Recommendations by the Committee for Hygiene, Construction and Technology

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

Part 10: Compressed air for reprocessing medical devices

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Introduction

Part 10 of the publication Requirements for Construction or Reconstruction of a Reprocessing Unit for Medical Devices (RUMED) focuses on compressed air for medical use, generally known simlply as medical compressed air.

It describes issues related to the use of medical compressed air in a RUMED, including for endoscope reprocessing, drying medical devices after disinfection and testing medical devices.

The focus here is on medical compressed air produced in healthcare establishments, also known as on-site production.

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

When planning to use compressed air for medical device reprocessing, the intended purpose must first of all be defined since there are major quality differences between medical compressed air and technical compressed air. That calls for close cooperation between the project managers, RUMED/Endoscopy Department management, pharmacist(s) and planning engineers.

Pursuant to the European Pharmacopoeia (Ph.Eur), a manufacturing licence is required for the production of medical gases. Since general healthcare establishments do not have their own manufacturing licence the responsibilities imposed by medicinal and pharmaceutical product legislation must be assigned to the hospital pharmacy, or the pharmacy supplying it. The responsibility is then on the latter to devise a quality assurance system in consultation with the relevant hospital departments, while also specifying the routine checks required.

Medical compressed air can also be supplied in factory-made canisters (compressed air cylinders). The responsibility for the quality of the compressed air is borne by the manufacturer.

KRINKO/BfArM Recommendation: “Hygiene requirements for reprocessing medical devices”, Paragraph 2.2.2: The final rinse and drying steps must be executed under conditions that rule out recontamination of the disinfected medical devices. Hence, thanks to its good and rapid effect, medical compressed air [56] is used for drying such devices.

DIN EN 16442: The air quality must not detract from the purity of the load or give rise to microbial contamination. The quality must be defined with respect to humidity, pressure, oil content, particle content, flow rate, and must be measured at specified intervals.

If the storage cabinet is supplied with compressed air the compressor must be fitted with a filter and a drying system for flexible endoscopes. The filter replacement interval must be specified.

The information below relates solely to the requirements for using compressed air in the RUMED/Endoscopy Department for reprocessing medical devices and does not apply to its use for patients.

Definitions

Technical compressed air:
- For technical applications, e.g. valve control in washer-disinfectors, washer disinfectors for flexible endoscopes or sterilizers
- Not intended for direct use on medical devices

Medical compressed air as per Ph.Eur:
- For direct use for patients, e.g. ventilation
- Comprehensive contingency/redundancy measures prescribed
- May be used for medical devices

COMPRESSED AIR QUALITIES

Compressed air of medical compressed air quality:
- Intended solely for reprocessing medical devices
- Quality identical to that of medical compressed air
- No contingency measures prescribed

Comparison

COMPARISON MEDICAL/TECHNICAL COMPRESSED AIR

Compressed air of medical compressed air quality
- Class 2 as per ISO 8573-1, Tab. 2 (Air purification when using surgical instruments)
- Particle content
- Multiple filtration always needed
  - Oil free (< 0.1mg/m³)
  - Max. humidity 870 ppm to 10 bar/at least 5°C in the event of overpressure or undertemperature max. 67 ppm
  - CO, CO_2, SO_2, NO_x content
  - Max. 10 cfu/m³

PURITY SPECIFICATIONS

Technical compressed air
- Generally, no filtration for technical applications due to pressure loss
- Oil content
- No other requirements

Planning aspects:

SUPPLY COMPRESSED AIR OF THE REQUISITE QUALITY

- Provision of compressed air of medical compressed air quality
- Note application pressure as specified by the medical device/equipment manufacturer
- If applicable, prescribe contingency/redundancy measures
- Note ambient conditions and room furnishings and the air intake for production of compressed air
- If applicable, link suction facility to the fire alarm system

INTERFACES

- Enlist the services of the pharmacist in the production of medical compressed air (including for compiling facility description as per QS).
- Enlist the services of the infection control team or quality assurance personnel for provision of compressed air of medical compressed air quality.
- Enlist the services of occupational health and safety personnel
- If applicable, limit access to the areas used to produce and store compressed air

Installation/maintenance/checks

FACILITY DESCRIPTION

- Detailed facility description and standard operating procedures
- Documentation of installation/facility qualification (installation engineer)

RELEASE OF COMPRESSED AIR FACILITY

- Release and incoming inspection

MAINTENANCE

- Define the testing and maintenance scope for each system
- Keep maintenance records (filter designations, replacement intervals, compare with the specifications)

TESTING

- Regular quality checks (twice yearly recommended)

MEASUREMENT

- Continuous measurement of humidity levels
- Microbiology tests (twice yearly recommended) in accordance with intended purpose)
- If applicable, validation of the test methods

List of References

KRINKO/BfArM
Recommendation for hygienic processing practices for medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM)

ISO 8573-1

VDMA 15390-1
Compressed air purity – Part 1: Typical application-specific purity classes according to ISO 8573-1:2010 and guidance for achieving and monitoring of a respective compressed air purity for industrial applications

DIN EN ISO 7396-1
Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2016 + Amd 1:2017) (includes Amendment A1:2019)

DIN EN 16442:
Controlled environment storage cabinet for processed thermolabile endoscopes; German version EN 16442:2015

MDR 2017/745
Medical Device Regulation

Ph. Eur
European Pharmacopoeia

GMP
Good Manufacturing Practice

Aide-memoire 07121401
Medical Gases

ApBetrO
German Pharmacy Operation Regulation