WFHSS ÖGSV

Sterile Supply Specialist Training Course Level II

PROCESS-ORIENTED MEDICAL DEVICE CIRCUIT

R. Zierler

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Process orientated Medical Devices Circuit

1 Introduction

When designing a RUMED (**R**eprocessing **U**nit for **Me**dical **D**evices), the constructional, spatial, technical and organisational structures as well as staff qualifications and procurement of instruments and equipment must be taken into account.

The requirements to be met by RUMED Categories (I – II – III) are tailored to the risk groups to which the medical devices to be reprocessed in the RUMED belong (see wfhss guideline 04 on Reprocessing Medical Devices).

The aim is to plan and implement a process-oriented medical devices circuit of the highest quality possible, so as to provide patients with safe treatment and nursing care within the various departments.

Medical devices must be reprocessed using a local validated process whereas the manufacturer's instructions should be kept in mind.

Note: The manufacturer`s instructions might not be in accordance with european or international standards, the state of the art or the standard processes carried out in the RUMED respectively. In this case a documented risk assessment based on the experience of the department shall be conducted.

Proof of the ongoing effectiveness of the process must be demonstrated and the safety and health of patients, users and third parties must be assured.

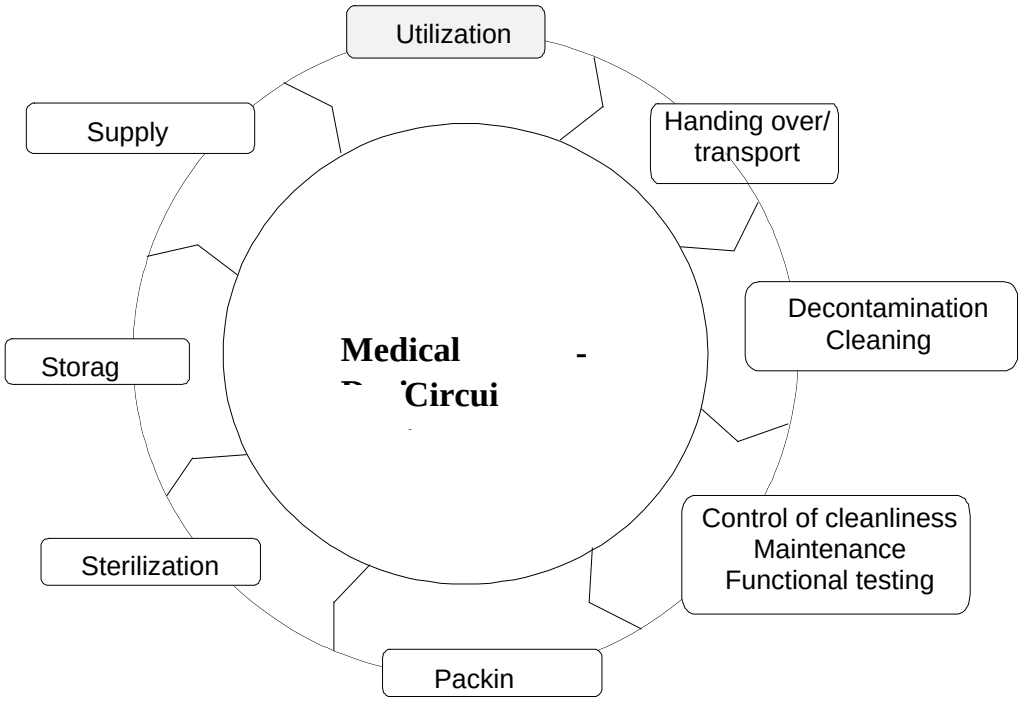

Fig.. 1: Medical devices circuit

The medical devices circuit starts already when the device is put to use (utilisation), followed by reprocessing and ends with reuse of the device or by withdrawal from circulation of any broken instruments or appliances. The circuit signposts the order in which reprocessing tasks are to be conducted and this must be complied with.

Note: Actually new MDs have to be fully processed before the first use,

2 Collection / transport of supplies after use

This means collection of the contaminated instruments and other medical devices at the site of use and their transportation to the RUMED for decontamination. The aim of this step of the reprocessing circuit is to ensure that the medical devices are properly collected already in the operating room (OR) or at the site of use so that their value is retained. As applicable, preparation/pretreatment of the medical devices by the OR staff (see below) helps to enhance the reprocessing quality, boost the efficiency of working practices and prevent injuries and accidents.

