

Recommendations by the Committee for Hygiene, Construction and Technology

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

## Part 3 – Rooms and their allocation

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### I Introduction

Part 3 of the publication Requirements for construction or reconstruction of a Reprocessing Unit for Medical Devices (RUMED) gives examples of the rooms required, of how they can be allocated and of the resultant routing systems.

Room concept 1 RUMED illustrates the spatial planning and routing systems for medical devices (MDs) and personnel for a RUMED.

Room concept 2 RUMED – one-room solution illustrates the spatial planning and routing systems for medical devices (MDs) and personnel for a reprocessing room in medical establishments that reprocess only a limited number and type of medical devices.

*Room concept*

*Spatial planning*

*Routing systems*

#### *Material routes*

- Red arrow – contaminated (unclean) MDs
- Yellow arrow – disinfected (low microbial count) MDs
- Green arrow – sterile MDs

#### *Staff routes*

- Staff – in cleaning/disinfection area
- Staff – in packing/sterile area
- External persons (not shown in the drawing)

These illustrations are strictly intended as examples and planning will have to be tailored to the individual structural circumstances.

The following must also be noted:

- The space required will depend on the quantity of MDs and on the reprocessing steps and methods.
- Interfaces to internal and external users
- Keep transport routes short
- Storage space within RUMED as per requirements
- Possibly, sterile supply store
- Hygiene and health and safety requirements may have implications for room sizes and room allocation

The reasons for using any alternative options or making compromises should be explained in line with risk assessment.

Part 4 will set out recommendations for equipping and furnishing rooms.

*What must be taken into account?*

### I Drawing 1 – RUMED with spatial separation

Cleaning and disinfection area (C+D area), contaminated (unclean)

- Incoming zone for contaminated MDs – with space for:
  - Parking bays for transport trolleys
    - Possibly, washing station for transport trolleys

*Room concept 1 – RUMED with spatial separation*

*Cleaning and disinfection area*

- Parking bays and zone for incoming containers with contaminated MDs
- Possibly, zone for incoming MDs from external users
- Incoming loan instruments/storage of transport packaging
- Documentation
- Cleaning /disinfection area – with space for
  - Sorting and preparation
  - Possibly, manual cleaning, including rinsing
  - Possibly, manual disinfection, including rinsing and drying
  - Possibly, release of manual reprocessing steps
  - Loading zone for washer/disinfectors (WDs)
    - Possibly, automated loading system
  - Parking bays for transfer trolleys
  - Parking bays for loading trolleys (universal/MIS/anaesthesia, etc.)
  - Storage space for accessories for loading WDs (e.g. for special MDs, small-item baskets, etc.)
  - Documentation

***Equipment-based barrier – hygiene barrier***

- Space for:
  - 2-door WDs (assure structural, and promote organizational, separation)
  - Maintenance access to WDs in C+D area
  - Container tunnel washer (CTW)
  - Return/hatch
    - Returning loading trolleys/loading racks
    - Returning MDs with residual soils from the packing area to be reprocessed again
    - Handing over manually reprocessed MDs in the packing area

***Packing area (clean)***

- Zone for unloading WDs – with space for:
  - Unloading MDs
    - Possibly, automated feed-out mechanism
  - Release/documentation of MDs after automated reprocessing
  - Transfer trolleys
- Packing zone – with space for:
  - Visual inspection of cleaning
  - Possibly, redrying MDs (compressed air)
  - Care/possibly, assembly
  - Functional testing
  - Packing
    - With hard packaging (container)
    - With soft packaging (fleece)
    - Paper/foil packaging (pouches and/or reels)
      - Possibly, other packaging materials (e.g. Tyvek®)
  - Storage
    - Consumables
    - Spare/replacement MDs
  - Documentation
    - IT/packing lists
    - Scanning/recording MDs
    - Label printout
- Intermediate storage
  - Optional space for parking bays for trolleys
    - Possibly, storage of packed supplies
- Zone for loading sterilizer – with space for:
  - Load configuration
  - Loading sterilizers
    - Possibly, automated feed-in mechanism

***Equipment-based barrier – Hygiene barrier***

***Separation between C+D area and packing area***

***Packing area***

***Packing zone***

***Packing station***

***Zone for loading sterilizer***

***Sterilizer-based barrier******Sterilizer-based barrier***

- Space for:
  - 2-door sterilizer (assures organizational separation)
  - Access to sterilizer maintenance zone
  - Possibly, hatch or passage
    - Possibly, returning loading systems
    - Returning rejected sterile supplies
    - Possibly, handing over disinfected, packed MDs without sterilization
    - Possibly, trolleys from container tunnel washer
  - Possibly, low-temperature sterilizer

