MEDICAL OXYGEN SYSTEMS
FOR HOMECARE SUPPLY
TD 36 /19 / E
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1 Introduction

Medical Oxygen is extensively used to supply additional oxygen to patients who suffer from respiratory disorders to compensate for the malfunction of their lungs. It is the responsibility of the homecare service provider to ensure that the Medical Oxygen systems they supply to patients, when used as recommended, provides a safe supply of oxygen for breathing therapy to the patient, as prescribed by their doctor.

This publication provides advice to the oxygen healthcare service provider on the installation, use and maintenance of equipment used for respiratory care. It specifies the need to provide adequate training to the patient or user to ensure that they are not subjected to undue risks from the use of oxygen for respiratory care.

In addition it also provides a number of simple guides for the homecare service provider to give to the patient and to help with their training to emphasise the safety issues surrounding Medical Oxygen supplies, both in the home and in healthcare facilities.

Medical Oxygen is classified as a medicinal product and its use is always prescribed by a doctor. The equipment used with Medical Oxygen therapy shall be CE or CE or FCC (The Federal Communications Commission in the US) marked, which indicates that it complies with the requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1] (this requirement only applies to medical devices that have been purchased after the 14th June 1998).

When prescribing Medical Oxygen to their patients, the doctor may consider the method of supplying oxygen to the patient. It is the homecare service provider’s responsibility to ensure that the specific prescription conditions are provided to the patient and changes to the prescription are only authorised by the patient's doctor. This is achieved by ensuring that only trained and qualified staff are used and that the correct advice is given to the patient.

Within this publication the term ‘Medical Oxygen’ has been used to describe the oxygen gas administered to the patient, as prescribed by their doctor. It includes:

- Medical Oxygen, supplied as a medicinal product under a marketing authorisation (MA) (issued by the national regulatory authority), compliant with the European Pharmacopoeia or US Pharmacopoeia specification for Medical Oxygen. This covers oxygen that is supplied as a compressed gas in cylinders or cryogenic liquid supplied in cryogenic containers, specified in the MA.
- Oxygen (nominally at 93%), produced from an oxygen concentrator, which has been CE or FCC marked to the medical device directive (MDD) [1]. It also relates to the oxygen filled into cylinders using a CE or FCC marked self-fill oxygen concentrator.

2 Scope and Purpose

2.1 Scope

This publication applies to the supply of Medical Oxygen supplied by homecare service providers using:

- compressed gas cylinders;
- transportable vacuum insulated cryogenic containers;
- oxygen concentrators, and
- oxygen cylinder filling system, (self-fill system)

References are shown by bracketed numbers and are listed in order of appearance in the reference section
The advice covers both the supply of Medical Oxygen to healthcare facilities and to patient’s homes and applies to the supply of the gas and the ancillary therapy equipment to the patient.

2.2 Purpose

This publication describes how the homecare service provider can provide a safe system for the use and handling of Medical Oxygen therapy supply systems. It describes the recommended precautions and safety procedures to be followed when Medical Oxygen 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 Medical Oxygen but does not cover all of the relevant applicable national regulations that could apply in some countries.

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

- Hazards associated with the supply of Medical Oxygen;
- Minimum operational characteristics of the Medical Oxygen supply equipment;
- Environment risk assessment by the operator at the patient’s home;
- Precautions to be observed whilst using the Medical Oxygen equipment, and
- Safe use of Medical Oxygen 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 Medical Oxygen equipment.

The instruction cards for each method of supply of Medical Oxygen 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 Medical Oxygen equipment and providing safety information on the safe use of the product within the domiciliary environment. It is intended that the card will be left with the patient/healthcare facility as a detailed instruction card to be referred to when specific issues are raised concerning the safe use and storage of the equipment.
- A patient user instruction card to be used by the patient/healthcare facility as a quick reference guide on the safe use and operation of the equipment.

It may be appropriate for these cards to be adapted to reflect the specific equipment supplied by an individual homecare service providers.

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

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.

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.

5 General hazards and safety precautions with oxygen therapy supply systems

There are a number of precautions that shall be observed with Medical Oxygen irrespective of the method of supply. When making the initial supply of Medical Oxygen, advice shall be given to the patient / carer or healthcare facility to explain the general hazards when using Medical Oxygen and shall include the following information:
• Materials that burn in air will burn much more vigorously in oxygen and burn at a higher temperature in an oxygen or oxygen-enriched atmosphere.
• Most serious incidents involving the use of Medical Oxygen are caused by the patient smoking.

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

• Never smoke whilst using their Medical Oxygen equipment;
• Never allow any other person to smoke in the vicinity of the patient using their Medical Oxygen;
• Keep sources of ignition away from areas where Medical Oxygen is used or stored, and
• 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 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 Medical Oxygen equipment with clean hands and tools and to keep the oxygen equipment clean and free from any oils or grease.
• Where the patient requires to use a moisturiser or cream to prevent their nostrils from drying out to only use approved products that are suitable for use with Medical Oxygen.

Absorbent materials, such as clothing or bedding, when saturated with oxygen, will readily ignite. 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, the bag shall be specifically designed for the Medical Oxygen container and be made from appropriate material and provide adequate ventilation. The design shall allow any oxygen that leaks out of the container to escape to reduce the possibility of oxygen enrichment.
• To prevent any unnecessary enrichment of the air, it is important that patients / carers / healthcare facility staff are instructed that the oxygen system must be turned off when not in use.

Only trained persons shall be allowed to operate the Medical Oxygen equipment. Care needs to be taken to ensure that children are not allowed to tamper with the equipment.
The total length of flexible unsupported 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. In addition, care is needed to prevent the kinking of the tube to prevent restrictions in the flow.

5.1 Hazards with compressed oxygen

There are a number of specific hazards with the supply of Medical Oxygen in gas cylinders. These hazards relate to the fact that the gas is stored at high pressures 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 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.

