

Reprocessing of Medical Devices in/ for Healthcare Establishments

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WFHSS Guideline on Reprocessing Medical Devices in / for Healthcare Establishments

This Guideline has been compiled pursuant to the Medical Devices Directive of the EU.

1 General requirements

Medical device (MD) reprocessing in or for healthcare establishments must be conducted with validated processes that demonstrate that a process continually meets the given specifications.

This does not apply for MDs belonging to the non-critical group, as defined by the Robert Koch Institute (RKI) (see Annex 2.)¹

Note: "Validation serves to furnish documented proof of the ongoing effectiveness of the reprocessing process under the operating conditions prevailing at the installation site, using the medical devices encountered in routine operation in their respective packaging and with the reference loads used (i.e. to ensure clean, disinfected or sterile devices)."

The functions of a MD, as dictated by its intended purpose, or compliance with the relevant safety requirements must not be adversely affected when the device is reprocessed.

Medical device reprocessing must be conducted in accordance with the state of the art in science and technology.

Note: The state of the art in science and technology is dictated by pertinent harmonised standards and by relevant national or international standards and guidelines, such as those published by specialist associations.

2 Competencies

Overall responsibility for medical device reprocessing in prescribed form is borne by the proprietor or authorities in charge of the respective establishment.

Before MDs are procured, those parties responsible for their reprocessing must be aware of the attendant reprocessing conditions and the requisite equipment must be available in the establishment (see wfhss guideline No 02: "Check List for Procurement of Medical Devices pursuant to EN ISO 17664").

The manufacturer of a reusable MD must supply instructions on how to reprocess the

¹ The RKI scheme rather than the Spaulding scheme takes into account the consequences for reprocessing of assigning MDs to risk groups.

device, using (pre-) validated² processes as per EN ISO 17664.

Competencies and working practices related to all steps of the reprocessing chain must be set out in writing in the form of standard operating

3 Risk analysis, evaluation, selection and definition of suitable reprocessing methods

To ensure that they are reprocessed in prescribed form, medical devices must be classified into risk groups in accordance with Annex 2.

Based on this classification, it must be set out in writing

- whether,
- how often,
- with which process
- and under what conditions

medical devices are to be reprocessed and stored.

The following aspects, in particular, must be borne in mind:

- the manufacturer's instructions, if relevant,
- the resistance profiles of the microorganisms and potentially infectious agents (e.g. prions) expected on the MDs,
- expected intervals between the time the MDs are used and the time reprocessed, with correspondingly more challenging reprocessing demands as well as
- special risks posed by the MD when using and/or reprocessing it.

4 Organisational measures, quality management (QM), validation, monitoring

Reprocessing Units for Medical Devices (RUMEDs) entrusted with medical device reprocessing are divided into three categories on the basis of the highest risk group to which the medical devices they reprocess are assigned (see Annex 3).

Competencies and responsibilities within the RUMED must be defined (e.g. in the form of an organogram). RUMED managers must have corresponding deputy managers.

² The term "prevalidation" is understood to mean tests conducted for the purpose of identifying a suitable reprocessing procedure; these are carried out on behalf of the manufacturer and should preferably be performed by an independent test body

The structural conditions must permit high quality reprocessing in line with the state of the art in science and technology.

The equipment, fittings and adjuncts needed for MD reprocessing must be available and comply with the state of the art (see Annex 3).

For medical device reprocessing all precautions and measures must be taken to assure a demonstrable and continually high quality of reprocessing, in line with the validation specifications.

Reprocessing of medical devices subject to ultra stringent reprocessing demands ("Critical C" devices as per Annex 2) must be conducted in line with a QM system pursuant to EN ISO 13485 (see Annex 3).

The quality of automated reprocessing (cleaning, disinfection and sterilisation) must be assured by the following measures:

- installation qualification
- validation of reprocessing procedures
- periodic (at least annual) revalidation
- routine daily tests on each day the RUMED is in operation
- batch-related routine tests
- monitoring and testing of process parameters using measurement technology.

5 Personnel qualification

Reprocessing in general, or any reprocessing task, may only be conducted by persons who by virtue of their training, knowledge and practical experiences are able to assure proper execution of such tasks (see Annex 3):

- All persons entrusted with MD reprocessing must have successfully attended Specialist Training Course 1 (series of training courses specifically designed for sterilisation assistants), or be in possession of an equivalent qualification.
- Managers and deputy managers of Category II RUMEDs must additionally have successfully attended Specialist Training Course 2
- Managers and deputy managers of Category III RUMEDs must additionally have successfully attended Specialist Training Course 3

Knowledge and skills must be acquired by attendance at appropriate continuing professional development seminars based on the state of the art in science and technology.

