

MEDICAL OXYGEN SYSTEMS FOR HOMECARE SUPPLY

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Amendments to 89/16

Section	Change
1	Inclusion of Hygienic and infection risks into the scope and other parts of the document
6.3	Risk analysis for Home Care Personnel – incorporate elements of Doc 198 – Security of Home Care Personnel, in order to archive EIGA Doc 198
Other sections	Alignment with other documents, denomination alignments, text simplifications
Annexes	Included content of former Doc 198 into the check lists and risk analysis list
	Included comments received from MGC

1 Introduction

Medical oxygen is used to supply additional oxygen to patients with respiratory disorders to compensate for the reduced functionality of the lungs. It is the responsibility of the homecare service provider to ensure that the medical oxygen systems they supply to patients, provides a safe supply of oxygen for therapy to the patient, as prescribed by their doctor.

This publication provides advice to the Homecare Service Provider (HSP) on the installation, instructions for use and maintenance of the equipment used for oxygen therapy. It specifies the need to provide adequate training to the patient or carer to ensure safe usage of the equipment for oxygen therapy.

The publication also provides a number of practical guides for the homecare service provider supporting the management of oxygen therapy in a safe and effective manner. It also provides practical guides to handle safety issues surrounding home oxygen therapy, including risks that be present in terms of hygienic challenges in the patient's environment, or potential behavioural risks.

Oxygen therapy is always prescribed by a doctor.

The equipment used with oxygen therapy shall be CE marked, which indicates that it complies with the European regulation on medical devices.

When prescribing oxygen therapy to their patients, the doctor may consider the method of oxygen source to the patient. It is the homecare service provider's responsibility to ensure that the specific prescription conditions are followed in full, and changes to the prescription are only authorised by the patient's doctor.

2 Scope and Purpose

2.1 Scope

This publication applies to the supply of homecare oxygen therapy supplied by homecare service providers using:

- compressed oxygen gas cylinders;
- transportable liquid oxygen system (TLOS);
- (portable) oxygen concentrators, and
- oxygen cylinder filling system (self-fill system)

The advice covers both the supply to healthcare facilities and to patient's homes and applies not only to the oxygen therapy but also to the ancillary equipment.

2.2 Purpose

This publication describes the recommended precautions and safety procedures to be followed when home oxygen therapy systems are used in healthcare facilities and in the patient's home. The publication endeavours to provide the best operating practices for the supply of home oxygen therapy but does not cover all of the relevant applicable national regulations that could apply in some countries.

This publication provides guidance to the homecare service provider about the:

- Hazards associated with the supply of medical oxygen;
- Minimum operational characteristics of the home oxygen therapy equipment;
- Environment risk assessment by the HSP at the patient's home and surroundings;

- Precautions to be observed whilst using the home oxygen therapy equipment, and
- Safe use of home oxygen therapy and the associated equipment.

The publication includes in the Appendices patient user instruction cards that provide basic advice on how to safely use the different types of home oxygen therapy equipment.

The instruction cards for each modality of home oxygen therapy are in two formats:

- A patient user training card to be used as a guide by the homecare service provider when training the patient/carer on how to use the home oxygen therapy and providing information on the safe use of the product.
- A patient user instruction card to be used by the patient/carer as a quick reference guide on the safe use and operation of the equipment.

It is intended that both the card will be left with the patient/carer for future reference and shall be adapted to reflect the specific therapy equipment that is supplied.

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 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 Homecare service provider (HSP)

Organisation that provides the medical oxygen and the medical oxygen equipment for treating patients either in their home or supplied direct to the healthcare facility treating the patient.

3.2.2 Healthcare facility

Organisation providing the medical oxygen therapy to the patient on their premises, where they are responsible for the care of the patient.

3.2.3 Home Oxygen

Oxygen provided to patient from either medical liquid oxygen systems, medical gas cylinders or oxygen concentrators.

4 Description of gaseous and liquid oxygen

The basic characteristics of gaseous and liquid oxygen are:

- Oxygen is essential to sustain life and is normally supplied from the earth's atmosphere, which is made up of approximately 20.9% oxygen.
- Gaseous oxygen is a colourless, odourless, tasteless gas with a specific density of 1.1 relative to air.
- Liquid oxygen is a light blue liquid that flows like water. It has a boiling point of -183.0 °C at atmospheric pressure and has a specific density of 1.14 relative to water.
- One volume of liquid oxygen will generate 860 volumes of gaseous oxygen at atmospheric pressure and temperature.
- Oxygen, in gaseous or liquid form, is a non-flammable, non-toxic powerful oxidiser. It is considered hazardous as it intensifies combustion (see point 5).

5 General hazards and safety precautions with oxygen therapy supply systems

There are precautions that shall be observed with medical oxygen irrespective of the therapy modality. When making the installation of home oxygen therapy, advice shall be given to the patient/carer or healthcare facility to explain the general hazards of using home oxygen therapy and shall include the following information:

- Materials that burn in air will burn much more vigorously at a higher temperature in an oxygen-enriched atmosphere.
- Most serious incidents involving the use of home oxygen therapy are caused by smoking or fire (fireplace, candles,...)
- Instructions shall be given to the patient/carer/healthcare facility staff to:
 - Never smoke or be exposed to open flames whilst using home oxygen therapy;
 - Never allow any other person to smoke in the vicinity of the patient using home oxygen therapy;
 - Keep sources of ignition away from areas where home oxygen therapy is used or stored;
 - Avoid ignition sources, including lighted cigarettes, gas cookers, electrical toys and equipment or open fires when in potentially high oxygen-enriched atmospheres.
- Oils and grease burn in an oxygen-enriched environment with explosive violence. Ignitions can occur with oxygen equipment if it has been contaminated with oil or grease. This can also be caused by handling equipment with hands that have been contaminated with petroleum jelly or hand/face creams containing petroleum-based ingredients or using tools contaminated with oil or grease.

Instructions shall be given to:

- Only handle or operate home oxygen therapy equipment with clean hands and tools.

- Keep the oxygen equipment clean and free from any oils or grease.
- Where the patient requires to use a moisturiser or cream, for example to prevent their nostrils from drying out, only use approved products that are suitable for use with oxygen.
- Take into consideration that absorbent materials, such as clothing or bedding, when saturated with oxygen, will readily ignite and that these materials can remain oxygen-enriched for some time after removal from the oxygen source.

Instructions shall be given to the patient/carer/healthcare facility staff to:

- Ventilate any clothing or bedding, where it is suspected that it has become saturated with oxygen, to ensure that any oxygen enrichment is cleared. It can take at least 15 minutes to adequately ventilate clothing or 30 minutes to ventilate bedding before it is safe to approach with a source of ignition.
- Never cover any oxygen equipment with any material or store it adjacent to curtains as they could become oxygen enriched.
- Never use the ambulatory unit under clothing.
- Where an ambulatory unit is carried in a bag or holder, select a bag specifically designed for the home care oxygen therapy container, made from appropriate material, provided with adequate ventilation and designed to allow any oxygen that leaks out of the container.
- Prevent any unnecessary oxygen-enrichment of the air by turning off the oxygen system when not in use.
- Only allow trained persons to operate the home oxygen therapy equipment.
- Ensure that children and pets are not allowed to tamper with the equipment.
- Keep the total length of flexible tubing, from supply source to the connection to the nasal cannula or mask to a minimum, but in any case no more than 15 metres.
- Prevent the kinking of the tube to avoid flow's restrictions.

5.1 Hazards with compressed oxygen

There are specific hazards with the supply of medical oxygen in gas cylinders. These hazards relate to the fact that oxygen is stored at high pressure and supplied in cylinders that are relatively heavy and require to be handled correctly. The hazards relate to high pressure cylinders supplied by the homecare service provider or cylinders filled using a self-fill oxygen concentrator.

Instructions concerning the handling and use of compressed oxygen systems shall include:

- Compressed oxygen supplied in cylinders is filled to a high pressure and care is needed to ensure that cylinder valves are kept closed when not in use to prevent leakage. It is important that cylinders' storage areas are kept well ventilated to prevent any build-up of oxygen concentration if a leak occurs.
- The stored energy in an oxygen cylinder under pressure is very high and care is needed to store cylinders correctly. As the pressure in a cylinder increases as the cylinder gets hotter (with corresponding increase in stored energy) it is important that cylinders are stored away from sources of heat.
- As the compressed oxygen is at a high pressure in the cylinder, care is needed to ensure that the regulator, where required, is fitted correctly and set at zero / minimum flow before opening the cylinder valve.

- Instructions shall always be given to open the cylinder valve slowly, to prevent adiabatic compression of the oxygen, which could lead to an ignition. When opening the cylinder valve the patient/carer should be at the side of cylinder valve and not in front or at the back of the cylinder valve



- Care is needed when storing or using compressed oxygen cylinders to ensure that they are suitably restrained to prevent them from falling so as to avoid the cylinder, cylinder valve or regulator being damaged.
- Due to the potential of a high-pressure gas release and because of the relatively high risk of an ignition and contamination, transferring compressed oxygen from one cylinder to another cylinder is dangerous and forbidden.

5.2 Hazards with liquid oxygen

The specific hazards relating to treating patients with medical oxygen in liquid form relate to the extremely low temperature of the liquid and the need to ensure that appropriate precautions are taken concerning cold temperatures when handling the equipment.

Instructions concerning handling and use of liquid oxygen systems shall include (see also appendix 3):

- Care shall be taken as liquid oxygen is extremely cold and stored at approximate $-183\text{ }^{\circ}\text{C}$.
- Touching spills of liquid oxygen or cold surfaces on liquid oxygen systems, such as the valves, pipes or couplings, can cause severe cryogenic burns or frostbite. When handling liquid oxygen systems do not allow liquid oxygen or frosted pipework to contact the skin or non-protective clothing.
- Moisture can accumulate on exposed surfaces of equipment containing liquid oxygen forming ice, causing components such as valves or filling couplings to freeze open or shut. If moisture is permitted to enter liquid oxygen lines or systems, it will freeze and can prevent components such as pressure relief devices or control valves from correctly functioning which could result in a potentially unsafe condition.
- One volume of liquid oxygen at standard atmospheric pressure when vaporised will produce approximately 860 volumes of gaseous oxygen at ambient temperatures. The large volume of gaseous oxygen resulting from the vaporisation of liquid oxygen has the potential, if trapped in a closed circuit not adequately protected by pressure relief devices, to generate gas pressures high enough to cause explosive rupture of containers, transfer hoses, piping or other system components. Care shall be taken to avoid blockage of the outlets of vent lines, ports and safety relief devices, for instance by dirt or ice.
- Due to the extremely cold temperature of liquid oxygen, it will constantly absorb heat through the container walls which will result in it vaporising to produce gaseous oxygen. Any gaseous oxygen produced in excess of the patient's requirements will be automatically vented which is normal. It is important to keep liquid oxygen containers in a well-ventilated area to avoid the generation of oxygen-enriched atmospheres and to keep them away from combustible

materials and protected from exposure to heat sources, which can accelerate the venting of oxygen from the container.

- Due to the density of the low temperature gas vented from a liquid container, it is heavier than air and will accumulate in low lying areas if not adequately ventilated.

Hazard with transfilling liquid oxygen

The main risk for transfilling liquid oxygen is associated with cryogenic temperatures. Provided that the equipment is specifically designed for transfilling and designed to protect the patient or user from these cold conditions, it is safe for liquid oxygen to be transfilled.

It is important that the homecare service provider supplies the patient/carer/healthcare facility with approved filling procedures prepared by or based on the equipment manufacturer's instructions.

These instructions shall provide the patient or user with sufficient information to ensure that when transfilling liquid oxygen:

- The container being filled is suitable for filling;
- The container is filled safely;
- During transfilling liquid oxygen spillages of oxygen are avoided, and
- When transfilling liquid oxygen into the mobile unit, care is taken to ensure that all connections are dry, clean and that leaks do not occur.

5.3 Hazards with stationary oxygen concentrators

As the stationary oxygen concentrator is supplying oxygen to the patient at relatively low flowrates and at low pressure, care is still required to ensure that the general precautions associated with the use of medical oxygen are still to be followed.

There are specific precautions concerning the electrical supplies to the concentrator that shall be followed and instructions concerning the handling and use of medical oxygen concentrator systems shall include the following (see also appendix 4):

- When operating oxygen concentrators, care is needed to connect the equipment to a suitable electrical supply and to avoid any possibility of electrical shock.
- Always switch off the machine and isolate it from the mains electrical supply when maintaining the medical oxygen concentrator or refilling the humidifier.
- Never operate the concentrator in a bathroom.

5.4. Hazards with portable oxygen concentrators

Portable concentrators, on top of the above risks, have some specific hazards that need to be taken into account, namely:

- Be aware of the autonomy of batteries, and battery deterioration over time. Damaged batteries shall not be used any longer and the Home Care Service Provider needs to be contacted for replacement
- Be aware of difference between settings and liter per minute equivalence
- Portable concentrators are not designed to be used continuously

- As portable concentrators are more fragile and mobile, they are exposed to various environmental conditions (dirt, moisture,...) and require adequate care by the patient
- Refer to the manufacturer's manual for specific instructions for use.

5.5 Hazards with self-fill systems

It is important that the homecare service provider supplies the patient / carer / healthcare facility staff with approved filling procedures prepared by or based on the equipment manufacturer's instructions.

These instructions shall provide the patient or user with sufficient information to ensure that:

- The self-fill concentrator/compressor system is correctly assembled and stable;
- The self-fill concentrator/compressor system should not be installed in a kitchen or garage, where there is a higher risk of contaminating connections with oil and/or grease;
- No leaks occur during the filling process;
- The cylinder being filled is suitable for filling. Only cylinders supplied by the medical oxygen homecare service provider should be filled;
- The self-fill concentrator/compressor system and cylinder are used in accordance with the user instructions and only for the use for which it is intended;
- The use of the system is dedicated to the patient and the cylinder can not be used to supply anyone else;
- The handling and the filling of the cylinder is carried out with care to avoid the cylinder being dropped, and
- The self-fill concentrator/compressor system is not moved whilst filling the cylinder.

The recommendations in 5.1, concerning high pressure cylinders and 5.3, concerning stationary oxygen concentrators should also be followed.

5.6 Hazards linked to contaminated devices, containers and cylinders

It is important for the safety of health care facility staff, caregivers and homecare service personnel to identify and treat any potentially externally contaminated equipment with care, as described in the following documents from EIGA See references [8 and 9].