A distinction is made between dry and wet transportation of contaminated supplies.

2.1.1 Dry transportation

The contaminated supplies are placed for intermediate storage in containers or on trays without addition of any solutions and then transported to the RUMED (see below) in closed transportation trolleys (see as well 2.2.2).

2.1.2 Wet transportation

The contaminated supplies are placed for intermediate storage in containers, i.e. they are fully immersed in a detergent and/or disinfectant solution or sprayed with an appropriate cleaning solution and are thus transported to the RUMED.

2.1 Task definition

- Compile a procedural instruction and standard operating procedures (SOPs) which, in addition to the working steps, take account of the following:
  - Personal protection / occupational protection (e.g. avoidance of injuries, infection, hazardous substance explosion, physical exertion due to lifting heavy loads, etc.)
  - Prevention of environmental pollution
  - Value retention of supplies

2.2 *Implementation of tasks*

2.2.1 Collection of contaminated supplies at the site of use

Personal protection equipment must be used!

The instruments must be **arranged properly** on the trays, i.e. do not place heavy instruments on top of delicate instruments**.**

Discard all disposable supplies after use. Broken instruments and any devices not suited to automated cleaning must be arranged separately.

Remove coarse soils from medical devices (MDs) immediately after use and at the site of use – do not use any fixing agents or hot water (> 40 °C) since this would lead to fixation of residues.

The MDs should be transported to the RUMED as soon as practically possible.

Medical devices belonging to semi-critical B as well as critical B and C risk groups should be transported to the RUMED immediately after use. If this is not possible they must be pretreated on site in such a way that automated cleaning will not be impeded (e.g. rinse hollow instruments to assure patency).

Definitions: **pretreatment** is understood to mean preparing a device at the site of use for subsequent reprocessing, whereas **precleaning** constitutes a (manual) step of the actual reprocessing circuit in the RUMED. In the interest of standardisation and occupational protection, the latter should be avoided as far as possible.
(pretreatment ≠ precleaning)

2.2.2 Dry transportation

Dry transportation should be given preference over wet transportation since this avoids the complications associated with disinfectant solutions (e.g. toxicity, spillage) and, in general, this is a more gentle approach for the medical devices.
As well heavier containers cause more ergonomic problems.

The tray with its load of contaminated supplies is placed in a transportation container. The transportation containers / trolleys must be closed for intermediate storage and transportation of contaminated supplies if there is no immediate connection to the RUMED. If there is a direct connection, the covered instruments can be taken directly to the RUMED.

2.2.3 Wet transportation

The transportation containers must be sealed tightly to prevent leakage of the solutions used. The containers should be filled with enough solution to fully cover the contaminated supplies.

The solution used for wet transportation must be prepared, at the collection site, in accordance with the cleaning and disinfection policy.

Containers which are filled with a liquid might be very heavy and should not be lifted or transported manually. Gloves and orofacial masks must be worn when handling disinfectant and detergent solutions, as well as water-impermeable protective clothing if there is a risk of splashing.

If wet transportation is used, the detergent/disinfectant solution is preferably to be removed before transportation. As well no protein-fixing agents are to be used.

The solution used for wet transportation must be discarded after removal of the supplies.

3 Taking charge of contaminated supplies in the RUMED

- Decontamination should be commenced as soon as possible.
- Use personal protective equipment (e.g. disposable apron, gloves, headgear). When handling solutions, a visor or goggles should be worn additionally.
- New instruments and instruments returned after repair must always be reprocessed in a washer-disinfector (WD) before they are stored.

4 Cleaning and disinfection

4.1 Automated cleaning and disinfection process

4.1.1 Requirements for a WD

The following minimum requirements must be met by the WD (this applies to WDs, which were commissioned prior to the release of EN ISO 15883):

- Automated programme cycle (if possible, freely selectable programmes)
- Mechanism to lock door during programme cycle
- (Adjustable) temperature displays
- Automated dosage of process chemicals (this should permit volumetric control)
- Continuous fault signalling if programme cycle faulty (water shortage, temperature undershot during disinfection phase, shortage of process chemicals)
- Batch counter (or documented control system)
- Fault report and display
- Process documentation (minimum temperature/time variables as ACTUAL values, date, time)
- Suitable supports for hollow instruments (microsurgical / anaesthesia instruments)

4.1.2 Factors that impact on the success of cleaning / disinfection

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- Precleaning
  - Water temperature and quality
  - Foam formation if rinse aid used at too high temperatures
  - Time
  - Spray mechanical action

