



Recommendations by the Committee for Hygiene, Construction and Technology Requirements for Construction, Reconstruction and Operation of a Reprocessing Unit for Medical Devices (RUMED)

Part 13: Maintenance of devices and equipment in a RUMED

Authors: A. Jones (Coordinator), M.-TH. Linner (Coordinator), A. Carter, U. Haffke, G. Lehnert, S. Lutzenberger, Monika Schick-Leisten, H. Schunk, R. Stens, A. Wentzler, K. Wiese; Email: hbt@dgsv-ev.de

RECOMMENDATIONS OF THE COMMITTEE for Hygiene, Construction and Technology No. 4, 5, 6, 9, 10, 11

MAINTENANCE MEASURES

IF APPLICABLE, CONDUCT RISK assessment and failure mode effects analysis (FMEA)

■ Introduction

The previously published **RECOMMENDATIONS** have described the technical equipment required for construction and operation of a RUMED in different settings, while focusing in particular on installation of the basic equipment systems.

Publication Part 13 now describes the maintenance and servicing measures needed and implemented for operation of a RUMED.

The laws, standards, recommendations, guidelines and other legal regulations cited here must always be applied in their currently valid version.

Note: This publication does not claim completeness.

■ Basic requirements

Continuous and reliable operation of a RUMED is absolutely essential to assure an uninterrupted supply of reprocessed medical devices. Following specialist installation of the equipment systems, the RUMED operation must therefore be ensured through routine maintenance schedules as well as ondemand **MAINTENANCE MEASURES**.

Routine maintenance reduces the risk of unscheduled downtime. Access to that effect must be provided at the planning stage, e.g. by means of inspection panel openings and routes as well as shut-off devices. Implementation of the requirements must be agreed in collaboration with the technical department and, as applicable, the infection control team.

Superordinate regulations apply in areas where failure of technical systems presents a hazard to people (e.g. Pressure Vessel Regulation, Workplace Regulation).

Some of these tests are carried out by governmental or certified bodies (e.g., in the case of Germany, the German Technical Inspectorate [TüV], the German Motor Vehicle Inspection Association [DEKRA], etc.).

Routine maintenance tasks must be executed in accordance with the instructions of the equipment manufacturer. These instructions must be incorporated into the maintenance plan implemented by the RUMED. A maintenance plan that helps anticipate all foreseeable eventualities will minimize operational disruptions, e.g. through downtime.

The RUMED operator is responsible for compilation of the maintenance plan, assignment of competencies and implementation.

A document-based summary of the maintenance and routine test plan is recommended. Please see annex for example.

The maintenance and servicing tasks to be undertaken in the RUMED must be identified in close collaboration with the RUMED management and specialist technical service and backed up by contingency measures.

■ Definition of maintenance terms

Maintenance can be divided into two key categories (DIN EN 13306):

- Preventive maintenance
- Corrective maintenance

Based on DIN 31051, maintenance comprises the following four fundamental measures:

- **INSPECTION** → preventive maintenance
 - Ascertainment of the actual state
 - e.g. material changes to a washer-disinfector (WD) dosing tube are identified and documented
- **MAINTENANCE** → preventive maintenance
 - Replacement of worn parts to preserve functionality and value
 - e.g. dosing tube is replaced as a preventative measure following inspection or as recommended in the manufacturer's instructions
- **REPAIR** → Corrective maintenance
 - Repair of a defect
 - e.g. a faulty dosing tube is replaced
- **IMPROVEMENT** → preventive and corrective maintenance
 - Material/design improvement based on practical experience and/or further development
 - e.g. dosing tube is replaced with tube made of more durable material

Because of the overlapping of the above terms, the scope of services must be described when awarding a contract.

■ **EXAMPLES:**

The following list does not claim to be exhaustive.