6 Installation of the oxygen therapy supply system

The homecare service provider is responsible for:

- Providing a safe and reliable source of home oxygen therapy in accordance with the prescription;
- Ensuring that equipment is correctly installed at the patient's home, or place of residence. In case of delivery to a health care facility, instruct the staff on how to correctly set-up the equipment.
- Instructing the patient, carer or health care staff on how to use the equipment correctly at the flowrate prescribed by their doctor, and

- In case oxygen is prescribed for use with another medical device, for example ventilator, sleep apnoea device, ensure these devices are suitable for use with oxygen and if this is the case then the manufacturers' instructions for use should be consulted.

The homecare service provider shall have a formal system to review the initial set up of the oxygen systems to ensure that:

- The installation has been carried out correctly, and
- The appropriate training, literature and advice have been provided and understood.

This review shall be recorded and signed.

A system of periodically auditing the quality and effectiveness of this initial set-up shall be carried out by the homecare service provider and the appropriate corrective actions put in place to address any short falls.

6.1 Initial setting up of patients at home for home care oxygen therapy

When the initial installation is made at the patient's home, it is very important that the appropriate information is given to the patient or carer to ensure that they are not put at risk by their own actions. Only fully trained and suitably assessed competent personnel shall be used for the initial training of the patient/ carer.

Irrespective of the method of supply, it is essential that the homecare service provider has carried out the following actions to ensure that:

- A user instruction manual has been provided to the patient/carer, which provides a detailed procedure on how to use the equipment both effectively and safely. Where appropriate, instructions shall also be provided in pictorial format for ease of understanding. The instructions shall cover the use of the equipment to provide the oxygen supply safely and routine responsibilities for the patient/carer to keep the equipment in an appropriate condition.
- The patient/carer has been adequately trained by the homecare service provider so he or she knows how to use their equipment effectively and safely.
- A formal assessment program has been followed to ensure that the patient/carer understands the principle actions they shall take both in the safe operation of the equipment and in the event of an emergency.
- The patient/carer has been requested to sign an acknowledgement sheet to indicate that they have understood their training and the safety requirements for the use of their oxygen equipment, recognise the importance of not smoking or letting anyone else smoke in the vicinity whilst the oxygen equipment is being used and know what to do in the event of an emergency.
- Advice has been given on the best location for the storage and use of the home care oxygen therapy to minimise any risks.
- The total length of flexible tubing, from supply source to the connection to the nasal cannula or mask shall be kept to a minimum, but in any case no more than 15 metres. Care is needed to prevent the kinking of the tube to prevent restrictions in the flow.
- Consideration shall be given to possible country requirements for providing the patient/carer with a draft letter which they could send to their own insurance company informing them of the presence of home care oxygen therapy in their home and their car. Where appropriate, this draft letter may also be sent to the local fire brigade to inform them of the presence of oxygen in the home.

- A contact number has been given that the patient/carer can use at any time (365 days per annum / 24 hours per day). The patient/carer shall be instructed to use this number only to contact the homecare service provider in case of problems with the equipment.
- A list has been given to the patient/carer of all the equipment provided at the initial supply and any ancillary therapy equipment that may need replacing. The user instruction manual shall also cover the use of this ancillary therapy equipment.

6.2 Initial setting up of healthcare facilities providing medical oxygen therapy

When the initial installation is made at the healthcare facility, it is very important that for the initial installation (as described under 6.1.), adequate information and training is given to the relevant healthcare facility staff to ensure safe supply to all of their patients.

It is the responsibility of the healthcare facility to ensure that they have sufficient trained and competency assessed personnel to ensure that the provided operating procedures are followed and to ensure that they continue to keep sufficient adequately trained staff to operate the equipment. It may be appropriate for the homecare service provider to assist the healthcare facility in the preparation of suitable protocols to ensure that the oxygen is delivered correctly and that their patients are not put at risk.

Irrespective of the method of supply of home care oxygen therapy to the healthcare facility, it is essential that the homecare service provider, on top of the elements under 6.1. has carried out the following actions:

- Adequate training, as well as suitable training material, has been provided by an approved trainer to a suitable number of healthcare facility representatives. The training shall be followed by an assessment to ensure that the healthcare facility staff have an understanding of both the safe use of the equipment and the actions to be taken in the event of an emergency.
- The healthcare facility representative has been requested to sign an acknowledgement sheet to indicate that they have understood their training and safety requirements and know what to do in the event of an emergency.
- Specific instructions are given on the possible best locations in the health care facility for storage and use to minimise any risks.

6.3 Homecare environment risk assessment

Risk analysis shall take in consideration also the environment surrounding the delivery and installation address, like vicinity, neighbourhood, isolated location, or potentially unsafe areas, and so it is not limited to the patients' residence alone.

In order to ensure that equipment is installed in a safe manner at the patient's home, the homecare service provider shall carry out a risk assessment at the patient's home, and the provider should acknowledge this risk assessment. In case of apparent risks, the technician starts the process of dealing with the risks found. Appendix 10 shows an example of a typical risk assessment checklist, with some of the most common potential risks.

The checklist can be used by the homecare service provider technician to assist in determining whether there are any significant risks. It also allows the technician and his supervisor to document the appropriate actions taken to address any of these identified risks.

Homecare environments can be emotionally charged and potentially unstable places which can present a unique set of security challenges. In unsafe locations, field homecare personnel can be at risk (injury, assault, hygiene situation...). Potential violence to field homecare personnel can result from patients and occasionally from hostile family members and/or others present in the home who feel stressed, disturbed, frustrated, vulnerable, or out of control.

The content of the onsite risk assessment should be reviewed at regular intervals to ensure that it remains actual, and any new information is adequately incorporated in day to day operations.

This can be done for example by the regular five-step approach (incorporating elements of risk management) such as the one presented below (example see appendix X).

Step 1: Identifying hazards and those at risk: Looking for those things at work that have the potential to cause harm, and identifying workers who could be exposed to the hazards.

Step 2: Evaluating and prioritising risks: Estimating the existing risks (the severity and probability of possible harm) and prioritising them in order of importance.

Step 3: Deciding on preventive actions: Identifying the appropriate measures to eliminate or control the risks.

Step 4: Taking action and putting in place the preventive and protective measures through a prioritisation plan.

Step 5: Monitoring and reviewing.

Suspicious incidents and/or behaviours, people, safety and or security concerns should be immediately reported to the management for inclusion in the review process of the risk assessment;

There are a number of factors which have to be taken into account in determining risk, including:

- known past safety and security incidents at the patients home, or at nearby locations or locations identified as unsafe by the authorities;
- Possible threat or hazards from interaction with people that live there and/or patients.

The employer must ensure that proper health and safety information, instruction, and training for work activities are provided to the employees.

Appendix 9 shows a completed Failure Mode and Effects Analysis (FMEA) study, which was used to develop a typical risk assessment checklist. It covers all aspects of the homecare installation which could have an impact on the safe and correct handling and use of the equipment in the patient's home. Such FMEA study identifies the specific risks associated with each of the modes of supply.

Such FMEA study may be used as training material to assist the technician in understanding how to determine where potential risks can occur with the installation of oxygen therapy systems in the patient's home.

7 Home oxygen incidents

Following installation of the home oxygen supply system it is important that the patient/carer or healthcare facility representative is informed of the actions that should be taken in the event of an incident with their oxygen supply. The type of incident can include the loss of supply, malfunction of the oxygen supply system, adverse reaction by the patient to the oxygen or the involvement of the equipment in a fire whether caused by the equipment or not.

Provided that the equipment is installed correctly and the user is adequately trained and warned about the potential hazards of using home oxygen, the likelihood of an incident is considered remote. Where incidents do occur, they are often caused by external events that impact on the medical oxygen supply system. The patient/carer/healthcare facility staff shall be instructed to contact their homecare service provider immediately if they have any doubt about the safety of any situation.

Most serious incidents involving the use of home oxygen are caused by the patient smoking.

Where the home oxygen supply system is involved in a fire, the patient/carer/healthcare facility shall be instructed to:

- contact the fire brigade, ensuring they are informed that oxygen is in use.
- If there is any doubt about the safety of the situation, not to touch the equipment and to leave the property immediately
- Isolate the oxygen supply system only when it is safe to do so, before following any other instructions.

Where there is a major leak of oxygen either from a home oxygen cylinder caused by the cylinder falling over and the attached pressure regulator sheering off or a large leak developing between the cylinder valve and the regulator or where a liquid oxygen containers develops a major gas or liquid leak the patient /carer /healthcare facility shall be instructed to:

- Close the cylinder or liquid container valve only if it is safe to do so;
- Ensure that external windows and doors are opened to ventilate the area, and
- Inform the homecare service provider immediately to obtain advice.

In the event of a cylinder or liquid container falling over, where there is no other apparent damage, the homecare service provider should still be notified immediately to obtain advice as to the appropriate actions to be taken.

If there is any evidence of a home oxygen concentrators running hotter than usual, the patient/carer/healthcare facility shall be advised to isolate the equipment from the mains supply and inform the homecare service provider immediately. Where applicable, the patient should be instructed to use their back-up cylinder supply.

In all cases the patient/carer/healthcare facility shall be advised to contact the homecare service provider whenever they are concerned that any unusual event may have occurred that they believe could lead to a failure of the home oxygen supply.

8 Maintenance of medical oxygen therapy equipment

8.1 General maintenance requirements

Prior to installing any equipment in the patients' home or healthcare facility, it is the responsibility of the homecare service provider to ensure that the equipment is functioning correctly and that there is no chance of contamination between patients:

- Components that can influence the cleanliness of the supply of the medical oxygen, such as bacterial filters, nasal cannula, and distribution tubing, shall be renewed before the equipment is installed at a new patient location, according to the manufacturers' instructions.
- Should any part of the home oxygen system fail to operate correctly it is important that the patient/carer/healthcare facility contacts the homecare service provider immediately so that an authorised, competent person can diagnose the fault and implement the appropriate corrective action.
- Under no circumstances shall any piece of equipment be disassembled by the patient/carer or healthcare facility staff other than the specified routine maintenance or the changing of consumable items from the breathing circuit detailed in the user manual.
- Repairs shall only be carried out by authorised and competent persons or organisations.

- The patient/carer/healthcare facility shall be informed that they are responsible for the routine hygiene maintenance of the equipment, including the humidifier, nasal cannulas, face masks, dust filters and the external surfaces of the devices. These responsibilities shall be defined in the user manual.
- Advice should be given to the patient/carer/healthcare facility about suitable non-abrasive cleaning agent or disinfectant that may be used for cleaning any home oxygen equipment.

When carrying out routine inspection and cleaning at the patient's or healthcare facilities premises, procedures based on the manufacturer's instructions shall be followed and include:

- Only use a dampened cloth using an approved, non-abrasive cleaning agent or disinfectant to wipe down the equipment, cylinder or container before use.
- When cleaning equipment with cleaning agents or disinfectants, ensure that no residues are left after cleaning that could come in contact with the oxygen.
- Do not allow free water to come into contact with any of the controls or fill connectors on a liquid oxygen container as this will lead to the malfunction of the equipment caused by ice freezing on the components.
- Do not allow free water to come into contact with oxygen concentrators/self-fill systems due to the risk of an electrical fault or short circuit.
- Never lubricate any part of any equipment with oil or grease.
- Always switch off the concentrator/self-fill systems and remove the power lead when the external surfaces are being wiped down or when changing the filter.

If any of the equipment fails to operate correctly or the controls become stiff to operate, the patient/carer/healthcare facility shall be instructed to contact their homecare service provider immediately.

8.2 Ancillary therapy equipment

- The accessories, such as humidifiers, cannulas, tubes and face masks used with home oxygen therapy equipment must comply with the essential requirements of the medical device regulation [1].
- If the patient has any specific requirements with respect to material allergies or irritations, the homecare service provider shall either provide a fitting alternative or be instructed of the specific needs by the patient's doctor.
- Only connectors, tubes, nasal cannulas, probes or masks designed for use with home oxygen therapy systems shall be used.
- It is important that only accessories supplied by the homecare service provider are used by the patient.
- Most ancillary items are designed for a single patient use and as such shall be disposed by the patient in accordance with national or local regulations.

Where the patient/carer/healthcare facility staff are cleaning humidifiers and face masks, they shall:

- Always follow the manufacturer's instructions when using or maintaining any ancillary equipment;
- Make sure 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 as per 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 when to change the equipment. They shall be advised to isolate the oxygen supply when any ancillary equipment is being changed.

The homecare service provider shall check regularly the cleanliness and condition of the ancillary equipment supplied to the patient to administer the home oxygen.

8.3 Therapy equipment spare parts

Only approved replacement spare parts, including filters, meeting the operating parameters of the supply equipment shall be used to maintain the medical oxygen therapy device.

Where the homecare service provider decides to use a replacement spare part not specified as original equipment of the medical device, it is their responsibility to obtain validation that the part is suitable for use for the specific model.

8.3.1 Therapy equipment replacement batteries

It is recommended that replacement batteries are sourced from the original equipment supplier. This is because of concerns that non original equipment replacement batteries do not fully meet the specification of the original batteries and could malfunction. Exception here is to be made for devices where the manual of the manufacturers allows use of generic batteries (eg. LOX).

8.4 Patient/carer/healthcare facility maintenance responsibilities

Apart from changing filters or ancillary equipment, home oxygen gas supply systems and their associated regulating equipment do not require to be maintained by the patient/carer/ healthcare facility staff.

Only authorised and competent persons shall carry out any maintenance on any of the equipment in accordance with the manufacturer's instructions. This includes the changing of 'O' rings and sealing washers on regulators and flowmeters.

The patient/carer/healthcare facility staff are responsible for keeping the cylinder, container, or concentrator externally clean, which may be carried out by wiping the surface with a clean cloth.

When cleaning the equipment always ensure that the home oxygen supply is turned off and for concentrators or self-fill system, always disconnect the unit from the mains before cleaning. Never use solvents or other flammable or abrasive products to clean the equipment.

9 Oxygen cylinder therapy supply

Medical oxygen cylinders can either be fitted with a standard cylinder valve that requires the use of an additional regulator to reduce the pressure to a useable level, or with an integrated cylinder valve (VIPR) [5,6] that has the pressure regulator built into it. Where patients require mobility, ambulatory medical oxygen cylinders can be prescribed.

