



GUIDANCE FOR SAFETY AND RELIABILITY OF OXYGEN SELF- FILL SYSTEMS

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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



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Prepared by WG-10

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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

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Amendments to Doc 193/14

Section	Content
Whole Document	Given the years of existence of the technology, detailed advice to manufacturer (materials, etc...) was removed.
Whole Document	Duplication with other EIGA documents was removed. References were updated.
Section 7 and 8	For the concentrator, reference is made to EIGA Doc 89.
Section 9	Life Cycle and environmental compliance was removed as it is covered in previous chapters.

1 Introduction

Many patients suffering from respiratory diseases receives ambulatory (mobile) oxygen therapy and services, among which self-fill systems.

Self-fill systems allow the patients to fill oxygen cylinders at high pressure, at home, for personal use only. These systems have been in use for a number of years.

The units described in this publication consist of assemblies of components that include compressors, stationary concentrators, cylinders with standard valves and oxygen conserving devices.

It remains important to maintain the safety aspects of these medical devices which are compressing oxygen at a high pressure and filling cylinders in an uncontrolled environment.

2 Scope and purpose

2.1 Scope

The publication covers the principles of design, filling process, maintenance and use of self-fill gaseous oxygen units.

2.2 Purpose

To provide guidance on these systems working in a home environment with high pressure oxygen and to provide advice to the manufacturers, designers, purchasers, homecare service providers, users (patients or care givers) and prescribers.

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

Indicates that the procedure is optional.

3.1.4 Will

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 Medical oxygen and Oxygen enriched air

- Medical oxygen, supplied as a medicinal product under a Marketing Authorisation (MA), compliant with the European Pharmacopoeia specification for medical oxygen. This covers