***Sterile supply area******Sterile supply area***

- Zone for unloading/cooling down – with space for:
  - Possibly, automated feed-out mechanism
  - Parking bays for loading trolleys
    - Zone for letting supplies cool down
  - Documentation
    - Release of sterilized MDs
- Consignment store/handing over sterile MDs – with space for:
  - Intermediate storage
  - Transporting trolleys

***Staffrooms******Other rooms***

- Staff changing rooms – with space for:
  - Changing room for RUMED personnel
    - Facilities for storing everyday clothes/work clothes, shoes, bags and for locking away valuables
    - Provision of departmental clothing
  - Toilets with access from changing rooms
  - Possibly, shower with access from changing rooms
- Recreation room
  - Access from clean RUMED areas
- Office
  - Access from clean RUMED areas
  - Possibly, access from outside the RUMED with restricted access
  - Space for documentation and archiving
- Staff sluice to access C+D area – with space for:
  - Protective clothing
  - Shoes
- Staff sluice to exit C+D area – with space for:
  - Depositing protective clothing
  - Depositing shoes

***Side rooms with assignment to cleaning/disinfection area******Side rooms with assignment to cleaning and disinfection area***

- Room for cleaning materials – with space for:
  - Storage of cleaning utensils, detergents and disinfectants
- Room for used/waste materials – with space for:
  - Storage of waste for collection
  - Storage of dirty laundry for collection
- Dosage centre – with space for:
  - Chemicals (observe safety instructions)
    - Large container (reduces workload)

***Side rooms with assignment to packing/sterilization area******Side rooms with assignment to packing and sterilization area***

- Room for cleaning materials – with space for:
  - Storage of cleaning utensils, detergents and disinfectants

- Sluice for waste materials – with space for:
  - Storing waste for collection
- Materials sluice – with space for:
  - Delivering, unpacking and handing over incoming consumables
  - Possibly, zone for incoming single-use sterile supplies, possibly, with access to consignment store\*
- Materials storage – with space for:
  - Incoming consumables
  - Storage
- Consignment store\* for sterile supplies with space for:
  - Storage of clean transport trolleys
  - Possibly, storage of sterile MDs
  - Possibly, storage of disinfected MDs
  - Possibly, storage of single-use supplies
- Handover – with space for:
  - Storage of closed transport trolleys
  - Collection of sterile supplies

**Optional space not featured in the drawing:**

- Lifts/elevators for goods between RUMED/user
- Steam generation
- Demineralized water generation

**Optional space**

## I Room concept 2 – RUMED one-room solution

### Organizational separation of zones

#### Cleaning/disinfection zone (unclean)

- Access and incoming supplies – with space for:
  - Protective clothing for unclean zone with facility for depositing used materials
  - Storage and reception of incoming contaminated MDs
  - Possibly, documentation
- Cleaning and disinfection area – with space for:
  - Sorting and preparation
  - Possibly, manual cleaning, including rinsing
  - WDs (single-door)
  - Loading/unloading WD
  - Possibly, parking bays for loading trolleys – WDs
  - Storage area for loading racks (e.g. for special MDs, small-item baskets, etc.)
  - Documentation

**Room concept 2 RUMED**

**One-room solution**

**Cleaning/disinfection zone**

**Optional space not featured in the drawing:**

- Manual chemical disinfection with space for:
  - Disinfection basin
  - Rinsing basin
  - Possibly, release of manual reprocessing steps

**Optional space**

#### Packing zone (clean) and sterile supplies zone

- Space for:
  - Visual inspection of cleaning
  - Possibly, redrying MDs (compressed air)
  - Care/possibly, assembly
  - Functional testing
  - Packing
    - With hard packaging (container)
    - With soft packaging (fleece)
    - Papier/foil packaging (pouches and/or reels)

**Packing zone**

**Sterilization zone**

\* Consignment store is where specific partial loads are assembled as per user requirements

- Storage
  - Consumables
  - Spare/replacement MDs
- Documentation
  - IT/packing lists
  - Scanning/recording MDs
  - Label printout
- Intermediate storage zone
  - Possibly, storage of packed supplies
- Sterilization – with space for:
  - Sterilizer (single-door)
  - Loading/unloading sterilizer
  - Cooling down
  - Documentation
    - Release of sterilized MDs