It is the responsibility of the homecare service provider to ensure that the equipment supplied is suitable to provide the home oxygen to the patient at the prescribed flowrate.

When installing an oxygen cylinder system at a new patient, the entire home oxygen circuit, including the oxygen therapy nasal cannulas or masks and distribution tubing, shall be new.

The humidifier shall either be changed or, where it is reusable, disinfected.

9.1 Storage of medical oxygen cylinders

When planning the storage arrangements for medical oxygen cylinders, whether used in healthcare facilities or by domiciliary patients at home, an assessment of the storage arrangements shall initially be carried out. This shall ensure that the patient or healthcare worker is not subjected to undue risk in the event of any cylinder storage incident. For domiciliary patients, the person supplying the cylinders shall carry out this assessment.

To enable the homecare service provider to determine the optimum cylinder stock, it is necessary to know the patient's prescribed flowrate, duration of use per day and the planned delivery frequency. To ensure that excessive numbers of cylinders are not held, stocks of medical oxygen cylinders shall be maintained at an optimum level, commensurate with the patient's requirements. It is important to maintain stocks at an appropriate level as excessive cylinder stocks can increase the potential of any incident that could occur on site.

Where cylinders are stored in the patient's home it may not be practicable to follow all of the guidelines given for cylinder stores in hospitals and clinics where purpose built facilities are recommended. The general principles for safe cylinder storage shall be applied to the storage facilities in the patient's home.

9.1.1 Storage of medical oxygen cylinders at the healthcare facility

Advice shall be given to ensure that purpose built medical gas cylinder storages in healthcare facilities are built according to local regulations, and as a minimum are:

- Under cover, preferably inside and not subjected to extremes of heat.
- Kept dry, clean and well ventilated, with ventilation grilles preferably at both high and low level.
- Large enough to allow for segregation of full and empty cylinders and permit separation of the different gases within the storage, with the different storage areas being well signed.
- Laid out to enable strict stock rotation of full cylinders to enable cylinders with the earliest expiry date to be used first.
- Totally separate from any non-medical gas storage areas.
- Sited to have good access for the delivery vehicle to enable cylinders to be off loaded safely onto a reasonably level floor.
- Located away from any sources of heat or ignition and storage tanks containing highly flammable materials and other combustible materials.
- Provided with suitable pens for the storage of large cylinders in the upright position and racking for the storage of small cylinders.
- Designed to prevent unauthorised personnel entry to protect cylinders from theft. and
- Provided with warning notices prohibiting smoking and naked lights within the vicinity of the store.

Where cylinders are stored in remote 'in use' cylinder storage areas nearer the point of use (adjacent to patient ward areas) the same cylinder storage conditions shall be observed. Advice shall be given to keep stocks in the 'in use' stores to a minimum to reduce the potential risk to patients and staff should there be an incident. When medical oxygen cylinders are stored together with liquid oxygen vessels, the cylinders shall be located or protected so that any spillage of liquid oxygen will not affect the integrity of the medical oxygen cylinders.

9.1.2 Storage of oxygen cylinders at the patient's home

For the storage of cylinders, the patient/carer shall be advised to:

- Keep number of cylinders to a minimum in the patient's home, ensuring that sufficient product is available depending on patient use and delivery frequency.
- Store in a secure location, where they will not be tampered with by unauthorised persons and not subject to theft
- Store cylinders in well ventilated areas and not stored in a confined space or cupboards.
- Store cylinders at a distance of minimum 1,5 m from heating source and at least 3 meters from open flames
- Store cylinders so they are not subject to extreme temperatures
- Not store cylinders in kitchens or garage areas, where there is a possibility of being contaminated with oils or greases.
- Take care that they do not block the exit.
- Secure cylinders to prevent them falling over.
- Store ambulatory cylinders on their side or in specifically designed racks. and
- Store full and empty cylinders in separate locations to ensure no confusion.

9.2 Handling of oxygen cylinders

When handling and moving oxygen cylinders, the patient/carer/healthcare facility shall be advised to:

- Preferably handle larger cylinders wearing safety shoes and gloves. Where larger cylinders are supplied for patient use at home the patient/carer shall also be advised not to move the cylinders.
- Use appropriately designed trolleys for the cylinder size, where cylinders are required to be moved in healthcare facilities.
- Use the approved carrying bag or trolley supplied for use with the appropriate cylinder where ambulatory cylinders are required to be carried.
- Ensure that hands are clean and hand creams are not used when handling cylinders.
- Never knock cylinders violently, drop or allow to them to fall over and to handle them with care.
- Never roll cylinders along the ground as this could cause the valve to be knocked open accidentally.
- Never handle cylinders with handwheel valves by the valve as they could be opened accidentally. Where fitted, these cylinders should be carried by the valve guard or cylinder body.
- Never apply any unauthorised labels or markings to cylinders.

9.3 Use of medical oxygen cylinders

9.3.1 Selecting cylinders for use

When selecting oxygen cylinders from the cylinder storage area for use, always:

- Select the cylinder with the earliest expiry date provided that it is within its expiry period shown on the batch label.
- Ensure that the cylinder is located in a safe position, where it is unlikely to be knocked over and where it does not obstruct passages and walkways. It is good practice to use the cylinder in a specifically designed rack, trolley or carrying bag to prevent it from being knocked over.
- Remove the tamper evident seal from the valve outlet and remove any valve caps fitted. If the cylinder is not fitted with a tamper evident seal and has not been used previously, advice shall be given to not use it and to return it to the homecare service provider.
- Check the valve outlet for any signs of oil or grease. If the valve is suspected of being contaminated, advice shall be given to not use the cylinder and to inform the homecare service provider immediately.

9.3.2 Connecting pressure regulators

For cylinders not fitted with cylinder valves with integral pressure regulators (VIPR), the patient/carer/healthcare facility shall be advised to:

- Check that the correct pressure regulator and downstream equipment is selected for use;
- Check that the connecting faces of the pressure regulator and cylinder valve and any 'O' ring or sealing washer are present, well housed, clean and in good condition. If the seal is damaged, the patient/carer/healthcare facility staff shall be advised to not use the equipment;
- Ensure only authorized persons shall be permitted to replace the seal;
- Ensure that the pressure regulator is attached to the cylinder valve using only moderate force; and
- Not to open the valve until the pressure regulator and downstream equipment has been fitted.

Cylinders with valves with integral pressure regulators (VIPR) do not require an additional regulator to be fitted prior to use.

9.3.3 Setting up medical oxygen cylinders

For all types of cylinders, to set up the medical oxygen delivery equipment the patient/user/healthcare facility shall be advised to:

- Ensure that no one is smoking in the vicinity where the oxygen therapy is being used.
- Set the regulator flow setting to zero or minimum flow.
- Stand at the side of the cylinder and not in front or at the back of the cylinder valve and open the cylinder valve slowly.
- Where the cylinder is not fitted with a handwheel (e.g. pin-index), only use an approved cylinder valve key.

- Slowly open the valve fully and then turn back a quarter turn to distinguish between an open and closed valve.
- When key operated valves are used, leave the cylinder key in the cylinder valve so that the valve can be closed in an emergency.
- Check the contents gauge on the valve / regulator to ensure that there is sufficient oxygen in the cylinder to provide oxygen for the appropriate time.
- Check that the oxygen flows out of the nasal cannulas or the oxygen tubing when it is disconnected from the mask or conserving device by placing the outlet(s) just under the surface of water in a glass. Flow will be indicated by bubbles. Where oxygen conserving devices are used, this test is not effective in determining whether the device is providing oxygen to the patient.
- Check for leaks between the cylinder valve and the attached equipment. Leaks can be detected by a hissing noise and if a leak is detected, to follow the procedures set out in 9.4,
- Ensure that the oxygen tubing is attached correctly to the nasal cannula, mask or humidifier.
- Set the flowrate on the equipment to the prescribed flowrate defined by the doctor.

A video tutorial on use of VIPR valves can be found under reference



[7].

9.3.4 After use

The patient/carer/healthcare facility staff shall be advised to ensure the availability of a backup cylinder when the cylinder in use is close to empty, as indicated on the cylinder contents gauge.

After using the medical oxygen, it is important to advise the patient/carer/healthcare facility staff to:

- Close the cylinder valve slowly, using reasonable force only.
- Release the pressure in the attached equipment by selecting a flow and allowing the gas in the equipment to vent to atmosphere.
- Set the flow to zero on the attached equipment.
- If the cylinder is empty, remove the attached equipment and either refit to a new cylinder or store the equipment in a clean location.
- When the cylinder is empty, keep the cylinder valve closed when it is returned to the homecare service provider.

9.4 Checking for leaks when using medical oxygen cylinders

When medical oxygen equipment is in use, leaks may occur between the cylinder valve and the pressure regulator. This is normally indicated by a hissing sound. Having connected the equipment to the cylinder it is good practice to check for leaks before the cylinder is used when the valve is first opened.

When a leak has been identified, the patient/carer/healthcare facility staff shall be advised to:

- Close the cylinder valve and verify the leak by observing the gauge on the attached pressure regulator. A leak will be indicated by a fall in the gauge reading.
- For cylinders not fitted with integral valves (VIPR), do not remove the pressure regulator while the equipment is still under pressure. Release the pressure from the connected equipment by opening the equipment supply valve to vent any trapped gas to atmosphere.
- Remove the pressure regulator and visually inspect for damages. If there are damages, do not use the pressure regulator and call the provider.
- If visual inspection does not show any damages, the pressure regulator may be reconnected to the equipment using only moderate force and a recheck for leaks may be done.
- Never use sealing tape or jointing compounds to cure any leaks. Never touch or modify any sealant on the pressure regulator.
- If the leak cannot be rectified, attach a warning label to the cylinder indicating the fault found and notify the homecare service provider, keeping the cylinder segregated from other cylinders on site.
- Where the equipment, e.g. regulator shows signs of damage, ensure that the equipment is returned to the homecare service provider.

9.5 Use of medical oxygen cylinders in vehicles

The transport of oxygen cylinders by the homecare service provider is covered by the European Agreement on the Carriage of Dangerous Goods Regulations (ADR) [2]. These regulations do not affect the transport of oxygen cylinders by the patient in a private vehicle.

Where a medical oxygen cylinder is used in a motor vehicle, the patient/carer shall be advised to:

- Prohibit smoking by anyone in the vehicle.
- Only carry the minimum number of cylinders to provide sufficient medical oxygen for the patient during the journey.
- Adequately restrain all cylinders carried in the vehicle to ensure that they cannot move so that in the event of an accident or harsh braking, they are kept safe.
- Preferably not keep any cylinders in the passenger compartment of the car when they are not in use.
- Keep the cylinder valve shut and the valve protection in place (where fitted) when the oxygen cylinder is not in use.
- Avoid using the cylinder whilst the vehicle is being re-fuelled.
- Keep the vehicle ventilated when the cylinder is in use, preferably by opening at least one window to prevent oxygen enrichment of the air within the vehicle.
- Preferably set the ventilation system in the vehicle to draw fresh air into the car and not to recycle the air.
- Fit the patient's vehicle with an anti-static strip to reduce possible build-up of static electricity.
- Never leave cylinders unattended in a vehicle.

Where oxygen cylinders are required to be used on public transport, such as buses, trains, ships and planes, it is the patient's responsibility to obtain permission from the transport provider.

10 Medical liquid oxygen containers therapy supply

Medical liquid oxygen systems are suitable for patients who require a high oxygen flow or mobility with oxygen. As one volume of liquid oxygen converts into 860 volumes of gas, the portable liquid oxygen container can be very small, making it particularly suitable for ambulatory use.

The liquid oxygen supply systems used for breathing therapy consist of a base reservoir, that holds the principal supply of medical liquid oxygen, and a smaller portable unit that can be filled with medical liquid oxygen from the base unit for ambulatory use. Both units are vacuum insulated cryogenic containers which maintain the medical liquid oxygen at cryogenic temperatures and have an internal vaporiser and flowrate device to provide gas oxygen to the patient at the appropriate flowrate and temperature.

It is the responsibility of the homecare service provider to ensure that the equipment supplied is suitable to provide the medical oxygen to the patient at the prescribed flowrate.

The patient/carer/healthcare facility are permitted to refill the portable unit from the base reservoir if they are adequately trained and have been provided with the appropriate written transfilling instructions.

As the portable unit only contains a relatively small volume, the heat inleak into the container can lead to the product evaporating prior to it being required for use. The patient/carer/healthcare facility shall be instructed to fill the portable unit only just before it is needed, to avoid any unnecessary evaporation losses.

The portable unit is used for mobility or when it is impractical to use the base unit.

There is always a small heat inleak into the container, causing the liquid to vaporise and increasing the pressure. When the oxygen is not used, it is normal for the pressure in the container to rise to the primary relief valve pressure setting, at which point the excess gas will vent to atmosphere, making a slight venting noise.

10.1 Installation and storage of medical liquid oxygen containers

When planning the installation and storage arrangements for liquid oxygen containers, whether used in healthcare facilities or by domiciliary patients at home, an assessment of the property shall be carried out. This should ensure that the patient/carer/healthcare facility staff are not subjected to undue risk in the event of any incident with a liquid oxygen container that is in use or being stored. For domiciliary patients, the homecare service provider could carry out this assessment.

Only new oxygen therapy nasal cannulas and distribution tubing shall be used when installing a liquid oxygen supply system to a new patient. The humidifier shall either be changed or, where it is reusable, disinfected before it is supplied.

Excessive stocks of full liquid oxygen containers increase the risk of any incident that may occur on site. The homecare service provider is responsible for setting the minimum stock levels based on the patient's or healthcare facility's consumption and the expected delivery frequency.

The patient/carer/healthcare facility staff shall be advised to store the liquid oxygen containers indoors.

When storing liquid oxygen containers at the patient's home, the patient/carer/healthcare facility staff shall be advised to avoid placing reservoirs:

- In corridors and hallways or near doorways.
- Where they could impede patient's / carer's movements, and

- Where they may be bumped into or tipped over.

It is important to remove sources of ignition from the immediate vicinity of liquid oxygen containers because the atmosphere may become oxygen enriched by venting of the containers.

The patient/carer/healthcare facility staff shall be advised to keep all liquid oxygen containers at least 1.5 metres¹ away from:

- Electrical appliances such as televisions, air conditioning fans or hair dryers, and
- Heating sources or stoves (where there are no open flames).

They shall also be advised to keep liquid oxygen containers at least 3 metres² away from:

- Open fires and any naked flames, and
- Heating sources or stoves with open flames.

