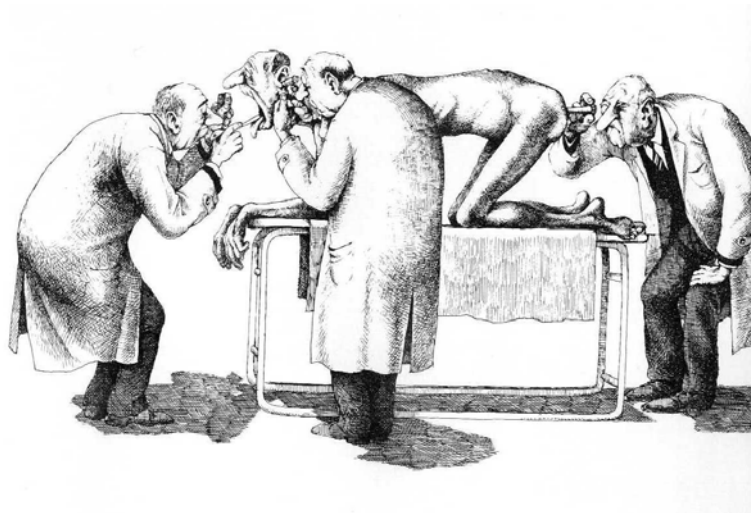


Sterile Supply Specialist Training Course Level II



REPROCESSING ENDOSCOPES

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Reprocessing Endoscopes

1 Introduction

A distinction is made between "flexible endoscopes" (bronchoscope, colonoscope, duodenoscope, gastroscope, urethroscope, etc.) and "rigid endoscopes" (bronchoscope, oesophagoscope, cystoscope, MIS instruments, etc.).

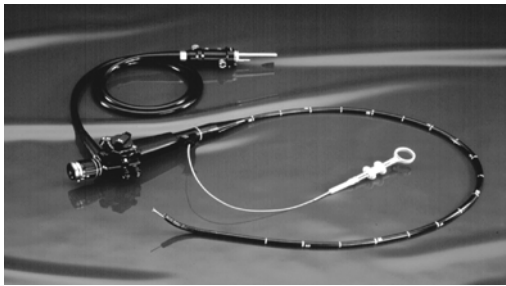


Fig. 1: Flexible endoscope



Fig. 2: Rigid endoscopes

1.1 Rigid endoscopes

Endoscopes that are inserted into the tissues or into sterile cavities must be sterile at the time of use. Examples of such endoscopes are laparoscopes, mediastinoscopes, thoracosopes, arthroscopes, intraoperative choledochoscopes, hysteroscopes and also cystoscopes intended for intraoperative use. Besides, there are the rigid endoscopes used in proctology. Such examples include rectoscopes, proctoscopes and anoscopes. Since these are metallic endoscopes and, as such, are heat resistant, they can be reprocessed and thermally disinfected in a washer-disinfector (WD). This calls for suitable supports and nozzles for direct purging of the long cavities – as found in minimally invasive surgical (MIS) instruments (critical B risk group).

The sterilization processes of first choice are those based on saturated pressurized steam at 134 °C. For "rigid" endoscopy there are instruments that can be dismantled and have autoclavable optics and matching accessories. They can be reliably sterilized with modern, well-maintained steam sterilizers.

The term "sterilization process" is permitted only for those processes that are endowed with effective sporocidal activity for suitably packed endoscopes.

Immersion in sporicidal solutions is not sterilization!

Low-temperature sterilization processes with formaldehyde ethylene oxide or hydrogen peroxide (“gas sterilization”) are commonly used alternative methods, but from a hygiene perspective they are more susceptible to interference and hence are not recommended for instruments amenable to steam sterilization.

1.2 Flexible endoscopes

Flexible endoscopes (fiberscopes, video endoscopes) are immensely difficult to effectively clean and disinfect with conventional methods because of their design (synthetic outer layer, narrow-lumened channel systems, complicated control elements, etc.). Older models do not even lend themselves to complete chemical immersion disinfection, whereas newer models can at least be fully immersed in a liquid solution. Strict limits are imposed in principle on thermal disinfection because of the endoscope materials and design.