6 Documentation

When reprocessing MDs belonging to Semi-Critical B as well as to Critical B and C risk groups, the measured values recorded for the process parameters and underlying the decision-making process for MD release must be documented, while indicating the batch name and name of the person responsible for release. These values must furnish proof that the reprocessing procedure was carried out in compliance with the standard operating procedures (SOPs), using the parameters set out in the validation protocol. This batch documentation must comprise at least:

- Date
- Equipment serial number
- Programme
- Serial batch numbers
- Designation of reprocessed load or similar code
- Operator's name
- Release by responsible person
- Printout of measured values in analog or digital form (actual values)
- If applicable, results of batch control (e.g. cleaning indicators, chemical indicators)

Documentation of reprocessing MDs belonging to the non-critical risk group is not required, while that of Semi-Critical A and Critical A risk groups must be adapted to the intended use on the basis of risk assessment and the mode of reprocessing inferred from that.

Category I RUMED documentation, as per Annex 3, must be archived in a well-assured readable form for at least five years, and Category II and III RUMED documentation for at least 10 years. Electronic documentation, including release documentation, is permitted provided that readability and data safety are assured for the specified period.

7 External reprocessing (outsourcing)

The term “external reprocessing” is used to describe a situation where healthcare establishments outsource reprocessing in general, or parts thereof, to an authorised external service provider. The same requirements refer to insourcing.

Outsourcing of reprocessing to a third party must not in any way negatively impact on the healthcare establishment's ability to meet the terms of its own service contract.

Reprocessing service providers or healthcare establishments that conduct MD repro-

cessing for other healthcare institutions must use validated reprocessing procedures.

Commercial service providers conducting MD reprocessing for healthcare establishments with Category II and III RUMEDs as per Annex 3 must have in place a certified QM system as per ÖNORM EN ISO 13485.

The following aspects, in particular, must be contractually regulated between the external service providers and the person (s) responsible for the respective healthcare establishment (Category II and III RUMEDs as per Annex 3):

- The conditions to be met to assure running operations (e.g. emergency measures as well as regulations on coping with bottle necks, breakdowns, standby);
- Duties, responsibilities and competencies of contract awarder and contractor (interfaces);
- Ownership rights as regards the MDs;
- Condition and quality of MDs to be reprocessed;
- Liability for (transport) damage;
- Handover conditions;
- Feedback system;
- Quality assurance measures (if necessary, certification as per ÖNORM EN ISO 13485, see above);
- Transport logistics, including protected transport of contaminated instruments;
- Maximum time interval before soiled MDs are reprocessed;
- Whether and how any pre-treatment measures are to be conducted for MDs already within the respective establishment, while taking account of specific types of soils;
- (Special) release regulations;
- Loaned instruments;
- Validation obligations of contract awarder and contractor;
- Qualifications of managers and staff in both premises (as per Annex 3);
- Nature, frequency and scope of checks to be conducted by contract awarder;
- Nature and scope of documentation to be provided by the contract awarder (validation, re-validation reports, if applicable batch release documentation).
- Compatibility with the quality management system of the hospital
- Compatibility with the documentation system of the hospital

8 Authors

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The guideline has been proof read and authorized by the wfhs education group

ANNEX 1: Standard operating procedures (SOPs)

The RUMED management must ensure that standard operating procedures are available and clearly displayed for the persons entrusted with the respective tasks. The RUMED management, or a person explicitly designated in writing to that effect by the latter, must ensure that RUMED employees are also able to understand the content of such SOPs.

This applies in particular for the following:

1. All partial steps, such as:

- **Measures conducted immediately after using an MD, e.g. pretreatment, dismantling, collection and intermediate storage**
- **Transport**
- **Cleaning**
- **Rinsing**
- **Disinfection**
- **Drying**
- **Verification of steps conducted hitherto (cleaning results, etc.)**
- **Maintenance and care**
- **Functional testing**
- **Packaging**
- **Arrangement of supplies for sterilisation**
- **Sterilisation**
- **Labelling**
- **Release**
- **Transport of sterile supplies**
- **Storage of sterile supplies**
- **Measures conducted immediately before use (e.g. checking that sterile supplies are undamaged)**

2. Special processes

2.1 Reprocessing MDs that have not been used

These medical devices include:

- **MDs which were supplied in an unsterile condition but must be sterile when put to use,**
- **Sterilised MDs whose packaging was damaged or opened without the MD having been used and which, as specified by the manufacturer's instructions, can be reprocessed.**
- **MDs whose sterile storage period has expired before the expiry date**

and which, in terms of their composition, are amenable to reprocessing.