5.2 Hazards with liquid oxygen

The specific hazards relating to supplying patients with Medical Oxygen in liquid form relate to the temperature of the liquid and the need to ensure that appropriate precautions are taken concerning cold temperatures when handling the equipment.

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

- Liquid oxygen is extremely cold and boils at -183.0 °C at atmospheric pressure.

- Touching 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 come in contact with 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. 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.

- The density of the low temperature gas vented from a liquid cylinder is heavier than air and will accumulate in low lying areas if not adequately ventilated.

### 5.3 Hazards with oxygen concentrators

As the oxygen concentrator is supplying Medical 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 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:

- 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 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 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 oxygen concentrators should also be followed.

5.5 Transfilling hazards

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 not permitted.

As liquid oxygen is at a lower pressure than compressed oxygen, the risks associated with transfilling liquid oxygen are significantly lower, with the main risk being 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 large spillages of oxygen are avoided, and
• When transfilling liquid oxygen from one container to another, care is taken to ensure that all connections are clean and that leaks do not occur.

6 Initial set up of the oxygen therapy supply system

The homecare service provider is responsible for:

• Providing a safe and reliable source of Medical Oxygen;
• Ensuring that equipment is correctly installed at the patient’s home;
• Instructing the patient or carer at home on how to use the equipment correctly at the flowrate prescribed by their doctor, and
• Giving advice to the healthcare facility staff on how to correctly set-up the equipment.

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 shortfalls.

6.1 Initial setting up of domiciliary patients for Medical 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 given 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 given in pictorial format for ease of understanding. Both the use of the equipment to provide the oxygen supply safely and any routine responsibilities for the patient / carer to maintain the equipment in an appropriate condition shall be covered by these instructions.
• The patient / carer has been adequately trained by the homecare service provider to ensure that they know how to use their equipment effectively and safely.
• A formal assessment programme 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 Medical Oxygen to minimise any risks.
• The total length of flexible unsupported 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. It may appropriate to fix the tubing between the supply source and fixed outlet
points, which incorporate an isolation valve, to prevent the tubing from being trapped and restricting oxygen flow.

- Consideration has been given to providing the patient / carer with a draft letter which they could send to their own insurance company informing them of the presence of Medical Oxygen 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 to inform of any 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 set up, 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 Medical Oxygen to the healthcare facility, it is essential that the homecare service provider has carried out the following actions to ensure that:

- Instruction manuals have been supplied to the healthcare facility providing detailed procedures on how to use the equipment both effectively and safely. The instructions shall cover both the use of the equipment to provide the oxygen supply safely and any routine responsibilities for the healthcare facility to maintain the equipment in an appropriate condition.

- Consideration is given to providing instructions in pictorial format for ease of training of the healthcare facility’s staff and their patients/carers.

- 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.

- Advice has been given on the best location for the storage and use of the Medical Oxygen supply systems to minimise any risks.
• A contact number has been given that the healthcare facility may use at any time (365 days per year / 24 hours per day) to inform the homecare service provider of the need to re-supply Medical Oxygen or of any problems with the equipment.

6.3 Homecare environment risk assessment at the patient’s home

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 prior to the initial installation of the equipment. Appendix 10 shows a typical risk assessment checklist, which lists the most of the common potential risks the homecare service provider, should check for prior to making the initial installation.

The checklist should 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. The checklist identifies the most common risks associated with the installation of Medical Oxygen systems in the patient’s home. The technician should also document other potentials risks identified when carrying out the risk assessment.

The risk assessment checklist addresses the potential risks associated with:

• Access to the home;
• The profile of the patient and carer;
• The environment in which the equipment will be used, and
• The environment where the cylinders or containers will be stored.

The risk assessment checklist should be completed by the homecare service provider technician prior to the initial installation of the therapy equipment at the patient’s home. (Sections of this checklist which could be in conflict with a local/national privacy act, may be hidden as appropriate). The risk assessment should be reviewed at regular intervals to ensure that there have been no adverse changes to the environment where the equipment is being used or stored.

The completed risk assessment checklist should be reviewed internally in the company to ensure that the appropriate actions have been taken to address or mitigate satisfactory the identified risk. The risk assessment checklist shall be retained by the homecare service provider.

Appendix 9 shows a completed Failure Mode and Effects Analysis (FMEA) study, which was used to develop the 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. The FMEA study identifies the specific risks associated with each of the three modes of supply.

The 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 Medical Oxygen incidents

Following installation of the Medical 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 gas 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 adequately trained and warned about the potential hazards of using Medical 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 Medical Oxygen are caused by the patient smoking.

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

- Initially contact the fire brigade, ensuring they are informed that a Medical 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
- To 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 Medical 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 the Medical Oxygen concentrators running hotter than usual, the patient / carer / healthcare facility shall be advised to isolate the equipment at the mains supply and inform the homecare service provider immediately. Where it is essential for the patient to receive oxygen they 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 Medical 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.

Should any part of the Medical 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 Medical 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 Medical 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 Medical Oxygen therapy equipment must comply with the essential requirements of the medical device directive [1]. These accessories shall be made from biocompatible materials, compatible with oxygen and free of any allergenic substances. If the patient has any specific requirements with respect to material allergies, the homecare service provider shall be instructed of their specific needs by the patient's doctor. Only connectors, tubes, nasal cannulas, probes or masks designed for use with Medical 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 of after the patient has finished using them 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 Medical 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.

The use of certain replacement spare parts which are not originally specified for use with the Medical Oxygen therapy equipment may reduce the performance of the equipment.

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.
8.4 Patient / carer / healthcare facility maintenance responsibilities

Apart from changing filters or breathing circuit components, Medical 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, including the changing of ‘O’ rings and sealing washers on regulators and flowmeters.