1.2.1 Disinfected flexible endoscopes

For flexible endoscopes that are used in microbially colonized body regions (semi-critical B risk group) high level disinfection is enough. These endoscopes must be reprocessed such that e.g. intestinal bacteria, TB pathogens, HIV, hepatitis B and C viruses, etc. are reliably killed or inactivated (high level disinfection).

To assure the quality of patient care, only fully immersable flexible endoscopes may be used.

1.2.2 Sterile flexible endoscopes

These are required if the endoscope is inserted into physiologically sterile body cavities or penetrate the skin or mucosal barrier (critical C risk group). Heat-resistant instruments should be subjected to steam sterilization (see rigid endoscopes). Heat-sensitive endoscopes and accessories must be sterilized with gas (formaldehyde, ethylene oxide, hydrogen peroxide) following (preferably) automated cleaning and chemothermal disinfection.

2 Organizational Prerequisites

- a) Spatial
- b) Personnel

Regarding a)

A dedicated reprocessing room must be made available, i.e. reprocessing is not permitted in a consulting/examination room.

Reprocessing room:

- Automated door-opening mechanism (contamination-avoidance measure)
- Ideally, spatial separation between the clean and unclean areas (double-door machines). If spatial separation is not possible: clearly designated clean and unclean

working areas (semi-critical B RUMED II (Reprocessing Unit for Medical Devices) permitted as per the risk classification system defined by the Robert Koch Institute (RKI)

- Two suitably sized washbasins (at least 60 x 40 cm with a depth of 20 cm)
- Leakage testers (preferably automated)
- Cleaning mechanism (e.g. jet washer, WISAP nozzle)
- Adequate number of **Endoscope Washer-Disinfectors** (EWDs) (possibly with space for printing labels)
- Adequate number of storage cabinets for endoscopes (preferably drying cabinets)
- Suitable facilities for washing and disinfecting hands (non-touch techniques such as e.g. elbow lever)
- Sufficient space for storing detergents and disinfectants, personal protection equipment (PPE), etc.
- Surfaces that are amenable to wipe disinfection (at least to working height)
- Make provision for good aeration and deaeration of the room (personnel protection!)
- Floors that are easy to clean (trained cleaning staff)

Consulting / examination room:

- Clear separation between areas used for examination of upper and lower gastrointestinal tract (If spatial separation is not possible, this aspect must be borne in mind when deciding on the order of examinations)
- Suitable facilities for washing and disinfecting hands (non-touch techniques such as e.g. elbow lever)

- Make provision for adequate PPE supply
- Closed storage cabinets for endoscopy accessories
- Defined clean and unclean areas
- Surfaces that are amenable to wipe disinfection
- Make provision for good aeration and deaeration of the room (personnel protection)
- Floors that are easy to clean (trained cleaning staff)

Regarding b)

- Structured induction guide for new employees
- Documented induction and briefing of staff (e.g. in the form of standard operating procedures, training seminars) for reprocessing endoscopes and accessories
- Documented training by manufacturers and/or in-house technology / engineering department for using all endoscopic equipment (e.g. equipment pass for personnel)
- Successful completion of Specialist Course 1 by all endoscopy personnel

- Successful completion of Specialist Course 2 by the endoscopy management and deputy management
- Regular evaluation of workplace and manpower requirements is a precondition for maintenance of standardized reprocessing activities.

