air to prevent contamination of the endoscope.		
	5.5	An overpressure is maintained in the cabinet.		
6 Support/training requirements			**yes**	**no**
	6.1	An English instruction manual is available.		
	6.2	English operating and loading instructions are available.		
	6.3	A protocol for corrective and preventive maintenance and inspection is available for technicians.		
	6.4	The technicians are trained in both corrective and preventive maintenance.		
	6.5	A technical manual is supplied		
	6.6	The supplier has access to an English speaking technical helpdesk.		
	6.7	The supplier provides user training		
7 Usability requirements			**yes**	**no**
	7.1	The drying cabinet is easy to use (describe)		
	7.2	In the event of an alarm or warning, the machine gives a clear description of the problem and gives instructions for resolving it suitable for users.		
	7.3	The loading and unloading doors can be opened hygienically.		
	7.4	The drying cabinet assists users with clear on-screen instructions during operation.		
	7.5	The drying cabinet has a maximum storage time setting and an alarm is triggered if the storage time is exceeded.		
8 Traceability and recording requirements			**yes**	**no**
	8.1	Functionality is available to record data on the endoscope, load, process, date and time, patient and operator.		
	8.2	Data (eg on cabinet, patient, endoscope, specialist and process flow) is recorded digitally and stored locally and remotely for each disinfection cycle		
	8.3	The drying cabinet can communicate with the management system.		
9 Installation requirements			**yes**	**no**
	9.1	Drawings and measurements of the facilities required for installation (drainage, ventilation, extraction, water) are supplied		
	9.2	Specific requirements for water quality are supplied		
10 Maintenance requirements			**yes**	**no**
	10.1	The supplier offers maintenance contracts, .		
	10.2	The company accepts the Standard Service Agreement (SSO) of the FHI.		
	10.3	All required components can be supplied within 24 hours.		
	10.4	The supplier provides passwords and codes for repair and maintenance of hardware and software or mechanical components		
	10.5	A supplier's technician can attend within 24 hours.		
	10.6	A loan drying cabinet can be made available within 2 days		
	10.7	The maximum downtime for software and hardware problems is 24 hours.		
	10.8	Software licenses should be valid for the service life of the machine.		
	10.9	Software and hardware updates and features for software and hardware updates can be provided for at least 10 year for procedural and control purposes.		

Appendix 17 – Endoscope Cleaning & Disinfection Audit Form

Questionnaire on behalf of endoscope cleaning & disinfection dept.

Department/location:
Audited:
Auditor (s):
Date:

Definition for prioritisation 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 which should be tackled directly.
2. An occurrence which has policy-level impact on the effectiveness of endoscope cleaning and disinfection processes, to be carried out within three months.
3. Lowest priority: should be implemented within six months.

n.a. = not assessed

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

1	Policy rules for cleaning and disinfecting endoscopes	yes	no	partly	notes / comments / advice
1.1	Endoscopes and accessories used in non-sterile body cavities are cleaned and disinfected by machine				
1.2	Endoscopes and accessories used in sterile body cavities are sterilised				
1.3	Used forceps, snares, etc. are sterilised or disposables are used				
	Work follows the correct principles:				
1.4	leak test				
1.5	pre-cleaning				
	process steps in disinfector:				
1.6	leak test				
1.7	cleaning				
	rinsing (if required)				
1.8	disinfection				
1.9	final rinse				
1.10	drying				

	recommendation / point for improvement	priority
1		
2		

2	Execution of manual endoscope cleaning	yes	no	partly	notes / comments / advice
2.1	The cleaning procedure is set out in the protocol				Date protocol:
2.2	The protocol is accessible near the sink and readily understood by anyone.				
2.3	Non-sterile gloves are worn during manual cleaning.				
2.4	A solution of a compatible cleaning agent in lukewarm water is used for cleaning.				used product:
2.5	The concentration of the solution is as specified in the instructions				used concentration:
2.6	This solution is refreshed every shift or in the event that contamination is observed				
2.7	A leak test is carried out before immersion.				
2.8	The endoscope is placed on the worktop immediately after the examination.				
2.9	The exterior of the endoscope is wiped off using a gauze or washcloth.				
2.10	The suction head is disassembled, sprayed with water, brushed, soaked in cleaning solution and then rinsed with water				
2.11	Ring, caps and any other removable parts (non-disposable) are brushed, soaked in cleaning solution and then rinsed with water.				

