

GOOD HOMECARE PRACTICE FOR OXYGEN THERAPY

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Prepared by WG-10

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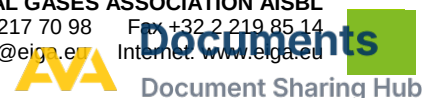


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Amendments from 158/09

Section	Change
	Editorial to align to new format
	Since the previous version of this document some content has been taken out and described in more detail in separate documents. Where this is the case, there is a reference to the new document.

1 Introduction

The supply of oxygen therapies to patients at home is a specific activity and service. It is performed within individual and varying environments from one patient to another.

Patient safety, quality of therapy and patient education are the prime objective of the Homecare Service Providers (HSP).

The HSP organises activities in compliance with the European and national legislation related with manufacture and supply of medicinal products and medical devices. This includes:

- Good Manufacturing Practice (GMP) [1]¹
- Good Distribution Practice (GDP) [2]
- General Data Protection Regulation (GDPR) [3].

In addition to the European and national legislation, the HSP will specifically act in accordance to the documented therapy prescription and contractual agreements and following industry guidelines including those in EIGA publications.

As an overview, this publication combines and refers to the elements above and provides guidance for HSPs on Good Homecare Practice for Oxygen Therapy.

2 Scope and purpose

2.1 Scope

This publication applies to the delivery of medical oxygen and related services by HSPs using:

- compressed oxygen cylinders
- transportable liquid oxygen systems
- oxygen concentrators
- oxygen self-fill systems.

2.2 Purpose

The purpose of the publication is to provide guidance for all HSPs for the supply of oxygen therapy.

The publication provides best operating practices for the supply of medical oxygen but does not cover all the relevant applicable national regulations that could apply in some countries.

The basic requirements include, but are not limited to:

- Services and supply of products are assured to each patient in compliance with the therapy prescription and according to the terms of the contract including installation, maintenance and removal of the equipment.
- Service and supply processes are clearly defined, systematically reviewed in the light of experience and shown to be capable of consistently delivering services and products.

¹ References are shown by bracketed numbers and are listed in order of appearance in the reference section.

- Each patient or carer is adequately trained in the safe and correct use of the therapy related products.
- Relevant service and supply processes are risk assessed to ensure the safety and health of personnel and patients.

3 Definitions

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 and Need not

Indicate 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 Base unit

Mobile device that is vacuum insulated intended to store oxygen and maintain it in the liquid state to refill portable units and that includes an internal vaporiser and a flow control valve for the direct supply of gaseous oxygen to the patient.

3.2.2 Basic maintenance

Maintenance according to the user manual.

3.2.3 Carer

Person (for example a relative or friend) who can assist the patient with their therapy.

3.2.4 Oxygen cylinders

Transportable pressure receptacle of a water capacity not exceeding 150 litres.

3.2.5 Equipment

Oxygen therapy related medical devices.