2.2 Reprocessing of MDs which may be used or reprocessed only for a limited number of times

2.3 Reprocessing of textile materials

2.4 Patient-related specific forms of reprocessing.

3. Critical processes

3.1. Reprocessing of heat-sensitive MDs (e.g. endoscopes)

3.2. Reprocessing of MDs with poorly accessible sites (e.g. minimally invasive surgical (MIS) instruments)

3.3. Reprocessing of MDs posing a risk of injury to users, personnel or patients (e.g. faulty electrical currents, pointed/sharp implements)

3.4. Reprocessing of MDs subject to more stringent reprocessing requirements (e.g. residues that are difficult to remove)

3.5. Reprocessing of MDs made of special materials or technical configuration (e.g. kinks, liable to scratches, antimagnetic, cannot be immersed in liquid, aluminium)

3.6. Manual reprocessing steps

3.7. Reprocessing of MDs subject to special reprocessing requirements because of specific infectious agents (e.g. prions)

ANNEX 2: Classification of medical devices into risk groups

(modified as per RKI)

Classification of MDs into risk groups is done on the basis of previous and subsequent use, transport and storage conditions, design and materials. If there is any doubt about the risk group to which the MD belongs, assign it to the higher group.

Preference must be given to automated reprocessing in a washer-disinfector because it assures better standardisation and occupational protection. Disinfection should preferably be performed with a thermal process.

| Classification | Description | Medical device Example | Pretreatment^a | Cleaning / Disinfection | Spec. label | Sterilisation | Critical process steps, special requirements |
|-----------------------|--|---|---------------------------------|--------------------------------|--------------------|----------------------|---|
| NON-CRITICAL | Contact with intact skin | ECG electrode, Kidney dish | | X | | (X ¹) | Inspection: visual cleanliness |
| SEMI-CRITICAL | Contact with mucosa or pathologically altered skin | | | | | | |
| A | No special reprocessing requirements ^b | Specula, Oral mirror, dental scoop, endoscopes without lumens | (X ²) | X | | (X ³) | Preferably automated cleaning (C) and disinfection (D), at least disinfection with suitable agents / process |
| B | Subject to more stringent reprocessing requirements | Flexible endoscopes with lumens ^c , Hand and angled pieces ^{cd} | X ⁴ | X | | (X ³) | Automated C/D |
| CRITICAL | Skin or mucosa penetration, contact with open wounds, drugs, blood or blood products that must be administered in sterile condition | | | | | | |
| A | No special reprocessing requirements | Wound retractors, Needle holders | (X ²) | X | | X | Automated C/D for Cat. III RUMED, otherwise preferably automated C/D Steam sterilisation |
| B | Subject to more stringent reprocessing requirements | Heat-sensitive MIS instruments, surgical drapes | X ^{4, e} | X | (X ⁵) | X | For all parts coming into direct contact with tissue, only automated thermal C/D in suitable WD and steam sterilisation |
| C | Subject to ultra stringent reprocessing requirements | Angioscopes Epiduroscopes | X ⁴ | X | X ⁵ | X | For non-thermal sterilisation processes, no evidence of prion inactivation has been furnished to date. This must be borne in mind for MDs belonging to this group |

^a Pretreatment: this is understood to mean removal of course soils or a measure aimed at prevention of incrustations, but need not be limited to these. Pretreatment is done at the site of MD use.