■ **TECHNICAL EQUIPMENT**

- **Medical devices**
 - WD-E (washer disinfector for flexible endoscopes), large capacity washer, sterilizer, drying cabinet, ultrasonic bath...
- **Devices**
 - Heat sealing device, decentralized dispensing units, Devices for functional testing, steamers ...,
- **Specified/recommended tests:**
These include, among others:
 - Institute for Work and Health of the German Social Accident Insurance (DGUV A3) – Testing electrical equipment – generally once yearly
 - Pressure vessel testing for large-steam sterilizers as per DIN EN 285 – in general:
 - Internal testing – every two years
 - External testing – every five years
 - Strength test– every 10 years
 - For small-steam sterilizers as per DIN EN 13060
 - Test after installation and before first operated and, if applicable, at regular intervals by a person accredited in accordance with Section 10 of Regulation BetrSichV*

■ **FITTINGS**

- Storage systems
- Furnishings
- Transport systems
- **Specified/recommended tests:** See “Guideline for storage of reprocessed medical devices and transport for supply and collection of reprocessible medical devices between the RUMED and user”

■ **TECHNICAL BUILDING FACILITIES (TBF)**

- Electrical systems
- Information technology/telecommunication systems (IT/ TC systems)
- Heating, ventilation and air conditioning (HVAC) systems
- Compressed air
- Vacuum
- Steam generation
- Water softening/demineralized water systems
- Refrigeration
- Heating

INSPECTION

MAINTENANCE

REPAIR

IMPROVEMENT

EXACT DESCRIPTION of scope of service

EXAMPLES

TECHNICAL EQUIPMENT

FITTINGS

NATURE AND SCOPE OF EXISTING TBF COMPONENTS IN THE INDIVIDUAL RUMED



- Sanitation system
- Elevators/lifts
- Fire protection
- Specified/recommended tests:
 - Tests to be carried out by a specialist/expert appointed by the competent trade body

■ References

DIN 31051	Fundamentals of maintenance
DIN EN 13306	Maintenance, definition of maintenance terms
BetrSichV*	Regulation concerning safety and health in providing work equipment and using it in work, concerning safety during operation of systems requiring inspection and organization of workplace health and safety
DruckbhV	Pressure Vessel Regulation
TRB	Technical Rules for the Pressure Vessel Regulation
TRR	Technical Rules for the Pressure Vessel Regulation – pipelines
Guideline 97/23/EC	Guideline for machinery/pressure vessels
Guideline of the Federal Institute for Materials Research and Testing, of the RKI and the KRINKO	“Requirements for design, features and operation of decentralized disinfectant dispensers“
DIN EN 285	Sterilization – Steam sterilizers – Large-steam sterilizers
DIN EN 13060	Small steam sterilizers
DGSV Guideline	“Storage of reprocessed medical devices and transport for supply and collection of reprocessable medical devices between the RUMED and user“

Example of a maintenance and routine test plan for the RUMED (The individual requirements must be tailored to the needs of the RUMED. This publication does not claim completeness.)

What	When	Who	Record of results / documents
WD			
Washer-disinfector (WD) check	Each working day	RUMED personnel in decontamination area, with proven expertise (general and specialist knowledge)	“Testing WD-E each working day“ checklist
pH test of WD residual rinse water	e.g. after each batch in programme for eye surgery instruments	RUMED personnel in packing area, with proven expertise	“pH value test“ checklist
Testing for residual protein soils	e.g. weekly or as specified during validation	RUMED personnel in decontamination area/packing area, with proven expertise	“Residual protein soils“ checklist
WD/AER maintenance	Based on interval given in manufacturer’s instructions	RUMED management - contract award to appointed firm	Maintenance report
Maintenance of large-capacity washer-disinfector	Based on interval given in manufacturer’s instructions	RUMED management - contract award to appointed firm	Maintenance report
Performance requalification of automated cleaning/disinfection processes	Annually	RUMED management - contract award to appointed firm	Performance qualification report
Performance requalification of manual cleaning and manual chemical disinfection processes	Annually	RUMED management - contract award to appointed firm	Performance qualification report