3 Personnel protection (occupational health and safety)

- Liquid-tight disposable gloves as well as gloves that protect against chemicals (EN 374)
- Liquid-tight protective clothing (disposable aprons and gowns)
- Orofacial mask (respiratory protection with filter P2, to be provided if there is poor aeration and deaeration) and eye protection (close-fitting goggles as per EN 166)
- Hygienic hand disinfection

| Examples of typical pathogens | MRSA | HBV, HCV, HIV | Open-lung tuberculosis | Gastritis |
|-------------------------------|---|--|--|--|
| Pathogens | Methicillin-resistant <i>Staphylococcus aureus</i> | Viruses | <i>Mycobacterium tuberculosis</i> | Bacteria (e.g. salmonellae, Yersinia, Campylobacter), viruses (e.g. rotaviruses, adenoviruses, coronaviruses, hepatitis A virus), exogenous faecal / oral |
| Transmission | Depending on colonization status, via endogenous, exogenous or aerogenic pathways | e.g. blood contact, close body contact, cannulas, biopsy forceps | Aerogenic, most commonly person-to-person through droplets and dust | Aerogenic, most commonly person-to-person through droplets and dust |
| Localization | Entire skin, nose, throat | e.g. blood, plasma, serum | e.g. saliva, bronchial secretion and gastric juice | e.g. saliva, bronchial secretion and gastric juice |
| Protective clothing | Orofacial mask, protective headgear, possibly goggles, disposable gloves | Active and passive immunization, long-sleeved gown, orofacial mask or facial protection, goggles, disposable gloves, antiviral hand disinfectant | Long-sleeved gown, TB mask FFP2 as per European standard EN 149 with exhalation valve, protective headgear, disposable gloves, hygienic hand disinfection 2 x 30 sec | Long-sleeved gown, TB mask FFP2 as per European standard EN 149 with exhalation valve, protective headgear, disposable gloves, hygienic hand disinfection 2 x 30 sec |

Tab. 1: Occupational health and safety measures to protect against specific pathogens

4 Reprocessing endoscopes and accessories

Transmission of pathogens from patient to patient must be prevented through disinfection of rigid /flexible endoscopes.

In the European Union, disinfection and sterilization of medical devices in healthcare institutions has been regulated by the Medical Devices Directive.

4.1 Manual reprocessing

Since manual or semi-automated reprocessing of endoscopes does not meet the state of the art in science and technology, it shall not be addressed here.

4.2 Automated cleaning and disinfection

Automated endoscope reprocessing is the state of the art and, in many respects, facilitates the cleaning and disinfection process. It assures standardized endoscope reprocessing and continuous documentation.

Endoscope reprocessing must be carried out in endoscope washer-disinfectors (EWDs) while observing the manufacturer's instructions such that successful performance of the process can be verified and the safety and health of patients, users or third parties are not endangered. Reprocessing must be organized to ensure that personnel are protected against infection – occupational health and safety!

Older EWD models, also known as semi-automated WDs, are supplied with detergents, disinfectants and cleaning solutions from tanks in which all liquids continue to be recirculated. This virtually inevitably results in the cleaning water becoming contaminated and colonized with undesirable microorganisms. Hence such types of machines are now obsolete.

Standard operating procedures (SOPs) must be available in every endoscopy unit for reprocessing the endoscopes and their accessories!

Reprocessing of flexible endoscopes begins already at the (patient) examination site!

4.2.1 Pretreatment of the endoscope following patient examination

- After withdrawing the endoscope from the patient, wipe the insertion tube with a disposable swab
- Hang the endoscope on the endo-trolley, while immersing the distal end into the cleaning solution
- Insert the cleaning valve as per the manufacturer's instructions into the air/water opening and use (see Fig.3) (cleans channels that cannot be brushed and detaches microorganisms and organic residues)
- Continue to press the red suction valve for at least 10 seconds (the cleaning solution is aspirated into working channel)
- Interrupt the air/water supply: e.g. switch off light source, reduce air supply at light source or pull out somewhat the power supply connector
- Hygienic working practices needed: switch off light source, disconnect cleaning bottle, camera unit (fit water-protection cap immediately) and suction tube from the endoscope power supply connector
- Place endoscope in the designated transport trolley and take it to the reprocessing room

