Superior
Health Council

RECOMMENDATIONS FOR THE PREVENTION OF INFECTIONS AND MANAGEMENT OF HEAT-SENSITIVE ENDOCAVITARY MEDICAL DEVICES AND ENDOSCOPES:

UPDATE AND EXTENSION OF THE PREVIOUS RECOMMENDATIONS (SHC 8355 - 2010)

MAY 2019
SHC № 9446 (VERSION ADAPTED FROM OCTOBER 2020)

.be

Federal Public Service Health, Food Chain Safety and Environment

Superior Health Council
Place Victor Horta 40 bte 10
B-1060 Bruxelles

Tel.: 02/524 97 97
E-mail: info.hgr-css@health.belgium.be

Please cite this document as follows:
Superior Health Council. Recommendations for the prevention of infections and management of heat-sensitive endocavitary medical devices and endoscopes: Update and extension of the previous recommendations (SHC 8355 - 2010). Brussels: SHC; 2019. Report 9446

Public advisory reports as well as booklets may be consulted in full on the Superior Health Council website:
www.css-hgr.be

Superior Health Council

PUBLICATION OF THE SUPERIOR HEALTH COUNCIL No. 9446

Recommendations for the prevention of infections and management of heat-sensitive endocavitary medical devices and endoscopes: Update and extension of the previous recommendations (SHC 8355 - 2010)

In this scientific advisory report, which offers guidance to the Belgian healthcare facilities and to public health policy-makers, the Superior Health Council of Belgium provides specific recommendations on the prevention, control and management of infections when using heat-sensitive endoscopes and medical devices.

This version was validated by the Board on
May 2019[1]
[version adapted from October 2020]

SUMMARY

These days, most rigid endoscopes are heat-resistant and undergo a complete autoclaving cycle (SHC 9256, 2017), unlike flexible endoscopes which are heat-sensitive. The latter are used in daily routine practice for several purposes: diagnostic, therapeutic and surgical procedures. Given the growing sophistication of these medical devices (MD) in recent years and the emergence of many epidemic phenomena related to certain endoscopes, it appeared essential for the Superior Health Council of Belgium (SHC) to review the previous recommendations no. 8355 from 2010 on preventing the transmission of infections when using heat-sensitive flexible endoscopic devices.

In this context, the SHC decided to broaden the focus to include heat-sensitive endocavitary MD and probes. Therefore, this document not only concerns heat-sensitive endoscopes with a channel, but also a whole series of devices without a channel (mainly including rigid and flexible ultrasound probes).

These recommendations, which describe the overall management of these heat-sensitive endocavitary MD, aim to optimise the safety of healthcare in medical practice, both within and outside healthcare facilities and, ultimately, to move towards a zero risk of infection for both patients and personnel.

Consistent with this objective, the first section focuses on the practical organisational aspects, i.e. the different types of requirements which healthcare providers must fulfil, the regulatory framework - more specifically, responsibilities - together with the updated information on the criticality of the device and, consequently, the required level of disinfection. Indeed, these

[1] The Council reserves the right to make minor typographical amendments to this document at any time. On the other hand, amendments that alter its content are automatically included in an erratum. In this case, a new version of the advisory report is issued.

endocavitary MD are perceived as semi-critical, as defined by the Spaulding classification. They should therefore undergo high-level disinfection.

As regards heat-sensitive endoscopes with a channel, the different steps for release of the endoscope are described in this document, namely: initial cleaning (by the user in the endoscopy room), transport, preparation of manual pre-cleaning, leak test, implementation of manual pre-cleaning, mechanical cleaning and disinfection and, finally, drying and storage of the device. In contrast to its advisory report no. 8355 (2010), the SHC no longer supports manual disinfection when the endoscope washer-disinfector is defective. Lastly, special attention has been given to managing specific accessories (cleaning/disinfection/single use).

The SHC also recommends high-level disinfection for MD without a channel, whether or not a protective sheath is used. User training of a sheath is essential is used. High-level disinfection techniques include automated systems, soaking and wipes. Each of these aspects is described in recommendations. The crucial principles concerning the organisation of the (re)processing procedure, transport and storage are reiterated.

In a chapter specifically dedicated to products used during cleaning and disinfection of heat-sensitive endocavitary MD with or without channel, guidelines have been defined for users with regard to selecting detergent-disinfectant products according to the situation encountered, as well as with regard to the biofilm issue.

This document also summarises key processes relating to quality monitoring and control tests. This section, which is of paramount importance for ensuring the safety of patients and personnel, has also been extensively revised. It includes process validation, which is essential in order to guarantee that a MD complies with quality requirements, but also the requirements and prerequisites related to indicators associated with the structure, process and results. These recommendations are also intended to be practical, by proposing examples of critical points which would be worth auditing. This part ends with recommendations on the procedure to be followed for conducting an epidemiological survey (isolated audit, traceability, etc.).

Lastly, the SHC recommends that each healthcare facility uses these recommendations as a basis for drawing up its own written procedures, which should be approved by the Hospital Hygiene Committee. A document relating to Good Practice guidelines should also be available in private practice.

The SHC would like to draw the competent authorities' attention to the fact that audits should be organised in healthcare facilities and in private practice.

CONTENTS

1. INTRODUCTION AND SCOPE OF THE RECOMMENDATIONS

1.1 Introduction

Endoscopy is a routine technique used to visualise the airways, heart, gastrointestinal system and urinary tract, etc. Endoscopy is not only used for diagnostic purposes. An increasing number of therapeutic or, indeed, surgical procedures are performed using endocavitary medical devices (MD)[2]. These devices are also used in the context of the recent move towards NOTES procedures (Natural Orifice Transluminal Endoscopic Surgery) which now enable conventional surgical procedures to be performed through the natural orifices.

Like all other MD in contact with patients, endoscopes should be clean, disinfected and, where appropriate, sterile. Heat-resistant endoscopes undergo cleaning, disinfection and a steam-sterilisation cycle (SHC 9256, 2017). However, heat-sensitive endocavitary MD, which cannot withstand temperatures above 60 °C, cannot undergo this type of sterilisation. Yet there are validated cold sterilisation processes available for heat-sensitive endocavitary MD which need to be sterilised (for example: UV, hydrogen peroxide).

Due to the nature of the technique, this type of MD is in constant contact with mucous membranes and biological fluids, including blood. Hence, there is a risk of transmission of infections. Single-use equipment should therefore be used and/or a sufficiently large collection of endocavitary MD and ancillary equipment should be available to ensure that stringent cleaning, disinfection and sterilisation processes are correctly followed.

The decontamination sequence for heat-sensitive endocavitary MD starts with mechanical pre-cleaning, followed by cleaning and, lastly, high-level disinfection. These different phases should be performed using adequate and effective products. Drying and storage are also key steps in the management of these MD.

These reprocessing recommendations, which describe the overall management of heat-sensitive endocavitary MD, aim to optimise quality assurance in medical practice and, ultimately, to move towards a zero risk of infection for both patients and personnel. Emphasis is also placed on process traceability to patient level, and on the type and frequency of the control tests to be set in place.

Other process methods or innovative techniques for the management of MD are authorised, provided these are implemented according to validated methods and prove to be equivalent in terms of quality.

These recommendations should be applied to all medical practices using heat-sensitive endocavitary MD, whether within or outside healthcare facilities. These recommendations can only be implemented if each stakeholder, at their own level of responsibility and with the necessary skills, is fully committed to the quality process.

This document should be adapted to scientific and technical progress in the short and medium term.

[2] Definition section 1.2.

1.2 Scope of the recommendations

These recommendations cover the management of heat-sensitive endocavitary MD, i.e.:

- heat-sensitive endoscopes **with a channel**
- heat-sensitive endocavitary MD **without a channel**
    - rigid ultrasound probes;
    - flexible ultrasound probes;
    - endoscopes including ultrasound endoscopes.

The term “endocavitary” in these recommendations indicates MD which enter the body via the natural orifices. MD used, for example, in the context of laparoscopy or thoracoscopy are excluded from these recommendations.

The management of heat-resistant MD (including heat-resistant endoscopes) is not covered in this document, but is described in the SHC guidelines "Good practices for the sterilisation of medical devices" (SHC 9256, 2017). This is also the case for certain heat-sensitive endoscopes which are required to be sterile, such as ureteroscopes. These devices undergo hydrogen peroxide sterilisation. Given the fact that they are sterilised, these devices do not fall within the scope of these recommendations.

Table 1: Risk and recommended reprocessing by type of endocavitary MD

Instrument	Access route	Site explored	Risk*	Recommended reprocessing	Section
Gastroenterology					
Gastroscope (upper gastrointestinal endoscopy): instrument with a single or double channel	Colonized	Colonized	Moderate	High-level disinfection	4
Colonoscope (lower gastrointestinal endoscopy): instrument with a single or double channel	Colonized	Colonized	Moderate	High-level disinfection	4
Enteroscope: instrument with a single or double channel	Colonized	Colonized	Moderate	High-level disinfection	4
Duodenoscope: instrument with a single channel and elevator	Colonized	Colonized	High	High-level disinfection	4
Choledochoscope: instrument with a single channel	Colonized	Colonized	High	High-level disinfection	4
Radial gastroabdominal ultrasound endoscope (EUS) instrument with a channel	Colonized	Colonized	High	High-level disinfection	4
Radial gastroabdominal ultrasound endoscope (EUS) instrument without a channel	Colonized	Colonized	High	High-level disinfection	5
Linear gastroabdominal ultrasound endoscope (EUS) instrument with a channel and elevator	Colonized	Colonized	High	High-level disinfection	4
Radial rectal ultrasound probes: instrument without a channel	Colonized	Colonized	Low	High-level disinfection	5

Anaesthesiology					
Flexible laryngoscope	Colonized	Colonized	Low	High-level disinfection	5
Tracheal tube: instrument without a channel	Colonized	Colonized	Low	High-level disinfection	5
Pulmonology					
Bronchoscope: instrument with a single channel	Colonized	Colonized	Moderate	High-level disinfection	4
Ultrasound endoscope (EBUS): linear instrument with a channel	Colonized	Colonized	High	High-level disinfection	4
Miniature ultrasound probe: instrument without a channel	Colonized	Colonized	Low	High-level disinfection	5
Ear-Nose-Throat					
Laryngoscope : instrument with a channel	Colonized	Colonized	Low	High-level disinfection	4
Laryngoscope : instrument without a channel	Colonized	Colonized	Low	High-level disinfection	5
Gynaecology/Urology					
Vaginal ultrasound probe: instrument without a channel	Colonized	Colonized	Low	High-level disinfection	5
Flexible cystoscope: instrument with a channel	Colonized	Sterile	Moderate	High-level disinfection	4
Flexible cystoscope: instrument without a channel	Colonized	Sterile	Low	High-level disinfection	5
Rectal ultrasound probe: instrument without a channel	Colonized	Colonized	Low	High-level disinfection	5
Manometric probes and equipment – rehabilitation with endovaginal/endorectal probes	Colonized	Colonized	Moderate	High-level disinfection	5
Cardiology					
Transoesophageal ultrasound endoscope: instrument without a channel	Colonized	Colonized	Low	High-level disinfection	5

* Not according to Spaulding's classification

New types of MD or endoscopes are expected to be made available to healthcare professionals after these recommendations are published. It will need to be determined whether the new endocavitary MD or endoscopes can be classed in any of the instrument/device categories shown in Table 1 and thus, in particular, whether the stipulated recommendations - in this specific category - can be applied, in order to define the reprocessing method. Otherwise, the manufacturer's instructions must be followed.

These recommendations should be applied to all medical practices using heat-sensitive endocavitary MD, whether within a healthcare facility **or in a private practice.**

As regards the implementation of specific measures for certain patients considered to be at risk, the Superior Health Council of Belgium (SHC) refers to the previous advisory reports issued by the SHC, such as

- the recommendations on the prevention of the transmission of transmissible spongiform encephalopathy (Creutzfeldt-Jakob disease) in a hospital setting (CSH 7276-2, 2006) which also comprise a section specifically on endoscopic procedures.

Reference is made to the document in question for specific measures. These measures are still applicable and should be referred to and followed by healthcare professionals in such situations;

- the recommendations relative to the prevention of tuberculosis in healthcare facilities (SHC 8579, 2013);
- the recommendations on the prevention, control and management of infections with *Clostridium difficile* in healthcare facilities (SHC 9345, 2017);
- the recommendations on the prevention, control and care provided to patients who are carriers of multidrug resistant organisms (MDRO) in Belgian healthcare facilities (SHC 9277, 2019).

Keywords and MeSH descriptor terms[3]

MeSH terms*	**Keywords**	**Sleutelwoorden**	**Mots clés**	**Schlüsselwörter**
Endoscope; Analytical, Diagnostic and Therapeutic Techniques and Equipment Category	Endoscopes	Endoscopen	Endoscopes	Endoskopen
	Probes	Sonde	Sondes	Sonden
	Medical devices	Medische hulpmiddelen	Dispositifs médicaux	Medizinische Vorrichtung
	Heat-sensitive	Warmtegevoelig	Thermosensible	Hitzeempfindlich
	Disinfection	Desinfectie	Désinfection	Desinfektion
	Sterilisation	Sterilisatie	Stérilisation	Sterilisierung
	Prevention	Preventie	Prévention	Prävention
	Control	Beheersing	Maîtrise	Kontrolle
Prevention and control	Management	Aanpak	Prise en charge	Management
Health Care systems; Delivery of Health Care	Healthcare facilities	Zorginstellingen	Institutions de soins	Krankenpflegeeinrichtungen

MeSH (Medical Subject Headings) is the NLM (National Library of Medicine) controlled vocabulary thesaurus used for indexing articles for PubMed http://www.ncbi.nlm.nih.gov/mesh.

[3] The Council wishes to clarify that the MeSH terms and keywords are used for referencing purposes as well as to provide an easy definition of the scope of the advisory report. For more information, see the section entitled "methodology".

2. METHODOLOGY

After analysing the request, the Board and working group Chair identified the necessary areas of expertise. On this basis, an *ad hoc* working group was created, which included experts

- in endoscopy methods (gastroenterology, pulmonology, ENT[4], urology, etc.);
- on the sterilisation and disinfection of medical equipment and treatment (methods, standards and products) and also;
- on the prevention of iatrogenic infections.

The experts of this working group provided a general and an ad hoc declaration of interests and the Committee on Deontology assessed the potential risk of conflicts of interest.

In the early stages of drafting these recommendations, the working group asked to meet with representatives from the "*Zorginspectie, Departement Welzijn, Volksgezondheid en Gezin*" department of "*Vlaams Agentschap Zorg en Gezondheid*" (VAZG) from the Flemish Community (late 2017). This coincided with the drafting of a document by the Flemish authorities ("*Eisenkader voor high level desinfectie van thermolabiele flexibele endoscopen in het ziekenhuis*"). This text was drawn up with contributions by experts, some of whom were part of the SHC working group. This guarantees the consistency of the future SHC recommendations with the document issued by VAZG.

Secondly, towards the final stages of drafting these recommendations (late 2018), the working group reviewed and discussed a series of opinions, questions and comments on the issue relating to disinfection of endocavitary MD arising from said agency. Some information was communicated to the latter and certain aspects were incorporated into this document.

These recommendations are an updated version of the document published in 1995 (SHC 5303-11) and revised in 2010 (SHC 8355). This latest version was revised and updated based on the standards and most recent international medical literature, and on the basis of expert opinion. The different European and US recommendations constituted the main theme for introducing the amendments.

Once the advisory report had been approved by the working group, it was ultimately validated by the Board.

[4] ENT: Ear, Nose and Throat

List of abbreviations and symbols used

ANSM	*Agence nationale de sécurité du médicament et des produits de santé* [National Agency for Medicines and Health Products Safety] (FR)
APB	*Association pharmaceutique belge* [Belgian Pharmaceutical Association]
CDC	Centers for Disease Control and Prevention
CFU	Colony-forming unit
CJD	Sporadic Creutzfeldt-Jakob disease
vCJD	New variant of Creutzfeldt-Jakob disease.
CSD	Central sterilisation department
EBUS	Endobronchial ultrasound
EC	European conformity
ENT	Ear-Nose-Throat
EUS	Endoscopic ultrasound
FDA	Food and Drug Administration
FFP	Filtering Facepiece Particles
FPS	Federal Public Service Health, Food Chain Safety and Environment
HPV	Human papillomavirus
HR HPV	High-risk human papillomavirus
HRMO	High-risk microorganism
IQ	Installation qualification
ISO	International Organization for Standardization
LRMO	Low-risk microorganism
MD	Medical device
NOTES	Natural Orifice Transluminal Endoscopic Surgery.
NRZV	*Nationale raad voor Ziekenhuisvoorzieningen*
OQ	Operational qualification
PBS	Phosphate buffered saline
PQ	Performance qualification
PT	Product type
SFERD	*Stuurgroep Flexibele Endoscopen Reiniging en Desinfectie* (NL)
SHC	Superior Health Council
UV	Ultraviolet
VAZG	*Vlaams Agentschap Zorg en Gezondheid*
WHO	World Health Organization
WIP	*Werkgroep Infectiepreventie* (NL)

3. GENERAL POINTS

As defined in the scope (section 1.2.), these recommendations shall only take into account high-level disinfection procedures.

3.1 Criticality and levels of disinfection

The historic Spaulding classification (CDC, 2008) defines three critical levels for the disinfection of the device. Each level requires appropriate microbiological purity, which may be obtained by sterilisation or different levels of disinfection:

- Critical device: a device is considered critical if it presents a risk of infection, if it is contaminated with a microorganism. Items which penetrate sterile tissue or the cardiovascular system must be sterile.
- Semi-critical device: a device is considered semi-critical if it comes into contact with mucous membranes or damaged skin. The items should be free from microorganisms, but a small number of spores is authorised. Semi-critical items require at least high-level disinfection (with chemical disinfectants or physical methods).
- Non-critical device: a device is considered non-critical if it comes into contact with intact skin. Non-critical items may be disinfected with low-level disinfectants.

Table 2: Spaulding classification

Use of the device	Classification	Risk level	Processing required
Insertion into the vascular system or sterile tissue	Critical	High risk of infection	Sterilisation or sterile single use, or chemical sterilisation
Contact with mucous membranes or superficially damaged skin	Semi-critical	Moderate to high risk of infection	High-level disinfection
Contact with patient's intact skin or no contact with the patient	Non-critical	Low risk of infection	Low-level disinfection

Chemical disinfection is defined as a reduction in the number of microorganisms in or on an inanimate matrix, obtained via the irreversible action of a product on their structure or metabolism, at a level deemed appropriate according to a given objective.

The levels of disinfection correspond to the efficacy on the different microorganisms.

Table 3: Recommended processing according to the type of microorganism concerned

	Vegetative bacteria	Mycobacteria	Fungi	Viruses	Spores
Sterilisation	YES	YES	YES	YES	YES
High level	YES	YES	YES	YES	Partially
Low level	Majority	-	Some	Some	-

Sterilisation is defined as a process which leads to the absence of viable microorganisms on the MD. The aim of sterilisation is therefore to destroy or irreversibly inactivate microorganisms present in or on this item so that the likelihood of there being no more than one viable microorganism per million treated units is achieved (10^{-6}) (European Pharmacopoeia 8.0, section 5.1.1.), and this state is maintained up to the use of the MD (SHC 9256, 2017).
Sterilisation can be achieved using certain disinfectants, at higher concentrations and longer contact times.

The majority of heat-sensitive endocavitary MD are semi-critical MD, hence they need to undergo adequate cleaning and high-level disinfection processing.

3.2 Practical organisation

Cleaning, disinfecting and storing heat-sensitive MD correctly is only possible if the suitable premises, equipment and competent personnel are available.

3.2.1 Requirements related to the premises: central or decentralised organisation?

Various scenarios are possible in practice:

- central endoscopy and endoscope reprocessing units;
- central cleaning, disinfection and drying room, decentralised endoscopy rooms,
- completely decentralised configuration, with a cleaning, disinfection and drying room for one or more endoscopy rooms;
- examination room/endoscopy room (mainly for endocavitary MD without a channel).

In terms of patient safety and guaranteed quality, complete centralisation is preferable for **endoscopes with a channel**. Theoretically, in particular, this scenario offers the most guarantees: presence of optimum infrastructure and machines, clear physical separation of the clean circuit and soiled circuit, and standard working methods thanks to the intervention of a limited group of qualified expert personnel.
However, due to architectural limitations, this preferred scenario is not always possible.

The following requirements should be the desired standard for both central and decentralised configurations.
Guaranteeing an appropriate and permanent circuit for soiled/clean endoscopes is essential, and is only possible if a clear architectural separation exists between the clean zone and the soiled zone. Ideally, this separation is demarcated by the endoscope washer-disinfector with an air-lock/service hatch. If no such endoscope washer-disinfectors are available, a sufficiently large distance (at least 1 m – droplet precautions, CDC, 2007) to avoid any contamination between the pre-cleaning area (soiled zone) and the endoscope washer-disinfector area (clean zone) is required (WIP, 2016).