What	When	Who	Record of results / documents
Dosing equipment			
Disinfectant dispensing unit	Annually	RUMED management - contract award to appointed firm	Maintenance report
Microbiology testing of disinfectant dispensing unit	Annually	RUMED management - contract award to appointed firm or infection control specialist	Microbiology test results
Dosing system for process chemicals in automated cleaning/ disinfection processes	As per manufacturer's instructions	RUMED management - contract award to appointed firm	Maintenance report
Ultrasonic bath			
Method recommended by the ultrasonic bath manufacturer for functional testing or aluminium test	e.g. monthly	RUMED personnel in decontamination area, with proven expertise	"Testing ultrasonic bath" checklist
Maintenance of ultrasonic bath	As per manufacturer's instructions	RUMED management - contract award to appointed firm	Maintenance report
Sterilizers			
Visual inspection of chamber Visual inspection of seals	Each working day	RUMED personnel in packing area, with proven expertise	"Sterilizers" checklist
Bowie and Dick Test	Large-steam sterilizers: each working day Small-steam sterilizers: as per manufacturer's instructions	RUMED personnel in packing area, with proven expertise	„Bowie & Dick test" checklist
Vacuum test	As per manufacturer's instructions, at least every 4 weeks	RUMED personnel in packing area, with proven expertise	"Vacuum test" checklist
Maintenance of sterilizers	As per manufacturer's instructions	RUMED management - contract award to appointed firm	Maintenance report
Pressure vessel test on sterilizer	As per valid regulations	Approved test body	Test report
Performance requalification of sterilization processes	Annually	RUMED management - contract award to appointed firm	Performance qualification report
Heat sealing device			
Investigation of sealing processes <ul style="list-style-type: none"> ■ Peel test ■ Sealing seam indicator (Seal Check) ■ Ink test 	Each working day	RUMED personnel in packing area, with proven expertise	"Routine control of sealing process " <ul style="list-style-type: none"> ■ Peel test ■ Sealing seam indicator ■ Ink test
Maintenance of heat sealing devices	Annually	RUMED management - contract award to appointed firm	Maintenance report
Performance qualification of sealing processes	Annually	RUMED management - contract award to appointed firm	Performance qualification report



What	When	Who	Record of results / documents
Folding and packing in non-woven sheets			
Examining the quality features folding and packing in non-woven sheets	Each working day	RUMED management	"Routine control of non-woven sheet packaging" checklist
Performance requalification of packaging processes with non-woven sheets	Annually	RUMED management	Performance qualification report
Filling and closing reusable containers - Sterilization containers			
Examining the quality features of reusable sterilization containers	Each working day	RUMED management	"Routine control of packaging in sterilization container" checklist
Performance requalification of packaging processes in sterilization containers	Annually	RUMED management	Performance qualification report
Pure steam generator/pure steam converter			
Checking the pure steam generator/pure steam converter	As per manufacturer's instructions	e.g. in-house technical department	"Pure steam generator" checklist
Descaling the pure steam generator/pure steam converter	Automated/manual	e.g. in-house technical department	"Descaling" checklist
Maintenance of pure steam generator/ pure steam converter	As per manufacturer's instructions	RUMED management - contract award to appointed firm	Maintenance report
Pressure vessel test on pure steam generator/ pure steam converter	As per valid regulations	Approved test body	Test report
Demineralized water system			
Checking the reservoir container	Each working day	e.g. in-house technical department	Checklist
Testing conductivity	Each working day	e.g. in-house technical department	Checklist
Maintenance of demineralized water system	Annually	RUMED management - contract award to appointed firm	Maintenance report
Chemical analysis of water	Annually	RUMED management - contract award to infection control specialists/laboratory	Report
Microbiology testing as per Drinking Water Regulation	Annually	RUMED management - contract award to infection control specialists/laboratory	Report