MEDICAL GASES

GUIDANCE FOR SAFETY AND RELIABILITY OF OXYGEN SELF-FILL SYSTEMS

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Prepared by WG-10

Disclaimer

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1 Introduction

Approximately half of the patients suffering from respiratory diseases receive ambulatory (mobile) services.

Manufacturers started producing portable systems in keeping with the changing patient lifestyles. Growing sophistication has allowed systems to offer enhanced mobility without compromising the ease of use. Technological innovations are the key drivers for the growth of oxygen systems market.

Self-fill systems allow the patients to fill oxygen cylinders at high pressure, at home, for personal use only. At present there is not wide experience of this equipment in Europe, although their use is increasing.

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

There are concerns amongst EIGA members, that these units use oxygen at high pressure, and that some of the designs and materials do not incorporate experience that EIGA members have gathered over many years of using oxygen at high pressure.

2 Scope and purpose

2.1 Scope

The publication includes the principles of design and material selection, filling process, maintenance and life cycle of self-fill gaseous oxygen units.

2.2 Purpose

To provide guidance on these units 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 on the safe design, operation, installation, use and maintenance of the self-fill units.

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

The term 'medical oxygen' has been used to describe the oxygen gas administered to the patient, as prescribed by their doctor. It includes:

- Medical oxygen, supplied as a medicinal product under a Marketing Authorisation (MA) (issued by the national regulatory authority), 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 produced from an oxygen concentrator which has been CE marked to the Medical Device Directive (MDD) *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as modified* [1][1]. It also relates to the oxygen filled into cylinders using a CE marked oxygen concentrator.

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. This method of supply should only be used where a specific risk assessment has been conducted and there is confirmation that the patient or caregiver have been both trained and competency assessed.

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)). 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.

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.

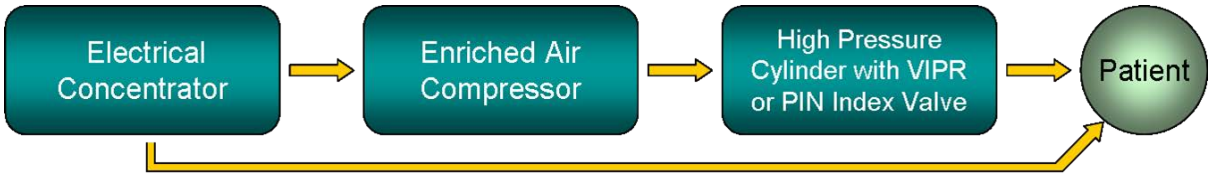

Figure 1 Schematic of patient self-fill system

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.

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

5 Design considerations and material selection

Each element of the assembly shall comply with international or harmonised standards and follow accepted design requirements for the equipment. A risk analysis of the product provides elements on how intended use and specifications shall be taken into consideration for the selection of materials. It shall also include safety rules considered for the design of the whole device and the connections between the different parts of the equipment.

The manufacturer shall present this risk analysis of the product when requested, especially when parts of the standards applicable to any of the components are not fully complied with.

5.1 Certification

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

- A declaration of conformity to the MDD [1] and the list of applicable standards used to demonstrate this conformity,
- The classification according to the MDD [1] and the information of which classification rules have been applied,
- A completed check list according Annex 1 of the MDD [1].

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 Documentation

All documents requested shall be provided by the manufacturer.

Instructions for use, technical user manual and maintenance guide shall be included.

Drawings and bills 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 EN ISO 8359 *Oxygen concentrators for medical use. Safety requirements* [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]

Materials used in the concentrator shall be considered not only for their flame resistant properties but also for the consequences of an ignition. For example emissions of a toxic gas during combustion, see EIGA Doc 73 *Design considerations to mitigate the potential risks of toxicity when using non-metallic materials in high pressure oxygen breathing gas systems* [5].

A flow indicator, indicating gas flow rate shall be provided on the oxygen concentrator. It shall be graduated in litres per minute and be accurate to ± 10 % of the indicated flow rate or ± 200 ml/min whichever is greater.