The patient/carer/healthcare facility staff shall also be advised to:

- Keep all liquid oxygen containers in well-ventilated areas at all times, as these units will periodically release small amounts of oxygen gas.
- Never drape clothing or any other material over the liquid oxygen container (including the portable unit), as it may become oxygen enriched and burn vigorously if ignited.

10.2 Handling of medical liquid oxygen containers

Liquid oxygen, when handled correctly, is a safe and effective method of supplying both domiciliary and healthcare facility patients with a reliable source of medical oxygen for breathing purposes.

It is important that all personnel who are required to operate liquid oxygen systems are adequately trained in the use and handling of the equipment.

Advice shall be given to the patient/carer/healthcare facility staff to make them aware of the:

- Potential hazards of using liquid oxygen and the care needed to not touch any cold or frosted surfaces;
- Operating characteristics of the equipment;
- provide contact details for emergencies, and
- Precautions to be taken when using the equipment.

10.2.1 Domiciliary use

It is the responsibility of the homecare service provider to ensure that adequate training is provided to the domiciliary patient/carer responsible for using the equipment.

1 This distance is based on the advice stated in Compressed Gas Association Pamphlet P-2.7 *Guide for the Safe Storage, Handling, and Use of Small Portable Liquid Oxygen Systems in Health Care Facilities* [3]

2 This distance is based on the advice stated in European Standard EN 1251-3, *Cryogenic vessels. Transportable vacuum insulated vessels of not more than 1000 litres volume. Operational requirements* [4]

Documents and information (user manual, product data safety information, etc.), including instructions on filling of the portable unit shall be provided through any appropriate communication channel to the patient/carer by the homecare service provider. The procedures shall include any other safety information required to be followed when using the equipment. The homecare service provider shall ensure that the patient/carer has read and understood the approved written procedures for using their equipment and filling the portable unit before the liquid oxygen system is used.

Where required to be mobile, a roller base designed for the liquid oxygen base unit shall be used. The patient/carer shall be advised of the locations in the property where the base unit can be used safely.

The patient/carer shall also be advised to only carry the portable unit using the built-in carrying handle or in an approved carrying bag or trolley.

10.2.2 Healthcare facility use

It is the responsibility of the healthcare facility to ensure that:

- All relevant personnel (employees and patients/carers) have received training in the operation and handling of the liquid oxygen equipment before use, and
- All personnel have received instructions about the potential hazards and recommended safety precautions for handling liquid oxygen equipment.

10.3. Operations and use of medical liquid oxygen containers

For detailed operations and instructions for use, we refer to DOC 98 Safe Supply of Transportable Medical Liquid Oxygen Systems. When handling liquid oxygen containers, the user shall ensure that:

- Medical liquid oxygen containers are always handled with care and never allowed to be knocked violently, dropped or pushed over.
- Unauthorised labels or any markings are never applied to the liquid oxygen containers.
- Any frosted parts on the liquid oxygen equipment are never touched as contact with parts of the system in contact with liquid oxygen can cause cryogenic burns or frostbite in severe cases.
- The oxygen tubing is attached correctly from the nasal cannula or humidifier in order to avoid leaks.
- A check is carried out to ensure that oxygen is flowing out of the nasal cannulas or tubing when it is disconnected from the mask or conserving device by placing the outlet(s) just under the surface of water in a glass. Flow will be indicated by bubbles. Where oxygen conserving devices are used, this test is not effective in determining whether the device is providing oxygen to the patient.
- The manufacturer's filling instructions are always followed when the portable unit is filled from the base unit.
- A safe location (well ventilated and properly aired room) is always selected for transfilling of the medical liquid oxygen. Care has to be taken where transfilling is carried out on an adsorbent or non-appropriate surface, such as a carpet, to ensure that the area remains well ventilated and to prevent the surface from becoming enriched with oxygen.
- The filling connectors on both containers are kept clean and dry in order to avoid malfunction due to freezing.
- Excessive force is not used to separate the units if the portable unit will not separate easily from the base unit after filling, as the units may be frozen together. The units shall be left for a short

period with the vent valve closed to allow the connection to warm, which will generally allow them to separate easily.

- If a minor liquid oxygen leak occurs after the portable unit is disengaged from the base unit, the portable unit is refitted to the base. This procedure will help to dislodge any ice or other obstruction in the filling valve. When the portable unit is disconnected the leak should be solved.
- If a major liquid oxygen leak or spill occur on either unit, the immediate area around the container is evacuated and the area ventilated by opening doors and windows. Instructions shall be given to inform the homecare service provider immediately to obtain advice as to the appropriate actions to be taken.
- Gloves and tools are clean and free from oil or grease before they come in contact with any part of the liquid oxygen equipment and hands must be clean before handling any medical equipment, especially when hand creams are used.
- No one is smoking in the vicinity where the oxygen therapy is being used.
- Highly flammable materials are kept away from liquid oxygen equipment.
- The base unit and portable unit are kept upright to prevent the spillage of liquid oxygen, unless the unit is designed to be used in other orientations.
- The flow control valve is closed after use and when the unit is empty.
- The unit is not left unattended whilst the transfilling process is operation.
- The portable unit is not kept connected to the transfer connector on the base unit whilst using the reservoir for therapy, unless the portable unit is being filled.
- A copy of the manufacturer's user's manual for the specific liquid oxygen container is available for reference by the patient/carer/healthcare facility staff when the unit is being used.
- The labels and pictograms applied to the liquid oxygen container by the manufacturer are explained to the patient/carer/healthcare facility staff during training.

Where the patient requires a flowrate that exceeds the output from a single base unit, the homecare service provider is responsible to provide the equipment to connect multiple units together to supply the patient and to ensure that the patient receives the prescribed flowrate. Additional care is needed when operating multiple units to provide higher flowrates to prevent the back feeding of water from the humidifier from one unit to the other.

10.4 Use of medical liquid oxygen containers in private vehicles

The transport of liquid oxygen containers by the homecare service provider is covered by the transport regulations, such as for road, the European Agreement on the Carriage of Dangerous Goods, (ADR regulations). These regulations do not affect the transport of liquid oxygen containers by the patient/carer in their own vehicle. However, national legislation could affect the carriage of liquid oxygen in privately owned vehicles.

There are potential risks involved with the transport and use of liquid oxygen containers in motor vehicles. Where a medical liquid oxygen container is used in a motor vehicle, the patient/carer/healthcare facility staff shall be advised to:

- Prohibit smoking by anyone in the vehicle.
- Both the patient and the driver are adequately trained in the correct method of operation of the liquid oxygen container whilst in use in the vehicle and the appropriate precautions to be taken

in the event of an incident. It is important to highlight the risks associated with oxygen enrichment within the vehicle.

- Only carry sufficient medical liquid oxygen for the patient to complete the journey. Under normal circumstances, only the portable tank should be carried in the vehicle.
- Keep the base unit and portable unit upright and adequately restrained to ensure that it cannot move should the vehicle be involved in an accident or under harsh braking, they are kept safe.
- Preferably not keep any liquid oxygen containers in the passenger compartment of the car when they are not in use.
- Keep the outlet valve shut when the liquid oxygen container is not in use.
- Avoid using the medical liquid oxygen container whilst the vehicle is being re-fuelled.
- Keep the vehicle ventilated when the cylinder is in use, preferably by opening at least one window to prevent oxygen enrichment of the air within the vehicle.
- Set the ventilation system in the vehicle to draw fresh air into the car and not to recycle the air.
- The patient is advised to fit an anti-static strip to their vehicle to reduce possible build-up of static electricity.
- Never leave medical liquid oxygen containers unattended in a vehicle.

It is the responsibility of the patient to determine whether the transport provider will permit the carriage and use of liquid oxygen containers on public transport such as buses, trains, ships and planes.

11 Oxygen concentrators therapy supply

Oxygen concentrators produce a continuous flow of oxygen enriched air for patient use by separating the oxygen and nitrogen in atmospheric air by passing it through a molecular sieve. This method of supply produces oxygen at approximately 93%, which is of an adequate quality for patients who require additional oxygen to treat respiratory disease. It is either administered by a nasal cannula or mask.

The performance of the concentrator is quoted at 21 °C and 1013 mbar and can change with temperature and altitude. It is important to maintain the environmental limit conditions detailed in the user's manual during transport, storage and use of the concentrator to avoid any reduction in oxygen concentrator's performance.

For battery powered concentrators, patient/carer/healthcare facility staff need to plan for the journey for the length of the charge of the battery. Patient/carer/healthcare facility staff need to be aware that the duration of the battery duration is dependent on environmental and technical factors such as temperature (for example battery life is shortened in cold weather) and life cycle of the battery.

The method of supplying oxygen for patient therapy with an oxygen concentrator varies from the other methods of supply in that there is no storage of oxygen on site. The delivery mode can operate in a continuous flow or pulse flow (or both) depending on the device model or manufacturer. As concentrator needs a power supply, an alternative oxygen solution should be delivered by Homecare provider to patients with continuous Oxygen supply required.

Concentrators may be divided in three families

- Stationary concentrator if weight is > 9kg. This method of supply is particularly suitable for those patients at home requiring oxygen for long periods of time. A stationary concentrator does not have a battery, and therefore needs an electric network connection.

- Transportable concentrator if weight is between 4 and 9 kg. They can be pulled by a trolley, they have rechargeable batteries that allow to produce and provide oxygen even without a direct connection on the electric network. They have continuous flow settings (shorter battery duration) and pulse flow settings (longer battery duration).
- Portable concentrator if weight is less than 4 kg. They can be carried on the shoulder in an appropriate bag or pulled by a trolley, they have rechargeable batteries that allow them to produce and provide oxygen even without a direct connection on the electric network. The Portable concentrator works with pulse flow settings and has no continuous flow setting.

11.1 Installation of oxygen concentrators

When planning the oxygen concentrator installation, whether used in healthcare facilities or by domiciliary patients at home, an assessment of the location of the unit shall be carried out to ensure that the patient/carer/healthcare facility staff are not subjected to undue risk in the event of any oxygen incident. For domiciliary patients, homecare service provider could carry out this assessment.

When supplying a concentrator to a new patient, the entire oxygen administration circuit, including the oxygen therapy nasal cannulas and distribution tubing, shall be supplied as new equipment. The humidifier shall either be changed or, where it is reusable, disinfected before it is supplied.

The bacterial filter and the dust filter shall be replaced between patients and the bacterial filter periodically, according to the manufacturer's instructions.

When choosing the site for the concentrator any associated piping and installed outlet points, it is important to instruct the patient/carer/healthcare facility staff of the concentrator to:

- Keep the concentrator and its tubing from open fire at least at the distance mentioned in the manual of the device or the local regulation, or if possible at a recommended 3 meter.
- Keep the concentrator and its tubing from other heat sources and electrical appliances at the distance mentioned in the manual of the device or the local regulation, or if possible at a recommended 1,5 meter.
- Not to use the concentrator close to curtains, upholstered seats or any other material surfaces. Allow a gap of at least 15 cm. around the concentrator to allow for adequate air circulation.
- Not to use the concentrator in a kitchen or garage where there is likely to be oils and greases used and stored.
- Not to use the concentrator so that the air intake or the concentrator exhaust is obstructed.
- Keep and use the concentrator in the upright position unless the unit is designed or allowed to be used in another orientation and permitted by the operating instructions.
- Locate the concentrator close to an electrical outlet point to avoid the use of extension cables or long trailing leads.
- Locate the concentrator at a suitable distance from the patient so that the concentrator alarm may be heard.

The general principles for the storage and use of medical oxygen cylinders (backup) are given in 9.1.2.

Where the patient is prescribed a flowrate that exceeds the output from one medical oxygen concentrator, the home care service provider can consider to provide the equipment to connect multiple units together to supply the patient and to meet the prescribed flowrate. When more than one machine is used to provide the patient with their prescribed flowrate, it is important to site the machines together, with minimal pipework between the units. It may be necessary to use tubing of a larger bore than normal

to prevent excessive pressure drop. Additional care is needed when operating multiple units to provide higher flowrates to prevent the back feeding of water from the humidifier from one unit to the other.

11.2 Use of oxygen concentrators

The homecare service provider is responsible for ensuring that the patient/carer/healthcare facility staff is adequately trained in the operation of the concentrator. The training shall be developed to cover all aspects of the operation of the equipment, including the cleaning and maintenance requirements and the general safety information for the use of oxygen within the home environment. The homecare service provider shall handover a copy of the manufacturer's user's manual and all useful information for the specific concentrator with the patient/carer/healthcare facility staff. When training the patient/carer, the labels and pictograms applied to the concentrator by the manufacturer shall also be explained to the patient/carer/healthcare facility staff.

The patient/carer/healthcare facility staff shall be instructed to ensure that:

- No one is smoking in the vicinity where the oxygen therapy is being used.
- If a humidifier is being used, the flask is unscrewed when it is filled, as defined in the humidifier instructions, and refitted to the concentrator.
- All of the equipment has been connected correctly to avoid leaks.
- The tubing and connectors are in good conditions.
- The oxygen flows out of the nasal cannulas or the oxygen tubing when it is disconnected from the mask or conserving device. This can be checked by placing the outlet(s) just under the surface of water in a glass and the flow will be indicated by bubbles. Where oxygen conserving devices are used, this test is not effective in determining whether the device is providing oxygen to the patient.

12 Oxygen self-fill systems

Oxygen self-fill systems are used for supplying medical oxygen to the patient and allowing the patient/carer/healthcare facility staff to fill medical oxygen high pressure gas cylinders that are provided specifically with the self-fill system by the HSP. This method of supply should only be used where a specific risk assessment has been conducted and there is confirmation that the patient/carer/healthcare facility staff are both trained and competency assessed.

The self-fill system either consists of a medical oxygen concentrator with an integral compressor as a single unit or as two separate units.

Dependant on the design of the system, the patient may be able to use the concentrator to supply oxygen for their therapy whilst the system is filling cylinders. In this case, the concentrator will preferentially supply the patient their medical oxygen requirements, thus extending the time to fill the cylinder,

The cylinders supplied with these units are fitted with a proprietary filling connection, designed for use with the specific filling system. The medical oxygen cylinders used for refilling are normally fitted with a cylinder valve that has an integral pressure regulator. The valve may also have an integral conserving device to maximise the usage time of the cylinder.