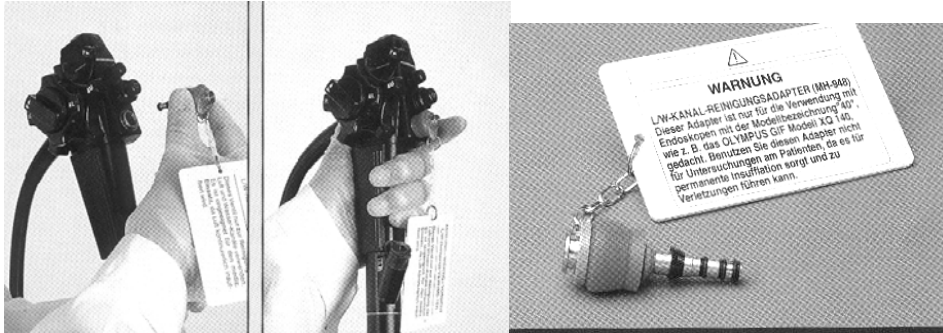


Fig. 3: Insertion of the cleaning valve

4.2.2 Manual precleaning of endoscopes

- Fit leakage tester to the endoscope water-protection cap
- Before immersing the endoscope in the cleaning basin, generate pressure as per the manufacturer's instructions, immerse endoscope in a basin filled with a disinfecting detergent solution- all parts must be completely covered with the solution.
- Look for any occurrence of air bubbles
- Remove air/water valve, suction valve, distal cap (endoscopic retrograde cholangiopancreatography (ERCP) endoscope) – place in container for soiled supplies (see reprocessing endoscope accessories)
- Remove and dispose of biopsy valve
- Carefully wipe off the endoscope insertion tube on the outside with a disposable cloth
- Then clean channels (working and supply channel) with a suitable soft brush – always working below the liquid solution level (avoid splashing, take health and safety precautions)
- When brushing, always keep the angled section of the endoscope straight (avoid damage to the endoscope working channel), use a suitable soft disposable brush to decontaminate sections that are difficult to access (e.g. region behind the Albarran lever in ERCP endoscope)
- Rinse off the cleaning solution by purging all channels (fit suitable cleaning adapter for additional cleaning channel and cleaning tube for the working and supply channel – this is generally included in the scope of delivery for new endoscopes – to that effect, fit cleaning tube to power supply connector)
- A jet washer (can be filled with sterile water) or water spray device (e.g. WISAP nozzle) are suitable purging adjuncts
- Then purge channels by introducing air (compressed air as per the manufacturer's instructions, alternatively use suitably sized disposable syringe) via the cleaning tube
- Remove endoscope from basin – allow to drip off
- Disconnect leakage tester (caution! remove pressure from endoscope)
- Dry off the endoscope on the outside with a suitable disposable cloth (this helps to avoid splashing within the reprocessing room)
- Manual reprocessing of endoscopes before loading the EWD is of paramount importance. Disinfectant solutions can exert their activity only on smooth, cleaned surfaces!

If the leakage test is not in order:

- Remove endoscope immediately from the water
- The endoscope must not be placed in any solution or in an EWD
- Dry off endoscope on the outside with a disposable cloth
- Wipe off the outside with alcohol, purge channels (expedites endoscope drying)
- Wrap in protective transport foil and place in suitably sized transport case
- Fill out a service information sheet, providing detailed information on defects – dispatch to service firm with comment: “contaminated!” or “not reprocessed”

4.2.3 Loading the endoscope washer disinfector (EWD)

- Most EWDs can accommodate two endoscopes
- Open the cleaning chamber door of the EWD, pull out tray
- Lift out upper basket
- Place endoscope on racks and supports provided by the manufacturer (assures secure position during the entire duration of reprocessing; if the EWD is equipped with a transponder, this can be read in the EWD - documentation)
- Special instructions such as e.g. positioning of a bronchoscope, rhinoscope, cystoscope, etc. must be implemented separately
- Select the corresponding set of tubes to connect endoscope
- Press connection adapter for the air/water and suction channel into the endoscope valve housing
- Fit second adapter for biopsy channel opening
- If applicable, fit additional tube adapter to additional cleaning channel (coloscope, emergency gastroscope)
- If applicable, fit Albarran tube adapter to additional cleaning channel of ERCP endoscope
- If applicable, bring Albarran lever to middle position
- Fit adapter for leakage test to water-protection cap, wrap supply tube (inlet tube / hose) around central console (avoids damage to tube when loading tray into cleaning chamber)