- Main cleaning step
  - Cleaning temperature (appropriate to the detergent)
  - Time
  - Spray mechanical action
  - Detergent (alkaline, enzymatic, neutral)
  - Dosage
  - Dosage temperature (risk of foam formation if dosage temperature too low for neutral detergents
  - Foam formation by detergent in the presence of blood
  - Water quality

- If applicable, neutralisation
  - Dosage

- Intermediate rinse
  - Temperature
  - Time
  - Water quality

- Disinfection phase (final rinse)
  - Temperature
  - Time
  - Water quality (only deionised water)
  - Dosage (rinse aid or disinfectant for chemothermal process)

- Additional factors
  - Type of MD
  - Incorrect loading
  - Overloading of trays (spray shadowing)
  - Drying time too long
  - Composition of instruments (age, wear, corrosion)
  - Trolleys not placed properly in WD

4.1.3 Operation of WD

Operation of the WD must be set out in SOPs.

These must contain:

- Specifications for loading and unloading
- Check according to the checklist and sign it
- Information on programme selection
- The measures to be taken in the event of a faulty programme cycle must be defined.

The following information is needed additionally:

- Description of programmes
- Operating instructions
- Description of detergents and disinfectants as well as of rinse aid (dosage instructions)
- Maintenance schedule as per the manufacturer's instructions / maintenance manual, etc.

4.1.4 Routine tests

A routine test schedule must be compiled, showing which tests are to be performed, how often and by whom. The scope of the various checks must be set out in SOPs and the findings and reports documented.

See also wfhss guideline 05 (in progress) for "Testing, Validation and Monitoring of Automated Cleaning and Disinfection Processes for Medical Devices in compliance with Standard EN ISO 15883 Part 1, 2 and CEN ISO/TS 15883-5"

4.1.4.1 Cleaning results:

- Visual inspection of each batch for cleanliness
- Conduct spot checks using a protein detection test (e.g. BCA reaction as per Annex E of EN ISO 15883-1) at least after reprocessing MDs belonging to the semi-critical B and critical B and C risk groups – at least weekly.
- If applicable, check cleaning results using cleaning indicators at regular intervals. A schedule should be defined for periodic checking of all critical sites in the WD.
- Annual testing by independent test body (or revalidation)

4.1.4.2 Disinfection results:

- Check that disinfection parameters are being complied with for each batch by comparing ACTUAL with TARGET values (parametric release based on batch documentation)
- If necessary, use device-independent temperature loggers
- Annual testing by independent test body (or revalidation)

4.1.4.3 Water quality

- Check conductivity of demineralised waters (weekly)

4.2 Ultrasound and manual cleaning

4.2.1 Ultrasound

Ultrasound is used only as a precleaning method for MDs that have been revealed to be difficult to clean using automated reprocessing (poorly accessible sites, no appropriate facilities available for connection to WD, e.g. biopsy forceps). The cleaning action of ultrasound is based on generation of cavitation. Cavitation entails the formation of bubbles in fluids at low pressure.

Whether decontamination is to be conducted together with ultrasonic treatment (recommended) or separately must be defined, and the specified treatment duration must be observed.

Demineralised or softened water must be given preference over tap water (drinking water quality). Provision must be made for adequate degassing, i.e. fill the ultrasonic basin, switch on unit and operate for 5 min without any instruments.

Ultrasonic equipment must never be operated without a solution (filled to correct level) since otherwise the oscillation system could be damaged. Do not reach into the basin while it is in operation.

Connect lumened instruments either to the connection facilities available or use a syringe to collect solution and leave syringe connected. The machine should always be kept closed and do not sonicate for more than five minutes as this could in the course of time give rise to cracks in the instruments.

The manufacturer's operating instructions should always be observed and the steps involved must be clearly defined in a SOP!

Automated cleaning and disinfection must be carried out in a WD immediately after ultrasonic cleaning.

4.2.1.1 Routine tests

A **functional test** checks distribution of ultrasonic energy within the basin**.** This should be performed after servicing tasks and quarterly. The **routine test** checks ultrasound performance under practical conditions. This test should be carried out with an instrument load. The process challenge device (PCD) undergoes a change in colour (e.g. from green to yellow). This result must be checked using a guide (based on the manufacturer's instructions), i.e. if the colour change does not manifest or is delayed, checks must be conducted. These procedures must be documented.