The patient / carer / healthcare facility staff are only 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 Medical 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 Medical Oxygen cylinder therapy supply

Medical Oxygen cylinders are normally used either as a back-up supply for a concentrator system or for ambulatory use. They 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 integral cylinder valve that has the pressure regulator built into it.

Where patients require mobility and their flow requirements are relatively low, it is appropriate to supply them with high pressure lightweight cylinders. This type of package can be supplied with a conserving device, which extends the use of the oxygen in the cylinder.

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.

When installing an oxygen cylinder system at a new patient, the entire Medical 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 could 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 lead to poor stock rotation and 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.

Where liquid oxygen containers are required to be stored with compressed gas cylinders, they may be stored together in the same storage area provided that the requirements are complied with for both types of storage facility.

9.1.1 Storage of Medical Oxygen cylinders at the healthcare facility

Advice shall be given to ensure that purpose built medical gas cylinders stores in healthcare facilities 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 store, 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.

9.1.2 Storage of oxygen cylinders at the patient’s home

Advice shall be given to ensure that oxygen cylinders stored at the patient’s home are:

- Kept to a minimum in the patient’s home, ensuring that sufficient product is available depending on patient use and delivery frequency.
- Stored in a secure location, where they will not be tampered with by unauthorised persons and not subject to theft. and
- Where significant number of cylinders are required for use by high demand patients, the bulk of the cylinders are preferably stored outside, under cover where possible, and not subjected to extremes of heat.
For the storage of spare cylinders, stored inside the patient’s home, the patient / carer shall be advised to:

- Keep cylinder stocks to a practical minimum.
- Where possible, store cylinders in well ventilated areas and not stored in a confined space or cupboards.
- Store cylinders away from fires and naked lights and not allow smoking near cylinders (either in use or in storage areas).
- Not store cylinders in kitchens or garage areas, where there is a possibility of being contaminated with oils or greases.
- Where possible store cylinders near an exit, taking care that they do not block the exit.
- Secure larger cylinders to prevent them falling over.
- Store small portable 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, 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 are clean and any ‘O’ ring or sealing washer is 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 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, 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 gas 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 gas 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.

9.3.4 After use

The patient / carer / healthcare facility staff shall be advised to not empty the cylinders below the 'residual' pressure level, as indicated on the cylinder contents gauge. It is the homecare service provider's responsibility to instruct the patient or healthcare facilities staff the appropriate residual pressure level when the cylinders should be exchanged.

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

• Close the cylinder valve, 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.

If any leak occurs between the valve and cylinder or from the valve spindle or handwheel, provided it is safe to do so, the valve shall be closed immediately and the homecare service provider informed.
For cylinders not fitted with integral valves, if a leak occurs between the cylinder valve and the equipment, the patient/user/healthcare facility staff shall be instructed not to rectify whilst the equipment is still under pressure.

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.
- 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 inspect the condition of the ‘O’ ring or sealing washer.
- If the ‘O’ ring or sealing washer is showing signs of wear or damage, either inform the homecare service provider or the authorised person. Only authorised persons shall be permitted to replace the seal.
- Reconnect the equipment using only moderate force and recheck for leaks.
- Never use sealing tape or jointing compounds to cure any leaks.
- 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 their own 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 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 provided that 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.

For most systems, the portable unit is intended to be 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. Under normal use, the rate of use by the patient will exceed the natural evaporation of oxygen caused by the heat inleak. When the gas 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 supplying the liquid oxygen 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 potential of any incident that may occur on site. The homecare service provider is responsible for setting the 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 metres 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 metres 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.
- Allow air to circulate around the liquid oxygen containers at all times to prevent any significant oxygen enrichment in the vicinity.
- Never store liquid oxygen equipment in small and closed areas such as cupboards or unventilated rooms.

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2 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]

3 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]
• Never place any form of cover over liquid oxygen equipment, as this will restrict ventilation.

• Never drape clothing or any other material over the liquid oxygen container, as it may become oxygen enriched and burn vigorously if ignited.

• Never carry or use the portable unit under any clothing to prevent the clothing from becoming oxygen enriched.

When planning the liquid oxygen container storage in a healthcare facility, in addition to the above they shall be advised to:

• Design the store to prevent unauthorised entry; and

• Provide warning notices prohibiting smoking and naked flames within the vicinity of the store.

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, 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.

A copy of the written procedure, including filling of the portable container shall be provided 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 container 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.

When handling liquid oxygen containers, advice shall be given to the healthcare facility to 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 gas to the patient.
• The manufacturer’s filling instructions are always followed when the portable unit is filled from the base unit.
• A safe location is always selected for transfilling of the medical liquid oxygen and that care is taken where transfilling is carried out on an adsorbent surface, such as a carpet, to ensure that the area is well ventilated to prevent the surface becoming enriched with oxygen in the unlikely event of a spillage.
• Transfilling is never be carried out on an asphalt surface.
• The filling connectors on both containers are be 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 cured.
• If a major liquid oxygen leak 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.
10.3 Operation and use of medical liquid oxygen containers

Advise shall be given to all domiciliary patients/carers and healthcare facility staff to ensure that:

- 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 that hands are clean before handling any of the Medical Oxygen equipment. It is essential that hands are washed before handling any Medical Oxygen delivery equipment if hand creams have been 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 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 (unless the unit is designed to be used in other orientations) 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 in order 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 charge is dependent on environmental factors such as temperature and for example battery life is shortened in cold weather.

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 a consequence, the homecare service provider should ensure that for those patients at home that require a continuous supply of oxygen should be provided with a service that ensures adequate oxygen is made available in the event of a failure of the unit or power supply.
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.

- **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, volumes of oxygen are lower than stationary concentrator as they are smaller (continuous flow) and with an average mobility around 3-4 hours / day outside their home.