Checks to be carried out

- Secure positioning of all endoscope parts in the supports and racks provided, paying special attention to the distal end
- Guide wheels able to move freely up/down and left/right (both locking levers facing forwards in position “F”)
- Stiffening mechanism in coloscope in position 0
- Albarran lever in ERCP endoscopes in middle position
- Secure fit of all adapters
- Close cleaning chamber door carefully, ensuring there is no resistance (hygienic hand disinfection and change of gloves)

Select and start EWD disinfection programme

- Select and start EWD programme as per the manufacturer’s instructions or as specified by the test centre (as applicable, scan user ID)

4.2.4 Withdraw disinfected endoscope from EWD

- Hygienic hand disinfection, disposable gloves, disposable apron!
- Check EWD display and printout (=disinfected)
- Open cleaning chamber door of EWD, withdraw pull-out unit with basket as far as the limit stop, check whether all cleaning connections and leakage testers were connected on endoscope
- After checking whether all connections had remained properly positioned, detach cleaning connections and leakage tester
- Check for cleanliness, dryness and functional capability
- Release endoscope (provisionally: definitive release only at examination site by physician or assistant performing functional test), tip: make manual entry on EWD batch printout for documentation of release
- If necessary, dry additionally with compressed air (possibly using alcohol to expedite drying). It is imperative that reprocessed endoscopes be dried between examinations performed in rapid succession
- ◆ **If the EWD is equipped with a self-disinfection programme, this must be run at least once weekly! (Preferably on Mondays before examinations)**

5 Storage of flexible endoscopes

- Store by suspending in a cabinet (preferably drying cabinet):
- Always keep cabinet /drying cabinet closed!
- Position endoscope securely in support
- Carefully bring distal end of endoscope (optics!) to hanging position
- Remove water-protection cap from power supply connector (twist counterclockwise), and place the latter in the side compartment of the drying cabinet
- Store endoscope without fitting valves
- Assign EWD printout
- Rarely used endoscopes must be reprocessed before use.
- For emergency-bronchoscopes it might be useful to sterilize them after cleaning and disinfection to guarantee a long shelf life, avoiding reprocessing in a certain frequency.

Never store endoscopes in a lying position in transport case or in a drawer

6 Reprocessing endoscopy accessories

- Remove course soils (blood, saliva, faeces) immediately after use, using a moist gauze disposable swab (at examination site)

6.1.1 Transporting accessories to reprocessing room

- Biopsy forceps, guide wires, etc. are transported in a basin from the examination site to the reprocessing room

6.1.2 Precleaning

- If necessary, dismantle medical device (MD) (e.g. diathermy loop and tube)
- Clean outer surfaces with non-linting disposable cloth and soft disposable brush, working beneath the water surface (to avoid splashing)
- Open jointed instruments (e.g. by means of the handle, in the case of biopsy forceps), all surfaces must be accessible
- Remove blood, secretions, faeces or tissues residues
- Diathermy loop: carefully remove incineration residues, incrustations and adhesions
- Then rinse off thoroughly and purge beneath the water level
- Secure MD with metal spring (do not roll to less than 15 cm)

6.1.3 Disinfection and cleaning in an ultrasonic basin

- The basket must be sufficiently large and deep to permit complete immersion of the instruments
- Place precleaned and dismantled MDs in the basket
- Make sure biopsy forceps stays open
- MDs with cavities are filled with aldehyde-free disinfectant, using the disposable syringe (leave in place); avoid introduction of air or air bubbles (avoid splashing)
- Open all joints (scissors)
- To ensure good sonication and avoid spray shadowing, do not overload basket
- Plastic components can have adverse impact on sonication performance
- Roll up long MDs and fix with a metal spring (do not roll to less than 15 cm)
- Close ultrasonic basin with lid
- During sonication, do not reach into the ultrasonic basin (current of around 45 kHz)
- Instruments are sonicated roughly as per the manufacturer's instructions, and cavitation gives rise to optimum detachment of particles from the surfaces of accessories

