

Recommendations by the Committee for Hygiene, Construction and Technology

Requirements for construction or reconstruction of a Reprocessing Unit for Medical Devices (RUMED)

Part 8: Room furnishings and equipment for a reprocessing unit for flexible endoscopes

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● Introduction

Part 8 of the publication “Requirements for construction or reconstruction of a Reprocessing Unit for Medical Devices (RUMED)” focuses on equipping and furnishing the rooms of a reprocessing unit for flexible endoscopes and is a continuation of Part 7 of this series of publications. Further reprocessing of medical devices used in a sterile state shall not be addressed in this publication. For information to that effect please consult publications Parts 4 and 5. The specific details of the present recommendations/regulations/standards on furnishings and fittings for a RUMED are summarized while citing examples from everyday practice.

No reference is made to the requirements for fire protection, building physics, statics or installation of the various utilities (e.g. gas/water installation, electricity installations, etc.) or to ventilation systems.

Note: This publication is not intended as a planning template.

● Basic requirements

Structural aspects, equipment and mobile furnishings

General requirements - construction

- Doors, possibly with viewing ports (apart from staff changing rooms/toilets)
- Telephone, possibly with intercom system for communication externally and within the RUMED
- External doors with limited access
- Cables concealed or enclosed in ductwork; outer surface amenable to wet disinfection
- Ductwork and shafts with close-fitting access openings
- Avoid condensate formation (appropriate insulation and ventilation)
- Position dosing equipment such that contamination from pathogenic liquids from the outlet is prevented

General requirements - furnishings

- Cabinets with sheathing finish to the ceiling and wall
- Cabinets for dustproof, closed storage of flexible endoscopes, with/without drying facility
- Transport trolley wheels resistant to detergents and disinfectants
- All furnishings must be installed such that transport and escape routes are not impeded (e.g. wall-mounted dispensers, fire extinguishers, etc.)

Wall surfaces / floors / surfaces / joints

- Smooth and even
- R10 anti-slip treatment for floors in the cleaning and disinfection area
- Few joints
- Joint sealing
- Grooved skirting board
- Floors with threshold-free access
- Ramming protection (height tailored to transport trolleys)
- Accessible for cleaning/disinfection
- Easy to clean/disinfect
- Resistant to

PLANNING TIPS FOR FURNISHINGS

GENERAL REQUIREMENTS

STORAGE WITH/WITHOUT DRYING

SURFACE CONDITION

ANTI-SLIP TREATMENT FOR FLOORS AS PER ASR 1.5/1,2



- Detergents and disinfectants and other chemicals used in the relevant areas (written evidence of material compatibility)
- Humidity/heat
- Mechanical stress tailored to use
- Wall/ceiling paint and coating tailored to expected use
 - Wet abrasion resistance
 - As per DIN EN 13300 class 2
 - As per DIN EN ISO 19998 class 1/2

LIGHTING AS PER ASR A 3.4

Lighting (German Workplace Regulation [ASR] A3.4 lighting)

- Workstation 1000 lx
- For other areas 500 lx

Planning

- For new projects and reconstruction close cooperation with the infection control team or hospital hygienist and users

GERMAN TECHNICAL REGULATION ON BIOLOGICAL SUBSTANCES (TRBA) 250

Hygienic hand washing facilities in the cleaning and disinfection area /zone

- Sufficiently large hand wash basin without overflow
- Non-touch fittings (water jet not directed into the drain)
- Hot/cold water
- Disposable towels from dispensers
- Dispensers for wash lotion
- Dispensers for hand disinfectant
- Facility for skin-protection and skin-care products
- Waste bin for disposable towels
- Possibly, splash guard
- Possibly, mirror

Hygienic hand disinfection

- Dispensers for hand disinfectant, in principle in each room at the entrance/exit and in addition based on risk assessment

TRBA 250 SCOPE OF PROTECTION 2 PPE

Personal protective equipment (PPE)

- Contamination-proof storage facilities for clean PPE
- Storage facility for reused PPE (specify in infection control policy)
- Wall-mounted facility for gloves (different sizes)
- Possibly shoes, liquid-tight, disinfectable
- Facility for depositing used PPE

ALIGNMENT OF RUMED AND IT FACILITIES

IT hardware

- Enclosed IT components, including cabling
- Wireless IT accessories (e.g. scanner, printers)
- Surfaces amenable to wipe disinfection
- Space for keyboard/mouse

WORK TABLE FOR DEPOSITING ENDOSCOPES

Cleaning and disinfection area/zone (C + D area)

- Automatic door drive (optimal)
- Surface for incoming and outgoing endoscopes
- Work table for depositing endoscopes
- Waste containers with non-touch lid
- Documentation workstation
- Possibly, with handheld scanner
- Area for reprocessing transport trolleys/transport boxes
- Worktop for sorting and preparations (table, trolley, etc.)
- Manual cleaning and disinfection zone (the equipment must be tailored to the sequences of the work steps, i.e. process oriented)
 - Manual leak test (dry/wet as prescribed by manufacturer)
 - Basins (at least two) of adequate size and depth for manual cleaning (brushing/rinsing), with splash guard above the basin (personnel protection) and possibly with extractor hood

