MEDICAL GASES

GUIDANCE FOR SAFETY AND RELIABILITY OF OXYGEN SELF-FILL SYSTEMS

Doc 193/21

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Disclaimer

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Table of Contents

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

oxygen that is supplied as a compressed gas in cylinders or cryogenic liquid supplied in cryogenic containers, specified in the MA.

- Oxygen enriched air produced from a concentrator which has been CE marked to the *Medical Device Regulation (*MDR) [1][1]. It also relates to the oxygen filled into cylinders using a concentrator ISO 8359 [2].

4 Description of a self-fill system

Oxygen self-fill systems are used for both supplying oxygen to the patient and allowing the patient or caregiver to fill oxygen into high pressure gas cylinders.

The self-fill system consists of the following components:

- oxygen concentrator,
- oxygen compressor,
- cylinder(s) (PIN index or equipped with a Valve with Integrated Pressure Regulator (VIPR)) EIGA Doc 180 [7]. These units are fitted with a proprietary filling connection, designed for use with the specific filling system,
- Additionally, the cylinder may be equipped with an oxygen conserving device.

Patients are normally supplied with more than one cylinder to allow them to use a cylinder whilst another one is being filled by the self-fill system.

The portable cylinders supplied with these systems are intended to be used for mobility or where it is impractical to use the concentrator within the home.

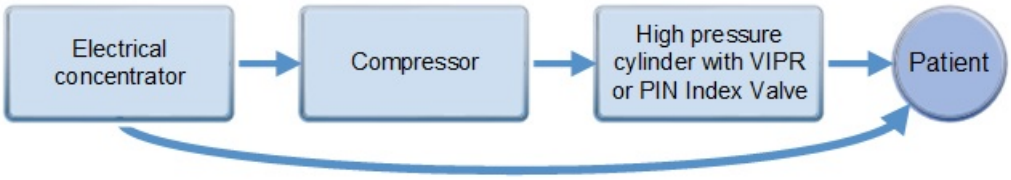

Figure 1 Schematic of patient self-fill system

Depending on the design of the system, the patient may be able to use the concentrator whilst the system is filling cylinders. In this case, the concentrator will preferentially supply the patients their oxygen requirements, thus extending the time to fill the cylinder or reducing the maximum limit of oxygen flow supplied. The patient needs to be aware of possible dose limitations when using the system while filling cylinders at the same time.

5 Design considerations

5.1 Certification

Documents shall be provided by the manufacturer regarding Medical Device Regulation [1], and shall include:

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

- a declaration of conformity to the MDR and the list of applicable standards used to demonstrate this conformity,
- the classification according to the MDR and the information of which classification rules have been applied,
- The MDR article 10 § 14 mentions the following required documents:
    - the device has been CE marked,
    - EU declaration of conformity of the device,
    - the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10 point 11,
    - for imported devices, the indication of the importer,
    - the assigned UDI (Unique Device Identification).

If the CE mark declaration of conformity refers to the assembly, it shall include reference to the standards applicable to each of the components (including, but not limited to the concentrator, compressor, cylinder or valve).

5.2 Product Documentation

The following documents shall be provided by the manufacturer:

- Instructions for use,
- technical user manual,
- maintenance guide.

Drawings and bill of materials shall be comprehensive and shall include references, part number identification and shall be linked together and with the other technical reports.

Technical documents are required to be dated and signed and a documented revision process followed. All documents submitted shall refer to the equipment version, specifically when components are submitted to tests.

5.3 Concentrators

The concentrator shall be designed and approved in accordance to the requirements of ISO 80601-2-69 Medical electric equipment Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment [18] and ISO 8359 Oxygen concentrators for Medical Use [2].

The design shall comply with IEC 60601-11 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment - and IEC 60601-1-6 General requirements for basic safety and essential performance - Collateral standard: Usability as appropriate [3,4]

5.4 Compressor

The compressor shall be designed and approved in accordance with the requirements of ISO 60601 - 11 [3].

Any oil usage is a concern for the compressor considering the respiratory use of the compressed oxygen. Specific attention shall be paid to evaluate the quantities of oil used, references chosen and place of application, to define if the compressor is oil free. If not, mitigation measures shall be defined by the manufacturer to ensure it is a topic managed and without consequences for the patient (fire hazards).

Specific attention needs to be given to the selection of the acoustic isolation foam, so that there are no risks to release harmful substances to patients.