The medical oxygen cylinders shall be PI-marked. The valve shall be PI-marked and CE-marked if it has an integral pressure regulator.

Patients are normally supplied with more than one cylinder, to allow them to use a cylinder whilst another one is being filled.

For most systems, 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.

12.1 Installation of oxygen self-fill systems

When planning the installation of medical oxygen self-fill system, in the patient's home or in the healthcare facility, the basic advice provided in 11.1 about where to install the concentrator, should be followed. The information provided in Section 9 should also be used to advise the patient/carer/healthcare facility staff how to store and handle their cylinders. These sections provide the basic information about safety distances, requirements for ventilation, and general advice about storage and handling cylinders.

When considering where to install the oxygen self-fill system, it is important not to install the concentrator where there is likely to be oils and greases used or stored. Oil and grease present a significantly higher risk with high pressure oxygen and care is needed to ensure that filling connections and valve filling ports are not contaminated. It is advised to not install these systems in a kitchen or garage with the air intake or the concentrator exhaust obstructed or too close to curtains as this can cause the compressor to overheat.

12.2 Oxygen self-fill system risk assessment

The risk assessment carried out by the home care service provider shall be used to evaluate whether:

- Patient/carer/healthcare facility staff is competent to operate the oxygen self-fill system;
- Patient/carer/healthcare facility staff understands the risks associated with filling of medical oxygen cylinders, and
- Location where the oxygen self-fill system will be used is suitable.

The risk assessment shall also:

- Assess what size of cylinder and type of valve is suitable for the patient. Cylinder valves fitted with conserving devices shall only be used where they have been prescribed for the patient.
- Assess whether the patient/carer/healthcare facility staff is physically capable to put the cylinder on and remove the cylinder from the compressor.
- Ensure that there is a suitable location for the oxygen self-fill system. It shall not be located in an enclosed area, such as a cupboard, or places where there is inadequate ventilation.
- Ensure that the safety distances specified in 11.1 can be achieved.
- Ensure, where the concentrator is being used to supply oxygen to the patient as well as to fill the cylinder, the flow delivered to the patient is sufficient to meet patient requirements.

12.3 Oxygen self-fill system set up

The homecare service provider is responsible for ensuring that the patient/carer/healthcare facility staff is trained to fill cylinders on the oxygen self-fill system and understands the operation of the concentrator. The training shall cover all aspects of the filling operation, including any cleaning requirements needed to be performed by the patient/carer.

The healthcare service provider shall also provide the general safety information covering the use of medical oxygen within the home environment and leave a copy of the user instructions with the patient/carer for reference.

The healthcare service provider shall provide the patient/carer/healthcare facility staff specific advice to ensure that:

- The oxygen self-fill system is installed on a flat firm stable surface and where the system cannot topple over;
- It is in a location where there is no risk of oxygen enrichment in the event of a leak;
- The manufacturer's instructions are followed when connecting and disconnecting the cylinder from the compressor, making sure that:
 - no tools are used when disconnecting the cylinder
 - two hands are used when handling cylinders
 - only a damp lint free cloth is used to clean the surfaces of the self-fill oxygen system and cylinder
- The filling connector is covered when cleaning the concentrator to protect against ingress of moisture or contaminants; and
- The patient/carer/healthcare facility staff understands how to move the oxygen self-fill system, and this includes that the oxygen self-fill system shall:
 - never be transported with a cylinder connected
 - never be moved whilst a cylinder is being filled
 - only be moved by lifting it using the handles provided or where wheels are fitted by pushing/pulling.
 - The correct flow is selected, in line with patient's prescription and the manufacturer's user instructions.

12.4 Precautions for filling cylinders using self-fill system

As the oxygen self-fill system is a medical device, it should only be used with the cylinders specified by the manufacturer and identified for use in the user instructions. Failure to do this could compromise the safe use of the equipment.

The patient/carer/healthcare facility staff shall be instructed to carry out the following checks on the cylinder filling concentrator prior starting the filling process to ensure that:

- Cylinder is within its test date (marked on the shoulder of the cylinder);
- Cylinder and equipment shows no signs of damage;
- Electrical lead and the plug are not damaged, and
- Filling coupling connection and the valve filling port have not been contaminated with oil or grease. Failure to keep the filling port clean may lead to an ignition whilst filling the cylinder.

If there are any signs of damage or oil and grease on the equipment, patient/carer/healthcare facility staff should be instructed to notify the homecare service provider.

Prior to connecting the cylinder to the cylinder filling concentrator, the patient/carer/healthcare facility staff should be instructed to:

- Set the oxygen self-fill system concentrator flow rate as detailed in the user instructions. Specific attention is needed when the patient is receiving oxygen from the concentrator whilst it is also filling a cylinder.
- Check the cylinder gauge for contents. If the cylinder is full it should not be connected onto the compressor.
- Check the cylinder valve is closed and flow control set to zero.

If there are any problems or concerns with the cylinder or valve, the patient/carer/healthcare facility staff shall be instructed to notify the homecare service provider.

Having completed the pre-filling checks, the patient/carer/healthcare facility staff shall be instructed to:

- Correctly position the cylinder on the compressor.

- Follow the procedures detailed in the user instructions.
- Where required, open the cylinder valve slowly.
- Check for leaks during the filling process.
- Leaks will be evident by a hissing noise. If a leak occurs, the compressor must be stopped, the cylinder valve closed, and the cylinder removed. The filling connection and the filling port on the valve should be inspected for faults. If there is no evidence of faults, refit the cylinder onto the filling connection and restart the filling process. If the leak continues, stop the filling process and contact the homecare service provider.

If the filling process takes longer than expected, the patient/carer/healthcare facility staff should check:

- Filling time against the specified time in the User Instruction.
- Cylinder flow control is set to zero.
- Cylinder is connected correctly by stopping the system, removing the cylinder and replacing as instructed.

If problem is not resolved, the patient/carer/healthcare facility staff shall be instructed to notify the homecare service provider.

After the cylinder has been filled, the patient/carer/healthcare facility staff shall be instructed to:

- Check the cylinder content gauge (where fitted) to ensure cylinder is full.
- Close the cylinder valve slowly.
- Remove the cylinder from the filling connector, if required. The patient/carer shall be warned that it is normal when removing the cylinder from the filling port, that there could be a noise generated by the gas escaping from the filling connector.
- Ensure that the filling port cover is replaced immediately after the cylinder is disconnected. The filling port cover shall be fitted at all times whenever the self-fill system is not in use.
- Treat the filled cylinder with the same precautions as for Medical Oxygen gas cylinders filled and supplied by the Homecare Service Provider

12.5 Maintenance of oxygen self-fill systems

Maintenance of the oxygen self-fill system shall follow the advice given in the user instructions and comply with the requirements in 9.1.

The patient/carer/healthcare facility staff shall be instructed not to modify the cylinder filling equipment in anyway, including replacement of seals and tightening of connections. The patient/carer/healthcare facility staff shall be instructed that if they have any problem with the equipment, they must notify the homecare service provider immediately.

When carrying out routine maintenance on the oxygen self-fill system at a patient's home or healthcare facility, 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.

13 References

Unless otherwise specified the latest revision shall apply.

[1] Medical Device Regulation (MDR) 2017/745 www.europa.eu

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- [2] European Agreement on the Carriage of Dangerous Goods Regulations (ADR) www.unece.org
 - [3] Compressed Gas Association Pamphlet P-2.7 Guide for the Safe Storage, Handling, and Use of Small Portable Liquid Oxygen Systems in Health Care Facilities www.cganet.com
 - [4] European Standard EN 1251-3, Cryogenic vessels. Transportable vacuum insulated vessels of not more than 1000 litres volume. Operational requirements www.cen.eu
 - [5] EIGA Doc 218 – Medicinal VIPR Package – Lifetime Performance of Drug Delivery Device www.eiga.eu
 - [6] EIGA Doc 180 – Design Considerations and Guidance for the Safe Use of Medical Gas VIPR www.eiga.eu
 - [7] EIGA TM1 video – *Operation of Medical VIPR* www.eiga.eu under E-learning page –
 - [8] EIGA Doc 222 – Guidelines for Cleaning Externally Contaminated Medical Gas Containers. www.eiga.eu
 - [9] EIGA Doc 157 - Hygienic Processes for Home Oxygen Respiratory Devices – www.eiga.eu

Appendices

Appendix 1 Patient User Training Card - Cylinders

Patient User Training Card

Use of Medical Oxygen Cylinders in the Home

Appendix 2 Patient User Instruction Card - Cylinders

Patient User Instruction Card

Use of Medical Oxygen Cylinders in the Home

Appendix 3 Patient User Training Card - Liquid Systems

Patient User Training Card

Use of Medical Liquid Oxygen Containers in the Home

Appendix 4 Patient User Instruction Card - Liquid Systems

Patient User Instruction Card

Use of Medical Liquid Oxygen Containers in the Home

Appendix 5 Patient User Training Card - Concentrators

Patient User Training Card

Use of Medical Oxygen Concentrators in the Home

Appendix 6 Patient User Instruction Card - Concentrators

Patient User Instruction Card

Use of Medical Oxygen Concentrators in the Home

Appendix 7 Patient User Training Card - Self-fill Systems

Patient User Training Card

Use of Medical Oxygen Self-fill Systems at Home

Appendix 8 Patient User Instruction Card - Self-fill Systems

Patient User Instruction Card

Use of Medical Oxygen Self-fill Systems at Home



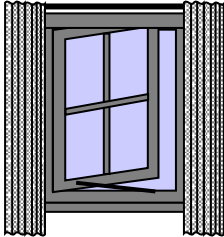

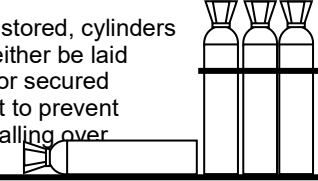

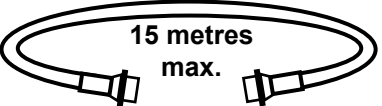
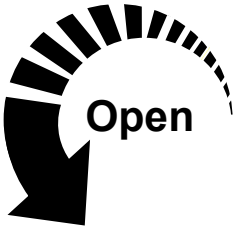
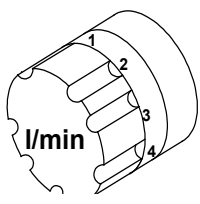
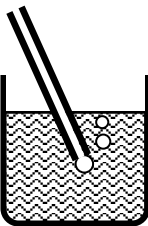
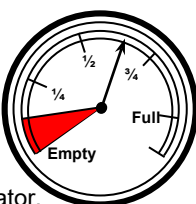


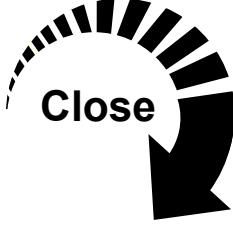

Appendix 9 FMEA Analysis

Failure Mode and Effects Analysis for "Homecare Patient Environment Risk Assessment – Oxygen Therapy"



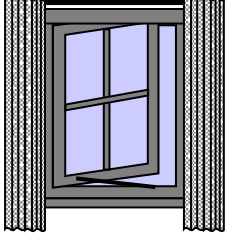



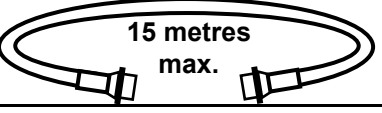
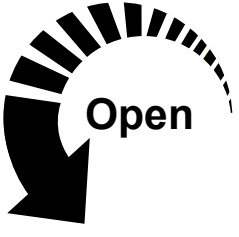
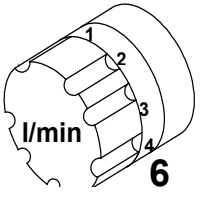
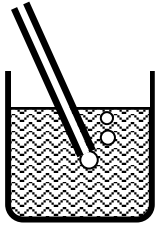
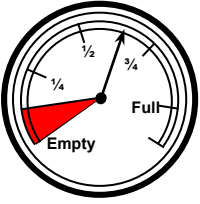

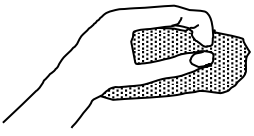
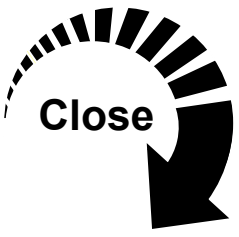

Appendix 10 Risk Assessment Checklist

Homecare Installation Risk Assessment Checklist




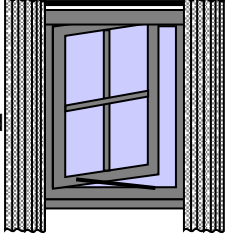
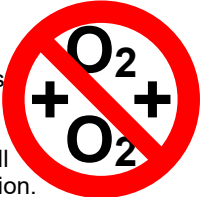


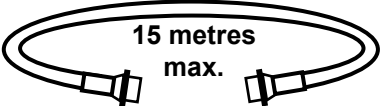
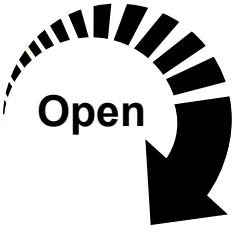
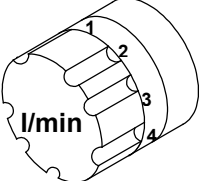
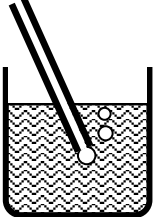
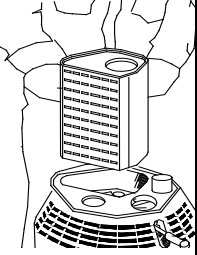

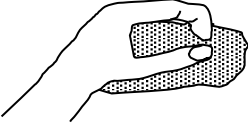
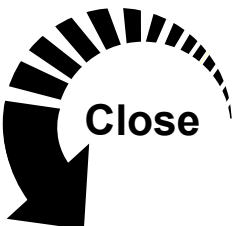