The soiled zone consists of

- a sufficiently large space for depositing and storing soiled endoscopes (take into account the transport container/transport system used);
- the rinsing tank/automatic rinsing station with curved inner corners, with suitable dimensions for the endoscopes used, and equipped with a water spray gun;
- a leak tester;
- a sufficiently large work surface which is easy to clean;
- the endoscope washer-disinfector (provided a system with an airlock/loading side);
- a suitable hand hygiene system (washing and disinfection). Personal splash protection equipment and an eye bath are available for personnel.

The clean zone consists of

- a suitable hand hygiene system (disinfection);
- an endoscope washer-disinfector (provided a system with an airlock/unloading side),
- a drying cabinet/storage cabinet;'
- sufficient space for transport preparation (take into account the transport container/transport system used).

Depending on the chosen traceability system, computer equipment may be necessary in the two zones (computer, screen, manual scanner). Electronic recording of loading and process data is the desired standard. Sufficient space should be provided for this equipment.

Adequate ventilation (at least 6 air changes/h) should be ensured in the cleaning and disinfection zones, depending on the types of disinfectants used and the type of endoscope washer-disinfector used (follow the manufacturer's instructions).
The products used are stored in fully secure conditions (according to SIPPT[5] and the manufacturer's instructions).

For endocavitary MD without a channel, in the event of manual cleaning and disinfection, these steps should be organised close to the MD. A sufficiently spacious work surface should be provided, equipped with the necessary items for ensuring high-level disinfection according to the chosen methods (automated systems, soaking, wipes). If a method involving soaking in toxic products is used (such as glutaraldehyde, for example), these containers are closed with a lid.

The fundamental principles for separating clean and soiled zones should be followed.

[5] SIPPT *Service Interne pour la Prévention et la Protection au Travail* [In-house Occupational Protection and Prevention Department]

3.2.2 Minimum requirements related to the equipment

The heat-sensitive endocavitary MD, automatic pre-rinsing station or rinsing tank intended for manual pre-cleaning and suited to the length of the endocavitary MD, the endoscope washer-disinfector, storage cabinet[6] and drying cabinet[7] must fulfil various minimum requirements in terms of prevention of infections and occupational medicine requirements, together with legislation on the subject. These minimum requirements are described in the directive "*Thermolabiele, flexibele endoscopen*" issued by the WIP (*Werkgoep Infectie Preventie,* 2015).

3.2.3 Minimum requirements related to personnel

Personnel involved in cleaning, disinfecting, drying and storing heat-sensitive endocavitary MD must have undergone documented training for this purpose, before being allowed to carry out the procedure independently. Minimum training covers hand-hygiene principles, the use of personal protective equipment, safe handling of chemicals, cleaning, disinfection/storage of heat-sensitive endocavitary MD, detailed knowledge of the endoscopes/probes present, and traceability systems. The necessary skills should be listed (Appendix 1) and matched with training, and periodic tests should be performed (see section 7) to ensure that personnel (still) maintain the necessary knowledge and skills.
There should be sufficient personnel in charge of reprocessing the devices to allow the procedures to be strictly applied.

3.2.4 Minimum requirements for water quality

The water used should generally be fit for human consumption. It should meet the quality criteria stipulated in the following standard: Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

The quality of water intended for human consumption should be tested at least once per year.

3.3 Regulatory framework and responsibilities

The MD must comply with Royal Decree 18/03/1999[8] (e.g. EC marking[9]). All materials used for reprocessing of MD (pressure gauge, reprocessing equipment, endoscope washer-disinfector) must display the EC marking logo and be classed as an MD in accordance with European Directive 2017/745/EEC (RD March 1999).

The regulatory framework for disinfectant products is described in section 6.2.1. of these recommendations.

Approval should be sought from the Hospital Hygiene Committee for any new materials acquired, in order to ensure optimum reprocessing quality.

[6] a storage cabinet is a clean, dry, dust-free cabinet in which cleaned/disinfected heat-sensitive endoscopes with a channel may be placed **for a maximum period of 4 hours**.
[7] a drying cabinet is a cabinet in which both the external surface and internal channels of cleaned/disinfected heat-sensitive endoscopes with a channel are dried in air free from bacteria (HEPA filtered air); a drying cabinet is also used as a storage cabinet.
[8] RD 18 March 1999: Royal Decree on medical devices
[9] EC: European conformity

The instructions for use of the present devices (endoscopes, MD, endoscope washer-disinfector, drying cabinet, etc.) are available.

Good safety management principles must be followed, which implies the involvement of and specific reference to all personnel concerned (management, pharmacy staff, doctors, nurses, technical medical department, team responsible for hospital hygiene). Appointing a coordinating expert (such as a responsible pharmacist (advisory report NRZV[10]/D/430-3, 2013)) for reprocessing (cleaning, disinfection and, where appropriate, sterilisation) endocavitary MD is strongly recommended.

[10] NRZV: *Nationale raad voor Ziekenhuisvoorzieningen*

4. CLEANING AND DISINFECTION PROCESS FOR HEAT-SENSITIVE ENDOSCOPES WITH A CHANNEL

Cleaning and disinfection of heat-sensitive endoscopes with a channel are particularly critical processes in healthcare facilities. If this process is not correctly performed, potentially fatal iatrogenic infections may develop.

This section provides a detailed description of the different steps of the cleaning/disinfection/drying/storage process for endoscopes, together with the specific aspects of these steps relating to accessories. The SHC recommends that each healthcare facility uses this as a basis for drawing up its own written procedure, which should be approved by the Hospital Hygiene Committee. A document relating to Good Practice guidelines should also be drawn up in private practice.

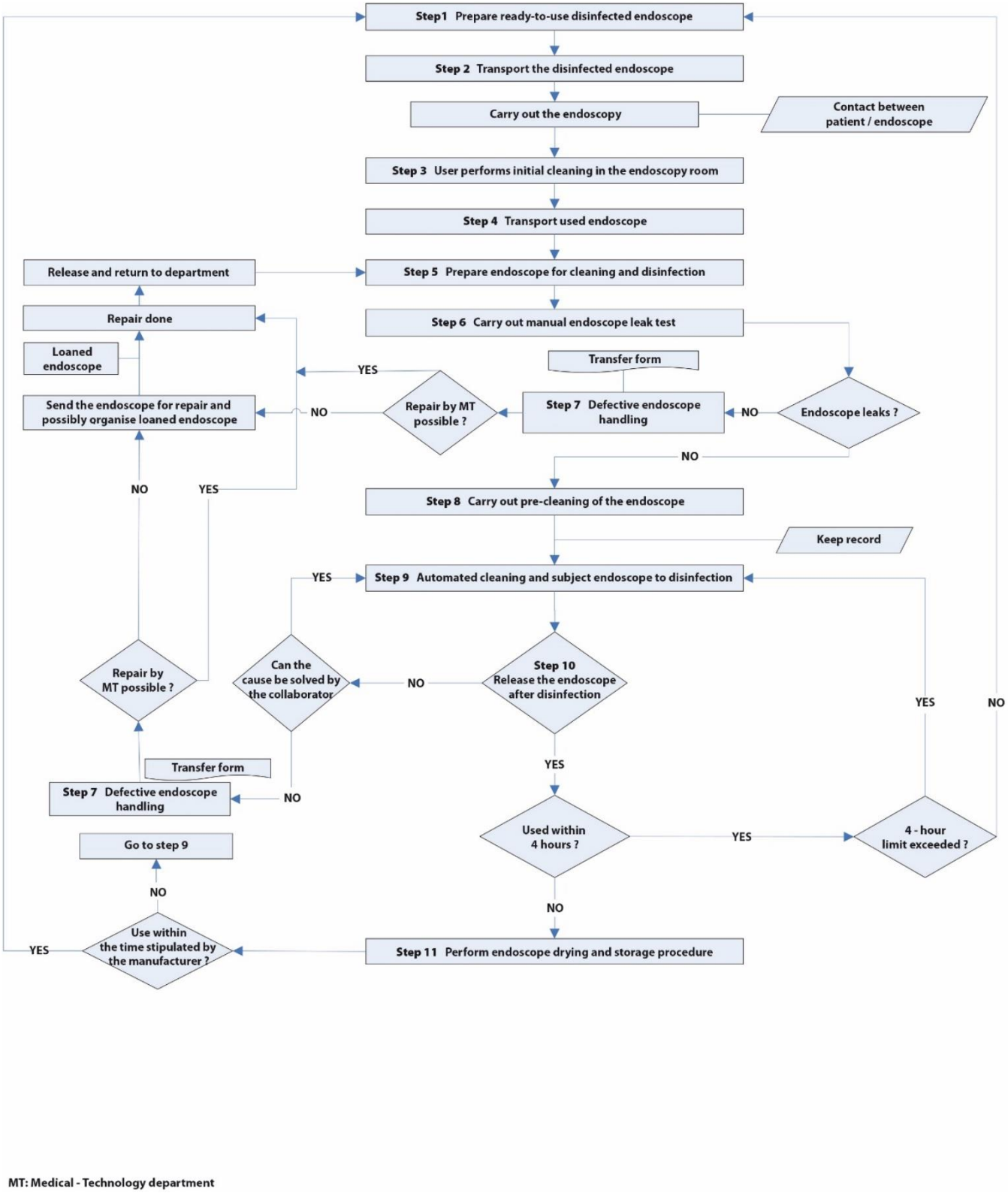
Patients suffering from *Creutzfeldt-Jakob disease* (CJD) – sporadic form - are not at higher risk during endoscopy given the absence of prions in the mucous membranes and submucosa. However, in patients with diagnosed or suspected *variant Creutzfeldt-Jakob disease* (vCJD), prions are also found in the tonsils, lymph nodes, and gastrointestinal mucosa and submucosa. In that case, endoscopic investigations and interventions (biopsies, injections, etc.) should thus be avoided as far as possible in these patients (SHC 7276-2, 2006; SHC 9256, 2017). If such procedures cannot be avoided, single-use endoscopes are recommended.

4.1 Cleaning/disinfection/drying process

High-level disinfection is sufficient for most heat-sensitive endoscopes with a channel. However, there are some heat-sensitive endoscopes with a channel which need to be sterile when used in sterile cavities (refer to the Spaulding classification). In this case, sterilisation is required, notably involving the use of hydrogen peroxide. Manufacturers of heat-sensitive endoscopes with a channel, jointly with the manufacturers of the steriliser, should assure users that sterilisation with hydrogen peroxide is possible (SHC recommendations relating to “Good MD Sterilisation Practice guidelines” (SHC 9256, 2017)).

The flow chart shown below describes the process steps to be followed for preventing infections. The order followed in this case corresponds to the preparation of a disinfected endoscope up to the drying and storage process for the endoscope.

Figure 1. Primary cleaning and disinfection process for a heat-sensitive endoscope with a channel (adapted from the SFERD quality manual, version 4.0, 2016).



MT: Medical - Technology department

4.1.1 Preparation of a ready-to-use disinfected endoscope

- All procedures concerning a disinfected endoscope should be performed after disinfecting the hands and, for cystoscopes, with sterile gloves.
- The endoscope should be taken out of the drying/storage cabinet or endoscope washer-disinfector (if the endoscope is taken straight out of the endoscope washer-disinfector, it should be used within 4 hours). The maximum time-limit for use of the endoscope is clearly indicated (on the transport container or label affixed to the endoscope, for example). After this time-limit, the endoscope should once again be mechanically cleaned and disinfected.
- Before the endoscope can be taken out of the endoscope washer-disinfector, it should be checked that the process has been carried out correctly (cf. 4.1.10.).
- Disinfected or single-use valves should be positioned as appropriate and a single-use biopsy cap should be placed on the biopsy channel.

4.1.2 Transportation of the disinfected endoscope

- The disinfected endoscope should be placed in a clean single-use or disinfected reusable transport container. When a sterile anatomical site is examined, the disinfected endoscope is transported in sterile packaging. This transport container is sealed in such a way that it is possible to see that the endoscope has been disinfected (cover, plastic case, colour code, etc.). The endoscope should be protected against damage resulting from transport.
- The transport container states the maximum time-limit for use, which takes into account the dryer processing time, and is taken to the endoscopy room.

4.1.3 Implementation of the endoscopy – contact between the patient/endoscope

- Both the endoscopist and assistant nurse apply hand-hygiene measures. Moreover, they should wear non-sterile gloves and a disposable protective apron. Sterile gloves are necessary when a sterilisation process is recommended for the endoscope.
- Additional personal protective equipment may be necessary (ultra-filtering FFP2 mask[11] for bronchoscopy and suspected pulmonary or laryngeal tuberculosis, for example).
- The endoscope used for the patient is recorded on the available paper form or in the patient's electronic record or any other system.

4.1.4 Initial cleaning by the user in the endoscopy room

The following procedures should be carried out immediately after the examination, in the endoscopy room itself. These procedures should always be performed also when endoscopy is performed outside normal working hours. Immediate cleaning prevents soiling from drying, and avoids the proliferation of microorganisms and the formation of a biofilm.

[11] FFP: *Filtering Facepiece Particles*

- Ensure that rinsing of the biopsy and aspiration channel is performed using water fit for human consumption.
- Rinse and flush water fit for human consumption and air into the air/water channel.
- Clean the external surface of the endoscope using a non-sterile moist compress or soft lint-free single-use cloth.
- Place the endoscope control buttons in the neutral position.
- Change gloves.
- Disconnect the endoscope and place in a transport container intended for this purpose, or a system which clearly indicates that the endoscope has been used.
- Remove gloves and disinfect hands.

4.1.5 Transportation of the used endoscope

- Take the identifiable soiled endoscope straight to the soiled zone of the disinfection room, for manual pre-cleaning, and automated cleaning and disinfection.
- If the endoscope is not wrapped, the transport container is closed. In any case, soiled endoscopes cannot be transported uncovered.
- It must be clear that the endoscope is soiled.

4.1.6 Preparation for manual pre-cleaning in the soiled zone of the disinfection room

In the soiled zone of the disinfection room, personnel have access to

- the necessary personal protective equipment (fluid-proof apron, non-sterile gloves, surgical mask covering the nose and mouth, eye protection);
- a protective cap for the endoscope;
- a leak tester;
- a suitable detergent for manual pre-cleaning;
- a rinsing tank/rinsing station with curved corners (cf. 3.2.1.);
- accessories for injecting/flushing air and water into the channels;
- single-use brushes compatible with the channel diameter;
- detergent and disinfectant products for the transport containers. The products required for cleaning and disinfection are discussed in section 6.

- Place the protective cap on the endoscope.
- Fill a clean rinsing tank with a detergent intended for manual pre-cleaning. The application time, concentration and temperature are adapted according to the manufacturer's instructions. The cleaning product should be changed after each process whether in the central endoscopy unit or in the decentralized endoscopy room (section 6).
- Remove the disposable caps and valves (unless valves are necessary for endoscopes for which the channels should not be brushed but which require injection of air/water).
- Clean reusable valves according to the manufacturer's instructions.
- Reusable transport containers should be cleaned/disinfected before any further use, with a surface disinfectant registered as a PT2[12] biocidal product with proven antimicrobial efficacy (see section 6).

[12] PT: product type

4.1.7 Endoscope leak test in the soiled zone of the disinfection room

The leak test is used to detect internal or external perforation of the channels or endoscope sheath. Infiltration of water damages the instrument. Furthermore, the endoscope is contaminated by microorganisms which cannot be eliminated in the endoscope washer-disinfector. The endoscope then represents a source of contamination and should be immediately withdrawn from use and tested and/or repaired by the manufacturer.

The leak test is carried out by flushing air into the endoscope sheath using a leak tester, with:

- A pressure gauge (manual or automatic): a pressure drop on the pressure gauge indicates a leak;
- Or an electric pump: air is continuously flushed into the sheath at constant pressure.

In both cases, the pressurised endoscope may be immersed without any risk of water infiltration. Bubbles indicate the perforation site. The device (still pressurised) should be taken out of the water immediately. The defective endoscope should be sent to the hospital medical technology department for repair. In most cases, the endoscope will be sent to a company for repair. A “contaminated” label should be affixed to the defective endoscope. After repair and prior to use, the repaired endoscope should always be mechanically cleaned and disinfected, and then undergo a leak test.

4.1.8 Manual pre-cleaning of the endoscope in the soiled zone of the disinfection room

The main objective of this step is to reduce microbial contamination by chemical and mechanical elimination of all soiling and organic residue. According to the data in the literature, cleaning enables a 1-5 log reduction in initial contamination of approximately 10^8 to 10^9 CFU (colony-forming units) per endoscope, depending on the type of microorganism present, the detergents used and the method of use.

Manual pre-cleaning, essential for effective disinfection and/or sterilisation, takes place as soon as possible and within a reasonable time-frame in order to reduce the risk of biofilm formation after initial cleaning performed in the endoscopy room.

The soiled zone of the disinfection room complies with the above-mentioned requirements in terms of organisation of the space. Personnel in charge of manual pre-cleaning have access to the necessary personal protective equipment and materials (3.2.1. and 4.1.6.).

- Fully immerse the endoscope in the detergent solution and ensure that all channels are filled.
- Use single-use brushes with a suitable diameter for each endoscope (or an equivalent mechanical cleaning accessory, which is able to yield at least the same result).
- Brush the biopsy/aspiration channel from the valve body towards the distal end.
- Rinse all channels with the detergent solution.

- Always follow the manufacturer's specific instructions relating to manual pre-cleaning. Special attention should be given to complex endoscopes, such as duodenoscopes and linear ultrasound endoscopes. Due to the elevator, the latter present an additional challenge for appropriate manual pre-cleaning. The manufacturer's specific cleaning instructions, including the use of specific single-use cleaning brushes, must always be followed.
- The sheath and control buttons on the control box should be cleaned.
- Remove the endoscope from the rinsing tank and place in the endoscope washer-disinfector.

4.1.9 Automated cleaning and disinfection

Automated cleaning and disinfection take place after initial cleaning and pre-cleaning of the endoscope in an endoscope washer-disinfector in compliance with standards NBN EN 15883-1 and NBN EN 15883-4. The SHC considers that a complete endoscope washer-disinfector cycle should comprise at least an automated leak test, rinsing, cleaning, disinfection, post-rinsing and, where appropriate, drying phase. Not all devices available on the Belgian market fulfil these requirements. Hence, semi-automatic systems exist which enable automated disinfection, but with completely manual pre-wash and rinsing phases.

- Wearing gloves, place the endoscope in the endoscope washer-disinfector.
- Connect all of the channels to the appropriate tubes, according to the instructions.
- Pay particular attention to the manufacturer's specific instructions in the endoscope manual (position of the elevator, for instance).
- Ensure that the tubes are not bent.
- Place the manually cleaned caps/valves (if not for single-use only) in a basket, in the endoscope washer-disinfector.
- Remove gloves, disinfect hands, close the door of the endoscope washer-disinfector and start the desired programme.

Record (preferably in numerical form) loading, process data, date, time and disinfectant batch number, together with the name of the operator.

If the endoscope washer-disinfector stops during the programme and displays an error message, follow the manufacturer's instructions. In contrast to its advisory report no. 8355, the SHC no longer supports temporary manual disinfection in situations involving a defective endoscope washer-disinfector.

4.1.10 Release of the endoscope after disinfection

A heat-sensitive endoscope with a channel may only be released (for use), after mechanical cleaning and disinfection, if:

- the cleaning and disinfection process takes place without interruption;
- all tubes, caps and channel separators are still in place;
- no macroscopic soiling is visible on the endoscope.

If any of these conditions are not fulfilled, the cleaning and disinfection process should be restarted.

