

HYGIENIC PROCESSES FOR HOME OXYGEN THERAPY DEVICES

Doc 157/21

Revision of Doc 157/09

EUROPEAN INDUSTRIAL GASES ASSOCIATION AISBL

AVENUE DE L'ASTRONOMIE 30 • B-1210 BRUSSELS
Tel : +32 2 217 70 98
E-mail : info@eiga.eu • Internet : <http://www.eiga.eu>



HYGIENIC PROCESSES FOR HOME OXYGEN THERAPY DEVICES

Prepared by WG-10 Homecare

Disclaimer

All technical publications of EIGA or under EIGA's name, including Codes of practice, Safety procedures and any other technical information contained in such publications were obtained from sources believed to be reliable and are based on technical information and experience currently available from members of EIGA and others at the date of their issuance.

While EIGA recommends reference to or use of its publications by its members, such reference to or use of EIGA's publications by its members or third parties are purely voluntary and not binding.

Therefore, EIGA or its members make no guarantee of the results and assume no liability or responsibility in connection with the reference to or use of information or suggestions contained in EIGA's publications.

EIGA has no control whatsoever as regards, performance or non performance, misinterpretation, proper or improper use of any information or suggestions contained in EIGA's publications by any person or entity (including EIGA members) and EIGA expressly disclaims any liability in connection thereto.

© EIGA grants permission to reproduce this publication provided the Association is acknowledged as the source

EUROPEAN INDUSTRIAL GASES ASSOCIATION AISBL
Avenue de l'Astronomie 30 B 1210 Brussels Tel +32 2 217 70 98
E-mail: info@eiga.eu Internet: www.eiga.eu



Table of Contents

1	Introduction	1
2	Scope and Purpose	1
2.1	Scope	1
2.2	Purpose	2
3	Definitions	2
3.1	Publication terminology	2
3.2	Technical definitions	2
4	Reprocessing – General	3
4.1	Responsibility	3
4.2	Pre-conditions	4
4.3	Provisions	5
4.4	Alternative Processes	7
5	Procedural Steps in Reprocessing Contaminated Medical Devices	7
5.1	Devices coming from the Manufacturer	7
5.2	Transportation and storage	7
5.3	Reprocessing	8
6	References	10
7	Additional references	11

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 be 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.