Appendix 1 - PATIENT USER TRAINING CARD – USE OF MEDICAL OXYGEN CYLINDERS IN THE HOME

<p>1 Read the User Instruction Manual carefully before operating your medical oxygen cylinder and equipment. Pay special attention to information where the hazard symbol is shown. </p>	<p>2 Materials burn much more vigorously in oxygen than air. Never smoke (or let someone else smoke near you) whilst using your oxygen equipment. Do not use your oxygen cylinders near open fires or naked flames.. </p>	<p>3 Only use your medical oxygen cylinder and equipment in a well ventilated area.  Keep internal doors open whilst your oxygen cylinder is in use.</p>
<p>4 Never place your oxygen cylinders near curtains or cover them with clothing as this will restrict air circulation.  Materials become oxygen enriched if any leak occurs with no ventilation. Never use or carry the portable oxygen container under any</p>	<p>5 Follow the advice your service provider has given you about where to safely store and use your cylinders. When stored, cylinders must either be laid down or secured upright to prevent them falling over. </p>	<p>6 Do not use oils or grease with your oxygen cylinders or equipment.  Ensure that your hands are clean when using the cylinder. Only use authorised creams and moisturisers when using your medical oxygen.</p>
<p>7 Attach the oxygen tubing to the outlet connector on the valve or regulator. Ensure that the length of the tubing does not exceed 15 metres </p>	<p>8 Ensure the flowmeter is set to zero before the valve is opened.  Open the cylinder valve slowly. Open the valve fully by turning the handwheel anti-clockwise.</p>	<p>9 Set the flow control valve to the flowrate prescribed by your Doctor.  Check for any leaks on the tubing connection after opening the cylinder valve.</p>
<p>10 Check for flow by placing the end of the tubing in a glass of water and watch for bubbles.  If bubbles do not appear, check a flow has been selected and there are no leaks. If a flow is still not evident, contact your service provider.</p>	<p>11 Check how much oxygen is available for use by checking the gauge on the valve or the regulator.  Never fully empty the cylinder. Always change over your cylinders so that you leave some gas in them after use.</p>	<p>12 If a regulator is used with your oxygen cylinder, ensure that it is only connected hand tight.  Never use excessive force. Never use spanners unless specifically instructed by your service provider.</p>
<p>13 Only use a clean damp cloth if it is necessary to clean your oxygen cylinder or any associated equipment.  Only use mild non-abrasive cleaning materials. Allow the cylinder to dry after wiping down.</p>	<p>14 Close the valve when the cylinder is not in use.  Close the valve by turning the handwheel clockwise. Never use excessive force.</p>	<p>15 If your cylinder or regulator fails for any reason call your service provider immediately.  Never try and repair any fault unless specifically instructed by your service provider</p>



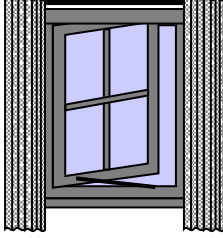

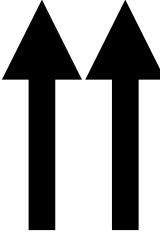

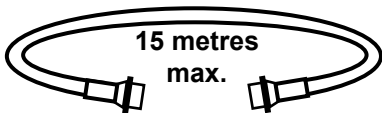
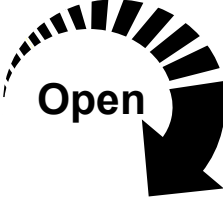
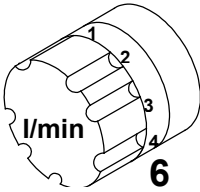
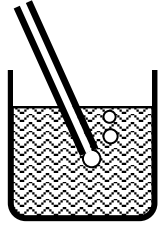
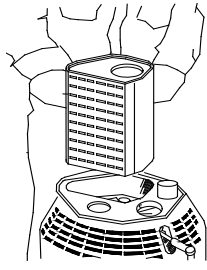

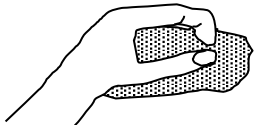
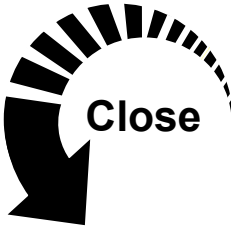
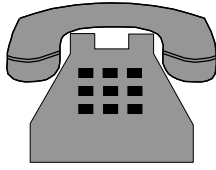
Appendix 2 - PATIENT USER INSTRUCTION CARD – USE OF MEDICAL OXYGEN CYLINDERS IN THE HOME

<p>1</p> <p>Always read instructions</p> 	<p>2</p> <p>No smoking</p> <p>No naked flames</p> 	<p>3</p> <p>Use in a ventilated area</p> 
<p>4</p> <p>Avoid oxygen enrichment</p> 	<p>5</p> <p>Secure cylinders upright or lay down</p> 	<p>6</p> <p>Never use oil or grease</p> 
<p>7</p> <p>Connect oxygen tubing</p> 	<p>8</p> <p>Open valve slowly</p> 	<p>9</p> <p>Adjust flowrate as prescribed</p> 
<p>10</p> <p>Check for flow</p> 	<p>11</p> <p>Check cylinder contents</p> 	<p>12</p> <p>Do not use excessive force</p> 
<p>13</p> <p>Only clean with a damp cloth</p> 	<p>14</p> <p>Close valve after use</p> 	<p>15</p> <p>Phone for assistance if required</p> 



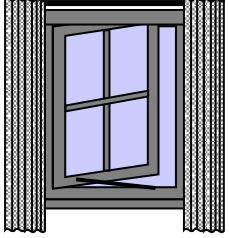

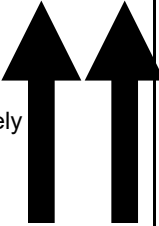
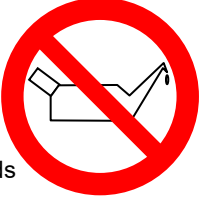
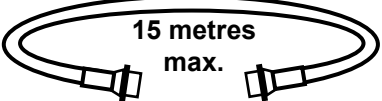
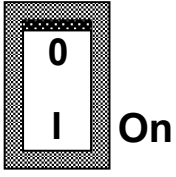
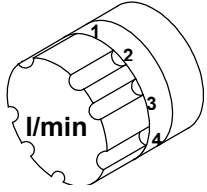
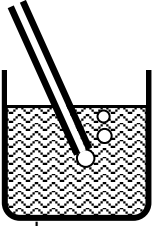
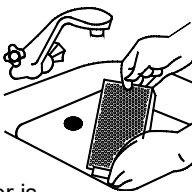
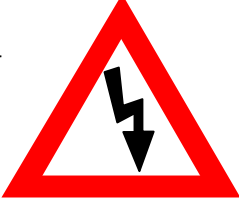

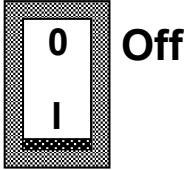

Appendix 3 - PATIENT USER TRAINING CARD – USE OF MEDICAL LIQUID OXYGEN CONTAINERS IN THE HOME

<p>1 Read the User Instruction Manual carefully before operating your liquid oxygen containers and equipment. Pay special attention to information where the hazard symbol is shown. </p> 	<p>2 Materials burn much more vigorously in oxygen than air. Never smoke (or let someone else smoke near you) whilst using your oxygen equipment. Do not use your oxygen containers near open fires or naked flames.</p> 	<p>3 Only use your liquid oxygen containers and equipment in a well ventilated area. Keep internal doors open whilst your oxygen containers are in use.</p> 
<p>4 Never place your oxygen containers near curtains or cover them with clothing as this will restrict air circulation. Materials become oxygen enriched if any leak occurs with no ventilation. Never use or carry the portable oxygen container under any</p> 	<p>5 Follow the advice your service provider has given you about where to safely store and use your liquid oxygen container. Use and store your liquid oxygen base unit upright. Use the portable unit only as shown in the Instruction Manual.</p> 	<p>6 Do not use oils or grease with your liquid oxygen containers or equipment. Ensure that your hands are clean when using the containers. Only use authorised creams and moisturisers when using your</p> 
<p>7 Attach the oxygen tubing to the outlet connector on the liquid oxygen container. Ensure that the length of the tubing does not exceed 15 metres</p> 	<p>8 To turn on your liquid oxygen container, turn the oxygen flow control valve clockwise.</p> 	<p>9 Set the flow control valve to the flowrate prescribed by your Doctor. Check for any leaks on the tubing connection after selecting the correct flowrate.</p> 
<p>10 Check for flow by placing the end of the tubing in a glass of water and watch for bubbles. If no bubbles appear, check a flow has been selected and there are no leaks. If a flow is still not evident, contact your service provider.</p> 	<p>11 When transfilling the portable unit, never leave it unattended until the unit is full. If the unit will not disconnect easily, never use force to remove it. Wait a few moments to allow it to thaw and then try again.</p> 	<p>12 Never touch any cold parts on either container or allow liquid oxygen to come into contact with your skin. This could cause a serious burn. Immerse affected parts in tepid water if you receive a cold burn.</p> 
<p>13 Use only a clean damp cloth to clean your liquid oxygen containers or any associated equipment. Only use mild non-abrasive cleaning materials. Allow the liquid oxygen containers to dry after wiping down.</p> 	<p>14 Select zero on the oxygen flow control valve after use. Keep closed when the liquid oxygen container is not in use.</p> 	<p>15 If either liquid oxygen container fails for any reason call your service provider immediately. Never try and repair any fault unless specifically instructed by your service provider</p> 



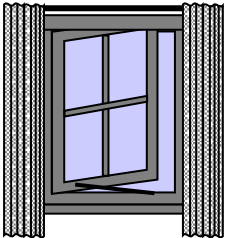

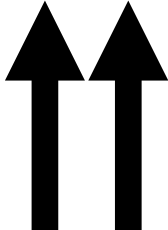

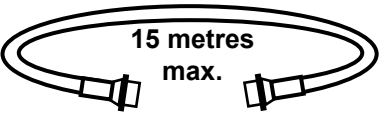
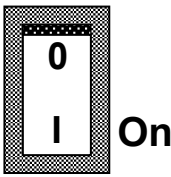
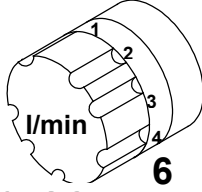
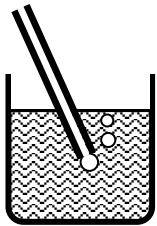
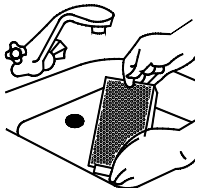
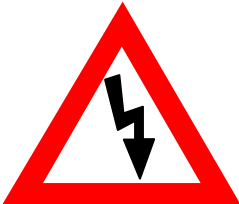
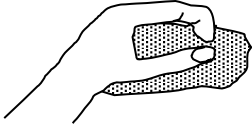
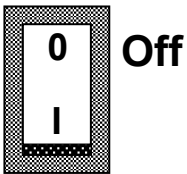

Appendix 4 - PATIENT USER INSTRUCTION CARD – USE OF MEDICAL LIQUID OXYGEN CONTAINERS IN THE HOME

<p>1</p> <p>Always read instructions</p> 	<p>2</p> <p>No smoking</p> <p>No naked flames</p> 	<p>3</p> <p>Use in a ventilated area</p> 
<p>4</p> <p>Avoid oxygen enrichment</p> 	<p>5</p> <p>Keep upright</p> 	<p>6</p> <p>Never use oil or grease</p> 
<p>7</p> <p>Connect oxygen tubing</p> 	<p>8</p> <p>Open flow control valve</p> 	<p>9</p> <p>Adjust flowrate as prescribed</p> 
<p>10</p> <p>Check for flow</p> 	<p>11</p> <p>Stay whilst transfilling</p> 	<p>12</p> <p>Do not touch cold parts</p> 
<p>13</p> <p>Only clean with a damp cloth</p> 	<p>14</p> <p>Select zero flow after use</p> 	<p>15</p> <p>Phone for assistance if required</p> 





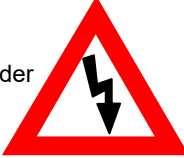
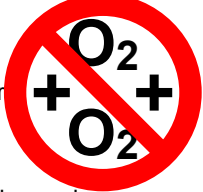
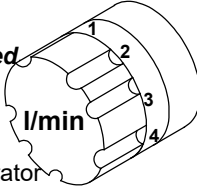
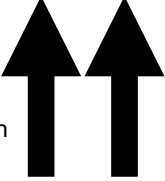
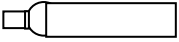
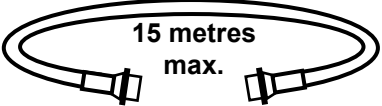
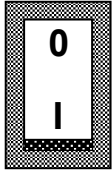

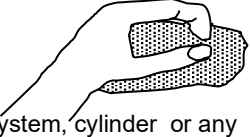
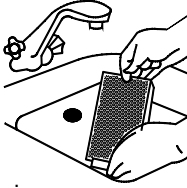

Appendix 5 - PATIENT USER TRAINING CARD – USE OF MEDICAL OXYGEN CONCENTRATOR IN THE HOME

<p>1 Read the User Instruction Manual carefully before operating your oxygen concentrator and equipment. Pay special attention to Information where the hazard symbol is shown.</p> 	<p>2 Materials burn much more vigorously in oxygen than air. Never smoke (or let someone else smoke near you) whilst using your oxygen concentrator. Do not use your concentrator near open fires or naked flames.</p> 	<p>3 Only use your oxygen concentrator and equipment in a well ventilated area. Keep internal doors open whilst your oxygen concentrator is in use.</p> 
<p>4 Never place your oxygen concentrator near curtains or cover it with clothing as this will restrict air circulation. Materials become oxygen enriched if any leak occurs with no ventilation.</p> 	<p>5 Follow the advice your service provider has given you as to where to safely position your oxygen concentrator when it is being used. Your concentrator must be used upright as detailed in the instruction manual.</p> 	<p>6 Do not use oils or grease with your oxygen concentrator. Ensure your hands are clean when handling your oxygen equipment. Only use authorised face creams and moisturisers when using your medical oxygen.</p> 
<p>7 Attach the oxygen tubing to the outlet connector on the oxygen concentrator. Ensure that the length of the tubing does not exceed 15 metres</p> 	<p>8 Connect your oxygen concentrator to the electrical supply and switch on. Never use extension leads to connect your concentrator unless instructed by your service provider.</p> 	<p>9 Set the flow control valve to the flowrate or setting prescribed by your Doctor. Check for any leaks on the tubing connection before use.</p> 
<p>10 Check for flow by placing the end of the tubing in a glass of water and watch for bubbles. If bubbles do not appear, check a flow has been selected and there are no leaks. If a flow is still not evident, contact your service provider.</p> 	<p>11 Regularly clean the air inlet filter as instructed in the user instruction manual. Ensure that the filter is dried before replacement. Switch off and isolate your medical oxygen concentrator from the mains supply when replacing the filter.</p> 	<p>12 Never open or remove the concentrator cover at any time. Do not use extension cables unless instructed. Only authorised personnel should carry out any repairs on your oxygen concentrator.</p> 
<p>13 Use only a clean damp cloth to clean your oxygen concentrator or any associated equipment. Only use mild non-abrasive cleaning materials. Allow the oxygen concentrator to dry after wiping down before using.</p> 	<p>14 Switch off your medical oxygen concentrator after use. Never leave you medical oxygen concentrator running when it is not in use.</p> 	<p>15 If your oxygen concentrator fails for any reason call your service provider immediately. Never try and repair any fault unless specifically instructed by your Service Provider</p> 