^b e.g. can cleanliness be checked through visual inspection

^c if it cannot be classified as "critical";

^d preferably, automated reprocessing, if this is not possible, then steam sterilisation with suitable pro-

cesses following manual reprocessing

^e does not apply to surgical drapes

(X) optional working step

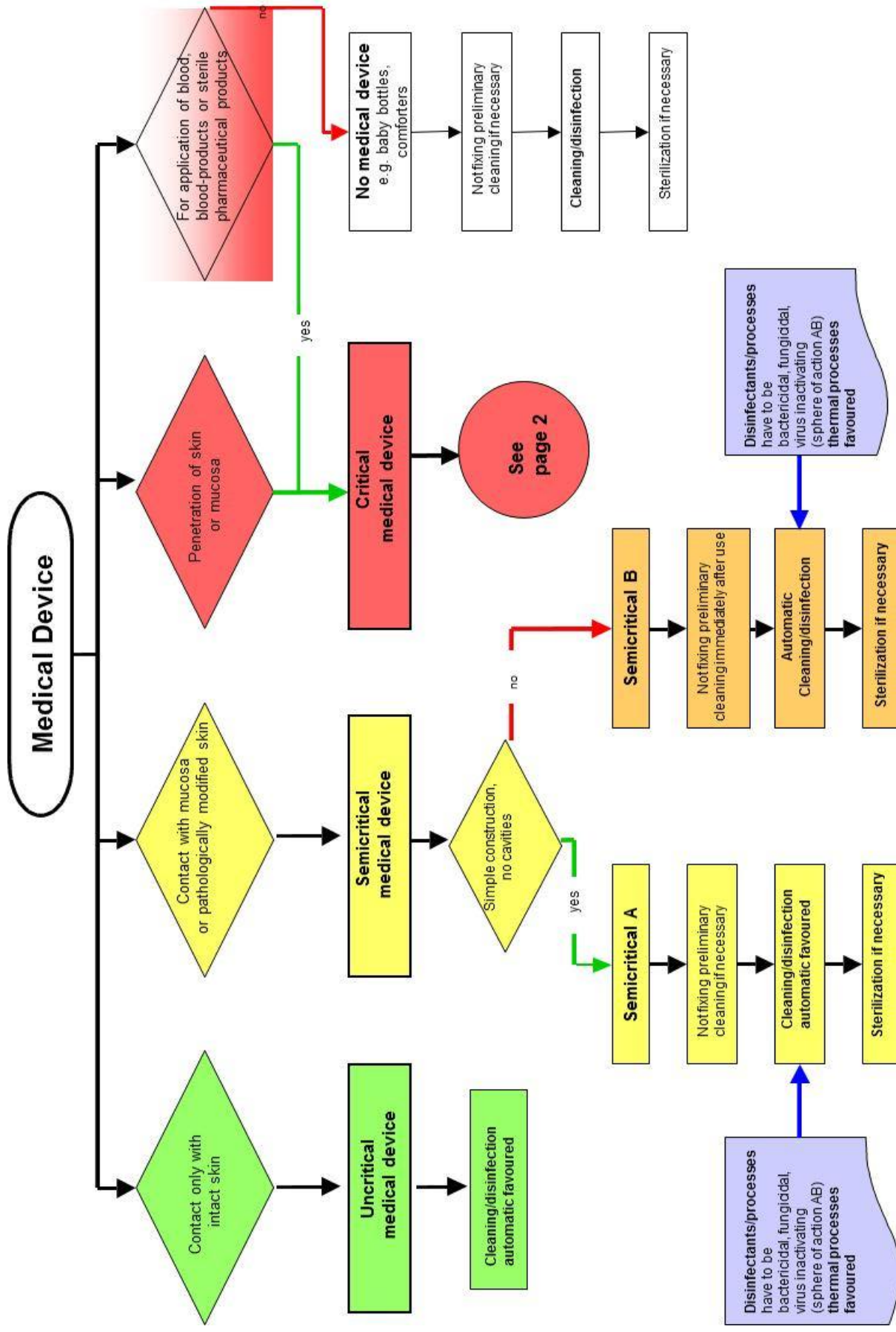
X¹ steam sterilisation may be needed, bearing in mind specific requirements.

X² pretreatment immediately after use with non-protein fixing agents/process

X³ for MDs that are not used in physiologically sterile body cavities, final disinfection suffices apart from cases of intraoperative use.

X⁴ these MDs (semi-critical B, critical B, C) must be treated immediately after use to pave the way for subsequent cleaning and disinfection, so that final cleaning is conducted as quickly as possible using automated processes, while preventing corrosion or other form of damage to the instruments. All factors of influence here must be defined and taken account of during validation..

X⁵ A special label is used for identification, information and tracking (as required, information must be displayed on the following: batch no., serial no., manufacturer's name, type and number of reprocessing cycles., max. number of reprocessing cycles permitted, safety and warning instructions, etc.).