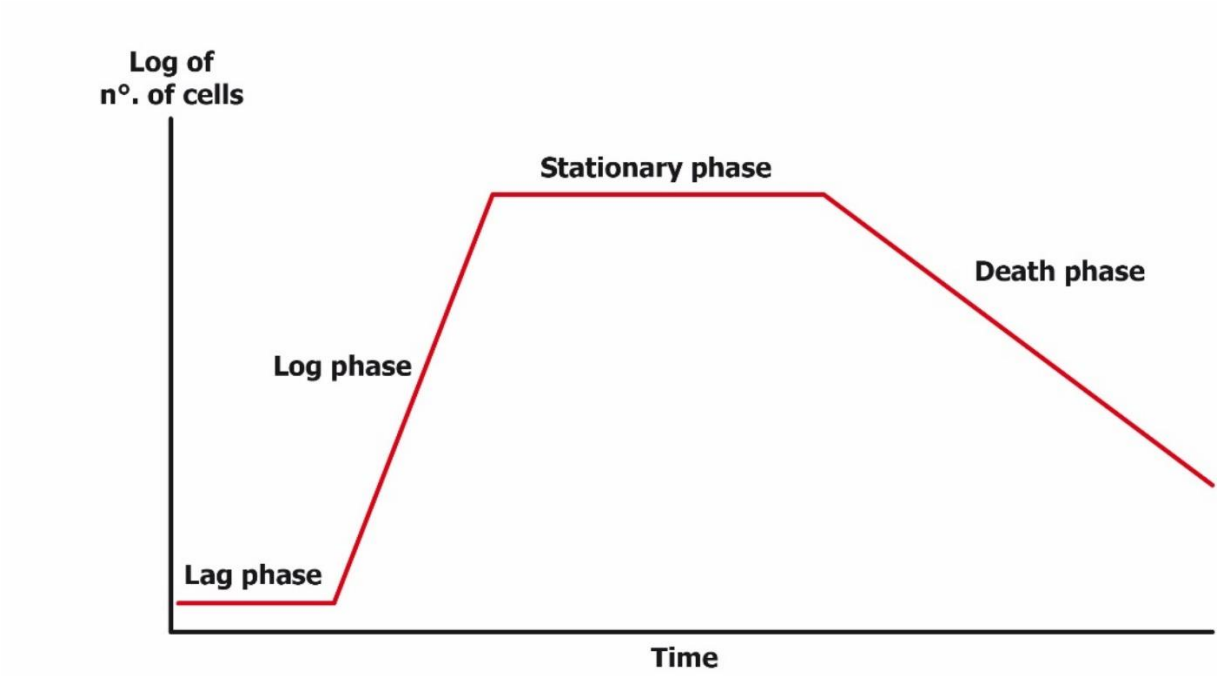
4.1.11 Drying and storage of the endoscope

Drying is the final crucial step of the cleaning/disinfection process for endoscopes. This prevents the proliferation of microorganisms such as *Pseudomonas* spp. and *Acinetobacter* spp. (Kovaleva et al., 2010; Alfa & Sitter, 1991). Active drying of heat-sensitive endoscopes with a channel takes place in a drying cabinet in compliance with standard NBN EN 16442 and the endoscope manufacturer's instructions.

As a reminder, a drying cabinet is a cabinet in which both the external surface and internal channels of cleaned/disinfected heat-sensitive endoscopes are dried in air free from bacteria (HEPA filtered air). A drying cabinet may also be used as a storage cabinet.

After mechanical cleaning and disinfection, if the endoscope is used within 4 hours, active drying in a drying cabinet is not necessary. However, if it is not used within this time-limit, the endoscope should be mechanically cleaned and disinfected once again (before use). The 4-hour rule is based on the fundamental microbiological principles, namely the bacterial growth curve. Exponential bacterial growth (the logarithmic phase during which a bacterial population doubles for each generation) is always preceded by a lag phase. Although the lag phase depends on several factors, a period of 4 hours for this lag phase is generally adopted at room temperature.

Figure 2: Changes in bacterial population growth over time



- If a drying cabinet is not available, a processed endoscope should be stored in a clean, dust-free airtight environment (clean storage cabinet or container, for example). The time-limit for use (4 hours) should be clearly indicated.
- If a drying cabinet is used, all of the endoscope channels should be connected according to the manufacturer's instructions. Depending on the type of drying cabinet, drying lasts 30 to 120 minutes. Ensure that the endoscopes do not rest on the bottom of the drying cabinet if a hanging drying cabinet is used. Valves and other detachable components stay with the endoscope.
- Drying cabinets in which the endoscopes are stored horizontally in a storage container after connecting the channels to the drying system are now also available.
- Once the drying procedure is complete, the endoscope and accessories may be used safely for a longer period of time. The safe storage period is determined by the drying cabinet manufacturer.
- Drying and storage cabinets for endoscopes and accessories are cleaned and disinfected according to the manufacturer's instructions.

Two innovative systems are currently available on the market, and may be used instead of traditional drying cabinets. These systems do not meet the technical requirements defined in standard NBN EN 16442.
The first system enables rapid drying of the internal channels of the endoscope with hot air, then the endoscope is placed in a single-use, hermetically sealed plastic bag into which ozone is briefly injected. For the second system, the internal channels are rinsed with diluted peracetic acid solution, and the endoscope is then placed in a single-use package under partial vacuum conditions. Both systems claim to guarantee safe prolonged horizontal storage of endoscopes in their specific packaging. The validation method used is based on the recommendations stipulated in standard NBN EN 16442.

4.1.12 Increased risk of contamination with duodenoscopes and ultrasound endoscopes with a linear probe

Special attention should be given to cleaning and disinfecting endoscopes fitted with an additional elevator, such as duodenoscopes and ultrasound endoscopes with a linear probe. Duodenoscopes are used for performing endoscopic retrograde cholangiopancreatography, whereas ultrasound endoscopes with a linear probe are generally used for transmural fine-needle aspiration biopsies or for advanced therapeutic endoscopy.

Several sites of bacterial transmission have been recently observed, following the use of contaminated duodenoscopes, having resulted in serious or even fatal infections. The elevator is incorporated into the endoscope and cannot be removed. Both the elevator and the space behind the elevator could remain contaminated after routine cleaning and disinfection. Scientific studies conducted via routine culturing of the elevator after high-level disinfection of duodenoscopes and ultrasound endoscopes with a linear probe show positive bacterial cultures in approximately 5 % of cases. Given the risk of transmission of potentially pathogenic bacteria from one patient to another, the need for more stringent cleaning and disinfection measures is being studied for endoscopes fitted with an elevator.

Additional measures studied (by the US Food and Drug Administration (FDA), 2018) are:

- double high-level mechanical disinfection;
- routine monitoring of endoscopes using microbial cultures;
- ethylene oxide sterilisation of disinfected endoscopes;
- chemical sterilisation using a peracetic acid solution.

The SHC no longer recommends the use of ethylene oxide disinfection in healthcare facilities (SHC 9256, 2017). The use of double high-level mechanical disinfection is not currently an option, and neither is routine chemical liquid or gas sterilisation.

Out of these additional measures, only the following may currently be selected as being sufficiently evidence-based:

- stringent monitoring of the manual cleaning and mechanical disinfection procedure (in compliance with the endoscope manufacturer's instructions);
- specific cleaning of the elevator (using appropriate brushes);
- routine monitoring of endoscopes using regular microbial cultures.

If contamination is confirmed, the cleaning and disinfection process should be thoroughly investigated with a view to identifying any errors. The necessary adjustments should be made and the endoscope should be cleaned and disinfected once again. Monitoring based on microbial cultures should be performed before the endoscope is used again. The endoscope may only be used if the cultures are negative (ASGE, 2018; Beilenhoff et al., 2017; FDA, 2018; Kim & Muthusamy, 2016; Muthusamy, 2017; Petersen et al., 2017; Rauwers et al., 2018; Ross, 2016).

4.2 Cleaning, disinfection and/or sterilisation of accessories

The accessories used during endoscopy may be classed according to four groups: instruments used during endotherapy (intervention materials), rinsing systems, endoscopy accessories, accessories used during the cleaning process (rinsing tank, aspiration tube and bag).

4.2.1 Accessories used during endotherapy

During the endoscopy, these instruments are in direct contact with sterile tissues and must be sterile, according to the Spaulding table. Single-use accessories are preferable. Reusable accessories may only be sterilised if the Central Sterilisation Department (CSD) has written authorisation from the manufacturer and if a procedure exists in which the manufacturer stipulates how and how many times the accessories may be resterilised.

4.2.2 Rinsing systems

The sterile rinsing flask is filled with sterile water and should be replaced each day. Reusable flasks should be sterilised (by steam sterilisation or according to the manufacturer's instructions).

4.2.3 Endoscopy accessories

This set of accessories (valves, caps, mouthpiece) is not in direct contact with sterile tissues, but there is a high risk of contamination by body tissues or fluids. Single-use materials are preferable.
Reusable accessories are cleaned and disinfected mechanically. Reusable valves should first be brushed in the open and closed position in order to eliminate contamination as far as possible.

4.2.4 Accessories used during the cleaning process

These accessories do not enter into direct contact with the patient. As too many conditions need to be met in order for reusable cleaning brushes to be used safely, only single-use brushes are recommended. Cross-contamination between patients and between patients and personnel, injuries when cleaning the brushes and the use of worn-out or defective brushes can thus be avoided.

4.2.5 Cleaning the rinsing tank

After each cleaning operation on an endoscope, empty the rinsing tank and clean using a detergent, then rinse carefully. Dry carefully at the end of the operation.

4.2.6 Aspiration tube and bag

Single-use liners (bags used to collect the aspirated fluids) are replaced daily. The aspiration connection tube is replaced for each patient.

5. CLEANING AND DISINFECTION PROCESS FOR HEAT-SENSITIVE ENDOCAVITARY MD WITHOUT A CHANNEL

5.1 Introduction

The heat-sensitive endocavitary MD covered by this section are shown in Table 1, section 1.2. of these recommendations.

This section provides a detailed description of the different steps of the cleaning/disinfection/drying process for heat-sensitive endocavitary MD without a channel. The SHC recommends that each healthcare facility draws up its own written procedure, which should be approved by the Hospital Hygiene Committee. A document relating to Good Practice guidelines should also be drawn up in private practice.

Three main groups of heat-sensitive endocavitary MD without a channel can be identified based on their specific characteristics:

- **rigid ultrasound probes** with the following specific characteristics:
  - use of a gel;
  - special storage: these often stay attached to the machine;
  - high-level disinfection possible via automated systems (UV[13] and atomization with hydrogen peroxide) or wipes;
  - implementation of ultrasound-guided biopsies.

- **flexible ultrasound probes**.

- **endoscopes including flexible ultrasound endoscopes** with the following specific characteristics:
  - inconsistent use of the sheath;
  - cleaning and disinfection possible outside the examination zone;
  - cleaning and disinfection possible via endoscope washer-disinfectors.

5.2 Gel

A gel is used with rigid ultrasound probes.
The SHC makes the following recommendations concerning this type of use

- follow the manufacturer's instructions;
- comply with the expiry date;
- opt for small pack sizes;
- discard the empty packaging (do not re-fill the packs).

5.3 Protective sheath

The protective sheath is

- a single-use MD (European Directive 2017/745/EEC) which may be a class I or class IIA device according to the intended use;

[13] UV: ultraviolet

The sheath is made of latex or synthetic elastomers such as polyurethane. The biopsy guide support brackets on endocavitary probes with a protective sheath or condom should not damage the sheath and cause leaks (Hajjar, 2010);

- a single-use latex-free condom, fulfilling standard NBN ISO[14] EN 4074;
- a sheath with a single-use external operating channel.

The use of a protective sheath is mandatory for rigid endovaginal and endorectal probes. This may be a condom for rigid endovaginal and endorectal ultrasound probes.

The protective sheath reduces contamination, and therefore increases the efficacy of disinfection, together with safety in the event of invisible damage to the MD (Alfa, 2015).
However, routine use of a sheath or condom is considered insufficient for preventing contamination with microorganisms as the sheath is regularly perforated during the examination (in 1-8 % of cases and up to 81 % in a study). Contamination of the probes with pathogenic bacteria and viruses, even in the absence of visible perforation of the sheaths or condoms has been documented. This contamination persists after low-level disinfection (Leroy, 2013). This therefore warrants the consistent use of high-level disinfection.
The SHC therefore recommends high-level disinfection whether a protective sheath is used or not, in contrast to SFERD recommendations[15].

A prospective clinical study on laryngoscopes demonstrated that the use of a sheath did not require high-level disinfection (Alvarado et al., 2009). However, since this is only based on a single publication, the SHC also recommends high-level disinfection for laryngoscopes.

The following measures are essential to the proper use of protective sheaths:

1. **Train users on how to fit and remove a sheath**;

The following points warrant particular attention:

Fitting the sheath

- Check the integrity of the packaging, the shelf life for use and the expiry date for sterile sheaths.
- Check for the absence of visible defects on the sheath (notably tearing) once it is in place.

Fitting the sheath during an examination with a biopsy

- Only use a sterilised or single-use guide.
- Place the biopsy guide outside the sheath so that it is not perforated by the needle during the biopsy.
- Routinely check that the whole sheath is intact during fitting and at the end of the intervention, particularly the external zone where the guide attaches to the probe.
- Please note that if a defective batch is suspected or detected, this should be reported according to medical device vigilance procedures (FAMHP[16]).

[14] ISO: International Organization for Standardization
[15] SFERD: *Stuurgroep Flexibele Endoscopen Reiniging en Desinfectie*
[16] FAMHP: Federal agency for medicines and health products

Removal of the sheath

- Investigate for any visible defects on the sheath, and tearing in particular.
- Investigate for visible soiling on the probe and clean the probe with a dry single-use wipe or unwoven compress to check for any soiling.

2. **Use a specific sheath** intended for and suited to the envisaged use, which does not interfere with the probe to be protected (Hajjar, 2010).

Under no circumstances should the protective sheath be used as a storage case.

5.4 Reprocessing of MD

5.4.1 Reprocessing of rigid ultrasound probes with sheath

Reprocessing concerns rigid endovaginal and endorectal ultrasound probes. The use of a protective sheath for these probes is mandatory. High-level disinfection is required between two examinations. After removing the protective sheath, the probe should be cleaned using a clean, dry wipe.

Washing and high-level disinfection are MANDATORY.

Washing takes place by manual cleaning using

- a detergent solution (soaking) or;
- a wipe or compress soaked with an appropriate detergent (section 6) or;
- a ready-to-use wipe.

High-level disinfection takes place

- preferably using automated systems able to perform high-level disinfection (section 5.5.1.);
- by soaking or application of a high-level disinfectant solution using wipes (ACIPC, 2017; Hajjar 2010; Rutala & Weber, 2016; SFERD, 2016).

Do not forget to disinfect the handle, in addition to the ultrasound probe itself.

5.4.2 Reprocessing of flexible ultrasound probes

Reprocessing concerns flexible ultrasound probes having been inserted via the channel and which are reusable, such as miniature probes.

Washing and high-level disinfection are MANDATORY.

Washing takes place by manual cleaning using

- a detergent solution (soaking) or;
- a wipe or compress soaked with an appropriate detergent (section 6) or;

- a ready-to-use wipe.

High-level disinfection is possible

- preferably using automated systems able to perform high-level disinfection (section 5.5.1.);
- by soaking or application of a high-level disinfectant solution using wipes (ACIPC, 2017; Hajjar 2010; Rutala & Weber, 2016; SFERD, 2016).

Do not forget to disinfect the handle, in addition to the ultrasound probe itself.

5.4.3 Reprocessing of endoscopes including ultrasound endoscopes

Reprocessing concerns heat-sensitive endoscopes without a channel.
Immediately after the examination, the endoscope should be wiped using a clean, dry compress.
A leak test should be performed if recommended by the manufacturer.
High-level disinfection should be routinely planned, with the endoscope washed beforehand, whether a protective sheath was used or not.

In the majority of cases, the use of protective sheaths is not recommended for ultrasound endoscope probes. Certain manufacturers recommend the use of a protective sheath specifically in the case of flexible transoesophageal endoscopic ultrasound for prolonged use (e.g.: heart surgery in the operating theatre). The sheaths used should display the EC marking logo and high-level disinfection is required between two examinations. After removing the sheath, the probe should be wiped using a clean, dry compress.

Washing takes place by manual cleaning using

- a detergent solution (soaking) or;
- a wipe or compress soaked with an appropriate detergent (section 6) or;
- a ready-to-use wipe.

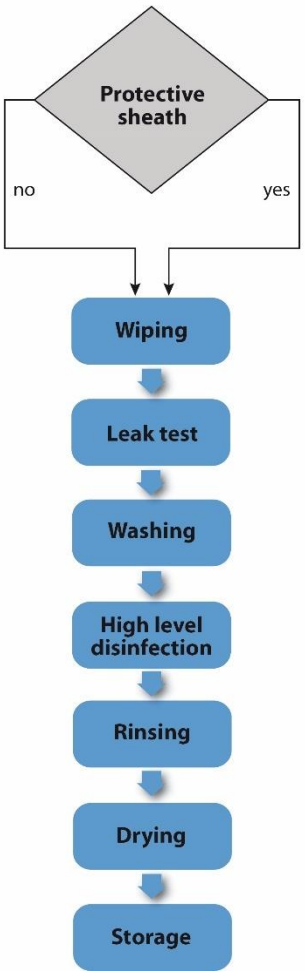
High-level disinfection is possible

- preferably using an endoscope washer-disinfector able to perform high-level disinfection (section 5.5.1.);
- by soaking or application of a high-level disinfectant solution using wipes (ACIPC, 2017; Hajjar 2010; Rutala & Weber, 2016; SFERD, 2016).

Do not forget to disinfect the handle, in addition to the ultrasound probe itself.

Note:
Multiple-use endocavitary MD intended for a single patient are available. For example: for perineal rehabilitation probes, given the number of treatments prescribed, the patient may be asked to purchase their own probe. In this case, at the end of each examination, the probe should be cleaned (low-level disinfection), wrapped and returned to the patient.

Figure 3: Reprocessing procedure for endocavitary MD



*[1] if recommended by the manufacturer
*[2]depending on the disinfection system used

5.5 High-level disinfection techniques

High-level disinfection techniques include automated systems, soaking and wipes.

5.5.1 Automated high-level disinfection techniques

Alternative automated high-level disinfection methods for endocavitary MD without a channel currently exist. This type of system has an advantage in relation to manual high-level disinfection techniques in that it is able to eliminate operator errors, increase user safety by reducing exposure to toxic chemicals and allows traceability and reproducibility.

5.5.1.1. Automated UV-C radiation disinfection systems

The UV-C chamber is a closed chamber. The ultrasound probe cleaned beforehand is suspended at the center of the chamber. The probe and handle are exposed to radiation from

6 low-pressure UV-C lamps (wavelength of 254 nm) attached to the walls and bottom of the chamber.

The energy from the photons denatures the nucleic acids of the microorganisms.

The duration of the disinfection cycle used in the efficacy studies on the device ranged from 90 seconds (Bloc et al., 2011) to 5 minutes (Kac et al., 2010) and 10 minutes (Kac et al., 2007).
The device has also been shown to be effective on HPV[17] (Meyers et al., 2017) in in vitro studies and routine conditions of use.

Two automated system models are currently available: a model for vaginal and rectal endocavitary ultrasound probes with a pre-programmed cycle of 90 seconds, and a model for transoesophageal ultrasound endoscopes with a cycle of 180 seconds.
The automated system is also equipped with software enabling traceability of the disinfection process.

UV-C treatment has the advantage of not being corrosive to the probes and thus preserving their function.

Irrespective of the type of machine, it is important to follow the manufacturer's recommendations.

5.5.1.2. Automated hydrogen peroxide disinfection system

An automated device uses 35 % hydrogen peroxide at 56 °C. The system uses sonication to produce an ultrafine mist of hydrogen peroxide which disinfects the ultrasound probe in a closed chamber following an automated cycle.
This device decontaminates the probe and handle simultaneously (Ngu et al., 2015).

The disinfection efficacy of the system was tested *in vitro* (Vickery et al., 2014) according to international bactericidal, fungicidal, mycobactericidal and virucidal disinfection standards and under routine clinical conditions of use. The system also effectively eliminates HPV (Meyers et al., 2014, Ryndock et al., 2016).

Irrespective of the type of machine, it is important to follow the manufacturer's recommendations.

5.5.1.3. Endoscope washer-disinfector

Endoscope washer-disinfectors exist which are mainly intended for disinfection of endoscopes without a channel. These automatic endoscope washer-disinfectors guarantee traceability.
This system disinfects the whole MD.

Irrespective of the type of machine, it is important to follow the manufacturer's recommendations.

[17] HPV: *Human papillomavirus*

5.5.2 Soaking technique

Prerequisites

- Personnel should be protected. They should be equipped with protective garments against contact and splashing with contaminated or toxic products: long-sleeve nitrile gloves, waterproof apron, surgical mask and protective eyewear.
- Containers and lids should be clean and dry before adding the soaking solutions.
- In the context of patient – disinfection process – MD traceability, the batch number should be recorded each time the batch of soaking solution is changed.
- The date and time of expiry of the disinfectant solution, together with the number of times it is used, should be stated on the container.
- The manufacturer's recommendations should be followed.
- Given the potential toxicity of the disinfectant used, endocavitary MD should be carefully rinsed after disinfecting. This also applies to accessories. Water intended for human consumption is used for this purpose.
- The MD is immersed in a container with a product used in accordance with the manufacturer's instructions.
- Drying takes place using a clean lint-free cloth.