In normal use the maximum A-weighted sound pressure level (steady or peak value) of the oxygen concentrator shall not exceed 60 dB.

5.4 Compressor

The compressor shall be designed and approved in accordance to 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.

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 the compressor when the maximum pressure is exceeded, or at least a visible and audible alarm. In addition there shall be a burst disc in case that the pressure switch does not operate.

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 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 VIPR 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. As a consequence, 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 Regulators (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]).

In a pure oxygen environment, most metals will burn (with large release of energy and possibly fire propagation). Aluminium alloys and stainless steels are examples of metals that can burn at a very low oxygen pressure. Parts such as springs shall be selected to avoid the risk of combustion.

For more detail on Medical Gas VIPR Design, see EIGA Doc 180 [7]. For compatibility of metallic materials with gases see ISO11114-1 "*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, in order to ensure a safe use with oxygen. For more information see ISO11114-2 *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 oxygen wetted parts.

The flow measured at the integrated valve 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 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 carryout the following tests in order 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 EN 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].

Metallic and non-metallic 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 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 gas wetted parts.

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

6 Test and test reports

This section describes the tests homecare service providers are recommended to perform in order to accept a self-filling system for the use at the patient's home. The components and device shall be certified to meet all regulatory requirements. It is the responsibility of the body placing the self-filling 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 EN 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 conducted by a certified laboratory and results documented in the approval of the equipment.

6.1.2 Cylinder filling test

A test of the cylinder filling capability of the self-fill system shall be carried out to confirm the performance of the system. The tests shall comply with ISO 8359 [2] and include:

- When the oxygen concentrator is operated at the maximum flow rate stated by the manufacturer, the mean concentration of oxygen in the product gas over an 8 hour period shall be not more than 3 % volume fraction below the value stated by the manufacturer, and no individual reading of oxygen content shall vary by more than ± 3 % volume fraction from the mean.

- The individual reading of oxygen content shall not vary by more than ± 3 % volume fraction from the mean.

- The concentration of oxygen in the product gas, at a flow rate of 2 ltr/min, shall not be more than 3 % volume fraction below the value stated by the manufacturer.

- The change in the maximum recommended flow rate when a backpressure of 7 kPa is applied shall be within ± 10% of the value stated by the manufacturer in the technical description.

- The filling time shall be as stated 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 exceeding 50 °C if made from metal or 60 °C if made from non-metal.

- To avoid the risk from water exposure in context with electrical failures a double isolation design is required.

- The shell is sufficiently robust such that the shell is not damaged from “general wear and tear” whilst in use.

7 Equipment operation

Oxygen self-fill systems are intended for both supplying oxygen to the patient and allowing the patient or care giver to fill their own oxygen high pressure gas cylinders.

Since the filling process is a critical activity a risk assessment shall be conducted and confirmation that the patient or care giver has been assessed to carry out self-fill of cylinders.

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.

The user shall understand that the system shall be installed in a well ventilated space and away from open flames or heat sources.

7.1 Pre-filling instructions

In the instructions for use it shall be indicated the checks 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.

Failure to do this could compromise the safe use of the equipment; for this reason clear documentation should be provided that explains how it is ensured that any possibility of making a connection error between the cylinder and the equipment is avoided.

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 in order to comply with the Medical Devices Directive regarding compliance with the Transportable Pressure Equipment Directive, [15].

7.3 Over pressure

The self-fill systems use a high pressure compressor to fill the gas cylinders, in this process the test pressure of the cylinder shall not be exceeded.

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 the 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 *Hygienic processes for respiratory homecare devices*, [16]

8.1 Patient / user's maintenance responsibilities

Apart from cleaning or changing filters (compressor or concentrator), any oxygen gas supply systems and their associated regulating equipment do not require to be maintained by homecare service provider staff.