- **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 to produce and provide oxygen even without a direct connection on the electric network. Volumes of oxygen are lower than stationary concentrator and transportable concentrator as they are smaller and with an average mobility around 3-4 hours / day outside their home.

### 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 and 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 at least 3 metres away from all naked flames.
- Keep the concentrator at least 1.5 metres away from other heat sources and electrical appliances.
- 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.

In addition consideration is needed to determine the location of any backup cylinders provided to the patient for use in the event of a concentrator failure. The general principles for the storage and use of Medical Oxygen cylinders are given in 9.1.2.

Where the patient requires a flowrate that exceeds the output from one Medical Oxygen concentrator, the healthcare 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. 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 backfeeding 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 Medical Oxygen within the home environment. The homecare service provider shall handover a copy of the manufacturer’s user’s manual 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 and it is filled, as defined in the humidifier instructions, and refitted to the concentrator.

• All of the equipment has been connected correctly so as 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 gas to the patient.
12 Oxygen self-fill systems

Oxygen self-fill systems are used for both supplying Medical Oxygen to the patient and allowing the patient / carer / healthcare facility staff to fill their own Medical Oxygen high pressure gas cylinders. This method of supply should only be used where a specific risk assessment has been conducted and there is confirmation that the patient / 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.

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 presents 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, 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 gas 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:
  o no tools are used when disconnecting the cylinder
  o two hands are used when handling cylinders
  o 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:
  o never be transported with a cylinder connected
  o never be moved whilst a cylinder is being filled
  o 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 CE marked 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 has 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.

### 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 healthcare 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.

2. European Agreement on the Carriage of Dangerous Goods Regulations (ADR) [www.unece.org](http://www.unece.org)

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

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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

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<table>
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<tr>
<td><strong>1</strong></td>
<td>Read the <strong>User Instruction Manual</strong> carefully before operating your medical oxygen cylinder and equipment. Pay special attention to information where the hazard symbol is shown.</td>
<td><strong>3</strong></td>
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<tr>
<td><strong>4</strong></td>
<td><em>Never</em> place your oxygen cylinders near curtains or cover them with clothing as this will restrict air circulation. Materials become <em>oxygen enriched</em> if any leak occurs with no ventilation. <em>Never</em> use or carry the portable oxygen container under any</td>
<td><strong>5</strong></td>
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<td><strong>7</strong></td>
<td>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.</td>
<td><strong>8</strong></td>
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<td><strong>10</strong></td>
<td>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.</td>
<td><strong>11</strong></td>
</tr>
<tr>
<td><strong>13</strong></td>
<td>Only use a clean damp cloth if it is necessary to clean your oxygen cylinder or any associated equipment. <em>Only</em> use mild non-abrasive cleaning materials. Allow the cylinder to dry after wiping down.</td>
<td><strong>14</strong></td>
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<tr>
<td><strong>15</strong></td>
<td>If your cylinder or regulator fails for any reason call your service provider immediately. <em>Never</em> try and repair any fault unless specifically instructed by your service provider.</td>
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## Appendix 2 - PATIENT USER INSTRUCTION CARD – USE OF MEDICAL OXYGEN CYLINDERS IN THE HOME

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<td>1</td>
<td>Always read instructions</td>
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<tr>
<td>2</td>
<td>No smoking No naked flames</td>
<td>Use in a ventilated area</td>
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<td>3</td>
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<tr>
<td>4</td>
<td>Avoid oxygen enrichment</td>
<td></td>
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<tr>
<td>5</td>
<td>Secure cylinders upright or lay down</td>
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</tr>
<tr>
<td>6</td>
<td>Never use oil or grease</td>
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<tr>
<td>7</td>
<td>Connect oxygen tubing</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Open valve slowly</td>
<td></td>
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<tr>
<td>9</td>
<td>Adjust flowrate as prescribed</td>
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</tr>
<tr>
<td>10</td>
<td>Check for flow</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Check cylinder contents</td>
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<tr>
<td>12</td>
<td>Do not use excessive force</td>
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</tr>
<tr>
<td>13</td>
<td>Only clean with a damp cloth</td>
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<tr>
<td>14</td>
<td>Close valve after use</td>
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<tr>
<td>15</td>
<td>Phone for assistance if required</td>
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</table>
Appendix 3 - PATIENT USER TRAINING CARD – USE OF MEDICAL LIQUID OXYGEN CONTAINERS IN THE HOME

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.

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.

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.

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 circumstances.

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.

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 liquid oxygen container.

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.

8. To turn on your liquid oxygen container, turn the oxygen flow control valve clockwise.

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.

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.

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.

12. Never touch any cold parts 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.

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.

14. Select zero on the oxygen flow control valve after use. Keep closed when the liquid oxygen container is not in use.

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

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<td><strong>1</strong></td>
<td><strong>2</strong></td>
<td><strong>3</strong></td>
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</table>
| **Always read instructions** | **No smoking**  
**No naked flames** | **Use in a ventilated area** |
| **4** | **5** | **6** |
| **Avoid oxygen enrichment**  
**Open** | **Keep upright**  
| **Never use oil or grease**  |
| **7** | **8** | **9** |
| **Connect oxygen tubing**  
**15 metres max.** | **Open**  
**flow**  
**control valve** | **Adjust flowrate**  
**as prescribed** |
| **10** | **11** | **12** |
| **Check for flow**  
**Stay whilst transfilling** | **Do not touch cold parts** |
| **13** | **14** | **15** |
| **Only clean with a damp cloth**  
**Zero flow after use** | **Select**  
**Phone for assistance if required** |
### Appendix 5 - PATIENT USER TRAINING CARD – USE OF MEDICAL OXYGEN CONCENTRATOR IN THE HOME

