MEDICAL GASES

HYGIENIC PROCESSES FOR HOME OXYGEN THERAPY DEVICES

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Table of Contents

Amendments to 157/09

Section	Change
All chapters	Updated to reflect MDR, instead of previous Directive
All chapters	Made coherent with MDR and EIGA Doc 222
Annex	Deleted because of limited added value with reduction of scope to Oxygen Therapy Medical Devices alone. Content worked into the core text.
All document	Changed scope from all HSP medical devices to only Oxygen Therapy Medical Devices
Annex	Tables in annex are deleted – given the scope limited to Oxygen Therapy Medical Devices, the vast majority of tables was no longer valid.

NOTE Technical changes from the previous edition are underlined.

1 Introduction

The goal is that patients are only receiving devices which are in clean and good operating condition.

Any medical device that has already been used by another patient could be potentially contaminated with reproductive micro-organisms.

All medical devices that have been potentially contaminated with micro-organisms are a potential source of infection in humans.

Medical devices shall not be operated or used if their condition could compromise the health and safety of the patient using them or the employees or third parties supplying them.

Appropriate handling and reprocessing procedures are essential to protect the next persons handling or using the device. Hence homecare medical devices which have been used shall be reprocessed, following the manufacturer's instructions, prior to reuse by another patient.

Medical devices used in home oxygen therapy require an appropriate level of disinfection, dependant on their use, but rarely need to be sterile. The term disinfection is defined as the process to produce a disinfected state, used to reduce the number of viable micro-organisms on the product to a level previously specified as appropriate for its further handling or use.

This document provides guidance for the reprocessing of medical devices used in oxygen home care therapy.

2 Scope and Purpose

2.1 Scope

The requirements described in this document apply to the reprocessing of medical devices for home oxygen homecare therapy that are intended to be re-usable (excluding disposables such as nasal cannulas). The scope includes the process steps before and after the actual reprocessing.

The manufacturer's instructions should define the requirements for reprocessing for each type of medical device used in respiratory home therapy.

The requirements of the manufacturer always apply when medical devices and their accessories are required to be brought into a disinfected state.

They shall be hygienically processed, i.e. cleaned and/or disinfected:

- prior to being used by another patient
- when serviced, maintained or repaired,
- prior to being used by a subsequent patient.

The scope of this document does not cover the reprocessing of medical devices that are to used in sterile condition. Also out of scope are cylinders and pressure regulators, for which reference is made to EIGA Doc 222 – *Guidelines for cleaning externally contaminated medical gas containers*. [1]

Applicable national or regional regulation shall always be complied with.

These requirements are especially aimed at (but not limited to) the reprocessing of the following types of medical devices for oxygen homecare therapy and their parts, including their accessories:

- Oxygen concentrators (stationary and portable)
- Self-fill systems
- Liquid Oxygen Systems
- Oxygen conserving devices

2.2 Purpose

The purpose of the document is to provide guidance to the Homecare Service Provider on how to carry out the hygienic reprocessing of the medical devices for Oxygen Therapy.

3. Definitions

For the purpose of this publication, the following definitions apply.

3.1 Publication terminology

3.1.1 Shall

Indicates that the procedure is mandatory. It is used wherever the criterion for conformance to specific recommendations allows no deviation.

3.1.2 Should

Indicates that a procedure is recommended.

3.1.3 May

Indicates that the procedure is optional.

3.1.4 Will

Is used only to indicate the future, not a degree of requirement.

3.1.5 Can

Indicates a possibility or ability.

3.2 Technical definitions

3.2.1 Cleaning

The physical removal of foreign material (e.g. dust, soil, domestic spillages and organic material such as blood or secretions). Cleaning physically removes rather than kills micro-organisms. It is accomplished with water, detergents and mechanical action.

3.2.2 Disinfection

Process to destroy viable microorganisms.

3.2.3 Reprocessing

Is the process of cleaning and (if required) disinfection.

3.2.4 Disposables

An article designed to be thrown away after use.

4. Reprocessing – General

Reprocessing is defined in the European Medical Device Regulation 2017/745 (MDR) [2] as *"a process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device" – Article 2.39.*

MDR defines the responsibility of the manufacturer in the reprocessing in Annex I:

- Chapiter II. 11.2*. "Where necessary devices shall be designed to facilitate their safe cleaning, disinfection, and/or re-sterilisation".*

- Chapter III. 23.4.i – *"details of any preparatory treatment or handling of the device before it is ready for use or during its use, such as sterilisation, final assembly, calibration, etc., including the levels of disinfection required to ensure patient safety and all available methods for achieving those levels of disinfection".*

- Chapter III. 23.4.k. – *"the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant: — details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection".*

- Chapiter III.23.4.n - "The instructions for use shall contain all of the following particulars: if the device is reusable, information on the appropriate processes for allowing reuse, including cleaning, disinfection, packaging and, where appropriate, the validated method of re-sterilisation appropriate to the Member State or Member States in which the device has been placed on the market. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses"

4.1 Responsibility

The manufacturer's responsibilities concerning the reprocessing of medical devices are stipulated in Clause 11 and 23 in Annex 1 of the MDR.