Manual disinfection has a number of disadvantages:

- risks of respiratory and cutaneous irritation for personnel in contact with the products,
- manual traceability;
- process difficult to control and possibly interrupted;
- risk of errors when using disinfectant solutions (correct concentration and soaking time);
- risk of noncompliance with the shelf life of the products and prepared solutions, together with the frequency of replacing the solutions.

Different high-level disinfection products are available on the market and are described in section 6.

5.5.3 Wipes

Some high-level disinfection processes may be performed using wipes.

These have a number of advantages:

- good bactericidal, virucidal, mycobactericidal and sporicidal activity, particularly due to the presence of compounds such as chlorine dioxide or peracetic acid, within a short time;
- simple logistics, such as no upkeep, maintenance contract, and use in the same room as the examination;
- a short turn-around (disinfection) time which reduces the time-frame for availability of MD;
- less toxicity for personnel and patients given the small volume of active product and the lower risk of splashes compared to soaking by immersion.

The use of wipes has its limits, such as:

- a limited mechanical effect compared with the manual cleaning technique recommended for invasive MD in contact with biological fluids or tissues;
- lack of harmonisation related to the manual aspect (operator-dependent wiping technique, potentially insufficient contact of the product in zones comprising crevices with respect to immersion);
- no automated traceability ;
- limited studies on the efficacy of wipes, apart from evaluations on nasolaryngoscopes (Alvarado et al., 2009);
- limited knowledge of the effects on premature wear of MD further to the use of certain active products present in the wipes.

5.6 Organisation

Touch screens and keypads must be disinfected between each patient and periodic disinfection of consoles and cables should take place (with the use of a low-level disinfectant for touch screens, in compliance with the manufacturer's instructions).

5.7 Storage

Heat-sensitive endocavitary MD without a channel which are not used immediately should be dried using a clean, lint-free cloth, on a dry surface, previously cleaned and stored in a clean and dry place. Storage in cases is prohibited.

For ultrasound examination, the MD is attached to its stand.

6. PRODUCTS USED DURING CLEANING AND DISINFECTION OF HEAT-SENSITIVE ENDOCAVITARY MEDICAL DEVICES

6.1 General observations

Beyond its definition, disinfection may be perceived as a mathematical concept with a view to estimating the safety level of reused devices.

It generally involves the use of reference organisms which represent the pathogens that are most contagious and difficult to eliminate. Numerous standards exist, allowing users to make the right choices among the range of products available on the market. These standards are based on laboratory tests which demonstrate the efficacy of a disinfectant on a given target.

It is thus essential to be aware of the relevant standards which disinfectants are required to fulfil, and choose the right product according to the intended use.

6.2 Selection of the disinfectant

6.2.1 Legal aspects

There are three statuses for disinfectants (APB[18], 2014). The user should select the disinfectant with the appropriate status for the intended use.

- Medical device (MD): product used for medical purposes, the action of which is not achieved by pharmacological, immunological or metabolic means. Identified by the EC marking logo.
- Biocide: active substances or preparations intended to destroy or repel a harmful organism, render it safe, block its action or counteract it in any other way, via a chemical or biological action. Identified by an authorisation number.
- Medicinal product: product having obtained marketing authorisation. Identified by the product licence number.

MD should be disinfected using a disinfectant having MD status (ANSM[19], 2017).

Surfaces, materials, equipment and furniture should be disinfected using a disinfectant with type 2 biocide status (FPS[20], 2018).

6.2.2 Efficacy

The efficacy of a disinfectant is not only based on its composition. The formulation (active ingredient concentration, excipients, synergism, temperature, etc.) and contact time are very important factors.

[18] APB : *Association pharmaceutique belge* [Belgian Pharmaceutical Association]
[19] ANSM: *Agence nationale de sécurité du médicament et des produits de santé* [National Agency for Medicines and Health Products Safety] (France)
[20] FPS: Federal Public Service Health, Food Chain Safety and Environment

The presence of an active ingredient is not sufficient to guarantee the efficacy of the disinfectant and, conversely, the absence of an active ingredient does not automatically imply the absence of efficacy.
For example, high-level disinfection (action on all microorganisms including spores) can only be achieved by a few active ingredients (Directive 2017/745/EEC, 1993) but not all products containing these active ingredients are high-level disinfectants. Furthermore, some, but not all, high-level disinfectants may act as chemical sterilisation agents (by increasing the concentration and/or contact time) (Directive 2017/745/EEC, 1993).
It is thus necessary to refer to standards (see below) to ensure that the product is effective in the desired indications.

MD intended for disinfection are described in European Directive 2017/745/EEC (1993) as amended by European Directive 2007/47/EC (2007). Annex I to this Directive includes 15 essential requirements to be fulfilled by MD, notably essential requirement 3 which stipulates that the performance claimed by the manufacturer must be achieved.

Biocides are subject to marketing authorisation, which aims to control risks related to the product, its efficacy and toxicity.

The claimed efficacy must be justified by conformity with standards. The activity of these products is evaluated based on European standards NBN EN.
Standard NBN EN 14885 "*Chemical disinfectants and antiseptics. Application of European Standards for chemical disinfectants and antiseptics*" provides an overview of the available standards. The standards are organised in phases then in steps:

- **Phase I**: serves to qualify the product.
  However, phase I tests are not sufficient to justify product claims.
- **Phase II**: serves to validate the conditions of use of the products.
  - Step 1: determination of the concentration and contact time in the presence of interfering substances using suspension techniques.
  - Step 2: determination of the concentration and contact time in the presence of interfering substances using carrier techniques.
- **Phase III**: serves to evaluate the activity of the products under actual conditions of use; however, this level is still in the planning stage. There are currently no standards corresponding to this phase available.

Table 4 shows the standards published to date that apply to disinfectants used for MD (NBN EN 14885, 2015).

Phase - Step	Standard number	Activity	Mandatory (instruments)	Test organism	Contact time	log	Interfering substances
Phase I	NBN EN 1040	Bactericidal	NA*		1 to 60 min	>5log	
	NBN EN 1275	Fungicidal	NA*		5 to 60 min	>4log	
Phase II – step 1	NBN EN 13727	Bactericidal (areas, MD)	Yes	*Staphylococcus aureus* *Pseudomonas aeruginosa* *Enterococcus hirae* *Enterococcus faecium if T> 40°C*	no more than 60 min	≥5log	Albumin/ erythrocytes
	NBN EN 13624	Yeasticidal (areas, MD)	Yes	*Candida albicans*	60 min	≥4log	Albumin/ erythrocytes
	NBN EN 13624	Fungicidal	Yes	*Candida albicans Aspergillus brasiliensis*	60 min	≥4log	Albumin/ erythrocytes
	NBN EN 14476	Virucidal (areas, MD)	Yes	Poliovirus type 1 Adenovirus type 5 Norovirus murin of Parvovirus murin if T°>40°C	60 min	≥4log	Albumin/ erythrocytes
	NBN EN 14348	Mycobactericidal (tuberculocidal) (MD)	Yes	*Mycobacterium avium* and *Mycobacterium terrae*	60 min	≥4log	Albumin/ erythrocytes
Phase II – steo 2	NBN EN 14561	Bactericidal (MD)	Yes	*Staphylococcus aureus* *Pseudomonas aeruginosa* *Enterococcus hirae*	60 min	≥5log	Albumin/ erythrocytes
	NBN EN 14562	Yeasticidal (MD)	Yes	*Candida albicans*	60 min	≥4log	Albumin/ erythrocytes
	NBN EN 14562	Fungicidal	Yes	*Candida albicans* *Aspergillus niger*	60 min	≥4log	Albumin/ erythrocytes
	NBN EN 14563	Mycobactericidal (tuberculocidal) (MD)	Yes	*Mycobacterium avium* and *Mycobacterium terrae*	60 min	≥4log	Albumin/ erythrocytes

NA= not applicable

Table 5: Summary of standards

Type of activity	Phase, step	Disinfection of surfaces Transport and soaking containers		Disinfection of instruments
		Without mechanical action	With mechanical action	
Bactericidal	II,1	NBN EN 13727		NBN EN 13727
	II,2	NBN EN 13697	-	NBN EN 14561
Yeasticidal	II,1	NBN EN 13624		NBN EN 13624
	II,2	NBN EN 13697	-	NBN EN 14562
Fungicide	II,1	NBN EN 13624		NBN EN 13624
	II,2	NBN EN 13697	-	NBN EN 14562
Tuberculocidal	II,1	NBN EN 14348		NBN EN14348
	II,2	-	-	NBN EN 14563
Mycobactericidal	II,1	NBN EN 14348		NBN EN 14348
	II,2	-	-	NBN EN 14563
Virucidal	II,1	NBN EN 14476		NBN EN 14476
	II,2	-	-	-

European standards may not exist for certain special requirements. Reference may then be made to a different standard.

The disinfectant must fulfil the standards corresponding to the desired efficacy. These standards do not always correspond to the conditions in which the products will be used (contact time, etc.). In the absence of efficacy standards under conditions of actual use (phase III), contact the manufacturer for the concentration and contact time able to achieve the results stipulated by the standards [("log") reduction in the microbial population].

Table 5b. Summary of standards for wipes

Type of activity	Phase, step	Disinfection with wipes	
		Mechanical action on non-porous surfaces	Disinfection of MD or surfaces
Bactericidal	II,2	NBN EN 16615	NBN EN 16615
Yeasticidal	II,2	NBN EN 16615	NBN EN 16615

6.2.3 Practical aspects

The choice of disinfectant should, moreover, take into account the practical aspects shown in the table below.

Table 6: Selection of disinfectants for manual disinfection of heat-sensitive MD

Status (MD)	Check the CE marking of the MD and the CE certificate validity date
Indications	Check that the intended use of the MD corresponds to the requirement
Composition	Check for the presence of the active ingredients required and any additional constituents necessary (anticorrosive agents, etc.)
Antimicrobial activity	Check that the claimed spectrum corresponds to high-level disinfection: bactericidal, fungicidal, virucidal, mycobactericidal and sporicidal (based on phase I and phase II EN standards)
Presentation	Check the product characteristics (ready-for-use, concentrate, activator), packaging and labelling
Storage conditions	Check the shelf life and check that the storage conditions are compatible with the conditions of use (temperature, rooms)
Operating method	Check whether activation and/or dilution is necessary; check stability during use and the possible use of reagent strips
Compatibility	Check the compatibility with the MD to be disinfected (tests carried out by the manufacturer or by the manufacturer of the MD to be disinfected)
Toxicity	Check the claimed toxicological risks, and obtain the material safety data sheet
Precautions for use	Check the need for ventilation or a vapour evacuation system
Protection of personnel	Check the type of protection required for personnel (garments, eyes, respiratory)
Measures to be taken in case of exposure	Check the measures to be taken in case of contact with skin, eyes or ingestion
Environmental risk	Check the presence of information on hazard to the environment

All of these properties must be provided by the manufacturer. The user must comply with the manufacturer's recommendations on use.

There are no official lists of disinfectants in Belgium or in Europe. The product manufacturers must provide evidence that the product enables high-level disinfection.

Some examples of high-level disinfectants: According to:
http://multimedia.3m.com/mws/media/465555O/chemical-sterilants-and-high-level-disinfectants.pdf?&COrrrrQ-

https://www.rki.de/DE/Content/Infekt/Krankenhaushygiene/Desinfektionsmittel/Desinfektionsmittellist/Desinfektionsmittelliste_node.html

The FDA has issued a list of recognised high-level disinfectants:
https://www.fda.gov/MedicalDevices/ucm437347.htm

6.2.4 Disinfection of endocavitary probes, the HPV issue

6.2.4.1. Issue

Fairly recently, several studies have highlighted the difficulty of disinfecting endocavitary ultrasound probes. Cross-contamination with HPV is effectively possible.
HR-HPV (High-risk human papillomavirus) is a naked virus, highly resistant in the external environment and to disinfection agents. In the dehydrated state, after 7 days, it is still 30 % infectious (Ma et al., 2012).
70 % of cervical cancer cases are thought to be due to HPV-16 and 18 infection worldwide (Casalegno et al., 2012). These also play a major role in the development of anogenital and oropharyngeal cancer (Ryndock et al., 2016).
Use of a condom or protective sheath on the probe does not guarantee the absence of HPV contamination. A study showed that after removing the sheath, 0.9 % of the probes studied were contaminated. Note that these probes were processed with a low-level disinfectant (quaternary ammonium) (Casalegno et al., 2012). The risk of HPV transmission is reiterated in several studies which observed traces of the viral genome on endocavitary ultrasound probes. However, transmission by an ultrasound probe and infectious potential related to transmission have never been proven (*Haut Conseil de la santé Publique*, 2016).

6.2.4.2. Disinfection

The action of several disinfectants was studied:

- 0.55 % ortho-phthalaldehyde: Inactive (Ryndock et al., 2016; Meyers et al., 2014;
- 2.4 % and 3.4 % glutaraldehyde: Inactive (Meyers et al., 2014);
- alcohol (70 % ethanol, 95 % ethanol, 70 % isopropanol and 95% isopropanol): Inactive (Meyers et al., 2014);
- **35 % hydrogen peroxide: Active:** > 5 log reduction in an automated system, nebulizing the disinfectant (Ryndock et al., 2016);
- **0.525 % hypochlorite: Active:** > 5 log reduction (Meyers et al., 2014;
- **1.2 % peracetic acid + silver ion: Active** > 4.8 log (Meyers et al., 2014).

HPV resistance to alcohol is common to most naked viruses. Their resistance to aldehydes (ortho-phthalaldehyde and glutaraldehyde) is probably due to the specific conformation of their capsid.

In the light of these studies, HPV appears to display sensitivity to oxidising agents (hypochlorite, chlorine dioxide, hydrogen peroxide and peracetic acid) (Meyers et al., 2014). The use of UV-C is also a potential avenue.

According to these findings, given the inefficacy of aldehydes on HPV, there is good reason to evaluate the potential risk of virus transmission during endocavitary examinations.

6.2.4.3. Recommendations

- Before any procedures, the indications should be carefully considered, taking into account **the cost - benefit - risk ratio** arising from the use of an endocavitary probe.
- Strict compliance with **hygiene rules** is essential:
    - It is essential to use a new pair of **gloves** and **hand hygiene**.
    - If a **protective sheath** is used, it must be for single use only. This should display the CE acronym. Note that the sheath should be inspected after the examination to verify its macroscopic integrity and seal (water leak test). Please note that if a defective batch is suspected or detected, this should be reported according to medical device vigilance procedures (FAMHP).
- The choice of probe should take the high-level disinfection techniques into account. A resistant material and totally **smooth** profile is important for adequate disinfection.
- Use of a high-level disinfectant after each use of the probe is mandatory (Casalegno et al., 2012).
- Use of a high-level oxidising disinfectant is recommended (hypochlorite, chlorine dioxide, hydrogen peroxide or peracetic acid). Note that the number of studies is too limited to recommend a specific disinfection method, at this stage. Furthermore, Polyomavirus SV40 used in order to carry out the tests described in the standard (Table 4) does not appear to be representative of HPV sensitivity. The products are notably tested on reference non-enveloped viruses, but not specifically on HPV.

6.2.5 Biofilm

6.2.5.1. Definition

A biofilm is a community of microorganisms which stick together, and also to a surface, characterised by the secretion of an adhesive, protective matrix. Due to specific phenotypic expression, the microorganisms are more resistant to external conditions. This is a natural behaviour observed in colonisation and adaptation to a hostile environment.

6.2.5.2. Issue

A biofilm is naturally more resistant to disinfectants. As the biofilm allows massive release of microorganisms in favourable external conditions, it gives rise to numerous infections.

It is thus essential to destroy biofilms and/or prevent their development.

6.2.5.3. Principles

Formation of a biofilm first requires the presence of an organic deposit on the MD. This organic deposit is colonized by the first microorganisms, which then stick together. At this stage, the deposit can be easily eliminated using a simple cleaning procedure as adhesion is still minimal. It takes several hours for a mature biofilm to form. It then becomes harder to eliminate. Moisture is essential to biofilm development.

6.2.5.4. Precautions

The **time factor** is vital, given the length of time necessary for a mature biofilm to become established.
Drying is also essential since a certain amount of moisture is necessary for a biofilm to develop (NOSO Info, 2018; Siala et al., 2017; Roberts, 2013).

6.3 Recommended products according to the type of reprocessing for MD

6.3.1 Detergent-disinfectant products for pre-disinfection and cleaning by immersion of MD

A detergent product may be used alone during the pre-cleaning phase (for example, enzymatic detergents); however, no specific standards exist concerning their use for reprocessing MD.

Objectives:

- elimination of soiling, in order to:
  - eliminate interfering substances with disinfection;
  - avoid biofilm development;
- reduction in bacterial load, for superior final disinfection;
- protection of personnel.

Detergent-disinfectant product

Products with both detergent and disinfectant properties. These products dissolve soiling in water (detergent action) and reduce the defined microbial contamination (disinfectant action) in a single operation. Pre-disinfection and the cleanness of the processed material determine its adequate final disinfection and safeguard intermediate handling (protection of personnel).

The detergent-disinfectant product is to be selected based on the type of material used, its intended use and, therefore, the nature of contamination, and any subsequent processing in order to avoid any incompatibilities.

Preference will be given to the use of enzymatic compounds, owing to their effective detergent action and their safety-in-use (compared to alkaline detergents).

Detergent-disinfectant products are MD accessories and EC marking is mandatory (European Directive 2017/745/EEC).

Precautions for use

Cleaning and pre-disinfection must take place as soon as possible after use of the MD. Ideally within half an hour after use. This is to avoid the possible build-up of soiling residue.

The solution is replaced after each use.

A timer should be used to allow the appropriate contact time with the disinfectant.

The water temperature should be checked to allow the detergent-disinfectant product to be effective. This should comply with the manufacturer's recommendations.

The water quality should be stipulated by the manufacturer and at least correspond to water intended for human consumption. Note that water hardness may interfere with the detergent activity.

6.3.2 Disinfectants used for disinfection of heat-sensitive endoscopes in an endoscope washer-disinfector

Standard NBN EN ISO 15883-4 acknowledges that national regulations for disinfectants may be applied once they cover the minimum requirements of the standard.
The spectrum of activity of the disinfectant should be adapted to the intended use of the endoscope. Disinfection efficacy tests using a substitute device, under the minimum conditions permitted (time, temperature and concentration), should achieve inactivation of at least:

- 6 log10 units of the vegetative bacterial population, including yeasts and yeast-like fungi;
- 5 log10 units of mycobacteria;
- 4 log10 of fungus spores and viruses;
- 6 log10 units of aerobic and anaerobic bacterial endospores, but with a contact time of 5 hours.

The manufacturer of the endoscope washer-disinfector states which disinfectants may be used, based on standard tests.
Note that the CE certification of the endoscope washer-disinfector was based on one (or more) disinfectant(s). Use of this endoscope washer-disinfector thus requires the specific use of one (or more) disinfectant(s).

Water fit for human consumption should be used for final rinsing, after disinfection (section 3.2.4.).

6.3.3 Disinfectants for manual disinfection of heat-sensitive MD

The disinfectants used for disinfection of the MD are MD accessories and EC marking is therefore mandatory for marketing, according to European Directive 2017/745/EEC.

High-level disinfection may be performed by soaking or cleaning with soaked wipes. Application standards are required for disinfectants used for MD (Table 5) in both cases.

A specific standard (NBN EN 16615, phase II standard, step 2) applies to products used for disinfection by cleaning with wipes soaked in disinfectant solution. This is in addition to the standards concerning the spectrum of activity for the products used.

Compliance with the operating method drawn up by the manufacturer is essential in order to achieve the claimed efficacy.

These disinfectants are used on instruments which have been previously cleaned and rinsed, and their activity should be tested under clean conditions.

6.3.4 Other non-critical non-endoscopic materials (e.g.: materials reserved for rinsing/soaking/transport)

Materials used for soaking, rinsing and transport correspond to the definition of non-critical materials and should therefore be disinfected using chemical disinfectants enabling low-level disinfection. According to its status as medical equipment, it should be disinfected using type 2 biocides.

This equipment does not fall within the scope of the definition of a MD. Nonetheless, in the event of thermal disinfection in a machine, the text of standard NBN EN ISO 15883-6 which defines the minimum temperature values for thermal disinfection of non-critical MD should be used as a basis. This standard recommends an A_0[21] value of at least 60 during the disinfection plateau in the endoscope washer-disinfector (SHC 9256, 2017).

[21] "A" is defined as the equivalent duration in seconds at 80°C for achieving a given disinfection effect. When the stipulated temperature is 80°C and the Z value is 10°C, the term "A_0" is used.

$$A_o = 10^{\frac{(T-80)}{Z}} * \Delta t$$

Z = 10°C (thermal destruction factor);
T = temperature observed;
Δt = measuring time interval.

