Recommendations by the Committee for Hygiene, Construction and Technology

Requirements for Construction or Reconstruction of a Reprocessing Unit for Medical Devices (RUMED)

Part 9: Supply/process media for a reprocessing unit for flexible endoscopes

Authors: A. Jones (coordinator), U. Beilenhoff, A. Carter, U. Haffke, S. Kauertz, M.-TH. Linner, S. Lutzenberger, M. Scherrer, M. Schick-Leisten, R. Stens, A. Wentzler, K. Wiese, Email: hbt@dgsv-ev.de

Introduction

Part 9 of the publication Requirements for Construction or Reconstruction of a Reprocessing Unit for Medical Devices (RUMED) focuses on the supply/process media for a reprocessing unit for flexible endoscopes.

It serves as guidance for new construction or reconstruction of a RUMED for flexible endoscopes with regard to the technical requirements to be met for the supply and disposal of the different media needed.

The regulations listed here (e.g. standards, recommendations, guidelines and other legal, normative technical regulations), must always be applied in their currently valid version.

Note: This publication is not a planning template.

Basic requirements

Media supply within a RUMED is essential for its operation and an important subject when planning that department. Today, at a time when technical building systems must meet increasingly more complex demands, while at the same time having to assure the security of supply despite growing cost pressures, planning is of key importance. The systems should be tailored as far as possible to the needs of a RUMED for flexible endoscopes, with inbuilt redundancy, while also assuring economical installation and operation. Such needs must be ascertained through close cooperation between the project managers, RUMED management and planning engineers.

Compressed air

COMPRESSED AIR
SEE PART 10

As used for endoscopy:

- Drying endoscopes
  - Compressed air pistols amenable to reprocessing
  - Reducible via pressure reducer
- Storage cabinets with drying function
- Possibly automated endoscope reprocessor (WD-E) for drying

Dosage systems

WD-E automated processes

Decentralized media supply from dispensing unit

- Note accessibility
- Monitoring process chemical supply
- Do not confuse connections for process chemicals
- Collecting basin as required
- Chemicals storage cabinet

ECONOMIC EFFICIENCY
ERGONOMICS
OCCUPATIONAL HEALTH AND SAFETY
FIRE PROTECTION
HAZARDOUS SUBSTANCES REGULATION

Centralized media supply for detergents/disinfectants

- Location of room (short pipes)
  - Self-contained room
  - Note accessibility
- Container monitoring
- Collecting basin as required
- Hose pipes in empty conduits (replace hose pipes regularly)
- or CrNi steel plumbing system (provision for cleaning/disinfection of pipeline)

EYE WASHES, PREFERABLY DISPOSABLE CONTAINERS

Manual processes

Surface/instrument disinfectants and instrument detergents

- Decentralized disinfectant dispensing unit
- Alternatively manual dosage, graduated basins

ARTICLE IN PREPARATION

Room air conditioning

Electrical

Current

CLARIFY REQUIREMENT
EQUIPMENT REQUIREMENTS
CONTINGENCY CONCEPT

- General supply 230 V, 400 V
- Safety equipment power supply 230 V, 400 V (emergency power supply generally not needed)
- Separate fuse protection for each WD-E
- Overvoltage protection
- Potential equalization/static dissipation as specified by installation/equipment manufacturer

Lighting/safety lighting

Information technology (IT)

SEE PARTS 7+8

Communication (telephones, intercom system)

DEVICE-DEPENDENT

Building control technology (BCT)

- Fault messages
- Measurement and control technology (MCT)
- Remote maintenance modules

INFORMATION TO USER

Drinking water

Aspects:

- Shut-off devices for each water pipes and/or piece of equipment , with labelling
- Preferably CrNi steel (stainless steel) pipeline networks
- Insulation of hot and cold water pipes
- No dead pipes, dismantle as far as supply line

Drinking water hot/cold

- Quality based on Drinking Water Regulation in respect of
  - microbiological
  - chemical aspects
  - All pipes must be rinsed out and undergo microbiological testing when first installed/ refitted before commissioning

E.G. GERMAN ASSOCIATION FOR GAS AND WATER (DVGW), DIN, VDI, UBA

- Installed in compliance with the regulations
- Hot water/cold water temperature
- Hardness grade (water treatment may be needed)

MINIMIZE CONTAMINATION RISK

- Non-return valves for connected equipment (for several pieces of equipment or possibly one central valve)
- Hot water circulation pipes (DVGW conform)

Water fittings

- Non-touch operation (e.g. single lever mixer)
- Sensor control (not recommended because of contamination risk)
- Wall fittings more hygienic than stand fittings (cleaning)

REGULAR REPLACEMENT OF JET CONTROL NEEDED

- Jet control, preferably lamellar jet control

Hand washbasins/sinks

- No overflow
- Do not direct water jet into siphon
- Sink with level drain
- Hand washbasin without stopper

Softened water

Drinking water of reduced hardness grade as per the needs of the operator or equipment manufacturer

Demineralized water

- Production of softened water of drinking water quality
- Limit values as per DIN EN ISO 15883-1/4 and/or as specified by equipment manufacturer
  - See Guideline for validation of WD-E
  - Conductivity value ≤ 15 μS/cm or as specified by equipment manufacturer

NOTE SILICATE/SILICIC ACID BREAKTHROUGH

Waste water

- Waste water connections (WD-E)
- Hand washbasins
- Sinks

WASTE WATER TEMPERATURE (NOTE PLUMBING SYSTEM QUALITY AND LOCAL WASTE WATER REGULATIONS)

List of References

EN ISO 7396-1
Medical gas pipeline systems and vacuum

EN 1717
Protecting drinking water from contamination in drinking water installations and general requirements for safety equipment to protect drinking water against contamination from backflow

BetrsichV
Regulation on health and safety in providing work equipment and using it in the workplace, on safety during operation of systems requiring inspection and organization of workplace health and safety

Directive of the German Federal Institute for Materials Research and Testing (BAM), and of the Robert Koch Institute (RKI) and of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO)
Requirements for design, features and operation of decentralized disinfectant dispensing units

VDI 100
Electrical installations

TrinkwV
German Drinking Water Regulation

DIN 2000
Centralized drinking water supply – Guidelines for requirements for drinking water, planning, construction, operation and maintenance of plants

VDI 6023
Hygiene in drinking water installations; requirements for planning, implementation, operation and maintenance

UBA
Recommendation by the German Federal Environmental Agency after consultation with the Drinking Water Commission: Recommendation for testing for *Pseudomonas aeruginosa*, for risk assessment and remedial measures if detected in drinking water. Federal Health Gazette 2017; 60: 1180–1183

DVGW
Various DVGW regulations

EnEV
German Energy Savings Regulation