The responsibilities of the Homecare Service Provider are usually stipulated in regional or national law, decree or regulations.

4.1.1 The Manufacturer's Responsibilities

The instructions provided by the manufacturers of the device and any related accessories shall be used as the basis for which the Homecare Service Provider decides on how the device and any accessories shall be used.

In the instructions for use the manufacturer must provide the following information:

- if device and any related accessories can be reused
- type and procedure of the reprocessing (product-specific hygiene scheme)
- details on reprocessing including detailed specifications on (see section 4):
    - cleaning/disinfection
    - rinsing
    - drying
    - transportation
    - storage

For devices that are considered reusable, the medical device manufacturer shall deliver in a clean condition and where required for patient safety also delivered in a disinfected state.

In addition, the medical device manufacturer shall either:

- supply the device in a suitable condition, packaged appropriately to enable the device to be supplied to the patient without further processing.
- supply the device in an appropriate condition and provide the Homecare Service Provider with information to allow the device to be used by the patient through the manual of the device.
  The information provided by the manufacturer shall be based on the procedures described above.

4.1.2 The Homecare Service Provider's Responsibilities

The Homecare Service Provider shall respect the cleaning and disinfection procedures of the manufacturer that are mentioned in the Instruction for Use or Clinical Manual or Maintenance Manual of the reusable medical device. The cleaning and disinfection products chosen by the HSP shall follow the requirements mentioned by the manufacturer.

The practical execution of the reprocessing is to be determined in all of its individual steps (see section 5). The training and qualification of the person authorised to carry out the reprocessing is to be considered.

These requirements also apply to the reprocessing by third parties.

4.2. Pre-conditions

The basic requirements for the reprocessing of homecare medical devices are:

- to protect the patient, the user, the employees and third parties (such as those in charge of reprocessing)

- to know the limits of the procedures used for reprocessing (such as the number of re-processing cycles)

- to standardize and control procedures guaranteeing a consistently high and verifiable quality, based on an established quality management system, e.g. ISO 9001, ISO 13485. [3], [4]

The type of reprocessing is determined by:

- The potential degree of contamination of the medical device

- The risk of infecting another patient resulting from reuse of the device and the type of application of the medical device.

4.3 Provisions

When the device manufacturer performs a risk analysis within the conformity assessment procedure, this shall include an assessment of whether a subsequent patient is at risk of infection when a medical device that has been potentially contaminated with human pathogen micro-organisms is reused. The risk analysis should specially consider the possible risk associated with the contamination of air conducting components due to the patient's re-breathing.

If the outcome of the risk assessment is that the danger of infection cannot be excluded, a verified (and if possible validated) documented reprocessing procedure must be specified in such detail so that the outcome is reproducible. As medical devices for home oxygen therapy are usually reprocessed manually, validation in most applications is not possible. An adequate level of safety against dangers of infection for the next patient can be assumed if the:

- documented reprocessing procedure's effectiveness has been verified through appropriate scientific methods by the manufacturer and

- reliability of the documented reprocessing procedures has been verified in practice through appropriate quality assurance measures by the party responsible for carrying out the reprocessing procedures, mainly the HSP.

4.3.1 Medical Devices reprocessing risk evaluation by the manufacturer

When selecting and evaluating the reprocessing procedures the manufacturer has to consider:

- the amount and type of human pathogen micro-organism to be expected with the medical device used.

- the risk for the human pathogen micro-organism to be transmitted to the patient.

- their resistance to the reprocessing procedures intended to be used.

The risks posed by reprocessed medical devices are determined by the following factors:

a) undesired effects, which can result from:

    - the previous use,

    - the previous reprocessing,

    - transportation,

    - storage

b) the risks from the type of subsequent uses, such as

- Residues from the previous use (such as. secretions and other bodily components, other drugs)
- Residues from the previous reprocessing (such as cleaning agents, disinfectants and other substances, including their reaction products)
- Changes of physical, chemical or functional properties of the medical product,
- Changes in the condition of the material (such as accelerated wear and tear, embrittlement and changed surface conditions, connectors and adhesive joints).

c) the risk of transmission of any human pathogen micro-organism.