7. QUALITY MANAGEMENT SYSTEMS

7.1 Introduction

In order to guarantee patient safety at all times and at every level, the following steps should be taken into account:

1. Validation: The working method should be defined. By doing so, the requirements relating to the structure, process and result should be fulfilled. Validation of the equipment and (laboratory) methods, along with the traceability of the different steps to be followed are essential. The final result should correspond to the expected result.

2. Audit: After recording and implementing the process, checks should be carried out to determine whether the working method has been followed. This may take place via an audit in which the structure, process and indicators for the result are taken into account.

3. Control tests: The process or structure may be adjusted in order to obtain a better result, based on microbiological control tests on endocavitary MD and the final rinsing water from the endoscope washer-disinfectors, together with the analysis of any possible incidents (infection related to the endocavitary MD).

In private practice, the responsible persons themselves should guarantee the quality and control of the heat-sensitive endocavitary MD.

7.2 Validation

Validation involves the verification, recording and interpretation of the results of the tests performed, which guarantee that the process remains within the pre-defined limits and yields a product which meets the requirements (disinfected, sterile, etc.).

To summarise, validation of the equipment consists of: installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ).
For each of these steps, the manufacturer must have drawn up a test protocol in keeping with the existing standards.

The following elements are generally found in the different sections:

- IQ: it is properly connected according to the manufacturer's specifications;
- OQ: it functions properly;
- PQ: the expected quality level is achieved.

PQ should be carried out by a third party, unlike IQ and OQ, which may be carried out by the manufacturer or installation engineer.

These three qualification are performed before an equipment item is commissioned. Routine tests are subsequently carried out in order to guarantee consistent product quality. The routine tests should be selected based on the tests used for the PQ.

The nature and frequency of these tests should be described in a validated, justified procedure, in keeping with current standards.
Annual revalidation and periodic tests are included in the routine tests (section 7.4.).
Furthermore, the equipment should be maintained in keeping with a preventive maintenance plan defined by the manufacturer.

7.2.1. Validation of endoscope washer-disinfectors

A validation plan should be introduced for all automated washing and disinfection processes. The minimum requirements recommended by the SHC include validation at installation, annual maintenance and quarterly control of the final rinsing water of the endoscope washer-disinfector.

Validation plan			
At installation			
Objective	**Description:**	**Frequency**	**Responsible person**
IQ	Determines that the machine is ready to operate	1	Manufacturer
OQ	Determines that the machine is functional	1	Manufacturer
PQ	Determines that the machine is able to reach its operational objectives	1	User/qualified external company
Routine			
Objective	**Description:**	**Recommended frequency**	**Responsible person**
Water quality	Analysis of final rinsing water➔ <10 CFU/100 ml and absence of HRMO	4x/year	User/qualified external company

Other control tests are described in standard NBN EN ISO 15883 and may be performed in addition to the validation plan. The frequency of these tests is determined based on the reliability of installation, the risk analysis, together with the results of the control tests on the endoscopes.

Objective	**Description:**
Detergent and disinfectant dosing	Dosing of all products
Cleaning efficacy	Evaluation of the washing result, using a soiled substitute device
Disinfection efficacy	Evaluation of the level of disinfection using a contaminated substitute device
Temperature determination	Evaluation of temperature throughout the process
Defective seal/obstruction/non-connection	Evaluation of seal, detection system for an obstructed channel or defective connection*

* these tests are performed if the endoscope washer-disinfector comprises a detection system for this type of defect.

7.2.2 Validation of drying cabinets

As is the case for endoscope washer-disinfectors, upon installation of the drying cabinets, a validation plan must be introduced for storage in a controlled atmosphere.
The minimum requirements recommended by the SHC include validation at installation, annual maintenance and filter replacement according to the manufacturer's instructions.

Validation plan			
At installation			
Objective	**Description:**	**Frequency**	**Responsible person**
IQ	Determines that the machine is ready to operate	1	Manufacturer
OQ	Determines that the machine is functional	1	Manufacturer
PQ	Determines that the machine is able to reach its operational objectives	1	User/qualified external company

Other control tests are described in standard NBN EN 16442 and may be performed in addition to the validation plan. The frequency of these tests is determined based on the reliability of installation, the risk analysis, together with the results of the control tests on the endoscopes.

Objective	**Description:**
Moisture content	Measurement of relative humidity in the chamber
Oil content (where appropriate)	Determination of the oil content in compressed air (<0.1 mg/m³) (if compressed medical air is used)
Particle testing	Particulate purity level (ISO 14644-1 class 8) + air filtration system test (as per ISO 14644-3)

7.3 Audit

Compliance with the procedures in place is verified as part of an audit. Its objective is to identify and resolve any discrepancies.

These discrepancies may be due to:

- insufficient knowledge;
- lack of resources;
- deliberate deviations from the agreed process steps.

The audit framework is not static. Implementation of the process will be followed by verification of the main steps defined (e.g. availability of the necessary resources). A more in-depth approach will be possible at a later stage, once these steps become firmly established practices (e.g. correct brushing of a channel). Hence, it will only be possible to compare the results of the different phases of the audit over an extended period, while the audit itself becomes an instrument for continuous improvement.

The frequency of audits should also be adapted over time. When these audits are initially performed on a weekly or monthly basis, they may gradually be extended to an annual basis where necessary. Initially, the audits will mainly result in adjustments based on practical factors (e.g. change in flow for more effective operations, etc.). Once the process has been developed, their frequency will depend more on the stability of the group of personnel involved (knowledge).

Furthermore, an audit should not be a “control test”. It is rather an observation process in which the auditor and the monitored entity enter into a dialogue, jointly identify and rectify any discrepancies, while drawing up an action plan.

Appendix 2 shows a few examples of critical points which are worth auditing. Each healthcare facility or private clinic may select the most relevant items.

An audit should preferably be performed unexpectedly, in order to evaluate daily practice. Certain aspects may be observed at any time (for example, the equipment present), whereas this may not always be possible for other aspects (for example, the different steps in the manual cleaning process for the endoscope). The audit may be performed based on questions, for these aspects.

An audit notably makes it possible to check that:

- The cleaning and disinfection procedure for endoscopic equipment is correctly followed in its entirety (e.g. appropriate products, correct concentration, adequate contact time, compliance with the different steps, etc.).
- The drying and storage procedure for the endoscopic equipment is correctly followed in its entirety.
- The products are replaced at the appropriate interval.
- Records are kept and traceability is possible.

In private practice, the practitioner is responsible for implementing and complying with procedures.

7.4 Microbiological control tests

- The conditions for the sampling procedures and interpretation of the results of microbiological control tests are stated in a document. In healthcare facilities, this document is approved by the Hospital Hygiene Committee.
- A sampling plan is defined for bacteriological control tests (routine, validation of the equipment, suspected transmission of iatrogenic infection).
- A register containing the previous culture results may be consulted in the endoscopy department.
- Instructions in the event of out-of-specification results are available in the endoscopy department.

At the time of publication of this document, there are limited established scientific arguments warranting routine microbiological control tests on endoscopes with a channel, as an indicator for the results. Furthermore, the criteria for interpretation of the microbiological control tests on the final rinsing water of the endoscope washer-disinfectors and endoscopes are still arbitrary. As regards endocavitary MD without a channel, microbiological control tests, other than for documentation of an epidemic phenomenon, do not appear to be indicated.

Nevertheless, the following microbiological control tests may be recommended:

- Rinsing water of endoscope washer-disinfectors: sampling as a part of validation at the time of acquisition, after repairs and after a major change to the procedure and, periodically, to verify the results.
- Endoscopes: If the transmission of infection is suspected in connection with the endoscopes. This takes place in addition to the introduction of a rotation system where samples are taken on an annual basis from at least each high-risk endoscope.

When this takes place, it should be noted that:

- Microbiological control tests may be perceived as additional control tests for the whole process. Technical inspection of the endoscope washer-disinfectors and control of the entire disinfection process are essential.
- Agreements are reached beforehand as part of a procedure relating to sampling frequency, the interpretation criteria and action plan in case of out-of-specification results. The endoscopy department managers, hospital hygiene personnel and disinfection process coordinator sign these agreements. The procedure is approved by the Hospital Hygiene Committee.
- Microbiological control tests are always conducted in agreement with the competent laboratory.
- Sampling is carried out by endoscopy and/or hospital hygiene personnel.
- This process should take place under aseptic conditions in order to avoid contamination of the sample and endoscope by microorganisms originating from the environment or personnel. After sampling, the endoscopes are disinfected once again and, where appropriate, dried if not used immediately.
- The endoscopes should be sampled in a clean zone of the endoscope processing room.

The coordinator (section 3.3.) interprets the results and defines the action plan as described in the institutional procedures.

7.4.1 Endoscope washer-disinfector using the final rinsing water

7.4.1.1. Frequency

The microbiological quality of **the final rinsing water** is verified:

- after installing or moving an endoscope washer-disinfector;
- at intervals of 3 months;
- once after repair and maintenance;
- once after a substantial amendment to the procedure (e.g.: change in disinfectant).

The endoscope washer-disinfector can operate pending the microbiological results.

7.4.1.2. Method

- Take a sample of the final rinsing water. Sample at least 2 x 100 mL of the final rinsing water, using a sterile syringe, and transfer the water to two sterile containers.

- Follow the sampling protocol provided by the manufacturer of the endoscope washer-disinfector.
- If a disinfectant is added to the final rinsing water in the endoscope washer-disinfector, add a neutraliser to the sample immediately after taking the sample. The manufacturer of the endoscope washer-disinfector may state the appropriate neutraliser.
- The rinsing water is concentrated in order to increase sensitivity. Mechanical membrane filtration should be performed for this purpose (filtration under vacuum, through a 0.22-0.45-µm filter). Centrifuging is an alternative method (FDA, 2018).
- Use of an enrichment medium is not required in routine practice as this causes unnecessary delays. However, it may be envisaged in the event of suspected contamination with a microorganism which is difficult to culture.
- The ideal culture conditions depend on the type of microorganism detected:
  - Intestinal bacteria multiply at a temperature of 30-35 °C, on blood agar, for two days;
  - Water bacteria or yeasts/moulds multiply at a temperature of 20-25 °C, in an appropriate medium (R2A, for instance), for five days.
    (NBN EN ISO 14698-1; FDA, 2001; FDA, 2004; Clontz, 2009).

7.4.2 Heat-sensitive endocavitary MD with a channel

7.4.2.1. Frequency of microbiological control tests

- If there are clinical or epidemiological indications for endoscope-related infections, microbiological control tests should be carried out on the endoscopes. In the above-mentioned situations, a sample should also be taken from the endoscope washer-disinfectors.
- When a technical problem concerning an endoscope washer-disinfector is suspected, and if the problem persists despite implementing the action plan, a sample should also be taken from the endoscopes.
- Routine microbiological control of the endoscopes may be considered as an additional control test for the overall process. A rotation system may be introduced, with samples being taken at least once a year from all high-risk endoscopes (Table 1). However, there is currently no scientific consensus for routine sampling of all other endoscopes at a given frequency. High-risk endoscopes may, to a certain extent, be used as an indicator for the microbiological quality of the other types of endoscopes since they are harder to clean owing to their more complex design and therefore more prone to technical problems. If there are several decentralised disinfection units, the procedure should be extended to include annual sampling and to incorporate all disinfection units and all types of endoscopes in a rotation system.
- When high-risk endoscopes are re-commissioned after repair, samples should be taken after the reprocessing procedure.
- When a **loaned** high-risk endoscope is commissioned, the supplier provides a cleaning and disinfection certificate. Samples should be taken after the reprocessing procedure (cf.https://www.infectiepreventieopleidingen.nl/downloads/SFERD_Kwaliteitshandboek_5.pdf on p.32 “Stap 14”). However, the endoscope can be used while waiting for the results.

7.4.2.2. Method.

A sample is taken from the endoscopes after a full washing, drying and storage process is performed.

Channels

- The timing of biological control tests should be determined based on the purpose of the culture. The most critical time for taking culture samples is after the end of the shelf life.
- Two operators are necessary when taking a sample from an endoscope. These two operators should disinfect their hands before starting the sampling procedure and should work under aseptic conditions.
- Place the endoscope on a disinfected surface or on a sterile field.
- Rinse each channel with at least 20 mL of sterile liquid, such as normal saline solution, PBS[22] or water. Collect all of the rinsing liquid from the channels in a single sterile container. In the event of a positive result, the procedure should be repeated using one container per channel, in order to detect the source of the problem.
- If necessary, use suitable sterile connectors to attach the syringe to the channel. Follow the endoscope manufacturer's instructions.
- Taking a sample from the biopsy/aspiration channel: rinsing and brushing/rinsing may be more effective than simply rinsing a channel. This should be envisaged when taking a sample from the biopsy/aspiration channel. After rinsing with half of the rinsing volume, the biopsy/aspiration channel is scrubbed using a sterile single-use brush, then rinsed again with the remaining volume. All of the rinsing liquid and the trimmed brush are collected in a single sterile container (Cattoir et al., 2017). Rinsing with water is always followed by flushing with air using the same syringe, in order to collect all of the rinsing water.
- Taking a sample from a duodenoscope
  - Use of a rinsing kit makes it easier to take samples from the intact channels.
  - Lift and lower the elevator when rinsing the elevator channel.
  - Also take a sample from the distal end of the elevator channel, using a very fine brush (elevator brush), in front and behind the elevator. To do so, lift and lower the elevator. Also place this small brush in the same sterile container.
- Take the sample to the laboratory as soon as possible after sampling.
- Vortex the sample for 10 to 20 seconds (rinsing water and brushes). The rinsing water is then concentrated by filtration on a mechanical membrane to increase sensitivity. Since a specific intestinal flora is investigated, simply incubate the filter on blood agar for two days, at 30-35 °C.
- If the results are positive, they should be expressed as CFU relative to the filtered volume and the endoscopes should be placed in quarantine.

7.4.3 Heat-sensitive endoscopes without a channel

As regards endocavitary MD without a channel, microbiological control tests, other than for documentation of an epidemic phenomenon, do not appear to be recommended.

[22] PBS: phosphate buffered saline

7.4.4 Interpretation of results

7.4.4.1. General observations

Both the microorganisms and the total number of microorganisms and type of endoscope are important. All microorganisms should therefore be identified down to the species.

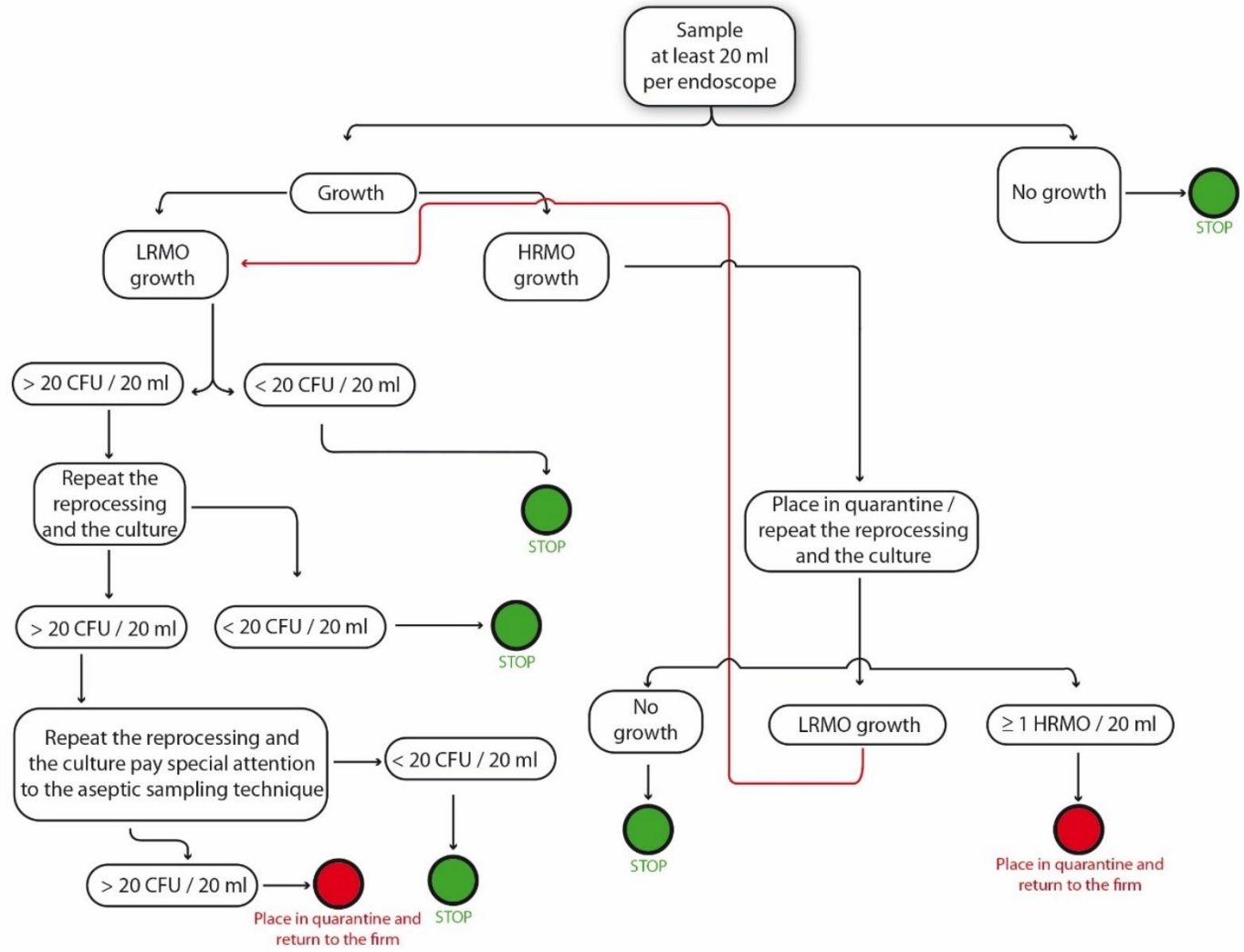
The microorganisms concerned are subdivided into low-risk microorganisms (LRMO) and high-risk microorganisms (HRMO) according to their most likely origin. HRMO usually originate from the patients themselves whereas LRMO originate from the environment (water) or may result from handling after the disinfection procedure (skin). The presence of HRMO is an indicator of a flaw in the cleaning and disinfection process. If present, the disinfection procedure should be tested in its entirety.

Table 7: Type of low- and high-risk microorganisms

LRMO (low risk): skin and water microorganisms	**HRMO (high risk): oral and intestinal flora**
Coagulase-negative *Staphylococci*	*Enterobacteriaceae*
Bacillus species	Enterococci
Micrococcus species	*Staphylococcus aureus*
Corynebacterium species	Yeasts
Pseudomonas species others than P. aeruginosa	*Pseudomonas aeruginosa*
Stenotrophomonas maltophilia	*Acinetobacter spec*ies
	Streptococcus viridans

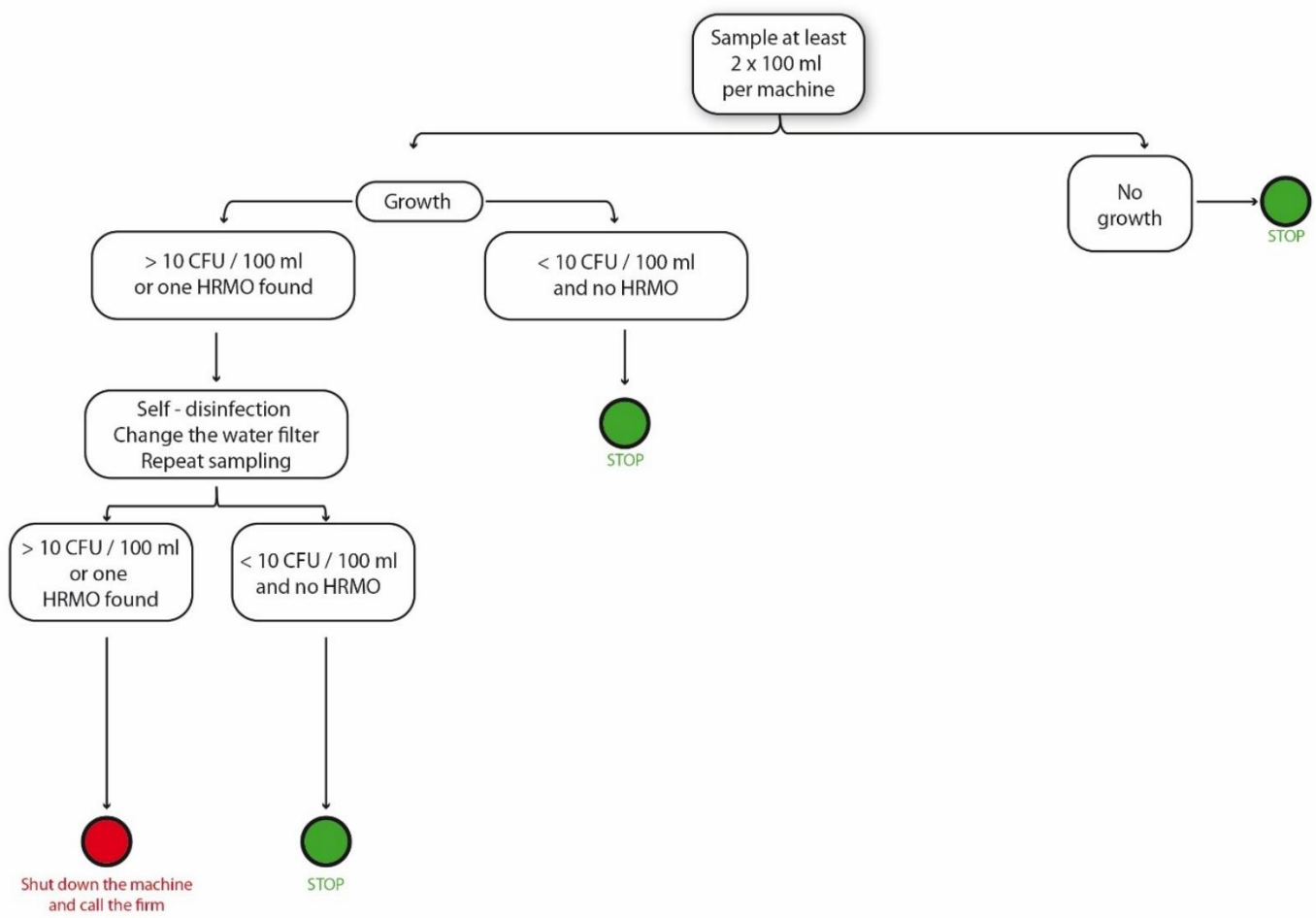
A culture of aerobic mesophilic bacteria is first prepared.