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<tbody>
<tr>
<td><strong>1</strong></td>
<td>Read the User Instruction Manual carefully before operating your oxygen concentrator and equipment. Pay special attention to Information where the hazard symbol is shown.</td>
</tr>
<tr>
<td><strong>2</strong></td>
<td>Materials burn much more vigorously in oxygen than air. <em>Never smoke</em> (or let someone else smoke near you) whilst using your oxygen concentrator. <em>Do not use</em> your concentrator near open fires or naked flames.</td>
</tr>
<tr>
<td><strong>3</strong></td>
<td>Only use your oxygen concentrator and equipment in a well ventilated area. Keep internal doors open whilst your oxygen concentrator is in use.</td>
</tr>
<tr>
<td><strong>4</strong></td>
<td><em>Never</em> place your oxygen concentrator near curtains or cover it with clothing as this will restrict air circulation. Materials become <em>oxygen enriched</em> if any leak occurs with no ventilation.</td>
</tr>
<tr>
<td><strong>5</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>6</strong></td>
<td><em>Do not</em> use oils or grease with your oxygen concentrator. Ensure your hands are <em>clean</em> when handling your oxygen equipment. Only use authorised face creams and moisturisers when using your Medical Oxygen.</td>
</tr>
<tr>
<td><strong>7</strong></td>
<td>Attach the oxygen tubing to the outlet connector on the oxygen concentrator. Ensure that the length of the tubing does not exceed 15 metres.</td>
</tr>
<tr>
<td><strong>8</strong></td>
<td>Connect your oxygen concentrator to the electrical supply and switch on. <em>Never</em> use extension leads to connect your concentrator unless instructed by your service provider.</td>
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<tr>
<td><strong>9</strong></td>
<td>Set the flow control valve to the flowrate or setting prescribed by your Doctor. Check for any leaks on the tubing connection before use.</td>
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<tr>
<td><strong>10</strong></td>
<td>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.</td>
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<tr>
<td><strong>11</strong></td>
<td>Regularly clean the air inlet filter as instructed in the user instruction manual. Ensure that the filter is <em>dried</em> before replacement. <em>Switch off</em> and isolate your medical oxygen concentrator from the mains supply when replacing the filter.</td>
</tr>
<tr>
<td><strong>12</strong></td>
<td><em>Never</em> open or remove the concentrator cover at any time. Do not use extension cables unless instructed. <em>Only</em> authorised personnel should carry out any repairs on your oxygen concentrator.</td>
</tr>
<tr>
<td><strong>13</strong></td>
<td>Use only a clean damp cloth to clean your oxygen concentrator or any associated equipment. <em>Only</em> use mild non-abrasive cleaning materials. Allow the oxygen concentrator to dry after wiping down before using.</td>
</tr>
<tr>
<td><strong>14</strong></td>
<td><em>Switch off</em> your medical oxygen concentrator after use. <em>Never</em> leave you Medical Oxygen concentrator running when it is not in use.</td>
</tr>
<tr>
<td><strong>15</strong></td>
<td>If your oxygen concentrator fails for any reason call your service provider immediately. <em>Never</em> try and repair any fault unless specifically instructed by your Service Provider.</td>
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### Appendix 6 - PATIENT USER INSTRUCTION CARD – USE OF MEDICAL OXYGEN CONCENTRATOR IN THE HOME

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

<p>| | | | |</p>
<table>
<thead>
<tr>
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</tr>
</thead>
</table>
| 1 | Always read instructions | ![Warning Symbol] Only use cylinders provided with self-fill system | ![No Smoking Symbol] No Smoking  
|   | ![Man Reading Symbol] | ![Warning Symbol] | ![No Naked Flames Symbol] No naked flames |
| 4 | ![No Oil Symbol] Never use oil or grease | ![Warning Symbol] Keep away from electrical equipment | ![No Oxygen Enrichment Symbol] Avoid oxygen enrichment |
|   | ![Flowrate Symbol] | ![Warning Symbol] Do not move with cylinder attached | ![Connect Securely Symbol] Connect cylinder securely |
| 10 | ![Connect Tubing Symbol] Connect tubing. | ![Turn Symbol] Turn | ![Check for Leaks Symbol] Check for leaks when filling |
|   | ![Check for Leaks Symbol] Check for leaks | ![Check Symbol] Check | ![Valve Symbol] Open and close valve slowly |
| 13 | ![Clean Symbol] Only clean with a damp cloth | ![Clean Symbol] Keep filter clean | ![Phone Symbol] Phone for assistance if required |
| 15 | ![Clean Symbol] Phone for assistance if required | ![Clean Symbol] Phone for assistance if required | ![Clean Symbol] Phone for assistance if required |

- Adjust flowrate as prescribed.
- Connect tubing.
- Connect cylinder securely.
- Turn.
- Check.
- Only clean with a damp cloth.
- Keep filter clean.
- Phone for assistance if required.
## Appendix 9 – FMEA ANALYSIS - Homecare Patient Environment Risk Assessment

