



# Recommendations by the Committee for Hygiene, Construction and Technology

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

### Part 7: Rooms and their allocation for reprocessing flexible endoscopes

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#### ■ Introduction

Part 7 of the publication on “Requirements for construction or reconstruction of a reprocessing unit for flexible endoscopes” describes a model approach to determination of the rooms needed, their allocation and the resultant routing systems. The spatial requirements in medical healthcare institutions shall be described.

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.).

The recommendations for equipping and furnishing rooms shall be addressed in Part 8.

The process employed to reprocess flexible endoscopes is the same regardless of the reprocessing site. The various constructional designs possible are illustrated in drawings A, B and C.

#### EXAMPLES OF ROOM LAYOUT

- “Drawing **A** Endoscope reprocessing as a multi-room solution within an endoscopy department”
- “Drawing **B** Endoscope reprocessing in a RUMED”
- “Drawing **C** Endoscope reprocessing as a one-room solution“

If after evaluation of all spatial/structural conditions, a multi-room solution is not deemed feasible, the minimum requirements for equipping and furnishing a reprocessing room as a “one-room solution” in healthcare institutions are presented as another option.

“One-room solutions” pose a continuous recontamination risk. If opting for a one-room solution, strict structural/technical measures must be taken and provision made for organizational/temporal separation of the various working steps.

It is explicitly pointed out here that these presentations are intended as examples and that, accordingly, planning must be tailored to the respective structural situations.

In Germany, the following recommendations and guidelines must be observed: KRINKO/BfArM Recommendation “Requirements for hygienic reprocessing of medical devices”, in particular Annex 8 “Requirements for reprocessing endoscopes and endoscopic ancillary instruments”; “Requirements for the structural and functional layout and technical equipment of endoscopy units”; New construction and reconstruction planning in hospitals with regard to occupational health and safety [German Social Accident Insurance as per DGUV BGI/GUV 8681-1; and the S2k Guideline for quality requirements in gastrointestinal endoscopy.

Planning should take account of the following:

- Space required
  - depending on the reprocessing steps/methods for the various endoscope families
  - depending on the number of flexible endoscopes to be reprocessed
  - depending on the reprocessing frequency
- Interfaces to external users
- Storage facilities for
  - Released endoscopes
  - Consumables

#### ENDOSCOPE FAMILIES?

#### QUANTITY?

#### FREQUENCY?

- Process chemicals
- Transport cases
- Transport routes
- Hygiene and occupational health and safety specifications

## LOGISTICS?

If manual reprocessing with automated support ('semi-automatic machine') is used, more space is required for the equipment and process steps.

## SEMI-AUTOMATIC MACHINE SPACE REQUIRED

It is assumed that the rooms and side rooms needed are available in the endoscopy department. Please see references 1, 2, 4, 5, 6

- Reprocessing of heat-resistant ancillary instruments and rigid endoscopes shall not be addressed here.
- If heat-resistant instruments are reprocessed, the requirements for reprocessing heat-resistant medical devices apply (please see references 9 a-f)
- No reference is made to TEE probes but they are not excluded.

## Basic structural requirements for endoscope reprocessing

## BASIC STRUCTURAL REQUIREMENTS

### Cleaning and disinfection area/zone (unclean)

Access and incoming supplies - with space for:

- Delivery and incoming zone for flexible endoscopes
- Parking bays for closed transport trolleys/boxes
- Storage facility for incoming flexible endoscopes and their accessories
- Delivery of loan endoscopes
- Delivery of endoscopes from other departments
- Documentation
  - Scanning / registration of flexible endoscopes

Cleaning and disinfection area/zone - with space for:

## CLEANING AND DISINFECTION AREA/ZONE

- Donning and removing PPE
- Hand wash basins
- Manual leakage test (dry/wet as per manufacturer's instructions)
- Basins for manual cleaning (brushing/rinsing)
- Basins for rinsing off the cleaning solution
- Storage space
- Documented release of leakage test and manual cleaning/rinsing
- Possibly, water treatment
- Reprocessing of closed transport trolleys/boxes
- Storage of loading racks – EWD (endoscope washer-disinfector)
- Possibly, parking bays for transport trolleys – EWD
- Storage facilities for:
  - Consumables (brushes/rinsing facilities, etc.)
  - Process chemicals (reserve stocks): observe provisions of the Hazardous Substances Regulation
  - Personal protective equipment (PPE)
- *Possibly, manual disinfection as a contingency measure (not shown in the drawings) in addition to*
  - Basin/bath for disinfection
  - Basin/bath for final rinse (clean)
  - e.g. hatch to packing area

## HAZARDOUS SUBSTANCES REGULATION

## CONTINGENCY MEASURES

### Separation of cleaning and disinfection area ("unclean") from packing area - clean endoscopes

## SEPARATION

- EWD as per DIN EN ISO 15883-1 and 4

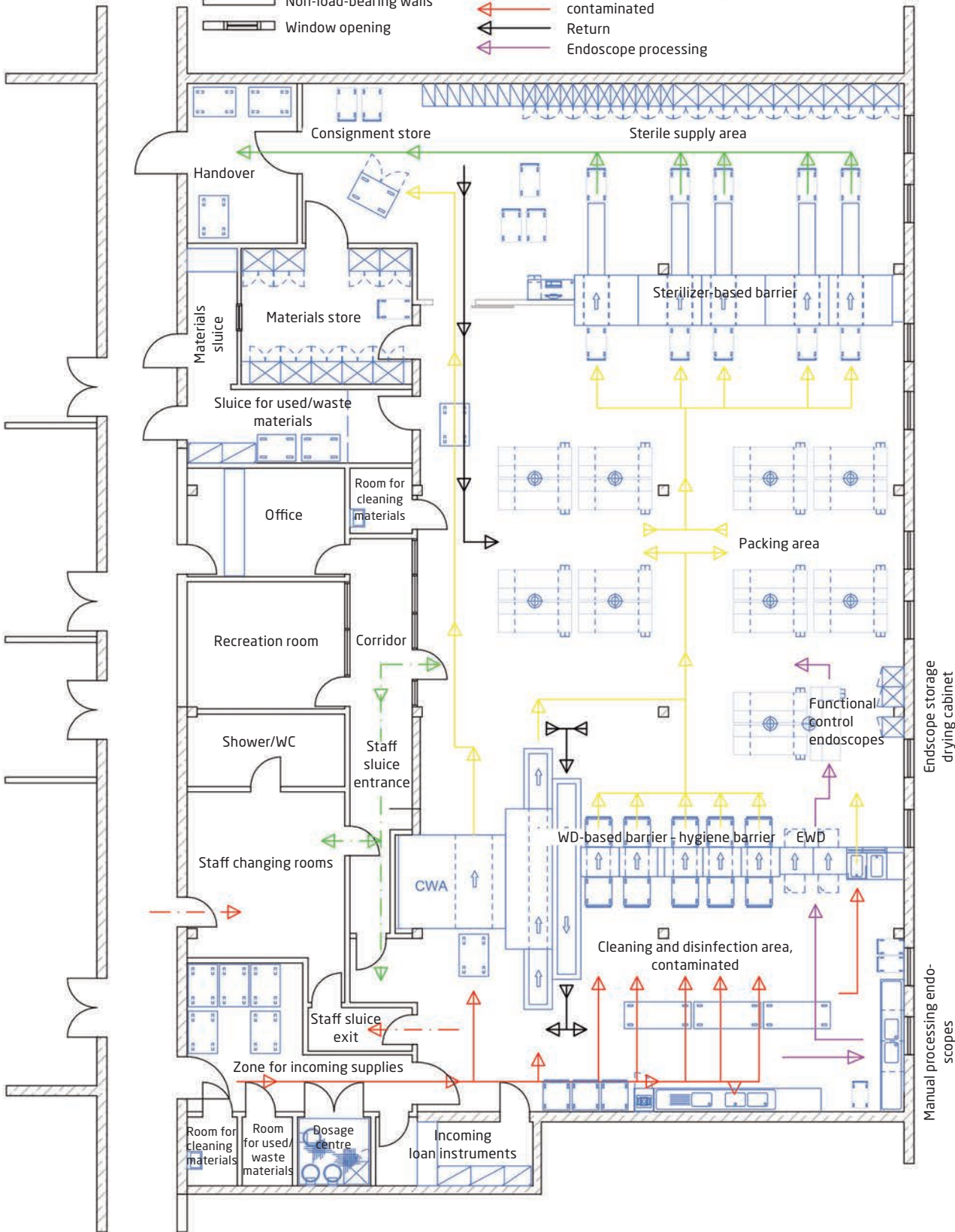
### Packing area/zone - clean endoscopes with space for:

- Unloading the flexible endoscopes from the EWD
- Drying – medicinal compressed air/drying cabinet
- Inspection, functional testing

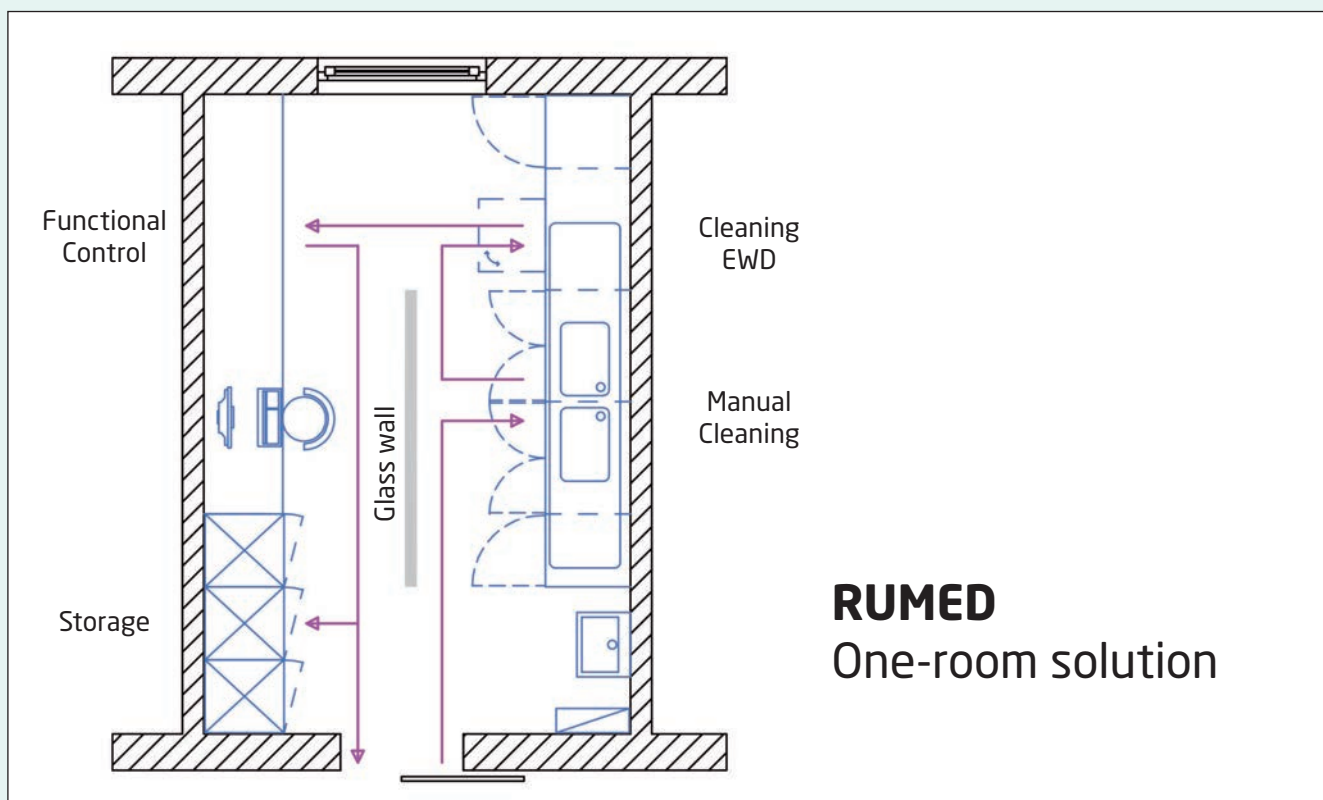
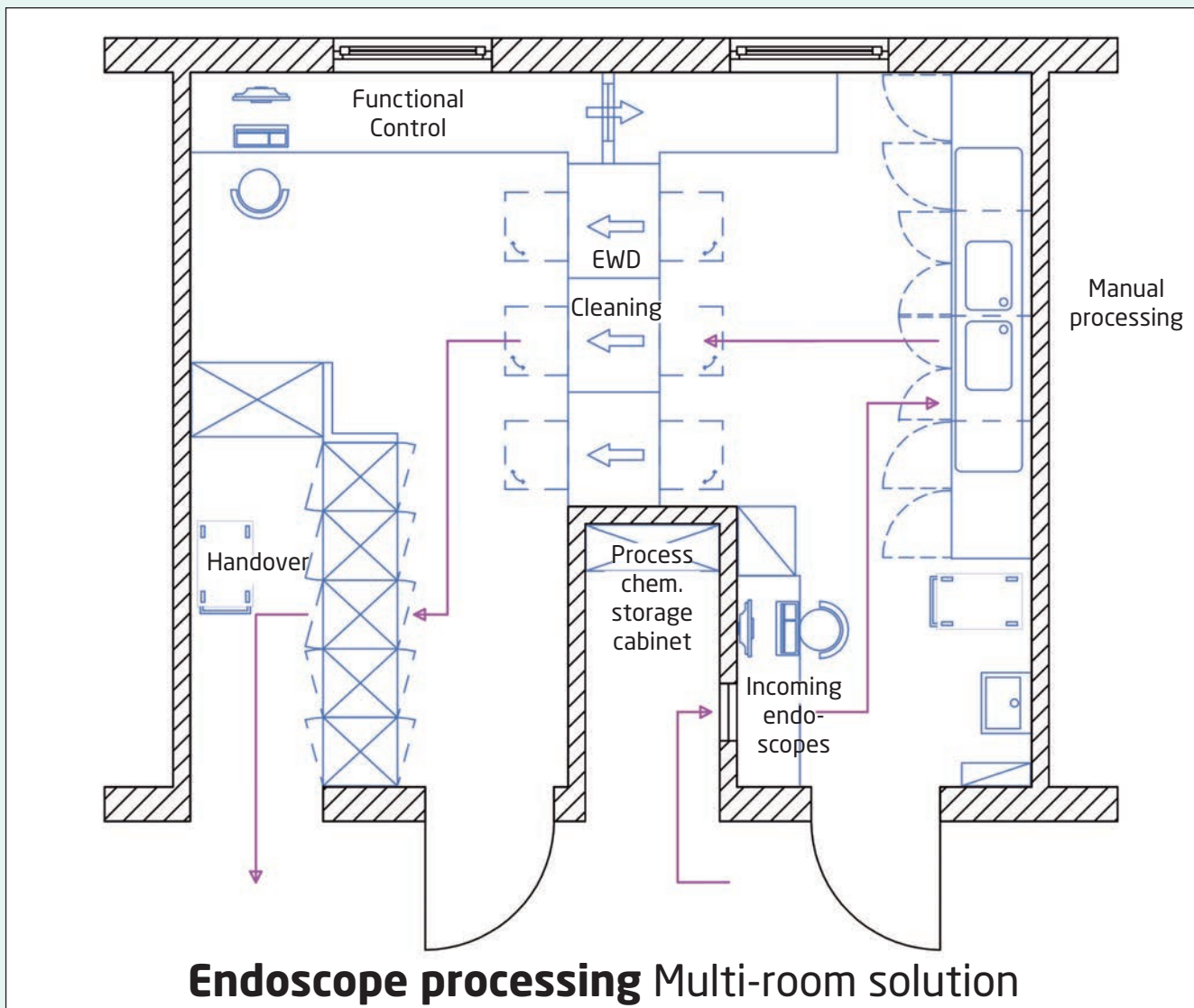