4.2.2 Manual cleaning

Manual cleaning does not reflect the state of the art, nor can it be validated. Therefore it should only be resorted to situations where there is no alternative. The manual cleaning steps should also be accurately described in SOPs.

A few remarks on manual cleaning:

- Personnel protection: headgear, orofacial mask with visor, rubber gloves with long U-arm cutout, disposable apron or water-impermeable gown.
- Remove coarse organic soils (e.g. tissues residues, faeces) – this should always be done at the time of use (as well as during automated reprocessing too).
- Immerse immediately in a detergent/disinfectant solution, while avoiding air bubbles (do not use fixing products!)
- All instrument surfaces should be fully immersed in the solution.
- Never clean under running water since generation of aerosols would lead to spread of microbes, i.e. always clean items below the water level.
- On expiry of the exposure time, clean instruments and rinse with tap water or preferably with demineralised water to remove solution residues. (spray pistol, etc.)
- Do not use brass brushes, scouring sponge pads or similar.
- Other reprocessing steps, e.g. drying (compressed air pistol, etc.) must be described in an SOP, as outlined above.

Note:

- Demineralised water is not sterile unless it is bottled in a sterile state and designated as a sterile solution.
- The concentration and use period of solutions should be defined in accordance with the manufacturer's instructions and in cooperation with the infection control team. This must be documented. (Reprocessing standard, cleaning and disinfection policy).

5 Functional testing and Care of Medical Devices

5.1 Withdrawal of MDs from the WD

At the end of the programme, check, document and archive the programme printouts.

Check that the instruments have not been displaced or disconnected from nozzels etc.

Now the instruments from the various trays are assigned on the basis of the tray or packing list. This task can be facilitated by devising a common designation system (e.g. numbers).

Always allow the instruments to cool down – otherwise there is a risk of metallic abrasion, which in turn can lead to fretting corrosion and pitting corrosion.

Visual inspection of the cleaning results (preferably using magnifying spectacles or lamp) – if residual soils are detected the instrument must be cleaned once again. This procedure must be set out in an SOP.

5.2 Inspection and maintenance of MDs

The aim of maintenance and functional testing – maintenance is performed before the functional test – is to ensure that the instrument will be perfectly suited to its intended use, and thus comprises the following tests:

- Jointed instruments must be easy to operate
- Instrument oils are applied selectively and manually to joints and sliding parts. Through repeated movements the oil is evenly distributed, thus preventing metallic abrasion. Remove excess oil with an absorbent cloth. Only steam-permeable oil may be used.
  Joint lubricants that prevent the sterilant from gaining access to the surfaces are not suitable.
  Care oil sprays should be avoided since, they would generate aerosols (personnel protection!) and, it is hard to apply them accurately.
- All lumens must be checked (e.g. use suitable mandrin to that effect).
- Any damaged or bent instruments (rust, loose screws) must be removed and sent for repair or discarded
- Current-conducting components (connections, patency, visible integrity of insulation)
- Motor systems, handpieces and rotating instruments must be checked and lubricated as per the manufacturer/s instructions.

5.3 Assembly

Instruments must be assembled as per the manufacturer's instructions to ensure impeccable functioning of the respective instrument. When assembling instruments, ensure that the sterilant will also be able to access to already assembled components. Instruments can be sterilized in an assembled state only if the manufacturer has specified this.

5.4 Documentation

To assure accountability, the person who carried out functional testing and packing must record their recognizable initials (or their name) with date on the tray/packing list.

6 Sterilization packaging

After decontamination, cleaning, maintenance and functional testing, the sterile items must be suitably packed.

The packaging must protect the sterile supplies against microbial contamination when withdrawn from the sterilizer chamber, during storage and transport and until the time of use.

The type of packaging is tailored to the sterilization process and the sterile supplies. It must not detract from the effectiveness of the sterilization process.

The packaging units must be assembled to meet the respective requirements. The sterile items must be packed to allow aseptic presentation of the product at the point of use. This must be agreed with the user. The packaging must not impede air expulsion from the supplies or penetration of steam/gas into the supplies.

The protective function of the packaging and subsequent drying /desorption of the items must not be adversely affected by condensate.

Sets, trays and laundry packs must be packed in a standard manner.

Detailed information on this topic is given in Specialist Training Course I Script.

7 Sterilization

See also chapter "Fundamentals of Sterilization"

7.1 Loading the sterilization trays

- Pouches are placed vertically in the trays.
- The trays should be filled such that there is enough space to fit a hand between them.
- No items should project from the trays.