### Homecare Patient Environment Risk Assessment
**Oxygen Therapy**

<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Access to property – Delivering Product</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Parking vehicle to deliver product to patient</td>
<td>Too far away from property to carry safely</td>
<td>1</td>
<td>No suitable location near patient’s house</td>
<td>4</td>
<td>Use of trolley lightweight cylinders assistance</td>
<td>1</td>
<td>4</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Tarmac road surface (transfiling)</td>
<td>Oxygen venting on road surface</td>
<td>5</td>
<td>Oxygen saturation / fire</td>
<td>2</td>
<td>Use of protection plates</td>
<td>1</td>
<td>10</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steep slope for parking vehicle</td>
<td>Difficulty to unload vehicle / injury</td>
<td>3</td>
<td>Slips and trips etc. Stability of container</td>
<td>2</td>
<td>Type of mechanical aid to unload vehicle</td>
<td>1</td>
<td>6</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Poor ground / surface between parking space and property</td>
<td>Difficult to carry equipment into house</td>
<td>3</td>
<td>Slips and trips etc. Stability of container</td>
<td>2</td>
<td>Use of trolley with large wheels Assistance</td>
<td>1</td>
<td>6</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Steps up to the property</td>
<td>Difficult to carry equipment into house</td>
<td>3</td>
<td>Slips and trips etc. Stability of container</td>
<td>2</td>
<td>Use of trolley with large wheels assistance</td>
<td>1</td>
<td>6</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Stairs up to property / apartment building</td>
<td>Difficult to carry equipment into house</td>
<td>3</td>
<td>Slips and trips etc. Stability of container</td>
<td>2</td>
<td>Use of trolley with large wheels Strapping to trolley assistance</td>
<td>1</td>
<td>6</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Use of lifts to property</td>
<td>Venting in an enclosed space</td>
<td>4</td>
<td>Oxygen enrichment of clothing of a passenger</td>
<td>1</td>
<td>Vent before carrying in lift. Control of lifts: avoid passengers</td>
<td>3</td>
<td>12</td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Steep slope to the property</td>
<td>Difficult to carry equipment into house</td>
<td>3</td>
<td>Slips and trips etc. Stability of container</td>
<td>2</td>
<td>Use of trolley with large wheels assistance</td>
<td>1</td>
<td>6</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

### Patient Profile

| 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.                                                      | Patient creates unsafe situation with equipment.                                   | 4        | 3          | • Carer to assist with equipment.                                                    | 1   | 12                                                                 | ✓              | ✓               | ✓             |
|                                                                                | Unable to operate in an emergency                                                       |                                                    |          |            | • 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.                                       |     |                                                                     |                |                 |               |
| Patients with language / communication problems                                | Unable to understand the instructions for use and unable to communicate back            | Operate equipment incorrectly or explain problems                                   | 3        | 3          | Carer to assist with equipment.                                                    | 2   | 18                                                                 | ✓              | ✓               | ✓             |
|                                                                                |                                                                                        |                                                    |          |            | Use of sign languages / manuals in picture format                                   |     |                                                                     |                |                 |               |
| Poor housekeeping standards / cleanliness in house                               | Contamination of equipment Blockage of filters etc.                                     | Cross contamination to engineer Failure of equipment                                 | 2        | 3          | Training for cleanliness Carer to assist                                            | 2   | 12                                                                 | ✓              | ✓               | ✓             |
| Bed or chair ridden patients                                                    | Unable to move around house with oxygen supply                                         | Oxygen enrichment of bedding / clothing Potential fire risk                         | 2        | 4          | Training. Conserving device where possible. Carer to assist with equipment.         | 2   | 16                                                                 | ✓              | ✓               | ✓             |
| Smoker                                                                         | Smoking with oxygen                                                                     | Fire Burning around the mouth / nose area                                             | 5        | 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 & 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   |                                                                                       |               | ✓              | ✓              | ✓             |
| 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/m annual. Use the original adaptors. | 2          | 12  | Keep oxygen source 1.5 m from electric appliances.                                   |               | ✓              | ✓              | ✓             |
| Other Occupants / Animals |                                                                                               |          |                   |            |                    |           |     |                                                                                       |               |               |               |               |
| 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  |                                                                                       | ✓            | ✓              | ✓              | ✓             |
## Homecare Patient Environment Risk Assessment
### Oxygen Therapy

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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Animals</td>
<td>Interference / damage of the equipment – interruption of supply etc Problems to the installer.</td>
<td>Malfunction of equipment – leading to leaks, fire etc. Lack of correct hygiene of the equipment</td>
<td>Clear instructions to parents / patient. Special advice to installer</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

### Carers (with responsibility for patient)

| Elderly people | Don’t understand or cannot remember the instructions | Slow reaction in case of emergency Incorrect handling Incorrect adherence to prescription | Try to get other carers/neighbourhood involved Provide other means of handling, e.g. trolley Provide tele-survey & emergency tel. | | | | ✓ | ✓ | ✓ | ✓ |
| Physical disabled Low mobility | Possibly cannot move the equipment | Cannot change out the container Incorrect adherence to prescription Cannot react adequately in case of emergency | Try to get other carers/neighbourhood involved Provide other means of handling, e.g. trolley Provide tele-survey & emergency tel. | | | | ✓ | ✓ | ✓ | ✓ |
| With low mental capabilities | Cannot apply the therapy safely/adequately | Incorrect adherence to prescription Cannot react adequately in case of emergency | The service provider is not going to install the therapy | 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. | | | | ✓ | ✓ | ✓ | ✓ |
## Homecare Patient Environment Risk Assessment
### Oxygen Therapy

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</tr>
</thead>
<tbody>
<tr>
<td>With language/communication problems</td>
<td>Do not understand the instructions</td>
<td>Slow reaction in case of emergency</td>
<td>2</td>
<td>Try to get other carers/nearest neighbours involved. Provide telephone surveillance and emergency tel.</td>
<td>2</td>
<td>12</td>
<td>Develop instructions based on pictograms/symbols. Photos, video recommending to find another carer or social assistant. Contact a 'patient association' when available.</td>
<td>✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>&quot;Do-it-yourself&quot; carers</td>
<td>Modifications done to the installation and/or equipment</td>
<td>Malfunctioning of equipment. Injury. Damage.</td>
<td>2</td>
<td>Stress to these carers that no changes are allowed prior approval of the service provider. No technical changes are allowed at all.</td>
<td>3</td>
<td>18</td>
<td></td>
<td>✓ ✓ ✓ ✓</td>
</tr>
</tbody>
</table>