Figure 4: Action to be taken based on the results of microbiological control tests on high-risk endoscopes



Endoscopes placed in quarantine should be checked by the company. Intraluminal cameras exist, which are able to visualise biofilms/defects in various endoscope channels. The endoscope washer-disinfector should be tested.

Figure 5: Action to be taken based on the results of microbiological control tests on the final rinsing water of endoscope washer-disinfectors



7.4.4.2. Reference values

There are currently no univocal acceptance criteria for taking microbiological samples. Furthermore, the sampling technique has an influence on the culture result. As a general rule, HRMO should be absent.

:

- Channel rinsing water:
  - < 20 CFU per 20 mL
  - No HRMO.

- Cultures of the final rinsing water:
  - < 10 CFU per 100 mL
  - No HRMO.

7.4.4.3. Interpretation and action

Table 8: Interpretation and recommended action depending on the microorganism concerned.

Micro-organism	**Interpretation**	**Action**
E. coli, Enterococci, other *Enterobacteriaceae* Yeasts	Inadequate cleaning or disinfection (channels not brushed, inadequate product concentration or contact time, etc.) • Mechanical or electronic defects affecting the endoscope washer-disinfector • Equipment design errors with stagnant water	• Control of the disinfection procedure, with emphasis placed on cleaning • Full control of the equipment
P. aeruginosa and other Gram-negative non-fermenters (atypical Mycobacteria, *Legionella)*	• Inadequate rinsing • Contamination of rinsing water • Contamination of the endoscope washer-disinfector due to a mechanical or electronic failure • Contamination of the filtration system • Equipment design errors with stagnant water • Inadequate drying prior to storage	Control of the water inlet and rinsing procedure • Water quality • Manual or machine rinsing • Full control of the machine Self-disinfection cycle Control of the drying and ventilation procedure in the storage premises
S. aureus Coagulase-negative *Staphylococci* *Corynebacterium species,* *Micrococcus species*	Re-contamination of endoscopes due to • Incorrect storage or transport • Inadequate hand hygiene Contamination during sampling	Control of storage, transport and manual handling procedures Repeat sampling

7.5 Epidemiological investigation in the event of infections related to endoscopy

Iatrogenic infections related to endoscopy - other than those due to self-infection (for example, retrograde cholangiography) - are mostly due to noncompliance with national and international directives on the subject. Isolated audits on the correct application of procedures in daily practice may prevent the risk of transmission.
If infections possibly related to an endoscopy procedure nonetheless develop, a thorough epidemiological investigation should then be initiated. This takes place jointly with the *Hospital Hygiene Team* and microbiology laboratory.

Detection of an unusual number of cases of infection or colonisation (increased incidence, clusters of cases, type of microorganism, etc.) apparently related to endoscopy should be reported to the endoscopy department and must be recorded. This again involves close cooperation between the microbiology laboratory, hospital hygiene team, coordinating expert and endoscopy department managers.

If several clustered cases occur and an epidemic is suspected, an active investigation for the different contamination sources or reservoirs must be carried out. This includes the following aspects at the very least:

- microbiological control tests on the endoscopes (all channels, internal and external surfaces and the wash bottle) and ancillary materials (biopsy forceps, etc.);
- control tests on the endoscope washer-disinfectors (microbiological control tests on the final rinsing water, verification of filters, periodic self-disinfection according to the manufacturer's instructions);
- microbiological control tests on the supply water;
- verification of any external filters.

In the event of an epidemic, the endoscopes/equipment concerned are taken out of use (placed in quarantine) until the microbiological tests and/or compliance with the process steps once again guarantee safety-in-use.
The absence of abnormalities or defects in the equipment or ancillary materials should be verified.

If an epidemic is suspected or clearly documented, it is important to promptly draw up an exhaustive list of exposed patients and rapidly determine whether or not it is necessary to recall the patients for evaluation and work-up for infection according to the risk analysis. In the majority of cases, the nature (genus/species) of the microorganisms concerned may offer guidance on the iatrogenic nature of transmission (e.g.: *Pseudomonas aeruginosa, Acinetobacter baumannii*) and possibly on the contamination source or reservoir.

7.6 Traceability

The traceability of the examination procedures, patients and operators handling the equipment, together with the disinfection, drying and storage procedures for the equipment should be guaranteed in order to determine the source of contamination in the event of infection. Hence, it should be possible to trace the endoscope used for a given patient, the operator who used it, the endoscope washer-disinfector in which the endoscope was cleaned and disinfected, and the drying cabinet where it was placed.

Manual or (preferably) automated recording of each cleaning, disinfection and storage procedure should be kept up to date and comprise the following information at the very least:

- identification of the endoscope and accessories;
- patient data;
- identification of operators having carried out the different partial procedures,
- batch number of the products used;
- microbiological culture results;
- any problems, their analysis, and action taken.

Each healthcare facility or private practice must have a data archiving procedure. These records should be available at all times and easily accessible. In compliance with the legislation relating to medical records and in accordance with Art. 46 of the Code of Medical Ethics, patient data are stored for 30 years. However, it is important to note that, according to the publication "*Archives des hôpitaux*" (Bodart & Devolder, 2012), data relating to sterilisation only need to be stored for 10 years. Nothing is specifically mentioned with regard to the disinfection of endoscopes. It is up to each institution to decide whether the data relating to the sterilisation/disinfection processes should be considered an integral part of the medical records.

The following data are therefore collected for each procedure:
Endoscopy itself:

- patient data;
- date and time of the procedure;
- identification of personnel assisting the specialist and carrying out pre-disinfection,
- identification of the specialist having carried out the procedure;
- endoscope identification number.

Transfer of the endoscope to the endoscope washer-disinfector:

- patient data;
- date of the procedure;
- identification of the operator having carried out the procedure;
- endoscope identification number;
- endoscope washer-disinfector identification number.

Release of the endoscope.

8. RELEVANT LITERATURE AND REFERENCES

8.1 References

- ACIPC – Australasian College for Infection prevention and control. ASEM - Australasian Society for Ultrasound in Medicine. Guidelines for Reprocessing Ultrasound Transducers AJUM; 2017.
- Alfa MJ. Intra-cavitary ultrasound probes: cleaning and high-level disinfection are necessary for both the probe head and handle to reduce the risk of infection transmission. Infect Control Hosp Epidemiol 2015;36(5):585-6.
- Alfa MJ and Sitter DL. In-hospital evaluation of contamination of duodenoscopes: a quantitative assessment of the effect of drying, J Hosp Infect, 1991, 19:89-98.
- Alvarado CJ, Anderson AG, Maki DG. Microbiologic assessment of disposable sterile endoscopic sheaths to replace high-level disinfection in reprocessing: a prospective clinical trial with nasopharyngoscopes. Am J Infect Control 2009;37(5):408-13.
- ANSM – Agence nationale de sécurité du médicament et des produits de santé. Désinfection des services d'endoscopie. 2017 http://ansm.sante.fr/Activites/Desinfection-des-dispositifs-medicaux-et-des-locaux-de-soins/Produits-desinfectants-utilises-dans-le-secteur-medical/Desinfection-des-services-d-endoscopie.
- APB - Association pharmaceutique belge - Centre d'Information Pharmaceutique – juin 2014.
- ASGE – American Society for Gastrointestinal Endoscopy. ASGE guideline for infection control during GI endoscopy; Gastrointest Endosc 2018;87:1167-1179.
- Beilenhoff U, Biering H, Blum R, Brijak J, Cimbro M, Dumonceau J-M et al. Prevention of multidrug-resistant infections from contaminated duodenoscopes: Position statement of the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA). Endoscopy 2017;49:1098-1106.
- Bloc S, Mercadal L, Garnier T, Komly B, Leclerc P, Morel B et al. Evaluation of a new disinfection method for ultrasound probes used for regional anesthesia: ultraviolet C light. J Ultrasound Med 2011;30(6):785-8.
- Bodart E & Devolder K. Archives des hôpitaux. Tableau de tri. 2012. Archives générales du royaume et archives de l'état dans les provinces. http://www.arch.be/docs/surv-toe/TT-SL/local_lokaal/hopitaux_ziekenhuizen/Archives_hospitalieres_TT_2012_DEF.pdf
- Casalegno JS, Le Bail Carval K, Eibach D, Valdeyron ML, Lamblin G, Jacquemoud H et al. High risk HPV Contamination of endocavity vaginal ultrasound probes: An underestimated route of nosocomial infection ? Plos one October 2012;7 (10) e48137.
- Cattoir I, Vanzieleghem T, Florin L, Helleputte T, De Vos M, Verhasselt B et al. Surveillance of endoscopes: comparison of different sampling techniques. Infect Control Hosp Epidemiol 2017;38:1062–1069.
- CDC – Centers for Disease Control and Prevention. Department of Health and Human Services Centers for Disease Control and Prevention. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings; 2007.
- CDC – Centers for Disease Control and Prevention. Guideline for disinfection and sterilization in health facilities; 2008.
- Clontz EP, Hoffmann KK, Rutala WA, Weber DJ. Statewide Program for Infection Control and Epidemiology spreads computer virus. Infect Control Hosp Epidemiol. 1998 Oct;19(10):737-8.

- CSS – Conseil Supérieur de la Santé. Recommandations pour la prévention de la transmission des encéphalopathies spongiformes transmissibles (Maladie de Creutzfeldt-Jakob) en milieu hospitalier. Bruxelles: CSH ; 2006. Avis 7276-2.
- CSS – Conseil Supérieur de la Santé. Recommandations en matière d'entretien du matériel endoscopique flexible thermosensible et de prévention des infections. Bruxelles: CSS; 2010. Avis n° 8355.
- CSS – Conseil Supérieur de la Santé. Recommandations relatives à la prévention de la tuberculose. Bruxelles: CSS; 2013. Avis n° 8579.
- CSS - Conseil Supérieur de la Santé. Bonnes pratiques en matière de stérilisation de dispositifs médicaux. Bruxelles: - *Good practices for the sterilisation of medical devices* CSS; 2017. Avis n° 9256.
- CSS – Conseil Supérieur de la Santé. Recommandations en matière de prévention, maîtrise et prise en charge des patients porteurs de bactéries multi-résistantes aux antibiotiques (MDRO) dans les institutions de soins. Bruxelles: CSS; 2019. Avis n° 9277.
- CSS – Conseil Supérieur de la Santé. Les recommandations en matière de prévention, maîtrise et prise en charge des infections dues à *Clostridium difficile* dans les institutions de soins. Bruxelles: CSS ; 2017. Avis n°9345.
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices; 1993.
- Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
- Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.
- FDA - Food and Drug Administration. Bacteriological Analytical Manual. 2001, 2004.
- FDA - Food and Drug Administration -cleared sterilants and high level disinfectants with general claims for processing reusable medical and dental devices. 2015 - https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm437347.htm.
- FDA/CDC/ASM - Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and American Society for Microbiology (ASM). Duodenoscope Surveillance Sampling and Culturing Protocols. Reducing the risks of infection. 2018. https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/UCM597949.pdf.
- FPS – Federal public service – Health, food chain safety and environment. Biocides. Belgium. 2018. https://www.health.belgium.be/en/environment/chemical-substances/biocides
- Hajjar J. Protection et entretien des sondes d'échographie endocavitaire. 2016.
- HCSP - Haut Conseil de la Santé Publique. Avis relatif à la désinfection des sondes à échographie endocavitaire (SEE). 2016.
- ISO 4074. Natural rubber latex male condoms — Requirements and test methods. 2015.
- ISO 14698-1. Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and methods; 2003.
- ISO 15883-4. Washer-disinfectors -- Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2008). 2008.

- ISO 15883-6. Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment 2011.
- Kac G, Gueneret M, Rodi A, Abergel E, Grataloup C, Denarie N et al. Evaluation of a new disinfection procedure for ultrasound probes using ultraviolet light. J Hosp Infect 2007;65(2):163-8.
- Kac G, Podglajen I, Si-Mohamed A, Rodi A, Grataloup C, Meyer G. Evaluation of ultraviolet C for disinfection of endocavitary ultrasound transducers persistently contaminated despite probe covers. Infect Control Hosp Epidemiol 2010;31(2):165-70.
- Kim S and Muthusamy VR. Current practice of duodenoscope reprocessing. Curr Gastroenterol Rep 2016;18:54-61.
- Kingdom of Belgium. Royal Decree of 18 March 1999 on medical devices. Belgian Official Gazette of 14 April 1999, No. 1999022270, p. 12105.
- Kovaleva J, Degener JE, van der Mei HC. Mimicking disinfection and drying of biofilms in contaminated endoscopes. J Hosp Infect 2010,76(4):345-50.
- Leroy S. Infectious risk of endovaginal and transrectal ultrasonography: systematic review and meta-analysis. J Hosp Infect 2013;83(2):99-106.
- Ma STC, Yeung AC, Sheung Chan PK, Graham CA. Transvaginal ultrasound probe contamination by the human papillomavirus in the emergency department. Emerg Med J 2012. doi:10.1136/emermed-2012-201407.
- Meyers J, Ryndock E, Conway MJ, Meyers C, Robison R. Susceptibility of high-risk human papillomavirus type 16 to clinical disinfectants. J Antimicrob Chemother 2014;69(6):1546-50.
- Meyers C, Milici J, Robison R. UVC radiation as an effective disinfectant method to inactivate human papillomaviruses. PLoS One 2017;12(10):e0187377.
- Muthusamy VR. Enhanced reprocessing of duodenoscopes: is doing more better? Gastroenterology 2017;153:892-894.
- NBN – Bureau of standardisation. NBN EN 14885. Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics. Brussel ; 2015.
- NBN – Bureau of standardisation. NEN-EN-ISO 15883-1: Washer-disinfectors - Part 1: General requirements, terms and definitions and tests.
- NBN – Bureau de standardisation. NBN EN ISO 16442. Controlled environment storage cabinet for processed thermolabileendoscopes. 2015.
- NBN – Bureau de standardisation. NBN EN 16615.Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) - Test method and requirements (phase 2, step 2). 2015.
- Ngu A, McNally G, Patel D, Gorgis V, Leroy S, Burdach J. Reducing transmission risk through high-level disinfection of transvaginal ultrasound transducer handles. Infect Control Hosp Epidemiol 2015;36(5):581-4.
- NOSO INFO – Bulletin pour la prévention et la maîtrise des infections associées aux soins. Les biofilms en milieu hospitalier : quels sont les enjeux pour l'hygiène hospitalière ? 2018;12:4. http://www.nosoinfo.be/nosoinfos/les-biofilms-en-milieu-hospitalier-quels-sont-les-enjeux-pour-lhygiene-hospitaliere/?ref=r418.
- NRZV - Nationale raad voor Ziekenhuisvoorzieningen - afdeling "Programmatie en erkenning", Advies betreffende de centrale sterilisatie, Brussel 2013, NRZV/D/430-3.
- Nyhsen CM, Humphreys H, Koerner RJ, Grenier N, Brady A, Sidhu P et al. Infection prevention and control in ultrasound – best practice recommendations from the

European Society of Radiology Ultrasound Working Group. Insights Imaging 2017. 8:523–535.
- Petersen BT, Cohen J, Hambrick RD, Buttar N, Greenwald DA, Buscaglia JM et al. Multisociety guideline on reprocessing flexible GI endoscopes: 2016 update. Gastrointest Endosc 2017;85:282-295.
- Pharmacopée européenne 8.0. 5.1.1. - Méthodes de préparation des produits stériles.
- Rauwers AW, Voor in 't holt AF, Buijs JG, de Groot W, Hansen BE, Bruno MJ, Vos MC. High prevalence rate of digestive tract bacteria in duodenoscopes: a nationwide study. Gut 2018;0:1–9.
- Regulation (eu) 2017/745 of the European parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
- Roberts CG. The role of biofilms in reprocessing medical devices. Am J Infect Control 2013;41(5 Suppl):S77-80.
- Kingdom of Belgium. Royal Decree of 18 March 1999 on medical devices. Belgian Official Gazette of 14 April 1999, No. 1999022270, p. 12105.
- Royaume de Belgique. Arrêté royal du 19 mai 2009 modifiant l'arrêté royal du 11 mars 2002 relatif à la protection de la santé et de la sécurité des travailleurs contre les risques liés à des agents chimiques sur le lieu de travail. MB du 11 juin 2009, n° 2009202011, p 41408.
- Rutala WA and Weber DJ. Reprocessing semicritical items: Current issues and new technologies. Am J Infect Control 2016;44(5 Suppl):e53-62.
- Ryndock E, Robison R, Meyers C. Susceptibility of HPV16 and 18 to high level disinfectants indicated for semi-critical ultrasound probes. J Med Virol 2016;88(6):1076-80.
- SFERD - Stuurgroep Flexibele Endoscopen Reiniging en Desinfectie - Kwaliteitshandboek reiniging en desinfectie flexibele endoscopen Versie 4.0, 2016.
- Siala W, Van bambeke F, Vanzieleghem T. Biofilm removal properties of endoscope cleaners: a comparative study. Hyg Med 2017:42 (9):D114-D122.
- Vickery K, Gorgis VZ, Burdach J, Patel D. Evaluation of an automated high-level disinfection technology for ultrasound transducers. J Infect Public Health 2014;7(2):153-60.
- WIP – Werkgroep Infectie Preventie Zorginstellingen. Thermolabiele, flexibele endoscopen; Nederland 2015.
- WIP – Werkgroep Infectie Preventie Addendum bij WIP-richtlijn Thermolabiele, flexibele endoscopen 2015; 2016.

8.2 Relevant literature

- AAMI – Association for advancement for the Medical Instrumentation. Water for the reprocessing of medical devices. AAMI TIR34; 2014.
- Abramowicz JS, Evans DH, Fowlkes JB, Marsal K, Terhaar G. Guidelines for cleaning transvaginal ultrasound transducers between patients. Ultrasound in Med. & Biol. 2017. 1–4.
- Amis S, Ruddy M, Kibbler CC, Economides DL, MacLean AB. Assessment of condoms as probe covers for transvaginal sonography. J Clin Ultrasound 2000;28(6):295-8.
- APSIC – Asia Pacific Society of Infection Control. The APSIC guidelines for disinfection and sterilisation of instruments in health care facilities; 2017.
- ASGE – American Society for Gastrointestinal Endoscopy. Automated endoscope reprocessors. Gastrointestinal endoscopy 2016: 84 N°6: 885-892.