	recommendation / point for improvement	priority
1		
2		

3	Ultrasonic Bath	yes	no	partly	notes / comments / advice

NOT APPLICABLE

4	Loading the washer-disinfector	yes	no	partly	notes / comments / advice
4.1	Loading instructions are present				disinfector type:
4.2	They are kept close to the machine and readily accessible to anyone.				date of instructions:
	The loading instructions include the following steps:				
4.3	Ring, caps and any other removable parts are put into a basket in the machine.				
4.4	The endoscope is placed into the machine in such a way that the entire distal section is "free" (e.g. disappears into the aperture of				
4.5	There is a system to prevent connection errors.				
4.6	The loading instructions describe which tubes should be connected to which channels				

	recommendation / point for improvement	priority
1		
2		

5	Operating the machine	yes	no	partly	notes / comments / advice
5.1	The general way in which the machine operates, including the technical aspects, is clear to staff.				
5.2	Operating instructions are located close to the machine and readily accessible to everyone				date regulation:
5.3	A written procedure has been drawn up showing the steps to take in the event of malfunctions; kept within reach and				date procedure:
5.4	The process parameters and process programs can only be altered by authorised staff				authorised persons
5.5	The endoscope compartment is locked during the process. If a process is interrupted, that process cannot then be restarted.				
5.6	The washer has an automatic leak tester.				
5.7	The washer monitors the pressure in the channels to identify obstructions				
5.8	The washer is disinfected weekly and any time that it is to be out of service for more than 24 hours using a self-disinfection				
5.9	The washer is frequently descaled				
5.10	Descaling is logged				last date recorded:
5.11	The washer has a system for preventing recontamination during the final rinse (bacteria-free water).				means:
5.12	The washer has a process counter to determine periodic maintenance requirements.				
5.13	The washer has a facility to allow patient tracking data to be entered.				
5.14	The washer undergoes preventive maintenance by an external or internal technical expert once a year.				Carried out by:
5.15	Checks and release after regular major maintenance and major repairs are recorded in a protocol for validation and release of endoscope washers.				Protocol date: Validated by: Released by:

	recommendation / point for improvement	priority
1		
2		

6	Cleaning and disinfecting the endoscope washer	yes	no	partly	notes / comments / advice
6.1	The washer has a system for monitoring the dosage of detergent and disinfectant.				which system:
6.2	The washer is fitted with connectors which prevent detergent and disinfectant from being wrongly attached.				
6.3	Detergent and disinfectant are kept in a locked cabinet using a FIFO principle				storage quantity:
6.4	The method for replacing the detergent and disinfectant containers is described in a protocol.				
6.5	This protocol is kept close to the machine and is readily accessible to everyone.				
6.6	The containers of detergent and disinfectant are replaced in accordance with this protocol.				

	recommendation / point for improvement	priority
1		
2		

7	Drying an endoscope in a drying cabinet	yes	no	partly	notes / comments / advice
7.1	The procedure for drying the endoscope is described in a protocol.				protocol date:
7.2	The protocol is kept close to the drying cabinet and readily accessible to everyone.				
7.3	Endoscopes which are not used within 4 hours of disinfection are dried in the drying cabinet for at least 30 minutes.				set drying time:
7.4	Endoscopes which are not used for a period of over 4 hours without being dried are disinfected again before use.				
7.5	There is written guidance on how long endoscopes may be hung in the drying cabinet.				applied storage life
7.6	The drying cabinet is given general cleaning once a month. The cleaning schedule is present and signed.				
7.7	A protocol covers periodic maintenance and filter change frequency.				protocol date: frequency of replacement:

	recommendation / point for improvement	priority
1		
2		

8	Transporting endoscopes	yes	no	partly	notes / comments / advice
8.1	The procedure for transporting contaminated and clean endoscopes is described in a protocol				protocol date:
8.2	The protocol is kept close to the drying cabinet and readily accessible to everyone.				
8.3	Endoscopes are only transported from the disinfection area to adjoining examination or storage areas				
	If the answer to 8.3 is not "yes", answer the remaining questions.				specify transport:
8.4	Endoscopes are transported using an enclosed transport system				system:
8.5	When endoscopes are transported, it is clear whether the endoscope is clean or contaminated.				
8.6	For clean endoscopes, the transport system is sealed.				
8.7	The transport system is cleaned and disinfected after contaminated endoscopes have been carried.				Method:

	recommendation / point for improvement	priority
1		
2		

9	Registration of data	yes	no	partly	notes / comments / advice
	A logbook is kept for each disinfector (whether automated or not) in which the following items are recorded.				system:
9.1	-Date				
9.2	-Patient number				
9.3	-Number of the endoscope				
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 and disinfectant, the following information is recorded:				system:
9.7	-Date of replacement				
9.8	Batch number detergent / disinfectant				
9.9	Machine number				
9.10	Signature of the staff member who replaced the container				
9.11	Signature for check by colleague				

	recommendation / point for improvement	priority
1		
2		

10	Hygiene and prevention of infection	yes	no	partly	notes / comments / advice
	Hygienic endoscopy working methods				
10.1	Clean and contaminated materials follow separate paths				
10.2	No rings, watches, or bracelets worn				
10.3	After every endoscopy the endoscopist washes or disinfects his/her hands before touching anything else.				
10.4	After every endoscopy the assistant washes or disinfects his/her hands before touching anything else.				
10.5	After every endoscopy hands are washed and disinfected after taking off the gloves.				
	disinfector hygiene				
10.6	The top of the lid, its seat, and the control panel are routinely cleaned and then disinfected				disinfectant: checklist present:
	The endoscopist wears:				
10.7	Gloves				
10.8	Protective jacket				
10.9	Mask (if pulmonary tuberculosis is suspected)				
10.10	Protective glasses or splash goggles				
	The assistant wears:				
10.11	Gloves				
10.12	Protective jacket				
10.13	Mask (if pulmonary tuberculosis is suspected)				
10.14	Protective glasses or splash goggles				
	Facilities				
10.15	Adequate hand washing facilities available.				
10.16	The tap can be operated with elbows or feet.				
10.17	Alcohol dispenser available.				
10.18	Soap dispenser available				
10.19	Towel dispensers 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	partly	notes / comments / advice
11.1	*Which staff members carry out the disinfection?*				function:
11.2	At least vocational secondary level (medical nurse)				
	Employees have specialist training?				
11.3	Complete settling-in programme				
11.4	Training from disinfector supplier				
11.5	Training from endoscope supplier				
11.6	Endoscopy training				More information
	Employees have frequent 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	partly	notes / comments / advice
12.1	Protocols are updated at predetermined regular intervals				
12.2	It is clear who is responsible for authorisation				
	The machine is validated at predetermined regular intervals				external/ internal: who:
12.3	technical				frequency:
12.4	functional validation				frequency:
12.5	microbiological				frequency:
12.6	use (audit)				frequency:
	The endoscopes are validated at predetermined regular intervals				external/ internal: who:
12.7	technical				frequency:
12.8	functional validation				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	partly	notes / comments / advice
13.1	There is a separate area for cleaning and disinfecting endoscopes				
13.2	The work surface is large enough for spatial separation of clean and contaminated endoscopes				
13.3	Is there adequate technical provision for occupational health and safety: splash screens, air treatment, extraction, etc.				ventilation / extraction: splash screen:
13.4	Is there enough working space for the preliminary cleaning of contaminated endoscopes and assembly of clean endoscopes				enlarged sink: separate worktops:
13.5	Is there a separate administrative workplace				
13.6	Is there a separate area for drying and storing endoscopes (with pass-through system where appropriate)				
13.7	Floors, walls, edges and ceiling are finished to building standards for healthcare institutions (smooth, shock-resistant, resistant to chemicals, etc.)				