6.1.4 Disinfection in the EWD

- Remove all valves, distal cap and cleaning key from endoscope
- Place cleaning brush and small brush after mechanical reprocessing of endoscope in EWD instrument basket. Secure long components with metal clip – do not roll more tightly than 15 cm!
- Place accessories in the instrument basket – close the latter (make sure components are securely positioned in the basket)
- Place instrument basket carefully on bottom of pull-out unit of EWD
- Clean, and if possible thermally disinfect, the cleaning water bottle and connecting tube each working day in the WD

6.1.5 Dispatch to the Reprocessing Unit for Medical Devices (RUMED)

- After reprocessing in the ultrasonic basin, disinfection basin or EWD, rinse off and purge accessories thoroughly with water containing at most only a low microbial count
- Check for cleanliness – pay attention to joints and jaw region of biopsy forceps, etc.
- Dry external surfaces and channels with compressed air
- Check that synthetic components are intact, otherwise discard them immediately since damaged accessories will make scratches on the channels in the endoscopes and can, in turn, result in injuries
- Pack – with suitable sterilization foil or Sterisafe boxes, etc.
- Use sterilization method as per manufacturer's instructions. The accessories must be sterilized since they penetrate the patient's skin or mucosal barrier when used

Preparation of accessories for dispatch to the RUMED is one of the most time-consuming tasks in endoscopy! Consideration should be given to whether endoscopy accessories can be placed in a container for used supplies or reprocessed as a single unit in the RUMED. Ultrasonic cleaners, disinfection basin, etc. need a lot of space, something that is lacking in most endoscopy units. Another point to ponder would be the procurement of single-use devices.

6.1.6 Storage of endoscopy accessories

- Store in a cabinet while protected against dust and moisture
- Observe shelf life expiry dates
- MDs are placed in wire basket (for secure transport) to RUMED
- Check the list of requirements returned from RUMED (does the number of dispatched MDs correspond to that returned?)
- Check MD sterile packaging and batch
- Store MDs in the boxes provided, while protected against dust in a dry place
- When removing accessories: Caution! first in – first out!

7 Requirements for WD used for heat-sensitive endoscopes

7.1 Minimum requirement for an endoscope WD (EWD)

Automated chemothermal cleaning and disinfection. Machines designed only for disinfection purposes (i.e. no cleaning phase) do not meet the requirements of the international standard EN ISO 15883-4. Compatibility of the chemical substances used for reprocessing (i.e. compatible detergent and disinfectant) is an important factor for successful reprocessing. If incompatible substances are used together, this can give rise to massive chemical reactions (e.g. white deposits on the endoscope). Ask the supplier to give a written confirmation of safety and compatibility!

- CE mark as per directive 93/2/EEC as evidence of European approval
- A positive hygiene expert opinion issued by an accredited test body, certifying that the machine is able to guarantee an effective cleaning and disinfection performance
- Mechanism to lock door while programme is running
- Automated programme sequence, freely selectable programmes
- Automated dosage of process chemicals
- Adjustable temperature displays
- Continuous error signalling in the event of a disrupted programme sequence (water shortage, temperature fluctuations, process chemicals' shortage)
- Process documentation (minimum: EWD identification, date, time, temperature)
- **Rinse Cleaning step between cleaning and disinfection phase (no 'Eco programme')**
- Optimized external and internal cleaning of the entire endoscope, incl. supply tube and coupling, suitable cleaning connections for all channels
- Suitable loading trolleys with matching racks and supports
- Decontamination facility for the last rinse water to prevent recontamination
- Operating manual in national language and documented training of personnel
- Provision must be made for adequate drying (possibly dedicated drying cabinet)

There is a European (and international) standard (EN ISO 15883-4) regulating endoscope washer-disinfectors, which sets out the requirements for an EWD as well as its performance criteria.