ANNEX 3: Requirements for RUMEDs in healthcare establishments

| Reprocessing unit category | I | II | III |
|--|---|---|--|
| Risk group of medical device (MD) to be reprocessed | Non-critical, semi-critical A, critical A ⁽¹⁾ | Non-critical, semi-critical A, B, critical A | All groups |
| Healthcare establishments | e.g. (homes for the elderly / nursing homes, outpatient departments, medical practices ⁽²⁾) | e.g. healthcare establishments without surgical units | e.g. healthcare establishments with surgical units |
| Quality assurance | Appropriate quality assurance measures | Appropriate quality assurance measures (minimum requirements as per Robert Koch Institute - RKI) | QM system preferably based on, for critical C devices based on EN ISO 13485:2003 |
| Structural requirements | <ul style="list-style-type: none"> - Dedicated area - Preferably with separate unclean / clean/ sterile zones (temporal separation possible) | <ul style="list-style-type: none"> - Dedicated reprocessing room - Separate unclean/clean/sterile zones ⁽³⁾ | <ul style="list-style-type: none"> - Dedicated premises - Separate unclean/clean/ sterile premises ⁽⁴⁾ |
| Staff qualifications | Management and staff at least Specialist Course I ⁽⁵⁾ | Management: at least Specialist Course II Staff: at least Specialist Course I | Management and deputies: Specialist Course III Staff: at least Specialist Course I |
| Technical equipment | <ul style="list-style-type: none"> - If necessary small steam sterilizer (Class B recommended) as per EN 13060 - If, necessary ultrasonic cleaning equipment - If necessary, washer-disinfector (WD) as per EN ISO 15883 - If necessary, heat sealing machine | <ul style="list-style-type: none"> - Steam sterilizers (big or small) as per EN 285 or EN 13060 - Endoscope WD as per EN ISO 15883 - If necessary, rotary sealing machine - If necessary, ultrasonic cleaning equipment | <ul style="list-style-type: none"> - Steam sterilizers (big) as per EN 285 - If necessary, equipment for special sterilization processes (e.g. low-temperature sterilizers) - Endoscope WD as per EN ISO 15883 - Rotary sealing machine - Ultrasonic cleaning equipment |

(1) Call for special consideration; (2) with the exception of lumened endoscopes (Cat. II) and surgical procedures (Cat. II), except for management of small wounds; (3) For new endoscopy units – centralisation and separate unclean/clean premises are recommended; (4) For new, extended or converted premises, clean area should meet requirements of ISO class 8 as per ISO 14644-1, as far as possible also for existing establishments; (5) deemed to have been met for degree-level nursing staff or for medical personnel

Concept for continuing professional development courses for "Reprocessing medical devices in/for healthcare establishments"

| COURSE | SPECIALIST COURSE I | SPECIALIST COURSE II | SPECIALIST COURSE III |
|-------------------------|--|--|--|
| TARGET GROUP | Semi-skilled staff and assistants; Dental staff ** or dental assistants | Semi-skilled staff with special duties (e.g. able to release MDs) and graduates with responsibility for a section | Managers and deputy managers |
| EXTENT | 80 hours: theory and practical exercises | 80 hours: 40 hours theory 16 hours practical exercises 24 hours practical work | 80 hours: 40 hours theory 40 hours concluding assignment |
| ADMISSION REQUIREMENTS | None | Successful completion of Specialist Course I. and at least 1 year's experience in a MD reprocessing unit or Suitably recognised Qualification (in accordance with national requirements) and successful examination on content of Specialist Course I (without attending course) | Suitably recognised Qualification (in accordance with national requirements) and successful completion of Specialist Course II |
| REQUIREMENT FOR | Management of RUMED Cat. I **, Staff of RUMD Cat. I **, II, III | Managers and deputy managers of RUMED Cat. II Responsibility for section of RUMED Cat. III. | Managers and deputy managers of RUMED Cat. III |
| DEADLINE FOR COMPLETION | Within 2 years of taking up position | Within 2 years of taking up position | Within 2 years of taking up position |
| EXAMINATION | Examination of knowledge | Examination and assignment | Examination and final assignment |

* if not covered in specialist OR course, ** except for degree-level nursing staff or for medical personnel

Source: Austrian Society for Sterile Supply (ÖGSV), www.oegsv.com