Halogenated components in contact with oxygen shall be avoided, see EIGA Doc 73 [5].

Internal casing ventilation is required to reduce internal oxygen enrichment as result of a leak. Guidance on oxygen compressors can be found in EIGA Doc 10, *Reciprocating oxygen compressors* [6]. Means to minimise the risk in single fault condition shall be present (burst disk, safety valve)

The compressor shall have means to automatically shut down when the maximum pressure is reached. In addition, a burst disc shall be available to avoid a risk of explosion in case of a failure of the pressure switch.

The compressor shall have controls to avoid hazards such as overheating or overpressure, and shall include:

- measures to ensure cylinders are not filled with an oxygen concentration of less than 82%;
- an alarm to indicate when the electrical power is interrupted;
- in the event of a loss of electrical power during cylinder filling the system shall shut down to a safe condition;
- in the event of a compressor shutdown, the patient shall be able to read the pressure available in the cylinder; and
- a check valve in place to avoid a flow back into the concentrator in the event of the compressor stopping.

5.5 Filling connector

To allow oxygen going from the compressor to the cylinder valve, a high-pressure filling connector is required with two different parts:

- connector directly attached to the compressor, usually a male fitting; and
- connector attached to the cylinder valve to receive the gas filled into the assembly, usually a female fitting.

The connection is critical due to the operation under high pressure, the type of gas used and the usage cycles. Therefore, the filling connector shall be designed according to high pressure requirements and oxygen compatibility principles.

Materials shall be chosen with the same criteria as for a VIPR, taking into account compatibility with oxygen, the generation of toxic gases in case of ignition and stress received by parts such as spring e.g. copper beryllium, see EIGA Doc 180 *Design considerations and guidance for the safe use of medical gas VIPR* [7] and EIGA Technical Bulletin TB 6 *Use of copper beryllium alloy for medical devices* [8]

The manufacturer shall add external protection means to protect this filling connector from dirt, dust and other external contamination.

5.6 Valves with Integrated Pressure Regulator (VIPR)

VIPRs shall be designed according to the requirements of ISO 10524-3: Pressure regulators for use with medical gases. Pressure regulators integrated with cylinder valves [9]

Tests shall be performed in accordance with the procedure described in ISO 10524-3 [9]. Depending on the application other tests could be required (e.g. ASTM G175; Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications [10]).

For more detail on Medical Gas VIPR Design, see EIGA Doc 180 [7]. For compatibility of metallic materials with gases see ISO 11114-1 Gas Cylinders – Compatibility of cylinder and valve materials with gas contents - Part 1: Metallic Materials [11]

Compatibility with oxygen shall be part of the requirements for non-metallic parts and lubricants used, to ensure a safe use with oxygen. For more information see ISO 11114-2 Gas Cylinders – Compatibility of cylinder and valve materials with gas contents - Part 2: Non-metallic Materials [12]

There shall be no aluminium in contact with high pressure oxygen wetted parts.

The flow measured at the patient's outlet shall be in line with flow settings of the device and in accordance with the tolerances of the applicable standards.

5.7 Cylinders

Specific attention is required for the cylinders used for this type of equipment.

As cylinders for self-fill systems are filled more often than cylinders in other services, attention should be paid when selecting the cylinder for the intended filling cycles.

The assembly is provided complete, which means cylinder and VIPR or PIN index valve attached together. The manufacturing assembly process shall ensure the cylinder is free from dust or contamination before installing the valve and tested for leaks at the valve/cylinder interface.

The design shall take in consideration the risk of microbiological contamination due to moisture in the cylinder. The manufacturer shall provide evidence that the following tests were carried out to determine the moisture content of the gas filled into the cylinder:

- moisture analysis of filled cylinders after devalving, drying and valving;
- flow and moisture measurement from the cylinder filling port of the self-fill unit; and
- moisture analysis of the gas from the plastic tubing that connects the concentrator to the self-fill unit.

5.8 Material selection

All materials shall comply with the requirements of ISO 10297, Transportable gas cylinders. Cylinder valves specification and type testing [13] and EN ISO 15001 Anaesthetic and respiratory equipment. Compatibility with oxygen [14], as applicable. The manufacturer shall provide drawings and information on the materials used in the device.

It is a known risk that the polymer materials used in filling systems, valves and regulators for breathing gases can ignite producing toxic products resulting in these products being inhaled. The constant flow valve, the seat of the regulator and the seat of the compressor piston shall not have halogenated polymers, see EIGA Doc 73 [5].