- ASGE – American Society for Gastrointestinal Endoscopy. Experts convene to explore the state of the science and set priorities for preventing antibiotic-resistant infections associated with advanced endoscopic procedures; 2015.
- AZG - Agentschap Zorg & Gezondheid. - Departement Welzijn, Volksgezondheid & Gezin. Desinfectie van flexibele endoscopen in ziekenhuizen heft nood aan duidelijke kwaliteitseisen; 2017.
- Baker KH, Chaput MP, Clavet CR, Varney GW, To TM, Lytle CD. Evaluation of Endoscope Sheaths As Viral Barriers. The Laryngoscope. 1999; 109(4), 636-639.
- Bashaw MA. Guideline Implementation: Processing Flexible Endoscopes. AORN J 2016;104(3):225-36.
- Becker B, Bischoff B, Brill FH, Steinmann E, Steinmann J. Virucidal efficacy of a sonicated hydrogen peroxide system (trophon((R)) EPR) following European and German test methods. GMS Hyg Infect Control 2017;12:Doc02.
- Bradley CR, Hoffman PN, Egan K, Jacobson SK, Colville A, Spencer W et al. Guidance for the decontamination of intracavity medical devices: the report of a working group of the Healthcare Infection Society. J Hosp Infect. 2018. S0195-6701(18)30414-6.
- British Columbia Ministry of Health. Best practice guidelines for cleaning, disinfection and sterilization of critical and semi-critical medical devices; 2011.
- Buescher DL, Mollers M, Falkenberg MK, Amler S, Kipp F, Burdach J, et al. Disinfection of transvaginal ultrasound probes in a clinical setting: comparative performance of automated and manual reprocessing methods. Ultrasound Obstet Gynecol 2016;47(5):646-51.
- Cavaliere M and Iemma M. Guidelines for reprocessing non lumened heat-sensitive Ear/Nose/Throat Endoscopes. Laryngoscope 2012.122 : 1708-1718.
- CClin Arlin – Réseau National de Prévention des Infections Associées aux Soins. Guide ESET. Aide au choix, à la qualification et à l'utilisation d'une enceinte de stockage pour Endoscopes thermosensibles. France; 2015.
- CClin Arlin – Réseau National de Prévention des Infections Associées aux Soins. Groupe d'évaluation des pratiques en hygiène hospitalière. Enquête exploratrice nationale relative aux pratiques d'hygiène appliquées aux sondes à échographie endovaginale. Résultats. 2016.
- CDC – Centers for Disease Control and Prevention. Department of Health and Human Services Centers for Disease Control and Prevention. Interim culture method for the duodenoscope – distal end and instrument channel; 2015.
- CDC – Centers for Disease Control and Prevention. Department of Health and Human Services Centers for Disease Control and Prevention. Interim sampling method for the duodenoscope – distal end and instrument channel; 2015.
- CDC – Centers for Disease Control and Prevention. Department of Health and Human Services Centers for Disease Control and Prevention. Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial of Duodenoscopes after Reprocessing. 2015.
- CDC – Centers for Disease Control and Prevention. National center for emerging and zoonotic infectious diseases. Division of healthcare quality promotion. Guide to infection prevention for our patient settings : minimum expectations for safe care; 2016.
- CDC – Centers for Disease Control and Prevention. Core infection prevention and control practices for safe healthcare delivery in all settings – Recommendations of the Healthcare Infection Control Practices Advisory Committee; 2017.
- CDC – Centers for Disease Control and Prevention. Essential elements of a reprocessing program for flexible endoscopes - Recommendations of the Healthcare Infection Control Practices Advisory Committee; 2017.

- CDC - Centers for disease control and prevention. Reported Tuberculosis in the United States. 2013.
- DH – Department of Health - Health Technical Memorandum 01-06: Decontamination of flexible endoscopes - Part A: Policy and management. 2016.
- DH – Department of Health - Health Technical Memorandum 01-06: Decontamination of flexible endoscopes - Part B: Design and installation. 2016.
- DH – Department of Health - Health Technical Memorandum 01-06: Decontamination of flexible endoscopes – Part C: Operational management. 2016.
- DH – Department of Health - Health Technical Memorandum 01-06: Decontamination of flexible endoscopes – Part D: Validation and verification (including storage/drying cabinets) 2016.
- DH – Department of Health - Health Technical Memorandum 01-06: Decontamination of flexible endoscopes - Part E: Testing methods.2016.
- ESGE – ESGENA – European Society of Gastrointestinal Endoscopy - European Society of Gastroenterology and Endoscopy Nurses and Associates – Guideline for quality assurance in reprocessing: microbiological surveillance testing in endoscopy. 2007;39:175-181.
- ESGE – ESGENA – European Society of Gastrointestinal Endoscopy - European Society of Gastroenterology and Endoscopy Nurses and Associates. Cleaning and disinfection in gastrointestinal endoscopy; 2008;40 : 939-957.
- ESGE – ESGENA – European Society of Gastrointestinal Endoscopy - European Society of Gastroenterology and Endoscopy Nurses and Associates - Technical specification for process validation and routine testing of endoscope reprocessing in washer-disinfectors according to EN ISO 15883, parts 1,4, and ISO/TS 15883-5. 2017;49: 1262-1275.
- ESGE – ESGENA – European Society of Gastrointestinal Endoscopy - European Society of Gastroenterology and Endoscopy Nurses and Associates – Position Statement on reprocessing of flexible endoscopes and endoscopic accessories in gastrointestinal endoscopy – 2018.
- Hernandez A, Carrasco M, Ausina V. Mycobactericidal activity of chlorine dioxide wipes in a modified prEN 14563 test. J Hosp Infect 2008;69(4):384-8.
- Hignett M, Claman P. High rates of perforation are found in endovaginal ultrasound probe covers before and after oocyte retrieval for in vitro fertilization-embryo transfer. J Assist Reprod Genet 1995;12(9):606-9.
- Hitchcock B, Moynan S, Frampton C, Reuther R, Gilling P, Rowe F. A randomised, single-blind comparison of high-level disinfectants for flexible nasendoscopes. J Laryngol Otol 2016;130(11):983-9.
- INRS – Institut national de Recherche et de Sécurité. Dioxyde de chlore - Fiche toxicologique n° 258 ; 2011.Internet: http://www.inrs.fr/publications/bdd/fichetox/fiche.html?refINRS=FICHETOX_258.
- Johnson S, Proctor M, Bluth E, Smetherman D, Baumgarten K, Troxclair L et al. Evaluation of a hydrogen peroxide-based system for high-level disinfection of vaginal ultrasound probes. J Ultrasound Med 2013;32(10):1799-804.
- Jørgensen PH, Slotsbjerg T, Westh H, Buitenhuis V, Hermann GG. A microbiological evaluation of level of disinfection for flexible cystoscopes protected by disposable endosheaths. BMC Urology 2013, 13:46.
- Kingdom of Belgium. Royal Decree of 4 March 1991 laying down the standards to be met by a hospital pharmacist in order to be accredited. Belgian Official Gazette of 23 March 1991, No. 19991025060, p. 5965
- Kovaleva J. Endoscope drying and its pitfalls. J Hosp Infect. 2017 Dec;97(4):319-328.

- Loukili HN, Lemaitre N, Guery B, Gaillot O, Chevalier D, Mortuaire G. Is a chlorine dioxide wiping procedure suitable for the high-level disinfection of nasendoscopes? J Infect Prev 2017;18(2):78-83.
- Loukili HN, Lemaitre N, Gaillot O, Guery B. La désinfection des nasofibroscopes - Comparaison de l'efficacité d'une procédure par trempage versus une procédure par essuyage. Vème Journée ALIAS - 31 mars 2015.
- Milki AA and Fisch JD. Vaginal ultrasound probe cover leakage: implications for patient care. Fertil Steril 1998;69(3):409-11.
- Molloy-Simard V, Lemyre JL, Martel K, Catalone BJ. Elevating the standard of endoscope processing: Terminal sterilization of duodenoscopes using a hydrogen peroxide−ozone sterilizer. American Journal of Infection Control 2019;47, 243−250.
- M'Zali F, Bounizra C, Leroy S, Mekki Y, Quentin-Noury C, Kann M. Persistence of microbial contamination on transvaginal ultrasound probes despite low-level disinfection procedure. PLOS ONE 2014 (9) ;4 ;e93368.
- Oh HJ, Kim JS. Clinical Practice Guidelines for Endoscope Reprocessing. Clin Endosc 2015;48(5):364-8.
- Perumpail RB; Marya NB, McGinty BL, Muthusamy VR. Endoscope reprocessing: Comparison of drying effectiveness and microbial levels with an automated drying and storage cabinet with forced filtered air and a standard storage cabinet. American Journal of Infection Control. 2019; 47:1083−1089.
- Qmentum International. Normes Retraitement et stérilisation des appareils et instruments médicaux réutilisables. Canada; 2017.
- République Française. Ministère des Affaires Sociales et de la Santé. Guide technique traitement des endoscopes souples thermosensibles à canaux. 2016.
- République Française. Ministère des Affaires Sociales et de la Santé. Annexe technique traitement des duodénoscopes. 2018.
- République Française. Ministère des Affaires Sociales et de la Santé. Instruction no DGOS/PF2/DGS/VSS1/2016/220 du 4 juillet 2016 relative au traitement des endoscopes souples thermosensibles à canaux au sein des lieux de soins. 2016.
- Rex DK, Sieber M, Lehman GA, Webb D, Schmitt B, Kressel AB et al. A double reprocessing high-level disinfection protocol does not eliminate positive cultures from the elevators of duodenoscopes. Endoscopy 2018; 50: 588–596.
- Rooks VJ, Yancey MK, Elg SA, Brueske L. Comparison of probe sheaths for endovaginal sonography. Obstet Gynecol 1996;87(1):27-9.
- Ross AS. Enhanced methods for duodenoscope reprocessing: answers or just more questions. Gastrointest Endosc 2016;84:263-265.
- Rutala WA and Weber DJ. Disinfection and sterilization: an overview. Am J Infect Control 2013;41(5 Suppl):S2-5.
- Rutala WA and Weber DJ. New developments in reprocessing semicritical items. Am J Infect Control 2013;41(5 Suppl):S60-6.
- Rutala WA, Gergen MF, Sickbert-Bennett EE. Effectiveness of a Hydrogen Peroxide Mist (Trophon) System in Inactivating Healthcare Pathogens on Surface and Endocavitary Probes. Infect Control Hosp Epidemiol 2016;37(5):613-4.
- Sattar SA and Maillard JY. The crucial role of wiping in decontamination of high-touch environmental surfaces: review of current status and directions for the future. Am J Infect Control 2013;41(5 Suppl):S97-104.
- Seavey R. High-level disinfection, sterilization, and antisepsis: current issues in reprocessing medical and surgical instruments. Am J Infect Control 2013;41(5 Suppl):S111-7.

- SF2H – Société Française d'Hygiène Hospitalière. Note technique de la commission Désinfection de la SF2H. Indications des lingettes en désinfection dans le domaine médical. 2013. Internet: https://sf2h.net/publications/indications-lingettes-desinfection-domaine-medical.
- SF2H – Société Française des Sciences de la stérilisation. Avis de la société française des sciences de la stérilisation et de la société française d'hygiène hospitalière relatif aux dispositifs médicaux réutilisables devant être utilises stériles. France. Juin 2016.
- SF2H – Société Française des Sciences de la stérilisation. Guide pour le choix des désinfectants. Produits de désinfection chimique pour les dispositifs médicaux, les sols et les surfaces. 2015 https://sf2h.net/publications/le-choix-des-desinfectants.
- SFERD- Stuurgroep Flexibele Endoscopen Reiniging en Desinfectie- richtlijn controle op microbiologische veiligheid van thermolabiele flexibele gastro-intestinale endoscopen, 2017.
- SFERD- Stuurgroep Flexibele Endoscopen Reiniging en Desinfectie - Professional standard handbook cleaning and disinfection of flexible endoscopes, version 4.1, September 2017.
- SFR – Société Française de radiologie. Recommandations de la SFR et de la SIU pour la désinfection des sondes pour les examens échographiques par voie endocavitaire. 2010.
- SGNA - Society of Gastroenterology Nurses and Associates, INC. Guideline for use of high level disinfectants & sterilants for reprocessing flexible gastrointestinal endoscopes. Chicago. 2013.
- SGNA - Society of Gastroenterology Nurses and Associates, INC. Position Statement. Reprocessing of endoscopic accessories and valves. 2014.
- SGNA- Society of Gastroenterology Nurses and Associates, INC. Position statement: Water and irrigation bottles used during Endoscopy. 2014.
- SGNA - Society of Gastroenterology Nurses and Associates, INC. Position Statement. Minimum registered nurse staffing for patient care in the gastroenterology setting. 2016.
- SGNA - Society of Gastroenterology Nurses and Associates, INC. Position Statement. Manipulation of gastrointestinal endoscopes during endoscopic procedures; 2017.
- Sowerby LJ and Rudmik L. The cost of being clean: A cost analysis of nasopharyngoscope reprocessing techniques. Laryngoscope 2018;128(1):64-71.
- Systchenko R, Sautereau D, Canard JM. Recommandations de la Société française d'endoscopie digestive pour l'organisation et le fonctionnement d'un plateau technique en endoscopie digestive. Acta Endosc ; 2013.
- The Joint Commission. High-level disinfection (HLD) and sterilization Booster Pak ; 2016.
- Tzanidakis K, Choudhury N, Bhat S, Weerasinghe A, Marais J. Evaluation of disinfection of flexible nasendoscopes using Tristel wipes: a prospective single blind study. Ann R Coll Surg Engl 2012; 94:185–188.
- Van Gansbeke B. Désinfectants-antiseptiques: aspects légaux et classification et sélection. ULB. Hopital Erasme. Présentation ppt 2016.
- Vlaamse Regering. Departement Welzijn, Volksgezondheid & Gezin. Zorginspectie – Beleidsrapport: desinfectie van flexibele endoscopen met lumen. 2017.
- WHO – World Health Organization. Decontamination and reprocessing of medical devices for health-care facilities. 2016.
- WIP - Werkgroep Infectie Preventie. Richtlijn tuberculose: preventie van aërogene transmissie & de Canadian tuberculosis standards. Nederland; 2014.
- WIP – Werkgroep Infectie Preventie Zorginstellingen. Prionziekten. Nederland. 2018.

9. COMPOSITION OF THE WORKING GROUP

The composition of the Committee and that of the Board as well as the list of experts appointed by Royal Decree are available on the following website: About us.

All experts joined the working group ***in a private capacity***. Their general declarations of interests as well as those of the members of the Committee and the Board can be viewed on the SHC website (site: conflicts of interest).

The following experts were involved in drawing up and endorsing this advisory report. The working group was chaired by **Anne SIMON**; the scientific secretary was Muriel BALTES and JEAN-JACQUES DUBOIS.

DE LOOZE Danny	Gastroenterology	UZ Gent, BSGIE[23]
DE MUNCK Jo	Nursing, Hospital hygiene	AZ Sint Blasius
DELHAUTEUR Blaise	Hospital pharmacy, Sterilisation	CHR Citadelle Liège
DEMAITER Guido	Nursing, Hospital hygiene	AZ Groeninge, NVKVV
DULIERE Benoît	Hospital pharmacy	Clinique St Luc Bouge
DUTERME Jean-Pierre	Ear-Nose-Throat	CHU Charleroi
GERARD Michèle	Hospital hygiene, Infectiology	CHU St Pierre, ULB
GLUPCZYNSKI Youri	Microbiology, Hospital hygiene	CHU UCL Namur, Mont Godinne
JANSENS Hilde	Microbiology, Hospital hygiene	UZA
MALFAIT Thomas	Pneumology	UZ Gent, société Belge de pneumologie
MANDERYCK Greet	Nursing, Hospital hygiene	AZ St Lucas
MOREELS Tom	Hepato-gastroenterology	UCL, BSGIE
MUTSERS Jacques	Nursing, Hospital hygiene	CHU - ULg
SIMON Anne	Microbiology, Hospital hygiene	CHU St Luc, UCL
STRALE Huguette	Nursing, Hospital hygiene	ULB Erasme
TAILLY Thomas	Urology, Infectiology	UZ Gent
VAN GANSBEKE Bernard	Hospital pharmacy	ULB Erasme
VAN NIEUWENHOVE Sabrina	Nursing, endoscopy	AZ St Blasius
VAN VAERENBERGH Kristien	Microbiology, Hospital hygiene	OLVZ Aalst

The following firms/associations/etc. were heard:

CLAEYS Anja	Inspector	*Zorginspectie, Departement Welzijn volksgezondheid en gezin*
LIEVENS Kurt	Inspector	*Zorginspectie, Departement Welzijn volksgezondheid en gezin*
VAN SEGBROECK Lieve	Manager	*Zorginspectie, Departement Welzijn volksgezondheid en gezin*

The following administrations and/or ministerial cabinets were heard:

GENE Luc	Endoscopy	AZ Monica, AIEVV

This advisory report was translated by an external translation agency.

[23] BSGIE: Belgian Society of Gastrointestinal Endoscopy

10. APPENDICES

APPENDIX 1: Required personnel skills

(example taken from AZ Groeninge, Courtrai)

The personnel member should have the following skills:

1. S/he is familiar with the 5 key hand hygiene steps stipulated by the WHO[24] and applies them automatically as part of his/her endoscopy work.
2. S/he is familiar with and correctly applies the 6-step hand hygiene method.
3. S/he is familiar with and uses the necessary personal protective equipment when processing soiled endoscopes ***(apron, protection eyewear, surgical mask or breathing mask (at a pulmonary disease centre), change gloves after handling a soiled endoscope and before handling a clean endoscope).***
4. S/he is familiar with and able to implement the agreed traceability procedure.
5. S/he knows how to prepare a cleaned/disinfected endoscope for use.
6. S/he is responsible for ensuring that the disinfected endoscope is correctly transferred from the disinfection room to the examination room ***(if the room is not adjacent, a hermetically sealed, clean transport container should be used).***
7. S/he correctly carries out manual pre-cleaning of the endoscope used in the examination room ***(rinse the internal channels of the endoscope, dry the external surface with a cloth).***
8. S/he is responsible for ensuring that the soiled endoscope is correctly transferred from the examination room to the disinfection room **(*hermetically sealed, clean transport container).***
9. S/he correctly performs the leak test ***(has access to a manual or electrical leak tester, protection of electronic video camera components).***
10. S/he is familiar with the manufacturer's instructions for cleaning/disinfection of all used endoscopes and has read through the instruction manual.
11. S/he correctly performs manual cleaning of a used endoscope (particular attention is given to cleaning all internal channels using the agreed standard method, dismantles flaps and valves, etc.).
12. S/he correctly performs manual cleaning of a used duodenoscope (cf. manufacturer's instructions).
13. S/he knows how to load the endoscope washer-disinfector properly and select the correct programme.
14. S/he knows how to unload the endoscope washer-disinfector properly and unloads the machine (if the safe validation conditions are fulfilled).
15. S/he is familiar with and able to apply the procedures relating to the storage/drying of endoscopes, including use of the drying cabinet (place the endoscope in the right place, in the right cabinet and connects it properly).
16. S/he is familiar with and able to apply the procedures relating to cleaning/disinfection of the drying cabinet.
17. S/he is familiar with the procedure to be followed when replacing the endoscope washer-disinfector detergent or disinfectant.
18. S/he is familiar with the procedure to be applied in the event of an anomaly (error messages) and/or endoscope washer-disinfector failure.

[24] WHO: World Health Organization

19. S/he is familiar with, understands and applies the procedures relating to weekly self-disinfection of the endoscope washer-disinfector and/or filter replacement.
20. S/he is familiar with, understands and applies the procedures relating to the possible reuse of endotherapy accessories, valves, caps, mouthpieces, rinsing bottles and cleaning brushes.
21. S/he is familiar with the procedures relating to periodic maintenance/validation of endoscope washer-disinfectors.
22. S/he is able to present the material safety data sheet, upon request, for the detergents and disinfectants used.
23. S/he is familiar with and able to apply the procedure to be followed for defective endoscopes.
24. S/he is familiar with the cleaning/disinfection procedure outside normal working hours.

APPENDIX 2: Examples of critical points which are worth auditing.

1. Structural indicators

1.1. Fundamental requirements

- A coordinating expert has been appointed (cf. section 3.3.).
  - His/her responsibilities have been defined.
- Procedures exist describing the following aspects
  - They provide an overview of each type of endoscope/flexible ultrasound probe/rigid endocavitary ultrasound probe available at the hospital.
  - They describe the pathway for each type of endoscope/flexible ultrasound probe/rigid endocavitary ultrasound probe available at the hospital (including loaned endoscopes).
  - They include a description of each process step (including traceability).
  - The process follows the manufacturer's recommendations.
  - They describe who does what at each process step.
  - They include procedures for examining patients suffering from vCJD (cf. section 4).
  - They include procedures for implementation of the process outside normal working hours.
  - They include procedures for withdrawing from use and recommissioning a defective endoscope or device/for loaned endoscopes.
  - They include agreements for bacteriological control tests and monitoring of results.
  - They include procedures for suspected transmission of an infection attributed to use of endoscopy equipment.
- The procedures are approved by the Hospital Hygiene Committee (cf. section 4).
- The Purchasing Department has introduced procedures for purchasing endoscopes, flexible ultrasound probes, rigid endocavitary ultrasound probes, devices and cabinets, etc.
  - The parts concerned are listed.
  - They include a system whereby the requirements to be fulfilled by the devices are listed and can be checked.
    - for the endoscope washer-disinfector
    - for the drying cabinet.
  - When selecting a device or product, their compatibility with all components is taken into account.
- The Biomedical Department has introduced a number of procedures:
  - to determine the periodic maintenance of the devices, together with the nature and frequency of routine tests (cf. section 7.1.),
  - describing the repair process for a defective endoscope or device, together with the tests to be conducted before the device is recommissioned.
- All devices and endoscopes are identified to ensure that traceability is possible (cf. section 7.7.).