ENSURE CLEANING AND DISINFECTION ZONE IS AT ERGONOMIC HEIGHT

- For entire manual reprocessing as a contingency concept at least three wash basins and one bath (bathtub) are needed.
 - Cleaning and disinfection area (unclean)
 - Basin for cleaning/brushing
 - Basin for rinsing
 - Bath for disinfection
 - Splash guard for separation of clean/unclean zones
 - Basin for final rinse (clean)
- Basin fittings of dimensions that permit installation of sterile filter without hampering use
- Possibly, purging pump for flushing the endoscopes
- Space for depositing and closed storage of work materials for manual cleaning of endoscopes (various brushes, syringes, cleaning adapters, compresses, etc.)
- Area for documented release of leak test and manual cleaning/rinsing
- Possibly, water treatment (softened/demineralized/sterilized water)
- Ultrasonic bath (reprocessing of valves) (table-top device with temperature display and lid, with preferably non-touch operation)
- Magnifying lamp suitable for wet rooms
- Possibly, decentralized dosing equipment for surface / instrument disinfectants
- Water pistol amenable to automated reprocessing
 - Possibly, for precleaning,
 - In the case of manual reprocessing (contingency concept) for final rinse after disinfection, demineralized water with sterile filter
- Compressed air pistol amenable to automated reprocessing
- Transport trolley wheels resistant to detergents and disinfectants
- Loading trolley wheels for endoscope washer-disinfector (EWD) , resistant to detergents and disinfectants
- Storage space/shelf for
 - Loading trolleys and
 - Accessories for loading the EWDs (e.g. adapters for various endoscopes)
- Facility for hanging/storing the adapters
- First aid kit as prescribed by occupational health and safety requirements

● **Central dosing system or storage cabinet for chemicals**

Endoscope washer-disinfector - see specific requirements

Packing area/zone for endoscopes - clean

- Hand disinfectant dispenser – no dripping/splashing at packing workstation
- Work table for depositing endoscopes
- Anti-glare work surfaces
- IT facilities
- Power sockets
- Magnifying lamp 1000 Lux
- Compressed air pistol (medical compressed air) amenable to automated reprocessing
- Trolley for cleaned/disinfected endoscopes, trolley wheels resistant to detergents and disinfectants
- Protected storage/stockage for
 - Consumables/packaging
 - Replacement/reserve accessories for endoscopes
- Cabinets with sheathing finish to the ceiling/wall
- Cabinets for dustproof, closed storage of flexible endoscopes, with/without drying facility

Specific requirements

Multi-room solution

- equipment-based barrier – hygiene barrier
- Double-door EWD

ASSURE CONTINGENCY CONCEPT

STERILE FILTER?

MAGNIFYING LAMP

**WATER PISTOL/
COMPRESSED AIR PISTOL**

PROCESS CHEMICALS

EWD

CLEAN WORKSTATION

**OBSERVE ERGONOMIC
REQUIREMENTS**

**WORKPLACE REGULATION (ASR)
A3.4**

DOUBLE-DOOR EWD



- Maintenance access
- Lockable return/hatch (with storage space)

One-room solution

- Single-door EWD, undercounter unit or top-loading machine
- Separation of clean/unclean zones
 - Preferably structural
 - or organizational

SINGLE-DOOR EWD

● References

- Anforderungen der Hygiene an die funktionelle und bauliche Gestaltung von Sterilisationseinheiten – Anlage zu Ziffer 4.4.1 der „Richtlinie für die Erkennung, Verhütung und Bekämpfung von Krankenhausinfektionen“ (aus Bundesgesundheitsblatt 23/1980, Nr. 11, S. 165–166)
- Anforderung der Hygiene an Kanal- und Schachtverbindungen, Leitungen – Anlage zu Ziffer 4.5.2 der „Richtlinie für die Erkennung, Verhütung und Bekämpfung von Krankenhausinfektionen“ (aus Richtlinie Krankenhaushygiene, Lieferung 9, Dezember 1988)
- Arbeitsstättenverordnung
- ASR A1.5/1,2 „Fußböden“
- ASR A3.4 „Beleuchtung“
- BGI/GUV-I 8681-1 “Neu- und Umbauplanung im Krankenhaus unter Gesichtspunkten des Arbeitsschutzes – Anforderungen an Funktionsbereiche”
- EN 13300 Beschichtungsstoffe – Wasserhaltige Beschichtungsstoffe und Beschichtungssysteme für Wände und Decken im Innenbereich
- TRBA 250 “Biologische Arbeitsstoffe im Gesundheitswesen”
- VAH Empfehlung zur Kontrolle kritischer Punkte bei dezentralen Desinfektionsmittel-Dosiergeräten