Materials in contact with the gas shall be compatible with the gas, under all intended operating conditions, see ISO 11114-1; ISO 11114-2 [11,12] and the material specifications of the producer. For

medical and breathing applications, see EN ISO 15001, [14] especially when selecting materials to reduce the risk of toxic products of combustion/decomposition from non-metallic materials including lubricants.

Aluminium alloys shall not be used in high pressure oxygen wetted parts.

Lubricants shall be suitable for use in oxygen service and the manufacturer shall provide documentation demonstrating suitability for oxygen service.

6 Test and test reports

This section describes the tests homecare service providers are recommended to perform to accept a self-fill system for the use at a patient's home. The components and device shall be certified to meet all regulatory requirements. It is the responsibility of the economic actor (manufacturer or importer) placing the self-fill system on the market to ensure all regulatory requirements are fulfilled.

When requested by the homecare service providers, the manufacturers shall present the relevant test reports.

6.1 Cylinders, valves and connections

6.1.1 Ignition and adiabatic compression test

All high-pressure components shall pass the tests described by the applicable standards. Specific attention shall be given to the fact that valves, regulators and filling connectors shall have passed the oxygen pressure test in accordance with ISO 10524-3 [9] and ignition test in accordance with ASTM G 175 [10] and to the adiabatic compression test for each independent part and reproducing the interaction between different connections. Tests shall be carried-out by a certified laboratory and results documented in the approval of the equipment.

6.1.2 Cylinder filling test

The cylinder filling tests need to comply with the technical manual provided by the manufacturer.

6.2 Compressor

Tests shall be performed on the complete filling connector to ensure the design is safe. Specifically, an adiabatic compression test is strongly recommended (one direction or two depending on the presence of depressurization holes) to reproduce the internal stresses while disconnecting the assembly from the compressor after filling.

6.3 Equipment cover

The following shall be verified for the cover:

- equipment parts that could, in normal use, have unintentional contact with a patient shall not attain temperatures harmful to the patient [4],
- to avoid the risk from water exposure in context with electrical failures a double isolation design is verified,
- the shell is sufficiently robust such that the shell is not damaged from "general wear and tear" whilst in use.

7 Equipment operation

The home care service provider shall ensure that manufacturers provide detailed instructions about the equipment and the filling process. This shall include guidance on connecting and disconnecting the cylinder to the system and about the correct sequence for filling operations. Equipment operation for

the concentrator part of the self-fill system is described in EIGA Doc 89 [17].

7.1 Pre-filling instructions

In the instructions for use the checks shall be indicated that need to be carried out on the cylinder filling system prior to starting the filling process. This shall include:

- visual inspection of cylinder and connections;
- pre-fill compressor checklist; and
- in case of a battery-powered conserving device, check the battery state.

7.2 Cylinders, valves and connections

As the oxygen self-fill system is a CE marked medical device components from different manufacturers are not interchangeable. The system shall be used only with the cylinders specified by the manufacturer and identified for use in the instructions.

In the user manual it should be explained how to keep the valve and equipment connections clean and which systems of protection should be adopted or provided by the manufacturer

The manufacturer shall provide information on cylinders and valves to comply with the Medical Devices Regulation including compliance with the Transportable Pressure Equipment Directive [15]. The home care service provider shall consider the transport rules for this type of cylinders.

7.3 Over pressure

The manufacturer shall provide documentation to the homecare service provider that explains how it is ensured that the pressure during the filling process is controlled and the technical solutions to prevent the over pressurisation of cylinders.

8 Maintenance instructions

Prior to installing any equipment in a patients' home, it is the responsibility of the homecare service provider to ensure that the equipment is functioning correctly and that there is no possibility of contamination between patients. Additional information on maintenance and cleaning by the homecare service provider is given in, EIGA Doc 157 [16], and EIGA Doc 89 [17]

8.1 Patient / user's maintenance responsibilities

The patient or carer's responsibilities in the routine maintenance are part of the training given by the homecare service provider, based on the manual provided by the manufacturer.

The patient or caregiver shall be instructed **not** to modify the cylinder filling equipment in anyway, including replacement of seals and tightening of connections. The patient or caregiver shall be instructed that if they have any problem with the equipment, they shall notify the homecare service provider immediately.

8.2 Maintenance

The periods defined by the manufacturers for preventative maintenance of each component shall be followed. Maintenance of equipment used by a patient shall be carried out that allows the continuity of treatment.