The patient or care giver shall be instructed **not** to modify the cylinder filling equipment in anyway, including replacement of seals and tightening of connections. The patient or care giver 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

8.2.1.1 Routine maintenance carried out by the patient of the oxygen concentrator

Routine maintenance is very important for ensuring reliability and in reducing extended maintenance or repairs. The oxygen patient / caregiver should, as a minimum, perform the following maintenance.

a) Oxygen humidifier (reusable bottles only)

The patient / caregiver should clean the humidifier bottle daily. The patient or caregiver should follow the instructions supplied by the manufacturer. If no cleaning instructions were supplied, these steps should be followed:

1. Wash the humidifier bottle in a solution of hot water and dishwashing detergent.

2. Soak the humidifier in a solution of one part white vinegar to three parts hot water for 30-45 minutes. This solution acts as a germicidal agent.

3. Rinse thoroughly with hot tap water and refill with distilled, demineralized, or boiled water for use. Do not overfill.

b) Cannula / mask and tubing

The patient or caregiver should clean and replace the cannula or mask and tubing as instructed by the homecare service provider.

c) Air filter and oxygen outlet connector

The air filter and oxygen outlet connector should be cleaned at least once a week by the patient / caregiver.

8.2.1.2 Periodic homecare preventative maintenance

To assure continued trouble-free performance, the following preventative maintenance should be performed by the homecare service provider during periodic oxygen patient visits (and respecting manufacturer recommendations).

1. Check the oxygen concentration with an oxygen analyzer at every patient home visit.

2. Check the audible alert and indicator lights (such as power failure, low flow) for every patient home visit.

3. Inspect intake filter every year. Replace as necessary.

4. Inspect the final bacteria filter every year. Replace as necessary or in conjunction with compressor service.

5. Inspect the compressor filter every 3 years or 5.000 hour usage. Replace as necessary or in conjunction with compressor service.The compressor could require replacement when:

   - The system pressure is not within specifications and there are no leaks detected.

   - The compressor bearings have worn to a point that make the compressor noticeably louder.

   - The oxygen purity has declined below specified levels.

The homecare service provider is responsible for determining a preventative maintenance interval frequency which takes into consideration the specific operating environment.

The homecare service provider shall use a reliable system to manage periodic maintenance dates.

8.2.2 Oxygen compressor

There are minimal serviceable parts on self-system 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

If any leakage (or abnormal behavior) of the oxygen cylinder is detected, the patient or care giver should 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.

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.

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 should 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. Never use solvents or other flammable or abrasive products to clean the equipment.

8.3.1 Oxygen compressor

The filter of the unit shall be cleaned periodically by the patient or during the preventive maintenance at patients home.

Warning: Before cleaning the oxygen compressor shall be unplugged from the wall outlet. The high pressure parts shall not be cleaned; they shall be protected by the adequate protection caps.

- **Compressor filter**:
  - Clean the filter according to manufacturer recommendations.
  - Dry the filter before reinstallation.
  - This cleaning procedure shall be performed at least once a week.

- **Cover**:
  - Clean the cover with a mild household cleaner and non-abrasive cloth or sponge.
  - The cleaning procedure for the cover shall be performed at least once a week

8.3.2 Cylinder

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.

8.3.3 Oxygen concentrator

The air inlet filter is the most important maintenance activity that the user will perform and should be carried out at least once a week.

General filter cleaning procedure:

1. Remove the filter cap (if used).
2. Remove the filter from the cover.
3. Visually inspect the filter for damage, such as holes or tears.
4. If damaged, replace with a new filter. (Contact the homecare service provider or manufacturer for a new filter if necessary).
5. Rinse and wash the filter in warm water. A mild detergent may be used if rinsed thoroughly.
6. Squeeze out the excess water and allow the filter to air dry. The filter should be completely dry before using again. Do not attempt to operate the unit without the air filter or while the filter is still damp excess moisture can impair the operation of the device.
7. Visually inspect the filter after cleaning. Ensure it is not damaged or clogged.
8. Reinsert the filter on the cover.
9. Reinstall the filter cap (if used).