	recommendation / point for improvement	priority
1		
2		

Appendix 18 – Endoscopy Department Audit Form

Checklist for use in endoscopy departments

Department:
Audited:
Date:
Auditors:

Definition for prioritisation 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 which should be tackled directly.
2. An occurrence which has policy-level impact on the effectiveness of endoscope cleaning and disinfection processes, to be carried out within three months.
3. Lowest priority: should be implemented within six months.

n.a. = not assessed

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

1	Endoscope cleaning and disinfection policy	yes	no	partly	notes / comments / advice
1.1	Staff are familiar with the endoscope management plan				
1.2	Endoscope policy is established at departmental level and known to the staff (protocols, operating instructions)				
1.3	Endoscopes are disinfected mechanically				
1.4	All equipment (used in sterile body cavities) is sterilised				
1.5	It is clear where 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 set out in writing				
1.8	There is a separate routing for articles which have to be cleaned and disinfected via the CSA or CSD				
1.9	Are the numbers and assortment of endoscopes adequate for existing CSD and transport procedures?				
1.1	Is equipment cleaned (or disinfected) in the department				

	recommendation / point for improvement	priority
1		
2		

2	Handling flexible endoscopes	yes	no	partly	notes / comments / advice
2.1	Disinfected flexible endoscopes are handled with disinfected hands				
2.2	Endoscope is used immediately in prepared room				
2.3	Attention is paid to what is happening with the tip				

	recommendation / point for improvement	priority
1		
2		

3	Preliminary cleaning of endoscopes by hand	yes	no	partly	notes / comments / advice
3.1	The procedure for preliminary cleaning is set out in a protocol: "returning soiled endoscope to CSD"				
3.2	The protocol is present and easily accessible to everybody.				
3.3	Endoscopes are rinsed through/aspirated by the using department and taken elsewhere for the most serious decontamination work				

	recommendation / point for improvement	priority
1		
2		

4	Transport/Logistics	yes	no	partly	notes / comments / advice
4.1	Are transport containers 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: What is the longest time that a wet endoscope remains in a container/ is en route between CSD and place of use?				
4.6	Transport containers with disinfected endoscopes: are supplied at a fixed location. It is ensured that they are not left unsupervised. In locked cabinet/space.				
4.7	Transport containers with soiled endoscopes: Is it ensured that they are not left unsupervised? In locked cabinet/space.				
4.8	Cabinets and carts for endoscope storage have a clearly visible separation between clean and dirty				
4.9	The cabinets appear to be clean				
4.1	Endoscopes are used on a FIFO basis				
4.11	Endoscopes remain in storage until used (in locked container or in drying cabinet)				
4.12	Is it clear who needs to be approached if transport does not run as it should?				

	recommendation / point for improvement	priority
1		
2		

5	Drying and storing endoscopes in drying cabinet	yes	no	partly	notes / comments / advice
5.1	The procedure for drying an endoscope is described in a protocol.				
5.2	The protocol is easily accessible to everybody.				
5.3	Endoscopes which are not used within four hours of disinfection are dried for at least 2 hours in the drying cabinet*.				
5.4	Endoscopes which are not used for longer than four hours without drying are disinfected again before use.				
5.5	It is clear how long endoscopes can be left in the drying cabinet.				
5.6	The bottom of the drying cabinet (drip tray) is cleaned daily and disinfected in accordance with protocol.				
5.7	The drying cabinet is routinely cleaned and disinfected once a month. Cleaning schedule is present and signed.				
5.8	Protocol for cleaning and disinfection for the drying cabinet is present and is being followed				
5.9	How is the endoscope operated? With disinfected hands?				
5.1	A logbook is kept for each drying cabinet.				
** 2 hours or 30 minutes, depending on drying cabinet*					