7.2 Loading the trolley

- For technical and economic reasons, the entire chamber space should be used up as far as possible
- Place heavy items at the bottom and light one on top
- Container on top of container, etc.
- Compile loading schema

7.3 Loading the sterilizer

- Load the sterilizer as per the validated loading schedule
- No items to be sterilized may have direct contact with the chamber walls, doors or the chamber floor
- Always place heavy items, which lead to a lot of condensate formation, at a lower level than lighter items
- Load the sterilizer chamber such that condensate can easily drain away
- Make sure that condensate will not accumulate in or on the sterile supplies

7.4 Placing steam sterilizers in operation

This is done as per the manufacturer's instructions and following briefing by the manufacturer/supplier

1. In the case of an internal steam generator, the steam generator is switched on
2. Wait until the operating pressure and temperature is reached. If necessary, start heating programme or blank load sterilization.
3. Perform steam penetration test (Bowie & Dick test) and record results (daily)
4. If specified, perform vacuum test and record results (at least weekly test recommended)
5. Release for use or - if test result negative – take sterilizer out of service

7.5 Selecting the sterilization process

The sterilization process will be determined, inter alia, by the material composition of the sterile supplies and the packaging. The manufacturers instructions as well have to be taken into account.

Steam sterilization is the process of choice. Low temperature sterilization should only be used for reusable heat-sensitive items.

7.6 Selecting the sterilization programme and starting the sterilizer

The choice of sterilization programme will depend on the load.

For steam sterilizers there is generally a choice of 134 °C or 121 °C programme. The 134 °C programme is mainly used (thanks to the shorter batch time), while the 121 °C programme is normally used for sterilization of MDs, which are not able to withstand 134 °C.

After loading and closing the chamber select and start the programme.

Liquids may only be sterilized in sterilizers specifically designated for that purpose, using appropriate programmes.

7.7 Post-sterilization tasks

These post-sterilization tasks include:

1. Intermediate storage of the sterile supplies until they cool down after steam sterilization
2. For gas sterilizers, cyclic degassing of sterile supplies in the sterlizer chamber or degassing chamber as per the manufacturer's instructions.

7.8 Release, labelling and documentation

- Check sterile supplies for dryness and integrity
- Wet load cannot not be stored, though it might be used immediately
- Check the sterilization results – batch control system
- Label the sterile supplies
- Label any item with a negative sterilization result (quarantine respective item) and repeat reprocessing procedure
- Release sterile supplies for storage or use
- Documentation

The documentation for each sterilized batch should entail:

- Date, time
- Sterilizer identity
- Result of pre-reprocessing test (B&D test)
- Designation of sterile item (code)
- Sterilization programme
- Record of process data
- Operator's name (code)
- Released by responsible person

7.9 Servicing equipment

Sterilizers may only be serviced by a person who has the necessary expertise

Servicing equipment entails:

- Observance of maintenance intervals (as per manufacturer's instructions) and conductance of related tasks
- Monitoring of operating equipment, spare parts, working materials
- Repairs
- Documentation of tasks in equipment logbook

After repairs to a sterilizer the effectiveness of the measures carried out must be verified or a special test conducted. In the case of validated sterilization processes, after extensive repairs or maintenance tasks conducted on the sterilizer, the test body responsible for validation should be consulted to determine whether performance requalification is necessary (e.g. replacement the vacuum pump can adversely affect the process).

See also wfhss guideline 01 “Checks / tests needed for the automated equipment used for cleaning, disinfection and sterilization after maintenance tasks / repairs carried out by (service) engineers”

Maintenance tasks, repairs or any major changes to gas sterilizers may be performed only by the manufacturer or by persons appointed by the latter. The safety of gas sterilizers must be tested by an expert at least once annually and the test results recorded. Pressurized containers of gas sterilizers are governed by pressurized container regulations and may be subject to mandatory testing. Any shortcomings detected in gas sterilizers must be immediately remedied.

Pursuant to the Medical Devices Directive in the European Union validation of the processes used to reprocess medical devices is mandatory. Validation should be carried out by an independent test body.

8 Transport and storage

8.1 Assembling consignments

Consignments are assembled on the basis of the selected sterilization process, packaging and on how the sterile supplies are organised. This can be done as individual packaging or sets. Loose packaging can be presented in closed or open transport containers. In principle, the extent to which additional protective measures, e.g. use of a cover, are needed must be clarified.