### Legend

- Load-bearing support beams
  - Load-bearing walls
  - Non-load-bearing walls
  - Window opening
- Goods and materials routes**
- sterile
  - disinfected
  - contaminated
  - Return
  - Endoscope processing
- Staff routes**
- clean
  - contaminated



## RUMED (reprocessing unit for medical devices)



**RELEASE**

- Documented release
  - Possibly, printing of labels
  - Scanning/registration of endoscopes
- Parking bays for transport trolleys
- Possibly, parking bays for closed transport trolleys/boxes
- Storage facilities for:
  - Consumables
  - Replacement materials / reserve stocks

**Consignment store - Handover area/zone**

- Dustproof, closed storage cabinets for endoscopes
- Possibly, cabinet for handing out supplies, with mutual interlocking system

**SPECIFIC REQUIREMENTS****■ Specific requirements tailored to room concept****MULTI-ROOM SOLUTION****■ Drawing A Endoscope reprocessing as a multi-room solution within an endoscopy department****Cleaning and disinfection area (unclean)**

- See basic structural requirements

**Separation of cleaning and disinfection area ("unclean") from packing area - clean endoscopes**

- Equipment-based barrier
  - Double-door EWD = Hygiene barrier (assures structural separation and facilitates organizational, separation)
  - Return/hatch (for transport systems)

**Packing area - clean endoscopes**

- See basic structural requirements

**Consignment store - Handover area**

- See basic structural requirements

**RUMED EXPANSION****■ Drawing B Endoscope reprocessing in a RUMED****Cleaning and disinfection area (unclean)**

- See basic structural requirements

**Separation of cleaning and disinfection area ("unclean") from packing area - clean endoscopes**

- Equipment-based barrier
  - Double-door EWD = Hygiene barrier (assures structural separation and facilitates organizational, separation)

**Packing area - clean endoscopes**

- See basic structural requirements

**Consignment store - Handover area**

- See basic structural requirements

The remaining requirements for structural separation are already assured by the RUMED concept.

**ONE-ROOM SOLUTION****■ Drawing C Endoscope reprocessing as a one-room solution**

The spatial planning must assure strict organizational separation of clean and unclean working steps.

**Cleaning and disinfection zone (unclean)**

- See basic structural requirements



### Separation of cleaning and disinfection zone (unclean) from packing zone - clean endoscopes

- Single-door EWD = The hygiene barrier is assured through spray protection as well as organizational measures

### Packing zone - clean endoscopes

- Recontamination risks must be avoided if possible through structural measures
- If that is not possible, organizational measures must be specified

### References:

1. KRINKO/BfArM Recommendation: "Requirements for hygienic processing practices for medical devices", jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM), in particular Annex 5 and 8 (2012)
2. KRINKO Recommendation: "Requirements for the structural and functional layout and technical equipment of endoscopy units" (2002)
3. Guideline for validation of automated cleaning and disinfection processes for reprocessing heat-sensitive endoscopes –Endoscope families (2011)
4. S2k Guideline: "Quality requirements in gastrointestinal Endoscopy" AWMF Register No. 021-022 (2015)
5. New construction and reconstruction planning in hospitals with regard to occupational health and safety [German Social Accident Insurance as per DGUV BGI/GUV-I 8681-1 (2011)]
6. German Technical Regulation for Biological Substances [TRBA 250 (2018)]
7. German Hazardous Substances Regulation [GefStV (2017)]
8. ZLG\* Form 002 (add-on module for flexible endoscopes) for VAW05\_001 Hygienic reprocessing of medical devices (2016) [\*German Central State Body for health protection with regards to drug and medical devices]
9. Publications by the Committee for Hygiene, Construction and Technology of the German Society of Sterile Supply (DGSV e.V).
  - a. Part 1 Basics
  - b. Part 2 Planning
  - c. Part 3 Rooms and their allocation
  - d. Part 4 Room furnishings and equipment for a RUMED
  - e. Part 5 Room furnishings and equipment for a RUMED – One-room solution
  - f. Part 6 Technical building systems