- A training plan exists for employees responsible for processing endoscopes (cf. section 3.2.3.).
  - This plan states the required skills (cf. section 3.2.3. and Appendix 1).
  - A register of personnel having carried out this training, and the date of training, should be maintained.
  - Training takes place when joining the department and when an audit shows that employee skills are lacking.
- Sufficient space is allowed for handling operations, without compromising the separation of clean/soiled equipment (cf. section 4.1.1 and section 5.4.).
- The devices may only be used for the first time once they have been validated (cf. section 7.2.).
- The environmental requirements drawn up by the manufacturer for use of the devices must be followed (e.g. electrical equipment, temperature of the surrounding environment, etc.).
- For the necessary products
  - the material safety data sheets are available.
  - adequate storage space is provided (according to the manufacturer's instructions and SIPPT recommendations).
- The water used for each process step should at least be fit for human consumption (cf. section 6.3.2.).

1.2. In the examination room

- The necessary materials for hand hygiene are available.
- One or more procedures/instructions are available on the use of the devices and, where appropriate, on fitting and removing protective sheaths, and on cleaning and high-level disinfection using wipes.
- Wipes/compresses for initial cleaning of the external surface are available.
- Water intended for human consumption is available.
- There is a container for irrigation of the channels, where necessary.
- The materials (computer, scanner or register) required for traceability of the patient, endoscope, flexible ultrasound probe are present (cf. section 3.2.1. and Figure 1).
- A protective sheath is available if rigid endocavitary ultrasound probes are used in this room (cf. section 5.3.).
- If a protective sheath is used, the model is suitable for use with the device concerned (cf. section 5.3.).
- If cleaning and high-level disinfection take place using wipes, the latter are available in the examination room.
- If manual pre-cleaning takes place via immersion or using a cloth soaked with a suitable detergent, the necessary materials are available.

1.3. In the "soiled" zone rinsing area

Not applicable

- for rigid endocavitary ultrasound probes,

- for endoscopes or flexible ultrasound probes without a channel undergoing cleaning and high-level disinfection using wipes.

- The necessary materials for hand hygiene are available; specific wash basin for hand hygiene.
- The procedure(s)/manual(s) are available.
- Presence of a rinsing tank for manual cleaning (cf. section 3.2.1 and section 3.2.2.)
  - The length of the tank is suited to the length of the endoscopes.
  - Suitable detergents are available (cf. section 4.1.6.).
  - Hot and cold water fit for human consumption is available (cf. section 3.2.4.).
  - The water temperature is set to the temperature recommended by the manufacturer (cf. section 3.2.4).
  - The equipment for the manual leak test is available, where appropriate.

  Specifically for endoscopes with a channel
  - The protective cap for the endoscope is available.
  - The necessary materials for rinsing the channels are available.
  - The materials (brushes, cleaning swab) for cleaning the channels are available.
- A suitable product for maintenance of the transport containers is available (cf. section 4.1.6.).
- Cleaning implements (e.g. brushes) (cf. section 4.2.4.) for the channel orifice (where appropriate), valves, etc. are available.
  - These are single-use implements.
- Personal protective equipment is available (apron, mask, splash-protection eyewear (or face mask), long-sleeve gloves (cf. section 3.2.1.).
- An eye rinsing kit is available (cf. section 3.2.1.).
- The materials (computer, scanner or register) required for traceability of the endoscope - leak test - endoscope washer-disinfector are present (cf. section 3.2.1. and Figure 1).
- Sufficient space is available for depositing used endoscopes.
- The endoscope washer-disinfector (cf. sections 3.2.2. and 4.1.9.)
  - is set up in the soiled zone.
  - once the process has ended, the endoscope may be easily transferred to the clean zone.
- The ventilation system extracts air and is set to the required flow rate, with at least 6 air changes/hour. (cf. section 3.2.1.).
- Clean/soiled zones are separated (cf. section 3.2.1.).
  - The distance between the soiled zone and clean is at least 1 m.
- A sterilisation device is available for non-heat-sensitive endoscopes which are required to be sterile (cf. section 3.1).

Specifically for endoscopes without a channel disinfected by soaking
- A container with a lid is provided in case toxic products are used.
- Do not use after the expiry date.
- Where appropriate: the activity of the product is evaluated according to the manufacturer's recommendations.

- ☐ The concentration and contact time recommended for the product concerned should be followed.

Specifically for endoscopes without a channel disinfected using disinfectant wipes

- ☐ A suitable system is available for disinfection using wipes.
- ☐ A known working method is applied (cf. section 6.3.2).

1.4. Storage area - “clean” zone

- ☐ The necessary materials for hand hygiene are available.
- ☐ The procedure(s)/manual(s) are available.
- ☐ Air humidity and temperature are adapted to the drying cabinet present.
- ☐ Storage cabinet (storage for 4 hours max.):
  - ☐ is set up in the clean zone;
  - ☐ is dry, dust-free and clean;
  - ☐ may be closed;
  - ☐ has ventilation slots.

And/or

- ☐ Drying cabinet (cf. section 3.2.2.)
  - ☐ Is set up in the clean zone,
  - ☐ The door is closed.

Specifically for endoscopes without a channel
To be stored in a clean, dry place.

2. Process indicators

2.1. Fundamental requirements

- ☐ The appointed coordinating expert and assistant are aware of their responsibilities.
- ☐ There is a stock of products (for manual pre-cleaning, endoscope washer-disinfector) suitable for use.
- ☐ The products are not used after their expiry date.
- ☐ The procedures outside normal working hours are known.
- ☐ For a decentralised system: the agreements for the collection, return and storage of endoscopes are known.
- ☐ When replacing products in the devices, the date and register number are recorded for a change of batch.
- ☐ The operator, time and date are stated for each record.
- ☐ No irregularities are present in the endoscope washer-disinfector register data.
  - ☐ If this is not the case, appropriate corrective measures are applied.

2.2. Step 1

2.2.1. Preparation of a disinfected endoscope/flexible ultrasound probe for use

cf. section 4.4.1.

- ☐ All procedures take place after disinfecting the hands.

- And sterile gloves for the cystoscopes.
- The final date of use is recorded.
  - The procedures to follow when the final date of use has been exceeded are known.
- The accessories (valves, where appropriate, biopsy cap) should be correctly fitted.
- Where appropriate: the protective sheath is positioned correctly (cf. section 5.3.).
- Loaned or repaired endoscopes are only commissioned once they have undergone the complete process (except for bacteriological control tests).

2.2.2. Preparation of a disinfected rigid endocavitary ultrasound probe for use

cf. section 5.3.

- All procedures are carried out after disinfecting the hands and wearing non-sterile gloves.
- Where appropriate: the protective sheath is positioned correctly (cf. section 5.3.).
- Where appropriate: ultrasound gel.

2.3. Step 2

2.3.1. Transport of the disinfected endoscope/flexible ultrasound probe

Not applicable for rigid ultrasound probes which are part of a fixed device, endocavitary MD without a channel.

cf. section 4.1.2.

- The endoscope is transported in a container provided for that purpose.
- This evidently concerns a disinfected or sterile endoscope which has not yet passed its expiry date.

2.4. Step 3

2.4.1. Implementation of the endoscopy examination

cf. section 4.1.3.

- Hand hygiene rules are properly applied.
- Both the endoscopist and the nurse wear gloves.
  - Sterile gloves for the cystoscopes,
  - Non-sterile gloves for endoscopes having undergone high-level disinfection.
- The endoscopist and nurse wear a single-use protective apron to protect against splashing.
- When a bronchoscopy needs to be performed on a patient suspected to have open tuberculosis, a breathing mask corresponding to at least type FFP2 is required.
- Traceability of the endoscope/patient will be possible (cf. Figure 1).

2.4.2. Implementation of the ultrasound examination

- Hand hygiene rules are properly applied.
- The person carrying out the examination wears non-sterile gloves.
- The flexible ultrasound probe is used with the protective sheath, according to the manufacturer's recommendations (cf. section 5.3.).

2.5. Step 4

2.5.1. Initial cleaning by the user in the endoscopy room

cf. section 4.1.4.

- ☐ The external surface of the endoscope is wiped
  - ☐ using a single-use cloth,
  - ☐ moistened with water fit for human consumption.

Furthermore, for endoscopes with a channel

- ☐ Biopsy and aspiration channels are rinsed with water fit for human consumption.
- ☐ The air/water channels are rinsed with water fit for human consumption.
- ☐ The control buttons are placed in the neutral position.
- ☐ The gloves are replaced.
- ☐ The endoscope is disconnected.
  - ☐ The endoscope is placed in a transport container.
  - ☐ The endoscope is identified as having been used.
- ☐ Gloves are removed, and hands disinfected.

Furthermore, for endoscopes with a channel

- ☐ The rinsing bottle (cf. section 4.2.2.)
  - ☐ is filled with sterile water (for cystoscopes),
  - ☐ is sterilised or changed daily.
- ☐ Aspiration tube and bag (single-use liner) (cf. section 4.2.6.).
  - ☐ The single-use liner is replaced once daily.
  - ☐ The aspiration tube is replaced for each patient.

2.5.2. Initial cleaning by the user of rigid and flexible endocavitary ultrasound probes

cf. section 5.3.

- ☐ Where appropriate: the protective sheath is removed correctly (cf. section 5.3.).
- ☐ The probe is wiped using a clean, dry compress.
- ☐ Manual cleaning is performed using the appropriate method (cf. section 5.4.1.).
  - ☐ The correct product is used.
  - ☐ The correct action is performed.
- ☐ Touch screens and keypads are disinfected between each patient, using a suitable low-level disinfectant (cf. section 5.6.).
- ☐ Computers and cables are disinfected periodically, using a suitable low-level disinfectant (cf. section 5.6.).

Specifically for rigid endocavitary ultrasound probes (cf. section 5.4.): :

- ☐ If the probe belongs to the patient,
  - ☐ low-level disinfection is performed,
  - ☐ the probe is wrapped,
  - ☐ the patient takes the probe home.

2.6. Step 5

Transportation of the used endoscope

Not applicable:

- for rigid ultrasound probes which are part of a fixed device,
- for flexible ultrasound probes which are cleaned in the examination room and undergo high-level disinfection.

cf. section 4.1.5

- ☐ The endoscope is taken to the soiled zone.
- ☐ The endoscope is clearly identified as having been used.

2.7. Step 6

Preparation for manual pre-cleaning in the soiled zone of the disinfection room

Not applicable for rigid and flexible endocavitary ultrasound probes.

cf. section 4.1.6.

- ☐ Personal protective equipment is used correctly.
- ☐ The rinsing tank is filled.
  - ☐ The concentration and temperature comply with the manufacturer's instructions.

Specifically for endoscopes with a channel

- ☐ The protective cap is affixed.
- ☐ The disposable caps and valves are removed.
- ☐ Reusable valves are cleaned according to the manufacturer's instructions (cf. section 4.2.3.).

2.8. Step 7

Manual leak test

Not applicable for rigid and flexible endocavitary ultrasound probes.

cf. section 4.1.7.

- ☐ Personal protective equipment is used correctly.
- ☐ Clean/soiled zones are separated.

Only for endoscopes with a channel

- ☐ The date of the leak test together with the name of the person having carried out the test are recorded.
- ☐ A pressure gauge or electric pump are connected and correctly pressurised (cf. manufacturer's instructions).
- ☐ The endoscope is immersed.
- ☐ If air bubbles escape,
  - ☐ The endoscope is removed from the solution while pressurised,
  - ☐ The endoscope is taken out of use.
    - ☐ The endoscope is clearly identified as no longer able to be used.
    - ☐ This information is recorded.
  - ☐ The endoscope is wrapped and a "contaminated" label is affixed.
  - ☐ It is placed in the case.

- The Medical Technology Department is notified.
- If no air bubbles escape,
  - The endoscope is disconnected.

2.9. Step 8

Manual pre-cleaning

Not applicable for rigid and flexible endocavitary ultrasound probes.

cf. section 4.1.8.

- Personal protective equipment is used correctly.
- Clean/soiled zones are separated.
- The endoscope is immersed.

Specifically for endoscopes with a channel

- The channels are filled with solution.
- A brush with a suitable diameter is selected.
- The channels are brushed correctly (cf. manufacturer's instructions): the biopsy/aspiration channel from the aspiration channel valve body to the distal end.
- The channels are flushed with a cleaning solution.
- The solution contact time is followed.
- The elevator (where appropriate) is cleaned according to the manufacturer's instructions.
- The sheath, control buttons, etc. are cleaned.
- Reusable endoscopy accessories (e.g. valves, caps, mouthpieces) (cf. section 4.2.3.) are cleaned.
  - Are placed in a waste bin.
- Endotherapy devices (e.g. biopsy forceps) (cf. section 4.2.1.) are cleaned.
  - Are sterilised.
- The endoscope is placed in the endoscope washer-disinfector.
- The endoscope and endoscope washer-disinfector are recorded.
- The rinsing tank is emptied, cleaned and rinsed, then dried at the end of activity (cf. section 4.2.5.).

2.10. Step 9

2.10.1. Mechanical cleaning and disinfection of the endoscope/flexible ultrasound probe

Not applicable for the rigid endocavitary ultrasound probe.

cf. section 4.1.9.

- Personal protective equipment is used correctly.
- Clean/soiled zones are separated.

Specifically for endoscopes with a channel

- The tubes are connected to the channels.
- The basket is placed in the endoscope washer-disinfector.
- Gloves are removed, and hands disinfected.

- The programme is started
  - If the endoscope is reused immediately, standard.
  - If the endoscope is to be stored after the programme, drying programme.
- The procedures in the event of an alarm during the endoscope washer-disinfector cycle are known.
  If the defective endoscope washer-disinfector cannot be repaired:
  - The device is downgraded - this information is recorded.
  - The Biomedical Department is notified.
  - The endoscopes are placed in other endoscope washer-disinfectors.

2.10.2. Mechanical cleaning and disinfection of the rigid endocavitary ultrasound probe/flexible ultrasound probe/endoscope without a channel employing a disinfector using UV radiation or hydrogen peroxide

cf. section 5.5.1.

- The personal protection equipment depends on the pre-cleaning procedure.
- Clean/soiled zones are separated.
- The MD is correctly positioned in the device.
- Gloves are removed, and hands disinfected before starting.
- The programme is started.
- The procedures in the event of an alarm during the endoscope washer-disinfector cycle are known.
  If the defective endoscope washer-disinfector cannot be repaired:
  - The device is downgraded - this information is recorded.
  - The Biomedical Department is notified.
  - The endoscopes are placed in other endoscope washer-disinfectors or undergo manual high-level disinfection as described in the procedure.

2.10.3. Manual cleaning and high-level disinfection

Not applicable for endoscopes with a channel.

cf. section 5.5.2. and section 5.5.3.

- Is performed only if cleaning and high-level disinfection using a machine are not available.
- Personal protective equipment is used correctly (section 5.5.2.).
- Clean/soiled zones are separated.
- In case of immersion:
  - an approved suitable product is used, at an appropriate concentration and contact time.
  - the storage limit (date and time) + the number of times the product has been used are stated on the container (cf. section 5.5.2.).
  - ensure that the handle is disinfected.
  - after disinfection, rinse in water fit for human consumption (cf. section 5.5.2.).
  - after rinsing, dry with a clean, lint-free cloth (cf. section 5.5.2.).

- If wipes are used,
  - approved suitable wipes are used.
  - the correct action is performed.
  - ensure that the handle is disinfected.
- The high-level disinfection action is recorded (cf. section 5.5.3.): : Not applicable for rigid ultrasound probes.

2.11. Step 10

Release of the endoscope after disinfection

Applicable for all items undergoing mechanical cleaning and high-level disinfection.

cf. section 4.1.10.

- The process is evaluated.
  - The process takes place without interruption.
  - All tubes, caps and channel separators are still in place.
  - No contamination is visible on the endoscope.
    - Process OK = release of the endoscope.
    - Process not OK = mechanical cleaning and disinfection are repeated.

2.12. Step 11

2.12.1. Drying and storage of the endoscope

Not applicable for rigid endocavitary ultrasound probes/flexible ultrasound probes, endocavitary MD without a channel.

cf. section 4.1.11.

- Clean/soiled zones are separated.
- No MD are kept in the transport case.
- Valves and buttons are not reassembled on the endoscope during storage.
  - A storage system which can be properly cleaned is envisaged for these items.

If a drying cabinet is available:

- The endoscopes are placed in the drying cabinet.
- The storage period is followed (cf. manufacturer's instructions).

Specifically for endoscopes with a channel

- The channels are connected properly (cf. manufacturer's instructions).

If an alternative ozone or peracetic acid system is available (cf. section 4.1.11.).

- Is used according to the manufacturer's instructions.
- At the end of the process, the endoscope may be stored horizontally.

If a drying cabinet or alternative system is not available:

- The endoscope undergoes mechanical cleaning and disinfection if ≥ 4 hours have passed since the last process.

2.12.2. Drying and storage of rigid endocavitary ultrasound probes

cf. section 5.7.

- Protective sheaths are not used for storing MD (cf. section 5.3.).
- No MD are kept in the transport case.

3. Result indicators

cf. section 7.4.

- Microbiological control tests are performed according to the operating method and frequency described in the procedure.
- Procedures exist for suspected transmission of an infection attributed to use of endoscopy equipment.

11. ERRATA

original version (page 50)	adapted version (page 50)
7.4.2 Heat-sensitive endocavitary MD with a channel When a loaned high-risk endoscope is commissioned, the supplier provides a cleaning and disinfection certificate.	***7.4.2 Heat-sensitive endocavitary MD with a channel*** When a **loaned** high-risk endoscope is commissioned, the supplier provides a cleaning and disinfection certificate. Samples should be taken after the reprocessing procedure (cf. https://www.infectiepreventieopleidingen.nl/downloads/SFERD_Kwaliteitshandboek_5.pdf on p.32 “Stap 14”). However, the endoscope can be used while waiting for the results.

www.css-hgr.be

This publication cannot be sold.

federal public service
HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT

About the Superior Health Council (SHC)

The Superior Health Council is a federal body that is part of the Federal Public Service Health, Food Chain Safety and Environment. It was founded in 1849 and provides scientific advisory reports on public health issues to the Ministers of Public Health and the Environment, their administration, and a few agencies. These advisory reports are drawn up on request or on the SHC's own initiative. The SHC takes no decisions on the policies to follow, nor does it implement them. It does, however, aim at giving guidance to political decision-makers on public health matters. It does this on the basis of the most recent scientific knowledge

Apart from its 25-member internal secretariat, the Council draws upon a vast network of over 500 experts (university professors, members of scientific institutions), 200 of whom are appointed experts of the Council. These experts meet in multidisciplinary working groups in order to write the advisory reports.

As an official body, the Superior Health Council takes the view that it is of key importance to guarantee that the scientific advisory reports it issues are neutral and impartial. In order to do so, it has provided itself with a structure, rules and procedures with which these requirements can be met efficiently at each stage of the coming into being of the advisory reports. The key stages in the latter process are: 1) the preliminary analysis of the request, 2) the appointing of the experts within the working groups, 3) the implementation of the procedures for managing potential conflicts of interest (based on the declaration of interest, the analysis of possible conflicts of interest, and a Committee on Professional Conduct) as well as the final endorsement of the advisory reports by the Board (ultimate decision-making body of the SHC, which consists of 30 members from the pool of appointed experts). This coherent set of procedures aims at allowing the SHC to issue advisory reports that are based on the highest level of scientific expertise available whilst maintaining all possible impartiality.

The advisory reports drawn up by the working groups are submitted to the Board. Once they have been endorsed, they are sent to those who requested them as well as to the Minister of Public Health and are subsequently published on the SHC website (www.shc-belgium.be), except as regards confidential advisory reports. Some of them are also communicated to the press and to target groups among healthcare professionals.

The SHC is also an active partner in developing the EuSANH network (European Science Advisory Network for Health), which aims at drawing up advisory reports at the European level.

In order to receive notification about the activities and publications of the SHC, you can send a mail to info.hgr-css@health.belgium.be .