Cleaning the device

Users should also clean the concentrator exterior cover by using a damp cloth or sponge with a mild household cleaner and wiping it dry. The cover should only be removed by a qualified technician

During the exterior cleaning, do not allow free water to come into contact with oxygen concentrators due to the risk of an electrical fault or short circuit.

8.3.4 Ancillary equipment

The accessories, such as cannulas, tubes, oxygen humidifiers and face masks used with oxygen therapy equipment shall comply with the essential requirements of the Medical Device Directive [1]. Only accessories designed for use with oxygen therapy systems shall be used.

Most ancillary items are designed for a single patient use and as such shall be disposed of after the patient has finished using them. It is important that only accessories supplied by homecare service provider are used by the patient.

Where the patient is cleaning their own humidifiers, cannulas or face masks, they shall:

- always follow the manufacturer's instructions when using or maintaining any ancillary equipment;
- ensure that nasal cannulas are free from grease and dirt especially inside the nasal prongs; and
- when the humidifier is refilled, ensure that it is cleaned and refilled in accordance with the manufacturer's instruction and the lid replaced so that oxygen leaks do not occur.

Where it is appropriate that the patient should change their ancillary equipment, sufficient supplies shall be provided and appropriate advice given about the periodicity of replacement.

During the patient's home visits, homecare service provider staff shall check regularly the cleanliness and condition of the ancillary equipment supplied to the patient to administer oxygen**.**

8.4 Spare parts and ancillary equipment

Only approved replacement spare parts, including filters, meeting the operating parameters of the supply equipment shall be used to maintain the device. The use of certain replacement spare parts which are not originally specified for use with the equipment, (even if it is validated by the homecare service provider), can reduce the performance of the equipment.

Spare parts shall be available as long as the products are commercially supplied and will still be provided after discontinuation.

9 Life cycle and environmental compliance

There shall be a system in place for the verification of the materials used in the construction of a self-fill system to ensure that they are as specified in the original design and approval. After the approval for use, any change to the design or materials used shall be subject to review and a management of change process.

Changes have to be managed and strictly followed on one hand in the information process between manufacturer and provider, and on the other hand in the update of documents.

The supplier shall engage to inform the homecare service provider about any modification to the design or the materials of the equipment

Periodic maintenance and security checks have to be considered for the different components of the self-fill system. The manufacturer shall provide instructions for use and references for periodic maintenance for every different component of the system.

As the cylinders for self-fill systems will generally meet the requirements of the Transportable Pressure Equipment Directive [15], this means that the maximum interval between periodic inspections for cylinders shall not exceed ten years. A shorter interval may be recommended by the manufacturers. Manufacturers should be able to provide a service for cylinders and valves to be maintained and periodically inspected and tested as required.

(Note that the homecare service provider will transport these cylinders empty as the intended use is for filling by the patients at home)

Cylinders that do not pass the periodic inspection tests shall not be reused. Cylinders shall be disposed of in accordance with local environmental regulations.

Maintenance of the oxygen self-fill system shall follow the advice given in the instructions for use and comply with the requirements specified.

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 Healthcare Service Provider immediately.

When carrying out routine maintenance on the oxygen self-fill system at a patient's home, the cylinders' statutory test 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.

The homecare service provider shall maintain the provided equipment in compliance with the manufacturer's instruction and local regulations. Guidance is given in EIGA Doc 157, *Hygienic processes for respiratory homecare devices* [16]. In order to manage the periodic maintenance for all components of the self-fill system following local regulations and the manufacturer's instructions the homecare service provider shall use a reliable system for tracking and to provide evidence.

10 References

[1] Medical Device Directive (MDD) *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices as modified* www.ec.europa.eu

[2] EN ISO 8359 *Oxygen concentrators for medical use. Safety requirements* *www.cen.eu*

[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 Technical Bulletin TB 6 *Use of copper beryllium alloy for medical devices*, www.eiga.eu

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

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

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

[13] EN ISO 10297*, Transportable gas cylinders. Cylinder valves. Specification and type testing* *www.cen.eu*

[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 respiratory homecare devices* *www.eiga.eu*