### Storage Facilities (for units not in use)

<p>| Product stored outside | Potential for vandalism / theft. Stored against flammable material. Animals present. | 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 | Fire leading to explosion | 2 | Advise patient of how / where to store safely. Limit stocks of containers. Review storage arrangements. | 1 | 10 | | ✓ ✓ ✓ ✓ |</p>
<table>
<thead>
<tr>
<th>Storage in Garage</th>
<th>Oils grease and solvents coming into contact. Presence of oxy-acetylene kit. Damage when parking vehicles</th>
<th>Self-ignition leading to explosion. Damage. Stability of container / fall over.</th>
<th>3</th>
<th>Review storage areas / advise not to store with oils and grease etc.</th>
<th>1</th>
<th>12</th>
<th></th>
<th>✓ ✓ ✓ ✓</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage in Workshop</td>
<td>Dust / chemicals / solvents etc. coming in contact with the containers. Presence of oxy-acetylene kit.</td>
<td>4 Self-ignition leading to explosion Damage. Stability of container / fall over.</td>
<td>3 Review storage areas / advise not to store with Dust / chemicals / solvents etc.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Storage in cupboards</td>
<td>Poor ventilation leading to oxygen enrichment if leaks occur. Storage of other materials such as solvents</td>
<td>4 Oxygen enrichment Potential fire Potential cooling affect from LOX container</td>
<td>3 Review storage areas with sufficient ventilation</td>
<td></td>
<td></td>
<td></td>
<td>✓ ✓ ✓ ✓</td>
<td>✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Storage in kitchens</td>
<td>Contamination with cooking oils etc. Presence of a naked flame / hot surfaces with cooker</td>
<td>4 Increased risk in case of fire</td>
<td>3 Review storage areas / advise not to store in the vicinity of cooking area</td>
<td></td>
<td></td>
<td></td>
<td>✓ ✓ ✓ ✓</td>
<td>✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Difficult access to container storage area</td>
<td>Tendency to store too many container in home and associated risks</td>
<td>2 Congestion / container falling etc. Large volume of oxygen stored.</td>
<td>3 Assign different storage location More frequent delivery Different mode of supply</td>
<td>To recommend a maximum number of containers to be kept in stock:</td>
<td>✓ ✓ ✓ ✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Storage under stairs</td>
<td>Poor ventilation leading to oxygen enrichment if leaks occur Poorly lit</td>
<td>2 Oxygen enrichment Increased risk in case of fire Trip, slips &amp; falls</td>
<td>2 Review storage areas with sufficient ventilation</td>
<td></td>
<td></td>
<td></td>
<td>✓ ✓ ✓ ✓</td>
<td></td>
</tr>
<tr>
<td>Storage in basements</td>
<td>Poor ventilation leading to oxygen enrichment if leaks occur Poorly lit</td>
<td>2 Oxygen enrichment Increased risk in case of fire Trip, slips &amp; falls. Dropping of containers.</td>
<td>2 Review storage areas with sufficient ventilation</td>
<td></td>
<td></td>
<td></td>
<td>✓ ✓ ✓ ✓</td>
<td></td>
</tr>
</tbody>
</table>
### Homecare Patient Environment Risk Assessment
**Oxygen Therapy**

<table>
<thead>
<tr>
<th>Potential Risk</th>
<th>Potential Effect of Risk</th>
<th>Severity</th>
<th>Potential Outcome</th>
<th>Occurrence</th>
<th>Current Protection</th>
<th>Detection</th>
<th>RPN</th>
<th>Recommended Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor access to storage areas</td>
<td>Difficult to handle the equipment/containers</td>
<td>2</td>
<td>Slips and trips etc.</td>
<td>3</td>
<td>Review alternative storage areas or install smaller units</td>
<td>1</td>
<td>6</td>
<td>✓ ✓ ✓ ✓</td>
</tr>
<tr>
<td>Limited room in storage area</td>
<td>Difficult to access</td>
<td>2</td>
<td>Slips and trips etc.</td>
<td>3</td>
<td>Review alternative storage areas or install smaller units</td>
<td>1</td>
<td>6</td>
<td>✓ ✓ ✓ ✓</td>
</tr>
</tbody>
</table>

**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 compartmen t. | 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 | ✓ ✓ ✓ ✓ |
| Open fire, candles or stove or electric heater | Heating of the oxygen source | 5 | Increased risk in case of fire | 2 | Recommen ded distance of 3m to open fires and 1.5 m to closed fires. | 1 | 10 | ✓ ✓ ✓ ✓ |
| Absorvent 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 |
## Homecare Patient Environment Risk Assessment
### Oxygen Therapy

<table>
<thead>
<tr>
<th>Potential Risk</th>
<th>Potential Effect of Risk</th>
<th>Potential Outcome</th>
<th>Current Protection</th>
<th>Recommended Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Severity</td>
<td>Occurrence</td>
<td>Detection</td>
</tr>
<tr>
<td>Water tanks or water reservoirs in the vicinity</td>
<td>Damage to the electric parts of the equipment</td>
<td>3</td>
<td>Short circuit</td>
<td>No functioning of the equipment</td>
</tr>
</tbody>
</table>