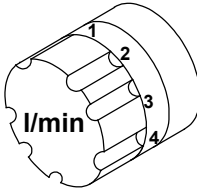
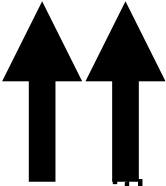
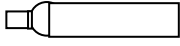
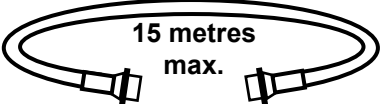
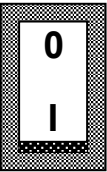
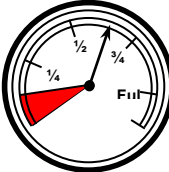
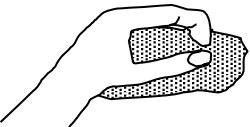
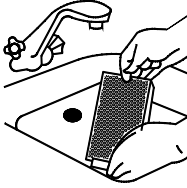

Appendix 6 - PATIENT USER INSTRUCTION CARD – USE OF MEDICAL OXYGEN CONCENTRATOR IN THE HOME

<p>1</p> <p>Always read instructions</p> 	<p>2</p> <p>No smoking</p> <p>No naked flames</p> 	<p>3</p> <p>Use in a ventilated area</p> 
<p>4</p> <p>Avoid oxygen enrichment</p> 	<p>5</p> <p>Keep upright</p> 	<p>6</p> <p>Never use oil or grease</p> 
<p>7</p> <p>Connect oxygen tubing</p> 	<p>8</p> <p>Turn on to obtain oxygen</p> 	<p>9</p> <p>Adjust flowrate or setting as prescribed</p> 
<p>10</p> <p>Check for flow</p> 	<p>11</p> <p>Keep filter clean</p> 	<p>12</p> <p>Do not open concentrator</p> 
<p>13</p> <p>Only clean with a damp cloth</p> 	<p>14</p> <p>Always turn off after use</p> 	<p>15</p> <p>Phone for assistance if required</p> 

Appendix 7 - PATIENT USER TRAINING CARD – USE OF MEDICAL OXYGEN SELF-FILL SYSTEMS AT HOME

<p>1 Read the User Instruction Manual carefully before operating your oxygen concentrator and equipment. Pay special attention to Information where the hazard symbol is shown</p> 	<p>2 Only fill cylinders provided with your self-fill system Never fill any other cylinder on the system Keep the cylinder filling connector covered when not in use. Check the test date on the cylinder to ensure it is suitable for filling.</p> 	<p>3 Materials burn much more vigorously in oxygen than air. Never smoke (or let someone else smoke near you) whilst using your oxygen concentrator or cylinder. Do not use or keep your concentrator or cylinder within 3 metres of open fires or naked flames</p> 
<p>4 Do not use oils or grease with your self-fill system or cylinder. Ensure your hands are clean when handling your oxygen equipment. Do not use aerosols near your equipment. Only use authorised face creams and moisturisers.</p> 	<p>5 Keep your oxygen concentrator / cylinder at least 1.5 metres from electrical equipment such as TVs and electrical heaters Only use your oxygen concentrator and cylinder in well ventilated area. Keep doors open whilst in use.</p> 	<p>6 Never place your oxygen self-fill system or cylinder near curtains or cover them with clothing. This will restrict air circulation and allow oxygen enrichment. Materials become oxygen enriched if any leak occurs with no ventilation.</p> 
<p>7 Set the flow to the flowrate prescribed by your Doctor. Check User Instructions when using the concentrator whilst filling cylinders. Check for leaks on the tubing connection after selecting the correct flowrate</p> 	<p>8 Install the self-fill system on level ground, in an upright position, as detailed in the User Instruction. Never move concentrator with a cylinder connected. Use two hands when moving the self-fill system</p> 	<p>9 Ensure the cylinder valve is closed when connecting cylinder to the self-fill system. Make sure the cylinder is secured firmly before starting filling. Ensure the correct flowrate is selected when filling cylinders as detailed in the user instruction</p> 
<p>10 Attach the oxygen tubing to the outlet connector on the oxygen concentrator. Check for leaks. Ensure that the length of the tubing does not exceed 15 metres Check for flow by immersing tubing in a water and watch for bubbles</p> 	<p>11 Connect your self-fill system to the electrical supply and switch on. Never use extension leads to connect your concentrator unless instructed by your service provider.</p> 	<p>12 Before filling check connections are clean. Open the cylinder valve slowly. If leaks occur, stop the filling and refit the cylinder. If leaks continue contact your service provider. Do not remove cylinder when filling. Check gauge at end of fill to ensure cylinder is full. Close valve slowly</p> 
<p>13 Use only a clean damp cloth to clean your self-fill system, cylinder or any associated equipment. Replace fill port cover when cleaning. Only use mild non-abrasive cleaning materials. Allow to dry after wiping down before using.</p> 	<p>14 Regularly clean the air inlet filter as instructed in the user instruction manual. Ensure that the filter is dried before replacement. Switch off and isolate your medical oxygen self-fill system from the mains supply when replacing filter.</p> 	<p>15 If your oxygen concentrator fails for any reason call your service provider immediately. Never try and repair any fault unless specifically instructed by your service provider</p> 

Appendix 8 - PATIENT USER INSTRUCTION CARD – USE OF MEDICAL OXYGEN SELF-FILL SYSTEMS AT HOME

<p>1</p> <p>Always read instructions</p> 	<p>2</p> <p>Only use cylinders provided with self-fill system</p> 	<p>3</p> <p>No Smoking No naked flames</p> 
<p>4</p> <p>Never use oil or grease</p> 	<p>5</p> <p>Keep away from electrical equipment</p> 	<p>6</p> <p>Avoid oxygen enrichment</p> 
<p>7</p> <p>Adjust flowrate as prescribed</p> 	<p>8</p> <p>Keep upright. Do not move with cylinder attached</p> 	<p>9</p> <p>Connect cylinder securely Open valve slowly</p> 
<p>10</p> <p>Connect tubing. Check for leaks</p> 	<p>11</p> <p>Turn on to obtain oxygen</p> 	<p>12</p> <p>Check for leaks when filling Open and close valve slowly</p> 
<p>13</p> <p>Only clean with a damp cloth</p> 	<p>14</p> <p>Keep filter clean</p> 	<p>15</p> <p>Phone for assistance if required</p> 

Appendix 9 – FMEA ANALYSIS - Homecare Patient Environment Risk Assessment

Homecare Patient Environment Risk Assessment Oxygen Therapy												
Potential Risk	Potential Effect of Risk	Severity	Potential Outcome	Occurrence	Current Protection	Detection	RPN	Recommended Actions	Concentrators	Self-fill System	Gaseous Oxygen	Liquid Oxygen
Access to property – Delivering Product												
Parking vehicle to deliver product to patient	Too far away from property to carry safely	1	No suitable location near patient's house	4	Use of trolley lightweight cylinders assistance	1	4		✓	✓	✓	✓
Tarmac road surface (transfilling)	Oxygen venting on road surface	5	Oxygen saturation / fire	2	Use of protection plates	1	10					✓
Steep slope for parking vehicle	Difficulty to unload vehicle / injury	3	Slips and trips etc. Stability of container	2	Type of mechanical aid to unload vehicle	1	6		✓	✓	✓	✓
Poor ground / surface between parking space and property	Difficult to carry equipment into house	3	Slips and trips etc. Stability of container	2	Use of trolley with large wheels Assistance	1	6		✓	✓	✓	✓
Steps up to the property	Difficult to carry equipment into house	3	Slips and trips etc. Stability of container	2	Use of trolley with large wheels assistance	1	6		✓	✓	✓	✓
Stairs up to property / apartment building	Difficult to carry equipment into house Potential to drop supplies	3	Slips and trips etc. Stability of container Damage to equipment	2	Use of trolley with large wheels Strapping to trolley assistance	1	6		✓	✓	✓	✓
Use of lifts to property	Venting in an enclosed space	4	Oxygen enrichment of clothing of a passenger	1	Vent before carrying in lift. Control of lifts: avoid passengers	3	12					✓
Steep slope to the property	Difficult to carry equipment into house	3	Slips and trips etc. Stability of container	2	Use of trolley with large wheels assistance	1	6		✓	✓	✓	✓
Unsafe neighbourhood (for parking,...)	Possible danger to technician or property (van)	5	Abuse, injury, theft	1	Park in populated and well lighted area	2	10		✓	✓	✓	✓
Patient Profile												

Homecare Patient Environment Risk Assessment Oxygen Therapy												
Potential Risk	Potential Effect of Risk	Severity	Potential Outcome	Occurrence	Current Protection	Detection	RPN	Recommended Actions	Concentrators	Self-fill System	Gaseous Oxygen	Liquid Oxygen
Patient with low mental capacity. Children/ babies.	Unable to understand the instructions for use	4	Operate equipment incorrectly or unsafely (spillage, cold burn, high pressure leaks)	3	Carer to assist with equipment.	2	24		✓	✓	✓	✓
Patient with low physical capacity and children/ babies.	Unable to handle equipment safely. Unable to operate in an emergency	4	Patient creates unsafe situation with equipment. Inability to open/close the cylinder valve and change the pressure regulator onto another cylinder.	3	<ul style="list-style-type: none"> • Carer to assist with equipment. • Change mode of supply. • Oxygen source should be accommodated to the profile of the patient (e.g. small patients require lower LOX stationary). • Provide integrated cylinder valve packages. 	1	12		✓	✓	✓	✓
Patients with language / communication problems	Unable to understand the instructions for use and unable to communicate back	3	Operate equipment incorrectly or explain problems	3	Carer to assist with equipment Use of sign languages / manuals in picture format	2	18		✓	✓	✓	✓
Poor housekeeping standards / cleanliness in house	Contamination of equipment Blockage of filters etc.	2	Cross contamination to engineer Failure of equipment	3	Training for cleanliness Carer to assist	2	12		✓	✓	✓	✓
Bed or chair ridden patients	Unable to move around house with oxygen supply	2	Oxygen enrichment of bedding / clothing Potential fire risk	4	Training. Conserving device where possible. Carer to assist with equipment.	2	16		✓	✓	✓	✓

Homecare Patient Environment Risk Assessment Oxygen Therapy												
Potential Risk	Potential Effect of Risk	Severity	Potential Outcome	Occurrence	Current Protection	Detection	RPN	Recommended Actions	Concentrators	Self-fill System	Gaseous Oxygen	Liquid Oxygen
Smoker	Smoking with oxygen	5	Fire Burning around the mouth / nose area	4	Training on safety issues Inform doctor/ insurance, if no change of patient attitude.	2	40	In case of no improvement by the patient, the equipment may be withdrawn (after consultation with responsible of prescription)	✓	✓	✓	✓
Hygiene standard	Infection for patient, carer, installer & workshop technician from equipment surface contamination	2	Patient is not taking care of the continuous cleanliness of the equipment	2	Training and reminding of the patient & carer (i.e. Specific, clear instructions). Technician has gloves and cleaning agent available and mark the unit to allow the workshop technician to take appropriate measures.	4	16	In case of no improvement by the patient, the equipment may be withdrawn (after consultation with responsible of prescription)	✓	✓	✓	✓
Behaviour of patient	Aggressive	1	Harassment to Installer	2	Involve carer/ neighbour Assistance in the installation	1	2		✓	✓	✓	✓
Behaviour of patient	<u>Physical</u> aggression	4	Harassment or assault to installer	2	Installation cannot be performed and technician shall try to safely leave the place and communicate with management	1	8		✓	✓	✓	✓
Patient has other illnesses	Has contagious disease, which is most often not told to the Installer or unknown to him	2	Infection of installer and carer Contamination of equipment	2	Installer consults the responsible prescriber Consideration to vaccinate installer	4	16		✓	✓	✓	✓
Patient is also using other therapy equipment , e.g. CPAP, ventilator	Oxygen used together with electric powered equipment	3	Oxygen compatibility risk and risk of ignition	2	Train and strictly follow the procedure/manual. Use the original adaptors.	2	12	Keep oxygen source 1.5 m from electric appliances.	✓	✓	✓	✓
Other Occupants / Animals												

Homecare Patient Environment Risk Assessment Oxygen Therapy												
Potential Risk	Potential Effect of Risk	Severity	Potential Outcome	Occurrence	Current Protection	Detection	RPN	Recommended Actions	Concentrators	Self-fill System	Gaseous Oxygen	Liquid Oxygen
Children	Interference / damage of the equipment – interruption of supply etc.	3	Malfunction of equipment – leading to leaks, fire etc.	2	Clear instructions to parents / patient / carer	1	6		✓	✓	✓	✓
Other smokers	Smoking with oxygen	4	Fire Damage to property	4	Training on safety issues	2	32		✓	✓	✓	✓
Animals	Interference / damage of the equipment – interruption of supply etc Problems to the installer.	2	Malfunction of equipment – leading to leaks, fire etc. Lack of correct hygiene of the equipment	2	Clear instructions to parents / patient. Special advice to installer	1	4		✓	✓	✓	✓
Animals (behaviour)	Potentially aggressive or defensive reaction of pets	3	Injury and conflict with patient	4	Request of animals to be restrained (leach or other room)	2	24					
Carers (with responsibility for patient)												
Elderly people	Don't understand or cannot remember the instructions	2	Slow reaction in case of emergency Incorrect handling Incorrect adherence to prescription	3	Try to get other carers/neighbors involved Provide other means of handling, e.g. trolley Provide tele-surveillance & emergency tel.	1	6		✓	✓	✓	✓
Physical disabled Low mobility	Possibly cannot move the equipment	3	Cannot change out the container Incorrect adherence to prescription Cannot react adequately in case of emergency	2	Try to get other carers/neighbors involved Provide other means of handling, e.g. trolley Provide tele-surveillance & emergency tel.	1	6		✓	✓	✓	✓

