

Recommendations by the Committee for Hygiene, Construction and Technology

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

Part 5 – Room furnishings and equipment for a RUMED: One-room solution

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I Introduction

Part 5 of the publication "Requirements for construction or reconstruction of a Reprocessing Unit for Medical Devices (RUMED)" focuses on equipping and furnishing the RUMED – one-room solution – and is a continuation of Parts 1, 2 and 3 of this series of publications. Based on experiences from everyday practice, it summarizes and characterizes by way of example the limited number of rather unspecific provisions given in the pertinent recommendations/guidelines/standards on furnishing and equipping a RUMED.

No information is provided on fire protection, structural physics, structural engineering or the various utility installations (e.g. gas, water and electricity connections, etc.) The "RUMED one-room solution" concept gives details of how to equip and furnish a RUMED in medical institutions which reprocess a limited number and type of medical devices.

Note: The floor plans are not a planning template but rather give an example of a "one-room solution".

*RUMED – one-room solution
Planing aids for equipment*

General requirements

I Basic requirements

Structural aspects

- General requirements
 - Surfaces
 - Resistant to detergents and disinfectants
 - Accessible for cleaning and disinfection
 - Transport trolley wheels – resistant to detergents and disinfectants
 - Cabinets with veneer finish to the ceiling
 - Cabinets/drawers dustproof (for closed storage)
 - Doors, possibly with automatic drive
 - Shut-off devices for media supply (nearby)
 - Non-opening windows, make provision for ventilation or supply/exhaust air of interior rooms
- Wall surfaces/floors/surfaces/joints
 - If possible, smooth and even
 - R10 anti-slip treatment for floors in the cleaning/disinfection area (ASR A1.5/1,2); following risk assessment R9 may be suitable
 - Few joints
 - Joint sealing
 - Chamfered skirting board
 - Ramming protection (height tailored to transport trolleys)
 - Accessible for cleaning/disinfection
 - Easy to clean/disinfect

Room equipment – observe details

- Resistant to
 - 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 standards and technical regulations
- Lighting (ASR A3.4 lighting)
 - Workstation 1000 lx
- 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)
- For new projects and reconstruction close cooperation with the infection control team
- If necessary, position dosing equipment such that contamination from pathogenic liquids from the outlet is prevented
- All furnishings must be installed such that escape routes are not impeded

Changing rooms

- Outside the RUMED one-room solution

Staff recreation rooms

- Outside the RUMED one-room solution

Hygiene requirements

Hand washing facilities

- In the entrance area, before the cleaning/disinfection area
- Non-touch fittings
- Hot/cold water
- Disposable towels from dispensers
- Dispensers for wash lotion
- Facility for skin-protection and skin-care products

Hygienic hand disinfection

- Hand disinfectant dispensers installed in the packing area and at the entrance/exit

Departmental clothing (only in the department, if necessary worn outside the RUMED)

Departmental clothing

- Based on establishment's risk assessment
 - Closed storage facilities for departmental clothing (cabinet or enclosed in packaging on a shelf)
 - Shoes on racks or shelves

Personal protective equipment

Personal protective equipment (PPE)

- Storage facilities for clean PPE
- Contamination-proof automatic door drive
- Disposable gloves (in original box) on wall-mounted fittings
- Facility for depositing used PPE
- Possibly, storage facility for reusable, waterproof gowns that are not visibly contaminated (specify in infection control policy)

Documentation

Documentation

- Preferably IT-based
 - Preferably wall-mounted facilities (free worktops)
- Alternatively, manual documentation

IT hardware

- Enclosed IT components, including cabling

- Wireless IT accessories (e.g. scanner, printers)
- Surfaces amenable to wipe disinfection

I Room furnishings and equipment

Access and incoming zone

- If possible, automatic door drive
- Handwashing facility, possibly with splash guard
- Cabinet/shelf for PPE
- Space for storage of deliveries at ergonomic height
- Wall dispensers for hand disinfectant
- Wall-mounted facility for gloves (in original box)
- Waste containers with non-touch lid

Cleaning and disinfection area

- Worktop for sorting and preparations
- Worktops, if necessary with elevation/overflow edge
- Manual cleaning and disinfection zone, if necessary (see "Guideline for validation of manual cleaning and manual chemical disinfection of medical devices", Annex 2, for example of worktables see Page 17).
 - The fittings must be tailored to the order in which procedural steps are executed (process-oriented)
- Only for precleaning/subsequent cleaning
- Or for manual cleaning and disinfection, incl. rinsing/drying
- Possibly, splash guard between the adjacent packing zone
- Ultrasonic cleaning (flush-mounted or tabletop device with temperature display and lid, with preferably non-touch operation)
- Possibly, magnifying lamp suitable for wet rooms
- Possibly, dosing equipment for surface/instrument disinfectants
- Space for depositing and storing work materials
- Possibly, water pistol (amenable to automated reprocessing) for precleaning
- In case of manual reprocessing – water pistol for final rinse after disinfection, demineralized water with sterile filter
- Storage space/shelf for
 - Loading trolley/racks (standard/MIS/anaesthesia, etc.) as needed
 - Accessories for loading the WDs (e.g. for special MDs, small-items baskets, etc.)
- WD (heat-resistant MDs)/EWD (endoscopes) as per standard
- Loading zone for washer/disinfectors (WDs)
 - Loading trolleys/racks
 - Access for servicing/repairs

Packing area (clean)