7.2 Additional requirements for new EWD models (as per EN ISO 15883-4)

- Type test report (at least certification)
- Cold pre-rinse
- Individual channel connections (no “pressure chambers”)
- Continuous documentation of programme steps (batch printer with ACTUAL values)
- Traceability (scanning of details of endoscopes, users)
- Automated leakage test
- Facility to check flow rate of all channels (automatic detection of blockage of individual endoscope channels)
- Self-disinfection programme (thermal)
- Currently, still optional: automatic identification of endoscopes

8 Testing EWD and process validation

8.1 Installation qualification (operational qualification, OQ):

If not otherwise contractually agreed, the manufacturer must take charge of this.

After the EWD has been installed, the technical acceptance test (installation qualification) is conducted by a technical expert designated by the respective institution.

- Check of documentation, including type test documentation
- Doors and seals
- Escape of liquids
- Supply of operating materials
- Safety engineering
- Design (e.g. solder seams)
- Check of other technical specifications (e.g. as per tender)
- Hygienic acceptance (after successful technical acceptance, but before commissioning the EWD) conducted by an independent (accredited) test centre or hygiene expert

8.2 Periodic tests

To be taken charge of by User.

Annually:

1. Verification of the cleaning performance using endoscope dummies and cleaning indicators or adequate test procedure according ISO/TS 15883-5.
2. Microbiological testing of total reduction of microbial count: bioindicators with *Enterococcus faecium* (possibly together with 1) or adequate test procedure according ISO/TS 15883-5.
3. Thermoelectric measurement of programme sequence using calibrated thermocouples
4. Microbiological testing of last rinse water
5. Check of dosage precision and temperature display

8.3 Routine checks by user

Assign competences to conduct such checks!

For each batch

- Visual checks for cleanliness of outer surfaces and critical areas such as e.g. Albarran lever
- Verification of compliance with disinfection parameters by comparing ACTUAL and TARGET values (temperature, time, dosage of detergent and disinfectant)

Daily:

- System check including leakage test (carried out automatically by the EWD)
- Check of filling level of operating materials (detergent and disinfectant, salt) – inspect also WD display (to be recorded in machine log book)
- Check cleaning connections

Weekly

- Start self-disinfection cycle
- Check filter
- Check spray arms
- Inspect cleaning chamber
- Check cleaning performance running a full cycle using cleaning indicators with corresponding test systems (preferably tubes with an internal diameter of 2 mm) at regular intervals, checking all connections in alternating order.
- Random tests for protein residuals in endoscope channels (e.g. BCA reaction or adequate commercially available test kits)
-

Annually:

- Technical testing (maintenance / servicing) by service engineer
- Hygienic testing and revalidation by independent (accredited) test centre or hygiene expert
- Microbiological testing of rinse solutions from endoscope channels and if applicable swab from the recess behind the Albarran lever at least once a year (if there are several endoscopes, it is recommended that inspections be conducted at three-monthly intervals, making sure that every endoscope is tested once a year).

Documentation of checks carried out in adequate protocols (to assure traceability).

8.4 Process validation

A further step towards greater process safety is the Validation of the cleaning and disinfection process as a whole as per EN ISO 15883-1 and 4 and national regulations/guidelines respectively.

The minimum requirements addressed to the EWD must be met in order to be able to conduct process validation.

9 References

- 1) EN ISO 15883 part -1 and -4, ISO/TS 15883-5
- 2) KRINKO-BfArm (RKI guideline): Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten, Bundesgesundheitsbl 2012 · 55:1244–1310, Springer-Verlag 2012
- 3) Guidelines of the European Society for Gastrointestinal Endoscopy/ Nurses Association (ESGE/ESGENA)

10 Links

- www.rki.de
- www.esgena.org/index.php/publ_guide/guide_esge_esgena/
- <http://www.wien.gv.at/gesundheit/strukturen/hygiene/>
- www.oegsv.com >guidelines
- Professional Standard Handbook Flexible Endoscopes - Cleaning and Disinfection (sferd guideline) http://www.wfhss.com/html/educ/recommendations/sferd-handbook-flexible-endoscopes-cleaning-disinfection_en.pdf

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