	recommendation / point for improvement	priority
1		
2		

6	Record keeping	yes	no	partly	notes / comments / advice
6.1	Use is made of an automatic track and trace system for both the cleaning, disinfection and drying process, and for the linking of patient data with the endoscope used				
6.2	Use: overruling does not occur. Explain how messages are handled				

	recommendation / point for improvement	priority
1		
2		

7	Hygiene and prevention of infection	yes	no	partly	notes / comments / advice
7.1	Staff are aware of the way they operate (as regards hand disinfection, operating (disinfected) endoscopes, etc.)				
7.2	Separate routings are maintained for clean and dirty				
7.3	Work is carried out aseptically				
7.4	Clothing instuctions are complied with				
7.5	No rings, wrist watches or armbands are worn				
7.6	Hands are disinfected after removing gloves.				
7.7	the endoscope is only hung on the hook in a clean state				
7.8	is the equipment and furniture cleaned and where necessary disinfected between operations.				
Facilities in surgery/consulting room?					
7.9	Adequate hand washing facilities present.				
7.1	The tap can be operated with elbow or foot.				
7.11	Hand alcohol dispenser present.				
7.12	Soap dispenser present.				
7.13	Hand towel dispenser with paper towels present.				
7.14	Foot-operated waste bin present				
7.15	Glove dispensers with gloves present (various sizes)				

	recommendation / point for improvement	priority
1		
2		

8	Staff expertise	yes	no	partly	notes / comments / advice
8.1	Are staff trained in dealing with flexible endoscopes?				
8.2	Do staff have free access to protocols, manuals, procedures, etc.				
8.3	Staff receive further and continuing training				
8.4	Are staff given individual assessments?				

	recommendation / point for improvement	priority
1		
2		

9	Quality assurance	yes	no	partly	notes / comments / advice
9.1	Staff knowledge of protocols is up to date.				
9.2	The procedure for handing a defective endoscope should be described in a protocol				
9.3	The protocol is easily accessible to everybody.				
9.4	Agreements have been reached on duties and responsibilities concerning maintenance of equipment, resources and materials.				
9.5	Agreements have been reached on procedures for requesting maintenance (corrective/preventive)				
9.6	Is the incident procedure known?				
9.7	Agreements have been reached on the cleaning of endoscopes outside regular working hours				
9.8	Is it known how a request should be made to hire/loan an endoscope?				

	recommendation / point for improvement	priority
1		
2		

Appendix 19 - Endoscope technology & maintenance Audit Form

Department / Location:	
Audited:	
Auditor (s):	
Date:	

Type of disinfector(s):

Type of endoscopes:

Definition for prioritisation 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 which should be tackled directly.
2. An occurrence which has policy-level impact on the effectiveness of endoscope cleaning and disinfection processes, to be carried out within three months.
3. Lowest priority: should be implemented within six months.

n.a. = not assessed

answer the questions by entering 'yes', 'no' or 'partly' in the appropriate column

T.1	Technical verification	yes	no	partly	notes / comments / advice
1.1	Washer-disinfectors are technically checked:				
1.2.1	* before entry into service/on acquisition				
1.2.2	* after repairs				
1.2.3	* after maintenance				
1.2.4	* If the washer-disinfector is used for a new type of endoscope?				
1.3	There is a release procedure before a washer-disinfector is taken into service				
1.4	There is an up-to-date technical logbook available for each washer-disinfector				
1.5	There is a procedure for planning and executing preventive maintenance on the washer-disinfector				

	recommendation / point for improvement	priority
1		
2		

T.2	Using the washer-disinfector	yes	no	partly	notes / comments / advice
2.1	The process parameters and process programs can only be changed by appropriately authorised persons				
2.2	The endoscope compartment is locked during the process. If a process is interrupted that process cannot then be restarted.				
2.3	The washer-disinfector monitors the pressure in the channels in order to detect obstructions				
2.4	The washer-disinfector is designed to prevent recontamination during the final rinse (bacteria-free water)				
2.5	The washer-disinfector has a process counter to determine periodic maintenance requirements				
2.6	The washer-disinfector has a facility for entering data for patient tracking				
2.7	The washer-disinfector is preventively maintained by an external or internal technical specialist at least once a year				
2.8	The procedure for checking and releasing the machine after routine major maintenance and major repairs is set out in a validation and release protocol for washer-disinfectors				
2.9	The washer-disinfector has a system for checking dosages of detergent and disinfectant				
2.10	The washer-disinfector uses connectors which prevent switching of detergent and disinfectant.				