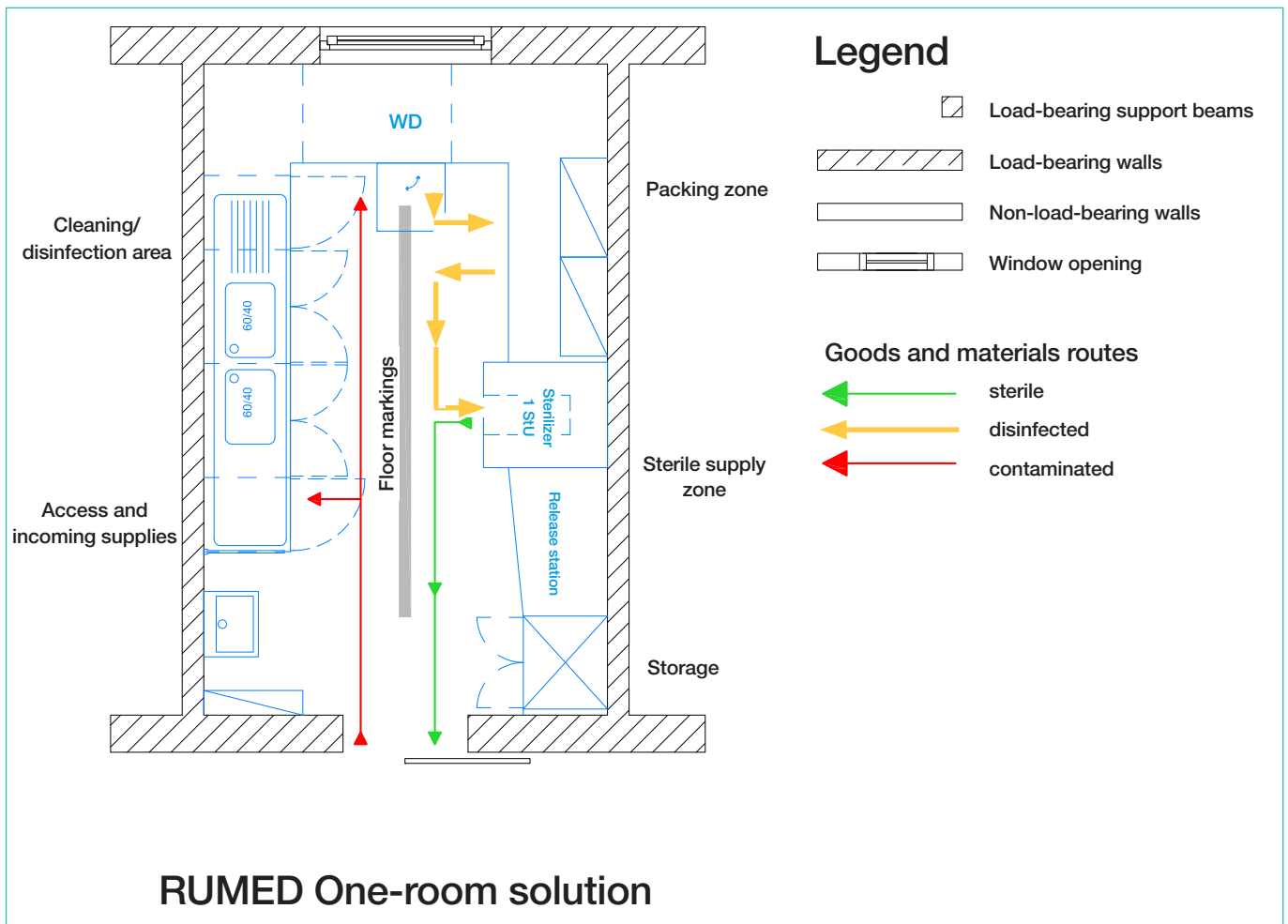
- Unloading WDs
 - Withdrawal of MDs
 - Storage area for reprocessed MDs
 - Release/documentation of reprocessed MDs
 - Possibly, scanner
- Packing zone
 - Hand disinfectant dispenser – no dripping/splashing at packing workstation
 - Work tables
 - Anti-glare work surfaces
 - Possibly, IT facilities
 - Possibly, facilities for standing/sitting
 - Chamfered base cabinet to floor/or ground clearance of at least 30 cm
 - Enough sockets

Room furnishings and equipment

Manual reprocessing required?

Avoid recontamination

Packaging concept



- Magnifying lamp 500 lux, ASR A3.4 Workplace Regulation
- Possibly, compressed air pistol (medical compressed air) amenable to automated reprocessing
- Possibly, equipment/materials for functional testing of MDs as per the manufacturer's instructions
- Racks for soft packaging
 - Reels, pouches, sheets
- Heat sealer as per standard
- Closed storage facilities for accessories (maintenance/assembly/consumables/ packaging)
 - Zone for loading sterilizer
 - Space for depositing packed MDs before sterilization

Sterilizer

Sterilizer

- Sterilizer as per standard
 - For packed supplies
 - If necessary, for non-packed supplies (only semi-critical A MDs)
- Loading racks
- Access for servicing/repairs

Sterile supplies area

- Place for cooling down
- Sterile supply release station
- If possible, with IT facilities

Sterile supply storage

- Storage cabinet, dustproof
- Possibly, cabinet system for handing out supplies, with mutual inter-locking system, dustproof

Storage

Optional areas not featured in the drawing will be addressed in the next report on technical prerequisites

I RUMED Drawing – One-room solution

Organizational separation of zones

References please see p. 392