### Types of Room where Therapy Equipment Used

<table>
<thead>
<tr>
<th>Room</th>
<th>Potential Risk Description</th>
<th>Ignition</th>
<th>Occurrence</th>
<th>Detection</th>
<th>RPN</th>
<th>To recommend</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Garage, workshop</td>
<td>Oils grease and solvents coming into contact. Presence of oxy-acetylene kits. Potential presence of sparks. Much dust, debris. Damage when parking vehicles.</td>
<td>5</td>
<td>Ignition leading to explosion. Damage. Stability of container / fall over. Unsafe path for the tubing.</td>
<td>2</td>
<td>Review storage areas / advise not to store with oils and grease etc.</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Kitchen</td>
<td>Oils, grease coming into contact. Presence of propane, electric appliances, open fire.</td>
<td>5</td>
<td>Ignition leading to explosion. Damage. Stability of container / fall over. Unsafe path for the tubing.</td>
<td>3</td>
<td>Best practice is not to install the oxygen therapy equipment in the kitchen.</td>
<td>2</td>
<td>30</td>
</tr>
<tr>
<td>Living room Bedroom</td>
<td>Furniture, open fires, etc.</td>
<td>3</td>
<td>Oxygen enrichment.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bathroom</td>
<td>Water splash</td>
<td>3</td>
<td>Short circuit</td>
<td>No functioning of the equipment</td>
<td>2</td>
<td></td>
<td></td>
</tr>
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<td>---------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Upstairs, downstairs</td>
<td>Kinking of tubing</td>
<td>2</td>
<td>Not correct flow of gaseous oxygen. Water condensation may occur. Slips and trips over the tubing. Unsafe path for the tubing. Disconnection of tubing.</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Install purpose build tubing on the wall. Fit humidifier &amp; flow meter close to patient. Use anti-collapse tubing.</td>
<td>1</td>
<td>6</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Balcony</td>
<td>Kinking of tubing</td>
<td>2</td>
<td>No or incorrect functioning of the equipment. Damage. Disconnection of tubing.</td>
<td>2</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rain, birds, animals, vandalism</td>
<td></td>
<td></td>
<td>Take precautions against Kinking of tubing. Rain, birds, animals, vandalism.</td>
<td>1</td>
<td></td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Apartment or fully attached house</td>
<td>Presence of many people</td>
<td>2</td>
<td>As result of a fire, adjacent buildings may catch fire. Interference of other people to the equipment.</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Currently no specific instructions given.</td>
<td>1</td>
<td>8</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
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</tr>
<tr>
<td>Hygiene situation of the room</td>
<td>Infection for patient, carer, installer &amp; workshop technician from equipment surface contamination</td>
<td>2</td>
<td>Patient is not taking care of the continuous cleanliness of the equipment.</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Training and reminding of the patient &amp; 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).</td>
<td>2</td>
<td>16</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>
### Homecare Patient Environment Risk Assessment

#### Oxygen Therapy

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</tr>
</thead>
<tbody>
<tr>
<td>Area where the equipment is installed is far away from the user</td>
<td>Kinking of tubing</td>
<td>3</td>
<td>Not correct flow</td>
<td>Install</td>
<td>1</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Water condensation</td>
<td>purpose build tubing</td>
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<td></td>
<td></td>
<td></td>
<td>Slips and trips over the tubing</td>
<td>on the wall</td>
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</tr>
<tr>
<td>Room Flooring</td>
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<td></td>
</tr>
<tr>
<td>Level of floor Steps</td>
<td>Unlevelled, steps</td>
<td>3</td>
<td>Slips, trips &amp; falls</td>
<td>1</td>
<td>9</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Stability of container</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Difficult/dangerous handling conditions.</td>
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<td></td>
<td></td>
<td></td>
<td>Disconnection.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Carpet, cork wooden floor linoleum and similar</td>
<td>Porosity Softness of the underground</td>
<td>4</td>
<td>Spillage, damage, oxygen enrichment</td>
<td>4</td>
<td>32</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
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</tr>
<tr>
<td>Tiles and similar</td>
<td>Finish of the surface</td>
<td>2</td>
<td>Damage e.g. cracks</td>
<td>4</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Supply Method and Requirements</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Static installation of the oxygen source</td>
<td>Cleanliness of the equipment Source equipment or containers take up space</td>
<td>2</td>
<td>Accumulation of dust/dirt Access and handling problems</td>
<td>3</td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
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</tbody>
</table>

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Note: The table represents the assessment of potential risks associated with oxygen therapy in a homecare environment. Each row details the potential risk, its effect, potential outcomes, current protection measures, recommended actions, and the installation of various systems to ensure safety. The table indicates the installation of various systems to ensure safety.
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Need to move the supply system</td>
<td>Restricted space for movement</td>
<td>3 Slips, trips and falls. Dropping of equipment/container</td>
<td>3 Patient training Provide trolleys/roller base</td>
<td>2</td>
<td>18</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Need for multiple outlet points Need for multiple units connected together</td>
<td>Disconnected tubing Leakages Ensure positive closure of unused outlets Oxygen compatibility of all installation components</td>
<td>2 Incorrect or stop of flow Oxygen enrichment from the leak</td>
<td>3 Use wall-outlet with quick connector or shut-off valve All installation components to meet medical devices directive</td>
<td>1</td>
<td>6</td>
<td>To recommend to technician to verify leak tightness of tubing installation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Location of multiple outlet points</td>
<td>Vicinity to combustibles Leakages</td>
<td>4 Oxygen enrichment</td>
<td>2 Follow instructions for installer</td>
<td>1</td>
<td>8</td>
<td>To recommend to technician to verify leak tightness of tubing installation</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Electric supply needed</td>
<td>Condition of the electric socket</td>
<td>4 Electrocution</td>
<td>2 Warn the patient of the risk Use the power cord delivered with the equipment</td>
<td>1</td>
<td>8</td>
<td></td>
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</tbody>
</table>

**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

**HOME CARE INSTALLATION RISK ASSESSMENT CHECKLIST**

<table>
<thead>
<tr>
<th>Patient’s Address</th>
<th>Patient’s Name</th>
<th>Installation Date</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

**Installation Type**

- Concentrator
- Liquid Cylinders
- Gas Cylinders
- Ambulatory Cylinders
- Backup Cylinders
- Multiple Units
- Pipeline
- Self-fill system

**Potential Risks**

### 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

### 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

### 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 / dog present

### 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 1.5 metres of open flame

### Installer’s Comments / Other Concerns or Potential Risks

**Installer’s Name / Signature**

<table>
<thead>
<tr>
<th>Date</th>
</tr>
</thead>
</table>

**Company Internal Comments / Actions**

**Company Internal Name / Signature**

<table>
<thead>
<tr>
<th>Date</th>
</tr>
</thead>
</table>