4.3.2. Feasibility

When considering the suitability of the reprocessing procedure and the feasibility of reprocessing the medical device, the manufacturer should consider the following points:

- The risks involved in the reprocessing process
- The practicability of the reprocessing process
- The availability of the cleaning equipment and the cleaning agents and methods specified in the reprocessing process
- The efficacy of the reprocessing process
- The reproducibility of the reprocessing process
- Quality management requirements of the reprocessing process
- Environmental impact of the reprocessing process and the disposal of the device
- The cost effectiveness of the reprocessing process

The results of the assessment should indicate whether it is appropriate to reprocess or dispose of the device and whether the method is practicable for use by all parties.

Where alternative cleaning equipment or agents are used, they must be at least as equivalent to those specified in the manufacturers' procedure.

4.3.3 Verification of the Reprocessing Procedures

Manual cleaning and disinfection of the device must always be carried out in accordance with documented procedures specified by the medical device manufacturer.

All cleaning agents and reprocessing procedures used must be verified with regard to their suitability and repeatability with the respective medical device, dependant on the type of use and in accordance with the cleaning agents mentioned by the manufacturer.

Monitoring, control and warning systems for the cleaning and disinfecting machines are the basis of demonstrating the efficiency of the cleaning and disinfecting process. Due to the importance of the cleaning and disinfecting performance, only machines which have been appropriately validated are recommended.

If the device manufacturer specifies validated automated cleaning and disinfection procedures, they must be followed, ensuring that the essential parameters used to demonstrate that the quantifiable cleaning and disinfecting requirements are met. Such parameters could include volume of water used, water pressure, temperature, pH-value, dosage of cleaning agents and disinfectants, or residence time.

To ensure the reproducibility of the automated reprocessing procedures, tests should be carried out on a regular basis, dependant on the risk assessment.

4.4 Alternative Processes

Processes and procedures, different from those specified by the manufacturer, shall be accepted if it can be demonstrated that an equivalent degree of hygiene status is obtained.

If alternative processes are applied validation by the HSP shall ensure equivalence to the proposed manufactures instructions.

5. Procedural Steps in Reprocessing Contaminated Medical Devices

5.1 Devices coming from the Manufacturer

For devices that are considered reusable, the medical device manufacturer shall deliver in a clean condition and where required for patient safety also delivered in a disinfected state.

Where the manufacturer does not supply the medical devices in a suitable condition for use by the patient, it shall be processed in accordance with this document and maintained in that condition until set up for use by the patient. Best practice is to have included in the contract that devices should be delivered by the manufacturer in a ready to use condition.

Automated and manual cleaning/disinfection, cleansing and drying procedures shall be reproducible, clearly defined, and their results verifiable.

5.2 Transportation and storage

Transportation and storage shall not have any negative impact on the properties of the processed medical device. Storage of the processed medical devices shall be based on the specifications of the manufacturer of the medical device and the manufacturer of the packaging material.

Generally, processed medical devices are to be stored dust-protected, in packaging that guarantees mechanical protection and at a temperature and humidity range specified by the manufacturer.

To minimise the risk of cross-contamination during transportation, processed or new medical device shall be strictly separated from contaminated devices, in the delivery vehicle, warehouse and workshop. Examples of such separation can be achieved by,

- suitable packaging such as plastic bags (suitable to withstand rough handling)
- Disinfection of the outside of the device before loading
- Separated area’s in the delivery vehicle

Contaminated medical devices and parts, including their accessories should only be handled with safety gloves or single-use gloves. Protection through facial mask can be useful, dependant on the situation. This applies to the collection of the devices at the patient’s home, their preparation for their transportation and their shipment. Any disposable single patient accessories are not to be

reprocessed and are to be disposed. Only reusable accessories are to be reprocessed (carrying bag, batterie, charger…).

The above applies also to contaminated medical devices handling during inspection, maintenance or repair, at the patient's home, at the hospital or in the service workshop.

These medical devices and their accessories are then to be taken into the individual reprocessing steps or immediately disposed accordingly.

5.3 Reprocessing

The reprocessing procedure generally comprises of the following steps:

a) appropriate preparation (pre-treatment, collection, pre-cleaning) and, if applicable, disassembling of the used medical products and application of protective packing to prevent damage during transportation.

b) cleaning / disinfection / cleansing and drying of the device,

c) examining the cleanliness and surface integrity of the device if applicable, repeating step (c),

d) service and maintenance

e) functional testing of the device as specified by the manufacturer,

f) labelling,

g) packaging and transportation.

The medical device shall be cleaned for use by the Homecare Service Provider and labelled accordingly, with the results documented in a log, with all individual steps aligned to the manufacturer's instructions.

The reprocessing procedure shall follow the instructions of the:

- Medical device manufacturer
- Manufacturer of the cleaning agent
- Manufacturer of the disinfectant

These instructions shall be considered when organising the work processes.