	recommendation / point for improvement	priority
1		
2		

T.3	User maintenance of the washer-disinfector	yes	no	partly	notes / comments / advice
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 washer-disinfector monitors the pressure in the channels in order to detect obstructions				
3.5	The UV unit is maintained at predetermined intervals				
3.6	The filters in the rinsing space are cleaned frequently				
3.7	The filters in the water supply are regularly checked				
3.8	The nozzles on the spray arm are regularly checked to ensure they are not blocked				
3.9	The sealing rings of the leak detector are regularly checked and replaced if necessary				
3.10	The nozzles and tubes of the inset trolley are examined and cleaned frequently				

	recommendation / point for improvement	priority
1		
2		

T.4	Other	yes	no	partly	notes / comments / advice
4.1	The drying cabinets are maintained regularly				
4.2	The drying cabinet filters are replaced regularly				
4.3	The drying cabinets use filtered dust-free air				
4.4	The drying cabinets have a preset minimum drying time				
4.5	The extraction channel from the drying cabinet vents outside				
4.6	An up-to-date technical logbook is present for each drying cabinet				
4.7	This technical logbook is up to date and contains useful data				

	recommendation / point for improvement	priority
1		
2		

T.5	Ultrasound				

T.6	Endoscopes	yes	no	partly	notes / comments / advice
6.1	Technical checks on endoscopes are carried out at the following times				
6.1.1	* on acquisition				
6.1.2	* after repairs (external)				
6.1.3	* after maintenance (annual major)				
6.2	There is a release procedure before an endoscope is put into service?				
6.3	An up to date technical logbook is present for each endoscope				
6.4	The endoscope has a unique code for automatic tracking and tracing				
6.5	Preventive maintenance is performed on the endoscope by an internal or external technical specialist at least twice a year				

	recommendation / point for improvement	priority
1		
2		

T.7	Quality assurance	yes	no	partly	notes / comments / advice
7.1	Protocols are updated regularly at predetrermined intervals				
7.2	It is clear who is responsible for authorisations				
7.3	Staff are familiar with the protocols. They are signed for.				
7.4	The procedure for dealing with a defective endoscope is described in a protocol				
7.5	The protocol is familiar to MT staff.				
7.6	Agreements have been reached on duties and responsibilities for maintenance of equipment, resources and materials.				
7.7	This is set out in a protocol.				
7.8	Agreements have been reached on the procedure for requesting maintenance (corrective/preventive)				
7.9	This is set out in a protocol.				
7.10	Contacts concerning defective equipment/endoscopes are always made via AT/MT - in other words, there is no direct contact between CSD staff and the company				
7.11	There are no omissions in the existing procedures/no additional procedures are required				

	recommendation / point for improvement	priority
1		
2		

T8	Hygiene	yes	no	partly	notes / comments / advice
8.1	MT staff know how to proceed with a contaminated endoscope				
8.2	This is set out in a protocol				
8.3	It is clear when an endoscope is contaminated				
8.4	A transport case is available to transport a contaminated endoscope				

	recommendation / point for improvement	priority
1		
2		

Appendix 20 – Response form SFERD handbook 3.1, 2014

Feedback Professional Standard Handbook Flexible Endoscopes Cleaning and Disinfection:

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

Date:

Contributor:

Institution:

E-mail:

You can send your response to the secretary of the SFERD:
J.vbergenhenegouw@hagaziekenhuis.nl

The translation of this standard handbook was made possible through:

Stichting Trainingen Infectie Preventie

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