Homecare Patient Environment Risk Assessment Oxygen Therapy												
Potential Risk	Potential Effect of Risk	Severity	Potential Outcome	Occurrence	Current Protection	Detection	RPN	Recommended Actions	Concentrators	Self-fill System	Gaseous Oxygen	Liquid Oxygen
With low mental capabilities	Cannot apply the therapy safely/adequately	3	Incorrect adherence to prescription Cannot react adequately in case of emergency	2	The service provider is not going to install the therapy	1	6	Consultation with the person responsible for prescription, recommending to find another carer or social assistant. Contact a 'patient association' when available. Develop a list of recommended conditions for appointment as Carer.	✓	✓	✓	✓
With language/communication problems	Do not understand the instructions	3	Slow reaction in case of emergency Incorrect handling Incorrect adherence to prescription	2	Try to get other carers/neighbors involved Provide tele-surveillance and emergency tel.	2	12	Develop instructions based on pictograms/symbols, photos, video recommending to find another carer or social assistant. Contact a 'patient association' when available.	✓	✓	✓	✓
"Do-it-yourself" carers	Modifications done to the installation and/or equipment	3	Malfunctioning of equipment. Injury. Damage.	2	Stress to these carers that no changes are allowed prior approval of the service provider. No technical changes are allowed at all.	3	18		✓	✓	✓	✓
Behaviour of carer	Physical aggression	4	Harassment or assault to installer	2	Installation cannot be performed and technician shall try to safely leave the place and communicate with management	1	8		✓	✓	✓	✓
Storage Facilities (for units not in use)												

Homecare Patient Environment Risk Assessment Oxygen Therapy												
Potential Risk	Potential Effect of Risk	Severity	Potential Outcome	Occurrence	Current Protection	Detection	RPN	Recommended Actions	Concentrators	Self-fill System	Gaseous Oxygen	Liquid Oxygen
Product stored outside	Potential for vandalism / theft. Stored against flammable material. Animals present.	2	Theft of equipment Interference leading to damage, leaks or fire	2	Advice to store securely	1	4		✓	✓	✓	✓
Product stored inside building	Potential hazard if containers leak	5	Fire leading to explosion	2	Advise patient of how / where to store safely Limit stocks of containers. Review storage arrangements	1	10		✓	✓	✓	✓
Storage in Garage	Oils grease and solvents coming into contact. Presence of oxy-acetylene kit. Damage when parking vehicles	4	Self-ignition leading to explosion Damage. Stability of container / fall over.	3	Review storage areas / advise not to store with oils and grease etc.	1	12		✓	✓	✓	✓
Storage in Workshop	Dust / chemicals / solvents etc. coming in contact with the containers. Presence of oxy-acetylene kit.	4	Self-ignition leading to explosion Damage. Stability of container / fall over.	3	Review storage areas / advise not to store with Dust / chemicals / solvents etc.	1	12		✓	✓	✓	✓
Storage in cupboards	Poor ventilation leading to oxygen enrichment if leaks occur Storage of other materials such as solvents	4	Oxygen enrichment Potential fire Potential cooling affect from LOX container	3	Review storage areas with sufficient ventilation	1	12		✓	✓	✓	✓
Storage in kitchens	Contamination with cooking oils etc. Presence of a naked flame / hot surfaces with cooker	4	Increased risk in case of fire	3	Review storage areas / advise not to store in the vicinity of cooking area	1	12		✓	✓	✓	✓
Difficult access to container storage area	Tendency to store too many container in home and associated risks	2	Congestion / container falling etc. Large volume of oxygen stored.	3	Assign different storage location More frequent delivery Different mode of supply	1	6	To recommend a maximum number of containers to be kept in stock:	✓	✓	✓	✓

Homecare Patient Environment Risk Assessment Oxygen Therapy												
Potential Risk	Potential Effect of Risk	Severity	Potential Outcome	Occurrence	Current Protection	Detection	RPN	Recommended Actions	Concentrators	Self-fill System	Gaseous Oxygen	Liquid Oxygen
Storage under stairs	Poor ventilation leading to oxygen enrichment if leaks occur Poorly lit	2	Oxygen enrichment Increased risk in case of fire Trip, slips & falls	2	Review storage areas with sufficient ventilation	1	4		✓	✓	✓	✓
Storage in basements	Poor ventilation leading to oxygen enrichment if leaks occur Poorly lit	2	Oxygen enrichment Increased risk in case of fire Trip, slips & falls. Dropping of containers.	2	Review storage areas with sufficient ventilation	1	4		✓	✓	✓	✓
Poor access to storage areas	Difficult to handle the equipment/containers	2	Slips and trips etc. Risk to empty the container due to not in time change-out Dropping of containers	3	Review alternative storage areas or install smaller units	1	6		✓	✓	✓	✓
Limited room in storage area	Difficult to access	2	Slips and trips etc. Risk to empty the container due to not in time change-out Dropping of containers	3	Review alternative storage areas or install smaller units	1	6		✓	✓	✓	✓
Other Products Stored Near Therapy Equipment / Containers												
Other gases e.g. LPG, Propane	Leaks from these gas containers	4	Increased risk in case of fire	2	Have these gas containers in a separate compartment.	1	8	To recommend a min. distance between these gases and oxygen equipment Be extra careful with LOX installation due to its normal function of venting periodically.	✓	✓	✓	✓
Tins of oils & greases, oil based paints, varnish Flammable products e.g. solvents.	Oils grease and solvents coming into contact with pure oxygen	4	Self-ignition leading to explosion	2	Review storage areas / advise not to store with oils and grease etc.	1	8		✓	✓	✓	✓

Homecare Patient Environment Risk Assessment Oxygen Therapy												
Potential Risk	Potential Effect of Risk	Severity	Potential Outcome	Occurrence	Current Protection	Detection	RPN	Recommended Actions	Concentrators	Self-fill System	Gaseous Oxygen	Liquid Oxygen
Open fire, candles or stove or electric heater	Heating of the oxygen source	5	Increased risk in case of fire	2	Recommended distance of 3m to open fires and 1.5 m to closed fires.	1	10		✓	✓	✓	✓
Absorbent furniture in the vicinity	Oxygen enrichment	4	Increased risk in case of fire	3	Currently no specific instructions given	1	12	To recommend a min. distance	✓	✓	✓	✓
Curtains in the vicinity	Oxygen enrichment	4	Increased risk in case of fire	3	Currently no specific instructions given	1	12	To recommend a min. distance	✓	✓	✓	✓
Water tanks or water reservoirs in the vicinity	Damage to the electric parts of the equipment Electrocution	3	Short circuit No functioning of the equipment	3	Instructions to avoid liquids in the vicinity	1	9		✓	✓	✓	✓
Types of Room where Therapy Equipment Used												
Garage, workshop	Oils grease and solvents coming into contact. Presence of oxy-acetylene kit. Potential presence of sparks Much dust, debris Damage when parking vehicles	5	Ignition leading to explosion Damage. Stability of container / fall over. Unsafe path for the tubing.	2	Review storage areas / advise not to store with oils and grease etc.	1	10	To recommend to not use oxygen therapy when welding and grinding	✓	✓	✓	✓
Kitchen	Oils, grease coming into contact. Presence of propane, electric appliances, open fire	5	Ignition leading to explosion Damage. Stability of container / fall over. Unsafe path for the tubing.	3	Best practice is not to install the oxygen therapy equipment in the kitchen	2	30	To recommend the same distance between container or concentrator as for open and closed fires (this distance does not apply to the nasal cannula)	✓	✓	✓	✓

Homecare Patient Environment Risk Assessment Oxygen Therapy												
Potential Risk	Potential Effect of Risk	Severity	Potential Outcome	Occurrence	Current Protection	Detection	RPN	Recommended Actions	Concentrators	Self-fill System	Gaseous Oxygen	Liquid Oxygen
Living room Bedroom	Furniture, open fires, etc.	3	Oxygen enrichment Dropping of room temperature when using LOX	4	Combination of most precautions given in this table	1	12		✓	✓	✓	✓
Bathroom	Water splash	3	Short circuit No functioning of the equipment	2	Best practice is not to install the oxygen therapy equipment in the bathroom	2	12		✓	✓	✓	✓
Upstairs, downstairs	Kinking of tubing	2	Not correct flow Water condensation Slips and trips over the tubing Unsafe path for the tubing. Disconnection of tubing.	3	Install purpose build tubing on the wall Fit humidifier & flow meter close to patient Use anti-collapse tubing	1	6		✓	✓	✓	✓
Balcony	Kinking of tubing Rain, birds, animals, vandalism	2	No or incorrect functioning of the equipment Damage. Disconnection of tubing.	2	Take precautions against Kinking of tubing Rain, birds, animals, vandalism	1	4		✓	✓	✓	✓
Apartment or fully attached house	Presence of many people	2	As result of a fire, adjacent buildings may catch fire. Interference of other people to the equipment	4	Currently no specific instructions given	1	8	To recommend to never install oxygen equipment in common areas	✓	✓	✓	✓

Homecare Patient Environment Risk Assessment Oxygen Therapy												
Potential Risk	Potential Effect of Risk	Severity	Potential Outcome	Occurrence	Current Protection	Detection	RPN	Recommended Actions	Concentrators	Self-fill System	Gaseous Oxygen	Liquid Oxygen
Hygiene situation of the room	Infection for patient, carer, installer & workshop technician from equipment surface contamination	2	Patient is not taking care of the continuous cleanliness of the equipment	4	Training and reminding of the patient & carer (i.e. Specific, clear instructions). Technician has gloves and cleaning agent available In case of no improvement by the patient, the equipment may be withdrawn (after consultation with responsible of prescription)	2	16		✓	✓	✓	✓
Area where the equipment is installed is far away from the user	Kinking of tubing	3	Not correct flow Water condensation Slips and trips over the tubing	3	Install purpose build tubing on the wall Fit humidifier & flow meter close to patient Use anti-collapse tubing	1	9		✓	✓	✓	✓
Room Flooring												
Level of floor Steps	Unlevelled, steps	3	Slips, trips & falls Stability of container Difficult/dangerous handling conditions. Disconnection.	3	Provide trolley or other handling tools Provide smaller/lighter oxygen source equipment Train/warn patients	1	9		✓	✓	✓	✓
Carpet, cork wooden floor linoleum and similar	Porosity Softness of the underground	4	Spillage, damage, oxygen enrichment	4	Ensure for sufficient ventilation Precautions/means (e.g. the rolling base) to prevent that the floor is damaged by the container's weight.	2	32		✓	✓	✓	✓

Homecare Patient Environment Risk Assessment Oxygen Therapy												
Potential Risk	Potential Effect of Risk	Severity	Potential Outcome	Occurrence	Current Protection	Detection	RPN	Recommended Actions	Concentrators	Self-fill System	Gaseous Oxygen	Liquid Oxygen
Tiles and similar	Finish of the surface	2	Damage e.g. cracks	4	Precautions/measures (e.g. the rolling base) to prevent that the floor is damaged by the container's weight.	1	8		✓	✓	✓	✓
Supply Method and Requirements												
Static installation of the oxygen source	Cleanliness of the equipment Source equipment or containers take up space	2	Accumulation of dust/dirt Access and handling problems	3	Patient training on hygiene Provide trolleys/roller base	2	12		✓	✓	✓	✓
Need to move the supply system	Restricted space for movement	3	Slips, trips and falls. Dropping of equipment/container	3	Patient training Provide trolleys/roller base	2	18		✓	✓	✓	✓
Need for multiple outlet points Need for multiple units connected together	Disconnected tubing Leakages Ensure positive closure of unused outlets Oxygen compatibility of all installation components	2	Incorrect or stop of flow Oxygen enrichment from the leak	3	Use wall-outlet with quick connector or shut-off valve All installation components to meet medical devices directive	1	6	To recommend to technician to verify leak tightness of tubing installation	✓	✓	✓	✓
Location of multiple outlet points	Vicinity to combustibles Leakages	4	Oxygen enrichment	2	Follow instructions for installer	1	8	To recommend to technician to verify leak tightness of tubing installation	✓	✓	✓	✓
Electric supply needed	Condition of the electric socket	4	Electrocution	2	Warn the patient of the risk Use the power cord delivered with the equipment	1	8		✓	✓	✓	✓

Note: 'container' indicates high pressure gas cylinder for stationary and portable use or portable liquid container

Note: some stationary units may have telemetry or heated humidifier that is with electric power

Appendix 10 – RISK ASSESSMENT CHECKLIST

HOMECARE INSTALLATION RISK ASSESSMENT CHECKLIST				
Patient's Address				
Patient's Name			Installation Date	
Installation Type	Concentrator <input type="checkbox"/>	Liquid systems <input type="checkbox"/>	Gas Cylinders <input type="checkbox"/>	Ambulatory Cylinders <input type="checkbox"/>
	Portable conc concentrator		Self-fill system	Pipeline <input type="checkbox"/>
Potential Risks				Observations / Recommendations
Property Access Profile			Yes	No
No suitable vehicle parking / Poor access/ surface condition to property / tarmac				
Steep / Narrow / Spiral / Limited use stairs to property / No guard rail				
Access to property using lift				
Unsafe area (risk for technician)				
Patient / Carer Profile				
Patient / Carer does not understand how to operate equipment/other language				
Patient / Carer not able to operate equipment				
Patient / Carer smokes				
Patient using other equipment in combination with oxygen therapy equipment				
Patient, carer or pets shows aggressive behaviour				
Hygienic risks (pets, contamination, ...)				
Usage Area Profile (for Equipment)				
Equipment required to be used in more than one location / needs to be mobile				
Equipment used in workshop / garage				
Equipment used in kitchen				
Equipment used within 1.5 metres of mains electrical appliances				
Equipment used within 3 metres of open flame				
Usage area not adequately ventilated and or maintained clean and suitable				
Usage area floor: carpet / linoleum / cork / other adsorbent material				
Pets interference with equipment				
Storage Area Profile (for Cylinders / Containers)				
Storage in garage / workshop / basement				
Storage in cupboard / basement / poorly ventilated area				
Stored within 1.5 metres of oils and grease / LPG / paints / flammable materials				
Stored within 3 metres of open flame				
Installer's Comments / Other Concerns or Potential Risks				
Installer's Name / Signature			Date	
Company Internal Comments / Actions				

Company Internal Name / Signature		Date	
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