Complex maintenance procedures shall only be carried out by a qualified repairer, when required approved by the manufacturer.

8.2.1. Oxygen concentrator

Equipment maintenance for the oxygen concentrator is described in EIGA Doc 89 [17]

8.2.2 Oxygen compressor

Any failure, malfunction or defect during the operation shall be notified to the homecare service provider.

Only authorized technical services shall check the functioning of the system. In case of device malfunctions homecare service providers should contact the manufacturer's technical services.

Repairs shall only be carried out by competent persons or organisations qualified by the manufacturer.

8.2.3 Cylinders

When carrying out routine maintenance on the oxygen self-fill system at a patient's home, the cylinders' statutory test / duration dates shall be checked to ensure that there is sufficient time left to enable all cylinders to be used up to the next routine maintenance visit. During the routine maintenance the filling connector and filling process shall be checked.

If any leakage (or abnormal behavior) of the oxygen cylinder is detected, the patient or care giver should check for alarms and turn the flow selector knob on the regulator to "0". If the problem persists, place the cylinder outdoors and notify your homecare service provider of this condition

Malfunctioning cylinders should be taken out of service immediately and sent to repair.

8.3 Cleaning

The patient or caregiver is only responsible for keeping the cylinder, compressor or concentrator externally clean, which may be done by wiping the surface with a clean cloth.

When cleaning the equipment always ensure that the oxygen supply is turned off and for concentrators, always unplug the unit from the mains before cleaning.

Advice shall be given to the patient or caregiver about suitable non-abrasive cleaning agent or disinfectant that may be used for cleaning any medical oxygen equipment. The advice shall include never to use solvents or other flammable or abrasive products to clean the equipment.

The high-pressure parts shall not be cleaned; they shall be protected by the original protection caps.

After each use, clean the exterior of the cylinder with a dry, lint free cloth only (Do not use cleaning solutions, or immerse product in any kind of liquid).

Afterwards, store the cylinder(s) in a clean area free from grease, oil and other contaminants.

For general cleaning instructions reference is made to EIGA Doc 89 [17].

9 References

[1] Medical Device Regulation (MDR) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices www.ec.europa.eu

[2] ISO 8359 *Oxygen concentrators for medical use. Safety requirements* *www.iso.org*

[3] IEC 60601-11 *Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment* www.iec.ch

[4] IEC 60601-1-6 *General requirements for basic safety and essential performance - Collateral standard: Usability* www.iec.ch

[5] EIGA Doc 73 *Design considerations to mitigate the potential risks of toxicity when using non-metallic materials in high pressure oxygen breathing gas systems,* www.eiga.eu

[6] EIGA Doc 10, *Reciprocating oxygen compressors* www.eiga.eu

[7] EIGA Doc 180 *Design Considerations and Guidance for the Safe Use of Medical Gas VIPR* www.eiga.eu

[8] EIGA TB 6 *Use of Copper Beryllium Alloy for Medical VIPRs*, www.eiga.eu

[9] ISO 10524-3, *Pressure regulators for use with medical gases. Pressure regulators integrated with cylinder valves* www.iso.org

[10] ASTM G175; *Standard test method for evaluating the ignition sensitivity and fault tolerance of oxygen regulators used for medical and emergency applications* www.astm.org

[11] ISO11114-1 *Gas Cylinders – Compatibility of cylinder and valve materials with gas contents -. Part 1: Metallic Materials www.iso.org*

[12] ISO11114-2 *Gas Cylinders – Compatibility of cylinder and valve materials with gas contents -. Part 2: Non-metallic Materials www.iso.org*

[13] ISO 10297*, Transportable gas cylinders. Cylinder valves. Specification and type testing www.iso.org*

[14] EN ISO 15001 *Anaesthetic and respiratory equipment. Compatibility with oxygen www.cen.eu*

[15] Directive 2010/35/*EU of The European Parliament and of the Council of 16 June 2010 on transportable pressure equipment* www.ec.europa.eu

[16] EIGA Doc 157 *Hygienic Processes for Home Oxygen Respiratory Devices www.eiga.eu*

[17] EIGA Doc *89 Medical Oxygen Systems for Home Care Supply www.eiga.eu*

[18] ISO 80601-2 Medical Electrical Equipment – Part 2-69 Particular requirements for the basic safety and essential performance of oxygen concentrator equipment www.iso.org