Following reprocessing, the medical device shall continue to fulfil its function in accordance with its purpose, and it shall meet all safety-relevant requirements. The entire reprocessing procedure and the processed medical device shall never compromise the health and safety of the patient, the user or any third party (such as with allergic and toxic reactions, infections or any changes to the technical functionality of the medical device). This also means that any contamination of the reprocessing area shall be avoided and, if appropriate, a surface cleaning or disinfection shall be carried out.

A documented quality management system is essential to ensure the reproducibility of the reprocessing of medical devices.

5.3.1 Preparation of the Reprocessing

Some medical devices require preparation to ensure proper reprocessing.

This could include:

- Pre-treatment (such as soaking),
- Pre-cleaning (such as wiping or brushing),
- Disassembling

To ensure that the hygienic safety and the functionality of the processed medical devices do not suffer any impairment, it is essential that, especially in cases when delays in cleaning/disinfection make pre-cleaning and perhaps interim storage necessary, the following requirements are met:

- Damage to the medical device caused during the transportation, pre-cleaning or possibly necessary interim storage shall be considered.
- The agents and procedures used for pre-cleaning shall be compatible with the subsequent reprocessing procedures.
- In all steps of the preparation work safety requirements shall be met.

5.3.2 Cleaning

Outer and inner surfaces (as far as required according to instructions) shall be accessible for the used cleaning agents and disinfectants. As far as instructed by the manufacturers' manual, it might be necessary to disassemble medical devices to clean them effectively.

An effective and residue-free cleaning procedure shall be applied.

Following the final step of the cleaning procedure, it shall be ensured by visual inspection that no residues either from the previous use or from the cleaning materials are left.

The agents and procedures shall meet the required cleaning performance and shall not result in adverse changes of the material.

Organic material and chemical residue contaminate the cleaning solution. To avoid microbial reproduction of lasting cross-contamination and impairment in the cleaning performance the cleaning solution is to be freshly prepared at least on every workday and each time it visibly shows contamination. The cleaning basin should be thoroughly cleaned and disinfected on every workday.

5.3.3 Disinfection

The medical device manufacturer shall ensure that the specified device disinfection procedure is verified to be bactericidal, fungicidal and virucidal. The cleaned and disinfected medical device shall not pose a risk of infection through reproductive human pathogen micro-organism when it comes in contact with the skin or mucous membranes.

Disinfectants listed by regional or national authorities are normally designed for manual disinfection of medical devices but not for automated disinfection. Therefore, the manufacturer has to verify the efficacy in cleaning and disinfecting devices through expert opinion under the conditions of automated reprocessing.

Effective disinfection requires that the instructions for the disinfectant, especially with regard to concentration and residence time, are followed.

5.3.4 Cleansing and drying

Cleaning and disinfecting solutions shall be removed using intense rinsing with water of an appropriate quality (at least drinking water quality) to avoid biological reactions and impairment in the material. With the use of disinfection wipes, the rinsing step may be unnecessary, in which case no rinsing is needed. Disinfection wipes shall not be reused on different Medical Devices.

During rinsing and drying recontamination of the processed medical device shall be avoided.

5.3.5 Functional testing

Following reprocessing, a safety and functional test of the medical product (in accordance with the manufacturer's instructions) shall be carried out. If necessary, safety-relevant functional testing shall be carried out directly before use of the product.

Extent and type of the tests depend on the medical device and are to be defined in the instructions.

5.3.6 Packaging

Generally, the packaging consists of a protective packaging**,** such as the original carrying bag or a plastic bag, to prevent contamination. Its purpose is to prevent the medical device from being contaminated with reproductive human pathogen micro-organism from the time after its reprocessing to its use.

The outer packaging should be appropriate for the specified storage and transportation of the device and should protect the specified protective packaging.

5.3.7 Labelling

The medical device or its packaging shall carry a label which indicates the status of the device, the identity of the re-processor and the date the equipment was re-processed. This labelling shall be clearly visible and may be applied to the outer packaging.

If the reprocessing is performed during the production process, a reprocessing label is not necessary.

5.3.8 Clearance for use

The reprocessing of medical devices ends with the clearance for use.

5.3.9 Documentation

To demonstrate that the reprocessing procedure has been carried out in accordance with the standard work instructions and in compliance with the criteria and parameters and to provide traceability, the clearance of the process and the identification of the responsible person shall be documented.

6 References

Unless otherwise specified, the latest edition shall apply.

[1] EIGA Doc 222 *Guidelines for cleaning externally contaminated medical gas containers*. www.eiga.eu

[2] European Medical Device Regulation 2017/745 (MDR).

[3] ISO 9001 Quality management systems – Requirements.

[4] EN ISO 13485 Medical Devices Quality Management – Requirements for Regulatory Purposes.

7 Additional references

EN ISO 14971 Medical devices – Application of risk management to medical devices.