The target site can be specified on the trolley, closed transport containers and at direct handover points for the wards.

Sluices or handover points can be designated to hand over the supplies for transport. The sterile side of the RUMED can also be directly linked to the surgical department.

8.2 Transporting sterile supplies

Items should be transported based on consignments, but in principle in a protected manner. Containers and closed trolleys are suitable to that effect.

How supplies are dispatched to the target site must be determined in accordance with hygiene requirements.

8.3 Storage of sterile supplies

The sterile supplies must be protected against dust, light, extreme temperature conditions/fluctuations and mechanical stress. Hence it is recommended that they be stored at room temperature (preferable 18 – 25 °C) in dry and dustproof cabinets or drawers (protected storage). Such cabinets / drawers must be smooth and undamaged so that they can be regularly cleaned/disinfected. Whereas containers can be placed one on top of the other, in the case of soft sterilization packaging one must ensure that the packaging is not damaged, for example because of sharp instruments.

The first-in-first-out principle is of paramount importance for storage, with the older supplies being used first.

The maximum storage period for packaged sterile supplies will depend on the type of packaging and storage method used. Unprotected storage, such as on shelves, should be used only for supplies intended for immediate use (up to a maximum period of 48 hours). Hence this form of storage should be avoided as far as possible.

The storage periods given below are guide values that can be amended upwards or downwards by the infection control team in accordance with the storage conditions.

The storage periods listed here apply not only for supplies sterilized by the respective institution itself but also for sterile single-use devices, i.e. the expiry dates on the packaging applies only for as long as the device remains enclosed in the storage packaging.

Guide values for storage of packaged sterile supplies (based on DIN 58953, Part 7-9)

Sterile supply packaging	**Unprotected storage** [(a)]	**Protected storage**
Sterile barrier system	For supplies intended for immediate use and should be avoided as storage method [(b).]	6 months, but not after the expiry date If a longer storage period is required, a protection packaging might be used
Sterile barrier system in protection packaging	As per the expiry date given by the manufacturer or RUMED[(c)]	

(a) e.g. on shelves

(b) Immediate use: application of the product within 48 hours

(c) The establishment can use own packaging systems as substitute to the original protection packaging. The original labelling has to be taken over in adequate manners

Important instructions for handling by the user:

- The primary and secondary packaging may only be opened immediately before use
- Before opening sterile protection packaging, any dust on it must be removed
- Once sterile protection packaging has been opened to take out a certain amount for a period of time (e.g. single use divices like syringes etc), it must be closed again without delay. Under such circumstances, the storage duration specified above for such sterile protection packaging applies.

8.4 Withdrawal of sterile supplies from their packaging

Before the sterile supply packaging is opened, it must be inspected. If one notices that it is moist, dusty, damaged or had been opened, such items will in general be deemed unsterile and must be reprocessed once again or discarded (single-use devices). Peel packaging must always be peeled open (never pierce the packaging with an instrument).

9 Competencies and monitoring

The tasks conducted from the time the medical devices are collected until they are made available again for reuse are carried out by the RUMED personnel based on procedural instructions and standard operating procedures.

The RUMED management must ensure that staff undergo commensurate continuing professional development and that this is verified at regular intervals.

10 References

(1) Applicable CEN and ISO Standards

(2) Qualitätssicherung in der Sterilgutversorgung: Arbeitskreis Qualitätssicherung im Krankenhaus, Teil 1-4, Zentralsterilisation Vol.2, Heft 3 (1994), Vol.3, Heft 1 (1995), Vol.3, Heft 2 and 3 (1995).

(3) Richtlinie für Krankenhaushygiene und Infektionsprävention: Robert Koch Institut, G. Fischer Verlag.

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(5) F. Weinig (Hrsg.): Handbuch Sterilisation: Fa. 3M Schweiz.

(6) ÖGSV: Leitlinie für die Prüfung, Validierung und Überwachung von maschinellen Reinigungs-/ Desinfektionsverfahren für Medizinprodukte

(7) ONR 112069: Leitlinie für die Validierung und Routineüberwachung von Sterilisationsprozessen mit feuchter Hitze für Medizinprodukte

11 Author

R. Zierler, LKH- Univ. Klinikum Graz, Univ. Klinik f. Kinder-, and Jugendchirurgie

Revised by: T. Miorini, Institute for Applied Hygiene, Graz

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